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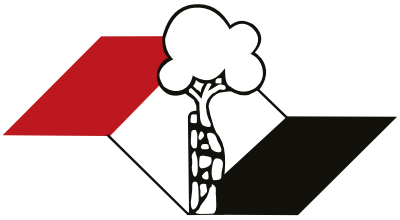

ISSN 1413-7852

Acta Ortopédica Brasileira

Volume 32 – Number 2 – Year 2024

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

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LEVELS OF EVIDENCE FOR PRIMARY RESEARCH QUESTION: Access the following link.

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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 32 – Nº 2 – 2024

Original Article

DOI: http://dx.doi.org/10.1590/1413-785220243202e275561

EVALUATION OF ARTHROGRYPOTIC FOOT TREATMENT: MINIMUM 10 YEARS FOLLOW-UP

AVALIAÇÃO DO TRATAMENTO DO PÉ ARTROGRIPÓTICO: SEGUIMENTO MÍNIMO DE 10 ANOS

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4. Fundação Altino Ventura, Recife, PE, Brazil.
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ABSTRACT

Objective: To evaluate patients with arthrogryposis submitted to extensive surgical treatment with a minimum of 10 years of follow-up regarding the clinical and radiological aspects and the quality of life, using the 36-Item Short Form (SF-36) and the Disease-Specific Instrument (DSI). Methods: A retrospective study selected 33 patients, totaling 64 operated feet. Results: The mean age of the patients was 17.9 years (12-39 years), and the mean follow-up time was 14.8 years (11-17). Amyoplasia represented 78.7% of syndromic diagnoses. Isolated posteromedial lateral release (PMLR) was performed in 21.8% of the feet, 27.2% of which required additional bone surgery, and about 50 feet (78.1%) were submitted to PMLR, lateral column shortening, and/or talectomy. In total, 46 talectomies were performed (71.8% of the feet), out of which 44 were the first procedure of choice. SF-36 questionnaire was evaluated and showed that 93.9% of the patients did not have restrictive and disabling pain, and the same percentage considered themselves as healthy and had good expectations for the future. Conclusion: Arthrogrypotic feet are difficult to treat, require many recurrent surgical procedures, and relapses are the rule. Stiffness is a common feature of these feet, and residual deformities were frequent. ***Level of Evidence IV; Case Series, Therapeutic Studies.***

Keywords: Arthrogryposis. Clubfoot. Quality of Life. Surgical Procedures, Operative.

RESUMO

Objetivo: Avaliar pacientes com artrogripose submetidos a tratamento cirúrgico convencional com um mínimo de 10 anos de seguimento quanto aos aspectos clínicos, radiológicos e qualidade de vida, utilizando o questionário de 36 itens Short Form 36 (SF-36) e o Instrumento específico de Doenças (IED). Método: No estudo retrospectivo foram avaliados 33 pacientes, totalizando 64 pés operados. Resultados: A média de idade foi de 17,9 anos (12-39 anos), e o tempo médio do seguimento foi de 14,8 anos (11-17). A amioplasia representou 78,7% dos diagnósticos sindrômicos. A liberação posteromedial lateral isolada (LP MI) foi realizada em 21,8% dos pés, 27,2%, com cirurgia óssea adicional, e cerca de 50 pés (78,1%) foram submetidos a LPM (liberação póstero medial), encurtamento da coluna lateral e/ou talectomia. Foram realizadas 46 talectomias (71,8% dos pés), sendo em 44 o procedimento de primeira escolha. O questionário SF-36 evidenciou que 93,9% dos pacientes estavam sem dor restritiva e incapacitante, consideravam-se saudáveis, com boas expectativas para o futuro. Conclusão: Os pés artrogripóticos são de difícil tratamento, requerendo muitos procedimentos cirúrgicos recorrentes. A rigidez é uma característica comum desses pés e as deformidades residuais foram frequentes. Estudos futuros poderão mostrar se haverá diferença no resultado do tratamento desses pés aplicando a abordagem inicial atual, mais conservadora. ***Nível de Evidência: IV; Estudos Terapêuticos; Série de Casos.***

Descritores: Artrogripose. Pé torto. Qualidade de vida. Procedimentos Cirúrgicos Operatórios.

Citation: Nogueira MP, Caiafa JB, Galdez APP, Fujino RP, Farcetta Junior F. Evaluation of arthrogrypotic foot treatment: minimum 10 years follow-up. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 6. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Arthrogryposis is a term used to designate signs associated with entities characterized by rigid, non-progressive contractures in two or more joints in different body areas.[1-2] Its incidence is relatively rare, with occurrence described in the literature ranging from 1:3000 live births,[3] with amyoplasia representing more than 1/3 of the cases, around 1:10,000 live births.[4-7] The causes of arthrogryposis are still unknown; however, it is believed to be of multifactorial origin.[3] The most frequent foot deformity in patients with arthrogryposis is rigid equinus, cavus, varus and adductus (78 to 90%).[2,7] This

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

The study was conducted at the Hospital do Servidor Público Estadual, Department of Pediatric Orthopaedics and Limb Reconstruction, São Paulo, SP, Brazil.
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Article received on 06/14/2023, approved in 08/30/2023.

deformity presents hypotrophy, thinner calf muscles, with fibrotic tendons and little mobility, characterized by being more severe and rigid than in the congenital clubfoot.

Treatment of arthrogrypotic feet deformities aims at obtaining plantigrade, braceable, and non-painful feet. However, the stiffness of the disease and the high risk of recurrence make the treatment of arthrogrypotic feet a challenge.[7]

One of the options of treatment for arthrogrypotic feet includes manipulation and serial casting before extensive surgical soft tissue release and talectomy. This method has satisfactory results, reducing extensive surgeries, the number of surgeries and complications.[6] However, the stiffness found in these feet can make manipulation difficult.[3,6-8]

Conventional surgical treatment is a widely used method involving posteromedial release (PMLR), talectomy, and tarsectomy.[2,3,6,7] PMLR is traditionally considered the first surgical method to be performed in young children and with less rigid deformities. This method consists of releasing peritalar capsules, ligaments, and tendons "à la carte" to correct deformities. Some studies suggest that PMLR alone has a higher recurrence rate.[3,6-8]

In the 1980s, Menelaus obtained good results with the talectomy in the treatment of rigid equinovarus feet in patients with arthrogryposis and those with myelomeningocele.[9] Today, the technique is used in severe, recurrent arthrogrypotic feet with structured deformities, working as a salvage procedure, with the advantage of creating the required space to correct the deformity without tension.[7,8,10]

Other less conventional surgical methods of treatment include the Verebelyi-Ogston procedure (subchondral excision of cancellous bone from the cuboid and talus), the progressive correction of the deformity through an external fixator using the Ilizarov method, and triple arthrodesis after 10 years of age.[4,7,11-13]

Few studies in the literature assess the quality of life and long-term functional results of patients with arthrogryposis after surgical treatment of feet deformities using standardized instruments.[6,14-18] The 36-Item Short Form (SF-36) is one of these instruments, measuring three aspects of health: functional ability, well-being, and general health.[19]

The aim of this study is to evaluate patients with arthrogryposis submitted to surgical treatment with a minimum of 10 years of follow-up regarding the clinical and radiological aspects (following the model proposed by the Clubfoot Study Group) and regarding their quality of life, using the SF-36 and the Disease-Specific Instrument (DSI).

proposed by the Clubfoot Study Group, considering clinical and radiographic parameters.

