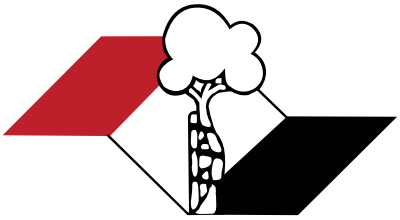
Indexed
PubMed and
PubMed Central
included
ISI and JCR (Journal Citation Reports®)



ISSN 1413-7852

Acta Ortopédica Brasileira

Volume 25 – Number 6 – Year 2017

Oxotron

loxoprofeno sódico

A NOVA OPÇÃO NO TRATAMENTO ANTI-INFLAMATÓRIO.[1,2]

RÁPIDO INÍCIO DE AÇÃO[2,3]

Início de ação a partir de 15 minutos[2]

- **Atividade preferencial sobre a COX-2[4,5]**
- **Fármaco seguro[4,6]**
- **Boa tolerabilidade[4]**
- **Tão eficaz quanto celecoxibe, ibuprofeno e naproxeno na redução da dor e inflamação em pacientes com dor pós-operatória, osteoartrite e ombro congelado[7]**

Referências Bibliográficas: 1) BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Consulta de produtos. Disponível em: <http://www7.anvisa.gov.br/datavisa/Consulta_Produto/rconsulta_produto_detalhe.asp>. Acesso em: Out. 2016. 2) Bula do produto OXOTRON: comprimidos. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 3) LANDIM, E. et al. Loxoprofeno sódico no tratamento das lombalgias. Revisão bibliográfica. RBM, v. 57, n. 4, p. 298-302, 2000. 4) DUTRA, F.G.; ENGELKE, F. O uso do loxoprofeno sódico* nos processos inflamatórios comuns em reumatologia e ortopedia: Estudo colaborativo. RBM, v. 58, n. 1/2, p. 39-48, 2001. 5) MARONE, S.; ENGELKE, F. Loxoprofeno sódico no tratamento complementar das infecções agudas das vias aéreas superiores: Estudo colaborativo. RBM, v. 58, n. 3, p. 171-178, 2001. 6) LEDERMAN, R.; GUIMARÃES, S.; VERZTMAN, J.F. Eficácia clínica e segurança do loxoprofeno sódico (Loxonin®) no tratamento da gonartrose. RMB, v. 58, v. 4, p. 263-271, 2001. 7) GREIG, S.L.; GARNOCK-JONES, K.P. Loxoprofen: A review in pain and inflammation. Clin Drug Investig, v. 36, n. 9, p. 771-81, 2016.

OXOTRON É UM MEDICAMENTO. DURANTE SEU USO, NÃO DIRIJA VEÍCULOS OU OPERE MÁQUINAS, POIS SUA AGILIDADE E ATENÇÃO PODEM ESTAR PREJUDICADAS

Oxotron está contraindicado em: Crianças e jovens menores de 18 anos de idade, gestantes no último trimestre da gravidez e durante o período de lactação; pessoas que apresentaram reações de hipersensibilidade ao loxoprofeno ou a qualquer um dos componentes da fórmula; portadores de úlcera péptica, graves distúrbios hematológicos, hepáticos ou renais.INTERAÇÕES MEDICAMENTOSAS: Coadministração cautelosa: Anticoagulantes cumarínicos, hipoglicemiantes sulfonilureicos, antibacteriano fluoroquinolona, metotrexate, sais de lítio, diuréticos benzotiazídicos, anti-hipertensivos.

Oxotron. Loxoprofeno sódico. MEDICAMENTO SIMILAR EQUIVALENTE AO MEDICAMENTO DE REFERÊNCIA. 60 mg. Comprimido. USO ORAL. USO ADULTO. Oxotron. Loxoprofeno sódico. APRESENTAÇÕES. Comprimidos 60 mg: embalagens com 8, 15 ou 30 comprimidos. USO ORAL. USO ADULTO. COMPOSIÇÃO. Cada comprimido de Oxotron contém: Loxoprofeno sódico anidro (como loxoprofeno sódico di-hidratado) 60 mg. Excipientes: lactose monoidratada, estearato de magnésio, hiprolose de baixa substituição, óxido férrico vermelho. INFORMAÇÕES TÉCNICAS AOS PROFISSIONAIS DE SAÚDE. **INDICAÇÕES.** Oxotron está indicado como anti-inflamatório e analgésico no tratamento de artrite reumatoide, osteoartrite, periartrite escapuloumeral, processos inflamatórios osteomusculares do pescoço, ombro, braço e lombalgias; como analgésico e anti-inflamatório em pós-cirurgia, pós-traumatismo e pós-exodontia; como analgésico anti-inflamatório e antitérmico em processos inflamatórios agudos do trato respiratório superior (acompanhados ou não de bronquite aguda). **CONTRAINDICAÇÕES**. Oxotron está contraindicado em: Crianças e jovens menores de 18 anos de idade, gestantes no último trimestre da gravidez e durante o período de lactação; pessoas que apresentaram reações de hipersensibilidade ao loxoprofeno ou a qualquer um dos componentes da fórmula; portadores de úlcera péptica, graves distúrbios hematológicos, hepáticos ou renais; portadores de disfunções cardíacas graves; indivíduos com asma induzida por AINE. Este medicamento é contraindicado para menores de 18 anos. Categoria de risco na gravidez: D (terceiro trimestre): este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica. Informe imediatamente seu médico em caso de suspeita de gravidez. **ADVERTÊNCIAS E PRECAUÇÕES: Oxotron deve ser administrado com cautela em: Pessoas com histórico de úlcera péptica; pessoas portadoras ou com histórico de distúrbios hematológicos; pessoas portadoras ou com histórico de disfunção hepática; pessoas portadoras ou com histórico de disfunção renal; pessoas com úlcera associada ao tratamento prolongado com anti-inflamatórios não esteroides, ainda que estejam em uso de misoprostol como medida profilática; pessoas com asma brônquica de qualquer causa; pessoas com disfunção cardíaca; pessoas com história de hipersensibilidade; pessoas com colite ulcerativa; pessoas com doença de Crohn; pessoas idosas. Durante tratamento prolongado com Oxotron, exames laboratoriais, tais como urina tipo I, hemograma completo e enzimas hepáticas devem ser realizados periodicamente. Se forem observadas alterações, recomenda-se redução da dose ou interrupção do tratamento. O uso de Oxotron, bem como de outros anti-inflamatórios, pode provocar alteração do controle da pressão arterial em indivíduos hipertensos sob tratamento. Alguns efeitos indesejáveis como tontura e sonolência têm sido relatados durante o uso de Oxotron. Para segurança do paciente, solicitar cuidado ao dirigir e ao operar máquinas. A segurança do uso de loxoprofeno sódico na gestação não foi estabelecida, portanto, Oxotron somente deverá ser administrado a gestantes se os benefícios terapêuticos justificarem os riscos potenciais para o feto (particularmente no terceiro trimestre) bem como durante a lactação. Categoria de risco na gravidez: B (primeiro e segundo trimestres): Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. INTERAÇÕES MEDICAMENTOSAS: Coadministração cautelosa: Anticoagulantes cumarínicos, hipoglicemiantes sulfonilureicos, antibacteriano fluoroquinolona, metotrexate, sais de lítio, diuréticos benzotiazídicos, anti-hipertensivos. REAÇÕES ADVERSAS. Oxotron pode causar os seguintes efeitos indesejados: rash cutâneo, urticária, sonolência, edema, dor abdominal, desconforto gástrico, anorexia, náusea e vômito, diarreia e aumento das transaminases hepáticas, prurido, úlcera péptica, constipação intestinal, pirose, estomatite, urticária, dispepsia, cefaleia, anemia, leucopenia, eosinofilia, aumento da fosfatase alcalina, palpitação, fogachos, febre, sede, distensão abdominal, úlcera no intestino delgado e/ou grosso, aumento da pressão arterial, entorpecimento, tontura, trombocitopenia, hematúria, proteinúria, disúria, dor no peito e mal estar.** Outras reações adversas clinicamente significantes: choque, sintomas anafilactóides, crise asmática, Stevens-Johnson, síndrome de Lyell (necrose epidérmica tóxica), agranulocitose, anemia hemolítica, leucopenia, trombocitopenia, insuficiência renal aguda, síndrome nefrótica, nefrite intersticial, insuficiência cardíaca congestiva, pneumonia intersticial, sangramento gastrintestinal, estenose e/ou obstrução do intestino delgado e/ou grosso, perfuração gastrintestinal, disfunção hepática, icterícia, meningite asséptica e rabdomiólise. Estes casos devem ser observados cuidadosamente. A terapia com Oxotron deve ser descontinuada imediatamente e adotadas medidas de tratamento apropriadas. Foi reportado que anemia aplástica pode ocorrer com o uso de drogas anti-inflamatórias não esteroides. Em caso de eventos adversos, notifique ao Sistema de Notificações em Vigilância Sanitária – NOTIVISA, disponível em www.anvisa.gov.br/hotsite/notivisa/index.htm, ou para a Vigilância Sanitária Estadual ou Municipal. **POSOLOGIA E MODO DE USAR.** Em geral recomenda-se para o adulto a posologia de um comprimido (60 mg de Loxoprofeno sódico), três vezes ao dia, por via oral. Em casos agudos poderá ser realizada uma única administração de um a dois comprimidos (60-120 mg de Loxoprofeno sódico), por via oral, ajustando-se a dose de acordo com a idade e os sintomas. Não ultrapassar a dose diária de 180 mg, bem como evitar a administração em jejum. A segurança em pacientes pediátricos não foi estabelecida. VENDA SOB PRESCRIÇÃO MÉDICA. MS - 1.0573.0495. "Material técnico científico de distribuição exclusiva à classe médica".

ISSN 1413-7852

Acta Ortopédica Brasileira

Department of Orthopedics and Traumatology, Faculdade de Medicina da Universidade de São Paulo (DOT/FMUSP), São Paulo, SP, Brazil

Affiliated with Associação Brasileira de Editores Científicos

Indexed in PubMed, PubMed Central, Web of Science, JCR, Scopus Elsevier, SciELO, Redalyc (Red de Revistas Cientificas de America Latina y el Caribe,España y Portugal), LILACS (Latin America Health Science Literature) and DOAJ (Directory of open access journals).

Editorial coordination, creation, desktop publishing and graphic production Atha Comunicação e Editora - e-mail: 1atha@uol.com.br

ACTA ORTOPÉDICA BRASILEIRA

INSTRUCTIONS TO AUTHORS

(Reviewed January 2016)

The journal Acta Ortopédica Brasileira, official organ of the Department of Orthopedics and Traumatology, Faculdade de Medicina da Universidade de São Paulo (DOT/FMUSP), is published bimonthly in six issues per year (jan/feb, mar/apr, may/jun, jul/aug, sep/oct, and nov/dec) with English version. The titles, abstracts and keywords are published in English and Portuguese. The publication follows entirely the international standard of the International Committee of Medical Journal Editors (ICMJE) - Vancouver Convention - and its uniform requirements [http://www.icmje.org/]. Submitted papers are sent for double-blind peer review evaluation to decide whether they should be published or not, suggesting improvements, asking the authors for clarification and making recommendations to the Editor-in Chief. The concepts and statements contained in the papers are the sole responsibility of the authors.
We ask authors to observe the following instructions for publication.

ARTICLES FORMAT

NUMBER OF WORDS RECOMMENDED ACCORDING TO THE PUBLICATION TYPE: The criteria specified below should be observed for each type of publication. The electronic counting of words should start at the Introduction and end at the Conclusion.

Recommendations for articles submitted to Acta Ortopédica Brasileira

Type of Article	Abstract	Number of words	References	Figures	Tables	Maximum number of authors allowed
Original	Structured, up to 200 words	2.500 Excluding abstract, references, tables and figures	20	10	6	6
Update / Review*	Non-structured, up to 200 words	4.000 Excluding abstract, references, tables and figures	60	3	2	2
Editorial*	No abstract	500	0	0	0	1

*These contributions shall be published at the Editors' criteria, with due replica, when applicable.

MANUSCRIPT PREPARATION: The journal *Acta Ortopédica Brasileira* receives the following types of contributions: Original Article, Update Article and Review Article. The Update and Review articles are only considered by invitation from the Editorial Board.
Manuscripts should be sent in .txt or .doc files, double-spaced, with wide margins. Measures should be expressed in the International System (*Système International*, SI), available at http://physics.nist.gov/cuu/Units and standard units, where applicable.
It is recommended that authors do not use abbreviations in the title and limit their use in the abstract and in the text.
The generic names should be used for all drugs. The drugs can be referred to by their trade name, however, the manufacturer's name, city and country or electronic address should be stated in brackets in the Materials and Methods section.

ABBREVIATIONS: The use of abbreviations should be minimized. Abbreviations should be defined at the time of its first appearance in the abstract and also in the text. Non-standard abbreviations shall not be used, unless they appear at least three times in the text.
Measurement units (3 ml or 3 mL, but not 3 milliliters) or standard scientific symbols (chemical elements, for example, Na and not sodium) are not considered abbreviations and, therefore, should not be defined. Authors should abbreviate long names of chemical substances and therapeutic combinations terms. Abbreviations in figures and tables can be used for space reasons, but should be defined in the legend, even if they were defined in the article.

PRESENTATION LETTER: The cover letter accompanying the submission of the manuscript should be signed by the corresponding author and should include the following information: Title, names of all authors, text authorizing the publication of the article, stating that it has not being submitted simultaneously elsewhere and it has not been previously published (publication in another language is considered as the same article). Authors should make sure that the manuscript is entirely in accordance with the instructions.

CLINICAL TRIALS: The journal *Acta Ortopédica Brasileira* supports the Clinical Trials Registry policy of the World Health Organization (WHO) and the ICMJE, recognizing the importance of these initiatives for the registration and international dissemination of clinical studies in open access. Therefore, it will only accept for publication articles involving clinical research that have received an identification number in one of the clinical trials registry platforms validated by WHO and ICMJE. The URLs of these registry platforms are available at the ICMJE page [http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/].

CONFLICT OF INTERESTS: As recommended by the ICMJE and resolution of the Brazilian Federal Council of Medicine nº 1595/2000, authors have the responsibility to recognize and declare any potential financial conflicts of interest, as well as conflicts of other nature (commercial, personal, political, etc.) involved in developing the work submitted for publication.

ACKNOWLEDGEMENTS: Authors can acknowledge financial support to the work in the form of research grants, scholarships and other, as well as professionals who do not qualify as co-authors of the article, but somehow contributed to its development.

CORRECTION OF GALLEY PROOFS: As soon as they are ready, the galley proofs in electronic form will be sent by e-mail to the corresponding author. Authors should return proofs, also by e-mail, with the necessary corrections within 48 hours maximum after its receipt. This aims to expedite the review process and publication of the article.

COPYRIGHT: All statements published in the articles are the authors' responsibility. However, all published material becomes the property of the publisher, which shall reserve the copyright. Therefore, no material published in *Acta Ortopédica Brasileira* can be marketed without the written permission of the publisher. All authors of articles submitted to *Acta* must sign a Copyright Transfer Agreement, which will take effect from the date of acceptance of the paper.

ORGANIZING THE ELECTRONIC FILE: All parts of the manuscript should be included in a single file. It should be formed by the cover page, then the text, references, figures (with their captions) and finally, tables and charts (with their respective captions).

COVERPAGE: The title page should contain:
a) The article category (original article, review article or update article);
b) The full title in Portuguese and English with up to 80 characters. The title should be concise, but informative;
c) The full name of each author (without abbreviations); and their institutional affiliations (the units should be presented in ascending order of hierarchy, e.g. department, faculty/institution, university). The names of institutions and programs should be submitted preferably in full and in the original language of the institution or in the English version when writing is not Latin (e.g. arabic, mandarin, greek);
d) The place where the work was performed;
e) Name, address, telephone number and e-mail of the corresponding author.

ABSTRACT: The abstract in Portuguese and in English should be structured in cases of original articles and shall present the study's objectives clearly, methods, results and main conclusions and should not exceed 200 words (do not include any reference citations). Moreover, the abstract should include the level of evidence and the type of study, according to the classification table attached at the end of this text.

KEYWORDS: The article should include at least three and at most six descriptors in Portuguese and in English, based on the Descriptors of Health Sciences (DeCS) http://decs.bvs.br/ or Medical Subject Headings (MeSH) of the National Library of Medicine, available at http://www.nlm.nih.gov/mesh/meshhome.html

INTRODUCTION: The introduction of the article shall present the matter and purpose of the study, including citations without, however, making an extensive review of the matter.

MATERIALS AND METHODS: This section should describe the experiments (quantitatively and qualitatively) and procedures in sufficient detail to allow other researchers to reproduce the results or provide continuity to the study.
When reporting experiments on humans or animals, authors should indicate whether the procedures followed the rules of the Ethics Committee on Human Trials of the institution in which the survey was conducted and whether the procedures are in accordance with the 1995 Helsinki Declaration and the Ethics in Experimentation Animals, respectively. Authors should include a statement indicating that the protocol was approved by the Institutional Ethics Committee (affiliate institution of at least one of the authors), with its identification number. It should also include whether a Free and Informed Consent Term was signed by all participants.
Authors should precisely identify all drugs and chemicals used, including generic names, dosages and administration. Patients' names, initials, or hospital records should not be included. References regarding statistical procedures should be included.

RESULTS: Results should be present in logical sequence in the text, using tables and illustrations. Do not repeat in the text all the data in the tables and/or illustrations, but emphasize or summarize only the most relevant findings.

DISCUSSION: Emphasize new and important aspects of the study and the conclusions that derive from it, in the context of the best evidence available. Do not repeat in detail data or other information mentioned elsewhere in the manuscript, as in the Introduction or Results. For experimental studies it is recommended to start the discussion by briefly summarizing the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study and explore the implications of these results for future research and for clinical practice.
Link the conclusions with the goals of the study, but avoid statements and conclusions that are not supported by the data, in particular the distinction between clinical and statistical relevance. Avoid making statements on economic benefits and costs, unless the manuscript includes data and appropriate economic analysis. Avoid priority claim ("this is the first study of ...") or refer to work that has not yet been completed.

CONCLUSION: The conclusion should be clear and concise, establishing a link between the conclusion and the study objectives. Avoiding conclusions not based on data from the study in question is recommended, as well as avoiding suggest that studies with larger samples are needed to confirm the results of the work in question.
ACKNOWLEDGEMENTS
When applicable, briefly acknowledge the people who have contributed intellectually or technically to the study, but whose contribution does not justify co-authorship. The author must ensure that people agree to have their names and institutions disclosed. Financial support for the research and fellowships should be acknowledged in this section (funding agency and project number).

AUTHORS IDENTIFICATION: The ORCID (Open Researcher and Contributor ID, http://orcid.org/) of each author should be informed in the authors' statement of contribution, according to the model below.

STATEMENT OF AUTHORS' CONTRIBUTION: The declaration of authors' contribution should be included at the end of the article, using minimum criteria for authorship, including:
- Substantial contribution in the work conception or design, or acquisition, analysis or interpretation of data to the study;
- Writing the article or critically reviewing its intellectual content;
- Approval of the final version of the manuscript to be submitted for publication;
- Agree to be responsible for all aspects of the work, to ensure that any matters regarding the completeness or accuracy of any of its parts are properly investigated and resolved;

All articles should include a description of the authors' contribution, as follows:
"Each individual author contributed individually and significantly to the development of this work. MJ (0000-0000-0000-0000)*: wrote and reviewed the and performed the surgeries; CPV (0000-0002-3904-2836)*: performed the surgeries, analyzed the data analysis and wrote the articles; JVC (0000-0003-3910-714x (0000-0000-0000-0000)*: performed statistical analysis, participated at the surgeries and reviewed the article; OMA (0000-0000-0000-0000)*: analyzed the slides and reviewed the article; MASP (0000-0000-0000-0000)*: drafted and reviewed the article and contributed to the intellectual concept of the study; ACA (0000-0001-6891-5935)*: performed the surgeries, wrote the article, performed statistical analysis and contributed to the intellectual concept of the study and the entire research project. *ORCID (Open Researcher and Contributor ID)."

REFERENCES: Original articles may include up to about 20 references, restricted to the essential bibliography to the article's content. Number the references consecutively in the order in which they are first mentioned in the text, using superscript Arabic numerals in the following format: (e.g., Reduction of terminal plate functions.[1]).
Authors should make sure that all references are cited in the text. Several citations within a single set of parentheses should be separated by commas without space ([1,5,7]). Where there are 3 or more sequential citations, use a numeric range ([4-9]). Include the first six authors followed by et al.
The titles of journals should be abbreviated according to *Index Medicus*.
a) Article: Author (s). Article title. Journal title. Year; volume: initial page –final page.
Ex.: Campbell CJ. The healing of cartilage defects. Clin Orthop Relat Res. 1969;64:45-63.
b) Book: Author(s) or editor (s). Book title. Edition, if it is not the first. Translator (s), if it applies. Publication place: publisher; year.
Ex.: Diener HC, Wilkinson M, editors. Drug-induced headache. 2nd ed. New York: Spriger-Verlag; 1996.
c) Book chapter: Chapter author (s). Chapter title. Book Editor (s) and supplementary data, likewise the previous item.
Ex.: Chapman MW, Olson SA. Open fractures. In: Rockwood CA, Green DP. Fractures in adults. 4th ed. Philadelphia: Lippincott-Raven; 1996. p.305-52.
d) Abstract: Author(s). Title, followed by [abstract]. Journal. Year; volume (supplement and its number, if it applies): page (s).

Ex.: Enzensberger W, Fisher PA. Metronome in Parkinson's disease [abstract]. Lancet. 1996;34:1337.

e) Personal communications: should only be mentioned in the text, between parentheses.

f) Thesis: Author, title, level (Master, PhD, etc.), city: institution; year.

Ex.: Kaplan SJ. Post-hospital home health care: the elderly's access and utilization [dissertation]. St. Louis: Washington Univ.; 1995.

g) Electronic material: Author (s). Article title. Abbreviated Journal title [medium]. Publication date [access date followed by the expression "accessed on"]; volume (number):initial page-final page or [approximate number of pages]. URL followed by the expression "Available from:"

Ex.: Pavezi N, Flores D, Perez CB. Proposição de um conjunto de metadados para descrição de arquivos fotográficos considerando a Nobrade e a Sepiades. Transinf. [Internet]. 2009 [acesso em 2010 nov 8];21(3):197-205. Available from: http://periodicos.puc-campinas.edu.br/seer/index.php/transinfo/article/view/501

TABLES: Tables should be numbered in order of appearance in the text with Arabic numerals. Each table should have a title and, when necessary, an explanatory caption. Charts and tables should be sent in editable source files (Word, Excel) and not as images. Tables and charts covering more than one page should be avoided. Do not use image elements, text boxes, or tabs.

FIGURES (ILLUSTRATIONS AND PHOTOS): Figures should be submitted on separate pages and numbered sequentially in Arabic numerals, according to the order of appearance in the text. To avoid issues that compromise the journal pattern, all material sent shall comply with the following parameters: all graphics, photographs and illustrations should have adequate graphic quality (300 dpi resolution) and present title and caption. In all cases, the files must have .tif or .jpg extensions. Files with extension .xls, .xlsx (Excel), .eps or .psd to curve illustrations (graphics, drawings and diagrams) shall also be accepted. Figures include all illustrations such as photographs, drawings, maps, graphs, etc. Black and white figures will be freely reproduced, but the editor reserves the right to set a reasonable limit on their number or charge the author the expense resulting from excesses. Color photos will be charged to the author.

Please note that it is the authors' responsibility to obtain permission from the copyright holder to reproduce figures (or tables) that have been previously published elsewhere. Authors must have permission from the copyright owner, if they wish to include images that have been published in other non-open access journals. Permission shall be indicated in the figure legend and the original source must be included in the reference list.

LEGENDS TO FIGURES: Type the legends using double space, following the respective figures (graphics, photos and illustrations). Each legend must be numbered in Arabic numerals corresponding to each illustration and in the order they are mentioned in the text. Abbreviations and acronyms should be preceded by the full name when cited for the first time in the text. At the bottom of figures and tables discriminate the meaning of abbreviations, symbols, signs and other informed source. If the illustrations have already been published, they shall be accompanied by written consent of the author or editor, stating the reference source where it was originally published.

PAPER SUBMISSION: From January 2008 *Acta Ortopédica Brasileira* adopts the SciELO Publication and Submission System available online at http://submission.scielo.br/index.php/aob/index. Authors should follow the registration and article inclusion instructions available at the website.

For further information please contact Atha Comunicação e Editora. Rua Machado Bittencourt 190, 4° floor. Vila Mariana, 04044-000. São Paulo, SP, Brazil. actaortopedicabrasileira@uol.com.br. Tel. +55 11 5087-9502 c/o Ana Carolina de Assis/Arthur T. Assis.

Levels of Evidence for Primary Research Question[a]

(This chart was adapted from material published by the Centre for Evidence-Based Medicine, Oxford, UK. For more information, please visit www.cebm.net.)

	Types of study			
Level	**Therapeutic Studies Investigating the Results of Treatment**	**Prognostic Studies – Investigating the Effect of a Patient Characteristic on the Outcome of Disease**	**Diagnostic Studies – Investigating a Diagnostic Test**	**Economic and Decision Analyses – Developing an Economic or Decision Model**
I	High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	High quality prospective study[d] (all patients were enrolled at the same point in their disease with ≥80% of enrolled patients)	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference ''gold'' standard)	Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses
	Systematic review[b] of Level RCTs (and study results were homogenous[c])	Systematic review[b] of Level I studies	Systematic review[b] of Level I studies	Systematic review[b] of Level I studies
II	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective[f] study	Development of diagnostic criteria on consecutive patients (with universally applied reference ''gold'' standard)	Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses
	Prospective[d] comparative study[e]	Untreated controls from an RCT	Systematic review[b] of Level II studies	Systematic review[b] of Level II studies
	Systematic review[b] of Level II studies or Level I studies with inconsis tent results	Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% followup)		
		Systematic review[b] of Level II studies		
III	Case control study[g]	Case control study[g]	Study of non consecutive patients; without consistently applied reference ''gold'' standard	Analyses based on limited alternatives and costs; and poor estimates
	Retrospective[f] comparative study[e]		Systematic review[b] of Level III studies	Systematic review[b] of Level III studies
	Systematic review[b] of Level III studies		Case-control study	
			Poor reference standard	
IV	Case series[h]	Case series		Analyses with no sensitivity analyses
V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

[a] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

[b] A combination of results from two or more prior studies.

[c] Studies provided consistent results.

[d] Study was started before the first patient enrolled.

[e] Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.

[f] The study was started after the first patient enrolled.

[g] Patients identified for the study based on their outcome, called "cases" eg, failed total arthroplasty, are compared with patients who did not have outcome, called ''controls'' eg, successful total hip arthroplasty.

[h] Patients treated one way with no comparison group of patients treated in another way.

SUMMARY

VOLUME 25–Nº 6–2017

Original Articles

OSTEOBAN
ibandronato de sódio

PREÇO ACESSÍVEL E COMODIDADE POSOLÓGICA
na prevenção e tratamento da osteoporose[1,2,3]

1x POSOLOGIA AO MÊS[2]

PREVENÇÃO

34,4% DE REDUÇÃO do risco de **FRATURAS NÃO VERTEBRAIS.**[4]

62% DE REDUÇÃO do risco de **FRATURAS VERTEBRAIS.**[5]

MELHORA DA DENSIDADE mineral óssea em mulheres com Osteopenia e Osteoporose.[6]

Risco **5X MAIOR** da segunda fratura vertebral, após a primeira.[7]

*Estudo mostra aumento da densidade mineral óssea demonstrando prevenção da osteoporose na pós menopausa.

Referência bibliográfica: 1. Kairos Web Brasil. Disponível em: <http://brasil.kairosweb.com>. Acesso em: Maio/2017. **2.** Bula do produto OSTEOBAN: comprimidos revestidos. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP: Aché Laboratórios Farmacêuticos S.A. **3.** BUMBASIREVIC, M. et al. Prospective clinical study of monthly ibandronate in the treatmetn of osteoporosis and prevention of fractures in postmenopausal women: ORPHEUM study. Srp Arh Celok Lek, v. 139, n. 11-12, p. 790-7694, 2011. **4.** HARRIS, S. T. et al. Ibandronate and the risk of nonvertebral and clinical fractures in women with postmenopausal osteoporosis: results of a metaanalysis of phase III studies. Curr Med Res Opin, v. 24, n. 1, p. 237-245, 2008. **5.** MILLER, P. D. et al. Efficacy of monthly oral ibandronate is sustained over 5 years: the MOBILE long-term extension study. Osteoporos Int, v. 23, n. 6, 2012. **6.** BOCK, O. et al. Impact of oral ibandronate 150 mg once monthly on bone structure and density in post-menopausal osteoporosis or osteopenia derived from in vivo µCT. Bone, v. 50, p. 317-324, 2012. **7.** STOLNICKI, B; OLIVEIRA, L.G. Para que a primeira fratura seja a última. Rev bras ortop, v. 51, n. 2, p. 121-126, 2016.

Interação Medicamentosa: Os pacientes devem esperar 60 minutos após ingerir OSTEOBAN, antes de tomarem outros medicamentos orais. Contraindicação: OSTEOBAN é contraindicado a pacientes que não conseguem ficar em pé ou sentados durante, pelo menos, 60 minutos.

Osteoban. ibandronato de sódio 150mg comprimido revestido. USO ORAL USO ADULTO. Indicações: OSTEOBAN é indicado para o tratamento da osteoporose pós-menopausa, com a finalidade de reduzir o risco de fraturas vertebrais. Em um subgrupo de pacientes de risco, com escore T < -3,0 DP no colo do fêmur, ibandronato de sódio também demonstrou reduzir o risco de fraturas não vertebrais. **Contraindicações: OSTEOBAN é contraindicado a pacientes com hipersensibilidade ao ibandronato de sódio ou aos demais componentes da fórmula e a pacientes com hipocalcemia não corrigida; pacientes com anormalidades do esôfago, como demora no esvaziamento esofágico, estenose ou acalasia; pacientes que não conseguem ficar em pé ou sentados durante, pelo menos, 60 minutos. Precauções e advertências: OSTEOBAN é contraindicado a pacientes com hipocalcemia não corrigida. Bisfosfonatos administrados por via oral podem causar irritação local da mucosa gastrintestinal superior. O risco de experiências adversas esofágicas graves parece ser maior para pacientes que não seguem as instruções de uso e/ou que continuaram a tomar bisfosfonatos por via oral após desenvolver sintomas sugestivos de irritação esofágica. Os pacientes devem prestar especial atenção e serem capazes de cumprir as instruções de administração. Considerando-se que anti-inflamatórios não esteróides e bisfosfonatos associam-se, ambos, à irritação gastrintestinal, recomenda-se cautela durante a administração concomitante de anti-inflamatórios não esteroides e ibandronato de sódio. Osteonecrose de mandíbula foi relatada em pacientes tratados com bisfosfonatos. A maioria dos casos em pacientes oncológicos submetidos a procedimentos dentários, mas alguns casos ocorreram em pacientes em tratamento para osteoporose pós-menopausa e outros diagnósticos. Fatores de risco conhecidos para osteonecrose de mandíbula: câncer, terapias concomitantes (ex: quimioterapia, radioterapia e corticosteroides) e distúrbios concomitantes (ex: anemia, coagulopatia, infecção e doença dentária pré-existente). A maioria dos casos foi relatada em pacientes tratados com bisfosfonatos de administração intravenosa, mas também em alguns pacientes tratados com bisfosfonatos orais.Relatos na literatura médica indicam que os bisfosfonatos podem estar associados à inflamação ocular, como uveíte e esclerite. Não foram realizados estudos sobre os efeitos de ibandronato de sódio sobre a capacidade de dirigir veículos e operar máquinas. Gestação e lactação: Categoria de risco na gravidez: B. Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista.** Não há experiência sobre o uso clínico de ibandronato de sódio em mulheres durante a gestação. OSTEOBAN não deve ser utilizado por mulheres que estejam amamentando sem orientação médica ou do cirurgião dentista. **Atenção diabéticos: contém açúcar (lactose). Interações medicamentosas:** é provável que suplementos à base de cálcio, antiácidos e alguns medicamentos orais que contenham cátions multivalentes (tais como alumínio, magnésio e ferro) interfiram na absorção de ibandronato de sódio. Os pacientes devem esperar 60 min após ingerir OSTEOBAN, antes de tomarem outros medicamentos orais. Foi demonstrada, em estudo de interação farmacocinética em mulheres na pós-menopausa, a ausência de qualquer interação potencial com tamoxifeno ou tratamentos de reposição hormonal (estrogênio). Não se observou interferência quando ibandronato de sódio foi administrado concomitantemente com melfalano / prednisolona em pacientes com mieloma múltiplo. **Interações com alimentos:** a ingestão de alimentos deve ser postergada em 60 min após a administração oral de ibandronato de sódio. **Reações adversas: reações adversas comuns (> 1/100 e ≤ 1/10): doença do refluxo gastroesofágico, diarreia, dor abdominal, dispepsia, náusea, flatulência, cefaleia, síndrome influenza–like, fadiga, artralgia, mialgia, exantema. Reação incomum (>1/1.000 e <1/100):** distúrbios gastrintestinais (gastrite, esofagite, incluindo ulcerações esofágicas ou estenose, vômitos e disfagia), distúrbios do sistema nervoso (tonturas), distúrbios musculoesqueléticos e do tecido conjuntivo (dor nas costas). **Reação rara (>1/10.000 e <1/1.000):** distúrbios gastrintestinais (duodenite), distúrbios do sistema imunológico (reações de hipersensibilidade), distúrbios da pele e do tecido subcutâneo (angioedema, edema facial e urticária). **Posologia** deve ser administrado em jejum, 60 min antes da ingestão do primeiro alimento ou bebida do dia (exceto água) e antes da administração de qualquer outro medicamento ou suplemento, inclusive cálcio. Os comprimidos devem ser deglutidos inteiros, com um copo cheio de água filtrada (180 a 240 mL). O paciente não deverá deitar-se nos 60 min seguintes após tomar o medicamento; A dose recomendada de OSTEOBAN é um comprimido de 150 mg, **uma vez por mês. Pacientes idosos:** não é necessário ajuste de dose. **Pacientes com insuficiência renal:** não é necessário ajuste de dose para pacientes com insuficiência renal leve a moderada e com depuração de creatinina ≥ 30 mL/min. Em pacientes com depuração de creatinina < 30 mL/min, a decisão de administrar OSTEOBAN deve ser baseada na avaliação individual da relação risco / benefício. **Pacientes com insuficiência hepática:** não há necessidade de ajuste de dose para pacientes com insuficiência hepática. "SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO." **VENDA SOB PRESCRIÇÃO MÉDICA**. MS - 1.0573.0422. **"Material técnico científico de distribuição exclusiva a profissionais de saúde habilitados à precrição e/ou dispensação de medicamentos"**. Para informações completas, consultar a bula na íntegra através da Central de Atendimento ao Cliente. MB 02-SAP. 4408302.

MOTORE
Curcuma longa 250 mg

O ANTI-INFLAMATÓRIO COMPROVADAMENTE[3] EFICAZ E SEGURO A LONGO PRAZO[1]

EXTRATO DE CURCUMINA COMPLEXADO
TECNOLOGIA EXCLUSIVA[3,4]

Exclusivo complexo curcumina-fosfatidilcolina (fitossomo): **18X mais biodisponível** em comparação à curcumina não complexada.[3]

Cientificamente comprovado
Curcumina principal fração (curcuminoide) com ação anti-inflamatória amplamente estudada.[3]

Referências Bibliográficas: 1) BELCARO, G et al: Efficacy and Safety of Meriva®, a Curcumin-phosphatidylcholine Complex,during Extended Administration in Osteoarthritis Patients. Alternative Medicine Review 15(4):337-344,2010. 2) BOSI,PL: saúde baseada em evidências. disponível em: http://disciplinas.nucleoead.com.br/pdf/Livro_SaudeBaseadaemEvidencias.pdf. Acesso em 11/2015. 3) JURENKA, S. J. Anti-inflammatory properties of Curcumin, a major constituent of Curcuma longa: a review of preclinical and clinical research. Alternative Medicine Review, v.14, n.2, p. 141-153, 2009. 4) CUOMO, J. et al. Comparative absorption of a standardized curcuminoid mixture and its lecithin formulation. J Nat Prod, v.74, p.664-669, 2011. 5) Bula do produto MOTORE: cápsulas. Responsável Técnico: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A.

Contraindicações: contraindicado em caso de alergia à curcumina, açafrão *(Curcuma longa)* ou a qualquer outro componente da fórmula. É contraindicado em pacientes que estejam em tratamento com medicações que alterem as características de coagulação como antiagregantes plaquetários, anticoagulantes, heparina de baixo peso molecular e agentes trombolíticos. É também contraindicado em casos onde haja risco de obstrução de vias biliares ou casos de cálculos biliares, úlceras estomacais e hiperacidez do estômago.

MOTORE curcuma longa Extrato seco. **Cápsulas 250 mg. USO ORAL. USO ADULTO. Indicações**: medicamento fitoterápico destinado ao tratamento da osteoartrite e artrite reumatóide, e tem ação antiinflamatória e antioxidante. **Cuidados e advertências: a curcumina é muito bem tolerada em seu uso por via oral pela grande maioria dos pacientes, sendo raros os relatos de efeitos prejudiciais. Raramente podem ocorrer queixas como desconforto gástrico leve e movimentos intestinais mais frequentes. Precauções e advertências: o uso da curcumina por via oral mostrou ser bem tolerada pela maioria dos pacientes. Em casos esporádicos foram relatados episódios de menor gravidade como desconforto gastrointestinal. Não há relatos de overdose ou efeito tóxico grave. Em caso de ocorrência de reação de hipersensibilidade, a medicação deve ser imediatamente descontinuada e os sintomas avaliados pelo médico. Motore deve ser tomado apenas por via oral. Os riscos do uso por via de administração não recomendada são a não obtenção do efeito desejado e a ocorrência de reações adversas indesejadas. Não há dados de segurança relativo ao uso da curcumina em portadores de insuficiência hepática e/ou renal, não sendo recomendável o uso da medicação em pacientes nessas condições. As doses de tratamento recomendadas não devem ser excedidas. Informe ao seu médico ou cirurgião-dentista se você está fazendo uso de algum outro medicamento. Não use medicamento sem o conhecimento do seu médico. Pode ser perigoso para a sua saúde. Gravidez e lactação:** apesar de não haver estudos conclusivos em humanos que mostrem efeito negativo na fertilidade humana, alguns estudos realizados em animais sinalizaram efeito negativo na implantação de embriões após uso injetável de altas doses de extrato etanol da curcuma. Desta maneira sugere-se evitar o uso da curcumina em pacientes com intenção de engravidar ou em gestantes. Mulheres em fase de lactação também devem evitar o uso desta medicação. Categoria de risco na gravidez C: Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. **Interações medicamentosas: é contraindicado para uso em pacientes que estejam fazendo uso de medicações que alterem as características de coagulação como antiagregantes plaquetários, anticoagulantes, heparina de baixo peso molecular e agentes trombolíticos, pois, pode haver aumento no risco de casos de sangramento. Reações adversas: o uso da curcumina por via oral mostrou ser bem tolerada pela maioria dos pacientes. Em casos esporádicos foram relatados episódios de menor gravidade como desconforto gastrointestinal. Não há relatos de overdose ou efeito tóxico grave.** Em caso de ocorrência de reação de hipersensibilidade, a medicação deve ser imediatamente descontinuada e os sintomas avaliados pelo médico. Motore deve ser tomado apenas por via oral. Os riscos do uso por via de administração não recomendada são a não obtenção do efeito desejado e a ocorrência de reações adversas indesejadas. Não há dados de segurança relativo ao uso da curcumina em portadores de insuficiência hepática e/ou renal, não sendo recomendável o uso da medicação em pacientes nessas condições. As doses de tratamento recomendadas não devem ser excedidas. **Posologia:** Motore deve ser ingerido por via oral, com um pouco de água. A dose habitual para adultos é de 2 cápsulas a cada 12 (doze) horas, ou seja, duas tomadas diárias, totalizando 500mg de medicação a cada tomada. "SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO." **VENDA SOB PRESCRIÇÃO MÉDICA.** MS - 1.0573.0442. **MB 03 SAP 4437701.**

REFERÊNCIAS BIBLIOGRÁFICAS: 1) IOLASCON, G. et al. Risendronate's efficacy: from randomized clinical trials to real clinical practice. Clinical Cases in Mineral and Bone Metabolism, v. 7, n. 1, p. 19-22, 2010. 2) Kairos Web Brasil. Disponível em: http://brasil.kairosweb.com. Acesso em: Março/2016. 3) Programa cuidados pela Vida (O Programa Cuidados pela Vida pode alterar ou interromper esta campanha sem aviso prévio. Desconto calculado sobre o Preço Máximo ao Consumidor). 4. BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Resolução - RE nº 921, de 4 de abril de 2017. Concede Certificação de Boas Práticas de Fabricação ao Aché. Diário Oficial da União, Brasília, DF, p. 37, 10 abril 2017.

CONTRAINDICAÇÕES: OSTEOTRAT está contraindicado em pacientes com hipersensibilidade a qualquer componente da fórmula, com hipocalcemia, durante a gravidez, lactação e para pacientes com insuficiência renal severa ("clearance" de creatinina < 30 mL/min). INTERAÇÕES MEDICAMENTOSAS: Não foram realizados estudos formais de interação medicamentosa, entretanto, durante os estudos clínicos não foi observada qualquer interação clinicamente relevante com outros medicamentos.

OSTEOTRAT. risedronato sódico 35 mg. comprimidos revestidos. USO ORAL. USO ADULTO. Indicações: tratamento e prevenção da osteoporose em mulheres no período pós-menopausa para reduzir o risco de fraturas vertebrais e não vertebrais. Tratamento da osteoporose em homens com alto risco de fraturas. C**ontraindicações: hipersensibilidade a qualquer componente da fórmula, hipocalcemia, gravidez e lactação e para pacientes com insuficiência renal severa ("clearance" de creatinina <30 mL/min), Precauções e advertências: Alimentos, bebidas (exceto água) e drogas contendo cátions polivalentes (tais como: cálcio, magnésio, ferro e alumínio) podem interferir na absorção dos bisfosfonatos e não devem ser administrados concomitantemente. Em mulheres mais idosas (> 80 anos), a evidência de manutenção da eficácia de risedronato sódico, é limitada. Alguns bisfosfonatos foram relacionados a esofagites e ulcerações esofágicas. Em pacientes que apresentam antecedentes de alteração esofágica que retardam o trânsito ou o esvaziamento esofágico (ex. estenosose ou acalasia), ou que são incapazes de permanecerem em posição ereta por pelo menos 30 minutos após a ingestão do comprimido, o risedronato deve ser utilizado com especial cautela. Os prescritores devem enfatizar a importância das instruções posológicas para pacientes que apresentam antecedentes de alterações esofágicas. A hipocalcemia deve ser tratada antes do início do tratamento com OSTEOTRAT. Outras alterações ósseas e do metabolismo devem ser tratadas quando iniciada a terapia com OSTEOTRAT.** Osteonecrose de mandíbula, geralmente associada com extração dentária e/ou infecção local foi relatada em pacientes com câncer em regimes de tratamento com bisfosfonatos, principalmente, na administração intravenosa. Osteonecrose de mandíbula também foi relatada em pacientes com osteoporose recebendo bisfosfonatos orais. Este medicamento contém lactose. Pacientes com problemas hereditários raros de intolerância à galactose, a deficiência da Lapp lactaseou má absorção da glucose-galactose, não devem tomar esse medicamento. Gravidez e lactação: O risco potencial para humanos é desconhecido. Risedronato sódico só deve ser utilizado durante a gravidez, se o risco benefício justificar o potencial risco para a mãe e o feto. A decisão de descontinuar a amamentação ou o produto deve considerar a importância do medicamento para mãe. Interações medicamentosas: Se considerado apropriado, OSTEOTRAT pode ser utilizado concomitantemente com a terapia de reposição hormonal. A ingestão concomitante de medicamentos contendo cátions polivalentes (ex. cálcio, magnésio, ferro e alumínio) irá interferir na absorção de OSTEOTRAT. O uso concomitante de antiácidos pode reduzir a absorção de risedronato. OSTEOTRAT não é metabolizado sistemicamente, não induz as enzimas do citocromo P450 e apresenta baixa ligação protéica. **Reações adversas: Estão listadas a seguir de acordo com a seguinte convenção: muito comum (>1/10); comum (>1/100; <1/10); incomum (>1/1000; <1/100); raro (>1/10000; <1/1000); muito raro (<1/10000). Comuns: dor de cabeça, constipação, dispepsia, náusea, dor abdominal, diarréia, dor musculoesquelética. Incomuns: gastrite, esofagite, disfagia, duodenite, úlcera esofágica Raros: glossite, estenose esofágica. Muito raramente foram observadas reações como: uveite, irite, osteonecrose de mandíbula, hipersensibilidade e reações cutâneas, incluindo angioedema, rachaduras generalizadas e reações bolhosas de pele, algumas severas. Raramente observaram-se anormalidades nos testes de função hepática. Relatos laboratoriais: foram observados em alguns pacientes discreta diminuição nos níveis de cálcio sérico e fosfato, as quais foram precoces, transitórias e assintomáticas. Posologia**: A dose recomendada nos adultos é de 1 comprimido de 35 mg uma vez por semana, por via oral. Deve ser administrado no mínimo 30 minutos antes da primeira refeição, outra medicação ou bebida (exceto água) do dia. Os comprimidos devem ser engolidos inteiros, sem deixá-los dissolvendo na boca ou mastigá-los. Os pacientes devem utilizar OSTEOTRAT enquanto estiverem na posição vertical, com um copo de água (120 mL) para auxiliar a chegada ao estômago. Os pacientes não devem deitar por 30 minutos após ingestão de OSTEOTRAT. O comprimido de Osteotrat deve ser tomado no mesmo dia de cada semana, não devem ingeridos dois comprimidos no mesmo dia. Nenhum ajuste de dose é necessário para pacientes com insuficiência renal leve a moderada. O uso do risedronato sódico é contraindicado em pacientes com insuficiência renal severa ("clearance" de creatinina menor que 30 mL/min.) "SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO." VENDA SOB PRESCRIÇÃO MÉDICA. MS - 1.0573.0418. MB 02_SAP 4389103. Material técnico científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos. Para informações completas, consultar a bula na íntegra através da Central de Atendimento ao Cliente.

Material técnico científico de distribuição exclusiva à classe médica.

Referências Bibliográficas: 1) Bula do produto NISULID: comprimidos dispersíveis. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 2) HELSINN. The original nimesulide. 2013. Disponível em: <http://www.nimesulide.net/Default.aspx?Pagina=home&SM=home&Lingua=EN>. Acesso em: Mar. 2017. 3) Kairos Web Brasil. Disponível em: <http://brasil.kairosweb.com>. Acesso em: Maio 2017.4) BIANCHI, M; BROGGINI, M. A randomised, double-blind, clinical trial comparing the efficacy of nimesulide, celecoxib and rofecoxib in osteoarthritis of the knee. Drugs, v.63, suppl.1, p. 37-46, 2003. 5) Banco de dados da Anvisa: http://consultas.anvisa.gov.br/#/medicame.

Contraindicação: crianças menores de 12 anos. **Interação medicamentosa:** Não se aconselha usar medicamentos que provoquem irritação no estômago durante o tratamento com NISULID® (nimesulida).

NISULID. nimesulida. 100 mg comprimidos. 100 mg comprimidos dispersíveis. 100 mg / envelope granulado. 50 mg/ml gotas. 10 mg/ml suspensão oral. uso oral. 100 mg supositórios. uso retal. uso adulto e pediátrico. MS – 1.0573.0301. INDICAÇÕES: Indicado em condições clínicas que requeiram atividade anti-inflamatória, analgésica e antipirética. CONTRAINDICAÇÕES: **Hipersensibilidade à nimesulida ou a qualquer outro componente do medicamento; história de hipersensibilidade ao ácido acetilsalicílico ou a outros AINES. Pacientes com úlcera péptica em fase ativa, ulcerações recorrentes ou com hemorragia gastrintestinal; paciente com distúrbios de coagulação grave; pacientes com insuficiência cardíaca grave; pacientes com disfunção renal grave; pacientes com disfunção hepática; crianças menores de 12 anos. A nimesulida não deve ser administrada durante a gravidez ou em mulheres que estejam amamentando.** CUIDADOS E ADVERTÊNCIAS: Raramente nimesulida foi relatada estar associada com reações hepáticas sérias, incluindo casos fatais. Pacientes que apresentaram sintomas compatíveis com dano hepático durante o tratamento com nimesulida (por exemplo, anorexia, náusea, vômitos, dor abdominal, fadiga, urina escura ou icterícia) devem ser cuidadosamente monitorados. A administração concomitante com drogas hepatotóxicas conhecidas e abuso de álcool, devem ser evitados durante o tratamento com nimesulida. Pacientes que apresentaram testes de função hepática anormais devem descontinuar o tratamento e não devem reiniciar o tratamento com a nimesulida. Em raras situações, onde ulcerações ou sangramentos gastrintestinais ocorrem em pacientes tratados com nimesulida, o medicamento deve ser suspenso. Em pacientes com insuficiência renal ou cardíaca, cuidado é requerido, pois o uso de AINES pode resultar em deterioração da função renal. Pacientes idosos são particularmente sensíveis às reações adversas dos AINES, incluindo hemorragia e perfuração gastrintestinal, dano das funções renal, cardíaca e hepática. O uso prolongado de AINES em idosos não é recomendado. A nimesulida deve ser usada com atenção em pacientes com história de ulceração péptica ou inflamações intestinais. Como os AINES podem interferir na função plaquetária, eles devem ser usados com cuidado em pacientes com hemorragia intracraniana e alterações da coagulação, como por exemplo, hemofilia e predisposição a sangramento. As drogas antiinflamatórias não-esteroidais podem mascarar a febre relacionada a uma infecção bacteriana subjacente. Com relação ao uso da nimesulida em crianças, foram relatadas algumas reações graves, incluindo raros casos compatíveis com síndrome de Reye. O uso concomitante de outros anti-inflamatórios não-esteroidais durante a terapia com nimesulida não é recomendado. Como os outros anti-inflamatórios não-esteroidais, a nimesulida deve ser usada com cuidado em pacientes com insuficiência cardíaca congestiva, hipertensão, prejuízo da função renal ou depleção do volume extracelular, que são altamente suscetíveis a uma redução no fluxo sangüíneo renal. Por ser a eliminação do fármaco predominantemente renal, o produto deve ser administrado com cuidado a pacientes com prejuízo da função hepática ou renal. Em pacientes com clearance de creatinina de 30-80 ml/min, não há necessidade de ajuste de dose. Em caso de disfunção renal grave o medicamento é contra-indicado. Em pacientes com história de perturbações oculares devido a outros AINES, o tratamento deve ser suspenso e realizado exames oftalmológicos caso ocorram distúrbios visuais durante o uso da nimesulida. Pacientes com asma toleram bem a nimesulida, mas a possibilidade de precipitação de broncoespasmo não pode ser inteiramente excluída. Os riscos de uso por via de administração não-recomendada são: a não-obtenção do efeito desejado e ocorrência de reações adversas. Atenção diabéticos: contém açúcar (nas apresentações da suspensão oral (300 mg/ml), granulado (1,774 g por envelope) e gotas (300 mg/ml)). GRAVIDEZ E LACTAÇÃO: Categoria de risco de gravidez C: este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. INTERAÇÕES MEDICAMENTOSAS: A potencial interação com glibenclamida, teofilina, varfarina, digoxina, cimetidina e uma preparação antiácida (ou seja, uma combinação de hidróxido de magnésio e alumínio) foram estudadas in vivo. Nenhuma interação clínica significante foi observada. A nimesulida pode antagonizar os efeitos dos diuréticos e em particular bloquear o aumento da atividade da renina plasmática induzida pela furosemida. O uso concomitante de furosemida e nimesulida requer cautela em pacientes renais ou cardíacos suscetíveis. A administração concomitante de nimesulida com anticoagulantes (varfarina) ou ácido acetilsalicílico pode causar efeitos aditivos (aumento do risco de complicações de sangramento). Portanto, esta combinação não é recomendada e é contra-indicada em pacientes com distúrbios de coagulação graves. Se a combinação não puder ser evitada, a atividade anticoagulante deve ser cuidadosamente monitorada. Se nimesulida for prescrita para um paciente sob terapia com lítio, os níveis de lítio devem ser monitorados cuidadosamente. Deve-se ter cuidado com pacientes que apresentem anormalidades hepáticas, particularmente se houver intenção de administrar nimesulida em combinação com outras drogas potencialmente hepatotóxicas. Não há evidência de que a nimesulida afete a glicemia em jejum ou a tolerância à glicose em pacientes diabéticos tratados com sulfoniluréias. Pode haver potencialização da ação da fenitoína. Embora não tenham sido relatados especificamente com a nimesulida, foram documentadas interações entre antiinflamatórios não-esteroidais e lítio, metotrexato, probenecida e nimesulida. Portanto, recomenda-se cuidado na administração concomitante de nimesulida com qualquer uma destas drogas, devido ao aumento do risco de hemorragias gastrintestinais. Devido ao seu efeito sobre as prostaglandinas renais, os inibidores da prostaglandina-sintetase como a nimesulida podem aumentar a nefrotoxicidade das ciclosporinas. Recomenda-se tomar NISULID após as refeições. Não se aconselha a ingestão de bebidas alcoólicas durante o tratamento. REAÇÕES ADVERSAS: **Pele e tecidos subcutâneos: prurido, rash e sudorese aumentada. Gastrintestinais: diarréia, náusea e vômito. Hepatobiliar: alterações dos parâmetros hepáticos (transaminases), geralmente transitórias e reversíveis. Casos isolados de hepatite aguda, falência hepática fulminante (algumas fatalidades foram relatadas), icterícia e colestase. Sistema nervoso: tonturas e vertigens. Sistemas visual e auditivo: raramente visão borrada. Sistema cardiovascular: hipertensão. Renais: raramente: disúria, hematúria e retenção urinária. Sistema sangüíneo e linfático: raramente: anemia e eosinofilia. Sistema imunológico: raramente hipersensibilidade. Sistema endócrino: raramente hipercalemia. Respiratórios: casos isolados de reações anafiláticas como dispnéia, asma e broncoespasmo, principalmente em pacientes com histórico de alergia ao ácido acetilsalicílico e a outros AINES. Distúrbios gerais: edema**. POSOLOGIA: USO PARA ADULTOS E CRIANÇAS ACIMA DE 12 ANOS. Comprimidos: 50 - 100mg (1/2 a 1 comprimido tomado com 1/2 copo de água) duas vezes ao dia, podendo alcançar até 200 mg duas vezes ao dia. A administração é por via oral. Comprimidos dispersíveis: 100mg (1 comprimido) duas vezes ao dia, podendo alcançar até 200 mg duas vezes ao dia. Dissolver o comprimido em 1/2 copo de água (100 mL) ou, se preferir, o comprimido poderá ser deglutido inteiro, sem a necessidade de dissolução prévia. A administração é por via oral. Granulado: 50 a 100mg (1/2 a 1 envelope dissolvido em um pouco de água ou suco) duas vezes ao dia, podendo alcançar até 200mg duas vezes ao dia. A administração é por via oral. Supositórios: 1 supositório de 100mg duas vezes ao dia, podendo alcançar até 200mg (2 supositórios de 100mg) duas vezes ao dia. Aplicar o supositório por via retal. Gotas: administrar 1 gota (2,5mg) por kg de peso, duas vezes ao dia, diretamente na boca da criança ou se preferir diluída em um pouco de água açucarada. Lembramos que cada gota contém 2,5mg de nimesulida e cada mL de NISULID contém 50mg de nimesulida. Cada mL do produto contém 20 gotas. Suspensão: a posologia recomendada é de 5mg/kg/dia - fracionada a critério médico em duas administrações. Agitar antes de usar. Colocar a dose recomendada no copo-medida que acompanha o produto e pedir para a criança tomar pela boca (1mL da suspensão contém 10mg de nimesulida). Pacientes com insuficiência da função renal: não há necessidade de ajuste de dose em pacientes com insuficiência renal moderada. Em casos de insuficiência renal grave o medicamento é contra-indicado. Pacientes com insuficiência hepática: contra-indicado em pacientes com insuficiência hepática. VENDA SOB PRESCRIÇÃO MÉDICA. SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. Material técnico científico de distribuição exclusiva à classe médica - Documentação Científica e informações adicionais estão à disposição da classe médica, mediante solicitação. MB_ 05 SAP4094207(A)09/09.