METHODS

The retrospective study was approved by the institutional research ethics committee. Forty-two patients with arthrogryposis syndromes who underwent surgical treatment to correct feet deformities from January 1, 1974, to December 31, 2002, were included, corresponding to a minimum follow-up of 10 years. Patients were excluded from the study when there were uncertain records regarding the diagnosis and procedure performed. Thus, 33 patients (64 feet) were selected for this study.

Data was collected through an assessment questionnaire according to the model The SF 36 and DSI questionnaires were also used to evaluate the quality of life. The following aspects were evaluated:

• Demographic aspects: age, sex, and type of activity performed by the patient;

• Treatment method: the surgical treatment method to which the patient was submitted. Check on the occurrence of previous manipulation with serial casting;

• Physical Examination: the patients underwent a complete physical examination, always performed by the same examiner, including weight, height, size of the lower limb (measured from the anterior superior iliac spine to the medial malleolus), calf circumference, and foot size and width. The foot was inspected for calluses. Goniometry was performed to measure ankle dorsiflexion and plantarflexion passively, as well as the varus and valgus of the subtalar, adduction, abduction, and pronosupination of the forefoot. The strength of the tibialis anterior and posterior, triceps surae, peroneal, extensor hallucis longus, extensor digitorum, flexor hallucis longus, and flexor digitorum longus muscles was measured clinically. Patients were requested to stand in a monopodal weight-bearing position and perform repeated plantar flexions, stopping after fourteen flexions or when there was moderate pain or triceps surae fatigue.

• Radiographic examinations: weight-bearing anteroposterior and lateral radiographs of the feet were requested, and the radiographic parameters were measured by a single examiner. In the anteroposterior view, it was obtained the talocalcaneal angle, the angle between the calcaneus and the fifth metatarsal, and the angle between the talus and the first metatarsal. In the lateral view, the talocalcaneal, talus-first metatarsal, calcaneus, and first metatarsal angles were measured, as well as the angle between the first and fifth metatarsal. Degenerative changes were checked.

• Quality of life questionnaires: each patient answered a quality of life questionnaire elaborated based on the SF-36 and DSI (Disease-Specific Instrument).[16,19]

• The data collected was organized and analyzed using Microsoft Excel; then, the treatment methods under study were correlated with the patients' functional status after a 10-year evolution period.

Informed consent was obtained from all patients for being included in the study, and after the ethical committee approval. Written informed consent was obtained from all patients/parents/legal guardians for publication of this manuscript and any accompanying images and videos.

RESULTS

The study group had 11 female patients (33.4%) and 22 male patients (66.6%) with a mean age of 17.9 years (12-39 years), totaling 64 feet. The group consisted of 26 (78.78%) patients with amyoplasia (AMC), two (6.06%) patients with Larsen Syndrome, three (9.09%) patients with Moebius Syndrome, one (3.03%) patient with Streeter Syndrome, and one (3.03%) patient with Schwartz-Jampel Syndrome. (Table 1)

The mean age at the first corrective surgery of the feet was 39.31 months (3.27 years; 1-14 years). The mean follow-up time for these patients was 14.8 years (11-17 years) for each foot submitted to surgery. No patient was submitted to previous manipulation with serial casting. (Table 2)

Isolated PMLR occurred in 14 (21.87%) feet and, later, 27.2% required additional bone surgery. Fifty feet (78.1%) underwent PMLR associated with a bone procedure, which could be the lateral column shortening and/or talectomy. Of these feet, 18% required a new bone approach, such as tarsectomy (six feet) and arthrodesis (three feet). These surgeries were performed an average of two years after the first procedure. In total, 46 (71.8% of the studied feet) talectomies were performed, out of which 44 were the first procedure of choice. PMLR associated with lateral column shortening was performed in 7.81% of the feet, PMLR associated with lateral column shortening and talectomy was performed in 56.25% of the operated feet, and PMLR associated with talectomy was performed in 14.06% of the feet. (Tables 2 and 3) Radiographic measurements were difficult due to the lack of talus in most feet. (Figure 1)

Based on the model proposed by the Clubfoot Study Group, the results concerning the physical aspect found in 45 (70.31%) feet were considered bad, 18 (28.12%) were terrible, and one foot (1.56%) was good. Eighteen patients (54.54%) felt pain, of

Table 1. Demographic aspects and diagnosis of patients with arthrogryposis.

Patient	Gender	Age (years)	Diagnosis
DPS	Female	18	AMC
APPS	Female	16	Larsen
MAP	Male	26	AMC
WJA	Male	11	AMC
JLF	Male	17	Schuwartz Jampel
VHR	Female	21	AMC
GAR	Male	15	AMC
MVMN	Male	13	AMC
NOC	Female	20	AMC
ALA	Male	15	AMC
NDJ	Female	18	AMC
TM	Male	15	AMC
VCS	Female	11	AMC
YSS	Female	15	AMC
EMP	Male	18	Moebius
LCM	Female	14	AMC
MAS	Male	13	AMC
KMC	Male	14	AMC
GAS	Male	16	Streeter
DPS	Male	20	Larsen
DAFS	Female	17	Moebius
VVS	Male	16	AMC
CNG	Female	17	AMC
GSC	Male	24	AMC
JCS	Female	23	AMC
BVLM	Male	25	AMC
GAM	Male	14	AMC
GTS	Male	12	AMC
MHSR	Male	15	Moebius
GRQ	Male	14	AMC
JKJS	Male	21	AMC
GIM	Male	39	AMC
MAP	Male	28	AMC

* AMC: Amyoplasia.

these, 13 feet (72.22%) ambulate, and 5 feet (27.77%) do not ambulate. Regarding the clinical aspect of the feet, 29 (45.31%) are plantigrade, five (7.81%) have an equinus deformity, 13 (20.31%) have an adductus deformity, eight (12.5%) have a varus deformity, three (4.68%) have an equinus, cavus, varus and adductus deformity, and six (9.37%) have a valgus deformity. Sensibility was preserved in all patients assessed. There was no casting manipulation before surgical treatment. Regarding the ability to ambulate, about 10 (30.3%) patients do not ambulate, while 23 (69.69%) of them ambulate.

Regarding the SF-36 questionnaire, about 60.6% of the patients considered that they had some kind of limitation to perform their daily activities, 79% of patients complained that they had difficulties to buy shoes due to the very small size of their feet (Figure 2). 78.78% of the patients reported not having problems at work due to their physical disability, and 93.93% of the patients did not have disabling and restrictive pain. Only 6.06% of the patients considered that their deformities often interfere with their social activities.

Furthermore, 93.93% of the patients considered themselves as healthy and with good expectations regarding future health, 84.84% considered themselves as excited and full of energy, 75.75% said they did not have any limitations due to the emotional aspects of the disability, and about 75.75% described themselves as happy. (Table 4)

Table 2. Surgical procedures in feet of patients with arthrogryposis.

Patient	Age at the first surgery (years)	Follow-up time (years)	Laterality	First surgery*	Follow-up surgery§
DPS	2	16	R	0	0
			L	3	3
APPS	1	15	R	1	1
			-	1	0
MAP	14	12	R	4	0
			L	4	0
WJA	2	11	R	3	0
			L	3	0
JLF	5	12	R	4	0
			L	1	0
VHR	3	17	R	1	1
			L	1	1
GAR	1	14	R	3	0
			L	3	0
MVMN	2	11	R	3	1
			L	3	0
NOC	8	12	R	3	0
			L	3	0
ALA	3	14	R	3	0
			L	3	0
NDJ	3	15	R	1	0
			L	2	0
TM	1	14	R	3	0
			L	3	0
VCS	2	11	R	4	0
			L	4	0
YSS	4	11	R	3	3
			L	3	0
EMP	4	18	R	3	2
			L	-	2
LCM	3	11	R	1	1
			L	3	1
MAS	1	12	R	3	1
			L	3	3
KMC	1	13	R	3	3
			L	3	0
GAS	1	13	R	3	3
			L	3	0
DPS	2	18	R	3	0
			L	2	0
DAFS	5	14	R	3	0
			L	3	0
VVS	2	14	R	3	1
			L	3	0
CNG	3	14	R	3	2
			L	3	2
GSC	6	18	R	4	0
			L	1	0
JCS	1	22	R	1	5
			L	1	5
BVLM	6	19	R	2	4
			L	2	0
GAM	3	11	R	3	3
			L	3	3
GTS	1	10	R	3	0
			L	3	0
MHSR	4	11	R	3	0
			L	3	0
GRQ	1	13	R	1	6
			L	1	6
JKJS	5	15	R	4	3
			L	4	0
GIM	4	35	R	1	3
			L	1	3
MAP	4	24	R	2	0
			L	2	0

*First surgery: 0 (No procedure); 1 (PMR); 2 (PMR+LCS); 3 (PMR+LCS+Talectomy); 4 (PMR+Talectomy). § Follow-up surgery: 0 (No procedure); 1 (PMR review); 2 (Debridement); 3 (Tarsectomy); 4 (Arthrodesis); 5 (LCS); 6 (Talectomy).

DISCUSSION

The term arthrogryposis is characterized by rigid joint contracture of two or more joints in different body areas. These clinical entities are divided into three subgroups. The first one encompasses all conditions with primary limb involvement, amyoplasia being its most common form. This disorder is characterized by rigid, symmetrical contractures such as extended elbow and feet in rigid equinus, cavus, and varus positions, which is the most frequent deformity of the feet and whose standard treatment is still surgery. The second subgroup includes those with intellectual impairment and joint contractures. The third subgroup comprises, for example, distal arthrogryposis, which may be associated with the hereditary pattern and with a normal intellectual development.[1-3,7,20,21]

Non-surgical treatment of arthrogryposis consists of physical and occupational therapy, psychological support, casting use, and stretching of the joints.[20-23] In this study, there were no cases treated conservatively, and all cases were treated surgically.

The surgical treatment consists of correcting deformities of the lower or upper limbs with soft tissue surgery and bone procedures in childhood. Widmann et al.[3] and Simis et al.[7] suggest that talectomy should be the procedure of choice for the correction of equinus, cavus, and varus deformities in the feet of patients with arthrogryposis older than 1 to 2 years old and for review after soft tissue surgery. Soft tissue surgeries have a higher recurrence rate than talectomies, especially in feet with more severe deformities and in older children.[3,20,23]

There are few reports of long-term follow-up of the treatment of patients with arthrogryposis, as most prior studies only report short or mid-term results. Long-term follow-up is necessary to establish long-lasting treatment options for each affected individual, improving their quality of life.[17,20,21]

With its 36 questions, the SF-36 questionnaire measures general health results and can be used to compare the disease burden in the population and the benefits of different treatments. In the study by Dobbs et al.,[15] the SF-36 questionnaire was used in 45 patients with congenital clubfoot treated with soft tissue surgery. Of these, eight patients underwent posterior release associated with plantar fasciotomy, while 37 were treated with posterior, subtalar, medial, and lateral releases for a mean follow-up period of 30 years, with long-term impairment of the physical function of the foot. Regarding the SF-36 questionnaire, the physical component was two standard deviations away from the average of the general population. The functional results of our arthrogrypotic patients are also low, as the surgical treated clubfeet described by Dobbs et al.[15] Our patients were younger with follow up about 14.8 years, against 30 years in Dobbs' paper. Dobbs patients' poor results in the functional aspect of the foot can be underestimated, as, in some cases, there was radiographic evidence of arthrosis, but the patients were asymptomatic.

The study by Amor et al.[18] used the Pediatric Outcomes Data Collection Instrument (PODCI) questionnaire, that were answered by the parents of 74 children diagnosed with amyoplasia with a mean age of 8.5 years. The results obtained were lower than those of children without musculoskeletal disorders in all 6 domains. During

Table 3. Surgical aspects of feet with arthrogryposis.

Isolated PMLR (14) = 21.8%	- (4) 28.5% no more procedures were required - (6) 42.8% required additional bone surgery - (4) 28.5% required review of PMLR
PMLR + bone procedure (LCS and/or talectomy) = (50) 78.1%	- (9) 18% required additional bone surgery: Arthrodesis (3 feet) / Tarsectomy (6 feet) - (34) 68% no more procedures were required
Of those 44 were talectomies, 68.7% of all procedures	- (4) 8% required review of PMLR - (3) 6% required debridement

*PMLR: posteromedial lateral release. Total talectomies: (46) 71.8%, out of which (44) 68.7% first.

Figure 2. Clinical picture of a patient showing corrected, but very small size feet.

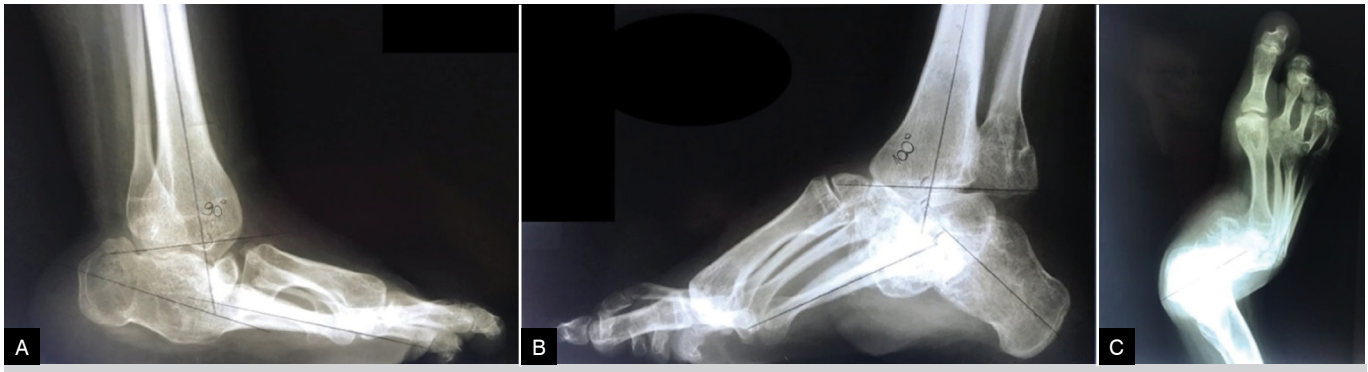

Figure 1. A) Lateral radiographic of the foot showing abnormal position due to talectomy in childhood, but the foot is plantigrade. B) Lateral alignment of a foot after talectomy with important cavus. C) Anteroposterior radiographic of a foot with lateral translation of the foot and adductus of the forefoot.