DOI: http://dx.doi.org/10.1590/1413-785220172506169042

PROGNOSTIC FACTORS IN PATIENTS WITH PRESSURE SORES IN A UNIVERSITY HOSPITAL IN SOUTHERN BRAZIL

FATORES PROGNÓSTICOS EM PACIENTES COM ÚLCERAS DE PRESSÃO EM HOSPITAL UNIVERSITÁRIO NO SUL DO BRASIL

Gustavo Palmeiro Walter[1], William Seidel[1], Renata Della Giustina[1], Jorge Bins-Ely[1], Rosemeri Maurici[2], Janaína Luz Narciso-Schiavon[2]

1. Plastic Surgery Division, Hospital Universitario Polydoro Ernani de Sao Thiago, Universidade Federal de Santa Catarina, Florianópolis, SC, Brazil.
2. Postgraduate Program in Intensive and Palliative Care, Universidade Federal de Santa Catarina, Florianópolis, SC, Brazil.

ABSTRACT

Objective: Despite advances in medical care, patients who are hospitalized or have spinal cord injuries often develop pressure sores. The objective of this study was to describe the epidemiological characteristics of pressure sores and evaluate factors associated with recurrence and cure. Methods: In this historical cohort study, clinical and laboratory data were collected from medical records between 1997 and 2016. Results: Sixty individuals with pressure ulcers were included; mean patient age was 38.1±16.5 (37.0) years, 83.3% were men, and 86.8% identified as white. Most patients (85.1%) had paraplegia, amputation, or trauma of the lower limbs with motor sequelae; the remainder (14.9%) were quadriplegic. Most (78.3%) underwent surgery, and the mean follow-up time was 1.8±2.5 years. The lesions were cured in 25 patients; they recurred in 25% of the patients, and recurrence was seen to be associated with the location of the lesions. Patients with recurrent lesions had more medical consultations and a longer treatment time. Individuals whose ulcers had healed had fewer lesions, higher body mass index (BMI), and a higher proportion of these patients underwent surgery. Conclusions: BMI and location and number of lesions are prognostic factors. ***Level of Evidence IV, Case Series.***

Keywords: Pressure ulcer/epidemiology. Pressure ulcer/mortality. Surgery, plastic. Recurrence. Spinal cord injuries.

RESUMO

Objetivo: Apesar do progresso dos cuidados médicos, os pacientes hospitalizados ou com lesões medulares frequentemente desenvolvem úlceras de pressão. O objetivo deste estudo foi descrever as características epidemiológicas das úlceras de pressão e avaliar os fatores associados à recorrência e à cura. Métodos: Neste estudo de coorte histórico, foram coletados dados clínicos e laboratoriais de prontuários médicos de 1997 a 2016. Resultados: Sessenta indivíduos com úlceras de pressão foram incluídos. A média de idade dos pacientes foi 38,1 ± 16,5 (37,0) anos, 83,3% eram homens e 86,8% foram identificados como brancos. A maioria dos pacientes (85,1%) tinha paraplegia, amputação ou trauma nos membros inferiores com sequelas motoras; os restantes (14,9%) eram tetraplégicos. A maioria dos pacientes (78,3%) foi submetida à cirurgia e o tempo médio de acompanhamento foi 1,8±2,5 anos. A cicatrização das lesões foi observada em 25 pacientes; houve recorrência em 25% dos pacientes e verificou-se que estavam associadas à localização das lesões. Os pacientes com lesões recorrentes tinham maior número de consultas médicas e maior tempo de tratamento. Os indivíduos cujas úlceras cicatrizaram tinham menos lesões, maior índice de massa corporal (IMC) e maior proporção deles foi submetida à cirurgia. Conclusões: O IMC, a localização e o número de lesões são fatores prognósticos. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Lesão por pressão/epidemiologia. Lesão por pressão/mortalidade. Cirurgia plástica. Recidiva. Traumatismos da medula espinal.*

Citation: Walter GP, Seidel W, Della Giustina R, Bins-Ely J, Maurici R, Narciso-Schiavon JL. Prognostic factors in patients with pressure sores in a university hospital in southern Brazil. Acta Ortop Bras. [online]. 2017;25(6):243-7. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Pressure sores are lesions caused by local ischemia in debilitated patients, who are chronically ill or suffer from spinal cord injury. Friction, moisture and the presence of bony protuberances in contact with support surfaces are risk factors for the development of these sores.[1]

Pressure sores have a negative impact on patients' quality of life and cause a considerable increase in hospital costs. Preventing the development of new lesions and their recurrence after treatment is fundamental to improving quality of life and reducing healthcare expenses.[2] A study conducted in the Netherlands in 2013 found that the average cost for treatment of multiple sores was approximately

All authors declare no potential conflict of interest related to this article.

Work conducted at the Serviço de Cirurgia Plástica, Hospital Universitario Polydoro Ernani de Sao Thiago, Universidade Federal de Santa Catarina, Florianópolis, SC, Brazil. Correspondence: Serviço de Cirurgia Plástica/HU Polydoro Ernani de São Thiago/UFSC. Rua Professora Maria Flora Pausewang s/nº, Laboratório de Técnica Cirúrgica, Florianópolis, SC, Brazil. 88040-900. gustavoplastica@gmail.com

Article received in 09/08/2016, approved in 07/03/2017.

40,882 Euros.[3] In the United States (US), 2.5 million sores are treated annually at a cost of 11 billion US dollars.[1]
Despite advancements in healthcare, the prevalence of pressure sores remains high, so much that in developing countries, more than 90% of patients with spinal cord injuries have pressure sores.[4]
The prevalence of pressure sores in hospitalized patients is 16.9% in Brazil[5] and 18.1% in Europe.[6] In Nebraska, the incidence is 8.5% in tertiary hospitals and 23.9% in nursing homes.[7]
Recurrence rates reach 70% after reconstructive surgery[8] as such patients have multiple risk factors: skin insensitivity, incontinence, immobility, joint contractures, muscle spasms and other comorbidities.[2]
Few studies have identified clinical and biochemical factors related to the post-treatment prognosis of patients with pressure sores. This study aims to evaluate the clinical and biochemical characteristics of individuals with pressure sores treated at a service that is regarded as a reference in plastic surgery in South Brazil, and to identify the characteristics associated with recurrence after curative treatment.

METHODS

Sample

This is a cross-sectional analytical study of adult individuals with pressure sores treated at the plastic surgery outpatient clinic of Polydoro Ernani de São Thiago, a public and tertiary University Hospital of Federal University of Santa Catarina (HU/UFSC) in Florianopolis – Brazil, between 1997 and 2016. Eligible patients were identified from the outpatient and surgical attendance record, and recruited by phone calls or during routine outpatient visits. The individuals or their family members were invited to participate in the study and to sign the informed consent form. Clinical data was extracted from the medical records and biochemical data was obtained from the laboratory registration system. Patients with insufficient registration data in their medical records were excluded.
Data on the following clinical and demographic variables were collected: gender, age, race, body mass index (BMI), presence of caretaker, smoking status, alcohol status, comorbidities (hypertension, diabetes mellitus (DM), dementia, previous stroke, myelomeningocele), disability (paraplegia, injury or amputation of lower limbs, quadriplegia). The appearance of pressure sores after hospitalization, outpatient nutritional follow-up, and number of medical consultations with the plastic surgery staff were also evaluated. Severity was evaluated according to the location and the number of sores. With regard to treatment, the conduct of reparative surgery and the total time of treatment were documented. Surgical treatment was decided at the discretion of the attending plastic surgeon, and was based on clinical assessment of the patient and the severity of the lesion.

Laboratory tests

The following biochemical variables were analyzed: hemoglobin, leukocyte count, fasting glucose, creatinine, serum sodium and prothrombin activation time (PAT). The test results were expressed in absolute values.

Statistical analysis

The patients were divided into two groups: presence of recurrence, and absence of recurrence with progression to cure. Bivariate analysis was used to compare the groups with regard to each clinical and biochemical characteristic of interest.
The mean and standard deviation (SD) of normally distributed numerical variables were compared using the Student's t-test. The medians of non-normally distributed numerical variables were compared with the Mann-Whitney test. Qualitative variables were expressed in frequencies (%); the Chi-square test or Fischer's exact test was used to analyze them where required. Values of $p<0.05$ were considered to be statistically significant.
The statistical program *Statistical Package for the Social Sciences*, version 17.0 (IBM SPSS statistics, Chicago, Illinois, US) was used to conduct the tests.
The study protocol met the ethical precepts of the Helsinki Declaration and was approved by the Human Research Ethics Committee of UFSC under the number 1215312.

RESULTS

Patients characteristics

Between 1997 and 2016, 92 patients with pressure sores were identified as eligible for this study. Thirty-two patients were excluded due to incomplete clinical data.
In total, 60 patients suffering from pressure sores were included in the study. The average age was 38.1 ± 16.5 (37.0) years, 83.3% were male and 86.8% identified as white. The majority (85.1%) suffered from paraplegia, amputation or trauma of the lower limbs with motor sequelae, 14.9% suffered from quadriplegia, and 10% had myelomeningocele. 3.4% of the patients had had previous stroke, 1.7% had dementia and 1.7% had developed the sores after hospitalization.
Among those with paraplegia, 26.5% were victims of stab wounds or firearm injuries, 23.5% were victims of road accidents and 14.7% of falls. Among individuals who suffered amputation or trauma to the lower limbs, 50.0% were victims of road accidents and 50% of falls. Among those with quadriplegia, 25.0% were victims of stab wounds or firearm injuries and 25.0% of road accidents.
With regard to the location of the pressure sores, 47.5% were sacral, 37.3% ischial, 8.5% trochanteric, 3.4% calcaneal and 3,4% in other sites. Two or more sores were present in 40.7% of the patients, and the commonest combinations were sacral and trochanteric sores (33.3%), and sacral and ischial sores (29.2%).
Most (78.3%) of the patients underwent plastic surgery. The mean follow-up time was 1.8 2.5 years. Twenty-two (36.7%) were lost to follow-up, 10 (16.6%) remain under follow up, 25 (41.7%) were considered cured and 3 have (5.0%) died. Of the 60 patients, 25% have suffered from recurrent lesions at some point during follow-up. The mean time to recurrence after treatment was 0.9 2.6 years.
The clinical and biochemical characteristics of the study participants are described in Table 1.

Clinical and biochemical characteristics of individuals with pressure sores, according to recurrence of lesions after treatment

On comparing individuals with and without recurrence after treatment, (Table 1) recurrence was found to be associated with a higher rate (8 or more) of outpatient visits with the plastic surgery team (80% *vs.* 37.8%; P = 0.005) and longer follow-up (1.8 vs. 0.8 years; P = 0.007). There was a difference in recurrence rate according to the location of the sores (P = 0.037): a higher rate of sores recurred in the sacral region (57.1 vs. 44.4%) and a lower rate in the ischial region (14.3 vs. 44.4%). There was no difference in relation to age, gender, race, BMI, presence of caretaker, smoking status, alcohol status, comorbidities (SAH, DM, CVA, myelomeningocele), disabilities (paraplegia, injury or amputation of lower limbs, quadriplegia, appearance of lesion during hospitalization, outpatient nutritional follow-up, number of sores, conduct of reparative surgery, hemoglobin levels, leukocytes, fasting glucose levels, creatinine, sodium and PAT.

Clinical and biochemical characteristics of individuals suffering from pressure sores, according to the healing of the lesions

Individuals who were completely healed had a higher median BMI (23.3 *vs.* 19.7 kg/m^2; P = 0.024), higher mean hemoglobin (12.2 2.5 *vs.* 9.7 3.6 g/dl; P = 0.033) and higher rate of undergoing

Table 1. Clinical and biochemical characteristics of patients with pressure sores, according to post-treatment recurrence with the Plastic Surgery staff.

Characteristic	N	All N = 60 (100%)	Recurrence N =15 (25%)	Non-Recurrence N = 45 (75%)	P
Age*	59	38.1 ± 16.5 (37.0)	41.4 ± 17.1 (38.0)	37.0 ± 16.3 (34.5)	0.433[m]
Male, n (%)	60	50 (83.3)	11 (73.3)	39 (86.7)	0.250[f]
White, n (%)	53	46 (86.8)	11 (73.3)	35 (92.1)	0.090[f]
Body Mass Index, n (%)	17	22.2 ± 3.2 (22.0)	23.6 ± 3.7 (23.0)	21.4 ± 2.8 (21.9)	0.200[t]
Have a caretaker, n (%)	47	32 (68.1)	10(71.4)	22(66.7)	1.00[f]
Current Smoker, n (%)	51	12 (23.5)	3(23.1)	9(23.7)	1.00[f]
Current Drinker, n (%)	49	2 (4.1)	1(7.7)	1(2.8)	0.464[f]
Diabetes Mellitus, n (%)	60	2(3.3)	0	2(4.4)	1.00[f]
Hypertension, n (%)	60	3(5)	2(3.3)	1(2.2)	0.151[f]
Stroke, n (%)	58	2(3.4)	1(7.1)	1(2.3)	0.428[f]
Dementia, n (%)	59	1(1.7)	0	1(2.2)	1.000[f]
Myelomeningocele, n (%)	60	6(10)	2(13.3)	4(8.9)	0.634[f]
Disability:	47				0.086[f]
--- Paraplegia/Limb amputation, n (%)		40 (85.1)	14 (100)	26 (78.8)	
--- Quadriplegia, n (%)		7 (14.9)	0 (0.0)	7 (21.2)	
Lesion after Hospitalization, n (%)	60	1 (1.7)	0	1 (2.2)	1.00[f]
Outpatient Nutritional Follow-up, n (%)	60	7 (11.7)	2 (3.3)	5 (11.1)	1.00[f]
Over 8 visits to plastic surgery, n (%)	60	29 (48.3)	12 (80)	17 (37.8)	0.005[q]
Two or more sores, n (%)	59	24 (40.7)	8 (57.1)	16 (35.6)	0.151[q]
Ulcer location:	59				0.037[q]
--- Sacral, n (%)		28 (47.5)	8 (57.1)	20 (44.4)	
--- Ischial, n (%)		22 (37.3)	2 (14.3)	20 (44.4)	
--- Trochanteric, n (%)		5 (8.5)	1 (7.1)	4 (8.1)	
--- Calcaneus, n (%)		2 (3.4)	1 (7.1)	1 (2.2)	
--- Others		2 (3.4)	2 (14.3)	0 (0.0)	
Surgery, n (%)	60	47 (78.3)	14 (93.3)	33 (73.3)	0.153[f]
Cure, n (%)	38	25 (65.8)	8 (72.7)	17(63)	0.714[f]
Treatment time (year)*	54	1.8 ± 2.5 (1.0)	3.7 ± 3.5(1.8)	1.2 ± 1.6 (0.8)	0.007[m]
Death, n (%)	38	3 (7.9)	1 (9.1)	2 (7.4)	1.00[f]
Hemoglobin* (g/dl)	45	11.4 ± 3.0 (12.2)	11.4 ± 3.4 (12.1)	11.4 ± 2.9 (12.2)	0.943[t]
Leukocytes* (thousand/mm^3)	42	8967 ± 3622 (7950)	9250 ± 4202 (8250)	8854 ± 3436 (7880)	0.759[m]
Fasting glucose* (g/dl)	27	93.8 ± 18.3 (91)	96.7 ± 26.0 (91.0)	93.0 ± 16.3 (89.0)	0.953[m]
Creatinine* (mg/dl)	34	0.8 ± 0.3 (0.7)	0.8 ± 0.3 (0.8)	0.7 ± 0.3 (0.7)	0.236[m]
Sodium* (mEq/L)	23	138.1 ± 4.4 (139.0)	138.3 ± 2.4 (139.0)	138.1 ± 25.1 (138.5)	0.759[m]
Prothrombin activity time*	24	78.0 ± 12.0 (76.8)	82.3 ± 13.3 (77.5)	75.8 ± 11.1 (76.8)	0.216[t]

*Mean ± standard deviation (median); m: Mann Whitney test; f: Fisher's exact test; q: chi-square test; t: Student's t-test.

plastic surgery (92.0% *vs.* 61.5%; P = 0.034). (Table 2) This group had the lowest proportion of individuals with two or more pressure sores in various regions (28.0% vs. 66.7%; P = 0.036). There was no difference in relation to age, gender, race, presence of caretaker, smoking status, alcohol status, comorbidities (SAH, DM, CVA, myelomeningocele), disabilities (paraplegia, injury or amputation of lower limbs, quadriplegia, prolonged hospitalization, outpatient nutritional follow-up, number of visits with plastic surgery team, leukocyte count, fasting glucose levels, creatinine, sodium and PAT.

DISCUSSION

The mean age of the participants in our study is similar to the 29 to 34 years described by Arora et al.[9] and Costa et al.[10] These differ from those of other studies, which had a mean participant age ranging between 56 to 60 years. This is because their study population comprised patients with lesions secondary to immobility from long periods of hospitalization.[11-14] In our study, only a minority of patients (7%) fitted this profile. The majority of our patients had spinal or congenital (myelomeningocele) traumatic lesions similar to those described by Yamamoto et al.,[13] in which 49% of the paraplegic patients had experienced trauma. Pressure sores are commoner in males,[10,13,14] possibly because they tend to be more exposed to situations involving the risk of trauma with spinal cord injury.[10]

With regard to the location of pressure sores, sacral sores tend to be commonest, varying from 72 to 87% in Hospital São Paulo[14-16] and 32% in Hospital das Clínicas.[10] These findings are similar to ours, and suggests that many of these patients remain in the dorsal decubitus position for a prolonged time.

The treatment of pressure sores can be divided into systemic and local options, and the latter can be subdivided into conservative and surgical. Surgical treatment of pressure sores is the therapeutic option of last resort, and is indicated for wounds refractory to clinical treatment or when fast scarring of the lesion is required.[17] Even then, reparative plastic surgery is indicated in 71% to 78% of patients.[2,10] The recurrence rate of lesions is usually high and ranges from 11% to 63%.[10,11,13,18-20] Recurrence rates in the last century reached 70%.[8] The high recurrence rate even after treatment implies that the initial causative factors had not been resolved, and also that complications persist.[11] In United Kingdom, low recurrence rates (6% after 33 months) are due to the implementation of a multidisciplinary patient follow-up program not reported in the other studies.[2]

With regard to prognostic factors, smoking and comorbidities have been associated with an increased prevalence of pressure

Table 2. Clinical and biochemical characteristics associated with cure after plastic surgery treatment.

Characteristic	N	All n = 38 (100%)	Cure N = 25 (66%)	Non-Cure N = 13 (34%)	P
Age*	37	39.2 ± 17.4 (35.0)	35.4 ± 14.5 (33.0)	46.2 +- 20.4 (43)	0.071[t]
Male, n (%)	38	30 (78.9)	21 (84.0)	9 (69.2)	0.407[f]
White skin color, n (%)	33	29 (87.9)	19 (86.4)	10 (90.9)	1.000[f]
Body mass index*	14	22.5 ± 3.4 (22.1)	23.6 ± 3.3 (23.3)	19.8 ± ± 1.8 (19.7)	0.024[m]
Have a caretaker, n (%)	32	23 (71.9)	16 (76.2)	7 (63.6)	0.681[f]
Current Smoking, n (%)	34	4 (11.8)	2 (8.3)	2 (20)	0.564[f]
Current Alcoholism, n (%)	33	1 (3.0)	0 (0.0)	1 (11.1)	0.273[f]
Diabetes mellitus, n (%)	38	2 (5.3)	0 (0.0)	2 (15.4)	0.111[f]
Hypertension, n (%)	38	3 (7.9)	1 (4.0)	2 (15.4)	0.265[f]
Stroke, n (%)	37	2 (5.4)	0 (0.0)	2 (15.4)	0.117[f]
Dementia, n (%)	37	1 (2.7)	0 (0.0)	1 (7.7)	0.351[f]
Myelomeningocele, n (%)	38	5 (13.2)	3 (12.0)	2 (15.4)	1.000[f]
Disability:	32				0.637[f]
---Paraplegia or Limb Amputation, n (%)		26 (81.3)	17 (77.3)	9 (90)	
--- Quadriplegia, n (%)		6 (18.8)	5 (22.7)	1(10.0)	
Lesion after hospitalization, n (%)	38	1 (2.6)	0 (0.0)	1 (7.7)	0.342[f]
Outpatient nutritional follow-up, n (%)	38	5 (13.2)	4 (16.0)	1 (7.7)	0.643[f]
Eight or more visits, n (%)	38	20 (52.6)	14 (56.0)	6 (46.2)	0.734[f]
Two or more sores, n (%)	37	15 (40.5)	7 (28.0)	8 (66.7)	0.036[f]
Surgery, n (%)	38	31 (81.6)	23(92.0)	8 (61.5)	0.034[f]
Death, n (%)	38	3 (7.9)	1(9.1)	2 (7.4)	1.000[f]
Hemoglobin (g/dl) *	28	11.4 ± 3.0 (12.2)	12.2 ± 2.5 (12.9)	9.7 ± 3.6 (10.5)	0.033[t]
Leukocytes (/mm^3) *	26	9.083 ± 4.168 (8.000)	8.411 ± 3.773 (7.144)	10.353 ± 4.800 (9.930)	0.178[m]
Fasting glucose (g/dl) *	14	91.7 ± 19.5 (90.0)	88.6 ± 12.7 (89.0)	97.8 ± 29.0 (92.0)	0.417[t]
Creatinine (mg/dl) *	18	0.8 ± 0.3 (0.8)	0.7 ± 0.3 (0.7)	0.9 ± 0.3 (0.8)	0.112[m]
Sodium (mEq/L) *	15	138.8 ± 4.8 ± (139.0)	137.9 ± 2.4 (139)	139.7 ± 6.7 (138)	0.857[m]
Prothrombin activity time *	21	81.5 ± 11.0 (78.5)	81.3 ± 12.1 (76.8)	81.9 ± 9.7 (80.4)	0.945[t]

*Mean ± standard deviation (median); t: Student's t-test; f: Fisher's exact test; m: Mann Whitney's test.

sores in patients with spinal cord injury.[21] Similarly, Berlowitz et al.[22] demonstrated that bedridden or wheelchair-bound patients with low hemoglobin levels have a lower rate of cure of pressure sores. Later, the same group identified factors significantly associated with the presence of sores, including change in level of awarenes, being bedridden or wheelchair bound, poor nutritional intake and hypoalbuminemia.[23] However, there is little evidence to justify the routine use of nutritional supplements, biological agents and adjuvant therapies when compared with standard therapies.[24]

Recurrence rates are the main problem in pressure sore reconstructions. Recurrence has been associated to glycated hemoglobin level exceeding 6%, repeating the same flap already used in a surgery that recurred[18] and being African-American.[11,25] Skin color did not attain statistical significance in our study, and Guihan et al.[11] notes a probable *bias* in their race criterion related to the socioeconomic status of the patients evaluated. The permanence of cure does not depend on adequate surgical treatment in selected patients, but rather on a combination of factors. Multidisciplinary care, focus on the nutritional state of the patient, and use of prophylactic measures are important.[1]

We would like to address some limitations to the present study. Considering the prevalence of pressure sores in the general population, the number of patients included in the study is small. However, the University Hospital is a tertiary center for plastic surgery and cares for individuals from the entire state of Santa Catarina, which is one of the smallest states in Brazil. In addition, the study's sample size is similar to that of other studies on pressure sores.[2,10,11,13,20,22] One of the problems in understanding the recurrence of pressure sores is the lack of clear terminology for evaluating sores that develop in the same anatomical region. When a sore develops, it may represent an incomplete healing of the previously treated sore or a new lesion adjacent to a healed sore. In our study, we defined recurrence as the appearance of a lesion in a previously treated location that had been considered healed after clinical assessment by the attending physician. As this is a retrospective study, specific characteristics relating to the severity of the ulcers (e.g. size and depth) were not available from the medical records and thus could not be described. Finally, the study could not evaluate the surgical techniques used to treat the pressure sores, as these depended on the discretion of the attending physician and the patient's clinical state.

This study enables us to conclude that the commonest cause of pressure sores are spinal cord injuries associated with trauma or congenital diseases, and they are most commonly located in the sacral and ischial regions. The majority of these patients undergo plastic surgery, and the recurrence rates of post-treatment lesions are similar to those found worldwide. Recurrence is associated with the location of the lesions, higher number of medical consultations and longer time of treatment. Cure is associated with higher BMI, higher mean hemoglobin, lower number of sores and plastic surgery treatment.

ACKNOWLEDGEMENTS

This paper was presented as a partial fulfillment of the requirements for the Masters in Intensive and Palliative Care from The Federal University of Santa Catarina.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. GPW (0000-0002-6615-8551)* and JLNS (0000-0002-6228-4120)* were the main contributors in drafting the manuscript. GPW, WS (0000-0001-6450-7829)*, and RDG (0000-0003-1207-144X)* performed surgery, followed patients, and gathered clinical data. JLNS and RM (0000-0001-9627-2112) evaluated the data from the statistical analysis. JBE (0000-0002-8226-0062)* performed critical review of the article. GPW, RDG, and JLNS conducted the bibliographic research, reviewed the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Cushing CA, Phillips LG. Evidence-based medicine: pressure sores. Plast Reconstr Surg. 2013;132(6):1720-32.
2. Tadiparthi S, Hartley A, Alzweri L, Mecci M, Siddiqui H. Improving outcomes following reconstruction of pressure sores in spinal injury patients: a multi-disciplinary approach. J Plast Reconstr Aesthet Surg. 2016;69(7):994-1002.
3. Filius A, Damen TH, Schuijer-Maaskant KP, Polinder S, Hovius SE, Walbeehm ET. Cost analysis of surgically treated pressure sores stage III and IV. J Plast Reconstr Aesthet Surg. 2013;66(11):1580-6.
4. Burns AS, O'Connell C. The challenge of spinal cord injury care in the developing world. J Spinal Cord Med. 2012;35(1):3-8.
5. Brito PA, de Vasconcelos Generoso S, Correia MI. Prevalence of pressure ulcers in hospitals in Brazil and association with nutritional status--a multicenter, cross-sectional study. Nutrition. 2013;29(4):646-9.
6. Vanderwee K, Clark M, Dealey C, Gunningberg L, Defloor T. Pressure ulcer prevalence in Europe: a pilot study. J Eval Clin Pract. 2007;13(2):227-35.
7. Bergstrom N, Braden B, Kemp M, Champagne M, Ruby E. Multi-site study of incidence of pressure ulcers and the relationship between risk level, demographic characteristics, diagnoses, and prescription of preventive interventions. J Am Geriatr Soc. 1996;44(1):22-30.
8. Disa JJ, Carlton JM, Goldberg NH. Efficacy of operative cure in pressure sore patients. Plast Reconstr Surg. 1992;89(2):272-8.
9. Arora M, Harvey LA, Chhabra HS, Sharawat R, Glinsky JV, Cameron ID. The reliability of measuring wound undermining in people with spinal cord injury. Spinal Cord. 2017;55(3):304-306.
10. Costa MP, Sturtz G, Costa FP, Ferreira MC, Barros Filho TE. Epidemiological profile and treatment of pressure sores: experience with 77 cases. Acta Ortop Bras. 2005;13(3):124-33.
11. Guihan M, Garber SL, Bombardier CH, Goldstein B, Holmes SA, Cao L. Predictors of pressure ulcer recurrence in veterans with spinal cord injury. J Spinal Cord Med. 2008;31(5):551-9.
12. Chacon JMF, Blanes L, Góis AFT, Ferreira LM, Zucchi, P. Epidemiologic aspects of the patient with pressure sores in the Intensive Care Unit of the emergency room of a teaching hospital in São Paulo. Saúde Coletiva. 2013;1(1):14-19.
13. Yamamoto Y, Tsutsumida A, Murazumi M, Sugihara T. Long-term outcome of pressure sores treated with flap coverage. Plast Reconstr Surg. 1997;100(5):1212-7.
14. Blanes L, Duarte IS, Calil JA, Ferreira LM. Avaliação clínica e epidemiológica das úlceras por pressão em pacientes internados no Hospital São Paulo. Rev Assoc Med Bras. 2004;50(2):182-7.
15. Pena SD, Di Pietro G, Fuchshuber-Moraes M, Genro JP, Hutz MH, Kehdy FS, et al. The genomic ancestry of individuals from different geographical regions of Brazil is more uniform than expected. PLoS One. 2011;16;6(2):e17063.
16. Chacon JM, Blanes L, Hochman B, Ferreira LM. Prevalence of pressure ulcers among the elderly living in long-stay institutions in São Paulo. Sao Paulo Med J. 2009;127(4):211-5.
17. Whitney J, Phillips L, Aslam R, Barbul A, Gottrup F, Gould L, et al. Guidelines for the treatment of pressure ulcers. Wound Repair Regen. 2006;14(6):663-79.
18. Keys KA, Daniali LN, Warner KJ, Mathes DW. Multivariate predictors of failure after flap coverage of pressure ulcers. Plast Reconstr Surg. 2010;125(6):1725-34.
19. Ljung AC, Stenius MC, Bjelak S, Lagergren JF. Surgery for pressure ulcers in spinal cord-injured patients following a structured treatment programme: a 10-year follow-up. Int Wound J. 2017;14(2):355-359.
20. Bates-Jensen BM, Guihan M, Garber SL, Chin AS, Burns SP. Characteristics of recurrent pressure ulcers in veterans with spinal cord injury. J Spinal Cord Med. 2009;32(1):34-42. P
21. Raghavan P, Raza WA, Ahmed YS, Chamberlain MA. Prevalence of pressure sores in a community sample of spinal injury patients. Clin Rehabil. 2003;17(8):879-84.
22. Berlowitz DR, Wilking SV. Pressure ulcers. JAMA. 1991;265(13):1688.
23. Berlowitz DR, Wilking SV. Risk factors for pressure sores. A comparison of cross-sectional and cohort-derived data. J Am Geriatr Soc. 1989;37(11):1043-50.
24. Reddy M, Gill SS, Kalkar SR, Wu W, Anderson PJ, Rochon PA. Treatment of pressure ulcers: a systematic review. JAMA. 2008;300(22):2647-62.
25. Li Y, Yin J, Cai X, Temkin-Greener J, Mukamel DB. Association of race and sites of care with pressure ulcers in high-risk nursing home residents. JAMA. 2011;306(2):179-86.

DOI: http://dx.doi.org/10.1590/1413-785220172506144577

ORIGINAL ARTICLE

EVALUATION OF FUNCTIONAL CHARACTERISTICS IN PATIENTS WITH KNEE OSTEOARTHRITIS

AVALIAÇÃO DAS CARACTERÍSTICAS FUNCIONAIS EM PACIENTES COM OSTEOARTRITE DO JOELHO

Serkan Bakirhan[1], Ozgur Bozan[2] , Bayram Unver[3], Vasfi Karatosun[4]

1. Departments of Physical Therapy and Rehabilitation, Lefke, Faculty of Health Sciences, European University of Lefke, TRNC Mersin 10, Turkey.
2. Private Clinician, Izmir, Turkey.
3. School of Physiotherapy , Dokuz Eylül University, Izmir, Turkey.
4. Department of Orthopedics, School of Medicine, Dokuz Eylül University, Izmir, Turkey.

ABSTRACT

Objective: This study evaluated the physical and functional characteristics of Turkish patients with knee osteoarthritis and how this disease affects their physical and functional status. Methods: This study included 320 patients, who were evaluated to assess body mass index (BMI) and Hospital for Special Surgery (HSS) score in terms of age, sex and functional characteristics. Results: Mean patient age was 66.92±8.89 years and mean BMI was 31.02±5.20 kg/m^2. Mean patient HSS score was 58.70±11.08. According to their sit-to-stand test results, 33% of the patients (n=104) were found to be independent. There was a significant relationship between BMI and functional activity score ($p<0.05$). Conclusions: The majority of the patients in our study were female and obese, and had low functionality levels. Function in patients with OA is restricted as a result of excess weight, so preventive measures can help Turkish patients with OA maintain their ideal weight. Furthermore, patient education can be help this population acquire the habit of regular exercise in order to reduce pain and improve their physical activity and quality of life. ***Level of Evidence IV, Case Series.***

Keywords: Osteoarthritis. Knee. Disability evaluation. Body weight.

RESUMO

Objetivo: Este estudo avaliou as características físicas e funcionais dos pacientes turcos com osteoartrite e como essa doença afeta seu estado físico e funcional. Métodos: O estudo incluiu 320 pacientes que foram avaliados quanto ao índice de massa corporal (IMC) e quanto ao escore Hospital for Special Surgery (HSS), em termos de idade, sexo e características funcionais. Resultados: A média de idade dos pacientes foi 66,92 ± 8,89 anos e a média do IMC foi 31,02 ± 5,20 kg/m^2. A média do escore HSS dos pacientes foi 58,70 ± 11,08. De acordo com os resultados do teste sentar/levantar, observou-se que 33% dos pacientes (n = 104) eram independentes. Houve relação significativa entre IMC e escore de atividade funcional (p < 0,05). Conclusões: A maioria dos pacientes em nosso estudo era do sexo feminino e obesos e tinham níveis baixos de funcionalidade. A função dos pacientes com OA foi restrita em decorrência do excesso de peso, de modo que as medidas preventivas podem auxiliar os pacientes turcos a manter o peso ideal. Além disso, a educação dos pacientes pode ajudar essa população a adquirir o hábito de exercícios regulares para reduzir a dor e melhorar a atividade física e a qualidade de vida. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Osteoartrite. Joelho. Avaliação da deficiência. Peso corporal.*

Citation: Bakirhan S, Bozan O, Unver B, Karatosun V. Evaluation of functional characteristics in patients with knee osteoarthritis. Acta Ortop Bras. [online]. 2017;25(6):248-52. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Osteoarthritis (OA) is the most prevalent chronic rheumatic disease, and is the leading cause of pain and disability in most countries worldwide. Several epidemiologic studies have investigated risk factors for knee OA, finding a consistent association between the incidence or progression of knee OA and age, obesity, weight change, sex, history of knee injury, occupational physical demands, physical activity, lifestyle and geographic regions.[1] The literature contains reports that physical characteristics, quality of life, pain, joint motion limitation, and functional activities of patients with knee OA are affected at different levels.[2,3]

The prevalence of OA varies in different geographic regions.[1] Activities such as sitting on the ground, kneeling, sitting cross-legged, squatting and performing the *salaat* (a form of Islamic prayer) are common in Asian, Far Eastern, and Middle East cultures. During these activities which require high knee flexion, OA process can be triggered because of the increased pressure applied to the knee.[4] Frequent repetition of these activities, which are an important part of daily life, leads to an increased incidence of OA in these societies. As in Far Eastern and Middle Eastern countries, the incidence of OA in Turkish population increases each year due to risk factors resulting from similar activities frequently performed by people in

All authors declare no potential conflict of interest related to this article.

Work conducted at the Department of Orthopedics and Traumatology, Faculty of Medicine, Dokuz Eylül University Hospital, İzmir, Turkey.
Correspondence: European University of Lefke, Faculty of Health Sciencesi Departments of Physical Therapy and Rehabilitation Lefke, TRNC Mersin 10, Turkey. bakirhan75@gmail.com

Article received in 01/11/2015, approved in 10/06/2016.

their daily lives, which, in turn, leads to significant limitations on their functional activities. It is estimated that 4% of the elderly Brazilian population has OA, with the knee being the second joint most affected by this disease, in 37% of cases.[5] In a study conducted on the prevalence of OA in Turkey, the prevalence of symptomatic knee OA in the population over 50 years of age was determined to be 14.8%.[6] Several studies have investigated the incidence and functional and physical impacts of OA in communities with life styles similar to Turkey,[7] but no studies have investigated the functional and physical effects of OA on this population. The purpose of this study is to evaluate the physical and functional characteristics of osteoarthritis patients and how OA affects the physical and functional status of patients with knee OA in Turkish society.

MATERIALS AND METHODS

A total of 320 patients (63 men and 257 women, mean age 66 years; range 40–87) with knee OA were included in the study. These patients were divided into 4 groups according to age: 40–59, 60–69, 70–79 and 80–89 years.

Body Mass Index (BMI) was defined as weight in kilograms divided by the square of patient's height in meters. Patients were stratified by obesity status into 4 groups according to their BMI values: <25 kg/m^2 (underweight), 25–29.9 kg/m^2 (overweight), 30–39.9 kg/m^2 (obese), and ≥40 kg/m^2 (morbidly obese).

Physical knee function was evaluated in all patients using the Hospital for Special Surgery (HSS) knee score criteria, which is based on a total of 100 points. The score is divided into the following categories: lack of pain (30 points); function (22 points); range of motion (18 points); muscle strength (10 points); flexion deformity (10 points); and lack of instability (10 points).[3,8] Active range of knee flexion was measured with a universal goniometer.[3] Extensor mechanism function was evaluated at the same time using the Sit-to-Stand (STS) test.[9] Patients were asked to rise from a 40-cm-high chair while keeping their arms folded across their chest.[10] Quadriceps femoris (QF) muscle strength was assessed via the manual muscle testing method while the patient was in the sitting position, and a score ranging from 0 to 5 was assigned.[3]

SPSS 22.0 software was used for statistical evaluation of the data. Data were presented as mean and standard deviation. The one-way ANOVA test was used to compare variables in the groups. Results in which $p<0.05$ were considered significant.

Our study is a retrospective study. The data were obtained by screening patient files. Therefore, ethic committee approval and patients' consent were not obtained.

RESULTS

This present study examined risk factors for knee OA among 320 Turkish people who ranged in age from 40 to 87 years. The majority of the patients were female (n=80%). (Table 1) All our patients had radiographic severity grade 4 OA on the Kellgren and Lawrence (KL) scale.

Table 1. Demographic characteristics of the patients with knee osteoarthritis.

Age (year)	66.92±8.89 (40–87)
Sex (male/female)	63 M, 257 F
Weight (kg)	77.49±12.63 (50–117)
Height (cm)	158.28±7.36 (142–180)
BMI (kg/cm^2)	31.02±5.20 (17.28–47.84)

BMI: Body Mass Index.

The patients were classified with respect to age; 64 patients were 40–59 years old, 114 patients were 60–69 years old, 127 patients were 70–79 years old and 15 patients were 80–89 years old. (Figure 1) BMI in the study population varied from 17.28 kg/m^2 to 47.84 kg/m^2, with a mean of 31.02 kg/m^2. (Table 1) The study population was classified according to BMI as follows; underweight, 36/320 (11%); overweight, 116/320 (36%); obese, 153/320 (48%); morbidly obese, 15/320 (5%). (Figure 2)

The mean HSS score (0-100) was 58.70±11.08 (range 22–89). The mean HSS pain score was 10.95±7.10 (range 0–30), and the mean HSS functional activity score was 10.36±3.69 (range 4–22). The mean degree of active knee flexion was 100.36±16.45 (range 35–136). The transfer activity score was 2.46±1.09 (range 2–5), stair climbing score was 2.24±0.82 (range 2–5), and walking activity score was 5.67±2.88 (range 2–5). Mean QF muscle strength was 4.02±0.37 (range 3–5). (Table 2) STS test results found that 33% (n=104) of cases were independent. (Table 2)

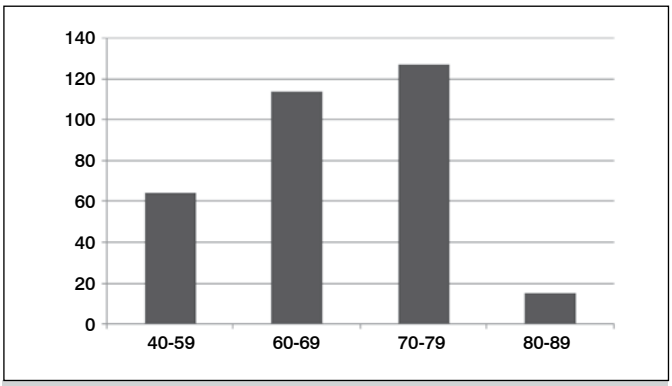


Figure 1. Patient age distribution.

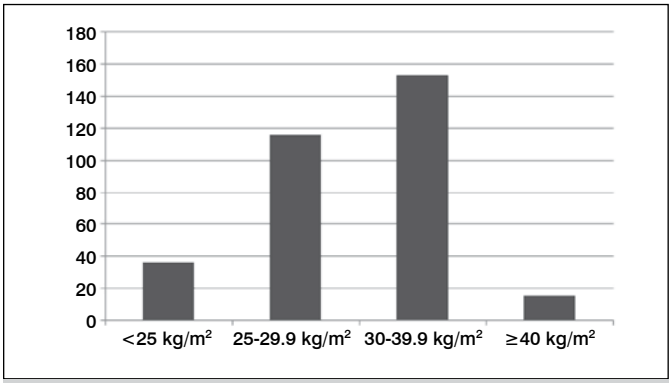


Figure 2. Patient BMI distribution.

Table 2. Results of evaluation parameters used in the study.

Degree of knee flexion (°)	100.36±16.45 (35–136)
HSS knee score	58.70±11.08 (22–89)
Pain scores[a]	10.95±7.10 (0–30)
Walking ability[a]	5.67±2.88 (2–5)
Stair climbing ability[a]	2.24±0.82 (2–5)
Transfer ability[a]	2.46±1.09 (2–5)
Functional activity score[a]	10.36±3.69 (4–22)
QF muscle strength	4.02±0.37 (3–5)
STS test	D: 216 (67%) I: 104 (33%)

HSS: Hospital for Special Surgery, D: Dependent, I: Independent, QF: Quadriceps femoris. STS: Sit-to-stand, [a]Graded by Hospital for Special Surgery score.

Comparison of the relationship between age groups and activity scores found no statistically significant correlation between knee flexion angles, HSS knee score, pain score, scores for walking/stair climbing/transfer, and functional activities scores, QF muscle strength and QF muscle strength scores ($p>0.05$). (Table 3) Analysis of the relationship between BMI and activity scores revealed a statistically significant difference in terms of HSS knee score, pain score, gait score and functional activity score ($p<0.05$). (Table 4) HSS knee score, pain score, and walking and functional activity scores were lower in the morbidly obese group ($p<0.05$). (Table 4)

DISCUSSION

This study investigated the physical and functional characteristics of Turkish patients with OA of the knee. We found that age, sex, and obesity are important factors in the development of OA; walking, stair climbing, transfer and overall functional activity scores are lower in these patients, their knee-joint movements were more limited, and they had high pain scores at rest or during movement. Reported risk factors for the incidence of knee OA in many countries are obesity (high BMI), sex (female), aging, previous knee trauma, occupational kneeling, squatting, or lifestyle.[1,4] This study also showed that obesity, female sex, and advanced age were significantly associated with an increased risk of radiographic knee OA in Turkish people. The results of our study were consistent with those in the literature.

Age is the greatest risk factor in the development of OA and the prevalence of the disease increases with age, reaching 20% in the 45 years of age group, 40% in the 55 years of age group, 70% in the 65 years of age group, and 80% in geriatric patients over age 75 with osteoarthritis of the knee.[11] Review of many studies in the literature reveals that the mean age of the OA patients in these studies is 65 years and over.[1] The mean age of the 320 patients in our study was 66.92 years, which supports the finding that the highest prevalence of osteoarthritis is observed in people aged 60–69. In this study, we found no statistically significant correlation between activity score and the different age groups. (Table 3) Although the functional activity levels of patients with knee OA were seen to decrease due to aging in the literature,[12] we found no relationship between age and activity levels in the present study. Future studies including more patients could obtain more objective results. Our study also indicates that OA progresses with age, and that patients require more radical surgical treatments in advanced stages of the disease. We consider activities intended to protect the knee (appropriate body weight, adaptive equipment, self-help tools, exercise, recommendations on activities of daily living) useful for healthy aging, and these may also help delay implementation of radical surgeries, such as prosthesis implantation.

Studies report that the incidence of developing osteoarthritis is higher in females than in males, in different parts of the world.[2] Women are more prone to knee OA due to several factors, such as changes in QF muscle strength, the presence of less muscle

Table 3. Comparison of age groups and activity score.

	40–59 group	60–69 group	70–79 group	80–89 group	f	p
Degree of knee flexion (°)	104.01±16.79	100.53±15.44	98.91±17.27	96.06±13.94	1.72	0.163
HSS knee score	60.87±11.22	57.89±11.99	58.30±10.11	59.20±10.94	1.07	0.360
Pain scores[a]	11.22±6.95	10.30±7.07	10.98±7.21	14.46±6.54	1.58	0.194
Walking ability[a]	6.09±3.07	5.56±3.05	5.59±2.73	5.33±1.95	0.59	0.617
Stair climbing ability[a]	2.19±0.73	2.39±1.01	2.14±0.63	2.20±0.77	2.01	0.112
Transfer ability[a]	2.38±1.00	2.69±1.22	2.37±0.99	2.40±1.05	1.24	0.292
Functional activity score[a]	10.63±3.81	10.58±4.06	10.08±3.38	9.93±2.57	0.55	0.647
QF muscle strength	4.03±0.43	4.05±0.41	4.00±0.29	3.93±0.25	0.60	0.611
QF muscle strength score	7.96±1.21	7.98±1.19	7.93±0.90	7.73±1.03	0.24	0.865

HSS: Hospital for Special Surgery, QF: Quadriceps femoris. [a]Graded by Hospital for Special Surgery score.

Table 4. Comparison of BMI groups and activity score.

	<25 kg/m² group	25-29.9 kg/m² group	30-39.9 kg/m² group	≥40 kg/m² group	f	p
Degree of knee flexion (°)	102.32±13.85	102.15±15.33	99.43±17.13	95.14±19.32	1.465	0.224
HSS knee score	62.82±9.07	61.40±11.73	57.00±10.18	51.14±11.24	8.786	0.000*
Pain scores[a]	13.35±7.89	12.42±7.01	9.87±6.84	7.61±5.61	5.848	0.001*
Walking ability[a]	6.64±2.98	6.02±2.84	5.44±2.80	4.00±2.82	4.663	0.003*
Stair climbing ability[a]	2.44±1.07	2.33±0.95	2.17±0.69	2.00±0.00	2.166	0.092
Transfer ability[a]	2.61±1.23	2.64±1.23	2.36±0.97	2.14±0.65	2.309	0.076
Functional activity score[a]	11.70±4.19	11.00±3.79	9.93±3.42	8.14±2.90	6.100	0.000
QF muscle strength	4.08±0.28	4.06±0.37	3.99±0.38	3.95±0.38	1.405	0.241
QF muscle strength score	8.17±0.57	8.05±1.00	7.86±1.17	7.71±1.30	1.503	0.207

HSS: Hospital for Special Surgery, QF: Quadriceps femoris. [a]Graded by Hospital for Special Surgery score.

mass and more fat mass, load on joints, pelvic structure, knee morphology, Q angle, neuromuscular strength, hormonal changes occurring with age, and changes in the balance between bone formation and bone resorption.[13] Women also squat more often than men during daily activities such as going to the toilet and doing housework.[14] A study conducted in Turkey found that women were expected to perform housework, while men are expected to work outside the home.[15] The traditional Turkish lifestyle in combination with the decreased muscle strength described above may impact women more than men. Furthermore, older men generally retire from their occupations around 60 to 70 years of age, while women continue to do household chores even after age 70.[7] All of these reasons may explain why the number of female patients exceeds male patients.[14-16] In line with the literature, of the 320 patients in our study, 257 (80%) were female and 63 (20%) were male. Since Turkish women squat more and are more likely to develop OA, it may be useful to inform them about OA and provide them with preventive physiotherapy.

Obesity is an important but preventable risk factor for osteoarthritis in weight-bearing joints, especially the knee. Studies on this topic found a strong correlation between obesity and knee osteoarthritis.[11,17] Weight loss can prevent the development of OA and reduce the symptoms of knee OA. The Framingham study found that a weight loss of 5 kg (11 lbs.) in women can reduce the risk of knee osteoarthritis by 50%.[18] The increasing prevalence of obesity is a significant health problem; there is evidence indicating that obese patients are more likely to require total knee prosthesis (TKP) than non-obese patients. Our study also found a higher proportion of obese patients than non-obese patients. In studies conducted in Turkey, Tekin et al.[16] found a mean BMI of 33.2 kg/cm^2 in patients who received TKP; Kocak et al.[3] found a mean BMI of 30.7 kg/cm^2 in patients with knee OA (KL 4), and Unver et al.[17] found a mean BMI of 33.7 kg/cm^2 in patients who were candidates for TKP. The results of our study agree with these aforementioned data, underscoring the fact that obesity is an important risk factor for OA in Turkish society. The mean age of obese patients was lower than that of non-obese patients, supporting the fact that obesity is a risk factor for knee osteoarthritis and that obese patients require TKP at an earlier age. More than 30% of the Turkish population is obese, suggesting that the prevalence of OA may rise significantly in the future. In the present study, a decrease was observed in patient HSS knee scores, pain scores, and walking and functional activity scores due to increased BMI, in turn leading to a decrease in functional activity levels. (Table 4) Studies have reported that if patients lose weight, reduce existing knee symptoms, and increase their functional activities with a combination of proper diet programs, exercise, weight loss and a combination of lifestyle modifications, they can reduce the rate of overload on the joint due to obesity.[19,20] Therefore, proper diet programs, exercise, and lifestyle changes should be recommended to prevent obesity and ensure that joints remain healthy while aging.[11]

The ability to rise from a chair is an important activity of daily living, and the inability to perform this task may limit independence or lead to institutionalization. The STS test focuses on the knee extensor mechanism and reveals the contraction ability of the QF muscle.[10] In patients with knee OA, this activity is reduced due to pain and reduced extensor muscle strength. Several studies report that this function is more difficult and takes more time in patients with knee OA compared to healthy subjects.[20] In our study, 33% of the patients (n=104) did not receive any support while rising from the chair during the STS. We think that this was probably due to fact that our patients with knee OA had sufficient QF muscle strength; we also observed low scores for transfer activity, and that 92% of our study population (n=293) depended on others for these activities.

In patients with knee OA, QF weakness is a clinical feature that has been described several times, and is considered an important determinant of disability.[21] Knee extensor strength is a highly prevalent and modifiable risk factor for disability in people who have OA and in elderly people without pain.[10] QF strength is important to maintain dynamic stability during the common basic and instrumental activities of daily living.[10] Reduced QF muscle strength has been associated with the degree of pain, disability and joint destruction.[22] However, one study found no correlation between the development of knee OA and QF muscle strength.[2] Kocak et al.[3] found a correlation between a higher degree of OA (according to KL) and decreased muscle strength, and reported that improved QF muscle strength would allow patients to perform functional activities of daily living better and be more independent. The study by these authors on QF muscle strength in knee OA patients with varying KL scores found that a muscle strength of 3.7±0.6 in OA patients (KL 4). In this present study, mean QF muscle strength was 4.02±0.37, which was considered good for that KL level, but pain and functional activity levels were found to be low.

In order to achieve functional activities of daily living, knee flexion of at least 105^o is necessary.[23] The relationship between functional activities and the knee flexion range of motion in patients with knee OA is limited. A study by Kocaket al.[3] found that as the radiographic grade of OA increases in terms of KL, knee flexion decreases. Our study found mean knee flexion of 100° in our patients with knee OA. This value was not sufficient for these patients to perform activities of daily living. For patients with knee OA to independently perform functional activities of daily living, they should use adaptive practices and self-care tools to facilitate these activities and protect the joint.

CONCLUSION

This study on Turkish patients with OA determined similar risk factors as the literature. Since obesity is a preventable risk factor, weight loss can prevent the development of OA and reduce symptoms of OA of the knee. Physical inactivity is reported to be one of the most important factors in the development of obesity, so it is very important for patients with knee OA to maintain regular physical activity. It is extremely important to first determine preventable risk factors for OA and then inform patients in order to reduce symptoms after they appear and decrease functional limitations. At this stage, preventive measures may help Turkish patients with knee OA maintain their ideal weights. Moreover, patient education and regular exercise may reduce pain, increasing physical activity and improving quality of life. In this respect, we concluded that in order to boost success in treating knee OA, more objective results can be achieved through studies evaluating risk factors in larger number of patients.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. SB (0000-0003-0044-8203)*, OB (0000-0001-8395-638X)*, BU (0000-0002-9829-5884)*, and VK (0000-0002-0385-4840)* were the main contributors in writing the manuscript. All authors participated in concept/research design, writing, data collection, and analysis and facilities. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Haq SA, Davatchi F. Osteoarthritis of the knees in the COPCORD world. Int J Rheum Dis. 2011;14(2):122-9.
2. Muraki S, Akune T, Oka H, En-yo Y, Yoshida M, Saika A, et al. Association of radiographic and symptomatic knee osteoarthritis with health-related quality of life in a population-based cohort study in Japan: the ROAD study. Osteoarthritis Cartilage. 2010;18(9):1227-34.
3. Kocak FU, Unver B, Karatosun V, Bakirhan S. Associations between radiographic changes and function, pain, range of motion, muscle strength and knee function score in patients with osteoathritis of the knee. J Phys Ther Sci. 2009;21(1):93-7.
4. Hodge WA, Harman MK, Banks SA. Patterns of knee osteoarthritis in Arabian and American knees. J Arthroplasty. 2009;24(3):448-53.
5. Dos Santos WT, Rodrigues Ede C, Mainenti MR. Muscle performance, body fat,pain and function in the elderly with arthritis. Acta Ortop Bras. 2014;22(1):54-8.
6. Kaçar C, Gilgil E, Urhan S, Arikan V, Dündar U, Oksüz MC, et al. The prevalence of symptomatic knee and distal interphalangeal joint osteoarthritis in the urban population of Antalya, Turkey. Rheumatol Int. 2005;25(3):201-4.
7. Muraki S, Oka H, Akune T, Mabuchi A, En-yo Y, Yoshida M, et al. Prevalence of radiographic knee osteoarthritis and its association with knee pain in the elderly of Japanese population-based cohorts: the ROAD study.Osteoarthritis Cartilage. 2009;17(9):1137-43.
8. Narin S, Unver B, Bakırhan S, Bozan O, Karatosun V. Cross-cultural adaptation,reliability and validity of the Turkish version of the Hospital for Special Surgery (HSS) Knee Score. Acta Orthop Traumatol Turc. 2014;48(3):241-8.
9. Bakırhan S, Angın S, Karatosun V, Ünver B, Günal I. Physical performance parameters during standing up in patients with unilateral and bilateral total knee arthroplasty. Acta Orthop Traumatol Turc. 2012;46(5):367-72.
10. Unver B, Karatosun V, Bakirhan S. ABility to rise independently from a chair during 6-month follow-up after unilateral and bilateral total knee replacement. J Rehabil Med. 2005;37(6):385-7.
11. Christensen R, Astrup A, Bliddal H. Weight loss: the treatment of choice for knee osteoarthritis? A randomized trial. Osteoarthritis Cartilage. 2005;13(1):20-7.
12. Dunlop DD, Song J, Semanik PA, Sharma L, Chang RW. Physical activity levels and functional performance in the osteoarthritis initiative: a graded relationship. Arthritis Rheum. 2011;63(1):127-36.
13. Hunter DJ, Niu J, Zhang Y, Nevitt MC, Xu L, Lui LY, et al. Knee height, knee pain, and knee osteoarthritis: the Beijing Osteoarthritis Study. Arthritis Rheum. 2005;52(5):1418-23.
14. Kim HA, Kim S, Seo YI, Choi HJ, Seong SC, Song YW, Hunter D, Zhang Yet al. The epidemiology of total knee replacement in South Korea: national registry data.Rheumatology (Oxford). 2008;47(1):88-91.
15. Elibol N, Unver B, Karatosun V. Investigation of expectations of patients having undergone total hip arthroplasty in our society. J Orthop. 2003;10(1):1-7.
16. Tekin B, Unver B, Karatosun V. Expectations in patients with total knee arthroplasty. Acta Orthop Traumatol Turc. 2012;46(3):174-80.
17. Unver B, Karatosun V, Bakırhan S. Effects of obesity on inpatient rehabilitation outcomes following total knee arthroplasty. Physiotherapy. 2008;94:198-203.
18. Sarzi-Puttini P, Cimmino MA, Scarpa R, Caporali R, Parazzini F, Zaninelli A,et al. Osteoarthritis: an overview of the disease and its treatment strategies. Semin Arthritis Rheum. 2005;35(1 Suppl 1):1-10.
19. Roddy E, Doherty M. Changing life-styles and osteoarthritis: what is the evidence? Best Pract Res Clin Rheumatol. 2006;20(1):81-97.
20. Unver B, Karatosun V, Bakirhan S, Gunal I. Effects of total knee arthroplasty on body weight and functional outcome. J Phys Ther Sci. 2009;21(2):201-6.
21. Patsika G, Kellis E, Amiridis IG. Neuromuscular efficiency during sit to stand movement in women with knee osteoarthritis. J Electromyogr Kinesiol. 2011;21(5):689-94.
22. Imoto AM, Peccin MS, Trevisani VF. Quadriceps strengthening exercises are effective in improving pain, function and quality of life in patients with osteoarthritis of the knee. Acta Ortop Bras. 2012;20(3):174-9.
23. Brandt KD, Heilman DK, Slemenda C, Katz BP, Mazzuca SA, Braunstein EM, et al. Quadriceps strength in women with radiographically progressive osteoarthritis of the knee and those with stable radiographic changes. J Rheumatol. 1999;26(11):2431-7.

DOI: http://dx.doi.org/10.1590/1413-785220172506165770

LATE EVALUATION OF PATIENTS UNDERGOING MANIPULATION OF THE KNEE AFTER TOTAL ARTHROPLASTY

AVALIAÇÃO TARDIA DOS PACIENTES SUBMETIDOS À MANIPULAÇÃO DO JOELHO APÓS ARTROPLASTIA TOTAL

Pedro Guilme Teixeira de Sousa Filho[1], Yuri Lubiana Chisté[1], Rodrigo Sattamini Pires e Albuquerque[1], Hugo Alexandre de Araújo Barros Cobra[1], João Maurício Barretto[1], Naasson Trindade Cavanellas[1]

1. Knee Surgery Center at the Instituto Nacional de Traumatologia e Ortopedia, Rio de Janeiro, RJ, Brazil.

ABSTRACT

Objective: We compared gains in range of motion in patients who underwent manipulation within 12 weeks of total knee arthroplasty (TKA) and after this period. We also evaluated maintenance of the arc obtained from knee manipulation in late follow-up, along with factors associated with poorer outcomes. Method: The study was divided into two groups according to the time after TKA; the surgeries took place between January 2008 and December 2014. Results: When comparing the range of motion between early and late manipulations, the group that underwent manipulation within 12 weeks of the TKA exhibited better outcomes, but these were not statistically significant. We observed that 14.3% of cases retained the same range attained at the time of manipulation. In late evaluation after manipulation, 47.7% of the sample had a range of less than 90 degrees. The significant risk factors for recurrence of knee stiffness in the long term are poor range of motion before TKA and before manipulation, female sex, and secondary arthritis. Conclusion: Women previously diagnosed with secondary osteoarthritis and poor range of motion before TKA or manipulation are at higher risk for late stiffness. ***Level of Evidence III, Retrospective Comparative Study.***

Keywords: Arthroplasty, replacement, knee/methods. Manipulation, orthopedic. Knee joint. Range of motion, articular.

RESUMO

Objetivo: Comparar o ganho de arco de movimento entre os pacientes submetidos à manipulação antes de 12 semanas pós-artroplastia total do joelho (ATJ), e depois desse período. Além disso, avaliar tardiamente a manutenção do arco obtido com a manipulação do joelho e fatores relacionados com os piores resultados. Método: O estudo foi dividido em dois grupos, de acordo com o tempo pós-ATJ. Os procedimentos ocorreram entre janeiro de 2008 e dezembro de 2014. Resultados: Quando comparamos os arcos de movimento entre as manipulações precoces e tardias, o grupo submetido à manipulação em 12 semanas da ATJ apresentou melhores resultados, porém, sem significância estatística. Foi observado que 14,3% dos casos mantiveram a mesma amplitude alcançada no momento da manipulação. Na avaliação tardia, 47,7% da amostra obtiveram amplitude menor que 90 graus. Os fatores de risco significantes para recidiva tardia de rigidez são arco de movimento ruim antes da ATJ e antes da manipulação, sexo feminino e artrites secundárias. Conclusão: Mulheres com diagnóstico prévio de osteoartrite secundária e com arco ruim antes da ATJ ou da manipulação têm maior risco de rigidez tardia. ***Nível de Evidência III, Estudo Retrospectivo Comparativo.***

Descritores: *Artroplastia do joelho/métodos. Manipulação ortopédica. Articulação do joelho. Amplitude de movimento articular.*

Citation: Sousa Filho PGT, Chisté YL, Albuquerque RSP, Cobra HAA, Barreto JM, Cavanellas NT. Late evaluation of patients undergoing manipulation of the knee after total arthroplasty. Acta Ortop Bras. [online]. 2017;25(6):253-7. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Total knee arthroplasty (TKA) is a highly effective surgical procedure for treating knee arthrosis; it significantly improves patient quality of life by relieving symptoms and restoring joint function.[1,2] Despite good results and constant advances in implant characteristics, surgical techniques, and postoperative recovery protocols, some patients have poor functional outcomes, which restrict their activities of daily living.[3,4]

More than 20% of patients who undergo TKA may develop stiffness, and consequently an arc of motion with less than 90° flexion.[5,6] A variety of factors have been described as influencing the occurrence of this complication; these include having a poor range prior to surgery, low socioeconomic levels, diabetes mellitus, lack of patient compliance to the post-surgical rehabilitation, and previous arthroplasty of the knee.[5,7]

There is no consensus in the literature precisely defining the arc of functional movement. In general, 90° flexion has been considered a minimal functional recovery after TKA. Not obtaining this mobility can be devastating, and negatively affects activities of daily living and patient satisfaction. Biomechanical studies have demonstrated

All authors declare no potential conflict of interest related to this article.

Work conducted at the Knee Surgery Center at the Instituto Nacional de Traumatologia e Ortopedia, Rio de Janeiro, RJ, Brazil.
Correspondence: Instituto Nacional de Traumatologia e Ortopedia – INTO/MS. Av. Brasil, 500 - São Cristóvão, Rio de Janeiro, RJ, Brazil. 20940-070. pedroguilme@gmail.com

Article received in 06/26/2016, approved in 06/09/2017.

the minimal ranges of flexion to perform some activities, such as 83° to go up and down stairs, 93° to sit, and 65°-70° to perform the swing phase of the gait cycle.[2,5,8]

Among the various options to treat stiffness after TKA, manipulation under anesthesia has been considered the first line of treatment after other non-surgical measures such as physiotherapy fail.[2,5,8] Nevertheless, the long-term results of this method have not been well studied. There is also no consensus in the literature regarding the ideal time to perform manipulation.[5,9] Some authors have suggested that between 2 and 12 weeks post-surgery is the ideal time to perform manipulation, since a more invasive procedure would be required after this time due to maturation of the scar tissue.[5,9-11] Meanwhile, other studies found no differences in gains of range of motion between a group that received early treatment (within twelve weeks of surgery) and a late-treatment group (manipulation more than twelve weeks after surgery).[5,8]

The objective of this study is to compare gains in range of motion between patients who received early manipulation (within 12 weeks of TKA), and those who received manipulation after this period. In addition, we assessed maintenance of the arc obtained from knee manipulation over the medium and long terms, and factors related to poorer outcomes.

MATERIALS AND METHODS

This is a historical cohort or retrospective study, in which patients who underwent knee manipulation under anesthesia to treat joint stiffness after total knee arthroplasty were selected according to the following inclusion criteria: TKA performed at our institute; TKA performed between January 2008 and December 2014; at least one year between knee manipulation and reassessment; procedures performed in accordance with the routine of the hospital's knee surgery group, as described below. The knee was x-rayed before indicating manipulation, in order to assess the size and positioning of the implant.

According to the knee surgery group routine, patients with primary TKA were approached in the initial intervention via medial parapatellar access, using ischemia via a pneumatic cuff. The pneumatic cuff was placed on the leg and inflated to 100 mmHg above systolic pressure minutes before the skin incision. This same pressure was maintained for up to 2 hours, on average, and the tourniquet was then deflated. We reviewed hemostasis, closed the wound by planes, and placed an extrarticular drain in a closed suction system. All patients were subjected to the same prophylaxis protocol for infection and deep vein thrombosis. All received guidelines and a schematic post-surgical rehabilitation protocol, in addition to monitoring with physical therapy at home or in the institute's rehabilitation department.

The manipulations were performed under sedation and a peripheral femoral block. The patient was positioned on the surgical table in dorsal decubitus with the muscles relaxed as much as possible. The hip was positioned in 90^0 of flexion and the tibia was stabilized in the proximal region, and the knee was flexed slowly and gently.[6] Both procedures were performed by orthopedists from the knee surgery center at the National Institute of Traumatology and Orthopedics (INTO). After the manipulation, a control X-ray was taken for medical documentation. The range of motion prior to manipulation and after the procedure was confirmed by the surgeon in charge and documented in surgical record.

All cases that met any of the following criteria were excluded: patients in whom manipulations were performed after other surgical procedures (non-TKA) performed at INTO; manipulations that developed immediate complications, such as periprosthetic fractures or deep vein thrombosis, which hindered rehabilitation and maintenance of the range of motion obtained during the manipulation; patients with less than one year of follow-up; patients with incomplete medical documentation.

The included patients returned for a follow-up appointment in which the maintenance of the range of flexion obtained from the manipulation was assessed, along with the Knee Society Score (KSS).[12] Demographic and clinical data were collected from the pre-, intra-, and postoperative periods via interviews and the medical records.

The patients who returned for follow-up were divided in groups according to the time elapsed between arthroplasty and manipulation: Group 1: patients who underwent early manipulation, within 12 weeks of TKA. Group 2: patients who underwent late manipulation, more than 12 weeks after TKA.

The implants used in the TKA varied between patients, and included PFC Sigma, TC3, and Natural Knee implants; the platform, type of stabilization, cementing, and placement of the patellar component also varied.

The study was approved in advance by the institutional review board (CAAE: 52871916.6.0000.5273). Participants were invited to participate in the study and asked to sign the informed consent form. From the collected data, we constructed a bank of data we analyzed using SPSS (Statistical Package for the Social Sciences) version 22.0 and Microsoft Excel 2007 software.

Fisher's exact test and the nonparametric Mann-Whitney test were used to compare the early and late manipulations groups for qualitative and quantitative variables, respectively. The p-values (all greater than 5%) did not exhibit significant differences in the qualitative variables (patient and surgery characteristics).

RESULTS

During the study period, 2865 knee total arthroplasties were performed, and a total of 45 patients underwent manipulation of the knee under anesthesia after total arthroplasty. After analysis of the inclusion and exclusion criteria, 6 patients were excluded: 2 had incomplete medical documentation, and 4 developed complications after the knee manipulation procedure. Of the 39 remaining patients, 3 underwent bilateral manipulation, totaling 42 manipulations; 16 of these procedures (38.1%) were performed in men, and 26 (61.9%) in women. The mean patient age was 62.2 years, ranging from 45 to 83 years. The majority of patients were classified as ASA II (78.6%), and hypertension was the most frequent comorbidity (66.7%).

The most common indication for TKA was primary osteoarthritis (71.4% of the cases), followed by rheumatoid arthritis (16.7%), sequelae of fracture (7.1%), hemophilic arthritis (2.4%), and sequelae of tuberculosis (2.4%). The most commonly used brand of implant was the PFC Sigma (88.1%). Only two individuals received arthroplasty with a semi-constrained implant, the TC3. Manipulation under sedation was most frequent between 7 and 12 weeks after TKA (59.5% of cases). Manipulation was performed within six weeks of the TKA in 26.2% of cases, and only in 6 cases (14.3% of the sample) was the manipulation performed late, between 13 and 26 weeks after TKA.

The arc of motion (maximum length, maximum flexion, and sum of arc) was measured at three different times: before manipulation, after manipulation, and in the ambulatory follow-up assessment. Figure 1 shows the change in the mean values for flexion and extension angles, as well as the total arc of motion at each assessment. When we compared the ranges of motion from early manipulation with late manipulations, we found better results in the values for cases when manipulation was performed before 12 weeks. However, these values were not statistically significant, which can be explained by the small sample size of the group in which late manipulation

was performed. (Figure 2) When we considered the incidence of knee stiffness (arc < 90°) in the long term, we found considerably higher recurrence in the late-treatment group, as shown in Figure 3. The follow-up time between the completion of the knee manipulation and the outpatient evaluation to collect the data ranged from 12 to 81 months. Table 1 shows the frequency of cases that maintained the arc achieved from manipulation to the time of the outpatient assessment. Only 14.3% of the cases maintained the same range which was achieved in manipulation. Considering a variation of 10% in the arc from manipulation, 33.3% maintained this range of motion at reassessment. If this is adjusted to a margin of 10 degrees of difference, the incidence increased to 35.7%. Only one patient in the late manipulation group maintained the same arc after manipulation. Despite the differences between the groups, Fisher's exact test did not detect a statistically significant difference. At the outpatient evaluation, the Knee Society Score (KSS)[12] values were calculated for the early and late manipulation groups.

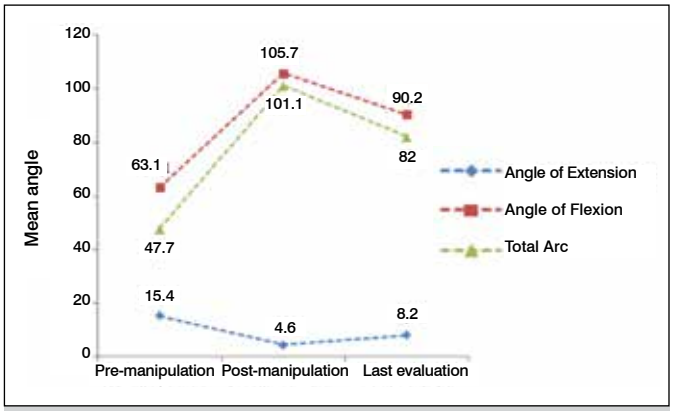


Figure 1. Change in mean angle of arc of motion at three distinct times.

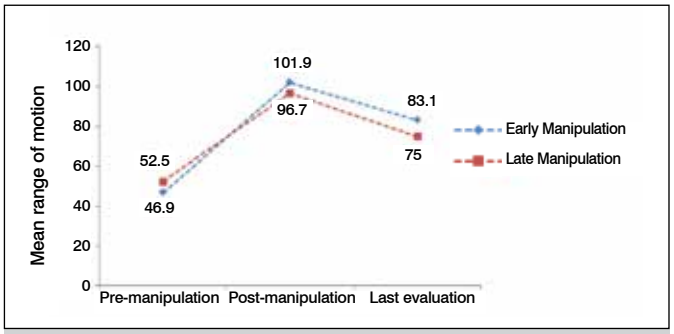


Figure 2. Change in mean arc of motion for the early and late manipulation groups.

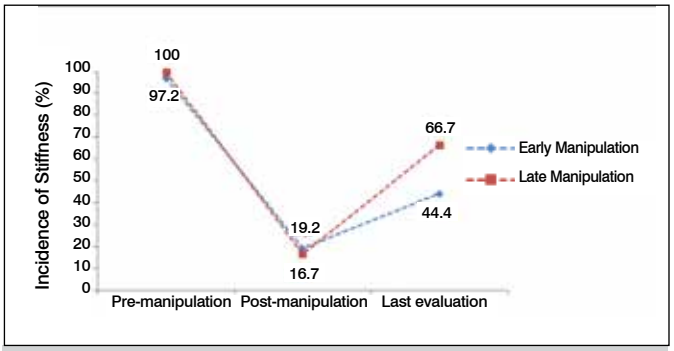


Figure 3. Incidence of stiffness in the study groups (Arc < 90°).

This evaluation combines subjective and objective information and separates the knee score (pain, stability, range of motion, among other components) from the patient's functional score (ability to walk and go up and down stairs). A significant difference was found between the knee scores for the groups in question. The p-value was 0.027, showing that the knee scores for the late manipulation group were significantly lower than those of the early manipulation group. (Table 2)

In the outpatient follow-up assessment, we perceived that stiffness (amplitude of less than 90 degrees) was present in 20 cases (47.7% of the sample). In addition, we compared the variables collected between patients with and without stiffness, in an attempt to find some statistically significant risk factor for limited range of motion in the long term, even after manipulation under anesthesia.

When comparing the ranges of motion before TKA and prior to manipulation, we noted that the values in patients who developed stiffness were significantly lower. (Table 3) Other significant risk factors were sex and indication for arthroplasty; women are 8.2 times more likely than men to develop stiffness after manipulation. As for the indication for TKA, the percentage of patients who undergo this procedure to treat primary osteoarthritis and develop stiffness in the long term (36.7%) is significantly lower than the percentage of patients who undergo TKA for another reason (75.0%). The odds ratio is 0.2, with a 95% confidence interval. Table 4 also shows other qualitative variables that had no statistical significance.

Table 1. Frequency of cases that maintained the arc obtained after manipulation in the long term.

Group	Maintained the same arc after manipulation	Maintained the same arc with variation of up to 10%	Maintained the same arc with up to 10 degrees of difference
Total (%)	6 (14.3%)	14 (33.3%)	15 (35.7%)
Early Manipulation (%)	5 (13.9%)	13 (36.1%)	14 (38.9%)
Late Manipulation (%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
P-value from Fisher's Exact Test	1.000	0.645	0.395

Table 2. Comparison between groups via KSS.

Variable	Manipulation	Mean	Median	Standard Deviation	P-value from Mann-Whitney Test
KSS for knee	Early	81.2	88	14.4	0.027
	Late	70.7	69	6.7	
KSS patient functional score	Early	72.4	78	18.2	0.103
	Late	61.7	60	12.5	

Table 3. Comparison of quantitative variables in patients with and without stiffness after manipulation.

Median of Variable	Post-manipulation stiffness		
	No	Yes	P-value from Mann-Whitney Test
Pre-TKA arc	95º	75º	0.010
Pre-manipulation arc	55º	32.5º	0.020

Table 4. Association between qualitative variables and stiffness after manipulation.

Variable	Qualification (subgroup) of the Variable	Number of cases in the Stiffness after Manipulation subgroup	Percent of cases in the Stiffness after Manipulation subgroup	P-value from Chi-squared Test comparing the frequency of the subgroups
Sex	F	17	65.4	0.003
	M	3	18.8	
ASA (CCECK)	1	3	33.3	0.460*
	2	17	51.5	
DM	No	16	45.7	0.691*
	Yes	4	57.1	
HBP	No	7	50.0	0.827
	Yes	13	46.4	
RA	No	15	42.9	0.229*
	Yes	5	71.4	
Smoking	No	18	47.4	1.00*
	Yes	2	50.0	
Has Any Comorbidity	No	2	28.6	0.414*
	Yes	18	51.4	
Indication for TKA: Primary Arthritis	No	9	75.0	0.040
	Yes	11	36.7	
Indication for TKA: Sequel of fracture	No	18	46.2	0.598*
	Yes	2	66.7	
Indication for TKA: Rheumatoid Arthritis	No	15	42.9	0.229*
	Yes	5	71.4	
Implant platform	Rotating	13	41.9	0.298*
	Fixed	7	63.6	
Patella substituted	No	8	40.0	0.374
	Yes	12	54.5	
Time at which manipulation under sedation was performed (Weeks)	0 to 6	6	54.5	0.435**
	7 to 12	10	40.0	
	13 to 26	4	66.7	
Late Manipulation	No	16	44.4	0.400*
	Yes	4	66.7	

* Fisher's exact test. ** Test inconclusive, we recommend increasing the samples in subgroups.

DISCUSSION

Stiffness in the knee after TKA is a well-known problem that can lead to poor patient outcomes and limit activities of daily living in patients.[13] The literature on this subject is somewhat controversial, starting with the definition itself. Fox and Poss[6] defined stiffness as less than 90^0 active knee flexion two weeks after TKA surgery. Other researchers such as Kim et al.[14] defined rigidity as a capsular contracture greater than or equal to 15° or a flexion less than 75°.[14,15] As a result, the literature is confusing and there are no studies with a high evidence.

The lack of a consensus on treatment or a standardized algorithm leads to other problems in the literature. Many forms of treatment have been described, including physiotherapy, knee manipulation under anesthesia, manipulation associated with arthroscopy, arthrotomy, and revision arthroplasty.[9] Movement gains through physiotherapy are often modest, with studies showing an average gain of 5° in knees with arthrofibrosis after TKA.[9] Manipulation under anesthesia is generally considered the initial surgical step in treating stiffness after TKA.[5] When associated with arthroscopy, this procedure allows the surgeon to examine the implants and assess the presence of impact on soft tissue, loose bodies, or adhesions.[9,16] Open release of adhesions or surgical revision are often used in refractory cases or in cases with poor positioning of the components.[9]

Our study only assessed patients subjected to manipulation under sedation in association with a femoral nerve block. Other studies have opted for general anesthesia;[6,8,9,15] there is no evidence in the literature that the type of anesthesia used influences the final outcome of the manipulation. Choi et al.[2] defended regional anesthesia as an improvement factor for the results of manipulation after TKA.

There is no consensus in the literature about the most appropriate time to perform surgical manipulation after TKA. Consequently, our research is pertinent and relevant. A series of studies have shown superior results when manipulation is performed early.[3,5,6,9] Many authors consider 12 weeks post-TKA to be the deadline for manipulation, since a more invasive procedure is necessary after this time because of maturation of the scar tissue.[5,9-11] However, some studies found no significant differences in gains in range of motion between early and late groups (undergoing manipulation before and after twelve weeks).[5,8]

When we compared the early and late groups in our study, a significant difference was seen between the mean KSS knee scores during the reevaluation in the medium and long term. This shows that although some patients did lose range over time, the functional score was still significantly higher in the group that underwent manipulation earlier. Issa et al.[5] demonstrated a significant difference in KSS scores when comparing early and late groups before and after manipulation, but did not perform a long-term assessment. Since this present study was retrospective, it was not possible to compare scores before and after manipulation.

The mean patient age was 62.2 years, which is considered low for patients who undergo TKA. According to the study by Fox and Poss,[6] more advanced age seems to be a factor in difficulty attaining range of motion after manipulation.

Although we did not find a statistically significant relationship between the implants used, the literature shows that they can

directly affect the final results of the arc of motion.[6] Studies show that prostheses which sacrifice the posterior cruciate ligament (PCL) demonstrate greater gain after manipulation than those which preserve this ligament.[2,15] In our sample, the majority of cases involved TKA with sacrifice of the PCL (92.9%). The only three patients who received implants where the PCL was retained were handled early after the TKA, and made good progress after manipulation, all showing at least 100° of range of motion in the reassessment.

The time elapsed between the manipulation and patient reassessment ranged from 12 to 81 months, which according to the interpretation of Esler et al.[17] can be considered a considerable clinical follow-up, since a minimal gain was observed after a period of 1 year.[2] We correlate this good result with a minimum range of 90^0, for the knee, as well as the research by Choi et al.,[2] which was based on the idea that this is considered the minimum arc to perform basic activities.

When we look at the variables for patients who had knee stiffness (arc < 90°) in the outpatient assessment, we found some statistically significant variables for this outcome, such as the arcs of movement pre-TKA and pre-manipulation, female sex, and the indication for arthroplasty. As for the range of motion in the prior to the primary TKA surgery being a determining factor in the postoperative results, we found studies that agree[6,18] and disagree [2,8] with this hypothesis. Several studies have shown a strong correlation between female sex and knee stiffness after manipulation,[2,5,6,9,15] even though not all of these were statistically proven.

With regard to pre-TKA etiology, we found that patients undergoing this procedure for primary osteoarthritis have significantly less risk of stiffness in the long term. Consequently, the group formed by other indications (rheumatoid arthritis, sequel of fracture, hemophilic arthritis, and sequela of infection) was considered a risk factor. Some studies have shown a direct relationship between arthroplasties performed for secondary arthritis and stiffness after manipulation.[2,6] Unfortunately, not all patients in our service were able to access the continuous passive movement device (CPM) because of cost. This tool directly impacts the maintenance of the range of motion achieved after manipulation.[2] Physiotherapy is an essential complementary phase after orthopedic procedures. All the patients in our study received guidance via booklets given to them by our team physiotherapists, and the institute's rehabilitation service was also available for post-procedure follow-up. Yoo et al.[3] emphasized the need for aggressive physical therapy after manipulation to achieve good outcomes.

Our main limitation was the fact that this is a retrospective study. Since we did not find other studies with this line of research in the country, we believe that the issue requires further study, especially research with level I evidence.

CONCLUSION

Knee manipulation under sedation is a procedure that can improve the functional outcomes of patients with knee stiffness after TKA, and presents better results in patients who undergo this procedure early. In the long-term follow-up, 14.3% of the patients maintained the range of motion they achieved from manipulation, and 47.7% of the sample developed a range of motion in the knee of less than 90 degrees. Patients at high risk for developing rigidity are women who underwent TKA to treat secondary osteoarthritis and already had poor range of motion before arthroplasty or before manipulation under anesthesia.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. PGTSF (0000-0002-3338-6267)*, YLC (0000-0002-8082-9374)*, and RSPA (0000-0003-2351-9449)* were the main contributors in writing the manuscript; PGTSF, RSPA, HAABC (0000-0002-7315-0961)*, JMB (0000-0003-3654-2031)*, and NTC (0000-0001-6849-464X)* performed the surgery, accompanied the patients, and gathered the clinical data. PGTSF and RSPA evaluated the data from the statistical analysis. PGTSF, YLC, RSPA, HAABC, JMB, and NTC conducted the bibliographical research, revised the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Blom AW, Brown J, Taylor AH, Pattison G, Whitehouse S, Bannister GC. Infection after total knee arthroplasty. J Bone Joint Surg Br. 2004;86(5):688-91.
2. Choi HR, Siliski J, Malchau H, Freiberg A, Rubash H, Kwon YM. How often is functional range of motion obtained by manipulation for stiff total knee arthroplasty? Int Orthop. 2014;38(8):1641-5.
3. Yoo JH, Oh JC, Oh HC, Park SH. Manipulation under Anesthesia for Stiffness after Total Knee Arthroplasty. Knee Surg Relat Res. 2015;27(4):233-9.
4. Seyler TM, Marker DR, Bhave A, Plate JF, Marulanda GA, Bonutti PM, et al. Functional problems and arthrofibrosis following total knee arthroplasty. J Bone Joint Surg Am. 2007;89 Suppl 3:59-69.
5. Issa K, Banerjee S, Kester MA, Khanuja HS, Delanois RE, Mont MA. The effect of timing of manipulation under anesthesia to improve range of motion and functional outcomes following total knee arthroplasty. J Bone Joint Surg Am. 2014;20;96(16):1349-57.
6. Fox JL, Poss R. The role of manipulation following total knee replacement. J Bone Joint Surg Am. 1981;63(3):357-62.
7. Vince KG. The stiff total knee arthroplasty: causes and cures. J Bone Joint Surg Br. 2012;94(11 Suppl A):103-11.
8. Yeoh D, Nicolaou N, Goddard R, Willmott H, Miles K, East D, et al. Manipulation under anaesthesia post total knee replacement: long term follow up. Knee. 2012;19(4):329-31.
9. Fitzsimmons SE, Vazquez EA, Bronson MJ. How to treat the stiff total knee arthroplasty?: a systematic review. Clin Orthop Relat Res. 2010;468(4):1096-106.
10. Namba RS, Inacio M. Early and late manipulation improve flexion after total knee arthroplasty. J Arthroplasty. 2007;22(6 Suppl 2):58-61.
11. Yercan HS, Sugun TS, Bussiere C, Ait Si Selmi T, Davies A, Neyret P. Stiffness after total knee arthroplasty: prevalence, management and outcomes. Knee. 2006;13(2):111-7.
12. Silva AL, Demange MK, Gobbi RG, da Silva TF, Pécora JR, Croci AT. Translation and Validation of the Knee Society Score - KSS for Brazilian Portuguese. Acta Ortop Bras. 2012;20(1):25-30.
13. Pivec R, Issa K, Kester M, Harwin SF, Mont MA. Long-term outcomes of MUA for stiffness in primary TKA. J Knee Surg. 2013;26(6):405-10.
14. Kim J, Nelson CL, Lotke PA. Stiffness after total knee arthroplasty. Prevalence of the complication and outcomes of revision. J Bone Joint Surg Am. 2004;86-A(7):1479-84.
15. Bawa HS, Wera GD, Kraay MJ, Marcus RE, Goldberg VM. Predictors of range of motion in patients undergoing manipulation after TKA. Clin Orthop Relat Res. 2013;471(1):258-63.
16. Jerosch J, Aldawoudy AM. Arthroscopic treatment of patients with moderate arthrofibrosis after total knee replacement. Knee Surg Sports Traumatol Arthrosc. 2007;15(1):71-7.
17. Esler CN, Lock K, Harper WM, Gregg PJ. Manipulation of total knee replacements. Is the flexion gained retained? J Bone Joint Surg Br. 1999;81(1):27-9.
18. Ipach I, Mittag F, Lahrmann J, Kunze B, Kluba T. Arthrofibrosis after TKA - Influence factors on the absolute flexion and gain in flexion after manipulation under anaesthesia. BMC Musculoskelet Disord. 2011;12;12:184.

DOI: http://dx.doi.org/10.1590/1413-785220172506152670

ORIGINAL ARTICLE

MAXILLOFACIAL TRAUMA, ETIOLOGY AND PROFILE OF PATIENTS: AN EXPLORATORY STUDY

TRAUMAS MAXILOFACIAIS, ETIOLOGIA E PERFIL DOS PACIENTES: UM ESTUDO EXPLORATÓRIO

Ilky Pollansky Silva e Farias[1], Ítalo de Macedo Bernardino[2], Lorena Marques da Nóbrega[3], Rafael Grotta Grempel[4], Sérgio d'Avila[3]

1. Program in Maxillofacial Surgery and Traumatology, Hospital Regional do Agreste, Caruaru, PE, Brazil.
2. Department of Dentistry, Universidade Estadual da Paraíba, Campina Grande, PB, Brazil.
3. Post-graduate Program in Dentistry, Universidade Estadual da Paraíba, Campina Grande, PB, Brazil.
4. Strategic Technology Center, Universidade Estadual da Paraíba, Campina Grande, PB, Brazil.

ABSTRACT

Objective: To describe the profile of patients with facial trauma admitted in a hospital located in a metropolitan area of Northeast Brazil. Methods: A cross-sectional and exploratory study was performed. A total of 244 cases were in agreement with the eligibility criteria. The variables include the sociodemographic characteristics of patients, etiology, type of trauma, treatment modalities, length of stay in a hospital and quarter of care. Descriptive statistics and Cluster Analysis were performed. Results: The average age of patients was 31.16 years (SD = 15.17 years) and average hospitalization was 6.32 days (SD = 7.75 days). It was verified the automatic formation of four clusters with different profiles of patients. The variables which most contributed to the external differentiation between clusters were: length of stay in a hospital ($p < 0.001$), etiology ($p < 0.001$), type of facial trauma ($p < 0.001$), presence of associated trauma ($p < 0.001$), treatment modalities ($p < 0.001$) and quarter of care ($p < 0.001$). Conclusion: The most of patients were men, victims of traffic accidents, which suffered fracture of zygomatic complex and underwent surgery. ***Level of Evidence III, Retrospective Study.***

Keywords: Facial injuries. Facial bones. Traumatology.

RESUMO

Objetivo: Traçar o perfil dos pacientes internados com trauma de face em um hospital localizado em região metropolitana do Nordeste do Brasil. Métodos: Tratou-se de estudo transversal e exploratório. Um total de 244 casos atendeu aos critérios de elegibilidade, sendo incluídos na amostra. As variáveis estudadas incluíram características sociodemográficas das vítimas, etiologia, tipos de traumas, modalidades de tratamento, tempo de internação e trimestre de atendimento. Foi feita estatística descritiva e análise de cluster. Resultados: A média de idade dos pacientes foi 31,16 anos (DP = 15,17 anos) e o tempo médio de internação foi de 6,32 dias (DP = 7,75 dias). Verificou-se a formação automática de quatro clusters com perfis distintos de pacientes. As variáveis que mais contribuíram para a diferenciação externa entre os clusters foram: tempo de internação ($p < 0,001$), etiologia ($p < 0,001$), tipo do trauma facial ($p < 0,001$), presença de trauma associado ($p < 0,001$), tipo de tratamento ($p < 0,001$) e trimestre de atendimento ($p < 0,001$). Conclusão: A maioria dos pacientes eram homens, vítimas de acidentes de trânsito, que apresentaram fratura do complexo zigomático, submetidos a tratamento cirúrgico. ***Nível de Evidência III, Estudo Retrospectivo.***

Descritores: *Traumatismos faciais. Ossos faciais. Traumatologia.*

Citation: Farias IPS, Bernardino IM, Nóbrega LM, Grempel RG, D´Avila S. Maxillofacial trauma, etiology and profile of patients: an exploratory study. Acta Ortop Bras. [online]. 2017;25(6):258-61. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Trauma from external causes represents one of the greatest challenges for public health services in different regions of the world.[1-3] In Brazil, thousands of people are daily victims of interpersonal violence and are involved in traffic accidents, overloading health services and generating high emotional and social costs. Trauma in head, neck and face is one of the most prevalent and among the etiological agents of facial trauma, traffic accidents, falls, aggressions and penetrating wounds (caused by firearms) stand out, with sociodemographic, cultural and environmental factors playing an important role in the epidemiology of these outcomes.[4-6]

Depending on severity, the treatment of trauma patients requires multidisciplinary and integrated care. In addition, facial trauma may be accompanied by other types of serious injury, which may result in emotional and psychological problems requiring lifelong follow-up.[7-9] Epidemiological studies are necessary for a better understanding

All authors declare no potential conflict of interest related to this article.

Work conducted at the Hospital of Emergency and Trauma Dom Luíz Gonzaga Fernandes, Campina Grande, PB, Brazil.
Correspondence: Prof. Sérgio d'Avila. Departamento de Odontologia, Universidade Estadual da Paraíba, Rua Baraúnas, 351. Bairro Universitário, Campina Grande, PB, Brasil. 58429-500. davila2407@hotmail.com

Article received in 07/30/2015, approved in 06/12/2017.

of the distribution patterns of lesions, etiological factors, and for providing valuable information for the planning of health actions. Understanding the patterns of facial injuries and the victims' profile may also help managers to refocus and improve the services offered. In this context, this study had the aim of determining the profile of hospitalized patients with facial trauma and describing the characteristics of lesions in an emergency and trauma hospital in a medium-sized city in northeastern Brazil.

MATERIAL AND METHODS

This was a cross-sectional and exploratory study carried out in a reference hospital in emergency and trauma care located in the city of Campina Grande, Paraíba, Brazil, during the period from January to December 2011. The municipality, which has population estimated at 386,000 inhabitants, is an industrialized city in the northeastern region of Brazil. It is located in a metropolitan region that includes 22 other municipalities, and has *per capita* income of approximately US$ 110 and Human Development Index (HDI) of 0.72. A total of 11,410 medical records regarding general hospital care were evaluated. To compose the sample, cases of people who presented facial trauma and who were treated with need for hospitalization were included. Exclusion criteria were: records that were considered incomplete (lacking three or more information), illegible (even when, after consultation with physician or maxillofacial surgeon, the information in the medical record was not yet deciphered), resulting in 244 cases.

The variables studied were: age (in years), gender (female / male), type of etiological agent of the face trauma[10] (traffic accident, interpersonal violence, falls, others such as work accident and accident during the practice of sports), type of facial trauma[11,12] (soft tissue injury - laceration, bruising, hematoma; mandible fracture, maxilla fracture, zygomatic complex fracture, nasal fracture, nasal-orbital-ethmoidal fracture, frontal fracture, fracture in more than one facial bone), presence of associated trauma in other regions of the body (yes / no), type of treatment (surgical / non-surgical), quarter of care (first / second / third / fourth) and length of hospital stay (in days).

Initially, descriptive statistical analysis was performed, which corresponded to the calculation of the absolute and relative frequencies of categorical variables and to the calculation of the central tendency (mean and median) and dispersion measures (standard deviation, minimum value, maximum value and interquartile range) of continuous variables. Subsequently, Cluster Analysis was used to describe the victims' profile. This is a multivariate, exploratory statistical analysis designed to allocate individuals with characteristics similar to each other in the same group (cluster), in order to identify profiles or trends that could go unnoticed if other techniques were used.[13] The method chosen was the TwoStep Cluster. One of the advantages of this method is the possibility of manipulating categorical and continuous variables simultaneously and the automatic identification of the number of empirical clusters based on the Bayesian and Akaike information criteria, which are used in a joint and comparative way to indicate the empirically optimal solution.[14] For the conformation of the clusters, variables that were able to define clusters capable of better guiding the implementation of prevention, management, assistance and rehabilitation strategies were used. Thus, variables related to the sociodemographic characteristics of patients, to the etiological agents of traumas, the nature of lesions, treatment and evolution were chosen. For the application of the method, the criterion of choice for the selection of the number of clusters was the Bayesian Information Criterion (BIC) and the distance measure used was the Log-likelihood. It is known that the denomination of clusters is a subjective process, but it was tried to standardize the description of clusters in such a way that they represented the most remarkable findings in data and could guide the reader in the understanding of the main characteristics demarcated by empirically obtained clusters. In order to identify the variables that most contributed to the external differentiation of clusters, the analysis of the difference of proportions (Pearson's Chi-square or Fisher's Exact Test) and the F-test (ANOVA) was used. The confidence interval considered was 95%. The organization of the database and all statistical analyses were performed using IBM SPSS software version 20.

This study was submitted to and approved by the Ethics Research Committee on Human Beings of the State University of Paraíba (CAAE protocol No. 33813.4.0000.5187) and followed the National and International Standards of Ethics in Research with Human Beings.

RESULTS

The mean age of victims was 31.16 years (SD = 15.17 years, minimum value: 1 year, maximum value: 78 years) and median of 27 years. The mean length of hospital stay was 6.32 days (SD = 7.75 days, minimum value: 1 day, maximum value: 28 days) and median 5 days. Table 1 presents the absolute and relative frequencies of variables related to the sociodemographic characteristics of patients, etiology and characteristics of traumas, type of treatment and quarter of care. The majority of patients were male (n = 224; 91.8%), and the male/female proportion was 11.2: 1. The main etiological agent of facial trauma corresponded to traffic accidents (n = 55; 63.5%) and the most frequent type of facial trauma was zygomatic complex fracture (n = 71; 29.1%) followed by situations of fracture in more than one facial bone (n = 49; 20.1%). In addition, it was observed that the presence of associated trauma in other regions of the body occurred in 16.4% of cases (n = 40), the type of treatment most adopted was surgical (n = 220; 90.2%), in the fourth quarter (n = 109; 44.7%), followed by the third quarter (n = 77; 31.6%).

Figure 1 shows the absolute distribution of clusters. The number of patients allocated to clusters 1, 2, 3 and 4 were, respectively, 22, 86, 67 and 69. Table 2 shows the distribution of clusters according to patient's age, length of hospital stay, gender, etiology of facial

Table 1. Absolute and relative frequencies of variables related to the sociodemographic characteristics of patients, etiology and characteristics of traumas, type of treatment and quarter of care.

Variables	n	%
Gender		
Female	20	8.2
Male	224	91.8
Etiology		
Traffic accident	155	63.5
Interpersonal violence	32	13.1
Falls	19	7.8
Others	38	15.6
Facial trauma		
Soft tissue injury	26	10.7
Mandible fracture	39	16.0
Maxilla fracture	15	6.1
Zygomatic complex fracture	71	29.1
Nasal fracture	44	18.0
Fracture in more than one facial bone	49	20.1
Presence of associated trauma		
Yes	40	16.4
No	204	83.6
Type of treatment		
Surgical	220	90.2
Non-surgical	24	9.8
Quarter of care		
First	23	9.4
Second	35	14.3
Third	77	31.6
Fourth	109	44.7

trauma, type of facial trauma, presence of associated trauma in another region of the body, type of treatment and quarter of care. The variables selected for conformation of clusters that most contributed to the external differentiation among clusters were: length of hospital stay ($p < 0.001$), etiology ($p < 0.001$), type of facial trauma ($p < 0.001$), associated trauma in another region of the body ($p < 0.001$), type of treatment adopted ($p < 0.001$) and quarter of care ($p < 0.001$). The automatic formation of four clusters with different profiles of patients was verified.

Cluster 1 consisted essentially of patients with mean age of 31.17 years (SD = 17.47, minimum value = 1, maximum value = 68) and median of 28.5 years (IIQ = 18.8), males (n=20; 90.9%), traffic accident victims (n = 16; 72.7%), who presented facial trauma characterized by soft tissue injury (n = 17; 77.3%), associated trauma in other regions of the body (n = 14; 63.6%), treated in the third quarter (n = 9; 40.9%) and submitted to non-surgical treatment (n = 21, 95.5%), with mean length of hospital stay of 1.73 days (SD = 2.14); minimum value = 1; maximum value = 10 and median 1 day (IIQ = 2).

Cluster 2 consisted essentially of patients with mean age of 33.23 years (SD = 17.15, minimum value = 2, maximum value = 78) and median age of 31.5 years (IIQ = 23.0), males (n = 76; 88.4%), victims of interpersonal violence (n = 32; 37.2%) or other external causes (n = 31; 36.0%), who presented with nasal fracture (n = 29; 33.7%), had no associated trauma in other regions of the body (n = 83; 96.5%), were treated in the third quarter (n = 37; 43.0%) and submitted to surgical treatment (n= 83; 96.5%), with mean length of hospital stay of 4.35 days (SD = 3.91, minimum value = 1, maximum value = 18) and median three days (IIQ = 3).

Cluster 3 consisted essentially of patients with mean age of 28.0 years (SD = 12.13, minimum value = 12, maximum value = 69) and a median of 24 years (IIQ = 15.0), males (n = 67; 100.0%), traffic accident victims (n = 65; 97.0%), with zygomatic complex fracture (n = 30; 44.8%), no associated trauma in other regions of the body (n = 48; 71.6%), treated in the third quarter (n = 31; 46.3%) and submitted to surgical treatment (n = 67; 100.0%), with mean length of hospital stay of 11.43 days (SD = 7.24, minimum value = 1, maximum value = 28) and median of nine days (IIQ = 12).

Cluster 4 consisted essentially of patients with mean age of 31.67 (SD = 14.22, minimum value = 8, maximum value = 77), and median of 28 years (IIQ = 15.5), males (n = 61; 88.4%), with fracture in more than one facial bone (n = 21; 30.4%), no associated trauma in other regions of the body (n = 65; 94.2%), treated in the fourth quarter (n = 64; 92.8%), submitted to surgical treatment (n = 69; 100.0%), with mean length of hospital stay of 5.28 days (SD = 2.85, minimum value = 1, maximum value = 14) and median of five days (IIQ = 4).

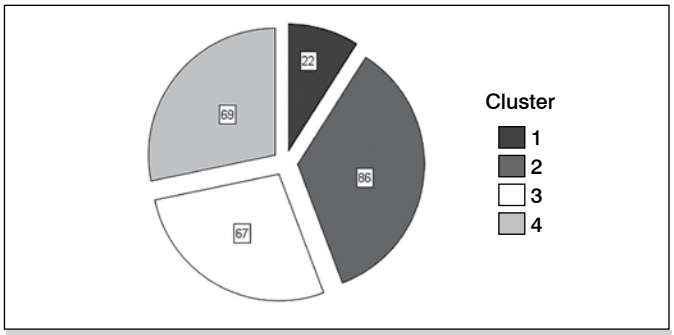


Figure 1. Absolute distribution of clusters.

DISCUSSION

The high prevalence of facial trauma in males found in this study corroborates the results found by other authors,[5,15] and this fact is probably attributed to the greater involvement of men in outdoor activities and their greater exposure to violent interactions. However, it is noteworthy that, due to the greater involvement of women in physical activity, high number of female drivers, as well as the increase in violence associated with greater participation of women in extra-community activities, together, contributes to their exposure to risk factors similar to those of men.[16]

Table 2. Distribution of clusters according to patient's age, length of hospital stay, gender, etiology of facial trauma, type of facial trauma, presence of associated trauma in another region of the body, type of treatment and quarter of care.