Table 4. SF-36 scores for patients with arthrogryposis surgically treated.

Patient	Physical functioning	Physical role functioning	Pain	General health	Vitality	Social functioning	Emotional well-being	Mental Health	Total
DPS	40	50	100	97	95	75	100	72	120.4
APPS	10	100	51	75	55	87.5	66.7	40	91.1
MAP	30	25	72	87	50	100	0	56	98.6
WJA	60	75	100	72	85	100	100	92	125.4
JLF	45	50	72	92	85	50	66.7	92	117.6
VHR	40	100	41	67	40	62.5	0	32	85.5
GAR	0	100	62	95	65	100	100	76	107.2
MVMN	55	50	100	100	80	87.5	66.7	88	130.8
NOC	5	75	100	65	75	100	100	96	113
ALA	45	75	100	100	75	62.5	66.6	88	111.4
NDJ	20	75	84	52	45	100	100	44	102.8
TM	80	100	62	62	50	100	50	88	121.4
VCS	35	75	52	60	90	100	66.6	88	119.2
YSS	10	75	72	65	70	62.5	66.6	68	102.2
EMP	0	100	74	47	45	62.5	100	60	90.8
LCM	35	75	62	50	75	75	100	28	107.6
MAS	45	100	62	57	80	100	100	20	112.6
KMC	85	100	100	60	80	100	66.6	72	125
GAS	85	100	62	60	80	100	72	72	123.2
DPS	10	25	84	70	65	87.5	50	64	107.4
DAFS	70	75	62	72	40	50	66.6	60	102.6
VVS	40	75	100	67	70	75	66.6	80	109.4
CNG	50	100	64	65	40	37.5	0	36	80.4
GSC	75	100	100	60	50	100	66.6	80	122
JCS	75	0	61	65	80	62.5	0	60	97.1
BVLM	70	100	74	70	80	100	100	88	105.4
GAM	5	75	74	57	65	100	66.6	80	103.8
GTS	50	75	52	57	50	75	66.6	32	93.6
MHSR	70	100	62	75	25	50	66.6	40	98.2
GRQ	20	25	62	47	85	100	66.6	80	105.6
JKJS	20	75	100	75	65	100	66.6	80	113
GIM	35	25	82	92	80	87.5	100	64	116.4
MAP	35	25	82	92	80	87.5	100	64	115.6

the mean follow-up period of approximately 3 years, children with amyoplasia had a statistically significant increase in the scores for upper extremity function, practicing of sports, and global function. These results showed that PODCI is useful in assessing the functional outcomes of children with amyoplasia and is sensitive to function changes over time.[18]

In our study, patients are older, and then heavier, then difficult to compare with those with amyoplasia with a mean age of 8.5 in the study by Amor et al.[18] It is also expected than arthrogrypotic patients in our study are less functional then their non-arthrogrypotic peers. The mental component was also better, not similar to general population, but reflect that those patients possibly adapt to their restrictions. Although most of the cases had unsatisfactory results due to the clubfoot study group method (including functional and radiographic results), the results of quality of life (base on the SF-36) were satisfactory in most patients.

The multicenter study by Nouraei et al.[20] aimed identify the long-term results of 177 adults with AMC in more than 15 countries. The study group consisted of 72% female patients with a mean age of 39 years, more than 90% of whom had involvement of the upper and lower limbs. As for the results of the SF-36 questionnaire, these patients had lower physical function and vitality scores than the general USA population.[18] In our study, about 60.6% of the patients considered to have some kind of limitation in the performance of their daily activities, and 21.3% of the patients reported having problems at work due to their physical disability. Still, they had higher scores in others, such as the pain, vitality, social, and mental components.

In a retrospective study involving six patients (12 feet), Widmann et al.[3] evaluated the results of the primary radical soft tissue release in feet presenting equinus, cavus, and varus positions in children younger than one-year-old with arthrogryposis. Mean age at primary surgery was 7.4 months, and the mean follow-up period was 4.3 years: short-term results were encouraging.

One frequent complain was the small size of the foot, consequent of multiple extensive resections that can be a problem, not only to buy shoes, but also to maintain balance.

Despite this study, in our case, radiographic measurements were significantly impaired by the high frequency of talectomy. There was a discrepancy between clinical and radiographic findings and the patient satisfaction.

In more recent years, the less invasive Ponseti treatment has been used also for arthrogrypotic feet, with promising results.[22,24-27] It will be interesting to compare the clinical and quality of life results with these extensive surgical methods in the long follow-up.

CONCLUSION

Arthrogrypotic feet are difficult to treat because they usually require many surgical procedures, and relapses are the rule. The standard protocol consisted of extensive posteromedial releases, including bone resections in the first years of life. In spite of the fact that most of the cases had unsatisfactory results according to Clubfoot Study Group score (functional and radiographic results included), the results of quality of life (based on SF-36) were satisfactory in most patients.

Stiffness is a common feature of these feet, a small size foot, and residual deformities were frequent. Future studies will show whether there will be a difference in the outcome of the treatment of these feet by applying the current, more conservative initial approach.

AUTHORS' CONTRIBUTION: All authors have contributed substantially to this article: MPN conceived and planned the activities that led to the study, participated in the review process, performed the surgeries, interpreted the study results, wrote the article, and approved the final version. JBC, APPG, RPF, and FFJ jointly performed the surgeries, collected the study data, analyzed and interpreted the results, and approved the final version.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e273746

LONG-TERM OUTCOMES OF USING VARIOUS GRAIN ALLOGRAFT SIZES IN PAPROSKY TYPE 3

RESULTADOS A LONGO PRAZO NO USO DE VÁRIOS TAMANHOS DE ALOENXERTO DE GRÃOS EM PAPROSKY TIPO 3

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ABSTRACT

Introduction: Severe acetabular bone defects can pose challenges in revision total hip replacement. The use of structural allografts and various sizes of grain allografts has been proposed as an alternative surgical technique for treating Paprosky type 3 acetabular defects. This study aimed to evaluate the long-term outcomes and potential complications associated with this approach. Methods: A retrospective review was performed on 102 hip reconstructions in patients with major acetabular bone loss, including 81 cases of type 3A and 21 cases of type 3B according to Paprosky's classification. Surgical procedures involved the use of structural allografts and various sizes of grain allografts in both reinforcement ring group and cementless cups group. Results: At a mean follow-up of 82.75 months, 76% of hips had no complications, while The others experienced pain changes in the cup position, post-operative dislocations, and infections. The mean pre-operative Modified Harris Hip Score improved in both groups at the last follow-up. Conclusion: The use of structural allografts and various sizes of grain allografts for treating type 3 acetabular defects in revision total hip replacement showed promising long-term outcomes and a low rate of complications. ***Level of Evidence IV; Retrospective Case Series.***

Keywords: Arthroplasty, Replacement, Hip. Allografts. Surgical Procedures, Operative.

RESUMO

Introdução: Defeitos ósseos acetabulares graves podem representar desafios na revisão da artroplastia total do quadril. O uso de aloenxertos estruturais e aloenxertos de grãos de vários tamanhos foram propostos como uma técnica cirúrgica alternativa para o tratamento de defeitos acetabulares Paprosky tipo 3. O objetivo deste estudo foi avaliar os resultados de longo prazo e as possíveis complicações associadas a essa abordagem. Métodos: Foi realizada uma revisão retrospectiva de 102 reconstruções de quadril em pacientes com grande perda óssea acetabular, incluindo 81 casos do tipo 3A e 21 casos do tipo 3B de acordo com a classificação de Paprosky. Os procedimentos cirúrgicos envolveram o uso de aloenxertos estruturais e aloenxertos de grãos de vários tamanhos, tanto no grupo do anel de reforço quanto no grupo das próteses sem cimento. Resultados: Em um acompanhamento médio de 82,75 meses, 76% dos quadris não apresentaram complicações, enquanto os demais apresentaram dor, alterações na posição da prótese, luxações pós-operatórias e infecções. A pontuação média pré-operatória do escore de quadril modificado de Harris melhorou em ambos os grupos no último acompanhamento. Conclusão: O uso de aloenxertos estruturais e aloenxertos de grãos de vários tamanhos para o tratamento de defeitos acetabulares do tipo 3 na substituição total do quadril de revisão mostrou resultados promissores em longo prazo e uma baixa taxa de complicações. ***Nível de Evidência IV; Série de Casos Retrospectivos.***

Descritores: *Artroplastia de Quadril. Aloenxertos. Procedimentos Cirúrgicos Operatórios.*

Citation: Ploynumpon P, Sritumma R, Chompoosang T. Long-term outcomes of using various grain allograft sizes in paprosky type 3. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Severe acetabular bone defects can present a challenging problem in revision total hip replacement. There are many treatment options available for managing acetabular bone defects, including the use of structural allografts from the distal femur, proximal tibia, and femoral head, combined with cemented or cementless cups or acetabular reinforcement rings. While these methods provide relatively good short-term results, the failure rate for mid and long-term outcomes can range between 4% and 47%.[1]

Another method proposed by Lebeau et al. involved the use of a dual-mobility acetabular cup cemented in a metal reinforcement (reconstruction acetabular ring) with bone graft filling the defect in revision total hip arthroplasty with severe acetabular bone defects and a high risk of dislocation. This approach provided good mid-term outcomes, with a survival rate of 91.9% for an 8-year follow-up period.[2]

In our study, we aimed to evaluate an alternative bone graft technique that involves the use of structural allografts and various sizes of

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

The study was conducted at the Rajavithi Hospital, Bangkok, Thailand.
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Article received on 04/08/2023, approved in 02/19/2024.

grain allografts for treating type 3 acetabular defects according to Paprosky's classification, with a focus on assessing the long-term outcomes and potential complications associated with this approach.

METHODS

A retrospectively reviews was performed in 102 hip reconstructions (101 patients) associated with major acetabular bone loss were conducted after received approval from the Ethics board Committee and Informed consent form(ICF) were signed by all participants. There were 81 hips in type 3A and 21 hips in type 3B according to Paprosky's classification. Pelvic discontinuity was 28 cases. The series included 52 right and 51 left with mean age of 57.3 years (34-83). All cases performed acetabular reconstruction from 2008 to 2019. There were 62 for aseptic loosening, 7 for protusio acetabuli post-hemiarthroplasty, 21 for second-stage revision after infected total hip arthroplasty, 5 for primary osteoarthritis, and 7 total hip arthroplasty instability.

Surgical procedures: The acetabular reconstructions were performed by structural allografts placed into cavity at super posterior part or the medial wall defect (Figure 1), then two sizes of grain bone graft by bone mill machine (Tracer design) were filled in the space(Figure 2 and 3). After all allografts were placed, 42 cases were performed with reinforcement ring and cemented cup, 60 cases with a cementless cup (Figure 4).

Statistical analysis

The study analyzed data using the SPSS Statistics program(IBM Corporation, Armonk, New York, USA), Version 22and the follow-up period for the participants was defined as the time between the acetabular component implantation and reoperation related to the component, death, or the end of the follow-up period. The Descriptive data was presented as median, minimum, maximum, and percentage values. The survival analysis was assessed on the Kaplan-Meier method.

RESULTS

One-hundred two hip reconstructions were performed (One-hundred one patients). Overall mean follow-up of 82.75 months (9 to 154), seventy-eight hips (76%) had no complications(Figure 5).

In the cementless cup group, one patient (1%) needed revision with a basic cementless cup after two years due to discomfort from

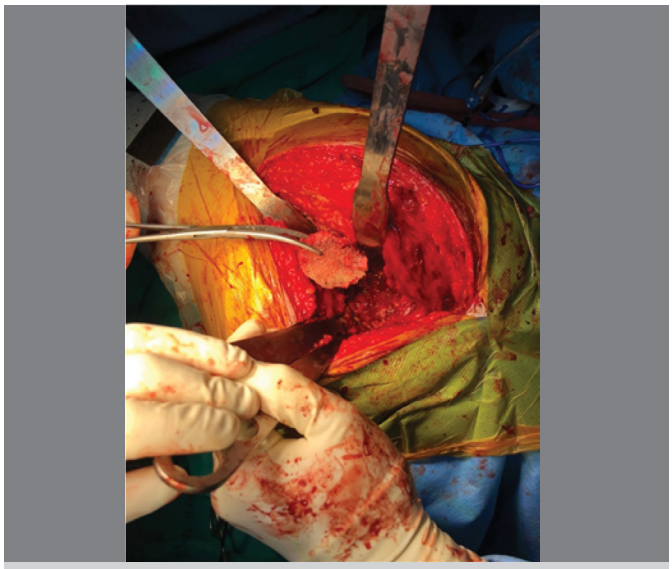

Figure 1. Structural allografts was placed into cavity at superoposterior part or the medial wall defect.