Variables	1	2	3	4	Total	p-value
	(n = 22)	(n = 86)	(n = 67)	(n = 69)		
Mean age (standard deviation)	31.17 (±17.47)	33.23 (±17.15)	28.0 (±12.13)	31.67 (±14.22)	31.16 (15.17)	0.200
Mean length of hospital stay (standard deviation)	1.73 (±2.14)	4.35 (±3.91)	11.43 (±7.24)	5.28 (±2.85)	6.32 (5.75)	<0.001
Gender						**0.008**
Female	2 (9.1)	10 (11.6)	0 (0.0)	8 (11.6)	20 (8.2)	
Male	20 (90.9)	76 (88.4)	67 (100.0)	61 (88.4)	224 (91.8)	
Etiology						**<0.001**
Traffic accident	16 (72.7)	6 (7.0)	65 (97.0)	68 (98.6)	155 (63.5)	
Intepersonal violence	0 (0.0)	32 (37.2)	0 (0.0)	0 (0.0)	32 (13.1)	
Falls	0 (0.0)	17 (19.8)	1 (1.5)	1 (1.4)	19 (7.8)	
Others	6 (27.3)	31 (36.0)	1 (1.5)	0 (0.0)	38 (15.6)	
Facial trauma						**<0.001**
Soft tissue injury	17 (77.3)	9 (10.5)	0 (0.0)	0 (0.0)	26 (10.7)	
Mandible fracture	0 (0.0)	15 (17.4)	14 (20.9)	10 (14.5)	39 (16.0)	
Maxilla fracture	0 (0.0)	0 (0.0)	8 (11.9)	7 (10.1)	15 (6.1)	
Zygomatic complex fracture	3 (13.6)	21 (24.4)	30 (44.8)	17 (24.6)	71 (29.1)	
Nasal fracture	1 (4.5)	29 (33.7)	0 (0.0)	14 (20.3)	44 (18.0)	
Fracture in more than one facial bone	1 (4.5)	12 (14.0)	15 (22.4)	21 (30.4)	49 (20.1)	
Presence of associated trauma						**<0.001**
Yes	14 (63.6)	3 (3.5)	19 (28.4)	4 (5.8)	40 (16.4)	
No	8 (36.4)	83 (96.5)	48 (71.6)	65 (94.2)	204 (83.6)	
Type of treatment						**<0.001**
Surgical	1 (4.5)	83 (96.5)	67 (100.0)	69 (100.0)	220 (90.2)	
Non-surgical	21 (95.5)	3 (3.5)	0 (0.0)	0 (0.0)	24 (9.8)	
Quarter of care						**<0.001**
First	7 (31.8)	5 (5.8)	10 (14.9)	1 (1.4)	23 (9.4)	
Second	3 (13.6)	10 (11.6)	18 (26.9)	4 (5.8)	35 (14.3)	
Third	9 (40.9)	37 (43.0)	31 (46.3)	0 (0.0)	77 (31.6)	
Fourth	3 (13.6)	34 (39.5)	8 (11.9)	64 (92.8)	109 (44.7)	

Maxillofacial trauma was more frequent in young adult patients, in agreement with previous findings in literature.[17] The frequent occurrence of these traumas at this stage of the life cycle can be attributed to the fact that this group performs exercises and dangerous sports; in addition to the use of transport means at high speeds.[18] The greater victimization of young people is very worrying, since it may possibly generate sequels that could compromise their performance of work activities. Future studies should be carried out to assess the association between absenteeism and morbidity resulting from external causes, especially traffic accidents and interpersonal violence.

Of the four identified clusters, three were related to victims of traffic accidents, reflecting their prominent role as an etiological agent for facial trauma, especially fractures. This information corroborates previous studies in literature showing the high prevalence of traumas due to traffic accidents.[5,17] Probably, due to high speed driving, non-permitted overtaking and the lack of citizenship exercise in traffic may explain the occurrence of traffic accidents in the region studied. Although not assessed in this study, alcohol consumption is an aspect to be considered in the etiology of facial fractures, and may be involved in traffic accidents. In many cases, patients attribute fracture to an accidental fall, omitting the alcohol consumption, which makes it difficult to verify the involvement of alcoholic beverages in cases of fractures.

The length of hospital stay is a crucial point that must be taken into account during the process of redesigning health services. In this study, the length of hospital stay ranged from 1 to 28 days. In the study developed by van Hout et al.,[19] this period was much longer (1 to 127 days). An explanation for the longer hospitalization period would be the absence of a standard hospitalization time, as this varies according to the patient's need. The most common fracture pattern in this study was that of the zygomatic complex, especially among patients in cluster 3, presenting a mean longer hospitalization time compared to those of the other clusters. The zygomatic region is commonly fractured due to its prominent anatomy on the face.[6,18] With the exception of cluster 1, the type of treatment most adopted corresponded to the surgical one. This result is a reflection of the complexity of trauma cases. The greater the energy associated with the cause of trauma, the greater the trauma complexity and the greater the probability of surgical treatment.[20]

In general, the highest care frequency was recorded in the fourth quarter. In a 10-year study at the University Hospital of Innsbruck (Austria), Gassner et al.[11] concluded that August was the month with the highest care frequency, emphasizing that this is a summer month in the north hemisphere. The distribution of months varies according to the place of study; and as Brazil is a tropical climate country, it has no drastic changes in temperature in seasons.[20] A large popular festivity takes place in the region under study in June, which increases the number of people who come from neighboring cities and other states to celebrate the June celebrations. The lower number of treatments performed on the second quarter may be a reflection of the awareness campaigns for the prevention of accidents and violence events developed in recent years.

One of the limitations of this study is its cross-sectional design, not allowing establishing causal relationships, and the fact that the sample was of the intentional type. In addition, it was not possible to measure the impact of trauma on the quality of life of victims, which requires future investigations. Studies with appropriate methodology to evaluate the influence of the use of psychoactive substances and the occurrence of facial traumas are essential and represent an area that can be approached in future research. The results obtained are expected to substantially contribute for the planning of prevention and management actions in health, epidemiological surveillance and reorientation of assistance practices to victims of facial traumas due to external causes.

CONCLUSION

According to the results obtained, it could be concluded that the majority of victims corresponded to men who were involved in traffic accidents, presenting fractures mainly of the zygomatic complex requiring surgical treatment.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. IPSF (0000-0002-3226-4647)* acquired and participated in the technical procedures to format the data; IMB (0000-0003-4750-5666)* and LMN (0000-0002-6484-8006)* acquired and interpreted the data, and drafted and revised the manuscript. RGG (0000-0002-1994-3506)* and SD (0000-0002-7836-896X)* supervised the study and participated in the conception and development of the method and critical review for final approval of the manuscript. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Mabrouk A, Helal H, Mohamed AR, Mahmoud N. Incidence, etiology, and patterns of maxillofacial fractures in ain-shams university, cairo, egypt: a 4-year retrospective study. Craniomaxillofac Trauma Reconstr. 2014;7(3):224-32.
2. Salentijn EG, Peerdeman SM, Boffano P, van den Bergh B, Forouzanfar T. A ten-year analysis of the traumatic maxillofacial and brain injury patient in Amsterdam: incidence and aetiology. J Craniomaxillofac Surg. 2014;42(6):705-10.
3. Kraft A, Abermann E, Stigler R, Zsifkovits C, Pedross F, Kloss F, Gassner R. Craniomaxillofacial trauma: synopsis of 14,654 cases with 35,129 injuries in 15 years. Craniomaxillofac Trauma Reconstr. 2012;5(1):41-50.
4. Rallis G, Stathopoulos P, Igoumenakis D, Krasadakis C, Mourouzis C, Mezitis M. Treating maxillofacial trauma for over half a century: how can we interpret the changing patterns in etiology and management? Oral Surg Oral Med Oral Pathol Oral Radiol. 2015;119(6):614-8.
5. Leles JL, dos Santos EJ, Jorge FD, da Silva ET, Leles CR. Risk factors for maxillofacial injuries in a Brazilian emergency hospital sample. J Appl Oral Sci. 2010;18(1):23-9.
6. Pombo M, Luaces-Rey R, Pértega S, Arenaz J, Crespo JL, García-Rozado A, et al. Review of 793 facial fractures treated from 2001 to 2008 in a coruña university hospital: types and etiology. Craniomaxillofac Trauma Reconstr. 2010;3(1):49-54.
7. Aduen PA, Kofler MJ, Cox DJ, Sarver DE, Lunsford E. Motor vehicle driving in high incidence psychiatric disability: Comparison of drivers with ADHD, depression, and no known psychopathology. J Psychiatr Res. 2015; 64:59-66.
8. Aduen PA, Kofler MJ, Cox DJ, Sarver DE, Lunsford E. Motor vehicle driving in high incidence psychiatric disability: Comparison of drivers with ADHD, depression, and no known psychopathology. J Psychiatr Res. 2015; 64:59-66.
9. Brasileiro BF, Passeri LA. Epidemiological analysis of maxillofacial fractures in Brazil: a 5-year prospective study. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2006;102(1):28-34.
10. Santos SE, Marchiori EC, Soares AJ, Asprino L, de Souza Filho FJ, de Moraes M, et al. A 9-year retrospective study of dental trauma in Piracicaba and neighboring regions in the State of São Paulo, Brazil. J Oral Maxillofac Surg. 2010;68(8):1826-32.
11. Gassner R, Tuli T, Hächl O, Moreira R, Ulmer H. Craniomaxillofacial trauma in children: a review of 3,385 cases with 6,060 injuries in 10 years. J Oral Maxillofac Surg. 2004;62(4):399-407.
12. Júnior SM, Santos SE, Kluppel LE, Asprino L, Moreira RW, de Moraes M. A comparison of motorcycle and bicycle accidents in oral and maxillofacial trauma. J Oral Maxillofac Surg. 2012;70(3):577-83.
13. Hair JF, Black WC, Babin JB, Anderson RE, Tatham RL. Multivariate data analysis. 7th ed. Prentice-Hall: Copyright; 2009.
14. Verma JP. Cluster Analysis: for segmenting the population. 2013 In: Verma JP, editor. Data Analysis Management with SPSS software. New Delhi: Springer; 2013. p. 317-58.
15. Kamulegeya A, Lakor F, Kabenge K. Oral maxillofacial fractures seen at a Ugandan tertiary hospital: a six-month prospective study. Clinics (Sao Paulo). 2009;64(9):843-8.
16. Al-Khateeb T, Abdullah FM. Craniomaxillofacial injuries in the United Arab Emirates: a retrospective study. J Oral Maxillofac Surg. 2007;65(6):1094-101.
17. Martini MZ, Takahashi A, de Oliveira Neto HG, de Carvalho Júnior JP, Curcio R, Shinohara EH. Epidemiology of mandibular fractures treated in a Brazilian level I trauma public hospital in the city of São Paulo, Brazil. Braz Dent J. 2006;17(3):243-8.
18. Singh JK, Lateef M, Khan MA, Khan T. Clinical study of maxillofacial trauma in Kashmir. Indian J Otolaryngol Head Neck Surg. 2005;57(1):24-7.
19. van Hout WM, Van Cann EM, Abbink JH, Koole R. An epidemiological study of maxillofacial fractures requiring surgical treatment at a tertiary trauma centre between 2005 and 2010. Br J Oral Maxillofac Surg. 2013;51(5):416-20.
20. Nardis Ada C, Costa SA, da Silva RA, Kaba SC. Patterns of paediatric facial fractures in a hospital of São Paulo, Brazil: a retrospective study of 3 years. J Craniomaxillofac Surg. 2013;41(3):226-9.

DOI: http://dx.doi.org/10.1590/1413-785220172506174133

ORIGINAL ARTICLE

PREVALENCE OF OSTEOPOROSIS AND HYPOVITAMINOSIS D AT SIRIRAJ METABOLIC BONE DISEASE CLINIC

PREVALÊNCIA DE OSTEOPOROSE E HIPOVITAMINOSE D NA SIRIRAJ METABOLIC BONE DISEASE CLINIC

Aasis Unnanuntana[1], *Pojchong Chotiyarnwong*[1]

1. Department of Orthopedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.

ABSTRACT

Objective: To identify the prevalence of osteoporosis and hypovitaminosis D among patients at the Siriraj Metabolic Bone Disease (MBD) Clinic, and to compare initial vitamin D levels in patients with and without a history of fragility fractures. Methods: Medical records of patients who attended our MBD clinic between 2012 and 2015 were retrospectively reviewed. Patient baseline demographic, clinical, bone mineral density (BMD), and laboratory data were collected and analyzed. Osteoporosis was diagnosed when patients had a BMD T-score ≤-2.5 or presented with fragility fractures. Results: There were 761 patients included in this study. Of these, 627 patients (82.4%) were diagnosed with osteoporosis and 508 patients (66.8%) had fragility fractures. Baseline serum 25-hydroxyvitamin D (25(OH)D) levels were available in 685 patients. Of these, 391 patients (57.1%) were diagnosed with hypovitaminosis D. When evaluated only in patients with fragility fractures, the average initial 25(OH)D level was 28.2±11.6 ng/mL, and the prevalence of hypovitaminosis D was 57.6%. Conclusion: A high prevalence of osteoporosis and hypovitaminosis D was found among patients at our clinic; two-thirds of patients had a history of fragility fractures, and no difference in initial 25(OH)D levels was seen between patients with and without fragility fractures. ***Level of Evidence III, Retrospective Study.***

Keywords: Osteoporotic fracture. Bone diseases, metabolic**.** Bone density. Vitamin D. Osteoporosis.

RESUMO

Objetivo: Identificar a prevalência de osteoporose e hipovitaminose D entre os pacientes na Siriraj Metabolic Bone Disease (MBD) Clinic e comparar o nível inicial de vitamina D em pacientes com e sem história de fratura por fragilidade óssea. Métodos: Os prontuários de pacientes atendidos em nossa clínica MBD durante o período de 2012 a 2015 foram analisados retrospectivamente. Os dados demográficos, clínicos, densidade mineral óssea (DMO) e os dados laboratoriais basais foram coletados e analisados. A osteoporose foi diagnosticada quando os pacientes tinham DMO com escore T≤ -2,5 ou fraturas por fragilidade óssea. Resultados: Foram incluídos 761 pacientes dos quais, 627 pacientes (82,4%) foram diagnosticados com osteoporose e 508 (66,8%) tinham fraturas por fragilidade. O nível sérico basal de 25-hidroxivitamina D (25(OH)D) estava disponível para 685 pacientes. Desses, 391 pacientes (57,1%) foram diagnosticados com hipovitaminose D. Quando avaliado apenas em pacientes com fratura por fragilidade óssea, o nível inicial médio de 25(OH)D foi de 28,2 ± 11,6 ng/ml e a prevalência de hipovitaminose D foi de 57,6%. Conclusão: Encontrou-se alta prevalência de osteoporose e hipovitaminose D entre os pacientes de nossa clínica, sendo que dois terços deles tinham história de fratura por fragilidade óssea e nenhuma diferença no nível basal de 25(OH)D entre pacientes com e sem fratura por fragilidade. ***Nível de Evidência III, Estudo Retrospectivo.***

Descritores: *Fraturas por osteoporose. Doenças ósseas metabólicas. Densidade óssea. Vitamina D. Osteoporose.*

Citation: Unnanuntana A, Chotiyarnwong P. Prevalence of osteoporosis and hypovitaminosis d at Siriraj metabolic bone disease clinic. Acta Ortop Bras. [online]. 2017;25(6):262-5. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

As people age, their chance of sustaining a fragility fracture increases. Approximately 50% of women and 20% of men will have a fragility fracture once in their lifetime.[1,2] Wade et al.[3] estimated the combined incidence rate of non-traumatic fracture in Japan, Australia, and ten countries in North America and Europe to be approximately 5.2 million, most of these in women. The treatment-related cost of fragility fracture is high. In Europe, the total direct costs of treating osteoporotic fracture was reported to be 32 billion euros per year,[4] and the total cost of treating osteoporotic fractures in the United States in 2002 was 20 billion USD.[5] However, previous studies have reported a surprisingly low rate of osteoporosis treatment in elderly individuals with fragility fractures, approximately 20%.[6]

The Department of Orthopedic Surgery at the Siriraj Hospital Faculty of Medicine was established in 1964, and after years of development and planning, the Siriraj Metabolic Bone Disease (MBD) Clinic was

All authors declare no potential conflict of interest related to this article.

Work conducted at the Department of Orthopedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.
Correspondence: Pojchong Chotiyarnwong. Department of Orthopedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University. 2 Prannok Road, Bangkoknoi. Bangkok 10700, Thailand. pojchong@hotmail.com; pojchong.cho@mahidol.ac.th

Article received in 01/05/2017, approved in 06/09/2017.

formally established in March 2012. The objectives of this special clinic are to provide diagnosis, treatment, and follow-up care to patients with metabolic bone diseases (particularly osteoporosis and osteomalacia); to teach medical residents and fellows the principles of metabolic bone disease and the application of treatment protocols; to conduct research in metabolic bone diseases; and to follow elderly patients with low-energy hip fractures as a part of the fracture liaison service at Siriraj Hospital. Since 2012, over 900 patients have sought treatment at the Siriraj MBD clinic.

The aims of this retrospective study were to evaluate the prevalence of osteoporosis and hypovitaminosis D in patients who attended the Siriraj MBD clinic during 2012 to 2015, and to compare the initial laboratory values in patients with and without a history of fragility fracture.

MATERIALS AND METHODS

After receiving institutional review board approval (approval number Si252/2016), the authors retrospectively reviewed medical records from patients who sought treatment at the Siriraj MBD clinic from March 2012 to December 2015. Because of the retrospective methodology, consent forms were not deemed necessary by the institutional review board. Criteria for accepting patients to the Siriraj MBD clinic include clinical risk factors for osteoporosis, history of fragility fracture, and/or diagnosis of other types of metabolic bone diseases such as osteomalacia and Paget's disease. Patients meeting one or more of these criteria were referred to our clinic and included in this retrospective study. Patients with incomplete data and/or pathologic fractures were excluded. Once they were enrolled in the MBD clinic, all information related to long-term management of the patient's disease was obtained and recorded in the Siriraj MBD clinic registry.

Patient information in the clinic registry is categorized into three sections: the first includes general patient information including risk factors for osteoporosis, the second includes history of falls, underlying diseases, and current medication, and the third includes laboratory testing and treatments given or prescribed at each follow-up visit. The subset of patients with a history of fragility fracture was also evaluated in a subgroup analysis. Fragility fracture is defined as any fracture that occurs spontaneously after a physiological load, such as fractures after falls from a standing height or less.[7]

Bone mineral density (BMD)

BMD was measured by Dual Energy X-ray Absorptiometry (DEXA) in the posteroanterior lumbar spine and proximal femur using the standard protocol provided by the manufacturer (Lunar Prodigy; GE Healthcare, Little Chalfont, United Kingdom). The average T-score for the lumbar spine from L1 to L4 levels was calculated. If there was any evidence of compression fracture or degenerative changes in this area, an alternative BMD T-score was calculated from at least two consecutive levels between L1 to L4 and used. If at least two consecutive levels of the lumbar spine were not available, that case was then classified as having an uninterpretable BMD at the lumbar spine, and BMDs of the femoral neck and total hip were used instead. Indications to screen for BMD were based on the Thai Osteoporosis Foundation guidelines.[8] According to the WHO definition, osteoporosis is diagnosed when a patient's BMD T-score is equal to or lower than -2.5.[9] However, patients who had fragility fractures were diagnosed with osteoporosis regardless of their BMD level.

Laboratory investigations

Fasting blood samples were obtained and sent for analysis at our hospital's central laboratory. Serum 25-hydroxyvitamin D (25(OH)D and parathyroid hormone levels were measured using the chemiluminescence technique. Normal serum vitamin D level was defined as serum 25(OH)D level $\geq$30 ng/mL. Low serum vitamin D level (hypovitaminosis D) was subcategorized as either vitamin D insufficiency (20-29 ng/mL) or vitamin D deficiency (<20 ng/mL).[10]

Other baseline laboratory investigations included blood urea nitrogen (BUN), creatinine, total calcium, phosphorus, and albumin. Estimated glomerular filtration rate (eGFR) was calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.[11] Baseline laboratory tests were compared between patients with and without a history of fragility fracture.

Statistical analysis

All statistical analyses were performed using SPSS Statistics version 18.0 (SPSS, Inc., Chicago, IL, USA). Data are shown as number and percentage for categorical variables and mean ± standard deviation (SD) for continuous variables. Differences in baseline demographic data and clinical characteristics between patients with and without a history of fragility fracture were evaluated using Student's t-test for continuous data and the chi-squared test for categorical data. A p-value $\leq$0.05 was regarded as statistically significant.

RESULTS

From March 2012 to December 2015, 761 patients sought treatment and became patients at the Siriraj MBD clinic. Six hundred and twenty-seven patients (82.4%) were diagnosed with osteoporosis (based on T-score $\leq$-2.5 or positive history of fragility fracture). Of these 627 patients, 508 patients (81.0%) had fragility fractures. There were 708 patients with baseline BMD results available; of these, 59.6% were diagnosed with osteoporosis based on a BMD T-score $\leq$-2.5, 34.5% were diagnosed with osteopenia (T-score between -1.0 and -2.5), and 5.9% of patients had normal BMD (T-score >-1.0). In a subgroup analysis of patients with a history of fragility fracture and baseline BMD results (480 patients), we found that 303 patients (63.1%) had a BMD T-score $\leq$-2.5.

Patient demographic data and clinical risk factors for osteoporosis are shown in Table 1. The mean age of all patients was 72.0 years, and 90.8% were female. The average patient BMI was 23.0 kg/m^2 (22.4 kg/m^2 in men and 23.1 kg/m^2 in women). In the subgroup of patients with a history of fragility fracture, mean patient age was 74.7 years. The mean BMI in fragility fracture patients was 23.1 kg/m^2, and 88.8% were female. As for risk factors for osteoporosis, 75% of patients received calcium supplementation and 45.4% received vitamin D supplementation prior to their first visit to the Siriraj MBD clinic. Fewer than 10% of patients had a history of smoking, alcohol consumption, or family history of osteoporosis.

Table 1. Demographic data and clinical risk factors for osteoporosis in all patients and in patients with fragility fractures at the Siriraj MBD clinic.

Data and risk factors	All patients (N=761)	Fragility fracture patients (n=508)
Sex (female)	691 (90.8%)	451 (88.8%)
Age (years)	72.0±11.0	74.7±9.6
BMI (kg/m^2)	23.0±4.1	23.1±4.4
History of		
Steroid use	97 (12.8%)	59 (11.7%)
Calcium supplementation	569 (75.0%)	377 (74.5%)
Vitamin D supplementation	343 (45.4%)	244 (48.3%)
Proton pump inhibitor use	248 (32.7%)	175 (34.6%)
Smoking	19 (2.5%)	16 (3.2%)
Alcohol consumption	21 (2.8%)	15 (3.0%)
Bisphosphonate use	208 (27.4%)	113 (22.3%)
Familial osteoporosis	65 (8.6%)	33 (6.5%)

Data presented as mean±standard deviation (SD) for continuous variables or frequency (percentage) for categorical variables.

Baseline laboratory investigations are shown in Table 2. Six hundred and eighty-five patients had serum 25(OH)D levels available for analysis. Among these patients, the mean serum 25(OH)D level was 28.4 ng/mL, which categorized the overall group as having vitamin D insufficiency. When we compared baseline serum 25(OH)D level between patients with and without a history of fragility fracture, we observed no statistically significant difference between groups (p=0.469). However, BUN and creatinine levels were higher, and serum calcium, albumin, phosphorus, and estimated glomerular filtration rate were lower in the fragility fracture group than in the group without fragility fractures. We also observed a trend toward lower parathyroid hormone levels in the fragility fracture group (p=0.084). When we compared serum 25(OH)D levels between patients with and without fragility fracture, there was no significant difference in the proportion of patients with low serum 25(OH)D levels (p=0.201). (Table 3)

Table 3. Baseline 25(OH)D levels of patients with and without fragility fractures.

Baseline 25(OH)D level	Fragility fracture patients (n=463)	Patients without fragility fractures (n=222)	p-value
Deficiency (<20 ng/mL)	110 (23.8%)	40 (18%)	0.201
Insufficiency (20-29 ng/mL)	156 (33.7%)	85 (38.4%)	
Sufficiency (≥30 ng/mL)	197 (42.5%)	97 (43.7%)	

Data presented as number (percentage). *p-value less than or equal to 0.05 indicates statistical significance.

DISCUSSION

Metabolic bone diseases (MBDs) are a group of bone disorders caused by abnormalities in calcium, phosphorus, magnesium, and vitamin D metabolism.[12] These disorders need to be differentiated from genetic bone disorders, since many MBDs are treatable. Over the last twenty years, a vast amount of valuable information has been discovered regarding cellular and molecular biology, pharmacology, and genetics. Accordingly, the pathophysiology of many MBDs is now better understood, with significant improvements in patient care as a result.

Domrongkitchaiporn[13] reviewed the prevalence of MBDs in Thailand in 2005 and reported the four most common MBDs to be renal tubular acidosis type 1, systemic fluorosis, thalassemia, and osteoporosis. Taechakraichana et al.[14] and Limpaphayom et al.[15] reported that 10% and 20% of women aged over 40 years were diagnosed with osteoporosis using hip BMD data and lumbar spine BMD data, respectively. In this study, we found a prevalence of osteoporosis at the Siriraj MBD clinic approximately 80%. The mean age of subjects in our study was 72.0 years, which is much higher than the mean age reported in the study from Limpaphayom et al.[15] In addition, we found that two-thirds of patients at our MBD clinic had a history of fragility fracture. This finding reflects the nature of our patient population, with most of our patients referred from orthopedic surgeons at our center. The most common MBD we encountered at the Siriraj MBD clinic during the study period was osteoporosis.

A comparison of baseline laboratory investigations between patients with and without a history of fragility fracture revealed statistically significant differences for many laboratory tests. (Table 2) However, the mean scores for each of those significantly different tests were still within the normal ranges for each test. This information suggests that, while statistically significant, these differences may not always be clinically relevant.

Several strategies have been developed to increase the rate of osteoporosis treatment (especially after osteoporotic fracture), including the American Orthopedic Association's Own the Bone® initiative[16] and Capture the Fracture® – a best practice framework tool.[17] The objectives of these strategies are to raise awareness among physicians, establish a proper treatment care plan, and promote long-term follow-up for osteoporosis patients, especially after fracture fixation. The Own the Bone® initiative was launched as a pilot project in 2005. This quality improvement tool was developed to stimulate behavioral changes in both physicians and patients after low-energy fractures.[16] The Capture the Fracture® campaign was launched in 2012 by the International Osteoporosis Foundation (IOF) to substantially reduce the incidence of secondary fractures worldwide. Both of these programs were created to improve rates of long-term patient follow-up and increase the rate of medical treatment to prevent future fractures. The Siriraj MBD clinic was established, in part, to follow patients with fragility fractures, and to function as part of the fracture liaison service in the Capture the Fracture® campaign. As a component of non-pharmacologic treatment, calcium and vitamin D supplementation should be administered to all patients in this population. Our study found that the majority of patients treated at the Siriraj MBD clinic had osteoporosis and low vitamin D levels. Of 508 patients with fragility fractures, 57.6% had hypovitaminosis D. This finding suggests that physicians should increase their awareness regarding the severe health implications associated with fragility fractures, and that a more effective prevention policy is necessary. A MBD clinic can also be used as a tool to follow patients after fragility fractures as part of the fracture liaison service.

This study has several limitations that can be mentioned. First, like all retrospective studies this study was subject to inherent biases in patient selection. Second, we did not have and were not able to include accurate information regarding patient dietary intake

Table 2. Initial laboratory testing for of all patients and patients with and without fragility fractures at the Siriraj MBD clinic.

Laboratory test	Laboratory reference range	All patients (N=761)	Fragility fracture patients (n=508)	Patients without fragility fractures (n=253)	p-value
Total calcium (mg/dL)	8.6-10.0	9.2±0.5	9.2±0.5	9.3±0.5	0.007*
Corrected total calcium (mg/dL)	8.6-10.0	9.1±0.7	9.0±0.8	9.2±0.9	0.001*
Albumin (g/dL)	3.5-5.5	4.0±0.5	3.9±0.5	4.2±04	<0.001*
Phosphorus (mg/dL)	2.5-4.5	3.5±1.7	3.4±0.5	3.6±0.5	0.001*
Parathyroid hormone (pg/mL)	15-65	51.5±23.2	50.5±23.6	53.7±22.1	0.084
25(OH)D (ng/mL)	≥30	28.4±11.3	28.2±11.6	28.8±10.7	0.469
BUN (mg/dL)	6-20	14.8±6.8	15.3±7.4	13.9±5.3	0.004*
Creatinine (mg/dL)	Female (0.51-0.95)	0.88±0.7	0.91±0.8	0.81±0.3	0.020*
	Male (0.67-1.17)	1.27±0.8	1.35±0.8	0.93±0.3	0.072
eGFR (mL/min/1.73m^2)		53.4±23.2	49.9±22.4	60.4±23.3.	<0.001*

Data presented as mean±standard deviation (SD). *p-value less than or equal to 0.05 indicates statistical significance.

of vitamin D. It is therefore possible that some patients may have received vitamin D supplementation that was higher than planned or estimated. Lastly, this is a single-center study that was conducted at Thailand's largest tertiary care center, which is located in Bangkok. As such, our findings may not be applicable to different centers or other regions of the country.

CONCLUSION

A high prevalence of osteoporosis and hypovitaminosis D was found among patients who attended the Siriraj MBD clinic, with almost two-thirds of patients having a history of fragility fracture. No difference was observed for initial 25(OH)D level between patients with and without fragility fractures.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. AU (0000-0002-5742-298X)* is the main author and edited the text, analyzed the data, and discussed the results. PC (0000-0002-0287-222X)* evaluated the text, conducted the statistical analyses, wrote the article, critically reviewed its intellectual content, and approved the final corrections in the manuscript. All the authors contributed to the intellectual concept of the study and agree to be responsible for all aspects of the work. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Kanis JA, McCloskey EV, Johansson H, Cooper C, Rizzoli R, Reginster JY; Scientific Advisory Board of the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) and the Committee of Scientific Advisors of the International Osteoporosis Foundation (IOF). European guidance for the diagnosis and management of osteoporosis in postmenopausal women. Osteoporos Int. 2013;24(1):23-57.
2. van Staa TP, Dennison EM, Leufkens HG, Cooper C. Epidemiology of fractures in England and Wales. Bone. 2001;29(6):517-22.
3. Wade SW, Strader C, Fitzpatrick LA, Anthony MS. Sex- and age-specific incidence of non-traumatic fractures in selected industrialized countries. Arch Osteoporos. 2012;7:219-27.
4. Kanis JA, Johnell O. Requirements for DXA for the management of osteoporosis in Europe. Osteoporos Int. 2005;16(3):229-38.
5. Cummings SR, Melton LJ. Epidemiology and outcomes of osteoporotic fractures. Lancet. 2002;18;359(9319):1761-7.
6. Greenspan SL, Wyman A, Hooven FH, Adami S, Gehlbach S, Anderson FA Jr, et al. Predictors of treatment with osteoporosis medications after recent fragility fractures in a multinational cohort of postmenopausal women. J Am Geriatr Soc. 2012;60(3):455-61.
7. Kemmler W, Bebenek M, Kohl M, von Stengel S. Exercise and fractures in postmenopausal women. Final results of the controlled Erlangen Fitness and Osteoporosis Prevention Study (EFOPS). Osteoporos Int. 2015;26(10):2491 9.
8. Royal College of Orthopaedic Surgeons of Thailand. 2010 Clinical practice guidelines on osteoporosis, 2010 [access in 2017 10 jan]. Disponível em: http://www.rcost.or.th.
9. Prevention and management of osteoporosis. World Health Organ Tech Rep Ser. 2003;921:1-164.
10. Holick MF, Binkley NC, Bischoff-Ferrari HA, Gordon CM, Hanley DA, Heaney RP, et al. Endocrine Society. Evaluation, treatment, and prevention of vitamin D deficiency: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2011;96(7):1911-30.
11. Levey AS, Stevens LA, Schmid CH, Zhang YL, Castro AF 3rd, Feldman HI, et al. CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration). A new equation to estimate glomerular filtration rate. Ann Intern Med. 2009;5;150(9):604-12.
12. Mankin HJ, Mankin CJ. Metabolic bone disease: a review and update. Instr Course Lect. 2008;57:575-93.
13. Domrongkitchaiporn S. Metabolic Bone Diseases in Thailand. Siriraj Med J. 2005;57(9):400-1.
14. Taechakraichana N, Angkawanich P, Panyakhamlerd K, Limpaphayom K. Postmenopausal osteoporosis: what is the real magnitude of the problem in the Thai population? J Med Assoc Thai. 1998;81(6):397-401.
15. Limpaphayom KK, Taechakraichana N, Jaisamrarn U, Bunyavejchevin S, Chaikittisilpa S, Poshyachinda M, et al. Prevalence of osteopenia and osteoporosis in Thai women. Menopause. 2001;8(1):65-9.
16. Tosi LL, Gliklich R, Kannan K, Koval KJ. The American Orthopaedic Association's "own the bone" initiative to prevent secondary fractures. J Bone Joint Surg Am. 2008;90(1):163-73.
17. Akesson K, Marsh D, Mitchell PJ, McLellan AR, Stenmark J, Pierroz DD, et al. IOF Fracture Working Group. Capture the Fracture: a Best Practice Framework and global campaign to break the fragility fracture cycle. Osteoporos Int. 2013;24(8):2135-52.

DOI: http://dx.doi.org/10.1590/1413-785220172506166548

ORIGINAL ARTICLE

EVALUATION OF SURGICAL TREATMENT OF PATIENTS WITH SHOULDER INSTABILITY

AVALIAÇÃO DO TRATAMENTO CIRÚRGICO ARTROSCÓPICO EM PACIENTES COM INSTABILIDADE DO OMBRO

Roberto Yukio Ikemoto[1], Joel Murachovsky[1], Luis Gustavo Prata Nascimento[1], Rogerio Serpone Bueno[1], Luiz Henrique Oliveira Almeida[1], Claudio Kojima[1]

1. Faculdade de Medicina do ABC, Departamento de Ortopedia e Traumatologia, Santo André, São Paulo, SP, Brazil.
2. Hospital Ipiranga, Departamento de Ortopedia e Traumatologia, Ipiranga, São Paulo, SP, Brazil.

ABSTRACT

Objective: To evaluate the results of arthroscopic surgery in patients with traumatic anterior shoulder dislocation. Methods: This retrospective study analyzed 76 patients with a mean age of 28 and mean postoperative follow-up period of 62 months. Evaluation consisted of physical examination, and X-rays; results were classified according to the UCLA and Rowe scales. Results: Patients showed decrease of range of motion in all planes, except elevation and lateral rotation with 90º abduction. According to the Rowe score, significant postoperative improvement was found compared with preoperative evaluations, with 89.4% of satisfactory results. According to the UCLA score, good or excellent results were observed in 97.4% of the cases. We found a 6.5% rate of recurrence. Conclusion: Arthroscopic treatment for traumatic anterior shoulder dislocation is effective, as long as indications are used. ***Level of Evidence IV, Case Series.***

Keywords: Orthopedic procedures. Arthroscopy. Bankart Lesions. Shoulder joint.

RESUMO

Objetivo: Avaliar os resultados da cirurgia artroscópica em pacientes com instabilidade traumática anterior do ombro. Métodos: Realizamos um estudo retrospectivo de 76 pacientes, com média etária de 28 anos e tempo médio de seguimento pós-operatório de 62 meses. A avaliação foi feita por meio de exame físico, radiográfico e classificação de resultados segundo as escalas funcionais da UCLA e Rowe. Resultados: Os pacientes apresentaram perda de amplitude de movimento em todos os planos, exceto elevação e rotação lateral em abdução de 90º. Na avaliação da escala de Rowe, observamos, em média, melhora estatisticamente significante dos resultados pós-operatórios comparadas às avaliações pré-operatórias, com 89,4% de resultados satisfatórios. Pela escala UCLA, observamos resultados satisfatórios em 97,4% dos casos. Encontramos um índice de recidiva de 6,5%. Conclusão: A cirurgia artroscópica para o tratamento da instabilidade traumática anterior do ombro é um método eficaz, desde que se respeitem as indicações. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Procedimentos ortopédicos. Artroscopia. Lesões de Bankart. Articulação do ombro.*

Citation: Ikemoto RY, Murachovsky J, Nascimento LG, Bueno RS, Almeida LH, Kojima C. Evaluation of surgical treatment of patients with shoulder instability. Acta Ortop Bras. [online]. 2017;25(6):266-9. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Primary anterior dislocation of the shoulder after trauma is a common injury, with a frequency of 0.5% to 1.7% of the population.[1] When it occurs in young patients, recurrence is seen in up to 90% of cases.[2] Recent advances in arthroscopy and the growing experience of surgeons have contributed to improved results from treatment utilizing arthroscopic views to treat shoulder instability.[3]

The development of the suture anchor technique has permitted all fixations for Bankart repair to be completed using intra-articular sutures.[4] However, according to Burkhart and De Beer,[5] the acceptable limit for bone deficiency in the anterior-inferior glenoid bone where labral-capsular repair can be done is 25% of its diameter; this repair has a high rate of recurrence when glenoidal bone injury exceeds 25%.[5]

The following criteria are favorable for arthroscopic repair: first episode of dislocation, traumatic instability, patients over 25 years of age, presence of Bankart lesion. Adverse criteria are presence of laxity, practitioner of contact sports, patients under 25 years of age, bone injury of more than 25%, and surgical revision.[6]

Although many surgeons use the arthroscopic technique and obtain good results, this method remains controversial since recurrence rates are considered high.[7] However, some studies have shown that the results for open and arthroscopic surgery are similar when these techniques are correctly indicated.[8]

The objective of this study is to evaluate the results of arthroscopic repair for anterior instability of the shoulder in patients with at least two years of follow-up.

All authors declare no potential conflict of interest related to this article.

Work conducted at the Hospital Ipiranga, Ipiranga, São Paulo, SP, Brazil.
Correspondence: Luiz Henrique Oliveira Almeida. Av. Tietê, 372, Apto 81-b, Santo André, São Paulo, SP. Brazil. 0970-310. lhalmeida3@uol.com.br

Article received in 07/12/2016, approved in 12/14/2016.

MATERIALS AND METHODS

Between February 2002 and December 2010, 101 patients underwent arthroscopic surgery to treat traumatic instability of the shoulder at our service. The project was registered with the institutional review board under protocol 158/2009, and all patients signed an informed consent form. Twenty-four individuals did not return for reevaluation and were not included in the study, so the sample consisted of a total of 76 individuals; 64 (84.2%) were male and 12 (15.8%) female, with a mean age of 28 years (17–60). The right side was affected in 46 patients (60.5%) and the left in 30 patients (39.5%). The dominant side was affected in 53.9% of cases. The mean postoperative follow-up period was 62 months (24–106). The mean number of dislocations prior to surgery was 10.3 (1–50). All patients had traumatic etiology.

At the preoperative evaluation, all patients were positive for the apprehension test, 54 patients (71.1%) were positive for the anterior drawer test, 7 (9.2%) were positive for the posterior drawer test, 31 (40.8%) were positive for sulcus sign, and 69 (90.8%) were positive for the relocation test.

To quantify bone loss, we took plain X-rays and computed tomography scans of the shoulder prior to surgery. We used bilateral Bernageau views in the X-ray[9] to measure the antero-posterior diameter of the glenoidal cavity. The tomographic slices were performed in the axial plane, and in both methods the bilateral values were compared. Arthroscopic surgery was indicated when bone erosion was less than 25%. The inclusion criteria were traumatic anterior instability subjected to Bankart repair with the use of anchors, and follow-up of at least two years. Patients with uncontrolled seizures were excluded.

The surgeries were performed with the patient in lateral decubitus, under general anesthesia combined with a brachial plexus block; the operated limb was placed in traction. Posterior, antero-superior, and antero-inferior arthroscopic portals were opened, and Bankart lesions were seen in 73 patients (96.1%), SLAP type 1 injury in 4 patients (5.3%), SLAP type 2 in 3 patients (3.9%), SLAP type 4 in 1 patient (1.3%), and ALPSA lesion in 3 cases (3.9%). (Table 1 and Figure 1) Of the total number of patients, 62 (81.6%) had no injury to the glenoid, and 14 (18.4%) exhibited damage to the glenoid (Table 2); the average lesion size was 14.43%(10%-20%). To repair the injury, we used two anchors in 6 patients (7.9%), three anchors in 58 patients (76.3%), and four anchors in 12 patients (15.8%); in 25 patients (32.9%) we used bioabsorbable anchors, and in 51 patients (67.1%) we used metallic anchors. (Figures 2 and 3) After the procedure, the patients kept the operated limb immobilized in a sling and performed exercises for elbow flexion-extension, swinging, and passive/active external rotation to neutral. After four weeks, the immobilization was discontinued and the patients began exercises to gain mobility, and muscle strengthening was started in the third month. (Tables 1 and 2)

Clinical evaluation in the postoperative period consisted of: measuring the entire range of motion of the shoulders to compare whether there was restricted mobility, the anterior apprehension test, X-ray evaluation in the corrected AP and axilla positions to diagnose signs of arthrosis (degrees were determined according to the classification by Samilson and Prietto[10]), and the functional scales of by Rowe[11] and UCLA,[12] comparing pre- and postoperative values.

Table 1. Intra-operative findings.

Finding	n	% (in 76 cases)
Bankart	73	96.1
Slap 1	4	5.3
Slap 2	3	3.9
Slap 4	1	1.3
ALPSA	3	3.9

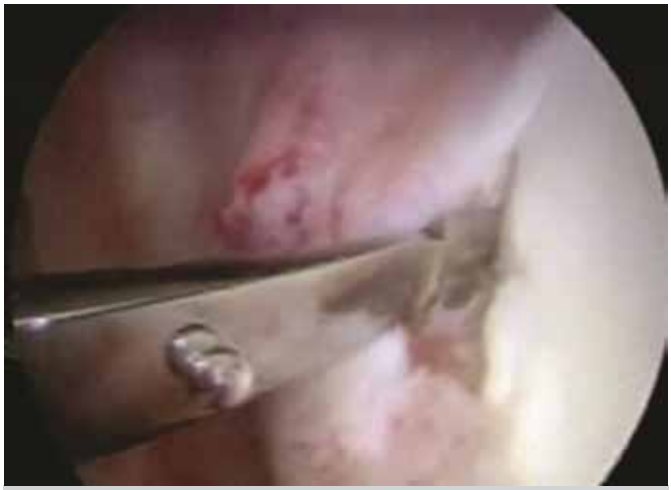


Figure 1. Detachment of the labrum.

Table 2. Bone erosion.

Injury	n	%
Yes	14	18.4
No	62	81.6
Total	76	100.0

Figure 2. Introduction of bioabsorbable anchor.

Figure 3. Labrum repair complete.

Statistical analysis of the results was performed using SPSS (Statistical Package for Social Sciences) version 15.0 software, adopting a 5% significance level. All variables were analyzed descriptively. For quantitative variables, this was done by observing minimum and maximum values and calculating the means, standard deviations, and medians. For the qualitative variables, absolute and relative frequencies (%) were calculated. Student's t-test was used to compare the means of the two groups, and when the assumption of normality was rejected, we used the non-parametric Mann-Whitney test. To test homogeneity between the proportions we used the chi-squared test or Fisher's exact test (when there were expected frequencies lower than 5). To compare pre- and post-surgery, we used the paired Student's t-test.

RESULTS

Assessment of the range of motion between the operated and non-operated shoulders showed a statistically significant decrease in lateral rotation (69° vs. 63.3°) (p=0.002), medial rotation (T5 vs. T6) (p<0.001), and medial rotation in 90° abduction (78.6° vs. 77.3°) (p=0.004). For elevation and lateral rotation in 90° abduction, although there was a decrease in the postoperative period this was not statistically significant (p=0.219).

According to the Rowe scale, a statistically significant improvement was seen between the pre- and postoperative periods: a mean of 39.9 in the preoperative and 91.5 in the postoperative period (p<0.001; 8 cases were poor (10.6%), 2 cases were good (2.6%), and 66 cases (86.8%) were excellent. There was also a statistically improvement between the pre- and postoperative periods according to the UCLA scale. The average pre-surgery score was 27.8 and postoperative score was 33.4 (p<0.001); 2 cases were regular (2.6%), 7 (9.2%) were good, and 67 (88.2%) were excellent.

We found 11 cases (14.5%) with intra-operatory complications: 1 broken bioabsorbable anchor (1.3%), 7 anchor losses (9.2%), 1 inability to repair the labrum (1.3%), 1 breach of the impactor (1.3%), and 1 protruding anchor (1.3%). Postoperative complications occurred in 22 patients (28.9%), 4 cases of recurrence (5.3%), 12 cases of arthrosis (15.7%), 5 cases of anchor extrusion (6.5%), (Figure 4) 2 cases of adhesive capsulitis (2.6%), and 1 superficial infection (1.3%).

As for the physical examination, the four patients who developed recurrent dislocation in the postoperative period were positive for the apprehension test.

There was no association between recurrence and intra-operative complications, according to Fisher's exact test (p = 1.000). No association was seen between recurrence and anchor type (Fisher's exact test, p=1.000). The number of episodes of dislocations had no statistical relationship with postoperative recurrence (Mann-Whitney non-parametric test, p=0.559). There was also no association between the number of episodes and postoperative arthrosis (Mann-Whitney non-parametric test, p=0.720). No relationship was seen between the number of anchors and recurrence (Fisher's exact test, p=0.381). There was also no relationship between recurrence and bone erosion (Fisher's exact test, p=0.172).

Presence of ALPSA-type injury was not a determining factor for recurrence (Fisher's exact test, p=1.000).

Furthermore, no statistical differences were seen between intra-operative and late complications with regard to anchor type (Table 1) (Fisher's exact test, p=1.000 and p=0.123, respectively).

On the other hand, we observed that the groups differed when we compared cases with pain and type of anchor used. In the 18 patients (23.7%) who presented pain, 2 cases (8%) received bioabsorbable anchors and 16 (31.4%) received metal anchors (descriptive level of probability of the chi-square test, p=0.024).

No statistically significant relationship was seen between the number of anchors and arthrosis (Fisher's exact test, p=0.009). No association was seen when arthrosis was compared with intra-operative complications (Fisher's exact test, p=0.668) and late complications (Fisher's exact test, p=0.080). No association was observed between pain and intra-operative complications (Fisher's exact test, p=0.716), but an association was seen between pain and late complications (Fisher's exact test, p=0.005). (Table 3)

As for X-ray assessment in the postoperative follow-up, 12 cases (15.8%) presented evidence of arthrosis. According to the classification by Samilson and Prietto, 9 were classified as grade I (11.8%) and 3 as grade II (3.9%).

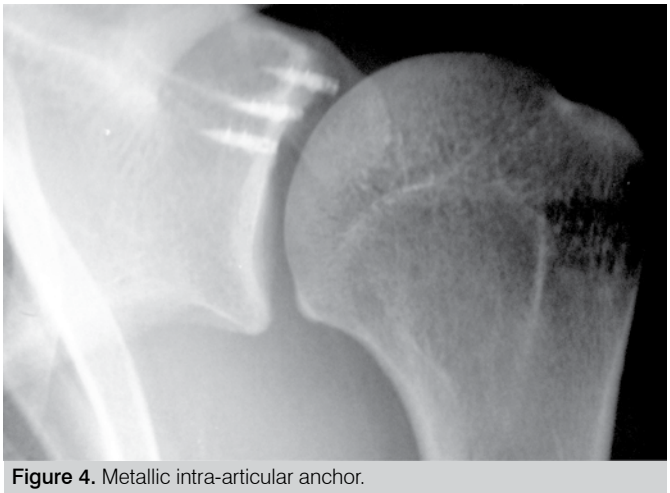


Figure 4. Metallic intra-articular anchor.

Table 3. Relation between complication by type of anchor.

Complication	Type	Bioabsorbable	Metallic
Intra-operative	Breakage of anchor	1	-
	Loss of anchor	2	5
	Impossible to repair the labrum	-	1
	Impactor breakage	-	1
	Protruding anchor	-	1
Late	Recurrence	1	3
	Arthrosis	1	11
	Protruding anchor	-	5
	Adhesive capsulitis	-	2
	Subluxation	-	1
	Infection	1	-

DISCUSSION

Open stabilization has a higher success rate, with a lower incidence of recurrence and less potential for complications when compared with arthroscopy.[3] However, if patients are carefully selected, the results may be equivalent.[13] In our study, all patients had bone erosion below 25%, which is the limit for arthroscopic repair according to the literature.[10]

Ferreira Neto et al.[14] obtained 10% recurrence in 159 patients, and Carreira et al.[15] had 10% recurrence of instability in 85 patients; Marquardt et al.[16] obtained 7.5% recurrence in 54 patients. Although the literature discusses greater chances of recurrence, we observed 4 cases (5.3%), and these were the same patients who continued to have a positive apprehension test.

In this study, the use of metal anchors (67.1%) was related to the presence of residual pain. This fact agrees with the literature; Jeong and Shin[17] assessed 43 patients, noting 33% of cases of residual

pain associated with the use of metal anchors. In our study, we found 6 cases in which the anchor required subsequent removal. Our study found a statistically significant reduction in lateral rotation, medial rotation in neutral, and medial rotation in 90° abduction. In the literature, no study observed a loss of range of motion.[17] However, the reduction of amplitudes did not result in compromised clinical and functional outcome. As for X-ray assessment, 15.8% of cases showed signs of arthrosis, justified by the osteochondral lesion associated with instability.[18]

In the Rowe score assessment, we observed a statistically significant improvement when comparing the pre- and postoperative means, with 89.4% attaining good results. In a study of 53 patients, Gartsman et al.[19] obtained 91.9 points for the Rowe score. Boileau et al.[20] presented the results of 91 patients who underwent surgery and were and evaluated according to the Rowe criteria, and obtained an average score of 77.8 points. Balg and Boileau[13] analyzed the results of 131 patients who were evaluated according to the Rowe criteria, and found an average score of 81.5 points.

In our study, it was not possible to correlate fewer anchors and recurrence, because few cases used only two anchors (7.9%); similarly, the presence of ALPSA-type lesions (3.9%) was not associated with recurrence, but according to the literature fewer anchors and ALPSA-type injury are related to recurrence.[20]

Although our results regarding recurrence have demonstrated compatibility with the values found in the literature, it is possible that, in an attempt to prevent recurrence in these severe cases by repairs to the labrum and plication, some range of motion was lost in these patients.

CONCLUSION

Arthroscopic surgery is an effective method for treating traumatic anterior instability in the shoulder. After a follow-up of at least two years, we observed a recurrence rate of 5.3%, which is established in the literature.