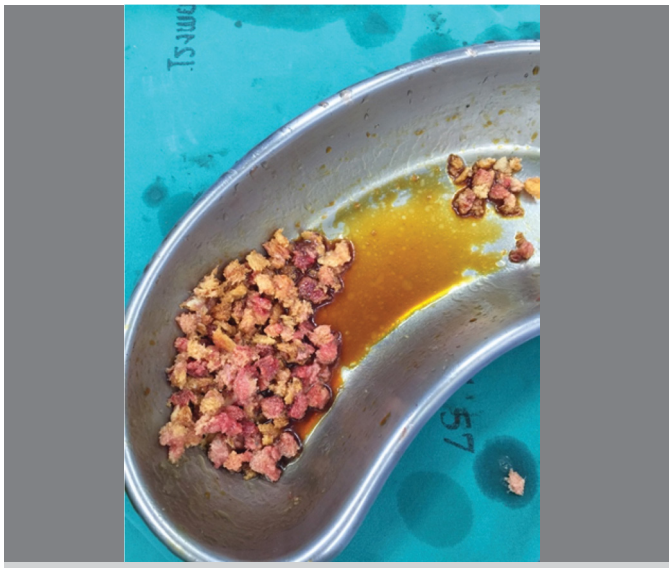

Figure 2. Using Various or multiple Grain sizes bone graft.

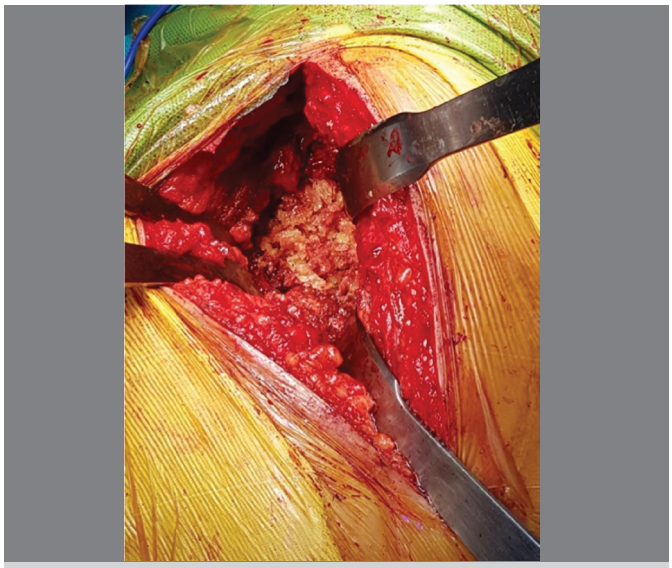

Figure 3. Grain bone graft were impacted into medial defect.

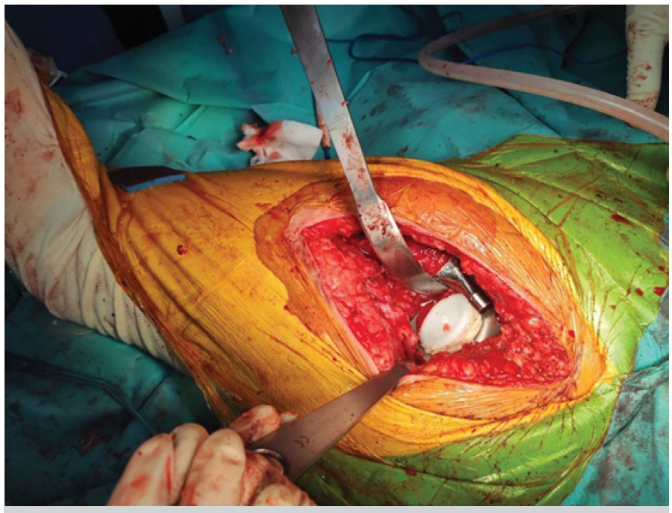

Figure 4. After gone graft was impacted ,reconstruction cage + cemented cup was placed.

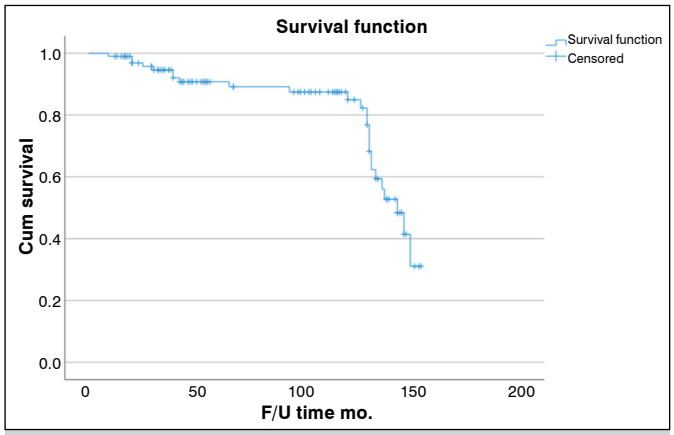

Figure 5. Survival of the acetabular implant.

a conspicuous implant. Two cases (2.1%) had the cup position change, but there were no symptoms and no revisions required. One hip (1.6% of all hips) had post-operative dislocations; this was addressed with open reduction and trochanter fixation. Two hips (2%) had deep infection after surgery; these were managed with debridement, and two case were lost follow up . There were two cases of deaths from congestive heart failure and ischemic heart disease. At the most recent follow-up, the mean pre-operative Modified Harris Hip Score increased from 28.3 points (range 16–44) to 89.1 points (range 73–95).

In the group of patients who received a reinforcement ring and cemented cup, only one hip (1%) had a change in the cup's position. However, it did not result in any symptoms or need a revision procedure. Two hips (3.2%) had post-operative dislocations, which were addressed by cup revision. Five hips (5%) had a deep infection after surgery, which was managed with a two-stage revision arthroplasty. Four follow-up cases were lost. Two cases were death from heart failure and pneumonia. The average pre-operative Modified Harris Hip Score increased from 22.7 points (13-39) to 82.1 points (60-89) at the final follow-up.(Table 1)

Table 1. Summary of the result of the study.

Result	Cementless cup (hip)	Reinforcement ring with cemented cup (hip)
Revision Rate	1	1
Cup position change	2	1
Post operative dislocation	1	2
Deep infection	2	5
Death	2	2
Follow up loss	2	4
Pre-operative Harris hip score (Mean +/-SD)	28.3 ± 8.2	22.7 ± 7.1
Post-operative Harris Hip Score (Mean SD)	89.1 ± 5.2	82.1 ± 8.4

DISCUSSION

Acetabular reconstruction is a surgical procedure used to rebuild the acetabulum, or the socket of the hip joint, in cases where there has been significant bone loss which is typically performed in patients who have experienced aseptic loosening, protusio acetabuli or revision after infected total hip arthroplasty.

There are a number of techniques available for restoring acetabular bone loss, including the use of structural allografts, cementless hemispherical cups, oblong cups, extra-large cups, modular porous augments, impaction bone grafting (IBG), reinforcement rings.Which depended on degree of bone loss , patient status , surgeon preference. However, Many study shown that biological reconstruction using impaction bone grafting has the added advantage of improving and potentially restoring bone stock for future revisions and has favorable longevity (85%-90% survival rate of implants).[3] But, the downside of this technique were technical demanded ,risk of graft resorption infection and time consuming.[4]

When compare to the technique as in the study by Perlbach et al., the use of extensive bone impaction grafting in combination with an uncemented component in acetabular revisions resulted in good implant survival rates of 96.3% (95% CI 94.1 to 98.5) after ten years and 92.8% (95% CI 89.2 to 96.6) after 15 years in a sample of 370 patients.[5] The implementation of tantalum augmentation as a viable alternative to allograft bone in the management of acetabular defects provides several advantages. Its high coefficient of friction and porous structure, like trabecular bone, impart stability and foster bone and fibrous ingrowth. The ability to tailor the various shapes and sizes of tantalum augments to specific defects also contributes to a reduction in operative time.[6] The mid-term outcomes of the utilization of tantalum augmentation in conjunction with cement cups and cages, as reported by Mahmoud et al, demonstrate favorable results with survivorship rates of 95.8% at a median follow-up of 5 years and 97.2% at a mean follow-up of 60.1 months.[7] However, the study of Qiang Xiao et el found that 4.9% of patients had a high hip center with measurements of 35.9 mm and 44.2 mm. The success of the results was attributed to restoring the hip center to normal biomechanics, as a high hip center can impact the function of the abductor muscles, and a longer neck length can mitigate this impact.[8]

Our case series assessed the use of a combination of structural allograft and different size impaction grafted bone allografts in the treatment of Paprosky type 3 bone deficiency, a severe bone defect. Complication rates did not differ significantly between the cementless and cemented cup groups in our study, which utilized grafts of varying sizes. This finding is noteworthy because it suggests that our grafting technique can be used in a range of scenarios, contingent on the patient's unique anatomy and the surgeon's needs, and that it can produce favourable outcomes with respect to complications,survival rate and Herris hip score.

Other than Being the first study to investigate the use combination of structural allograft and various grain allograft as a technique for improving outcomes, providing an alternative to traditional allograft use. This study has several strengths, including a comprehensive, long-term follow-up period based on registered data and the consistent application of the surgical technique by a small team of highly experienced surgeons.

However, This study has a number of limitations due to its retrospective design,moderate lost follow up and mortality rate, which hindered the ability to complete follow-up for all participants and some of the data were missing which can affect statistical analysis.

CONCLUSION

The goal of using allografts in the treatment of acetabular bone defects is to restore bone stock for stability in primary or revision hip replacement surgeries. The combination of structural allografts and grain allografts of various sizes can be effective in achieving this goal. The larger particles provide improved mechanical stability and better vascularization and cement penetration, while the smaller particles fill in the spaces between the larger particles and facilitate ongoing biological healing.

Based on our long-term results, it appears that acetabular reconstruction using a combination of structural allografts and various sizes of grain allografts is effective in the treatment of Paprosky type 3 bone deficiency.

AUTHORS' CONTRIBUTION: Conceptualization, T.K.; methodology, T.K.; validation,P.P; formal analysis, T.K.; data collection,R.S.; preform experiment ,T.K.; writing - original draft preparation, T.K. ,P.P.writing - review & editing,P.P. All authors have read and agreed to the published version of the manuscript.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e274225
ORTHOPEDIC ONCOLOGY

CLINICAL AND EPIDEMIOLOGIC EVALUATION OF DESMOID TUMORS IN A BRAZILIAN SARCOMA REFERENCE CENTER

AVALIAÇÃO CLÍNICA E EPIDEMIOLÓGICA DE TUMORES DESMÓIDES NO CENTRO DE REFERÊNCIA DE SARCOMA DO BRASIL

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ABSTRACT

Introduction: Desmoid Tumors (DT) are rare neoplasms with higher incidence in younger women. Methods: Retrospective, single-center analysis of patients with DT. Variables were age, sex, biopsy, treatment and recurrence. The disease-free survival (DFS) was calculated with the Kaplan-Meier method. Results: 242 patients were evaluated, mean age was 34 years, 70.7% women, 44.4% originated in the trunk/abdomen and 54.5% had size > 5cm. Surgery was performed in 70.2%, 31% with negative margin and only 57% with previous biopsy. Recurrence rate was 38% and 1,2,5-year DFS was 75.3%, 64.2%, 57.8%, respectively. Size (p = 0.018) and tumor location in the dorsum (p = 0.001), extremities (p = 0.003) and pelvis (p = 0.003) were related to higher relapse rate. Conclusion: our data reinforces the need to gather data from real world practice and the importance of awareness of DT and medical education about DT behavior and best approach due to the high rates of surgery and elevated number of patients treated without biopsy. ***Level of Evidence III; Retrospective Comparative Study.***

Keywords: Desmoid. Fibromatosis. Epidemiology.

RESUMO

Introdução: Os tumores desmóides (TD) são neoplasias raras com maior incidência em mulheres jovens. Métodos: Trata-se de uma análise retrospectiva, em um único centro, de pacientes com TD. As variáveis foram idade, sexo, biópsia, tratamento e recorrência. A sobrevida livre de doença (SLD) foi calculada pelo método de Kaplan-Meier. Resultados: Foram avaliados 242 pacientes, com idade média de 34 anos, 70,7% mulheres, 44,4% com origem no tronco/abdômen e 54,5% com tamanho > 5 cm. A cirurgia foi realizada em 70,2%, 31% com margem negativa e apenas 57% com biópsia prévia. A taxa de recorrência foi de 38% e a SLD de 1, 2 e 5 anos foi de 75,3%, 64,2% e 57,8%, respectivamente. O tamanho (p = 0,018) e a localização do tumor no dorso (p = 0,001), nas extremidades (p = 0,003) e na pelve (p = 0,003) foram relacionados a uma maior taxa de recidiva. Conclusão: Nossos dados reforçam a necessidade de coletar dados da prática do cenário real e a importância da conscientização da TD e da educação médica sobre o comportamento da TD e a melhor abordagem, devido às altas taxas de cirurgia e ao elevado número de pacientes tratados sem biópsia. ***Nível de Evidência III; Estudo Comparativo Retrospectivo.***

Descritores: *Desmoide. Fibromatose. Epidemiologia.*

Citation: Silva C, Pinto FFE, Lopes A, Aruquipa MPS, Aguiar Junior S, Nakagawa SA, Mello CAL. Clinical and epidemiologic evaluation of desmoid tumors in a brazilian sarcoma reference center. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 5. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Desmoid Tumors (DT), also known as Aggressive Fibromatosis, are rare neoplasms originating in connective tissues and are characterized by local deep infiltration capacity, but without metastatic potential. The most frequent location is the trunk wall and limbs but can arise in any part of the body.[1] History of Familial Adenomatous Polyposis (FAP) syndrome is the most known risk factor and pregnancy is linked to the occurrence of abdominal wall tumors.[2] The diagnosis is based on histomorphology with proliferation of uniform fibroblasts in a collagenous stroma with nuclear staining for beta-catenin protein on immunohistochemistry.[3]

Treatment for DT is challenging and requires a discussion at a multidisciplinary tumor board.[4,5] When indicated, the goal of treatment is to obtain local control with the minimum possible morbidity, considering tumor location size, growing rate and patient preferences. Surgery was the main modality employed for most of the patients. However, due to the elevated rates of local recurrence after tumor resection a more conservative approach in currently advocated by

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

The study was conducted at the A.C.Camargo Cancer Center, Sao Paulo, SP, Brazil.
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Article received on 04/25/2023, approved in 08/04/2023.

most of the guidelines.[4,6] Active surveillance is the most appropriate approach for most of patients with asymptomatic disease.