In this study, the use of metal anchors is associated with greater pain in the postoperative period.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. RYI (0000-0001-7718-1186)* and JM (0000-0003-1812-8566)* made substantial contributions to the conception and design of the study, and the acquisition, analysis, and interpretation of the data. LGPN (0000-0003-0889-3360)*, RSB (0000-0003-4672-0380)*, LHOA (0000-0003-1247-971X)*, and CK (0000-0002-8580-2082)* actively participated in discussion of the results. CK drafted the article and also participated in the critical review of its intellectual content. All authors contributed to the revision and final approval of the manuscript. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Hovelius L. Incidence of shoulder dislocation in Sweden. Clin Orthop Relat Res. 1982;(166):127-31.
2. Hovelius L. Shoulder dislocation in Swedish ice hockey players. Am J Sports Med. 1978;6(6):373-7.
3. Godinho GG, Souza JMG, Freitas JMA, Santos FML, Vieira AW, João FM. Tratamento da instabilidade anterior do ombro. Rev Bras Ortop. 1997;32(4):265-71.
4. Wolf EM. Arthroscopic capsulolabral repair using suture anchors. Orthop Clin North Am. 1993;24(1):59-69.
5. Burkhart SS, De Beer JF. Traumatic glenohumeral bone defects and their relationship to failure of arthroscopic Bankart repairs: significance of the inverted pear glenoid and the humeral engaging Hill-Sachs lesion. Arthroscopy. 2000;16(7):677-94.
6. Calvo E, Granizo JJ, Fernández-Yruegas D. Criteria for arthroscopic treatment of anterior instability of the shoulder: a prospective study. J Bone Joint Surg Br. 2005;87(5):677-83.
7. Lenters TR, Franta AK, Wolf FM, Leopold SS, Matsen FA 3rd. Arthroscopic compared with open repairs for recurrent anterior shoulder instability. A systematic review and meta-analysis of the literature. J Bone Joint Surg Am. 2007;89(2):244-54.
8. Hobby J, Griffin D, Dunbar M, Boileau P. Is arthroscopic surgery for stabilization of chronic shoulder instability as effective as open surgery? A systematic review and meta-analysis of 62 studies including 3044 arthroscopic operations. J Bone Joint Surg Br. 2007;89(9):1188-96.
9. Edwards TB, Boulahia A, Walch G. Radiographic analysis of bone defects in chronic anterior shoulder instability. Arthroscopy. 2003;19(7):732-9.
10. Samilson RL, Prieto V. Dislocation arthropathy of the shoulder. J Bone Joint Surg Am. 1983;65(4):456-60.
11. Rowe CR, Patel D, Southmayd WW. The Bankart procedure: a long-term end result study. J Bone Joint Surg Am. 1978;60(1):1-16.
12. Amstutz HC, Sew Hoy AL, Clarke IC. UCLA anatomic total shoulder arthroplasty. Clin Orthop Relat Res. 1981;(155):7-20.
13. Balg F, Boileau P. The instability severity index score. A simple pre-operative score to select patients for arthroscopic or open shoulder stabilisation. J Bone Joint Surg Br. 2007;89(11):1470-7.
14. Ferreira Neto AA, Camanho GL, Felix AM, Benegas E, Bitar AC, Ramadan LB, et al. Tratamento artroscópico da instabilidade anterior do ombro. estudo retrospectivo de 159 casos. Acta Ortop Bras. 2011;19(1):41-4.
15. Carreira DS, Mazzocca AD, Oryhon J, Brown FM, Hayden JK, Romeo AA. A prospective outcome evaluation of arthroscopic Bankart repairs: minimum 2-year follow-up. Am J Sports Med. 2006;34(5):771-7.
16. Marquardt B, Witt KA, Liem D, Steinbeck J, Pötzl W. Arthroscopic Bankart repair in traumatic anterior shoulder instability using a suture anchor technique. Arthroscopy. 2006;22(9):931-6.
17. Jeong JH, Shin SJ. Arthroscopic removal of proud metallic suture anchors after Bankart repair. Arch Orthop Trauma Surg. 2009;129(8):1109-15.
18. Brophy RH, Marx RG. Osteoarthritis following shoulder instability. Clin Sports Med. 2005;24(1):47-56.
19. Gartsman GM, Roddey TS, Hammerman SM. Arthroscopic treatment of anterior--inferior glenohumeral instability. Two to five-year follow-up. J Bone Joint Surg Am. 2000;82(7):991-1003.
20. Boileau P, Villalba M, Héry JY, Balg F, Ahrens P, Neyton L. Risk factors for recurrence of shoulder instability after arthroscopic Bankart repair. J Bone Joint Surg Am. 2006;88(8):1755-63.

DOI: http://dx.doi.org/10.1590/1413-785220172506174033

ORIGINAL ARTICLE

MID-LONG TERM RESULTS OF MANIPULATION AND ARTHROSCOPIC RELEASE IN FROZEN SHOULDER

RESULTADOS A MÉDIO E LONGO PRAZO DA MANIPULAÇÃO E LIBERAÇÃO ARTROSCÓPICA DE OMBRO CONGELADO

Haluk Celik[1], Mustafa Faik Seckin[2], Mehmet Akif Akcal[3], Adnan Kara[4], Bekir Eray Kilinc[5], Senol Akman[6]

1. Department of Orthopedics and Traumatology, Zonguldak Ataturk State Hospital, Zonguldak, Turkey.
2. Department of Orthopedics and Traumatology, Faculty of Medicine, Bilim University, Istanbul, Turkey.
3. Department of Orthopedics and Traumatology, Antalya Ataturk State Hospital, Antalya, Turkey.
4. Department of Orthopedics and Traumatology, Faculty of Medicine, Istanbul Medipol University, Istanbul, Turkey.
5. Department of Orthopedics and Traumatology, Golhisar State Hospital, Burdur, Turkey.
6. Department of Orthopedics and Traumatology, Florence Nightingale Hospital, Istanbul, Turkey.

ABSTRACT

Objective: Surgical treatment options should be discussed in cases of frozen shoulder, which is usually treated in a conservative manner. In this study, we evaluated the efficacy of manipulation and arthroscopic release in cases of frozen shoulder which resisted conservative treatment. Methods: A total of 32 patients who underwent manipulation and arthroscopic capsular release in 34 shoulders were included in the study. The average follow-up period was 49.5 months (range: 24–90 months). No reason for onset could be found in 8 (25%) patients, who were classified as primary frozen shoulder; twenty-four (75%) patients were classified as secondary frozen shoulder due to underlying pathologies. The average pre-operative complaint period was 11 months (range: 3–24 months). After arthroscopic examination, manipulation was performed first, followed by arthroscopic capsular release. The range of motion in both shoulders was compared before the procedure and in the last follow-up visit. Constant and Oxford classifications were used to assess functional results, and the results were assessed statistically. Results: Patient values for passive elevation, abduction, adduction-external rotation, abduction-external rotation, and abduction-internal rotation increased in a statistically significant manner between the preoperative assessment and follow-up evaluation ($p<0.01$). The average change of 47.97±21.03 units observed in the patients' values obtained in the control measurements against the pre-op Constant scores was determined to be statistically significant ($p<0.01$). According to the Oxford classification, 29 shoulders were sufficient. Conclusion: Successful results can be obtained with arthroscopic release performed after manipulation in patients with frozen shoulder resistant to conservative treatment. ***Level of Evidence IV, Case Series.***

Keywords: Bursitis/physiopathology. Bursitis/surgery. Bursitis/therapy. Joint capsule release. Manipulation, orthopedic/methods.

RESUMO

Objetivo: As opções de tratamento cirúrgico devem ser discutidas nos casos de ombro congelado que, em geral, são tratadas de modo conservador. Neste estudo, avaliamos a eficácia da manipulação e da liberação artroscópica nos casos de ombro congelado refratário ao tratamento conservador. Métodos: Um total de 32 pacientes submetidos a manipulação e liberação capsular artroscópica em 34 ombros foram incluídos no estudo. O período médio de acompanhamento foi de 49,5 meses (faixa: 24 a 90 meses). Não foi possível determinar o motivo do início da afecção em 8 (25%) pacientes, que foram classificados como ombro congelado primário; 24 (75%) pacientes foram classificados como ombro congelado secundário, devido a patologias subjacentes. O período médio de queixa pré-operatória foi de 11 meses (faixa: 3 a 24 meses). Depois do exame artroscópico, realizou-se manipulação, seguida por liberação capsular artroscópica. A amplitude de movimento em ambos os ombros foi comparada antes do procedimento e na última visita de acompanhamento. As classificações de Constant e Oxford foram usadas para avaliar os resultados funcionais, e os resultados foram avaliados estatisticamente. Resultados: Os valores dos pacientes para elevação, abdução, adução-rotação externa, abdução-rotação externa e abdução-rotação interna aumentaram de modo estatisticamente significante entre a avaliação pré-operatória e a do acompanhamento ($p < 0,01$). A mudança média de 47,97 ± 21,03 unidades observada nos valores dos pacientes, obtidos nas medidas de controle com relação aos escores de Constant no pré-operatório foi determinada como estatisticamente significante ($p < 0,01$). De acordo com a classificação de Oxford, 29 ombros foram suficientes. Conclusão: Os resultados bem-sucedidos podem ser atingidos com liberação artroscópica realizada depois da manipulação dos pacientes com ombro congelado, resistentes ao tratamento conservador. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Bursite/fisiopatologia. Bursite/cirurgia. Bursite/terapia. Liberação da cápsula articular. Manipulação ortopédica/métodos.*

Citation: Celik H, Seckin MF, Akcal MA, Kara A, Kilinc BE, Akman S. Mid-long term results of manipulation and arthroscopic release in frozen shoulder. Acta Ortop Bras. [online]. 2017;25(6):270-4. Available from URL: http://www.scielo.br/aob.

All authors declare no potential conflict of interest related to this article.

Work conducted at the Sisli Etfal Hospital and Florence Nightingale Hospital, Şişli/İstanbul, Turkey.
Correspondence: Tepebası Mah, Kapuz Cad. Turkuaz apt. 28/10. 67030. Zonguldak, Turkey. drhalukcelik@gmail.com

Article received in 01/01/2017, approved in 06/19/2017.

INTRODUCTION

Frozen shoulder (FS) is a common reason for shoulder pain and loss of function. It is characterized by active and passive restriction of glenohumeral motion following frequent shoulder pain, with spontaneous onset.[1] It was first defined by Duplay in 1872 as 'scapulohumeral periarthritis'.[2] The American Shoulder and Elbow Surgeons Union (ASES) defines adhesive capsulitis as a condition which occurs without the presence of a known shoulder disease, without clear etiology, in which shoulder movements are actively and passively limited at a significant level.[3] Manipulation, arthroscopic release, or both may be performed in cases in which conservative treatment has not been successful. There is no consensus on whether manipulation should be done before or after arthroscopic release.[4-6] In this study, we investigated the efficacy of manipulation and arthroscopic release in patients with cases of frozen shoulder which resisted conservative treatment.

MATERIALS AND METHODS

We retrospectively evaluated patients who underwent manipulation and arthroscopic capsular release surgery to treat a diagnosis of frozen shoulder between January 2005 and July 2012. All patients in the study signed an informed consent form (Protocol number: BDH17-12-C).

We considered FS to mean active and passive range of motion (ROM) in least at two planes accompanied by shoulder pain. Criteria for inclusion in the study were existence of unilateral or bilateral FS, unsuccessful conservative treatment for at least six months, and a follow-up period of at least 24 months. Patients who had stiffness after trauma, fracture treatment, or shoulder surgery, as well as patients whose disease was associated with a non-joint pathology, were excluded from the study.

We investigated the patients' complaints, onset of complaints, and time of first admission, and previous treatments (if any) in detail. Any concomitant systemic diseases, if present, were recorded. The patients were classified according to the method developed by Lundberg, which is based on asking whether there is an onset factor.[7,8] According to this method, patients who did not have any factors that caused onset, any abnormal findings other than restriction of motion in the x-ray and examination, and who had an idiopathic condition were considered to have primary frozen shoulder. Patients who had a known intrinsic, extrinsic, or systemic pathology were classified as secondary FS patients. Diseases such as diabetes mellitus, hypothyroidism, hyperthyroidism, and hypoadrenalism were considered systemic reasons; diseases such as cardiopulmonary diseases, cervical disc herniation, cerebrovascular diseases, humerus fractures, and Parkinson's disease were considered extrinsic reasons; and pathologies such as rotator cuff tendinitis, rotator cuff tear, biceps tendinitis, calcified tendinitis, and acromioclavicular arthritis were considered intrinsic reasons. The three-stage system defined by Reeves was used during patient follow-up.[8,9]

Both shoulders were examined comparatively. Values for passive elevation towards the front side, abduction, external rotation in abduction, and internal rotation in abduction were measured for each patient using a standard goniometer. The measurement of internal rotation in adduction was recorded based on the highest point the patient could reach behind his or her back. Constant and Oxford scoring were used for functional assessment.

Patients received conservative treatment for an average of 9.5 months prior to surgery (range: 6–12 months). Surgical treatment was planned for patients who did not respond to conservative treatment or who had progressive shoulder stiffness. The disease stage was considered inflammatory in patients who had severe pain as well as restriction of motion. Because surgical treatment can cause capsule damage and restriction of motion, it was postponed until the frozen stage was reached. Since the pain was felt only at the end of range of motion, it was decided that the inflammatory stage ended and frozen stage started at this point.

Surgical technique

All patients underwent a standardized procedure in beach-chair position. Projections of anatomic structures and entry points were marked on the skin with a pen. In order to not damage cartilage due to capsule contracture and decreased joint volume, a scope was gently inserted through the posterior portal from the head section of humerus; the joint was examined arthroscopically, and synovitis and intra-joint pathologies were recorded. Afterwards, the scope was defined and manipulation was performed. The scapula was fixed and force was gently applied through the proximal section of the humerus to elevate towards the front section and perform abduction. In patients in whom an opening was not felt, we did not proceed to the next stage. In patients in whom an opening was felt, external rotation at 0 degree abduction, external rotation in 90 degrees abduction, internal rotation in 90 degrees abduction and cross-body adduction were performed, respectively, and the manipulation was completed. After manipulation, the scope was again inserted through the posterior portal. In most cases, we observed that the anterior capsule was torn substantially. The biceps tendon was found to reach the upper border of the rotator interval. The mid-glenohumeral ligament was released from the labrum edge with a radiofrequency probe and motor trimmer inserted through a portal opened directly below the biceps tendon. The scar tissue that covered the subscapularis muscle was excised, and the subscapularis tendon was made mobile. Afterwards, the thickened scar tissue was removed from the rotator interval area of the capsule (starting from the lower edge of the biceps tendon until the upper edge of subscapularis tendon). (Figure 1) The coracohumeral ligament was separated from the coracoid process with a radiofrequency probe, and the supraspinatus tendon in the superior section, the subscapularis tendon in the inferior section, and the rotator interval section of the capsule up to the inferolateral section of the coracoid bone in the anterior section were subsequently surgically released. After release, an external rotation opening was provided in most of the patients, since the arm was on the side. The joint was examined and additional pathologies were determined. Bleeding was controlled with hypotensive anesthesia, pressurized irrigation, and radiofrequency probes. Posterior capsule release was performed in patients in whom external rotation was provided

Figure 1. Release of rotator interval in left shoulder. Scope was inserted from posterior portal and radiofrequency probe was inserted in anterior portal.

but who still did not achieve complete internal rotation, horizontal adduction, and elevation towards front section. To do so, the portals were changed on the changing rod and posterior capsule release was performed. (Figure 2) The inferior section of capsule was observed to be torn as a result of manipulation in almost all patients. Release was performed with arthroscopic scissors in patients who did not have torn structures.

A lateral portal was opened and arthroscopic subacromial bursectomy and acromioplasty were performed in patients who were considered to have subacromial compression syndrome. Afterwards, manipulation was repeated in patients who still had restricted motion. An arm sling was used after the portals were closed.

Active and passive joint motion exercises in all directions and isometric exercises were started on the first day post-operative. The patients were enrolled in a three-day intensive exercise program after the procedure, and were discharged afterward. Sutures were removed on the tenth day post-procedure, and the patients were transferred to the physical therapy and rehabilitation clinic for enrolment in a special rehabilitation program. The patients were invited for follow-up visits at week 1, week 4, month 3, month 6, and month 12 post-procedure.

NCSS (Number Cruncher Statistical System) 2007&PASS (Power Analysis and Sample Size) 2008 Statistical Software (Utah, USA) software was used for the statistical analysis. As the study data were evaluated, descriptive statistical methods (average, standard deviation, median, frequency, ratio, minimum, maximum) were used and Mann-Whitney U test was used in two-group comparisons of parameters that did not have normal distribution for comparing the quantitative data. A paired-sample T-test was used in intragroup comparison of parameters with normal distribution. The Wilcoxon signed-rank test was used in intragroup comparison of parameters without normal distribution. Significance was evaluated at $p<0.01$ and $p<0.05$ levels.

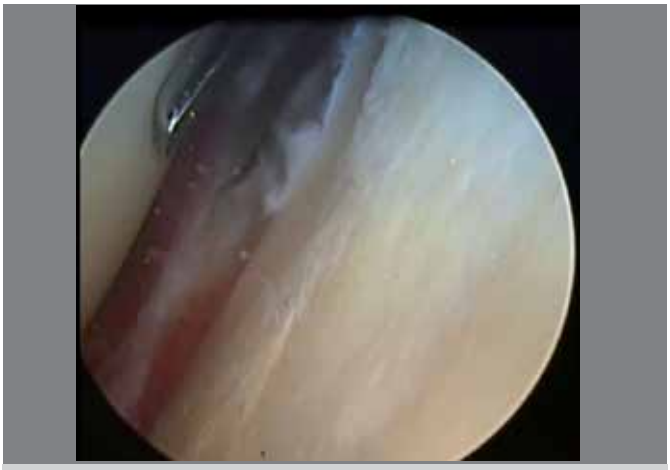


Figure 2. Release of posterior capsule in right shoulder. Scope was inserted from posterior portal and arthroscopic scissor was inserted in anterior portal.

RESULTS

A total of 32 patients with 34 shoulders were included in the study. The average age was 48 (range: 35–63). Twelve (37%) of the patients were male and 20 (63%) were female. While the right shoulder was affected in 18 patients and left shoulder was affected in 12 patients, bilateral involvement was present in two patients. The average follow-up period was 49.5 months (range: 24–90 months).

According to the Lundberg classification, no reason for onset could be found in 8 (25%) patients, and these were consequently classified as primary frozen shoulder. Twenty-four (75%) patients were classified as secondary frozen shoulder due to underlying pathologies. (Table 1) All patients received surgery during the frozen stage. The average pre-op complaint period was 11 months (range: 3–24 months).

C-reactive protein and sedimentation levels were normal in all patients included in the study. Additionally, two patients had trigger finger, one patient had Dupuytren's contracture, one patient had osteoporosis, and one patient had carpal tunnel syndrome.

The increase in the patients' values for passive elevation towards the front, abduction, adduction-external rotation, abduction-external rotation, abduction-internal rotation measured during check-up compared to the preoperative values was statistically significant ($p<0.01$). (Table 2) In the preoperative evaluation, adduction internal rotation was in the hips in 12 patients, in L1 in 1 patient, in L3 in 4 patients, in the lateral thigh in 3 patients, in the L5 area in 13 patients and in T12 in 1 patient. In the follow-up evaluation, this value was in the interscapular T7 area in 21 patients, in the hips in 3 patients, in L3 in 2 patients and in the T12 area in 8 patients.

The Constant score was poor in all patients before the operation. In the final follow-up visits, it was fair in 5 (15%) patients, good in 4 (12%) patients, and excellent in 25 (74%) patients. We determined that the average change of 47.97±21.03 units observed in the patients' values obtained in the control measurements according to the pre-op Constant scores of the patients was statistically significant ($p<0.01$).

According to the Oxford classification used during follow-up, 1 shoulder (3%) was considered bad, 4 shoulders (12%) were considered moderate, and 29 shoulders were considered to be in sufficient condition (85%), out of a total of 34 shoulders. Three of the five patients with poor condition had diabetes (one case was bilateral).

Table 1. Etiologic distribution of secondary frozen shoulder.

Secondary-systemic	Secondary- extrinsic	Secondary- intrinsic
Insulin-dependent diabetes mellitus (n:7)	Coronary bypass (n:2)	Supraspinatus calcific tendinitis (n:3)
Insulin-independent diabetes mellitus (n:5)	Coronary stent (n:3)	Supraspinatus partial thickness tear (n:1)
Hyperthyroidism (n:1)	Cervical disc hernia (n:2)	

Table 2. Evaluation of range of motion in preoperative and follow-up periods.

(n=34)	[1]Preoperative	[2]Follow-up	Difference [(2-1)]	Difference (%)	[a]p
	Average ± SD	Average ± SD	Average ± SD	Average ± SD	
Forward elevation	86.32 ± 19.67	157.35 ± 20.20	71.03 ± 29.33	41.78 ±17.25	0.001**
Abduction	66.47 ± 25.63	151.76 ± 29.59	85.29 ± 42.16	50.17 ± 24.80	0.001**
Adduction-external rotation	21.03 ± 20.07	64.12 ± 20.61	43.09 ± 25.94	53.86 ± 32.42	0.001**
Abduction-external rotation	33.53 ± 16.86	76.47 ± 20.87	42.94 ± 24.99	47.71 ± 27.76	0.001**
Abduction–internal rotation	38.24 ± 16.51	72.79 ± 16.06	34.56 ± 19.67	38.40 ± 21.86	0.001**

[a]Paired samples t test. **p<0,01 SD: standart deviation.

The other patient with poor condition had performed heavy lifting at work and had primary FS. These four patients stated that they could not continue their previous jobs; the remaining patients stated that they were able to continue their previous jobs and maintain their lifestyles without any problems.

No statistical difference was observed between diabetic patients and the other patients in terms of preoperative and follow-up Constant scores (p>0.05). (Table 3)

Table 3. Comparison of constant scores between diabetic and non-diabetic patients.

	Diabetic patients	Non-diabetic patients	*p*
	Average ± SD	Average ± SD	
Preoperative constant score	39.24 ± 5.72 (38.00)	38.23 ± 4.30 (38.00)	0.694
Follow-up constant score	91.24 ± 15.99 (95.00)	79.69 ± 25.85 (91.00)	0.066

[c]Mann Whitney U test.*p<0,05.

DISCUSSION

The initial studies which investigated frozen shoulder, considered spontaneous remission to be absolute, and that patients could wait for recovery to occur.[10] Although it is believed that spontaneous remission generally occurs in frozen shoulder disease, this pathological condition causes early remission in patients, and with it loss of labor and disability. Optimistic outcomes on the normal course of frozen shoulder disease have been questioned in the literature; a study published by Hand et al. with 223 patients reported that the recovery rate for this disease was 59%, complaints were still ongoing in the remaining patients, and there was functional loss in 6% of patients.[11] During the average follow-up period of 49.5 months in our study, we observed that complaints were still ongoing in five (15%) shoulders.

Despite the fact that manipulation under anesthesia was successful in some patients, this method has been reported to cause various complications, such as humerus fracture, nerve injury, and shoulder luxation.[12] Many successful outcomes have been reported with arthroscopic capsular release in the treatment of frozen shoulder.[13-15] However, no agreement has been reached on the surgical technique, and opinions vary on whether it should be performed with manipulation. One study reported sufficient results in 83% of cases after arthroscopic debridement in the glenohumeral joint and subacromial area after manipulation under anesthesia, but the rate fell to 64% in the group of patients with diabetes.[16]

Another study with 26 patients evaluated anterior and anteroinferior release procedures after manipulation. No complications were reported as a result of manipulation, and poor results were obtained in three patients.[17] Watson et al.[15] performed arthroscopic selective release in 73 patients and followed these patients for one year; at the end of follow-up, these researchers observed that pain and restriction of motion were ongoing in 11% of the patients. Berghs et al.[18] reported performing arthroscopic anterior and posterior capsular release in 25 patients with adhesive capsulitis, releasing the inferior capsule with manipulation; they found that the Constant score, which was 25.3 before the operation, increased to 75.5. In a similar study, arthroscopic capsule release was performed and followed by manipulation and bursoscopy in 16 patients, producing a 50-point increase in the American Shoulder and Elbow Surgeons shoulder assessment.[19]

Uhthoff and Boileau found that contractile proteins increased in the anterior capsule and rotator interval in DOH, and fibrodysplasia occurred in the posterior structures.[20] Therefore, we also consider rotator interval release is important. In our study, we first performed an arthroscopic examination in the patients to determine existing pathologies. We then performed a gentle manipulation in an attempt to increase the range of motion. We did not observe significant complications after manipulation. We performed the manipulation before arthroscopy, contrary to other authors who performed the manipulation after arthroscopy. We believe that manipulation performed after arthroscopic capsulotomy is not effective because of fluid extravasation and swelling. We performed specific capsular release to open the range of motion in restricted directions after manipulation. We performed rotator interval release, mid-glenohumeral ligament release, coracohumeral release, and anterior and posterior capsular release, according to the direction of restriction of motion. We performed subacromial bursoscopy and bursectomy and acromioplasty in patients who were considered to have compartment syndrome and subacromial bursitis as a result of direct x-ray and magnetic resonance examinations. As a result, we observed a statistically significant increase in range of motion in all directions and Constant scores. During follow-up, good or excellent results were obtained in 29 of 34 shoulders, according to the Constant score, and sufficient result were obtained in 85% of the shoulders, according to the Oxford score.

One detail we observed in our research was outcome of surgical treatment in patients with diabetes. The relationship between frozen shoulder and diabetic patients has been mentioned in many publications; the prevalence of frozen shoulder disease is around 29–38.6% in patients with diabetes.[21,22] The rate of occurrence is higher in patients with Type 1 diabetes than in patients with Type 2, and use of insulin and high hemoglobin A1c are among the risk factors. The risk for frozen shoulder disease increases when diabetes mellitus has been present for a long period (more than 13 years).[23] Cınar et al.[23] compared arthroscopic capsular release in 14 patients with diabetes and 12 patients with primary frozen shoulder, and reported that lower Constant scores were obtained in patients with diabetes. We evaluated 14 shoulders in 12 patients with diabetes in our study. We observed that the complaints were ongoing in four of the fourteen shoulders. However, no statistically significant results were obtained in the comparison of Constant scores of patients with diabetes and other patients. All of the patients who had poor results had insulin-dependent diabetes mellitus and had been using insulin for an average of 9.5 years (distribution 8-12). In addition, according to their patient history, they did not administer their insulin treatment regularly and could not obtain regular glucose regulation.

CONCLUSION

Manipulation and arthroscopic release is an effective treatment option for frozen shoulder that resists conservative treatment. Poor results may occur in patients with insulin-dependent diabetes mellitus or treatment-resistant diabetes.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. HC (0000-0003-4798-1400)* and MFS (0000-0003-4798-1400)* were the main contributors in drafting the manuscript. HC, MFS, SA (0000-0001-7327-4270)*, and AK (0000-0001-5899 6910)* performed the surgeries, followed patients, and gathered clinical data. MAA (0000-0002-3851-4256)*, BEK (0000-0003-1229-9815)*, and SA evaluated the data from the statistical analysis. HC, MAA, AK, and BEK performed the literature search, reviewed the manuscript and contributed to the intellectual concept of the study.
*ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Grey RG. The natural history of "idiopathic" frozen shoulder. J Bone Joint Surg Am. 1978;60(4):564.
2. Neviaser JS. Adhesive capsulitis of the shoulder: a study of the pathological findings in periarthritis of the shoulder. J Bone Joint Surg Am. 1945;27:211.
3. D'Orsi GM, Via AG, Frizziero A, Oliva F. Treatment of adhesive capsulitis: a review. Muscles Ligaments Tendons J. 2012;2(2):70-8.
4. De Carli A, Vadala A, Perugia D, Frate L, Iorio C, Fabbri M, et al. Shoulder adhesive capsulitis: manipulation and arthroscopic arthrolysis or intra-articular steroid injections? Int Orthop. 2012;36(1):101-6.
5. Andersen NH, Sojbjerg JO, Johannsen HV, Sneppen O. Frozen shoulder: arthroscopy and manipulation under general anesthesia and early passive motion. J Shoulder Elbow Surg. 1998;7(3):218-22.
6. Wang JP, Huang TF, Hung SC, Ma HL, Wu JG, Chen TH. Comparison of idiopathic, post-trauma and post-surgery frozen shoulder after manipulation under anesthesia. Int Orthop. 2007;31(3):333-7.
7. Lundberg BJ. The frozen shoulder. Clinical and radiographical observations. The effect of manipulation under general anesthesia. Structure and glycosaminoglycan content of the joint capsule. Local bone metabolism. Acta Orthop Scand Suppl. 1969;119:1-59.
8. Cuomo F. Diagnosis, classification, and management of the stiff shoulder. In: Iannotti JP, Williams GR, editors. Disorders of the shoulder: diagnosis and management. Philadelphia: Lippincott Williams & Wilkins; 1999. p. 397-417.
9. Reeves B. The natural history of the frozen shoulder syndrome. Scand J Rheumatol. 1975;4(4):193-6.
10. Codman EA. The shoulder: rupture of the supraspinatus tendon and other lesions in and about the subacromial bursa. Brooklyn, NY: G. Miller & Co. Medical Publishers; 1984.
11. Hand C, Clipsham K, Rees JL, Carr AJ. Long-term outcome of frozen shoulder. J Shoulder Elbow Surg. 2008;17(2):231-6.
12. Warner JJ, Allen A, Marks PH, Wong P. Arthroscopic release for chronic, refractory adhesive capsulitis of the shoulder. J Bone Joint Surg Am. 1996;78(12):1808-16.
13. Griggs SM, Ahn A, Green A. Idiopathic adhesive capsulitis. A prospective functional outcome study of nonoperative treatment. J Bone Joint Surg Am. 2000;82(10):1398-407.
14. Pearsall AWt, Osbahr DC, Speer KP. An arthroscopic technique for treating patients with frozen shoulder. Arthroscopy. 1999;15(1):2-11.
15. Watson L, Dalziel R, Story I. Frozen shoulder: a 12-month clinical outcome trial. J Shoulder Elbow Surg. 2000;9(1):16-22.
16. Pollock RG, Duralde XA, Flatow EL, Bigliani LU. The use of arthroscopy in the treatment of resistant frozen shoulder. Clin Orthop Relat Res. 1994;(304):30-6.
17. Beaufils P, Prevot N, Boyer T, Allard M, Dorfmann H, Frank A, et al. Arthroscopic release of the glenohumeral joint in shoulder stiffness: a review of 26 cases. French Society for Arthroscopy. Arthroscopy. 1999;15(1):49-55.
18. Berghs BM, Sole-Molins X, Bunker TD. Arthroscopic release of adhesive capsulitis. J Shoulder Elbow Surg. 2004;13(2):180-5.
19. Ozbaydar MU, Tonbul M, Altun M, Yalaman O. Arthroscopic selective capsular release in the treatment of frozen shoulder. Acta Orthop Traumatol Turc. 2005;39(2):104-13.
20. Uhthoff HK, Boileau P. Primary frozen shoulder: global capsular stiffness versus localized contracture. Clin Orthop Relat Res. 2007;456:79-84.
21. Tighe CB, Oakley WS, Jr. The prevalence of a diabetic condition and adhesive capsulitis of the shoulder. South Med J. 2008;101(6):591-5.
22. Balci N, Balci MK, Tuzuner S. Shoulder adhesive capsulitis and shoulder range of motion in type II diabetes mellitus: association with diabetic complications. J Diabetes Complications. 1999;13(3):135-40.
23. Cinar M, Akpinar S, Derincek A, Circi E, Uysal M. Comparison of arthroscopic capsular release in diabetic and idiopathic frozen shoulder patients. Arch Orthop Trauma Surg. 2010;130(3):401-6.

DOI: http://dx.doi.org/10.1590/1413-785220172506173893

QUALITY OF LIFE IN PATIENTS WITH ROTATOR CUFF ARTHROPATHY

QUALIDADE DE VIDA NOS PACIENTES COM ARTROPATIA DO MANGUITO ROTADOR

Arnaldo Amado Ferreira Neto[1], Eduardo Angeli Malavolta[1], Jorge Henrique Assunção[1], Mauro Emilio Conforto Gracitelli[1], Guilherme Pereira Ocampos[1], Evelinda Marramon Trindade[2]*

1. Instituto de Ortopedia e Traumatologia, Hospital das Clínicas, Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brazil.
2. São Paulo State Health Technology Assessment Network, São Paul State Department of Health, São Paulo, SP, Brazil.

ABSTRACT

Objective: To compare quality of life (according to the SF-12) in patients with rotator cuff arthropathy with controls paired by sex and age. Secondary objectives are to compare the groups according to the ASES and VAS scales. Methods: This cross-sectional study with controls paired by sex and age compared patients with rotator cuff arthropathy with surgical indication for reverse shoulder arthroplasty. The groups were compared according to the SF-12, ASES, and VAS scales. Results: The groups consisted of 38 individuals, 28 women. The SF-12 demonstrated a significant difference in the physical component, with the cases scoring 31.61 ± 6.15 and the controls 49.39 ± 6.37 ($p<0.001$). For the mental component, the difference was not significant, with the cases scoring 44.82 ± 13.18 and the controls 48.96 ± 8.65 ($p=0.109$). The cases scored 7.34 ± 2.11 on the VAS and 31.26 ± 15.12 on the ASES, while the controls scored 0.55 ± 1.31 and 97.53 ± 6.22, respectively ($p<0.001$). Conclusion: Patients with rotator cuff arthropathy had poorer results for the physical component of the SF-12 than the controls. They also had poorer functional results according to the ASES scale, and more pain according to the VAS. ***Level of Evidence III, Case Control Study.***

Keywords: Arthroplasty, replacement. Joint diseases. Osteoarthritis. Rotator cuff. Quality of life.

RESUMO

Objetivo: Comparar a qualidade de vida, de acordo com o SF-12, entre pacientes com artropatia do manguito rotador e controles pareados por sexo e idade. É objetivo secundário a comparação dos grupos de acordo com as escalas ASES e EVA. Métodos: Estudo transversal com controles pareados por sexo e idade, que comparou pacientes com artropatia do manguito rotador e indicação de artroplastia reversa do ombro com indivíduos sadios. Os grupos foram comparados quanto às escalas SF-12, ASES e EVA. Resultados: Os grupos foram formados por 38 indivíduos, sendo 28 do sexo feminino. O SF-12 apresentou diferença significativa no componente físico, tendo os casos registrado 31,61 ± 6,15 e os controles 49,39 ± 6,37 ($p < 0,001$). Para o componente mental, a diferença não foi significativa, tendo os casos apresentado 44,82 ± 13,18 e os controles 48,96 ± 8,65 ($p=0.109$). Os casos apresentaram EVA de 7,34 ± 2,11 e ASES de 31,26 ± 15,12, enquanto os controles apresentaram 0,55 ± 1,31 e 97,53 ± 6,22, respectivamente ($p < 0,001$). Conclusão: Os pacientes com artropatia do manguito rotador apresentam piores resultados no componente físico do SF-12 quando comparados aos controles. Têm, ainda, piores resultados funcionais pela escala da ASES e mais dor pela EVA. ***Nível de Evidência III, Estudo de Caso-Controle.***

Descritores: *Artroplastia de substituição. Artropatias. Osteoartrose. Manguito rotador. Qualidade de vida.*

Citation: Ferreira Neto AA, Malavolta EA, Assunção JH, Gracitelli ME, Ocampos GP, Trindade EM. Quality of life in patients with rotator cuff arthropathy. Acta Ortop Bras. [online]. 2017;25(6):275-8. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Arthropathy of the rotator cuff is arthritis of the glenohumeral joint associated with massive rupture of the rotator cuff.[1] This injury affects 2.5% of the population over age 70[2] and can lead to pain and significant functional limitations.[1]

Scales that assess quality of life (QOL) are often used in studies of osteoarthritis. The significant impact this condition has on patient QOL has already been described for osteoarthritis of the knee,[3-6] the hip,[3,5,6] and the hand.[6,7]

Few studies evaluate the effect of reverse arthroplasty of the shoulder on patient QOL, whether this procedure treats degenerative injury[8] or fractures.[9] However, no study as of this time has compared QOL in patients with arthropathy of the rotator cuff with that of a control group.

The primary objective of this study is to compare QOL as measured by the Short Form 12 Health Survey (SF-12)[10] between patients with rotator cuff arthropathy with indication of reverse arthroplasty and controls matched for sex and age. Secondary objectives are to

All authors declare no potential conflict of interest related to this article.

Work conducted at the Grupo de Ombro e Cotovelo do Instituto de Ortopedia e Traumatologia, Hospital das Clinicas, Faculdade de Medicina, Universidade de São Paulo, São Paulo, SP, Brazil.
Correspondence: Rua Dr. Ovídio Pires de Campos, 333, 3° andar, São Paulo, SP, Brazil. 05403-010. drjorgeassuncao@gmail.com

Article received in 12/26/2016, approved in 05/26/2017.

compare the groups according to function and pain, using the scales from the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ACES)[11] and the visual analog scale for pain (VAS).

MATERIALS AND METHODS

We conducted a cross-sectional study with matched controls at a 1:1 ratio. At our institution's outpatient clinic, we assessed patients with a diagnosis of arthropathy of the rotator cuff and indication for reverse arthroplasty of the shoulder, with respect to their QOL. The control group was composed of people accompanying patients to the same outpatient clinic, who were matched by sex and age. An age difference of ±2 years was tolerated.
The patients were assessed between July 21, 2015 and April 13, 2016. The study was approved by the institutional review board under process number 1103 and did not receive any type of funding.

The criteria for indication of reverse arthroplasty were:

- Diagnosis of arthropathy of the rotator cuff
- Active elevation of less than 90°
- Unsuccessful non-surgical treatment performed for at least 6 months.

After the informed consent form was signed, information on the following variables was collected in an interview:

- The quality of life scale from the Short Form 12 Health Survey (SF-12),[10] considering the primary outcome;
- Functional scale from the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES)[11] and visual analog pain scale (VAS), secondary outcomes;
- Demographic data: sex, age, clinical comorbidities (cardiovascular, pulmonary, neurological, rheumatic, urological, endocrine, psychiatric, immunological, and neoplastic disorders), orthopedic comorbidities (spine, shoulder and elbow, wrist and hand, hip, knee, foot and ankle), body mass index (BMI), and number of medications taken daily;
- Presence or absence of pain in the shoulder, and duration of symptoms.

Calculation of the sample

The minimal clinically important difference (MCID) on the SF-12 has not yet been established for rotator cuff arthropathy. In a study on total knee arthroplasty, the MCID was determined to be 4.8 points for the physical component of the SF-12, with a standard deviation of 10.4.[12] In a conservative scenario, considering a MCID of 10 points and a standard deviation of 15, we would need 36 individuals in each group.

Statistical analysis

We assessed the normality of the continuous variables using the Kolmogorov-Smirnov test, and homogeneity using the Levene test. The continuous quantitative variables were expressed as means and standard deviation, while the categorical variables were expressed as absolute values and percentages.
The comparison between the cases and controls with respect to the different variables was performed using the chi-squared or Fisher's exact test for the categorical variables. For the continuous variables, this comparison was assessed using the non-paired Student's t test if the data was parametrically distributed, or the Wilcoxon test for non-nonparametric distribution.
We used SPSS version 20.0 software (SPSS Inc, Chicago, Illinois, USA) for the data analysis, and a significance level of 5%.

RESULTS

The institution's database included 45 patients recommended for reverse arthroplasty of the shoulder. Five of these could not be located, one had died, and one did not agree to take part in the study. Consequently, 38 patients were interviewed to comprise the case group cases, and an equal number were selected as controls. The two groups had 28 women.
The cases had involvement of the right side in 68.4% (26/38), the left side in 23.7% (9/38), and bilateral involvement in 7.9% (3/38). The mean time they experienced symptoms was 128.97 months.
The groups did not differ significantly in age, BMI, or previous surgeries in sites other than the shoulder (p=0.878, p=0.159 and p=0.489, respectively). The comorbidities, excluding rheumatic diseases (p=0.028), also showed no differences between the groups. The patients recommended for reverse arthroplasty used a significantly larger number of medications (p=0.021). With respect to orthopedic diseases, the cases had significantly more shoulder symptoms (p<0.001) and no significant difference in other locations. The general characteristics of the sample can be seen in Table 1.

Table 1. General characteristics of the sample.

	Cases	Controls	p
Sex			
Men	10	10	>0.999
Women	28	28	
Age (years)	67.34 ± 8.02	67.05 ± 8.33	0.878
Body mass index	28.10 ± 5.65	26.54 ± 3.66	0.159
Comorbidities			
Hypertension	28	27	0.798
Cardiovascular diseases	1	3	0.615
Rheumatic diseases	8	1	0.028
Lung diseases	1	0	>0.999
Neurological diseases	3	1	0,615
Urological diseases	0	0	>0.999
Diabetes mellitus	5	7	0.754
Hypercholesterolemia	6	4	0.736
Hypothyroidism	6	2	0.262
Psychiatric diseases	6	5	>0.999
Immunologic diseases	0	0	>0.999
Neoplastic diseases	0	1	>0.999
Number of medications per day/patient	4.47 ± 3.28	2.87 ± 2.63	0.021
Previous orthopedic surgeries (other than shoulder)	23	19	0.489
Number of patients with previous shoulder surgeries	13	1	<0.001
Orthopedic diseases			
Spine	4	6	0.736
Shoulder	38	5	<0.001
Hand and wrist	3	1	0.615
Hip	4	0	0,115
Knee	11	4	0.082
Foot and ankle	3	1	0.615

The SF-12 showed a significant difference in the physical component, with the cases scoring 31.61 ± 6.15 and the controls 49.39 ± 6.37 ($p<0.001$). For the mental component, the difference was not significant, with the cases scoring 44.82 ± 13.18 and the controls 48.96 ± 8.65 ($p<0.109$). The cases presented a VAS score of 7.34 ± 2.11, and ASES score of 31.26 ± 15.12, while the control scores were 0.55 ± 1.31 and 97.53 ± 6.22, respectively ($p<0.001$). The data can be seen in Table 2.

Table 2. Outcomes.

	Cases	Controls	p
VAS	7.34 ± 2.11	0.55 ± 1.31	<0.001
ASES	31.26 ± 15.12	97.53 ± 6.22	<0.001
SF-12 Physical	31.61 ± 6.15	49.39 ± 6.37	<0.001
SF-12 Mental	44.82 ± 13.18	48.96 ± 8.65	0.109

VAS: Visual Analog Pain Scale; ASES: Functional scale of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; SF-12: Quality of life scale of the Short Form 12 Health Survey.

DISCUSSION

Arthropathy of the rotator cuff affects approximately 4% of patients with rotator cuff tears.[13] The clinical manifestations of this disease are variable, and patient symptoms may be minimal with satisfactory function or range up to pseudoparalysis.[1] The treatment of rotator cuff arthropathy represents a challenge to orthopedists, but reverse arthroplasty is a viable solution that can improve QOL.[8]

In a systematic review of the indications for reverse arthroplasty of the shoulder, Smith et al.[14] found that painful pseudoparalysis is the main reason to perform surgery. Analyzes of QOL in indicating surgery are not cited in this or other studies.[8,14,15] We believe that QOL should be evaluated before and after arthroplasty, and should be part of the clinical reasoning at the time surgery is recommended. Many patients with this condition are elderly, with comorbid conditions and limitations inherent to age.[16]

Our results demonstrate that patients with a diagnosis of rotator cuff arthropathy and indication for reverse arthroplasty show significant impact on the physical component of QOL according to the SF-12, when compared to controls adjusted for sex and age. Sick individuals tend to have poorer outcomes on the mental component of this scale. Several studies have demonstrated the impact of osteoarthritis of the knee,[3-6] the hip,[3,5,6] and the hand[6,7] in QOL, comparing sick individuals with healthy controls. However, these studies do not evaluate the involvement of the glenohumeral joint, whether by primary osteoarthrosis or arthropathy of the rotator cuff. The predominant impact on the physical component of QOL has been observed by other authors.[5,6] Our study also stressed that the arthropathy of the rotator cuff significantly affects shoulder pain and function when these are analyzed by the VAS and ASES scale. The other studies comparing patients with osteoarthritis in other joints with healthy controls do not assess these outcomes.[3-7,17] Castricini et al.,[8] in a study on the use of reverse arthroplasty of the shoulder in degenerative disorders (arthropathy of the rotator cuff, irreparable rupture of the rotator cuff, and primary glenohumeral arthritis), noted that the procedure provides QOL similar to that of the healthy population. Mangano et al.[15] found similar results, studying only elderly patients. In a study on the use of reverse arthroplasty in proximal fractures of the humerus, Lopiz et al.[9] also observed final QOL outcomes comparable to the unaffected population. However, these articles do not detail the preoperative QOL values, like the other case series evaluated.[18-22] As of this writing, this present study is the first to compare QOL, function, and pain in patients with a diagnosis of rotator cuff arthropathy and an unaffected population. The groups, although they were only paired for sex and age, showed a similar distribution for most of the analyzed variables, reinforcing the validity of the inclusion criteria. It should be emphasized that the cases consumed significantly more medications than the controls, which increases the risk of side effects and drug interactions. Furthermore, the groups showed no difference in relation to BMI. Excess weight can be a confounding factor in the analysis, since obesity negatively affects QOL.[23] Some authors of studies that evaluated QOL in patients with osteoarthritis of the legs did not mention this variable,[4,5] while others found that the arthritis group had a higher BMI.[6] Moreover, the tool we used to assess QOL, the SF-12, is self-applied, validated, and its results are comparable to the SF-36.[10]

This study has limitations. The sample consisted of patients with surgical indication for reverse arthroplasty for rotator cuff arthroplasty, representing only the symptomatic cases of this disease that did not improve after conservative treatment. Patients with rotator cuff arthropathy may present few symptoms and satisfactory shoulder function.[1] The absence of a group of oligosymptomatic patients with rotator cuff arthropathy is the main limitation of our study. Although the sample was small, it was sufficient to prove our hypothesis, given the significant difference we found. Furthermore, the cross-sectional design did not allow us to evaluate temporal variations in the outcomes and we did not analyze pre- and postoperative pain.

CONCLUSION

Patients with rotator cuff arthropathy who were recommended for reverse arthroplasty have poorer results for the physical component of the SF-12 when compared to controls. They also had poorer functional outcomes as measured by the ASES scale and more pain as measured by the VAS.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. AAFN (0000-0001-5097-9542)* and EMT (0000-0002-2394-3808)* contributed to the concept or design of the study and revised the article. EAM (0000-0003-1956-6445)* and JHA (0000-0002-2566-3471)* conducted the data analysis and bibliography review, and drafted the article. MECG (0000- 0002-0214-9576)* and GPO (0000-0001-5179-2907)* collected the data and conducted the startistical analysis. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Visotsky JL, Basamania C, Seebauer L, Rockwood CA, Jensen KL. Cuff tear arthropathy: pathogenesis, classification, and algorithm for treatment. J Bone Joint Surg Am. 2004;86(Suppl 2):35-40.
2. Nové-Josserand L, Walch G, Adeleine P, Courpron P. Effect of age on the natural history of the shoulder: a clinical and radiological study in the elderly. Rev Chir Orthop Reparatrice Appar Mot. 2005;91(6):508–14.
3. Salaffi F, Carotti M, Stancati A, Grassi W. Health-related quality of life in older adults with symptomatic hip and knee osteoarthritis: a comparison with matched healthy controls. Aging Clin Exp Res. 2005;17(4):255–63.
4. Ferreira AH, Godoy PBG, Oliveira NRC, Diniz RAS, Diniz REAS, Padovani R da C, et al. Investigação da ansiedade, depressão e qualidade de vida em pacientes portadores de osteoartrite no joelho: um estudo comparativo. Rev Bras Reumatol. 2015;55(5):434–8.
5. van der Waal JM, Terwee CB, van der Windt DAWM, Bouter LM, Dekker J. The impact of non-traumatic hip and knee disorders on health-related quality of life as measured with the SF-36 or SF-12. A systematic review. Qual Life Res. 2005;14(4):1141-55.
6. Lourenço S, Lucas R, Araújo F, Bogas M, Santos RA, Barros H. Osteoarthritis medical labelling and health-related quality of life in the general population. Health Qual Life Outcomes. 2014;12:146.

7. Slatkowsky-Christensen B, Mowinckel P, Loge JH, Kvien TK. Health-related quality of life in women with symptomatic hand osteoarthritis: a comparison with rheumatoid arthritis patients, healthy controls, and normative data. Arthritis Rheum. 2007;57(8):1404–9.
8. Castricini R, Gasparini G, Di Luggo F, De Benedetto M, De Gori M, Galasso O. Health-related quality of life and functionality after reverse shoulder arthroplasty. J Shoulder Elbow Surg. 2013;22(12):1639–49.
9. Lopiz Y, García-Coiradas J, Serrano-Mateo L, García-Fernández C, Marco F. Reverse shoulder arthroplasty for acute proximal humeral fractures in the geriatric patient: results, health-related quality of life and complication rates. Int Orthop. 2016;40(4):771–81.
10. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996;34(3):220–33.
11. Richards RR, An KN, Bigliani LU, Friedman RJ, Gartsman GM, Gristina AG, et al. A standardized method for the assessment of shoulder function. J Shoulder Elbow Surg. 1994;3(6):347–52.
12. Clement ND, MacDonald D, Simpson AHRW. The minimal clinically important difference in the Oxford knee score and Short Form 12 score after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2014;22(8):1933–9.
13. Neer CS 2nd, Craig EV, Fukuda H. Cuff-tear arthropathy. J Bone Joint Surg Am. 1983;65(9):1232–44.
14. Smith CD, Guyver P, Bunker TD. Indications for reverse shoulder replacement: a systematic review. J Bone Joint Surg Br. 2012;94(5):577–83.
15. Mangano T, Cerruti P, Repetto I, Felli L, Ivaldo N, Giovale M. Reverse shoulder arthroplasty in older patients: is it worth it? A subjective functional outcome and quality of life survey. Aging Clin Exp Res. 2016;28(5):925-33.
16. Germain CM, Vasquez E, Batsis JA, McQuoid DR. Sex, race and age differences in muscle strength and limitations in community dwelling older adults: Data from the Health and Retirement Survey (HRS). Arch Gerontol Geriatr. 2016;65:98–103.
17. Cook C, Pietrobon R, Hegedus E. Osteoarthritis and the impact on quality of life health indicators. Rheumatol Int. 2007;27(4):315–21.
18. Amaral MV, Faria JL, Siqueira G, Cohen M, Brandão B, Moraes R, et al. Artroplastia reversa do ombro no tratamento da artropatia do manguito rotador. Rev Bras Ortop. 2014;49(3):279–85.
19. Fávaro RC, Abdulahad M, Filho SM, Valério R, Superti MJ. Artropatia de manguito: o que esperar do resultado funcional da artroplastia reversa? Rev Bras Ortop. 2015;50(5):523–9.
20. Young SW, Zhu M, Walker CG, Poon PC. Comparison of functional outcomes of reverse shoulder arthroplasty with those of hemiarthroplasty in the treatment of cuff-tear arthropathy: a matched-pair analysis. J Bone Joint Surg Am. 2013;95(10):910–5.
21. Al-Hadithy N, Domos P, Sewell MD, Pandit R. Reverse shoulder arthroplasty in 41 patients with cuff tear arthropathy with a mean follow-up period of 5 years. J Shoulder Elbow Surg. 2014;23(11):1662-8.
22. Wiater JM, Moravek JE Jr, Budge MD, Koueiter DM, Marcantonio D, Wiater BP. Clinical and radiographic results of cementless reverse total shoulder arthroplasty: a comparative study with 2 to 5 years of follow-up. J Shoulder Elbow Surg. 2014;23(8):1208–14.
23. Batsis JA, Zbehlik AJ, Barre LK, Bynum JPW, Pidgeon D, Bartels SJ. Impact of obesity on disability, function, and physical activity: data from the Osteoarthritis Initiative. Scand J Rheumatol. 2015;44(6):495–502.

DOI: http://dx.doi.org/10.1590/1413-785220172506170954

STUDY OF SECONDARY OSSIFICATION CENTERS OF THE ELBOW IN THE BRAZILIAN POPULATION

ESTUDO DOS CENTROS SECUNDÁRIOS DE OSSIFICAÇÃO DO COTOVELO NA POPULAÇÃO BRASILEIRA

Cesar Satoshi Miyazaki[1], Daniel Augusto Maranho[2], Paulo Moraes Agnollitto[1], Marcello Henrique Nogueira-Barbosa[1]

1. Division of Radiology, Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, SP, Brazil.
2. Department of Biomechanics, Medicine, and Rehabilitation of the Locomotor System, Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, SP, Brazil.

ABSTRACT

Objective: To evaluate the age in which the secondary ossification centers of the elbow appear and fuse in the Brazilian population. Methods: Nearly thirty radiographs were randomly selected for each age group from 0 to 18 years, with a total of 544 radiographs from 439 patients, between 2010 and 2015, without abnormalities secondary to trauma, metabolic or bone tumor diseases. Radiographs were retrospectively evaluated by two blind and independent observers, according to the presence or not of the ossification centers, and the fusion between them. Results: The age interval of appearance and fusion were, respectively: capitulum (0 to 1 year; 10 to 15 years), radius head (2 to 6 year; 12 to 16 years), medial epicondyle (2 to 8 years; 13 to 17 years), trochlea (5 to 11 years; 10 to 18 years), olecranon (6 to 11 years; 13 to 16 years), e lateral epicondyle (8 to 13 years; 12 to 16 years). Appearance and fusion were earlier in girls compared to boys (exception to capitulum and radius head). Conclusion: The chronological order was similar to the literature. For girls, the radius head and medial epicondyle appeared simultaneously. There was a tendency of the olecranon center to appear before the trochlea for both sexes. ***Level of Evidence III, Diagnostic Study.***

Keywords: Child. Elbow. Radiography. Epiphyses. Growth plate. Growth and development.

RESUMO

Objetivo: Avaliar a idade de surgimento e a união dos centros secundários de ossificação do cotovelo na população brasileira. Métodos: Foram selecionadas aleatoriamente aproximadamente 30 radiografias simples do cotovelo na faixa etária de 0 a 18 anos, no total de 544 radiografias de 439 pacientes, entre 2010 e 2015, sem alterações secundárias a trauma, doença osteometabólica ou tumor. Foram avaliadas retrospectivamente de forma cega e independente por dois observadores, quanto à presença dos centros de ossificação secundária e a união entre eles. Resultados: O intervalo de idade de aparecimento e de união dos centros foram, respectivamente: capítulo do úmero (0 a 1 ano; 10 a 15 anos), cabeça do rádio (2 a 6 anos; 12 a 16 anos), epicôndilo medial (2 a 8 anos; 13 a 17 anos), tróclea (5 a 11 anos; 10 a 18 anos), olécrano (6 a 11 anos; 13 a 16 anos), e epicôndilo lateral (8 a 13 anos; 12 a 16 anos). No sexo feminino, o aparecimento e união são mais precoces do que no masculino (exceto capítulo do úmero e cabeça do rádio). Conclusão: A ordem cronológica foi semelhante à da literatura. No sexo feminino, o centro da cabeça do rádio e do epicôndilo medial surgiram simultaneamente. Houve tendência não significativa de o olécrano surgir antes da tróclea em ambos os sexos. ***Nível de Evidência III, Estudo Diagnóstico.***

Descritores: *Criança. Cotovelo. Radiografia. Epífises. Lâmina de crescimento. Crescimento e desenvolvimento.*

Citation: Miyazaki CS, Maranho DA, Agnollitto PM, Nogueira-Barbosa MH. Study of secondary ossification centers of the elbow in the brazilian population. Acta Ortop Bras. [online]. 2017;25(6):279-82. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

The bone age evaluation in the skeletally immature patient is important for therapeutic decision-making, and the knowledge about the skeletal development is essential for the results interpretation. The ossification pattern of the secondary centers of the elbow was described in literature,[1,2] and these studies have clinical significance because of the complex radiographic anatomy and associated challenging interpretation for the frequent pediatric cases of trauma.[3]

The conventional radiography of the elbow has an intrinsic limitation for evaluating the bone anatomy, considering that the ossification pattern of the cartilaginous component is gradual, fragmented and with contour irregularities. (Figure 1) Some skeletal injuries may not be easily identified in the elbow radiographs. Furthermore, normal radiographic patterns may be misinterpreted as fractures, dislocations, or other abnormalities.[4] Evaluating the presence or absence of the ossification centers, according to their location and patient's age, is essential for the diagnosis of traumatic injuries.

All authors declare no potential conflict of interest related to this article.

Work conducted at the Division of Radiology, Hospital das Clínicas, Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, SP, Brazil.
Correspondence: Daniel Augusto Maranho. Department of Biomechanics, Medicine e Rehabilitation of the Locomotor System, Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, SP, Brazil. Av. Bandeirantes, 3900, 11º floor. Ribeirão Preto, São Paulo, Brazil. 14049-090. dacmaranho@usp.br; dacmaranho@gmail.com

Article received in 10/23/2016, approved in 06/19/2017.

The age of appearance of the ossification centers of the pediatric elbow has a relatively well-established chronological sequence in literature: humerus capitulum, radius head, medial or internal epicondyle, humerus trochlea, olecranon, and lateral or external epicondyle. [4-6] The mnemonic CRITOE or CRITOL may be applied. The age range for the radiographic appearance of the ossification centers was previously described, however there are some variations that can be associated with differences in ethnic patterns or study methodology.[4-6] Potentially, distinct characteristics in elbow ossification may exist in the Brazilian population, and this information is lacking in the literature. Here, we aimed to evaluate the sequence of appearance and fusion of the ossification centers in radiographs of the pediatric elbow, and correlate with age and sex.

PATIENTS AND METHODS

This is a retrospective study approved by the Institutional Review Board (11611/2011), with waive of the informed consent. The inclusion criterion was boys and girls with age between zero and eighteen years, who underwent anterior-posterior and lateral elbow radiograph. The exclusion criteria were (1) previous or current elbow fracture; (2) previous surgery, presence of intraosseous orthopaedic implants, or casting apparatus that could compromise the visualization of the ossification centers; (3) suspected or confirmed diagnoses of osteometabolic (e.g. osteogenesis imperfecta), inflammatory (e.g. idiopathic juvenile or piogenic arthritis), bone or soft tissue tumor or any other disorder that could modify the ossification center characteristics, and (4) bad quality radiograph technique (e.g. movement artifacts, inadequate acquisition) or availability of only one incidence.

The patients were allocated in groups according to the age range. Group 0 included new-borns and children aged up to one year; group 1 included patients aged from one to two years, and the same criterion was applied up to 18 years old. Each individual was included in one group only, and for those who were radiographically evaluated more than one time, only the initial exam was considered. We included young adults (18 years) to allow for the inclusion of patients who achieved the skeletal maturity and complete ossification and fusion of the elbow ossification centers. Initially, we included 926 patients who underwent elbow radiographs between 2010 and 2015. For each age group, we selected approximately 30 patients, using a chronological sequence from the most recent to the oldest exams. The final sample included 544 radiographs from 439 patients (312 boys, 127 girls), with age between 22 days and 18 years. One hundred and five patients were bilaterally evaluated.

The presence or absence of each secondary ossification center (Figure 1) was evaluated following the classification (1) absent; (2) present with no fusion, partial or incomplete fusion; or (3) present with complete fusion. We considered a complete fusion when the growth plate was totally obliterated and ossified.

The imaging evaluation was performed by two radiologists, using a a blind and independent approach without information about age or sex. A second reading was performed following a two-month interval by both observers.

Statistical analysis

We assessed the inter- and intraobserver agreement using the Kappa coefficient.[7] Poor reliability is suggested for values between 0 and 0.20; fair reliability from 0.21 to 0.40; moderate reliability from 0.41 to 0.60; substantial or good reliability from 0.61 to 0.80, and almost perfect or very good reliability from 0.81 to 1.0.[8]

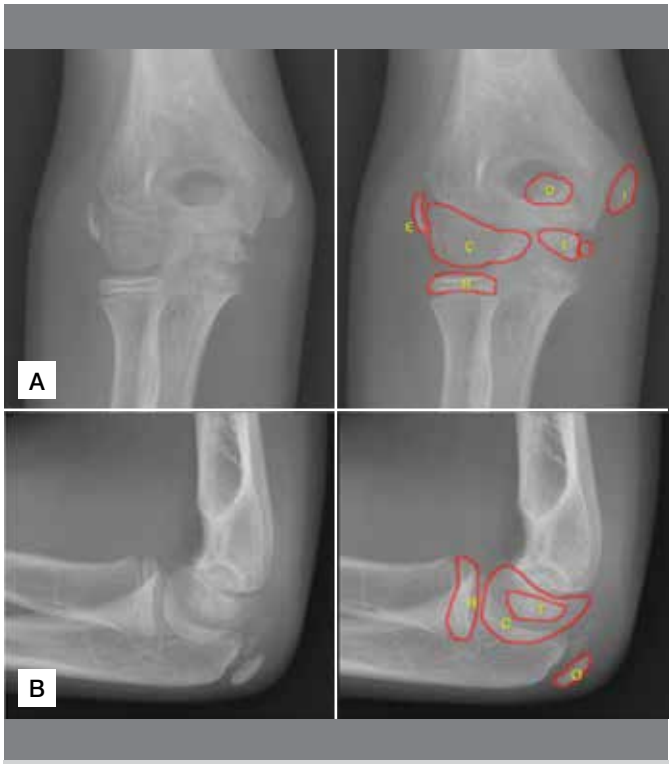


Figure 1. Anterior-posterior (A) and lateral (B) elbow radiographs of a boy with 11 years and six months old. Elbow ossification centers were identified by: C - Capitulum; R - Radius head; I - Medial epicondyle; T - Trochlea; O - Olecranon; E - Lateral epicondyle.

A linear regression model with mixed effects (random and fixed effects) was applied to analyze the presence or absence of the ossification centers, and their fusion status, according to patient's age and sex. The orthogonal contrast test was applied for pos-test estimation. Comparisons among sexes were performed using the Mann-Whitney test. This approach allowed for the estimation of the age of appearance and fusion for boys and girls. The level of significance was set at 5%.

RESULTS

The intra and interobserver agreement was considered almost perfect for the presence and fusion of all ossification centers. The Kappa coefficient varied between 0.89 e 0.98 for all analysis. The first ossification center to appear was the capitulum, around the age one year in both sexes. (Table 1, Figure 2) In girls, the ossification center of the radius head and the medial epicondyle appeared at the same age (median, 6.1 years). In contrast, we observed that the ossification center of the radius head appeared earlier (median, 6.5 years) than the medial epicondyle (median, 8.7 years) in boys. (Table 1 and Figure 2) Although we did not observe significant difference, there was a tendency for the olecranon to ossify earlier than the trochlea in girls and boys, at a median of 8.7 and 10.7 years (olecranon) versus 9.6 and 11.3 years (trochlea) (Table 2 and Figure 3). The estimated difference was 0.39 years in girls (95% confidence interval [95%IC] -0.31 - 1.09, p=0.27) and 0.23 years in boys (95%IC -0.25-0.71, p=0.34). Table 2 describes the estimated differences for the age of appearance between boys and girls.

All the secondary ossification centers of the elbow presented with a tendency to show a complete fusion at earlier ages in girls compared to boys. (Table 1 and Figure 2)

Table 1. Age (in years) of appearance and fusion of the elbow ossification centers for boys and girls.

		Age of appearance of the ossification centers (mean ± standard deviation; years)					Age of fusion of the ossification centers (mean ± standard deviation; years)			
Center	n	Girls	n	Boys	p	n	Girls	n	Boys	p
C	19	1.26 ± 0.45	9	1.36 ± 0.36	<0.01	11	12.50 ± 1.22	59	15.25 ± 1.05	<0.01
R	30	5.52 ± 1.60	53	6.19 ± 1.27	<0.01	7	13.64 ± 0.71	39	16.19 ± 1.28	<0.01
I	24	5.75 ± 1.60	53	8.21 ± 1.36	<0.01	5	13.95 ± 0.43	64	16.69 ± 1.90	<0.01
T	19	9.06 ± 1.86	56	10.98 ± 1.44	<0.01	9	12.75 ± 1.20	55	15.32 ± 1.01	<0.01
O	23	8.60 ± 1.40	38	10.59 ± 0.87	<0.01	6	13.86 ± 0.45	47	16.01 ± 1.21	<0.01
E	11	10.36 ± 0.89	46	12.18 ± 1.12	<0.01	6	13.33 ± 0.55	57	15.82 ± 1.23	<0.01

C - Capitulum; R - Radius head; I - Medial epicondyle; T - Trochlea; O - Olecranon; E - Lateral epicondyle. *P-value refers to the comparison between boys and girls.

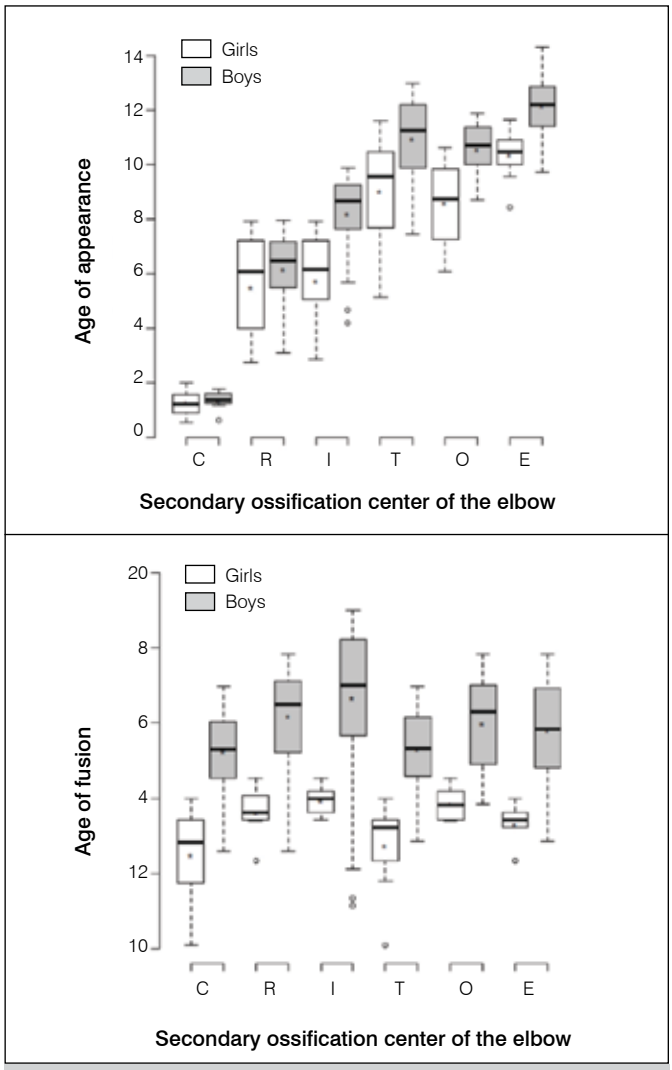


Figure 2. Box plot of age (years) of appearance and fusion of the ossification centers of the elbow. C – Capitulum; R - Radius head; I - Medial epicondyle; T - Trochlea; O - Olecranon; E - Lateral epicondyle.

Table 2. Estimated difference (years) in the age of appearance of the elbow secondary ossification centers between boys and girls.

Center	Estimated difference between boys and girls	95% confidence interval		p-value*
C	0.10	-0.96	1.17	0.85
R	0.70	0.11	1.29	0.02
I	2.45	1.83	3.08	<0.01
T	2.16	1.48	2.84	<0.01
O	2.32	1.65	2.99	<0.01
E	2.19	1.34	3.04	<0.01

C – Capitulum; R - Radius head; I - Medial epicondyle; T - Trochlea; O - Olecranon; E - Lateral epicondyle. * p-value refers to the comparison between boys and girls.

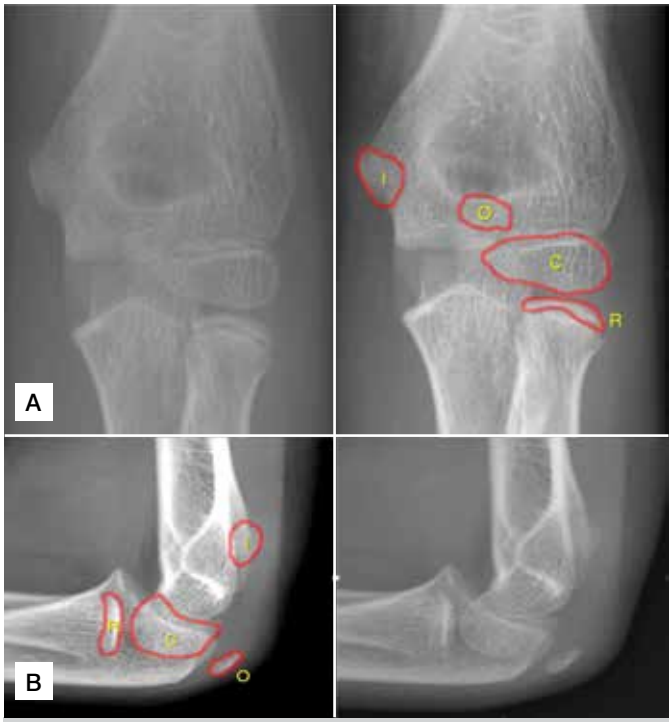


Figure 3. Anterior-posterior (A) and lateral (B) elbow radiographs of a boy with ten years old. It is possible to observe the ossification center of the olecranon without observing the trochlea. C – Capitulum; R - Radius head; I - Medial epicondyle; O – Olecranon.

DISCUSSION

The evaluation of the bone age is an important tool for several therapeutic decision-makings, including orthopaedic conditions such as scoliosis and lower limb asymmetry in skeletal immature patients. In Endocrinology, the bone age is routinely assessed in the suspicion of precocious puberty. The bone age may be estimated using several techniques for different anatomic regions, for example the hand, pelvis, foot, knee and elbow.

A classical example is the Risser classification, which evaluate the potential for growth during the scoliosis treatment planning.[9] Other clinically relevant method for bone age assessment is the Greulich and Pyle,[10] using posterior-anterior hand and wrist radiographs. In 1962, Sauvegrain et al.[11] evaluated anterior-posterior radiographs of the elbow for the bone age assessment in children and adolescents. They evaluated the lateral epicondyle, trochlea, olecranon

and radius head, based on the shape and development of these ossification centers. A grading system was compared to a graph that correlates the estimated bone age with the puberty evaluation and pre-puberal stage after age 10 years.

Evidence has been reported in literature on the age of appearance and fusion of the secondary ossification centers of the elbow ,[1,2,5,12,13] (Table 3) however small population samples and incomplete information regarding methodology may decrease the generalizability.

The methodology used in our study was similar to the study from Cheng et al.,[5] who evaluated the elbow ossification center in the Chinese population. We added the differences among sexes, similarly to the methodology of Patel et al.,[12] who evaluated the age of fusion of the ossification centers of the elbow in the Canadian population.

We identified a mean difference of approximately two years in the age of appearance of the ossification centers between girls and boys, and this difference is in line with the studies from Cheng et al.[5] e Patel et al.[12] However, the difference was smaller for capitulum and the radius head. For the age of fusion of the ossification centers, we did not observe a clear sequence compared to the age of appearance. Nevertheless, girls had an age of fusion significantly smaller than boys, for all ossification centers.

Table 3. Age (years) of appearance of the secondary ossification centers of the elbow in boys and girls, according to different studies in literature.

Center	Girdany and Golden[1]		Garn et al.[2]		Cheng et al.[5]		Patel et al.[12]		Bajaj et al.[13]	
	♀	♂	♀	♂	♀	♂	♀	♂	♀	♂
C	0.3	0.1-0.7	1	0.3		1			0.5	0.5
R	5.2	2.9-5.5	7	3.9	5.9	5	4.2	5.9	3.5	6.2
I	2.3 - 5.1	4.7-5.7	3.4		5	7	4.2	6.8	5	7.4
T		7 - 9	11	6.3	9.7	9	8.4	9.7	7.7	7.9
O	9.7	8 - 11	11	8.0	9.9	9	8.3	9.9	8.6	10.4
E	11.2	11 - 14	12	9.2	11.2	10	9.4	11.2	7.5	10.2

C - Capitulum; R - Radius head; I - Medial epicondyle; T - Trochlea; O - Olecranon; E - Lateral epicondyle.

Ossification patterns may be influenced by genetic and environmental factors, as well as other conditions that can affect the skeletal growth and maturity. The comparison with the population from India,[13] China[5] and Canada[12] confirmed probable regional differences, which may explain some variations in these studies.

The secondary ossification centers of the elbow may present physiological multicentric and fragmentation aspect. Determining the chronological sequence of appearance and their physiological characteristics plays an important role in the pediatric trauma evaluation. The differential diagnosis between fractures, growth plate injuries and normal radiographic variations is challenging.

Some study limitations must be cited. During the patient allocation, we could not match patients by sex, because trauma was much more common in boys than in girls. As consequence, our sample had a greater number of boys. There was no longitudinal and controlled radiographic evaluation of our patients, therefore we could not evaluate the sequence of appearance of the ossification centers using a longitudinal methodology. However, we estimated the chronological sequence using the prevalence by age group. We observed some discrepancies because of a low number of girls in the groups five years (low prevalence of the capitulum presence) and nine years (low prevalence of the trochlea presence). Nevertheless, high reliability was observed by means of Kappa coefficient between observers.

CONCLUSION

The olecranon center showed a tendency to ossify earlier than the trochlea center in girls and boys, although we did not find significant difference with our sample size. The radius head and medial epicondyle centers appeared simultaneously in girls. In general, the ossification centers appear two years earlier in girls compared to boys, except for the capitulum and radius head. Girls were younger when the ossification center showed complete fusion, however we could not observe a clear chronologic sequence of fusion. Our results showed that the secondary ossification centers of the elbow appear sequentially with a chronologic order in the Brazilian population, that is similar to the orders previously described.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. CSM (0000-0002-6099-3855)* was the main researcher, contributing to the radiographic reading, study development, writing, and data interpretation. DAM (0000-0002-3893-0292)*, contributed to data interpretation, writing and translation, critical review of the intellectual content, approval of the final manuscript version for publication. PMA (0000-0003-1818-3266)* contributed to the radiographic reading, study development, and data interpretation. MHNB (0000-0002-7436-5315)*, was the principal investigator, contributed to the study design conception, methodology, data analysis, critical review of the intellectual content, and approval of the final manuscript version for publication. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Girdany BR, Golden R. Centers of ossification of the skeleton. Am J Roentgenol Radium Ther Nucl Med. 1952;68(6):922-4.
2. Garn SM, Rohmann CG, Blumenthal T, Silverman FN. Ossification communalities of the hand and other body parts: Their implication to skeletal assessment. Am J Phys Anthropol. 1967;27(1):75-82.
3. Crowther M. Elbow pain in pediatrics. Curr Rev Musculoskelet Med. 2009;2(2):83-7.
4. Freyschmidt J, Brossmann J, Wiens J, Sternberg A. Radiologia óssea - limites do normal e achados patológicos precoces. 14ª. ed. Rio de Janeiro: Revinter; 2005.
5. Cheng JC, Wing-Man K, Shen WY, Yurianto H, Xia G, Lau JT, et al. A new look at the sequential development of elbow-ossification centers in children. J Pediatr Orthop. 1998;18(2): 161-7.
6. Kamath AF, Baldwin K, Horneff J, Hosalkar HS. Operative versus non-operative management of pediatric medial epicondyle fractures: a systematic review. J Child Orthop. 2009;3(5):345-57.
7. Cohen J. A coefficient of agreement for nominal scales. Educ Psychol Meas 1960;20:37-46.
8. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33(1):159-74.
9. Risser JC. The iliac apophysis; an invaluable sign in the management of scoliosis. Clin Orthop. 1958;(11):111-9.
10. Greulich WW, Pyle SI. Radiographic atlas of skeletal development of the hand and wrist. 2nd ed. Stanford: Stanford University Press; 1959.
11. Sauvegrain J, Nahum H, Bronstein H. Study of bone maturation of the elbow]. Ann Radiol (Paris). 1962;5:542-50.
12. Patel B, Reed M, Patel S. Gender-specific pattern differences of the ossification centers in the pediatric elbow. Pediatr Radiol. 2009;39(3):226-31.
13. Bajaj ID, Bhardwaj OP, Bhardwaj S. Appearance and fusion of important ossification centres: a study in Delhi population. Indian J Med Res. 1967;55(10):1064-7.

DOI: http://dx.doi.org/10.1590/1413-785220172506168821

TERRIBLE TRIAD OF THE ELBOW: FUNCTIONAL RESULTS OF SURGICAL TREATMENT

TRÍADE TERRÍVEL DO COTOVELO: RESULTADOS FUNCIONAIS DO TRATAMENTO CIRÚRGICO

Roberto Yukio Ikemoto[1,2], Joel Murachovsky[1], Rogério Serpone Bueno[1], Luis Gustavo Prata Nascimento[1], Adriano Bordini Carmargo[1], Vitor Elias Corrêa[1]

1. Shoulder and Elbow Surgery Group, Faculdade Medicina do ABC, Santo André, SP, Brazil.
2. Department of Orthopedics, Hospital Ipiranga (UGA II), São Paulo, SP, Brazil.

ABSTRACT

Objective: To evaluate the functional and radiographic results of patients who underwent surgical treatment for terrible triad-type elbow injuries (TTE). Methods: We retrospectively evaluated 20 patients, including one case with bilateral injuries (total of 21 elbows) that were surgically treated from January 2004 to July 2014. We evaluated the functional results of treatment by measuring the restored range of motion (ROM) of the elbow, using the DASH (Disabilities of the Arm, Shoulder and Hand) and MEPS (Mayo Elbow Performance Score) scores. Complications and the development of osteoarthritis and heterotopic ossification (HO) were also evaluated. Results: Eight elbows (38%) required additional surgical treatment; HO was observed in eight elbows (38%) and severe osteoarthritis (Broberg-Morrey type IV) was seen in only one case (4%). Nevertheless, we obtained good functional results, 14.27 on the DASH and 84 on the MEPS. The average ROM for flexion-extension was 101° (20–140°) and for pronation-supination was 112.85° (0–180°). Conclusion: When TTE injuries are treated systematically, even despite variations in these injuries, functional ROM and scores ranging from good to excellent can be obtained. ***Level of Evidence IV, Case Series.***

Keywords: Elbow joint/physiopathology. Elbow joint/surgery. Joint dislocations. Treatment outcome.

RESUMO

Objetivo: Avaliar os resultados funcionais e radiográficos dos pacientes que sofreram lesões do tipo tríade terrível do cotovelo (TTC) e foram tratados cirurgicamente. Métodos: Foram avaliados retrospectivamente 20 pacientes, um caso com lesão bilateral (21 cotovelos), que foram tratados cirurgicamente no período de janeiro de 2004 a julho de 2014. Os resultados funcionais do tratamento foram avaliados pela medida da restauração do arco de movimento (ADM) do cotovelo, de acordo com os escores DASH (Disabilities of the Arm, Shoulder and Hand) e MEPS (Mayo Elbow Performance Score). Além da presença de complicações, avaliou-se osteoartrose e ossificação heterotópica (OH). Resultados: Oito cotovelos (38%) foram submetidos a novo procedimento cirúrgico; observou-se OH em oito cotovelos (38%) e apenas um caso (4%) de artrose grave (tipo IV de Broberg-Morrey). Apesar disso, foram obtidos bons resultados funcionais, DASH de 14,27 e MEPS de 84. E o ADM médio de flexão-extensão foi de 101º (20º e 140º) e de pronação-supinação, 112,85º (0º até 180º). Conclusão: Quando se realiza tratamento sistematizado nas lesões do tipo TTC, mesmo com suas variações, pode-se obter um ADM funcional e escore funcional entre bom e excelente. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Articulação do cotovelo/fisiopatologia. Articulação do cotovelo/cirurgia. Luxações articulares. Resultado do tratamento.*

Citation: Ikemoto RY, Murachovsky J, Bueno RS, Nascimento LG, Carmargo AB, Corrêa VE. Terrible triad of the elbow: functional results of surgical treatment. Acta Ortop Bras. [online]. 2017;25(6):283-6. Available from URL: http://www.scielo.br/aob..

INTRODUCTION

Hotchkiss first used the term terrible triad of the elbow (TTE) to describe injuries combining posterior-lateral elbow dislocation with fractures of the radial head and the coronoid process.[1] The "terrible" denotation comes from the fact that this type of injury historically has been difficult to treat and presents poor functional outcomes, especially when compared to simple cases of elbow dislocation.[1] The goal in treating these injuries is to restore early elbow stability to avoid complications such as loss of function and joint stiffness.[1,2] Over time, surgery has been shown to be the best option for obtaining satisfactory functional results.[3] The literature shows differences between the surgical techniques used with regard to access routes and the approach to the affected bone structures and ligaments.[3,4] Despite the difficulty in treating TTE-type injuries, a recent systematic review showed that mean functional scores in current studies for the Disabilities of Arm, Shoulder and Hand (DASH) and Mayo Elbow Performance Score (MEPS) assessments are generally between excellent and good.[5-7]

All authors declare no potential conflict of interest related to this article.

Work conducted at the Ambulatory Orthopedics and Traumatology Division of the Orthopedic Services Department, Hospital Ipiranga (UGA II), São Paulo, SP, Brazil, and Hospital Mario Covas of the Faculdade de Medicina do ABC, Santo André, SP, Brazil.
Correspondence: Vitor Elias Corrêa. Av. Benedito Rodrigues Lisboa 1776, Casa B1. Jd Vivendas, São José do Rio Preto, SP, Brazil. 15085-890. vitorecor@yahoo.com.br; vitoreliasc@gmail.com

Article received in 09/04/2016, approved in 06/05/2017.

Because this injury is complex and difficult to treat (even though good results may be obtained when complications are present), we conducted an evaluation of the cases we have treated surgically in our service over a 10-year period. We compared whether the protocol we used for treatment, functional outcomes, and complication rates were similar to those described in the literature.

The objective of this study was to conduct a retrospective evaluation of the functional and radiographic outcomes in patients who suffered terrible triad-type injuries to the elbow and were surgically treated from January 2004 to July 2014.

MATERIALS AND METHODS

We identified 29 patients who suffered TTE-type injuries and underwent surgery from the Shoulder and Elbow Surgery Group at Hospital Mário Covas in Santo André, SP and at the Hospital do Ipiranga in São Paulo, SP from January 2004 to July 2014. The study included patients who had a minimum follow-up time of six months and a maximum follow-up of 10 years. We excluded patients who had associated injuries to the affected elbow or forearm, which could alter functional outcome, such as ipsilateral fractures in the arm and forearm, as well as patients who were skeletally immature. The project was approved by the institutional review board at the Hospital do Ipiranga - SP (UGA II) under process number 1659206, and participants signed a term of free and informed consent.

Twenty patients met the criteria, and one case had bilateral involvement, totaling 21 elbows. Most of the patients (16) were male, and four patients were women. The mean patient age was 38.75 years (18–64). Nineteen patients were right-handed and only one was left-handed. The dominant side was affected in 11 individuals. The most common trauma mechanism was falls from height, which occurred in 10 patients (50%), followed by falls to the ground in 4 patients (20%). The other mechanisms were motorcycle accidents in 3 patients (15%), falls from skateboards in 2 patients (10%), and falling down the stairs in 1 patient (5%).

The patients' professions are shown in Figure 1. Of the 20 patients, two were not employed at the time of the trauma. Of the employed patients, 78% took an average of 7.84 months (one month to 18 months) of injury leave, as shown in Table 1.

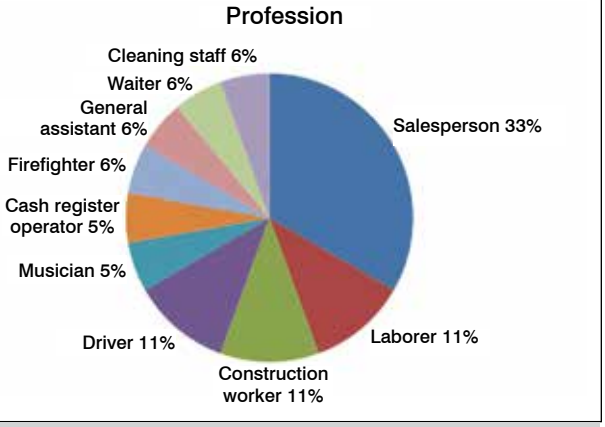


Figure 1. Patient occupations at time of trauma.

Table 1. Percent of patients who returned to work, and average time of leave.

Return to work		Time (months)
Yes	13 (72%)	7.84
No	5 (28%)	19

Imaging studies, x-rays, and computed tomography scans were used to obtain preoperative classification of the radial head and coronoid fractures. According to the Mason-Johnston classification for radial head fractures, all cases were type IV, associated with dislocation of the elbow.[8] We also evaluated the number of fragments. Two cases showed only one fragment; 9 elbows (42.8%) had two fragments, 3 cases (14.2%) had three fragments, and 7 elbows (33.3%) had more than 4 fragments. To assess the fractures of the coronoid process, we used the classification proposed by Reagan-Morrey (RM).[9] Sixteen cases (76%) were type I, 3 (14%) were type II, and 2 (10%) were type III.

The average time from trauma until surgery was 18.8 days (2–38). All patients were operated in the dorsal decubitus position. The most common access route was a single lateral access, in 14 elbows (66.67%). To treat the radial head fractures, we used arthroplasty and internal fixation equally (10 cases each), and in only one case the fragment was removed. Three of the 10 arthroplasties were modular-type procedures, and 7 were non-modular procedures. The coronoid process was not approached in 16 patients (76.2%). The lateral ligament complex (LLC) was approached in 20 elbows, while the medial ligament complex (MLC) was not approached in most of the cases, in 16 elbows (76.2%). External articulated fixation was used in 4 patients (19%) due to residual instability. The distal radioulnar joint was treated with provisional stabilization using Kirschner wires in 3 cases (14.3%). Treatment data are summarized in Table 2.

Postoperative treatment involved the use of an axillary-palmar cast at 90º flexion for an average of 18 days (8–20). After the cast was removed, the patients began physical therapy with exercises at home and outpatient sessions.

Functional performance was assessed using DASH and MEPS scores, and also by assessing the range of motion (ROM) of the elbow on the affected side in comparison with the contralateral limb.[5,6] The Broberg-Morrey scale was used to evaluate postoperative arthrosis, and the physicians also looked for formations of heterotopic ossification (HO) at the interview via anteroposterior and lateral x-rays of the elbow.[10]

The statistical analysis of the data used Fisher's exact test with a 5% significance level (α=0.05).

RESULTS

The mean postoperative follow-up period was 31.25 months (8–93). The ROM on the affected side showed an average loss of extension from 21° to -70° (standard deviation [SD] 18º), while the average flexion was 123° (90–140°, SD 18.7°). The total average ROM for flexion-extension was 101° (20–140°, SD 33.4°). Mean pronation was 49.7° (-40–90°, SD 34.5°), and mean supination was 64.5° (0–90°, SD 26.6°), which consequently produced an average total ROM of 112.85° (0–180º, SD 54º).

The mean MEPS score was 84 (55–100); 7 patients (35%) were considered excellent, 10 (50%) good, 2 (10%) regular, and only 1 patient (5%) was considered to have poor results. The average DASH score was 14.27 points (0–48.3).

Residual instability was only seen in the physical examination in 7 elbows (33%), but none of these patients were symptomatic. One elbow was positive for the pivot-shift test, 1 was positive for varus stress, and 5 were positive for valgus stress.[1]

The mean ROM, tests for residual instability, and functional evaluation scores are shown in Table 3.

In 16 elbows in which the coronoid process was not approached, better ROM scores than the study average were found, 107° flexion-extension and 112.5º pronation-supination; the functional results for these cases were also better, 11.8 on the DASH and 86.6 for the MEPS. However, there was no significant difference compared

Table 2. Treatment.

Patient	Age	Sex	Via		RH	TT RH	Prot	RM	TT RM	LLC	MLC	Art Fe	DRUJ	Other
1	45	M	Dup	LAT-MED	2	Prosthesis	BIP	2	Trans	Trans	Trans	No	No	No
2	46	M	Uni	LAT	3	Rafi		1	No	No	No	No	No	No
3	33	M	Uni	LAT	4	Prosthesis	UNI	1	No	Anc	No	Yes	Kirsch W	No
4	46	M	Uni	LAT	4	Prosthesis	UNI	1	No	Trans	No	No	No	No
5	36	M	Dup	LAT-MED	2	Ressec		1	No	Trans	Trans	No	No	No
6	64	F	Post	LAT	2	Rafi		1	No	Trans	No	No	No	No
7	49	M	Uni	LAT	4	Prosthesis	UNI	1	No	Trans	No	No	Kirsch W	No
8	18	F	Uni	LAT	2	Rafi		1	No	Trans	No	No	No	No
9	32	F	Uni	LAT	3	Prosthesis	BIP	2	Anc	Trans	No	No	No	No
10	28	M	Uni	LAT	4	Prosthesis	BIP	1	No	Trans	No	No	No	No
11	32	M	Dup	LAT-MED	2	Prosthesis	UNI	2	Anc	Anc	Trans	No	Kirsch W	No
12	48	M	Uni	LAT	4	Prosthesis	UNI	1	No	Anc	No	No	No	No
13	55	M	Post	LAT-MED	4	Prosthesis	UNI	3	No	Trans	No	Yes	No	Vasc
14	29	M	Uni	LAT	2	Rafi		1	No	Trans	No	No	No	No
15	35	M	Uni	LAT	2	Rafi		1	No	Trans	No	No	No	No
16	34	M	Uni	LAT	1	Rafi		1	No	Trans	No	No	No	No
17	40	M	Uni	LAT	1	Rafi		1	No	Trans	No	No	No	No
18	33	M	Dup	LAT-MED	4	Prosthesis	UNI	3	Rafi	Anc	Anc	No	No	No
19	45	F	Uni	LAT	3	Rafi		1	No	Anc	No	No	No	No
20 R	27	M	Uni	LAT	2	Rafi		1	No	Trans	No	No	No	No
20 L			Dup	LAT-MED	2	Rafi		1	Trans	Trans	Trans	No	No	No

Notes: VIA: access route used in surgery; DUP: double access; RH: radial head fracture classification; TT RH: radial head fracture treatment; PROT: type of prosthesis used in cases of radial head arthroplasty was used; UNI: unipolar/non-modular; BIP: bipolar/modular; RM: Reagan-Morrey classification for coronoid fractures; TT RM treatment used for coronoid fractures; LLC: treatment of lateral collateral ligament complex; MLC: treatment of medial collateral ligament complex; ART EF: articulated external fixator; DRUJ: distal radioulnar joint injury; OTHER: other associated injuries. Note: patient 20 had bilateral injury (R: right, L: left).

Table 3. Results.

	EXT	FLE	MFE	PRO	SUP	MPS	PSH	VRI	VGI	DASH	MEPS	BMR
1	-70	90	20	30	30	60	No	No	No	14.6	85	3
2	-15	135	120	50	70	120	No	No	No	7.5	85	1
3	-30	115	85	20	15	35	No	No	Yes	5	95	1
4	-5	140	135	90	90	180	No	No	No	0	100	1
5	-5	140	135	50	50	100	No	No	No	11.3	100	2
6	-20	90	70	0	0	0	No	No	No	9.1	85	2
7	-30	90	60	-40	40	0	No	No	No	48.3	80	2
8	-20	140	120	90	80	170	No	No	No	0.8	100	2
9	0	140	140	90	90	180	No	No	No	0.8	100	1
10	0	140	140	90	70	130	No	No	No	0	85	2
11	-30	110	80	30	80	110	No	No	No	39	60	2
12	-5	145	140	60	90	150	No	No	No	5.8	100	1
13	-30	120	90	10	80	90	Yes	No	Yes	11.6	75	4
14	-50	120	70	55	75	130	No	No	Yes	30.8	55	3
15	-15	110	95	30	80	110	No	No	No	8.3	80	1
16	-20	120	100	60	70	130	No	No	No	10	85	2
17	-10	140	130	80	80	160	No	No	No	3.33	100	1
18	-40	100	60	40	40	80	No	No	No	31.6	60	1
19	-40	140	100	70	45	115	No	Yes	No	15	80	3
20R	-5	135	130	90	90	180	No	No	Yes	23.5	80	2
20L	-10	130	120	50	90	140	No	No	Yes			3

Notes: EXT: extension; FLE: flexion; MFE: mean flexion-extension; PRO: pronation; SUP: supination; MPS: mean pronation-supination; PSH: pivot-shift test; VRI: varus instability; VGI: valgus instability; DASH: DASH score; MEPS: MEPS score; BMR: Broberg-Morrey classification.

to patients who underwent a coronoid approach process ($p>0.05$ for ROM and functional scores).

A better average ROM was obtained for cases in which the medial ligament complex was not approached (mean 107° flexion-extension and 117° pronation-supination), and better functional scores on the DASH and MEPS (11.23 and 86.5, respectively) compared to cases where this approach was required. In cases requiring the MLC approach, the average ROM was 83° flexion-extension and 98° pronation-supination. The functional scores were 23 for the DASH index and 77 for the MEPS index. Again, there was no statistical difference between the groups ($p>0.05$ for ROM and functional scores).

As for the presence of osteoarthrosis in the joint, the Broberg-Morrey scores showed 8 type I cases (38%), 8 type II cases (38%), 4 type II cases (19%), and only 1 type IV case (4%).[10]

Eight elbows (38%) showed radiographic signs of HO. According to the classification by Brooker et al.[11] 7 were type I and only 1 was type II. Eight elbows (38%) required additional surgical treatment. The average time between the first and second surgery was six months (1–12 months). The reasons were 1 deep infection of the surgical site, 2 cases in which the synthesis material was removed because of pain, 4 cases in which the external fixator required removal, and 1 case of joint release for elbow stiffness.

Complications were observed in 4 patients (19%); 1 case of pseudoarthrosis in the neck of the radial head (in an asymptomatic patient), 1 case of neuropraxia of the posterior interosseous nerve, 1 contralateral fracture of the distal humerus, and 1 case of persistent postoperative paresthesia of the ulnar nerve.

DISCUSSION

The literature currently demonstrates results generally ranging from good to excellent for surgical treatment of TTE injuries.[1,3,4,7,12-14] We obtained mean functional scores of 14.27 points on the DASH and 84 on the MEPS for our patients, with 85% of results classified as excellent or good. This corresponds with the literature, including national studies that resemble our socio-economic reality. (Table 4) The average ROM obtained in our study, 101° flexion-extension and 112.85° pronation-supination, also agrees with the literature (Table 4) and is located within functional ROM of the elbow.[1]

Despite the differences between the protocols for surgical treatment, its primary objective is to provide sufficient stability to begin early mobility and return function to this joint. Most of the protocols recommend fixation or arthroplasty of radial head fractures in association with treatment of the fracture/avulsion of the coronoid process, followed by repair of the LLC through transosseous sutures or the use of anchors.[4,12,13,15] Cases with residual instability have been treated with an articulated external fixator and/or repair of the MLC.[13,14]

In terms of fractures and avulsions of the coronoid process, the treatment protocols indicate the need to fix or repair these injuries, particularly in cases where large fragments are present (RM type III).[12] However, Papatheodoru et al.[16] demonstrated that good results and functional ROM can be obtained in cases where small fragments are present (RM types I and II), without the need for a coronoid process approach. The results obtained in our study corroborate this fact,

Table 4. TTE articles.

	Year	N	FE ROM	PS ROM	DASH	MEPS	HO
Current study		21	101	112.85	14.27	84	8
Chen et al.[7]	2015	12	125	126			
Gonçalves et al.[19]	2014	26	112	133	12	87	
Naoki Miyazaki et al.[20]	2014	15	115	132			
Papatheodoru et al.[16]	2014	14	123	145	14		1
Fitzgibbons et al.[17]	2014	11	112	153	19.7		
Garrigues et al.[15]	2011	40	115		16		
Zeiders et al.[13]	2008	32	100		23		
Forthman et al.[14]	2007	22	117	137			
Pugh et al.[12]	2004	36	112	136		88	

Notes: N: number of patients evaluated; FE ROM: mean flexion-extension range of motion, in degrees; PS ROM: mean pronation-supination range of motion, in degrees; DASH: DASH score; MEPS: MEPS score; HO: patients with heterotopic ossification.

because even though the coronoid process was not approached in the majority of cases (16 elbows, 76%), these patients had better functional ROM than the average for the study (107° flexion-extension and 112.5° pronation-supination) and also better functional results (11.8 on the DASH and 86.6 on the MEPS), although no statistical difference was found.

The MLC is a key structure in valgus stability in the elbow, but there is no consensus in the surgical protocols on the need to approach this complex during TTE treatment.[12,13] When treatment of the coronoid process or anterior capsule, radial head, and LLC provide enough stability for early mobilization of the elbow, the medial approach and use of external fixation can be avoided.[14,17] In contrast, Toros et al.[18] demonstrated better flexion-extension and flexion ROM in patients who underwent MLC repair than in those who did not receive this repair. Our study obtained better ROM and higher average functional outcomes in cases where the MLC was not approached, in comparison with cases requiring this approach. Even though this difference was not statistically significant, it may arise from the fact that the lesions had lower trauma energy and less tissue damage, consequently leading to a lower rate of complications.[16]

In a recent systematic review, Chen et al.[7] showed that the most common complication in TTE which did not require surgical treatment was HO, in 12.5% of cases, followed by ulnohumeral arthrosis in 11.2% of cases. These authors concluded that although the complication rates were high, patients generally obtained satisfactory functional results.[7] We corroborated this conclusion in our study, because even though there was a 38% rate of HO and reoperation in eight elbows (38%), we obtained functional results which were mostly classified as good or excellent, similar to findings in the national literature. Gonçalves et al.[19] obtained a total of five complications requiring surgical treatment, and Naoki Miyazaki et al.[20] presented two cases of neuropraxia of the ulnar nerve and a case of heterotopic ossification with stiffness of the elbow.

We understand that there are limitations in our study. Because it is retrospective in nature, the injury treatment protocol could not be further standardized. Another limitation was the small number in the sample; even though it is similar to others found in the literature, this number hindered the statistical analysis.

There are differences between the protocols used in treating TTE injuries, but even despite these differences, the use of a systematic treatment in the surgical approach ultimately provides good functional results and ROM.[12,13,17]

CONCLUSION

Despite the difficulty of treating this injury and the high rates of complications, when systematized treatment is followed to treat TTE-type injuries, even with their variations functional ROM and function scores ranging between good and excellent can be obtained in most cases. We use these protocols in our service, especially with increased understanding of the complexity of this injury and the structures involved. As a result, in the majority of patients we obtained functional results ranging from good to excellent.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. VEC (0000-0002-2489-3005)*, ABC (0000-0002-4169-5211)*, and RSB (0000-0003-4672-0380)* were the main contributors in assessing patients, gathering the clinical data to write the manuscript, and performed the literature search. LGPN (0000-0003-0013-2217), RYI (0000-0001-7718-1186)*, and JM (0000-0003-1812-8566)* performed the surgeries and followed the patients. VEC, ABC, RSB, RYI, LGPN, and JM evaluated the data from the statistical analysis, revised the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Ring D. Fractures and dislocations of the elbow. In: Bucholz RW, Heckman JD, Court-Brown C, editors. Rockwood and Green's fractures in adults. 6th ed. Philadelphia: Lippincott Williams & Wilkins; 2006. p. 1034.
2. Pipicelli JG, Chinchalkar SJ, Grewal R, Athwal GS. Rehabilitation considerations in the management of terrible triad injury to the elbow. Tech Hand Up Extrem Surg. 2011;15(4):198-208.
3. Dodds SD, Fishler T. Terrible triad of the elbow. Orthop Clin North Am. 2013;44(1):47-58.
4. Mathew PK, Athwal GS, King GJ. Terrible triad injury of the elbow: current concepts. J Am Acad Orthop Surg. 2009;17(3):137-51.
5. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). Am J Ind Med. 1996;29(6):602-8.
6. Gill DR, Morrey BF. The Coonrad-Morrey total elbow arthroplasty in patients who have rheumatoid arthritis. A ten to fifteen-year follow-up study. J Bone Joint Surg Am. 1998;80(9):1327-35.
7. Chen HW, Liu GD, Wu LJ. Complications of treating terrible triad injury of the elbow: a systematic review. PLoS One. 2014;15;9(5):e97476.
8. Johnston GW. A follow-up of one hundred cases of fracture of the head of the radius with a review of the literature. Ulster Med J. 1962;31:51-6.
9. Regan W, Morrey B. Fractures of the coronoid process of the ulna. J Bone Joint Surg Am. 1989;71(9):1348-54.
10. Broberg MA, Morrey BF. Results of delayed excision of the radial head after fracture. J Bone Joint Surg Am. 1986;68(5):669-74.
11. Brooker AF, Bowerman JW, Robinson RA, Riley LH Jr. Ectopic ossification following total hip replacement. Incidence and a method of classification. J Bone Joint Surg Am. 1973;55(8):1629-32.
12. Pugh DM, Wild LM, Schemitsch EH, King GJ, McKee MD. Standard surgical protocol to treat elbow dislocations with radial head and coronoid fractures. J Bone Joint Surg Am. 2004;86(6):1122-30.
13. Zeiders GJ, Patel MK. Management of unstable elbows following complex fracture-dislocations--the "terrible triad" injury. J Bone Joint Surg Am. 2008;90 Suppl 4:75-84.
14. Forthman C, Henket M, Ring DC. Elbow dislocation with intra-articular fracture: the results of operative treatment without repair of the medialcollateral ligament. J Hand Surg Am. 2007;32(8):1200-9.
15. Garrigues GE, Wray WH 3rd, Lindenhovius AL, Ring DC, Ruch DS. Fixation of the coronoid process in elbow fracture-dislocations. J Bone Joint Surg Am. 2011;93(20):1873-81.
16. Papatheodorou LK, Rubright JH, Heim KA, Weiser RW, Sotereanos DG. Terrible triad injuries of the elbow: does the coronoid always need to be fixed? Clin Orthop Relat Res. 2014;472(7):2084-91.
17. Fitzgibbons PG, Louie D, Dyer GS, Blazar P, Earp B. Functional outcomes after fixation of "terrible triad" elbow fracture dislocations. Orthopedics. 2014;37(4):e373-6.
18. Toros T, Ozaksar K, Sügün TS, Kayalar M, Bal E, Ada S. The effect of medial side repair in terrible triad injury of the elbow. Acta Orthop Traumatol Turc. 2012;46(2):96-101.
19. Gonçalves LB, Neto JA, Correa Filho MR, de Andrade RP, de Andrade MA, Gomes AH, et al. Terrible triad of the elbow: influence of radial head treatment. Rev Bras Ortop. 2014;49(4):328-33.
20. Naoki Miyazaki A, Santos Checchia C, Fagotti L, Fregonez M, Doneux Santos P, da Silva LA, et al. Evaluation of the results from surgical treatment of the terrible triad of the elbow. Rev Bras Ortop. 2014;49(3):271-8.

DOI: http://dx.doi.org/10.1590/1413-785220172506169618

INCIDENCE OF ACUTE TRAUMA ON HAND AND WRIST: A RETROSPECTIVE STUDY

INCIDÊNCIA DE TRAUMAS AGUDOS NA MÃO E NO PUNHO: ESTUDO RETROSPECTIVO

Giovanna Damm Raphael Junqueira[1], André Luiz Machado Lima[2], Robison Boni[1], Joelmar César de Almeida[1], Rafael Souza Ribeiro[2], Leandro Azevedo de Figueiredo[1,2]

1. Orthopedics and Traumatology Service, Santa Casa de Misericórdia de Vitória Hospital, Vitória, ES, Brazil.
2. Hand Group, Orthopedics and Traumatology Service, Hospital Estadual Doutor Jayme dos Santos Neves, Serra, ES, Brazil.

ABSTRACT

Objectives: A retrospective statistical data gathering of wrist and hand complaints assisted over two years in the orthopedic emergency department of a regional referral hospital, seeking to know the profile of these patients. Methods: Information obtained by analysis of 31.356 orthopedic visits from May 2013 to April 2015, of which 6.754 related to hand complaints and/or wrist, at the Hospital Estadual Doutor Jayme dos Santos Neves (HDJSN) and analyzed by IBM SPSS Statistics software version 21. Results: The data revealed that the average age was 37,5 ± 15,7 years and the male gender was predominant (60,72%). Bruises (52,58%) and fractures (30,49%) were the most common diagnoses. Conclusion: The complaints of wrist and hand accounted for 21,44% of all orthopedic emergency room visits. Detailed data description and correct definition of the International Classification of Diseases (ICD-10) are needed to better define the epidemiological profile of patients seeking orthopedic emergency. ***Level of Evidence III, Retrospective Study.***

Keywords: Hand injuries/epidemiology. Wrist injuries/epidemiology. Emergency medical services. Orthopedics.

RESUMO

Objetivos: Fazer um levantamento de dados estatísticos retrospectivos dos atendimentos de lesões de punho e mão, ao longo de dois anos no pronto-socorro ortopédico de um hospital de referência regional, visando conhecer o perfil desses pacientes. Métodos: Informações obtidas por análise de 31.356 atendimentos ortopédicos no Hospital Estadual Doutor Jayme dos Santos Neves (HDJSN) entre maio de 2013 e abril de 2015, dos quais 6.754 apresentaram lesões na mão e/ou punho. Os dados foram analisados pelo programa IBM SPSS Statistics versão 21. Resultados: Os dados revelaram que a média de idade foi de 37,5 ± 15,7 anos, com predominância do sexo masculino (60,72%). Contusões (52,58%) e fraturas (30,49%) foram os diagnósticos mais frequentes. Conclusão: As lesões do punho e da mão corresponderam a 21,44% do total de atendimentos ortopédicos de emergência. A descrição detalhada dos dados e a definição exata na Classificação Estatística Internacional de Doenças e Problemas Relacionados com a Saúde (CID-10) são necessárias para determinar melhor o perfil epidemiológico do paciente que procura a emergência ortopédica. ***Nível de Evidência III, Estudo Retrospectivo.***

Descritores: *Traumatismos da mão/epidemiologia. Traumatismos do punho/epidemiologia. Serviços médicos de emergência. Ortopedia.*

Citation: Junqueira GD, Lima AL, Boni R, Almeida JC, Ribeiro RS, Figueiredo LA. Incidence of acute trauma on hand and wrist: a retrospective study. Acta Ortop Bras. [online]. 2017;25(6):287-90. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Acute traumas involving upper limb in the emergency room are common, however, they are little understood from an epidemiological perspective.[1] The injuries that affect the distal extremity of the upper limb are considered a major social and public health problem both due to the physical and mental impact, as well as to high costs of initial treatment of its sequels.[2,3] According to the *National Eletronic Injury Surveillance System* (NEISS), lacerations and fractures of the fingers and hands are the anatomical sites most affected in the work accidents attended in the American emergency services.[1] It is estimated that approximately 11-20% of visits to emergency departments in the United States are due to injuries to the hands and wrists, making the epidemiological analysis of these lesions of paramount importance.[3-5] It is known that the costs of falling productivity due to absence from work , in general, are more expensive than the treatment of the injury itself.[3] When added, the costs of absence from work with medical and hospital expenses can reach an average of thirty thousand dollars per injury.[6] The social and economic costs cannot be measured only by the social security aspect, for not expressing its real dimension. The issue becomes more important if we consider, for example, the cost of specialized medical care, with more complex procedures, the

All authors declare no potential conflict of interest related to this article.

Work conducted at the Orthopedics and Traumatology Service of Hospital Estadual Doutor Jayme dos Santos Neves, Serra, ES, Brazil.
Correspondence: Rua Quinze de Novembro, 232/801, Praia da Costa, Vile Velha, ES, Brazil. 29101-055. giovannadamm@yahoo.com.br

Article received in 09/21/2016, approved in 06/19/2017.

drop in production resulting from absenteeism and the functional reduction consequent to the possible sequelae.[7] The purpose of this study is to evaluate the characteristics of the injuries as well as to calculate epidemiological estimates of the traumatic injuries that affect the hand and the wrist by means of a population sample of patients attended in the orthopedic emergency of a reference hospital in trauma during two years, in the state of Espírito Santo. The hand would be the terminal segment of the upper limb, continuation of the fist, ending distally with the fingers. Its proximal limit would be given by a horizontal plane that passes through the pisiforme and the scaphoid. Its skeleton would correspond to the second row of the carpus (trapezoid, trapezoid, capitate and hamato), metacarpal bones and phalanges. The first row (scaphoid, lunate, pyramidal and pisiform) along with the distal end of the radius and ulna would belong to the wrist region.

MATERIALS AND METHODS

This is a cross-sectional epidemiological study. All information was obtained by means of data collection in the medical records of the orthopedic emergency room, defining the complaints concerning the wrist and the hand. Trauma denominations in these regions were classified according to the International Code of Diseases (ICD-10) and individual assessment of medical records. The study will cover visits between May 2013 and April 2015.

All researches used as a bibliographic source were collected using search sites such as PubMed and ClinicalKey, using the keywords "injury", "wrist", "hand", "emergency", "epidemiology" and "trauma".

Calculation of rate:

The sample size was 6,767. The variables analyzed in the wrist and hand traumas were: gender, color, age, municipality of origin and affection.

The project of this research was approved by the Ethics Committee (CAAE 50648015.1.0000.5065) of the Superior School of Sciences of Santa Casa de Misericórdia de Vitória on March 29, 2016.

The program used in the analyzes was the IBM SPSS Statistics version 23.

The data characterization was performed through the observed frequency, percentage, minimum, maximum, mean and standard deviation.

The Chi-square test verified the association between qualitative variables. To compare quantitative and qualitative variables, variance analysis (ANOVA) was used using Dunnett's multiple comparison test, since the variances were not homogeneous (Levene's test).

The level of significance adopted in all analyzes was 5% with a 95% confidence interval.

RESULTS

Between May 2013 and April 2015, there were 101,769 visits to the emergency room of the reference trauma hospital in the city, orthopedic visits were 31,718, which is the specialty with the highest number of records, followed by the medical clinic, with 30,207 And general surgery, with 26,212.

Of the orthopedic visits, 21.6% were of complaints related to wrist and hand. Even though this number is relatively large, corresponding to around 282 calls per month, this number is known to be far from realistic. Many of the injuries of the wrist and hand give entry to the PS for other specialties (mainly of the general surgery), it is up to the orthopedist to respond only to the opinion requested by the surgeon, thus keeping the record of the service as general surgery. The present study showed that the orthopedic care of all the visits in the emergency room of the reference unit in trauma during the period evaluated corresponded to 31.2%. (Table 1)

Among the orthopedic visits, 21.6% corresponded to the complaints due to complaints in the distal regions of the upper limb, demonstrated in this work by the wrist or hand. (Table 2)

The male gender corresponded to 60.7% of the total sample. The parda color obtained 46.3%. The municipality of Serra was the one that presented the highest proportion of attendances with 90.7%, in which, together with the other municipalities of Grande Vitória, in addition, they presented 97.8% of the origin of those served, 1.8% referring to other municipalities of the state and 0.5% to municipalities in other states. The monthly distribution of attendances maintained a similar absolute value, varying from 512 (December months) to 592 (October months). The minimum age was 7 years, maximum of 99 years, an average age of 37.5 years and standard deviation of ± 15.7 years. (Table 3)

Table 1. Orthopedic PS attendances.

	n	%
Orthopedic attendances	31718	31.2
Other attendances	70051	68.8
Total	101769	100.0

Source: Data from PS records.

Table 2. Wrist/hand complaints at the orthopedic PS.

	n	%
Wrist and hand complaints at the orthopedic PS	6767	21.6
Other orthopedic attendances	24588	78.4
Total	31355	100.0

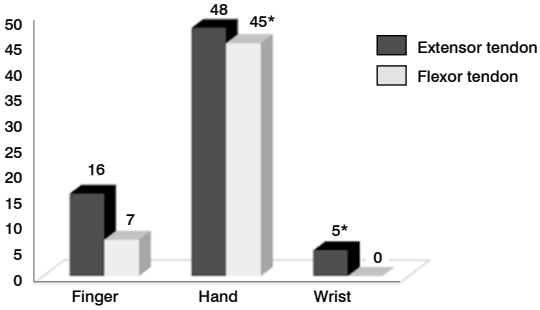
Fonte: Data from orthopedic PS records.

Table 3. Demographic characterization.

		n	%
Gender	Male	4109	60.7
	Female	2657	39.3
Color	Pardo color	3141	46.4
	White	1440	21.3
	Black	596	8.8
	Yellow/Indigene	105	1.6
	No Information	1485	21.9
Procedence	Grande Vitória	6616	97.8
	Other municipalities of ES	119	1.8
	Outher States	32	0.5
Monthly Distribution	January	564	8.3
	February	529	7.8
	March	591	8.7
	April	524	7.7
	May	576	8.5
	June	556	8.2
	July	576	8.5
	August	589	8.7
	September	589	8.7
	October	592	8.7
	November	569	8.4
	December	512	7.6
Age	Minimum	Maximum	Medium
	7.0	99.0	37.5 (± 15.7)

Source: Data from orthopedic PS records.

Regarding the affection, Contusion (52.5%) and Fracture / Dislocation (34.3%) had higher percentages. (Table 4)
The topographic distribution of the complaints was done as follows: Fist (40.8%), Fingers (32.0%) and Hand (22.8%). Regions that were not specified in the medical records accounted for 4.4% of complaints. (Table 5)
A significant association of gender with affection (value / p = 0.000) was observed, and the positive contribution to significance occurred in the male gender with amputation, short-blunt injury, fracture / dislocation, and infection. In the female gender, positive significance occurred with contusion, pain and tenosynovitis. (Figure 1)
The association between topographic distribution and tendinous lesions was significant (p value = 0.042). The lesions, when they occurred in the central region of the Hand, had a statistically significant relationship with lesions of the flexor tendons. The extensor lesions were positively associated with wrist injuries. (Figure 2)



Source: Data from orthopedic emergency medical records. (*) Statistical significance with p = 0.042

Figure 2. Tendon lesions according to topographic distribution.

Table 4. Affection.

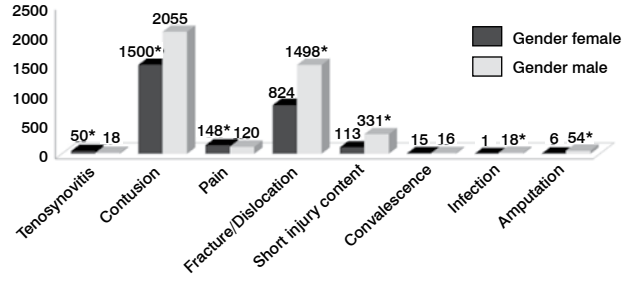
	n	%
Contusion	3555	52.5
Fracture/dislocation	2322	34.3
Short injury content	444	6.6
Pain	268	4.0
Tenosynovitis	68	1.0
Amputation	60	0.9
Convalescence	31	0.5
Infection	19	0.3
Total	6767	100.0

Source: Data from orthopedic PS records.

Table 5. Topographic Distribution of the complaints.

	n	%
Wrist	2763	40.8
Finger	2164	32.0
Hand	1545	22.8
Not specified	295	4.4
Total	6767	100.0

Source: Data from othopedic PS records.



Source: Data from orthopedic emergency medical records. (*) Statistical significance with p <0.000.

Figure 1. Disorders distributed by gender.

DISCUSSION

In a study carried out in a university hospital in Ribeirão Preto, an analysis of the demand for emergency care was made in 2000, in which 27.6% corresponded to traumatic injuries involving the hands.[6] Comparing the data obtained in this study with the literature, a strong predominance of the male gender was observed, with 60.7%. The data of this work presented results similar to those of Santos et al.,[8] Lopes[9] and Batista and Filgueira.[10] The results found are in accordance with clinical experience, since men are more exposed to the risk of accidents, men in this way were responsible for more severe trauma records, such as amputation, short-blunt injury, fracture / dislocation and infection. On the other hand, women with 39.3% presented trauma considered milder, such as bruising, pain and tenosynovitis, and were statistically significant in both cases.

Accidents related to work tasks include, mainly, trauma and short bruised wounds on the hand, wrist and head, along with eye injuries. More intensive supervision in the use of protective equipment, more appropriate training in risk recognition, and safe working practices, including vehicle operation in the workplace, should be implemented to reduce work-related injuries.[11]
A 2009 consultation by the National System of Electronic Surveillance (NEISS) resulted in 92,601 records of upper extremity lesions treated in an emergency department in the US in 2009, which translates into an estimated total of 3,468,996 such injuries that year. This corresponds to an incidence of 1,130 upper extremity lesions per 100,000 population per year.[12]
It was observed in this study that the incidence of flexor tendon injuries is greater when compared to extensor tendon injuries, most of them in the palm region, while extensor injuries affected the wrist region more, according to data from the literature. These lesions are usually associated with nerve damage. This is usually due to the hand-inflicted mechanism of trauma (often a knife or glass) that contains many delicate anatomical structures in the vicinity (superficial and deep flexor tendons, Joint ligament, arteries, and nerves)[13] which are often not reported in the ICD-10 registry, so despite the effectiveness of the computerization of care, and the mandatory registration of ICD-10 to initiate care, many times the code may not correspond with actual patient injury.
This study raised the data of the emergency room visits during two years, stratifying the orthopedic care, and showing that more than 1/5 of all care is related to hand and wrist trauma, with a great impact on the volume of care delivered for orthopedics. Based on this survey, other studies may be designed with a view to reducing trauma-related accidents on the hand, or even the need for specialized care by a hand surgeon in the initial evaluation of the patient.

CONCLUSIONS

Among all those attended, the male gender and the parda race had a higher prevalence.

The most prevalent affections were contusion and fractures, with the hand being the region most affected.
Wrist and hand conditions accounted for 21.44% and all orthopedic care in the HDJSN emergency room between May 2013 and April 2015. Standardized information and registration methods are essential for data to be compared.

The results of previous studies in the area of hand and wrist injury may be comparable in some areas, but differences may occur due to variations in methods of data recording and classification. Better utilization of the international disease code (ICD-10), with accurate injury record, would facilitate and standardize the searches and documentation of patients with trauma to the wrist and hands.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. ALML (0000-0002-7702-9800)* and GDRJ (0000-0003-2891-1837)* were the main contributors in drafting the manuscript. RB (0000-0003-0685-7155)* and JCA (0000-0002-1338-6577)* performed the data collection and collected the clinical data. LAF (0000-0003-0120-5828)* and RSR (0000-0003-4779-3645)* evaluated the data for the statistical analysis. AL and GJ carried out the bibliographic research, reviewed the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Sorock GS, Lombardi DA, Courtney TK, Cotnam JP, Mittleman MA. Epidemiology of occupational acute traumatic hand injuries: a literature review. Saf Sci. 2001;38(3):241-56.
2. Larsen CF, Mulder S, Johansen AM, Stam C. The epidemiology of hand injuries in The Netherlands and Denmark. Eur J Epidemiol. 2004;19(4):323-7.
3. de Putter CE, Selles RW, Polinder S, Panneman MJ, Hovius SE, van Beeck EF. Economic impact of hand and wrist injuries: health-care costs and productivity costs in a population-based study. J Bone Joint Surg Am. 2012;94(9):e56.
4. Brown TS, Hinojosa LS, Cline KE, Black SR, Jamieson MD, Starr AJ. Lack of Acute Hand Care in the Southwest United States. J Orthop Trauma. 2016;30(4):e129-31.
5. de Jong JP, Nguyen JT, Sonnema AJ, Nguyen EC, Amadio PC, Moran SL. The incidence of acute traumatic tendon injuries in the hand and wrist: a 10-year population-based study. Clin Orthop Surg. 2014;6(2):196-202.
6. Fonseca MCR, Mazzer N, Barbieri CH, Elui VMC. Traumas da mão: estudo retrospectivo. Rev Bras Ortop. 2006;41(5):181-6.
7. Ohara GH. Traumatismos complexos da mão – Princípios de tratamento. In: Pardini Junior AG, Freitas A. Traumatismos da mão. Rio de Janeiro: Medbook; 2008. p. 181-96.
8. Santos UP, Wünsch Filho V, do Carmo JC, Settimi MM, Urquiza SD, Henriques CM. Epidemiological surveillance system for occupational accidents: experience in the northern area of the municipality of São Paulo (Brazil). Rev Saude Publica. 1990;24(4):286-93.
9. Lopes EI. Aspectos sociais e econômicos dos traumatismos da mão. In: Pardini Júnior AG. Traumatismos da mão. 2a. ed. Rio de Janeiro: Medsi; 1992. p. 1-7.
10. Batista KT, Filgueira IC. Trauma complexo de mão: análise epidemiológica na Unidade de Cirurgia Plástica do Hospital Regional da Asa Norte/ FHDF/SeS. Rev Saúde Dist Fed. 1997;8(4):25-31.
11. Aggazzotti G, Righi E, Patorno E, Fantuzzi G, Fabiani L, Giuliani AR, et al. Work-related injuries in young workers: an Italian multicentric epidemiological survey. Ann Ist Super Sanita. 2006;42(1):69-75.
12. Ootes D, Lambers KT, Ring DC. The epidemiology of upper extremity injuries presenting to the emergency department in the United States. Hand (N Y). 2012;7(1):18-22.
13. Miranda BH, Spilsbury ZP, Rosala-Hallas A, Cerovac S. Hand trauma: a prospective observational study reporting diagnostic concordance in emergency hand trauma which supports centralised service improvements. J Plast Reconstr Aesthet Surg. 2016;69(10):1397-402.

DOI: http://dx.doi.org/10.1590/1413-785220172506160670

WRIST ARTHROSCOPY: BASIC TIPS FOR DRY ARTHROSCOPIC EXPLORATION

ARTROSCOPIA DE PUNHO: DICAS BÁSICAS PARA EXPLORAÇÃO ARTROSCÓPICA A SECO

Henrique de Barros Pinto Netto[1,2], Suzilaine Ramos de Oliveira[1], Flavia Curvo Pereira[1], Nilton Mazzer[2]

1. Hospital Federal da Lagoa, Rio de Janeiro, RJ, Brazil.
2. Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo, SP, Brazil.

ABSTRACT

Objective: This article provides details and tips on the dry arthroscopic technique, based on our experience and its clinical applications. Method: The technique was applied to 65 patients (33 men and 32 women) aged between 20 and 62 years (average of 35.4 years) for treating: synovial cyst resection, scapholunate ligament injury repair, ulnocarpal impact correction, triangular fibrocartilage injury repair, and assisted reduction of distal radius fractures. Results: A minimally invasive intra-articular evaluation has been observed as a benefit, with low infection rate, small scars, and high rates of early recovery, without affecting intra-articular fluid use, reducing the risk of compartment syndrome and infiltrated soft tissues, in the case of need for associated open surgery. As for the difficulties, we report the surgeon's view, which is commonly prevented by optical blurring or debris that hit the lens, and the need for radiofrequency care, since the heat generated is dissipated with greater difficulty than in the classical technique. Conclusion: Dry arthroscopy emerges as an effective choice to treat wrist pathologies, however, deep knowledge and ease with the classical technique, as well as a learning curve, are key to obtain a good outcome. ***Level of Evidence V, Expert Opinion.***

Keywords: Wrist/pathology. Arthroscopy/methods. Compartment syndromes. Learning curve. Treatment outcome.

RESUMO

Objetivo: Este artigo apresenta detalhes e dicas sobre a técnica de artroscopia seca, baseada em nossa experiência e em suas aplicações clínicas. Método: A técnica foi aplicada em 65 pacientes (33 homens e 32 mulheres) com idades entre 20 e 62 anos (média de 35,4 anos) para o tratamento de ressecção de cisto sinovial, reparo de lesão do ligamento escafo-semilunar, correção do impacto ulnocarpal, reparo de lesão da fibrocartilagem triangular e assistência na redução de fraturas da parte distal do rádio. Resultados: A avaliação intra-articular minimamente invasiva foi observada como benefício, com baixo índice de infecção, cicatrizes pequenas e altas taxas de recuperação precoce, sem prejuízo do uso intra-articular de líquido, reduzindo o risco de síndrome compartimental e tecidos moles infiltrados, no caso de necessidade de cirurgia aberta associada. Quanto às dificuldades, relatamos a visibilidade para o cirurgião, comumente impedida pelo turvação da óptica ou detritos salpicados na lente e a necessidade de cautela com a radiofrequência, pois o calor gerado é dissipado com maior dificuldade do que na técnica clássica. Conclusão: A artroscopia seca surge como opção efetiva no tratamento das patologias de punho, entretanto, o conhecimento profundo e as facilidades com a técnica clássica, bem como a curva de aprendizado, são fundamentais para obter um bom resultado. ***Nível de Evidência V, Opinião do Especialista.***

Descritores: *Punho/patologia. Artroscopia/métodos. Síndromes compartimentais. Curva de aprendizado. Resultado do tratamento.*

Citation: Pinto Netto HB, Oliveira SR, Pereira FC, Mazzer N. Wrist arthroscopy: basic tips for dry arthroscopic exploration. Acta Ortop Bras. [online]. 2017;25(6):291-4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Since the 1980s, the use of wrist arthroscopy as a diagnostic tool for intra-articular wrist pathology, which allows minimally invasive treatment of many diseases, has been widely disseminated among surgeons as a routine.

Traditional arthroscopy, or 'wet' arthroscopy, uses fluid to distend and create a working cavity. However, distending the joint with fluid is not a complication-free procedure. The fluid infiltrates the tissues, escapes through the gateways, and this can cause serious problems, such as the compartment syndrome. Finally, the use of fluid greatly complicates any concomitant surgery after arthroscopic exploration, making it difficult to combine arthroscopy with open procedures, such as osteotomies and ligament reinsertions, e.g. for triangular fibrocartilage, due to the loss of anatomical frame definition by the massive fluid infiltration.[1,2]

This article is a retrospective study based on surgical experience by means of 65 wrist arthroscopies, using the dry technique, whose aim is providing the reader with a description of the surgical technique, its challenges, and tips, allowing its reproduction.

All authors declare no potential conflict of interest related to this article.

Work conducted at the Hospital Federal da Lagoa, Rio de Janeiro, RJ, Brazil.
Correspondence: Hospital Federal da Lagoa. Rua Jardim Botânico, 501, Jardim Botânico. Rio de Janeiro, RJ, Brazil. 22470-050. hbportopedia@gmail.com

Article received in 03/04/2016, approved in 06/27/2017.

MATERIAL AND METHODS

Between April 2013 and September 2015, 65 patients underwent an arthroscopic wrist procedure using the dry technique for treating pathologies and defining the diagnosis. These medical records were analyzed within the period from October 2015 to December 2015; 32 patients were women and 33 were men; their ages ranged from 20 to 62 years (average of 35.4 years); 40 patients had synovial cysts; 16, triangular fibrocartilage injury; 5, distal radius fracture; 5, scapholunate ligament injury; and 2, ulnocarpal impact. Because this is an analysis of medical records belonging to previously operated patients, this study did not require the use of a free and informed consent term and it has not been submitted to the evaluation of a research ethics committee.

The surgical technique was applied with the patient in the supine position on the operating table, under regional anesthesia — axillary block and sedation, with the shoulder along the table edge. The shoulder was abducted, and the forearm, vertically suspended, using Chinese mesh on the index and middle fingers by a traction system supported by the surgical table. The traction obtained was measured by a dynamometer, obtaining values between 5 and 8 kgf. After exsanguination, the pneumatic cuff above the elbow was inflated between 250-300 mmHg. (Figure 1) The arthroscope used was 2.5 mm with a viewing angle of 30º. There were basically two gateways, 3-4 and 6R, which depending on the pathology, work either as a visualization gateway or as an instrumentation gateway. Radial pathologies use the gateway 6R for visualization, while ulnar pathologies use the gateway 3-4 for this purpose. The gateway 3-4 is established 1 cm distal to Lister's tubercle, with a 40 × 12 mm needle inserted first at a 10° volar angle and parallel to the articular surface, thus reducing the risk of cartilage damage. The gateway 6R is established by carpal ulnar extensor tendon palpation, and the fixed radial point to the tendon palpated is then also demarcated using a needle. When the viewing portal is determined, the demarcation needle is removed and a longitudinal incision is obtained with a number 15 scalpel blade, dilated with hemostatic forceps, then a trocar is inserted into the joint for optic input.

All the arthroscopic explorations were performed using the dry technique, allowing the identification of major points to be addressed. So, we observe the following aspects:

Regarding the determination of gateways, once the gateway for visualization has been chosen, the needle demarcating the instrumentation gateway must be kept to ensure, by internal vision, its proper positioning, posterior incision, dilation, and introduction of instruments.

Scope valves should be kept open throughout the procedure to allow air to circulate freely in the joint cavity. Otherwise, the shaver suction of the does not work properly, causing collapse and preventing full visualization of the space. (Figure 2)

One of the scope valves should be pre-prepared with a 20 mL syringe of 0.9% saline, positioned in the scope to promptly wash the joint cavity, functioning as a pre-assembled irrigation system, used as needed and still not de-characterizing the dry technique. Salt irrigation is sometimes needed to clean the field or cool the shaver. The joint should be irrigated to remove debris and blood whenever needed. Optical blurring, as well as the presence of blood and spatter, can obscure the surgeon's view. And continued shaver use can generate its heating as a result of friction, perceptible in the surgeon's hand, with possible device damage.

Regarding the possibility of thermal damage to the cartilage and adjacent soft tissues, caused by the use of radiofrequency, it is

Figure 1. Positioning in the traction tower.

Figure 2. Scope valve kept open.

recommended to use them only briefly and punctually, and never continuously, also using the irrigation system whenever needed.
When used simultaneously with osteosynthesis of the intra-articular fracture of the distal radius, the gateway 4-5 and the knee probe help achieving and controlling joint surface reduction.
During the triangular fibrocartilage reinsertion, the dry technique has the advantage of no liquid resistance, which occurs with the classical technique.

DISCUSSION

Arthroscopic wrist examination should include the radiocarpal and mediocarpic joints. Several gateways are described, each having a technique of its own and adequate function. Traditionally, 3-4, 4-5, 6R and midcarpal gateways have been used as visualization and working gateways. The traditional gateways for wrist arthroscopy are dorsal because of the presence of fewer neurovascular structures in the wrist dorsum, as well as the initial emphasis on assessing their volar ligaments.[3,4] With the advent of new volar gateways, it is possible to have visualization and working gateways that surround the wrist as a whole.[5,6] This allows the surgeon to use the arthroscope for display and instrumentation in all directions — the box concept. (Figure 3)
These are some of the indications for wrist arthroscopy: it is a useful tool for diagnosis in patients with wrist pain, limited arc of movement, and reduced force, in which a non-invasive diagnosis and a conservative treatment have failed. And also in synovial cyst resection, especially in cases where the patient has concomitant wrist pain, distal radius fractures with deviation greater than 2 mm, isolated radial styloid fractures, distal radius fractures with suspected associated ligament or capsular injury, Reparable peripheral injuries of triangular fibrocartilage, among others, for which minimally invasive solutions are sought.[7]
As for contraindications of classical arthroscopy, some typical ones are the large capsular injuries, which have fluid leakage risk,[8] active infection, neurovascular impairment, and distorted anatomy. In addition to these, there are distal radius fractures with metaphyseal comminution and shear and volar fractures, as they require open treatment, although the arthroscope can be inserted to help reducing the joint. Compartment syndrome risk has also been considered a contraindication for arthroscopy, particularly after severe fractures.

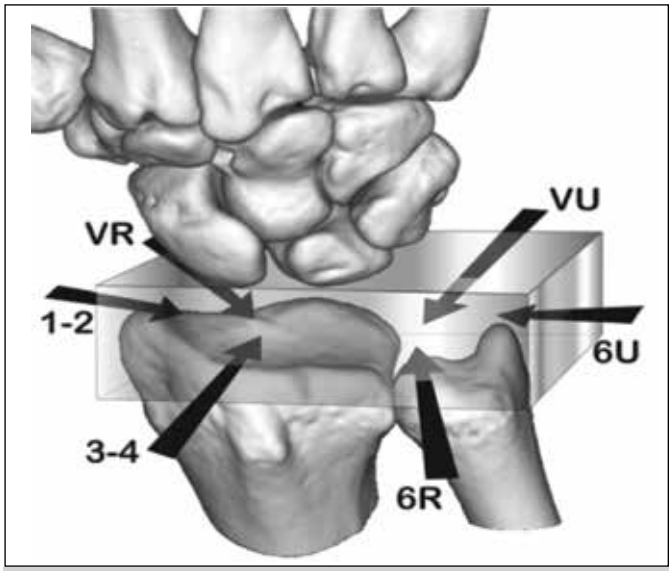


Figure 3. Box concept, the wrist can be observed in many directions.[5]

Rupenian reports that performing traditional arthroscopy, introducing fluid in an attempt to maintain the optic cavity, is not a problem-free procedure.[9] The imbalance between fluid input and output associated with extravasation through gateways often results In loss of visualization and risk of compartment syndrome. We observed that dry arthroscopy sets aside all concerns about intra-articular fluid management and pressure, and thanks to the lack of tissue infiltration, the wrist volume and contour are preserved during surgery.
In other surgery fields, such as laparoscopy, water is not used to keep the optic cavity; instead, gas is used. Gas (air, carbon dioxide, oxygen, or nitrous oxide) was the first intra-articular substance used to distend the joint and perform arthroscopy since the first description of this procedure by Bircher, in 1921.[10] Levin et al.[11] devised a balloon for this purpose that, when placed between the soft tissue frames, creates air pockets that serve as actual optical cavities, facilitating the dissection of free flaps. Friedlander and Sundin[12] used external skin traction, creating a cavity without fluid insufflation, to facilitate minimally invasive dissection of the dorsal large muscle flap. These researchers used soft tissue traction to develop the optic cavity when they took up the flaps.[11,12] To summarize, water is neither crucial or needed to determine any cavity. It was then considered that in the wrist, traction itself would keep the optic cavity open.[13]
Another major advantage of the dry technique reported by Rupenian[9] is the possibility of assessing injuries in their natural setting. We notice, for instance, in the excision of cysts and pathologies involving the presence of synovitis, that the infiltration of tissues by the fluid prevents a rather real view of anatomical structures, which are distorted and distended; however, in the dry technique these structures show a higher definition.
Slutsky[3] reported the benefit of providing reduced intra-articular distal radius fractures with arthroscopic assistance through the dry technique by eliminating the concern with fluid extravasation. We observed that an advantage of the dry technique is being able to perform an open procedure, such as volar plate osteosynthesis of the distal radius, concomitant with arthroscopy.
Del Piñal et al.[13] and Del Piñal[1] mention in their studies some details and tips to put the dry arthroscopic technique into practice and to guarantee a safe and uneventful procedure: they indicate that, sometimes, the surgeon's view may not be so clear due to the presence of blood and debris, generating optical blurring, which can overshadow the optic tip. The researchers have used a neurosurgical swab for cleaning the field, whose need was discarded over time. The currently used method is a pre-assembled irrigation system that has a syringe installed in the scope valve which, when needed, makes it possible to use small amounts of fluid in order to clean the field. With a refined operative technique, we observed that, during the procedures, the amount of fluid required was gradually lower. According to Del Piñal,[1] the suction needed to clean the field paradoxically blurs the vision by agitating the joint contents and generating the cavity collapse. So, the researcher advises to open the shaver suction only when aspiration is needed. We kept the scope valve open at all times for free air circulation in the cavity and the suction used only when needed.
One of the surgeons' concerns in terms of dry arthroscopy is the possibility of thermal damage within the joint by the use of radiofrequency. Del Piñal[1] reports that the heat generated may have difficulty to dissipate, and there is a risk of thermal damage to soft tissues and cartilage surfaces. For this reason, the author does not advise to use this type of device continuously, without fluid to cool. In case of need, we do not see any problem to use the irrigation system, but this does not characterize the dry technique. Del Piñal[1,14] reported intercurrence cases observed with regard to the shaver heating during its use, perceptible to the surgeon's

touch, preventing her/him from continuing the procedure without proper cooling. The rotation mechanism of these instruments heats up, as a result of friction, when used for long periods of time. Such heating, obtained as an intercurrence in three of our procedures, is easily overcome when we irrigate the device externally with saline, which cools it and makes it fit to be used again.

Still according to Del Piñal et al.,[13] the dry technique has a learning curve not only to overcome the difficulties secondary to vision and overshadow, but because some signs and findings differ from those observed in the classical technique. These differences between the two techniques do not prevent a surgeon familiar with the classical arthroscopy technique from rapidly incorporating the dry technique and benefiting from its advantages. Just as it occurs with any change from a familiar technique to a new one, there is a need to be prepared to accept some frustration at first. We adopted progressive changes until developing and adapting to this operative procedure, making good use of it and obtaining results considered satisfactory.

Del Piñal et al.,[13] in his works, does not mention the technique used to work up the mediocarpic joint, either the dry or classic technique. In our experience, we performed the mediocarpic joint arthroscopies using irrigation with saline solution, through a syringe adapted to scope.

CONCLUSION

Wrist arthroscopy with the dry technique has shown to be a safe procedure to detect and treat wrist pathologies. However, it is understood that this procedure requires a systematic approach, knowledge on the technique, and a learning curve to minimize complications and ensure successful outcomes.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. HBPN (0000-0001-9012-9999)*, SRO (0000-0002-5774-0777)* and FCP (0000-0003-2760-8182)* were the main contributors in drafting the manuscript, performed surgery, followed patients, and gathered clinical data. SRO and FCP, carried out the bibliographic research, active participation in the discussion of results and review of the manuscript. HBPN and NM (0000-0002-1239-7602)* contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

REFERENCES

1. Del Piñal F. Dry arthroscopy and its applications. Hand Clin. 2011;27(3):335-45.
2. Del Piñal F. Technical tips for (dry) arthroscopic reduction and internal fixation of distal radius fractures. J Hand Surg Am. 2011;36(10):1694-705.
3. Slutsky D. Wrist arthroscopy portals. In: Slutsky DJ, Nagle DJ, editors. Techniques in hand and wrist arthroscopy. Amsterdam: Elsevier; 2007; 2-16.
4. Berger RA. Arthroscopic anatomy of the wrist and distal radioulnar joint. Hand Clin. 1999;15(3):393-413.
5. Bain GI, Munt J, Turner PC. New advances in wrist arthroscopy. Arthroscopy. 2008;24(3):355-67.
6. Van Meir N, Degreef I, De Smet L. The volar portal in wrist arthroscopy. Acta Orthop Belg. 2011;77(3):290-3.
7. Slutsky D. Wrist arthroscopy: Portals and procedures. In: Trumble T, editor. Hand surgery update IV. American Society for Surgery of the Hand; 2007; 1-34.
8. Slutsky DJ, Nagle DJ. Wrist arthroscopy: current concepts. J Hand Surg Am. 2008;33(7):1228-44.
9. Rupenian P. Dry arthroscopy of the shoulder. Arthrosc Tech. 2013;24;2(4):e437-40.
10. Bircher E. Die Arthroendoskopie. Zentralbl Chir. 1921;48:1460-1.
11. Levin LS, Rehnke R, Eubanks S. Endoscopic surgery of the upper extremity Hand Clin. 1995;11(1):59-70.
12. Friedlander L, Sundin J. Minimally invasive harvesting of the latissimus dorsi. Plast Reconstr Surg. 1994;94(6):881-4.
13. Del Piñal F, García-Bernal FJ, Pisani D, Regalado J, Ayala H, Studer A. Dry arthroscopy of the wrist: surgical technique. J Hand Surg Am. 2007;32(1):119-23.
14. Del Piñal F. Dry arthroscopy of the wrist: its role in the management of articular distal radius fractures. Scand J Surg. 2008;97(4):298-304.

Ad hoc peer reviewers
Acta Ortopédica Brasileira

"In order to improve the quality of **Acta Ortopédica Brasileira** it is very important to rely on the effective and constant participation of reviewers of such high technic and scientific profile. We acknowledge the collaboration of the professionals listed below during 2017."

Olavo Pires de Camargo

Editor-in-Chief

Adilson Hamaji - Universidade de São Paulo, São Paulo, SP, Brasil;
Adriano Marques de Almeida - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Alberto Naoki Miyazaki - Faculdade de Ciências Médicas da Santa Casa de São Paulo, SP, Brasil;
Alejandro Enzo Cassone – Fundação Centro Médico de Campinas & Centro de Oncologia Infantil Domingo Boldrini, Campinas, SP, Brasil;
Alexandre Fogaça Cristante - Universidade de São Paulo, São Paulo, SP, Brasil;
Alexandre Leme Godoy - Universidade de São Paulo, São Paulo, SP, Brasil;
Alexandre Sadao Iutaka - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, S P, Brasil;
Aloisio Fernandes Bonavides Junior - Escola Superior de Ciências da Saúde, Brasília, DF, Brasil;
Alvaro Baik Cho - Universidade de São Paulo, São Paulo, SP, Brasil;
Américo Zoppi Filho - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Ana Lúcia Lei Munhoz Lima - Faculdade de Ciências Médicas de Santos, Santos, SP, Brasil;
André Ferrari de França Camargo - Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Angélica Alonso Castilho - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Antonio Egydio de Carvalho - Universidade de São Paulo, São Paulo, SP, Brasil;
Arnaldo Amado Ferreira Neto - Universidade de São Paulo, São Paulo, SP, Brasil;
Benno Ejnisman - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Bruno Sergio Ferreira Massa - Instituto de Ortopedia do Hospital das Clinicas de São Paulo, São Paulo, SP, Brasil;
Caio Oliveira D'Elia - Instituto Vita, São Paulo, SP, Brasil;
Camilo Partezani Helito - Instituto de Ortopedia e Traumatologia do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, SP, Brasil;
Carlos Augusto Malheiros Luzo - Universidade de São Paulo, São Paulo, SP, Brasil;
Carlos Eduardo Algaves Soares Oliveira - Hospital dos Servidores Públicos Estadual, São Paulo, SP, Brasil;
Carlos Eduardo Sanchez Vaz - Universidade Estadual de Londrina, Paraná, PR, Brasil;
Cláudia Regina G. C. M. de Oliveira - Universidade de São Paulo, São Paulo, SP, Brasil;
Consuelo Junqueira - Universidade de São Paulo, São Paulo, SP, Brasil;
Danilo Masiero - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Edgard de Novaes França Bisneto - Universidade de São Paulo, São Paulo, SP, Brasil;
Edilson Forlin - Hospital de Clínicas Universidade Federal do Paraná, Curitiba, PR, Brasil;
Edmilson Takata - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Eduardo Angelini Malavolta - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Eduardo Benegas - Universidade de São Paulo, São Paulo, SP, Brasil;
Eduardo de Souza Meirelles - Universidade de São Paulo, São Paulo, SP, Brasil;
Eloisa Silva Dutra Oliveira Bonfá - Universidade de São Paulo, São Paulo, SP, Brasil;
Emerson Kiyoshi Honda - Irmandade da Santa Casa de Misericórdia de São Paulo, São Paulo, SP, Brasil;
Emygdio Jose Leomil de Paula - Universidade de São Paulo, São Paulo, SP, Brasil;
Eneida Ritsuko Ono Kageyama - Departamento de Ortopedia e Traumatologia – HCFMUSP, São Paulo, SP Brasil;
Fabiano Inácio de Souza - Pontifícia Universidade Católica de Goiás, Goiânia, GO, Brasil;
Fabio Anauate Nicolao – Universidade de Santo Amaro, São Paulo, SP, Brasil;
Fábio Batista - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Fernando Brandao de Andrade Silva - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Flavio Moral Turíbio - Hospital Santa Marcelina, São Paulo, SP, Brasil;
Flavio Robert Sant'Ana - Escola Bahiana de Medicina, Salvador, BA, Brasil;
Geraldo Sérgio de Mello Granata Júnior - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Giancarlo Cavalli Polesello - Irmandade da Santa Casa de Misericórdia de São Paulo, São Paulo, SP, Brasil;
Gilberto Hiroshi Ohara - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Guilherme Carlos Brech - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Gustavo Constantino de Campos - Hospital de Clínicas da Universidade Estadual de Campinas, Campinas, SP, Brasil;
Gustavo Trigueiro - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Henrique Antonio Berwanger de Amorim Cabrita - Universidade de São Paulo, São Paulo, SP, Brasil;
Henrique Melo de Campos Gurgel - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Ibsen Coimbra - Universidade Estadual de Campinas, Campinas, SP, Brasil;
Itiro Suzuki - Universidade de São Paulo, São Paulo, SP, Brasil;
Jamil Natour - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
João Antonio Matheus Guimarães - Instituto Nacional de Traumatologia e Ortopedia, Belo Horizonte, MG, Brasil;
João Baptista Gomes dos Santos - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
João Carlos Belotti - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Jorge Mitsuo Misuzaki - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
José Ricardo Negreiros Vicente - Universidade de São Paulo, São Paulo, SP, Brasil;
José Ricardo Pécora - Universidade de São Paulo, São Paulo, SP, Brasil;
Julia Maria D'Andrea Greve - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Leandro Ejnisman - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Lindomar Guimarães Oliveira - Universidade Federal de Goiás, Goiânia, GO, Brasil;
Luciano Miller Reis Rodrigues - Faculdade de Medicina do ABC, Santo André, SP, Brasil;
Luiz Augusto Ubirajara Santos - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Luiz Carlos Ribeiro Lara - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Luiz Eduardo Passarelli Tirico - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Luiz Koiti Kimura - Universidade de São Paulo, São Paulo, SP, Brasil;
Marcelo Bordalo Rodrigues - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Marcelo Rosa Rezende - Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Marcelo Wajchenberg - Universidade Federal de São Paulo, São Paulo, SP, Brasil; Hospital Israelita Albert Einstein, São Paulo, SP, Brasil;
Márcia Uchoa de Rezende - Universidade de São Paulo, São Paulo, SP, Brasil;
Marcio Passini Gonçalves de Souza - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Marco Antonio Castro Veado - Faculdade de Ciências Médicas de Minas Gerais, Belo Horizonte, MG, Brasil;
Marco Kawamura Demange - Universidade de São Paulo, São Paulo, SP, Brasil;
Marcos de Camargo Leonhardt - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Marcos Hideyo Sakaki - Universidade de São Paulo, São Paulo, SP, Brasil;
Marcos Korukian - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Mario Carneiro Filho - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Marta Imamura - Universidade de São Paulo, São Paulo, SP, Brasil;
Mauricio Kfuri Junior - Faculdade de Medicina de Ribeirão Preto, Ribeirão Preto, SP, Brasil;
Mauro dos Santos Volpi - Universidade Estadual Paulista Júlio de Mesquita Filho, Botucatu, SP, Brasil;
Mauro Emilio Conforto Gracitelli - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Natália Mariana Silva Luna - Universidade Federal de São Carlos, São Paulo, SP, Brasil;
Nei Botter Montenegro - Universidade de São Paulo, São Paulo, SP, Brasil;
Nelson Elias - Universidade do Estado do Rio de Janeiro, Rio de Janeiro, RJ, Brasil;
Neylor Lasmar - Faculdade de Ciências Médicas de Minas Gerais, Belo Horizonte, MG, Brasil;
Nilson Roberto Severino - Irmandade da Santa Casa de Misericórdia de São Paulo, São Paulo, SP, Brasil;
Olavo Biraghi Letaif - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Patricia Moreno Granjeiro - Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Paulo Gilberto Cimbalista de Alencar - Universidade Federal do Paraná, Curitiba, PR, Brasil;
Paulo Sérgio dos Santos - Universidade Federal do Paraná, Curitiba, PR, Brasil;
Pérola Grinberg Plapler - Universidade de São Paulo, São Paulo, SP, Brasil;
Rafael Trevisan Ortiz - Universidade de São Paulo, São Paulo, SP, Brasil;
Ralph Walter Christian - Irmandade da Santa Casa de Misericórdia de São Paulo, São Paulo, SP, Brasil;
Raphael Martus Marcon - Universidade de São Paulo, São Paulo, SP, Brasil;
Raul Bolliger Neto - Universidade de São Paulo, São Paulo, SP, Brasil;
Reginaldo Perilo Oliveira - Universidade de São Paulo, São Paulo, SP, Brasil;
Rene Jorge Abdalla - Hospital do Coração, São Paulo, SP, Brasil;
Renée Zon Filippi - Universidade de São Paulo, São Paulo, SP, Brasil;
Ricardo Fuller - Universidade de São Paulo, São Paulo, SP, Brasil;
Roberto Dantas Queiroz - Universidade Federal de São Paulo, São Paulo, SP, Brasil;
Roberto Freire da Mota e Albuquerque - Universidade de São Paulo, São Paulo, SP, Brasil;
Roberto Guarniero - Universidade de São Paulo, São Paulo, SP, Brasil;
Roberto Yukio Ikemoto - Faculdade de Medicina do ABC, Santo André, SP, Brasil;
Rodrigo Bezerra de Menezes Reiff - Universidade de São Paulo, São Carlos, SP, Brasil;
Rogério Fuchs - Universidade Federal do Paraná, Curitiba, PR, Brasil;
Rômulo Brasil Filho - Hospital do Servidor Público Municipal, São Paulo, SP, Brasil;
Ronald Bispo Barreto - Universidade Tiradentes, Sergipe, Alagoas, Brasil;
Rui Maciel de Godoy Junior - Universidade de São Paulo, São Paulo, SP, Brasil;
Sérgio Augusto Xavier - Serviço Social da Indústria - São Paulo, SP, Brasil;
Sergio Yoshimasa Okane - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Teng Hsiang Wei - Universidade de São Paulo, São Paulo, SP, Brasil;
Teng Hsiang Wei - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Tiago Lazaretti Fernandes - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Valter Penna - Hospital de Câncer de Barretos, Barretos, SP, Brasil;
Vladimir Cordeiro de Carvalho - Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Walter Cintra Ferreira Junior - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brasil;
Wu Tu Hsing - Universidade de São Paulo, São Paulo, SP, Brasil.

acheflan

Cordia verbenacea DC. 5 mg

alfa-humuleno*

SUPERIORIDADE
ao diclofenaco dietilamônio tópico[2**]

DOR CRÔNICA
Eficaz no tratamento de tendinite crônica e dor miofascial[2,3]

DOR AGUDA
excelente eficácia em casos de afecções musculoesqueléticas[2,3**]

INTEGRIDADE
As vibrações do US (fonoforese) não alteram os princípios ativos[4,5]

1º MEDICAMENTO 100% BRASILEIRO[1]

Pesquisa e Desenvolvimento Aché em Parceria com CPQBA UNICAMP

*Equivalente a 0,130mg de alfa-humuleno[6,7]
**Considerada superior ao diclofenaco dietilamônio nos casos de tendinite crônica[3]

Referências Bibliográficas: 1) REDETEC. Acheflan. Disponível em:<http://www.redetec.org.br/inventabrasil/acheflan.htm>. Acesso em: Julho 2014.2) BRANDÃO, D.C. et al. Estudo fase III, duplo-cego, aleatório, comparativo para avaliar a eficácia e tolerabilidade da Córdia verbanácea e do diclofenaco dietilamônio, em pacientes portadores de contusões, entorses, traumas e lesões musculares, com início inferior a 24 horas. Rev. Bras. Med., v.63, n. 8, p. 408-415, 2006. 3) REFSIO, C. et al. Avaliação da eficácia e segurança do uso de estrato padronizado da Cordia verbenacea em pacientes portadores de tendinite e dor miofascial. Rev. Bras. Medc., v. 62, n. 1/2, 2015. 4) SHIMIDT, K.B; LIANZA, S. Teste de condução de ondas ultrassônicas pelo fitomedicamento creme de Cordia verbanacea. Med Reabil, v. 29, n. 3, p. 65-8, 2010. 5) OLIVEIRA JÚNIOR, E.M. et al. Estudo piloto de avaliação da influência do ultrsom na estabilidade do alfa-humuleno e trans-cariofileno presentes no fitomedicamento anti-inflamatório, creme de Cordia verbenacea 5mg/g. Med Reabil, v. 25, n. 2, p. 50-4, 2006. 6) Bula do produto ACHEFLAN: creme. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 7) Bula do produto ACHEFLAN: aerossol. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A.

CONTRAINDICAÇÕES: INDIVÍDUOS SENSÍVEIS A CORDIA VERBENACEA DC. OU A QUALQUER COMPONENTE DA FÓRMULA. INTERAÇÕES MEDICAMENTOSAS: NÃO HOUVE RELATO DE INTERAÇÃO MEDICAMENTOSA NOS ESTUDOS CONDUZIDOS PARA AVALIAÇÃO DO ACHEFLAN.

ACHEFLAN. Cordia verbenacea DC - MS - 1.0573.0341. **Indicações: ACHEFLAN** é indicado nas seguintes situações: tendinites, afecções músculo-esqueléticas associadas à dor e inflamação, como dor miofascial (como dorsalgia e lombalgia), em quadros inflamatórios dolorosos associados a traumas de membros, entorses e contusões. **Contra-indicações: ACHEFLAN é contra-indicado nas seguintes situações: Indivíduos sensíveis a *Cordia verbenacea DC.* ou a qualquer componente da fórmula. Ocorrência de soluções de continuidade (feridas, queimaduras, lesões infeccionadas, etc). Advertências: ACHEFLAN** É PARA USO EXTERNO E NÃO DEVE SER INGERIDO. NÃO DEVE SER UTILIZADO ASSOCIADO A OUTROS PRODUTOS DE USO TÓPICO. RARAMENTE PODE CAUSAR AUMENTO DA SENSIBILIDADE LOCAL. TESTES REALIZADOS EM ANIMAIS INDICAM QUE **ACHEFLAN** NÃO APRESENTA ATIVIDADE IRRITANTE NA MUCOSA OCULAR. ENTRETANTO, RECOMENDA-SE LAVAR ABUNDANTEMENTE O LOCAL COM ÁGUA EM CASO DE CONTATO COM OS OLHOS. **Uso em idosos, crianças e outros grupos de risco:** não existe experiência clínica sobre o uso de **ACHEFLAN** em idosos, crianças abaixo de 12 anos, gestantes e lactantes. **Gravidez e lactação:** categoria de risco na gravidez C: Não foram realizados estudos em animais prenhes e nem em mulheres grávidas. "ESTE MEDICAMENTO NÃO DEVE SER UTILIZADO DURANTE A GESTAÇÃO OU AMAMENTAÇÃO SEM ORIENTAÇÃO MÉDICA". **Interações medicamentosas:** não houve relato de interação medicamentosa nos estudos conduzidos para avaliação do **ACHEFLAN**. Entretanto sua associação a outros fármacos deverá ser avaliada pelo médico. **Reações adversas:** O USO DE **ACHEFLAN** NÃO ESTÁ ASSOCIADO A RELATO DE REAÇÕES ADVERSAS. RARAMENTE PODE CAUSAR AUMENTO DA SENSIBILIDADE LOCAL. "ATENÇÃO: ESTE É UM MEDICAMENTO NOVO E, EMBORA AS PESQUISAS TENHAM INDICADO EFICÁCIA E SEGURANÇA ACEITÁVEIS PARA COMERCIALIZAÇÃO, EFEITOS INDESEJÁVEIS E NÃO CONHECIDOS PODEM OCORRER. NESTE CASO, INFORME SEU MÉDICO." **Posologia:** aplicação tópica, sobre a pele íntegra, de 8 em 8 horas. A duração do tratamento varia conforme a afecção que se pretende tratar. Nos ensaios clínicos a duração do tratamento variou entre 1 a 2 semanas podendo ser prolongado até 4 semanas. Farmacêutica Responsável: Gabriela Mallmann - CRF-SP nº 30.138. **VENDA SOB PRESCRIÇÃO MÉDICA.** MB03 SAP 4052805 e SAP 4053004

CAC Central de Atendimento a Clientes
0800 701 6900
cac@ache.com.br
8:00 h às 17:00 h (seg. a sex.)

Campanha RESPEITO PELA PRESCRIÇÃO E PELA ADESÃO AO TRATAMENTO achē

Material técnico-científico de distribuição exclusiva à classe médica.

achē
mais vida para você

Referências Bibliográficas:1. Internal Report – CLOSE UP Junho/2017.

Contraindicação: Hipersensibilidade a qualquer dos componentes da fórmula. Interação Medicamentosa: A administração concomitante de glicocorticóides e outros agentes anti-inflamatórios não-esteróides pode levar ao agravamento de reações adversas gastrintestinais.

TANDRILAX é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

TANDRILAX (cafeína 30 mg / carisoprodol 125 mg / diclofenaco sódico 50 mg / paracetamol 300 mg) Comprimidos. USO ORAL. USO ADULTO. Indicações: Tratamento de reumatismo nas suas formas inflamatório-degenerativas agudas e crônicas; crises agudas de gota, estados inflamatórios agudos, pós-traumáticos e pós-cirúrgicos. Exacerbações agudas de artrite reumatóide e osteo-artrose e estados agudos de reumatismo nos tecidos extra-articulares e como coadjuvante em processos inflamatórios graves decorrentes de quadros infecciosos. **Contraindicações: Nos casos de úlcera péptica em atividade; hipersensibilidade a quaisquer dos componentes de sua fórmula; discrasias sanguíneas; diáteses hemorrágicas (trombocitopenia, distúrbios da coagulação), porfiria; insuficiência cardíaca, hepática ou renal grave; hipertensão grave. É contra-indicado em pacientes asmáticos nos quais são precipitados acessos de asma, urticária ou rinite aguda pelo ácido acetilsalicílico e demais inibidores da via da cicloxigenase da síntese de prostaglandinas. Precauções e Advertências: O uso em pacientes idosos, geralmente mais sensíveis aos medicamentos, deve ser cuidadosamente observado. Desaconselha-se o uso do TANDRILAX durante a gravidez e lactação. A possibilidade de reativação de úlceras pépticas requer anamnese cuidadosa quando houver história pregressa de dispepsia, hemorragia gastrintestinal ou úlcera péptica. Nas indicações do TANDRILAX por períodos superiores a dez dias, deverá ser realizado hemograma e provas de função hepática antes do início do tratamento e, periodicamente, a seguir. A diminuição da contagem de leucócitos e/ou plaquetas, ou do hematócrito requer a suspensão da medicação. Em pacientes portadores de doenças cardiovasculares, a possibilidade de ocorrer retenção de sódio e edema deverá ser considerada. Observando-se reações alérgicas pruriginosas ou eritematosas, febre, icterícia, cianose ou sangue nas fezes, a medicação deverá ser imediatamente suspensa. Não use outro produto que contenha paracetamol. Não é indicado para crianças abaixo de 14 anos, com exceção de casos de artrite juvenil crônica. Interações medicamentosas:** O diclofenaco sódico, constituinte do TANDRILAX, pode elevar a concentração plasmática de lítio ou digoxina, quando administrado concomitantemente com estas preparações. Alguns agentes antiinflamatórios não-esteróides são responsáveis pela inibição da ação de diuréticos da classe da furosemida e pela potenciação de diuréticos poupadores de potássio, sendo necessário o controle periódico dos níveis séricos de potássio. A administração concomitante de glicocorticóides e outros agentes antiinflamatórios não-esteróides pode levar ao agravamento de reações adversas gastrintestinais. A biodisponibilidade do TANDRILAX é alterada pelo ácido acetilsalicílico quando este composto é administrado conjuntamente. Recomenda-se a realização de exames laboratoriais periódicos quando anticoagulantes forem administrados juntamente com TANDRILAX, para aferir se o efeito anticoagulante desejado está sendo mantido. Pacientes em tratamento com metotrexato devem abster-se do uso do TANDRILAX nas 24 horas que antecedem ou que sucedem sua ingestão, uma vez que a concentração sérica pode elevar-se, aumentando a toxicidade deste quimioterápico. **Reações adversas: Distúrbios gastrintestinais como dispepsia, dor epigástrica, recorrência de úlcera péptica, náuseas, vômitos e diarréia. ocasionalmente, podem ocorrer cefaléia, sonolência, confusão mental, tonturas, distúrbios da visão, edema por retenção de eletrólitos, hepatite, pancreatite, nefrite intersticial. Foram relatadas raras reações anafilactóides urticariformes ou asmatiformes bem como síndrome de stevens-johnson e síndrome de lyell, além de leucopenia, trombocitopenia, pancitopenia, agranulocitose e anemia aplástica. o uso prolongado pode provocar necrose papilar renal. TANDRILAX é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas. Posologia:** A dose mínima diária recomendada é de um comprimido a cada 12 horas e a duração do tratamento deve ser a critério médico e não deverá ultrapassar 10 dias. Tratamentos mais prolongados requerem observações especiais (vide "Precauções"). Os comprimidos do TANDRILAX deverão ser ingeridos inteiros (sem mastigar), às refeições, com auxílio de líquido. "SE PERSISTIREM OS SINTOMAS O MÉDICO DEVERÁ SER CONSULTADO." VENDA SOB PRESCRIÇÃO MÉDICA - MS - 1.0573.0055 - MB 08 - SAP 4104203

CAC
Central de Atendimento a Clientes
0800 701 6900
cac@ache.com.br
8:00 h às 17:00 h (seg. a sex.)

osteo muscular

MATERIAL TÉCNICO-CIENTÍFICO DE DISTRIBUIÇÃO EXCLUSIVA À CLASSE MÉDICA.

achê
mais vida para você

ALÍVIO COM[1,2]

dorene pregabalina

Rápido, eficaz e seguro no tratamento da fibromialgia.[3]

Redução da dor
a partir da primeira semana de tratamento na fibromialgia[4]

A pregabalina é eficaz
em reduzir a dor dos pacientes com fibromialgia[5]

Melhora da disfunção do sono
relacionada à fibromialgia.[6]
Grande parte desse benefício foi devido:[6]

- Efeito da pregabalina na insônia[6]
- Atividade analgésica do medicamento[6]

Referências Bibliográficas: 1) TOLLE, T. et al. Pregabalin for relief of neuropathic pain associated with diabetic neuropathy: a randomized, double-blind study. European Journal of Pain, v. 12, n. 2, p. 203-213, 2008. 2) OHTA, H. et al. A randomized, double-blind, multicenter, placebo-controlled phase III trial to evaluate the efficacy and safety of pregabalin in Japanese patients with fibromyalgia. Arthritis Research & Therapy, v. 14, N. 217, 2012. 3) BOOMERSHINE, C. S. Pregabalin for the management of fibromyalgia syndrome. Journal of Pain Research, v. 3, p. 81-88, 2010. 4) PAUER, L. et al. An international, randomized, double-blind, placebo-controled, phase III trial of pregabalin monotherapy in treatment of patients with fibromyalgia. J Rheumatol, v. 38, n. 12, p. 2643-2652, 2011. 5) HEYMANN, R.E. et al. Consenso Brasileiro do tratamento da fibromialgia. Rev Bras Reumatol, v. 50, n.1, p.56-66, 2010. - A pregabalina é eficaz em reduzir a dor dos pacientes com fibromialgia (grau de recomendação A, nível de evidência 1b. Página 60, coluna 1, 5º parágrafo. - Consenso brasileiro do tratamento da fibromialgia, que indica a pregabalina no tratamento da fibromialgia com grau de recomendação A e nível de evidência 1B. 6) RUSSELL, I.J. et al. The effects of pregabalin on sleep disturbance symptoms among individuals with fibromyalgia syndrome. Sleep Med., v. 10, n. 6, p. 604-610, 2009.

DORENE (pregabalina) 75 mg e 150 mg. Cápsula. USO ORAL. USO ADULTO E PEDIÁTRICO ACIMA DE 12 ANOS (vide Indicações). Indicações: Dor Neuropática; Epilepsia; Transtorno de Ansiedade Generalizada (TAG); Fibromialgia. Contraindicações: Dorene é contraindicado a pacientes com hipersensibilidade conhecida à pregabalina ou a qualquer componente da fórmula. Precauções e advertências: **Pacientes com problemas hereditários raros de intolerância a galactose, deficiência de lactase ou má- absorção de glicose-galactose não devem utilizar pregabalina cápsulas. Alguns pacientes diabéticos sob tratamento com pregabalina que obtiverem ganho de peso podem necessitar de ajuste da medicação hipoglicêmica. Houve relatos de reações de hipersensibilidade, incluindo casos de angioedema. Pregabalina deve ser descontinuado imediatamente se ocorrerem sintomas de angioedema, tais como edema facial, perioral ou da via aérea superior. O tratamento com pregabalina está associado com tontura e sonolência, que pode aumentar a ocorrência de acidentes (queda) na população idosa. Pacientes devem ser alertados para ter cautela até que os efeitos potenciais de pregabalina sejam familiares. Visão borrada transitória e outras alterações na acuidade visual foram reportadas por pacientes tratados com pregabalina. A descontinuação da pregabalina pode resultar na resolução ou melhora desses sintomas visuais. Foram observados sintomas de retirada em alguns pacientes após a descontinuação do tratamento prolongado e de curto prazo com pregabalina. Os seguintes eventos foram mencionados: insônia, dor de cabeça, náusea, ansiedade, hiperidrose e diarreia (vide item Reações Adversas). Como é o caso com qualquer droga ativa do SNC, deve-se avaliar cuidadosamente o histórico de pacientes quanto ao abuso de drogas e observá-los quanto a sinais de abuso da pregabalina. Foi relatada melhora da função renal após a descontinuação ou redução da dose de pregabalina. Houve relatos pós-comercialização de insuficiência cardíaca congestiva em alguns pacientes recebendo pregabalina. Devido aos dados limitados de pacientes com insuficiência cardíaca congestiva grave, Dorene deve ser administrado com cautela nesses pacientes (vide item 9. Reações Adversas).** Efeitos sobre a Habilidade de Dirigir e Operar Máquinas: Dorene pode produzir tontura e sonolência que, portanto, podem prejudicar a habilidade de dirigir e operar máquinas. Os pacientes devem ser aconselhados a não dirigir, operar máquinas complexas, ou se engajar em outras atividades potencialmente perigosas até que se saiba se este medicamento afeta a sua capacidade de executar tais atividades. Uso em Idosos, Crianças e Outros Grupos de Risco: Vide item Posologia. **Gravidez e lactação: Uso durante a Gravidez:** Não há dados adequados sobre o uso de pregabalina em mulheres grávidas. Estudos em animais mostraram toxicidade reprodutiva. O risco potencial a humanos é desconhecido. Portanto, Dorene não deve ser utilizado durante a gravidez. Métodos contraceptivos eficazes devem ser utilizados por mulheres com potencial de engravidar. **A pregabalina é um medicamento classificado na categoria C de risco de gravidez. Portanto, este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. Uso durante a Lactação:** Não se sabe se a pregabalina é excretada no leite materno de humanos. Entretanto, está presente no leite de ratas. Portanto, a amamentação não é recomendada durante o tratamento com Dorene. **Interações medicamentosas:** A pregabalina provavelmente não inibe o metabolismo de fármacos ***in vitro*** e nem se liga a proteínas plasmáticas. A pregabalina pode potencializar os efeitos do etanol e lorazepan. A pregabalina parece ser aditiva no prejuízo da função cognitiva e coordenação motora grosseira causado pela oxicodona. Em experiência pós-comercialização, houve relatos de insuficiência respiratória e coma em pacientes sob tratamento de pregabalina e outros medicamentos antidepressivos do SNC. Há relatos pós-comercialização de eventos relacionados à redução da função do trato gastrintestinal inferior (por ex., obstrução intestinal, íleo paralítico, constipação) quando a pregabalina foi coadministrada com medicamentos que têm o potencial para produzir constipação, tais como analgésicos opioides. Não foram conduzidos estudos de interação farmacodinâmica específica em voluntários idosos. **Reações adversas: As reações adversas mais comuns foram tontura e sonolência, em geral, de intensidade leve a moderada. As reações adversas comuns foram: Aumento de apetite, Confusão, desorientação, irritabilidade, humor eufórico, diminuição da libido, insônia, Ataxia, coordenação anormal, transtorno de equilíbrio, amnésia, distúrbios de atenção, dificuldade de memória, tremores, disartria, parestesia, sedação, letargia, Visão turva, diplopia, Vertigem, Vômitos, distensão abdominal, constipação, boca seca, flatulência, disfunção erétil, edema periférico, edema, marcha anormal, sensação de embriaguez, sensação anormal, fadiga e aumento de peso. As seguintes reações adversas foram relatadas durante a pós-comercialização: Sistema imune: angioedema, reação alérgica, hipersensibilidade. Sistema nervoso: dor de cabeça, perda de consciência, prejuízo mental.** Oftalmológicos: *cegueira*. Cardíacos: insuficiência cardíaca congestiva. Respiratório e torácico: edema pulmonar. Gastrintestinais: edema de língua, diarreia, náusea. Pele e tecido subcutâneo: inchaço da face, prurido. Renais e urinários: retenção urinária. Reprodutor e mamas: ginecomastia. Geral: mal-estar. Idosos (acima de 65 anos de idade). Num total de 938 pacientes idosos, não foram observadas diferenças quanto a segurança geral, em comparação aos pacientes com menos de 65 anos de idade. **Posologia:** Dorene deve ser utilizado por via oral, com ou sem alimentos. Cada cápsula de Dorene contém 75 mg ou 150 mg de pregabalina. **Dor Neuropática:** A dose inicial recomendada de Dorene é de 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos. Para a maioria dos pacientes, 150 mg duas vezes ao dia é a dose ideal. Com base na resposta individual e na tolerabilidade do paciente, a dose poderá ser aumentada para 150 mg duas vezes ao dia após um intervalo de 3 a 7 dias e, se necessário, até uma dose máxima de 300 mg duas vezes ao dia após mais uma semana. **Epilepsia:** A dose inicial recomendada de Dorene é de 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos. Com base na resposta e tolerabilidade individuais do paciente, a dose poderá ser aumentada para 150 mg duas vezes ao dia após 1 semana. A dose máxima de 300 mg duas vezes ao dia pode ser atingida após mais 1 semana. **Transtorno de Ansiedade Generalizada (TAG):** A dose varia de 150 a 600 mg/dia, divididas em duas ou três doses. A necessidade para o tratamento deve ser reavaliada regularmente. **Fibromialgia:** A dose recomendada de Dorene é de 300 a 450 mg/dia. A dose deve ser iniciada com 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos, e a dose pode ser aumentada para 150 mg duas vezes ao dia (300 mg/dia) em uma semana baseado na eficácia e tolerabilidade individuais. **Descontinuação do Tratamento:** Se Dorene for descontinuado, recomenda-se que isto seja feito gradualmente durante no mínimo 1 semana. **Uso em Pacientes com Insuficiência Renal:** A redução da dosagem em pacientes com a função renal comprometida deve ser individualizada de acordo com o **clearance** de creatinina. Para pacientes submetidos à hemodiálise, a dose diária de Dorene deve ser ajustada com base na função renal. Além da dose diária, uma dose suplementar deve ser administrada imediatamente após cada tratamento de 4 horas de hemodiálise. **Uso em Pacientes com Insuficiência Hepática:** Nenhum ajuste de dose é necessário para pacientes com insuficiência hepática. **Uso em Crianças:** A segurança e a eficácia de pregabalina em pacientes pediátricos abaixo de 12 anos de idade ainda não foram estabelecidas. O uso em crianças não é recomendado. **Uso em Adolescentes (12 a 17 anos de idade):** Pacientes adolescentes com epilepsia podem receber a dose como adultos. A segurança e a eficácia de pregabalina em pacientes abaixo de 18 anos de idade com dor neuropática não foram estabelecidas. **Uso em Pacientes Idosos (acima de 65 anos de idade):** Pacientes idosos podem necessitar de redução da dose de Dorene devido à diminuição da função renal. **Dose Omitida:** Caso o paciente esqueça de tomar Dorene no horário estabelecido, deve tomá-lo assim que lembrar. Entretanto, se já estiver perto do horário de tomar a próxima dose, deve desconsiderar a dose esquecida e tomar a próxima. **Este medicamento não pode ser partido, aberto ou mastigado.** SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. **VENDA SOB PRESCRIÇÃO MÉDICA. SÓ PODE SER VENDIDO COM RETENÇÃO DA RECEITA.** MS - 1.0573.0457. **MB 02_VP SAP 4475900.**

Contraindicações: Dorene não deve ser utilizado se você tem hipersensibilidade (alergia) conhecida à pregabalina ou a qualquer componente da fórmula.
Interações medicamentosas: A pregabalina pode potencializar o efeito da oxicodona (analgésico), bebidas alcoólicas e de lorazepam (tranquilizante).

DORENE é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

CAC
0800 701 6900
cac@ache.com.br
8:00 h às 17:00 h (seg. a sex.)

Campanha RESPEITO PELA PRESCRIÇÃO E PELA ADESÃO AO TRATAMENTO
achê

snc

MATERIAL TÉCNICO CIENTÍFICO DE DISTRIBUIÇÃO EXCLUSIVA À CLASSE MÉDICA.
REVISTAS ACTAS DORENE CL.4 2017

achê
mais vida para você

Referências Bibliográficas: 1. 1. Internal Report. Dados de auditoria IMS Health. Fevereiro/2017. **2.** Internal Report. Dados de auditoria IMS-PMB. Fevereiro/2017. **3.** Bula do produto ARTROLIVE: cápsulas. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **4.** Bula do produto ARTROLIVE: granulado em sachê. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **5.** MARTEL-PELLETIER, J. et al. First-line analysis of the effects of treatment on progression of structural changes in knee osteoarthritis over 24 months: data from the osteoarthritis initiative progression cohort. Ann Rheum Dis, v. 74, n. 3, p. 547-556, 2015.

Contraindicação: Pacientes que apresentem hipersensibilidade a quaisquer dos componentes de sua fórmula. Interação medicamentosa: É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com Artrolive.

ARTROLIVE CAPS. sulfato de glicosamina + sulfato de condroitina. MS – 1.0573.0286. **INDICAÇÕES: ARTROLIVE** é indicado para osteoartrite, osteoartrose ou artrose em todas as suas manifestações. **CONTRAINDICAÇÕES: ARTROLIVE** É CONTRAINDICADO EM PACIENTES QUE APRESENTEM HIPERSENSIBILIDADE A QUAISQUER DOS COMPONENTES DE SUA FÓRMULA, GRAVIDEZ E LACTAÇÃO. **PRECAUÇÕES E ADVERTÊNCIAS:** SÃO NECESSÁRIOS O DIAGNÓSTICO PRECISO E O ACOMPANHAMENTO CUIDADOSO DE PACIENTES COM SINTOMAS INDICATIVOS DE AFECÇÃO GASTRINTESTINAL, HISTÓRIA PREGRESSA DE ÚLCERA GÁSTRICA OU INTESTINAL, DIABETES MELLITUS, OU A CONSTATAÇÃO DE DISTÚRBIOS DO SISTEMA HEMATOPOIÉTICO OU DA COAGULAÇÃO SANGUÍNEA ASSIM COMO PORTADORES DE INSUFICIÊNCIA DAS FUNÇÕES RENAL, HEPÁTICA OU CARDÍACA. SE OCORRER EVENTUALMENTE ULCERAÇÃO PÉPTICA OU SANGRAMENTO GASTRINTESTINAL EM PACIENTES SOB TRATAMENTO, A MEDICAÇÃO DEVERÁ SER SUSPENSA IMEDIATAMENTE. DEVIDO À INEXISTÊNCIA DE INFORMAÇÕES TOXICOLÓGICAS DURANTE O PERÍODO GESTACIONAL, **ARTROLIVE** NÃO ESTÁ INDICADO PARA SER UTILIZADO DURANTE A GRAVIDEZ. NÃO EXISTEM INFORMAÇÕES SOBRE A PASSAGEM DO MEDICAMENTO PARA O LEITE MATERNO SENDO DESACONSELHADO SEU USO NESSAS CONDIÇÕES E AS LACTANTES SOB TRATAMENTO NÃO DEVEM AMAMENTAR. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. FORAM RELATADOS POUCOS CASOS DE PROTEINÚRIA LEVE E AUMENTO DA CREATINO-FOSFOQUINASE (CPK) DURANTE TRATAMENTO COM GLICOSAMINA E CONDROITINA, QUE VOLTARAM AOS NÍVEIS NORMAIS APÓS INTERRUPÇÃO DO TRATAMENTO. **INTERAÇÕES MEDICAMENTOSAS:** O tratamento concomitante com antiinflamatórios não-esteroidais pode incorrer no agravamento de reações adversas do sistema gastrintestinal, sendo recomendado um acompanhamento médico mais rigoroso nesses casos. Alguns autores da literatura médica descrevem que o uso de glicosamina e condroitina pode incorrer em um aumento da resistência à insulina, porém, esses estudos foram realizados com doses muito superiores às indicadas na terapêutica clínica normal e sua validade ainda é discutida por vários outros autores. Estudos recentes demonstraram que a associação condroitina e glicosamina, quando empregada em pacientes portadores de diabetes mellitus tipo II, não levou a alterações no metabolismo da glicose. Os resultados destes estudos não podem ser extrapolados para pacientes com diabetes mellitus descompensado ou não-controlado. É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com **ARTROLIVE**. O uso concomitante de **ARTROLIVE** com os inibidores da topoisomerase II (etoposídeo, teniposídeo e doxorrubicina) deve ser evitado, uma vez que a glicosamina induziu resistência in vitro a estes medicamentos em células humanas cancerosas de cólon e de ovário. O tratamento concomitante de **ARTROLIVE** com anticoagulantes como o acenocoumarol, dicumarol, heparina e varfarina, pode levar ao aumento das chances de sangramento, devido a alterações nos valores de INR (International Normalized Ratio). Há relato de um caso na literatura de potencialização do efeito da varfarina, com consequente aumento dos valores sanguíneos de INR. Portanto, o uso concomitante de **ARTROLIVE** com anticoagulantes orais deve levar em conta avaliações rigorosas do INR. **Reações adversas: SISTEMA CARDIOVASCULAR:** EDEMA PERIFÉRICO E TAQUICARDIA. JÁ FORAM RELATADOS COM O USO DA GLICOSAMINA, PORÉM NÃO FOI ESTABELECIDA UMA RELAÇÃO CAUSAL. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **SISTEMA NERVOSO CENTRAL:** MENOS DE 1% DOS PACIENTES EM ESTUDOS CLÍNICOS APRESENTARAM CEFALEIA, INSÔNIA E SONOLÊNCIA NA VIGÊNCIA DO TRATAMENTO COM A GLICOSAMINA. **ENDÓCRINO-METABÓLICO:** ESTUDOS RECENTES DEMONSTRARAM QUE A ASSOCIAÇÃO CONDROITINA E GLICOSAMINA, QUANDO EMPREGADA EM PACIENTES PORTADORES DE DIABETES MELLITUS TIPO II, NÃO LEVOU A ALTERAÇÕES NO METABOLISMO DA GLICOSE. OS RESULTADOS DESTES ESTUDOS NÃO PODEM SER EXTRAPOLADOS PARA PACIENTES COM DIABETES MELLITUS DESCOMPENSADO OU NÃO-CONTROLADO. É RECOMENDÁVEL QUE PACIENTES DIABÉTICOS MONITOREM SEUS NÍVEIS SANGUÍNEOS DE GLICOSE MAIS FREQUENTEMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **GASTRINTESTINAL:** NÁUSEA, DISPEPSIA, VÔMITO, DOR ABDOMINAL OU EPIGÁSTRICA, CONSTIPAÇÃO, DIARREIA, QUEIMAÇÃO E ANOREXIA TÊM SIDO RARAMENTE DESCRITOS NA LITERATURA NA VIGÊNCIA DE TRATAMENTO COM GLICOSAMINA E CONDROITINA. **PELE:** ERITEMA, PRURIDO, ERUPÇÕES CUTÂNEAS E OUTRAS MANIFESTAÇÕES ALÉRGICAS DE PELE FORAM REPORTADAS EM ENSAIOS CLÍNICOS COM GLICOSAMINA. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. **POSOLOGIA: Adultos:** Recomenda-se iniciar a terapêutica com a prescrição de 1 cápsula via oral 3 vezes ao dia. Como os efeitos do medicamento se iniciam em média após a terceira semana de tratamento deve-se ter em mente que a continuidade e a não-interrupção do tratamento são fundamentais para se alcançar os benefícios analgésicos e de mobilidade articular. **SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA.** MB03a SAP4470700. **ARTROLIVE**. 1,5 g sulfato de glicosamina + 1,2 g sulfato de condroitina. MS – 1.0573.0286. **INDICAÇÕES: ARTROLIVE** é indicado para osteoartrite, osteoartrose ou artrose em todas as suas manifestações. **CONTRAINDICAÇÕES: ARTROLIVE** É CONTRAINDICADO EM PACIENTES QUE APRESENTEM HIPERSENSIBILIDADE A QUAISQUER DOS COMPONENTES DE SUA FÓRMULA, GRAVIDEZ E LACTAÇÃO. **PRECAUÇÕES E ADVERTÊNCIAS:** SÃO NECESSÁRIOS O DIAGNÓSTICO PRECISO E O ACOMPANHAMENTO CUIDADOSO DE PACIENTES COM SINTOMAS INDICATIVOS DE AFECÇÃO GASTRINTESTINAL, HISTÓRIA PREGRESSA DE ÚLCERA GÁSTRICA OU INTESTINAL, DIABETES MELLITUS, OU A CONSTATAÇÃO DE DISTÚRBIOS DO SISTEMA HEMATOPOIÉTICO OU DA COAGULAÇÃO SANGUÍNEA ASSIM COMO PORTADORES DE INSUFICIÊNCIA DAS FUNÇÕES RENAL, HEPÁTICA OU CARDÍACA. SE OCORRER EVENTUALMENTE ULCERAÇÃO PÉPTICA OU SANGRAMENTO GASTRINTESTINAL EM PACIENTES SOB TRATAMENTO, A MEDICAÇÃO DEVERÁ SER SUSPENSA IMEDIATAMENTE. DEVIDO À INEXISTÊNCIA DE INFORMAÇÕES TOXICOLÓGICAS DURANTE O PERÍODO GESTACIONAL, **ARTROLIVE** NÃO ESTÁ INDICADO PARA SER UTILIZADO DURANTE A GRAVIDEZ. NÃO EXISTEM INFORMAÇÕES SOBRE A PASSAGEM DO MEDICAMENTO PARA O LEITE MATERNO SENDO DESACONSELHADO SEU USO NESSAS CONDIÇÕES E AS LACTANTES SOB TRATAMENTO NÃO DEVEM AMAMENTAR. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. FORAM RELATADOS POUCOS CASOS DE PROTEINÚRIA LEVE E AUMENTO DA CREATINO-FOSFOQUINASE (CPK) DURANTE TRATAMENTO COM GLICOSAMINA E CONDROITINA, QUE VOLTARAM AOS NÍVEIS NORMAIS APÓS INTERRUPÇÃO DO TRATAMENTO. **INTERAÇÕES MEDICAMENTOSAS:** O tratamento concomitante com antiinflamatórios não-esteroidais pode incorrer no agravamento de reações adversas do sistema gastrintestinal, sendo recomendado um acompanhamento médico mais rigoroso nesses casos. Alguns autores da literatura médica descrevem que o uso de glicosamina e condroitina pode incorrer em um aumento da resistência à insulina, porém, esses estudos foram realizados com doses muito superiores às indicadas na terapêutica clínica normal e sua validade ainda é discutida por vários outros autores. Estudos recentes demonstraram que a associação condroitina e glicosamina, quando empregada em pacientes portadores de diabetes mellitus tipo II, não levou a alterações no metabolismo da glicose. Os resultados destes estudos não podem ser extrapolados para pacientes com diabetes mellitus descompensado ou não-controlado. É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com **ARTROLIVE**. O uso concomitante de **ARTROLIVE** com os inibidores da topoisomerase II (etoposídeo, teniposídeo e doxorrubicina) deve ser evitado, uma vez que a glicosamina induziu resistência in vitro a estes medicamentos em células humanas cancerosas de cólon e de ovário. O tratamento concomitante de **ARTROLIVE** com anticoagulantes como o acenocoumarol, dicumarol, heparina e varfarina, pode levar ao aumento das chances de sangramento, devido a alterações nos valores de INR (International Normalized Ratio). Há relato de um caso na literatura de potencialização do efeito da varfarina, com consequente aumento dos valores sanguíneos de INR. Portanto, o uso concomitante de **ARTROLIVE** com anticoagulantes orais deve levar em conta avaliações rigorosas do INR. **Reações adversas: SISTEMA CARDIOVASCULAR:** EDEMA PERIFÉRICO E TAQUICARDIA JÁ FORAM RELATADOS COM O USO DA GLICOSAMINA, PORÉM NÃO FOI ESTABELECIDA UMA RELAÇÃO CAUSAL. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **SISTEMA NERVOSO CENTRAL:** MENOS DE 1% DOS PACIENTES EM ESTUDOS CLÍNICOS APRESENTARAM CEFALEIA, INSÔNIA E SONOLÊNCIA NA VIGÊNCIA DO TRATAMENTO COM A GLICOSAMINA. **ENDÓCRINO-METABÓLICO:** ESTUDOS RECENTES DEMONSTRARAM QUE A ASSOCIAÇÃO CONDROITINA E GLICOSAMINA, QUANDO EMPREGADA EM PACIENTES PORTADORES DE DIABETES MELLITUS TIPO II, NÃO LEVOU A ALTERAÇÕES NO METABOLISMO DA GLICOSE. OS RESULTADOS DESTES ESTUDOS NÃO PODEM SER EXTRAPOLADOS PARA PACIENTES COM DIABETES MELLITUS DESCOMPENSADO OU NÃO-CONTROLADO. É RECOMENDÁVEL QUE PACIENTES DIABÉTICOS MONITOREM SEUS NÍVEIS SANGUÍNEOS DE GLICOSE MAIS FREQUENTEMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **GASTRINTESTINAL:** NÁUSEA, DISPEPSIA, VÔMITO, DOR ABDOMINAL OU EPIGÁSTRICA, CONSTIPAÇÃO, DIARREIA, QUEIMAÇÃO E ANOREXIA TÊM SIDO RARAMENTE DESCRITOS NA LITERATURA NA VIGÊNCIA DE TRATAMENTO COM GLICOSAMINA E CONDROITINA. **PELE:** ERITEMA, PRURIDO, ERUPÇÕES CUTÂNEAS E OUTRAS MANIFESTAÇÕES ALÉRGICAS DE PELE FORAM REPORTADAS EM ENSAIOS CLÍNICOS COM GLICOSAMINA. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. **POSOLOGIA: Adultos:** Recomenda-se iniciar a terapêutica com a prescrição de 1 envelope por dia, dissolvido em um copo com água. Como os efeitos do medicamento se iniciam em média após a terceira semana de tratamento deve-se ter em mente que a continuidade e a não-interrupção do tratamento são fundamentais para se alcançar os benefícios analgésicos e de mobilidade articular. **SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA.** MB03a SAP4406702.

Material técnico-científico de distribuição exclusiva à classe médica.

A ação eficaz[1] no tratamento da Osteoartrite.

Glicolive
sulfato de glicosamina

Qualidade Aché e preço acessível para o tratamento da OA.[2-5]

Referências Bibliográficas: 1) MATHESON, A. J; PERRY, C. M. Glucosamine: a review of its use in the management of osteoarthritis. Drugs Aging, v. 20, n. 14, p. 1041-60, 2003. **2)** Kairos Web Brasil. Disponível em: http://brasil.kairosweb.com Acesso em: Agosto/16. **3)** Programa Cuidados pela Vida (" O Programa Cuidados pela Vida pode alterar ou interromper esta campanha sem aviso prévio". Desconto calculado sobre o Preço Máximo ao Consumidor)". **4)** Bula do produto GLICOLIVE: pó para solução oral. Farmacêutica Responsável: Gabriela Mallmann, Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **5)** BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Resolução - RE nº 1.101, de 9 de abril de 2015. Concede Certificação de Boas Práticas de Fabricação ao Aché. Diário Oficial da União, Brasília DF, p. 133, 9 abr 2015. **6)** Internal Report.

Contraindicações: hipersensibilidade a glicosamina ou a qualquer outro componente da fórmula. Interações medicamentosas: o sulfato de glicosamina pode favorecer a absorção gastrintestinal de tetraciclinas e reduzir a de penicilina e cloranfenicol.

GLICOLIVE é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

GLICOLIVE (sulfato de glicosamina) 1500 mg pó para solução oral. USO ORAL. USO ADULTO. **Indicações:** GLICOLIVE é indicado no tratamento deartrose ou osteoartrite primária e secundária e suas manifestações. Contraindicações: **GLICOLIVE é contra-indicado em pacientes com hipersensibilidade a glicosamina ou a qualquer outro componente da fórmula. Não deve ser utilizado durante a gravidez, lactação ou em fenilcetonúricos. Cuidados e advertências: informar ao médico caso esteja utilizando outros medicamentos. Recomenda-se cautela em pacientes com sintomas indicativos de distúrbios gastrintestinais, história de úlcera gástrica ou intestinal, diabetes mellitus, portadores de insuficiência renal, hepática ou cardíaca. Caso ocorra ulceração péptica ou sangramento gastrintestinal a medicação deverá ser suspensa imediatamente. Recomenda-se evitar a ingestão de bebidas alcoólicas, durante o tratamento.** Gravidez e lactação: não há dados com relação ao uso de GLICOLIVE na gravidez e lactação humana, portanto, seu uso não é recomendado nestes casos. Interações medicamentosas: o sulfato de glicosamina pode favorecer a absorção gastrintestinal de tetraciclinas e reduzir a de penicilina e cloranfenicol. Não existe limitação para administração simultânea de analgésicos ou anti-inflamatórios esteroides e não esteroides. **Reações adversas: os efeitos colaterais mais comuns são de origem gastrintestinal, de intensidade leve a moderada, consistindo em desconforto gástrico, diarreia, náusea, prurido e cefaléia. Reações hematológicas: não foram observadas alterações clínicas significativas.Testes laboratoriais: não se observaram diferenças significativas nos valores médios nem nos dados individuais das provas laboratoriais e constantes vitais. Glicolive é um medicamento. "Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas."** Posologia: GLICOLIVE apresenta-se na forma de pó branco a levemente amarelado, com odor e sabor de abacaxi. Dispensar o conteúdo do envelope em um copo com água. Aguardar entre 2 a 5 minutos, mexer a solução com o auxílio de uma colher e consumir. Consumir 1 envelope por dia antes das refeições ou segundo indicação médica. A duração do tratamento fica a critério do médico. Para informações completas, consultar a bula na íntegra através da Central de Atendimento ao Cliente.VENDA SOB PRESCRIÇÃO MÉDICA. MS - 1.0573. 0403. MB05 SAP 4423401. "Material técnico científico de distribuição exclusiva à classe médica." SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO.

Artrosil
lisinato de cetoprofeno

SMR
SMART MODULATED RELEASE[3]

O ÚNICO lisinato de cetoprofeno[1]
com **TECNOLOGIA SMR**[2,3]

SEGURANÇA[2]
- Tolerabilidade gástrica 3 a 4 vezes maior comparado ao cetoprofeno comum.[2]

RÁPIDO INÍCIO DE AÇÃO[2]

EFICÁCIA[2]
- **Potência** anti-inflamatória, analgésica e antipirética superior ao cetoprofeno.[2]
- **Liberação prolongada:** Níveis plasmáticos mantidos por até 24h.[2,4]

Apresentações[4]
Cápsulas de liberação prolongada
de 160 e 320 mg com 10 e 20 cápsulas

Referências Bibliográficas: 1) ANVISA. Consulta de produtos. Disponível em: <http://www7.anvisa.gov.br/datavisa/Consulta_Produto/consulta_medicamento.asp>. Acesso em: Abr/2016. **2)** PELOGGIA, C.C.N.; BRITO NETO, A.J.; CUNHA, J. Avaliação da eficácia terapêuta e da tolerância do antiinflamatório lisinato de cetoprofeno, na forma cápsulas. Estudo multicêntrico aberto e não comparativo. Revista Brasileira de Medicina, v.57, n.6, p.617-624, 2000. **3)** Internal Report. **4)** Bula Do Produto ARTROSIL: Cápsulas. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A.

Contraindicações: Úlcera péptica na fase ativa. Interações medicamentosas: Devido à elevada ligação de cetoprofeno com proteínas plasmáticas, é necessário reduzir a dosagem de anticoagulantes, fenitoínas ou sulfamidas quando administrados concomitantemente.

ARTROSIL (lisinato de cetoprofeno) - 160 mg e 320 mg - Cápsulas de liberação prolongada - Uso oral - Uso Adulto - Indicações: Artrose, coxartrose, espondiloartrose, artrite reumatóide, bursite, flebite e tromboflebite superficial, contusão, entorse, luxação, distensão muscular. **Contraindicações: Úlcera péptica na fase ativa, anamnese positiva de úlcera péptica recorrente, dispepsia crônica, gastrite, insuficiência renal grave, leucopenia e plaquetopenia, grave distúrbio de hemocoagulação.** Hipersensibilidade à quaisquer componentes de sua fórmula. Existe a possibilidade de hipersensibilidade cruzada com ácido acetilsalicílico ou outros fármacos anti-inflamatórios não-esteroidais. Portanto, o cetoprofeno não deve ser administrado a pacientes nos quais o ácido acetilsalicílico ou outros fármacos antiinflamatórios não-esteroidais tenham provocado sintomas de asma, rinite, urticária. O uso de lisinato de cetoprofeno é contra-indicado durante o primeiro e o último trimestre de gestação, pois pode causar hipertensão pulmonar e toxicidade renal no feto, característica comum aos inibidores da síntese de prostaglandinas. Pode também levar ao aumento do tempo de sangramento das gestantes e fetos e conseqüentemente eventuais manifestações hemorrágicas no recém-nascido. Há risco de retardar o trabalho de parto. **Precauções e advertências: O uso de cetoprofeno em pacientes com asma brônquica ou com diáteses alérgicas pode provocar uma crise asmática. Em pacientes com função renal comprometida, a administração de cetoprofeno deve ser efetuada com particular cautela levando-se em consideração a eliminação essencialmente renal do fármaco.** Embora não tenha sido observada experimentalmente toxicidade embriofetal com cetoprofeno nas doses previstas para uso clínico, a administração em mulheres grávidas, durante a amamentação ou na infância não é recomendada. **Interações medicamentosas: Devido à elevada ligação de cetoprofeno com proteínas plasmáticas, é necessário reduzir a dosagem de anticoagulantes, fenitoínas ou sulfamidas quando administrados concomitantemente.** O uso com ácido acetilsalicílico reduz o nível sérico de cetoprofeno e aumenta o risco de distúrbios gastrintestinais. No caso da administração com lítio há aumento de seu nível sérico podendo levar à intoxicação. Foi observado aumento da toxicidade do metotrexato em decorrência da diminuição de seu "clearance" renal. A probenecida reduz as perdas de cetoprofeno e aumenta seu nível sérico. A metoclopramida reduz a biodisponibilidade do cetoprofeno e pode ocorrer uma pequena redução de sua absorção no uso simultâneo com hidróxidos de magnésio ou alumínio. **Reações adversas: Assim como com outros antiinflamatórios não-esteroidais, podem ocorrer distúrbios transitórios, no trato gastrintestinal, tais como gastralgia, náusea, vômito, diarréia e flatulência.** Excepcionalmente foram observadas hemorragia gastrintestinal, discinésia transitória, astenia, cefaléia, sensação de vertigem e exantema cutâneo. O produto pode ser tomado às refeições ou com leite, a fim de evitar possíveis distúrbios gastrintestinais. **Posologia:** ARTROSIL 160 mg: Uma cápsula duas vezes ao dia durante ou após às refeições. A duração do tratamento deve ser a critério médico. ARTROSIL 320 mg: Uma cápsula ao dia durante ou após às refeições. A duração do tratamento deve ser a critério médico. SE PERSISTIREM OS SINTOMAS O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA. MS – 1.0573.0128. MB_08 SAP 4057006

Material técnico-científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos.

Referências Bibliográficas: 1) ALFANO, G. et al. Analgesia with paracetamol/tramadol vs. paracetamol/codeine in once DaySurgery: a randomized open study. European Review for Medical and Pharmacological Sciences, v.15,p.205-21, 2011. 2) PERROT, S. et al. Efficacy and Tolerability of Paracetamol/Tramadol (325 mg/37.5 mg) Combination Treatment Compared with Tramadol (50 mg) Monotherapy in Patients with Subacute Low Back Pain: A Multicenter, Randomized, Double-Blind, Parallel-Group, 10-Day Treatment Study. Clin Ther, v. 28, n. 10, p. 1592-1606, 2006. 3) Bula do produto REVANGE: comprimidos revestidos. Farmacêutica Responsavel: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 4) MEDVE, R.A.; WANG, J.; KARIM, R. Tramadol and acetaminophen tablets for dental pain. Anesth Prog, v.48, n.3, p.79-81 , 2001.

Contraindicações: hipersensibilidade ao tramadol, paracetamol ou a qualquer componente da fórmula ou aos opioides; intoxicações agudas pelo álcool, hipnóticos, analgésicos de ação central, opioides ou psicotrópicos; pacientes em tratamento com inibidores da monoaminoxidase (MAO) ou tratados com estes agentes nos últimos 14 dias. Interações medicamentosas: REVANGE® comprimido revestido não é recomendado como medicação pré-operatória obstétrica ou na analgesia pós-parto em lactantes, pois a segurança em lactentes e recém-nascidos não foi estudada.

REVANGE® é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

REVANGE®, cloridrato de tramadol e paracetamol. 37,5 MG + 325 MG comprimidos revestidos. USO ORAL. USO ADULTO. Indicações: dores moderadas a severas de caráter agudo, subagudo e crônico. **Contraindicações:** hipersensibilidade ao tramadol, paracetamol ou a qualquer componente da fórmula ou aos opioides; intoxicações agudas pelo álcool, hipnóticos, analgésicos de ação central, opioides ou psicotrópicos; pacientes em tratamento com inibidores da monoaminoxidase (MAO) ou tratados com estes agentes nos últimos 14 dias. Cuidados e advertências: convulsões foram relatadas em pacientes recebendo tramadol na dose recomendada. Relatos espontâneos pós-comercialização indicam que o risco de convulsões está aumentado com doses de tramadol acima das recomendadas. A administração de tramadol pode aumentar o risco de convulsão em pacientes tomando inibidores da MAO, neurolépticos ou outros fármacos que reduzem o limiar convulsivo. REVANGE® comprimido revestido não deve ser administrado à pacientes dependentes de opioides. O tramadol reinicia a dependência física em alguns pacientes previamente dependentes de outros opioides. REVANGE® comprimido revestido deve ser usado com cautela e em dose reduzida em pacientes recebendo depressores do SNC como álcool, opioides, agentes anestésicos, fenotiazinas, tranquilizantes ou sedativos hipnóticos. REVANGE® comprimido revestido deve ser usado com bastante cautela em pacientes sob tratamento com inibidores da monoaminoxidase pois os estudos em animais mostraram aumento da incidência de óbito com a administração combinada de inibidores da MAO e tramadol. Precauções e advertências: REVANGE® comprimido revestido não deve ser administrado em conjunto com outros produtos à base de tramadol ou paracetamol. REVANGE® comprimido revestido deve ser administrado com cautela em pacientes sob risco de depressão respiratória. REVANGE® comprimido revestido deve ser usado com cautela em pacientes com pressão intracraniana aumentada ou traumatismo craniano. Alterações da pupila (miose) provocadas pelo tramadol podem mascarar a existência, extensão ou curso da patologia intracraniana. Gravidez e lactação: uso na gravidez e lactação: REVANGE® comprimido revestido somente deverá ser utilizado durante a gravidez se o potencial benefício justificar o potencial risco para o feto. Interações medicamentosas: REVANGE® comprimido revestido não é recomendado como medicação pré-operatória obstétrica ou na analgesia pós-parto em lactantes, pois a segurança em lactentes e recém-nascidos não foi estudada. Reações adversas: efeitos sobre a capacidade de dirigir e operar máquinas: mesmo quando usado de acordo com as instruções, REVANGE® comprimido revestido pode afetar a habilidade mental ou física necessária para a realização de tarefas potencialmente perigosas como dirigir ou operar máquinas, especialmente no início do tratamento, na mudança de outro produto para REVANGE® comprimido revestido e na administração concomitante de outras drogas de ação central e, em particular, do álcool. **REVANGE® é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.** Os eventos adversos relatados com maior freqüência ocorreram no sistema nervoso central e gastrintestinal, sendo que os relatos mais comuns foram vertigem, náusea e sonolência. Posologia: a dose diária máxima de REVANGE® comprimido revestido é 1 a 2 comprimidos a cada 4 a 6 horas de acordo com a necessidade para alívio da dor, até o máximo de 8 comprimidos ao dia. A administração dos comprimidos pode ser feita independentemente das refeições. Nas condições dolorosas crônicas, o tratamento deve ser iniciado com 1 comprimido ao dia e aumentado em 1 comprimido a cada 3 dias, conforme a tolerância do paciente, até atingir a dose de 4 comprimidos ao dia. Depois disso, REVANGE® comprimido revestido pode ser administrado na dose de 1-2 comprimidos a cada 4-6 horas, até o máximo de 8 comprimidos ao dia. Nas condições dolorosas agudas, o tratamento pode ser iniciado com a dose terapêutica completa (1-2 comprimidos a cada 4-6 horas), até o máximo de 8 comprimidos ao dia. Pacientes com disfunção renal: em pacientes com "clearance" de creatinina inferior a 30 mL/min, recomenda-se aumentar o intervalo entre as administrações de REVANGE® comprimido revestido de forma a não exceder 2 comprimidos a cada 12 horas. VENDA SOB PRESCRIÇÃO MÉDICA. SÓ PODE SER VENDIDO COM RETENÇÃO DA RECEITA. Farmacêutica Responsável: Gabriela Mallmann CRF-SP 30.139. MS - 1.6673.0449. MB02 SAP 4388020.

CHEGOU

FOXIS
CELECOXIBE

Eficácia, segurança e preço acessível
no tratamento anti-inflamatório.[1-4]

COX-2[5] EM FOCO

- **Melhora significante** dos sinais e sintomas de osteoartrite.[6]
- **Eficaz** no tratamento de dor aguda.*[7]
- Inibidor da COX-2 **mais utilizado no mundo.**[5]

* Devido a entorse de tornozelo em 24 horas após o início do tratamento.

Referências bibliográficas: 1. SIMON, L.S. et al. Anti-inflammatory and upper gastrointestinal effects of celecoxib in rheumatoid arthritis: A randomized controlled trial. JAMA, v. 282, n. 20. 1999. **2.** ESSEX, M.N; BHADRA, P; SANDS, G.H. Efficacy and tolerability of celecoxib versus naproxen in patients with osteoarthritis of the knee: a randomized, double-blind, double-dummy trial. The journal of international medical research, v. 40, p. 1357-1370, 2012. **3.** LÉRIAS, J.R. Celecoxibe e rofecoxibe: eficácia e segurança dos inibidores seletivos da Cox-2 comparativamente aos AINEs não seletivos. Rev Port Clin Geral, v. 20, p. 47-64, 2004. **4.** Kairos Web Brasil. Disponível em: <http://brasil.kairosweb.com>. Acesso em: JUL/2017. **5.** SOLOMON, S.D. et al. Cardiovascular risk of celecoxib in 6 randomized placebo-controlled trials: The cross trial safety analysis. Circulation, v. 117, p. 2104-2113, 2008. **6.** BENSEN, W.G. et al. Treatment of osteoarthritis with celecoxib, a cyclooxygenase-2 inhibitor: A randomized controlled trial. Mayo ClinProc, v. 74, p. 1095-1105. 1999. **7.** CARDENAS-ESTRADA, E. et al. Efficacy and Safety of Celecoxib in the Treatment of Acute Pain due to Ankle Sprain in a Latin American and Middle Eastern Population. The Journal of International MedicalResearch, v. 37, p. 1937-1951, 2009.

FOXIS - celecoxibe. Cápsulas. 200 mg. USO ORAL. USO ADULTO. Indicações: Tratamento dos sinais e sintomas da osteoartrite e da artrite reumatoide; alívio dos sinais e sintomas da espondilite anquilosante; alívio da dor aguda (principalmente no pós-operatório de cirurgia ortopédica ou dental e em afecções musculoesqueléticas); alívio dos sintomas da dismenorreia primária e da lombalgia. **Contraindicações: Não deve ser usado por pacientes: que tenham tido crise de asma, urticária ou reações alérgicas após uso de ácido acetilsalicílico ou outros anti-inflamatórios; com doença hepática e/ou com insuficiência renal grave; que tenham dor relacionada à cirurgia de revascularização do miocárdio; com hipersensibilidade ao celecoxibe ou a qualquer componente da fórmula. Cuidados e advertências:** O uso de AINEs pode retardar ou inibir a ovulação, o que pode estar associado com a infertilidade reversível em algumas mulheres. Não deve ser usado por grávidas sem orientação e seguimento médico; especialmente durante o primeiro e segundo trimestres. O uso de celecoxibe durante a gravidez requer que se pesem os potenciais benefícios para a mãe e riscos para a criança. **Celecoxibe é um medicamento classificado na categoria C de risco de gravidez.** Embora reduza o risco de desenvolvimento de complicações gastrintestinais associadas ao uso de anti-inflamatórios, esse risco não está eliminado pelo uso de celecoxibe, sendo maior em maiores de 65 anos, consumo de bebidas alcoólicas ou com história anterior de perfuração, úlcera ou sangramento gastrintestinal. Celecoxibe deve ser usado com cautela em pacientes com: hipertensão, pois pode piorá-la; portadores de insuficiência renal, alterações da função hepática em idosos; portadores das alterações das enzimas metabolizadoras CYP2C9. Celecoxibe deve ser descontinuado ao aparecimento de rash cutâneo, lesões nas mucosas ou outros sinais de alergias. **Interação medicamentosa: anticoagulantes; anti-hipertensivos das classes dos inibidores da enzima conversora de angiotensina (ECA) e/ou antagonistas da angiotensina II diuréticos e betabloqueadores podem ter seu efeito reduzido; em pacientes idosos, com desidratação (incluindo aqueles em tratamento com diuréticos) ou com função renal comprometida, a coadministração de antiinflamatórios, incluindo os inibidores específicos da COX-2, com inibidores da ECA, pode resultar no comprometimento da função renal, incluindo possível insuficiência renal aguda; fluconazol pode aumentar os níveis sanguíneos de celecoxibe; lítio pode ter seu nível sanguíneo aumentado; medicamentos anti-inflamatórios podem aumentar o risco de toxicidade no rim associada à ciclosporina; a administração concomitante de dextrometorfano ou metoprolol com celecoxibe 200 mg duas vezes ao dia resultou em aumento de 2,6 vezes e 1,5 vezes das concentrações no sangue de dextrometorfano e metoprolol, respectivamente; lisinopril administrado concomitante com celecoxibe pode não controlar a pressão alta. Foxis 200 mg: Este produto contém o corante amarelo de TARTRAZINA que pode causar reações de natureza alérgica, entre as quais asma brônquica, especialmente em pessoas alérgicas ao ácido acetilsalicílico. Atenção: Este medicamento contém Açúcar, portanto, deve ser usado com cautela em portadores de Diabetes. Reações adversas: Comuns** (ocorre entre 1% e 10% dos pacientes) inflamação dos brônquios e seios da face, infecção do trato respiratório superior, infecção urinária, insônia, tontura, hipertensão e piora da hipertensão, tosse, vômito, dor abdominal, dispepsia, flatulência, prurido, rash, edema periférico. Incomuns (ocorre entre 0,1% e 1% dos pacientes): faringite; rinite, anemia, hipersensibilidade, ansiedade, hipertonia, sonolência, visão borrada, zumbido; palpitação, úlceras no estômago; doenças dentárias; aumento da quantidade de enzimas hepáticas, urticária, equimose, edema facial, doença semelhante à gripe, lesão. Infecção pela bactéria Helicobacter, pelo vírus Herpes zoster, infecções na pele, em feridas e gengiva, labirintite, infecção por bactéria, lipoma, distúrbio do sono, infarto cerebral, hemorragia conjuntival, depósitos no humor vítreo, hipoacusia, angina instável, insuficiência da valva aórtica; aterosclerose da artéria coronária; bradicardia sinusal, hipertrofia ventricular; trombose venosa profunda; hematoma; distonia, sangramento da hemorroida; evacuações frequentes; ulceração da boca; estomatite; dermatite alérgica; cisto sinovial, noctúria, cisto ovariano, sintomas da menopausa; sensibilidade nas mamas; dismenorreia; aumento da quantidade de potássio e sódio no sangue, redução da testosterona no sangue; redução do hematócrito, aumento nos níveis de hemoglobina, fraturas, epicondilite, ruptura do tendão. Posologia: Celecoxibe deve ser engolido com ou sem alimentos. Para o tratamento de dor aguda e dismenorreia primária: 400 mg na primeira dose, seguidos de uma dose de 200 mg por via oral após 12 horas, seguido de 200 mg a cada 12 horas nos dias seguintes conforme necessário. Uso para o tratamento de dor crônica: menor dose diária eficaz durante o menor período possível. As doses sugeridas de celecoxibe para essas doenças são as seguintes: Osteoartrite e Espondilite anquilosante: 200 mg em dose única ou 100 mg duas vezes; Artrite reumatoide: 100 ou 200 mg duas vezes ao dia; Lombalgia: 200 mg ou 400 mg em dose única ou dividida em duas vezes de 100 mg ou 200 mg. SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. **VENDA SOB PRESCRIÇÃO MÉDICA. SÓ PODE SER VENDIDO COM RETENÇÃO DA RECEITA. MS - 1.0573.0491. MB 02 VP_SAP 4591400_SAP 4585100. *Material técnico científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos.**

CONTRAINDICAÇÕES: Não deve ser usado por pacientes: que tenham tido crise de asma, urticária ou reações alérgicas após uso de ácido acetilsalicílico ou outros anti-inflamatórios; com doença hepática e/ou com insuficiência renal grave; que tenham dor relacionada à cirurgia de revascularização do miocárdio; com hipersensibilidade ao celecoxibe ou a qualquer componente da fórmula. **INTERAÇÕES MEDICAMENTOSAS:** Anticoagulantes; anti-hipertensivos das classes dos inibidores da enzima conversora de angiotensina (ECA) e/ou antagonistas da angiotensina II diuréticos e betabloqueadores podem ter seu efeito reduzido; em pacientes idosos,) ou com função renal comprometida, a coadministração de anti-inflamatórios, incluindo os inibidores específicos da COX-2, com inibidores da ECA, pode resultar no comprometimento da função renal, incluindo possível insuficiência renal aguda; fluconazol pode aumentar os níveis sanguíneos de celecoxibe; medicamentos anti-inflamatórios podem aumentar o risco de toxicidade no rim associada à ciclosporina.

CAC
0800 701 6900
cac@ache.com.br
8:00 h às 17:00 h (exceto feriados)

Campanha RESPEITO PELA PRESCRIÇÃO E PELA ADESÃO AO TRATAMENTO
aché

osteo muscular

Material técnico-científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos. 7021022 – Julho/2017.

aché
mais vida para você