Over the last decade many trials showed promising results with systemic treatment. Conventional chemotherapy with liposomal doxorubicin, vinblastin and methotrexate are the most frequently used cytotoxic agents.[4] More recently, tyrosine kinase inhibitors such as sorafenib[7] and pazopanib[8] were evaluated in prospective trials and showed response rate around 40% and good symptom control. In the prospective randomized trial that evaluated the efficacy of sorafenib, patients randomized to placebo arm presented a spontaneous tumor regression rate of almost 20%. The arsenal of systemic agents is increasing and recently, a novel agent Nirogacestat, a gamma secretase inhibitor, was evaluated in a phase III trial and proved to be effective and with adequate safety profile.

In Brazil there is limited information regarding the epidemiology of patients diagnosed with soft tissue tumors, including desmoid fibromatosis.[9] Moreover, there is limited information regarding the clinical presentation and treatment patterns and outcomes of patients treated in Brazilian centers.[10] The disparities in treatment access among patients in developing countries is well known and it may be more prominent in patients diagnosed with rare cancers and sarcomas as demonstrated by a large cancer database study conducted in Brazil.[9]

As a result, it is important to analyze the clinical and epidemiological aspects of patients with desmoid tumor to better guide future health policies. Our study aimed to provide real world dada of patients diagnosed with desmoid fibromatosis and treated at a large cancer center in Brazil by analyzing the clinical and demographic characteristics and to identify potential prognostic factors related with tumor relapse.

MATERIAL AND METHODS

Patients and variables

This is an observational, retrospective, transversal and single center study that evaluated patients treated from 1992 to 2022. Data were extracted from medical records and inserted in the Redcap platform. The project was approved by the Institutional Ethics Committee (number). The inclusion criteria were patients with diagnosis of desmoid fibromatosis, at least one treatment at the Institution, available medical data, follow up > 12 months. Exclusion criteria were concomitant active neoplasm at diagnosis. Initially 290 patients were identified, 48 were excluded due to incomplete medical information and 242 were included in the analysis.

The analyzed variables were age, sex, history of familial adenomatous polyposis, symptoms at diagnosis, history of previous local trauma, biopsy prior to treatment, type of treatment upon admission, tumor site and size, treatment received (surgery, systemic, radiation, other), status of surgical margins, disease relapse.

Statistical Analysis

The database was constructed in the RedCap platform. Descriptive data as frequencies was presented in absolute (n) and relative (%) frequency, mean and standard deviation. To evaluate the association among qualitative variables we used the qui-squared test or the Fisher exact test and for the quantitative variables we used the t test for independent samples or the non-parametric Mann-Whitney test. The primary endpoint was Disease-Free Survival (DFS). The DFS was defined from the time of surgery to first recurrence and was estimated by the Kaplan-Meier method and the log rank-rank test was used to compare the survival curves. A p value <0,05 adopted in order to establish the statistical significance. SPSS version 28 was used for statistical analysis.

RESULTS

Population characteristics

A total of 242 patients were include and analyzed. The mean age was 34 years (1-82), 71% was female, 74% had private health insurance, 6% had history of FAP. Initial symptoms were growing mass in 52% of patients and pain in 38% and only 17% reported history of previous trauma, table 1. Primary tumor site was 44.6% in trunk and abdomen, 20.6% in extremities, 8.7 in head and neck, 25% others. Tumor size was $\leq$ 5 cm in 30%, >5 and < 10 cm in 34% and $\geq$ 10 cm in 18%. Biopsy had been performed in 57% of patients prior to the treatment. (Table 1)

Treatment

Upon admission only 16.9% had previous surgery and 73.6% had intact tumor and information was not available in 9.5%. After diagnosis, the initial therapeutic approach was surgery in 170 patients

Table 1. Demographic and clinical characteristics (n = 242 patients). São Paulo, 2023.

Variable	Category	N (242)	(%)
Sex	Female	171	70.7
	Male	71	29.3
Age	Mean	34	(1-82)
	< 19 years	35	14.5
	20 - 39 years	96	39.7
	40 - 59 years	53	21.9
	>60 years	13	5.4
	Unknown	45	18.5
Family history of neoplasm	Yes	126	52.1
	No	66	27.3
	Unknown	50	20.6
FAP Syndrome	Yes	14	5.8
	No	228	94.2
Initial Symptoms	Asymptomatic nodule	2	0.8
	Growing lump	145	59.9
	Pain	69	28.5
	Functional restriction	3	1.2
	Imaging finding	10	4.1
	Others	39	16.1
	Unknown	31	12.8
Previous Trauma	Yes	13	5.4
	No	201	83.1
	Unknown	28	11.5
Health plan	Public health care	46	19.0
	Health Insurance	179	74.0
	Privated (Out of pocket)	17	7.0
Location	Abdomen	91	37.6
	Head and neck	23	9.5
	Dorsum	12	5.0
	Extremities	62	25.6
	Pelvis	22	9.1
	Trunk	32	13.2
Primary tumor size	< 5 cm	83	34.3
	5-10cm	74	30.6
	>10 cm	43	17.8
	Uknown	42	17.3
Biopsy	No	61	25.2
	Yes	138	57.0
	Uknown	43	17.8

(70%), systemic anti-neoplastic treatment in 9.9%, radiation therapy in 2.9% and follow-up was adopted in 9.5%. (Table 2)
We observed a recent decrease in surgery in the past 4 years as described in Figure 1. Surgery was more frequently employed between the periods of 1992-2001 and 2002-2012 and decreased the last 3 years (2018-2022). The surgical margins status in 170/242 patients treated with surgery was negative in 40,0%, positive in 32,9% and unknown in 25,9%. (Table 2)
After first, second and third relapse, surgery was employed in 47/65, 19/30 and 7/15 of patients. (Table 2)

Disease Free survival

The median follow-up time was 91.2 months, and 65 disease relapses were observed in the group of patients treated with surgery. Health insurance ($p = 0.001$) and tumor size ($p = 0.024$) and location ($p = 0.001$) correlated with relapse (Table 3). The median DFS was not reached and the 1-, 2-, 5- and 10-year DFS were 75,3%, 64,2%, 57,8% and 56,4%, respectively. (Figure 2) Patients with tumor located in the extremities, pelvis and dorsal had inferior DFS as compared to trunk, abdomen and head and neck (24, 14, 12 months versus NR, $p = 0,001$). The median DFS for patients with larger tumors (> 10 cm) was 21 months versus NR for patients with < 10 cm tumors ($p = 0,018$). In the Cox regression analysis, patients with tumor > 10 cm had 2.5 increase in the risk of relapse

Table 2. Distribution of treatment modalites (n = 242). São Paulo, 2023.

Variable	Category	N	(%)
Initial approach	observation	23	9.5
	Surgery	170	70.2
	Chemotherapy	24	9.9
	Radiotherapy	7	2.9
	others	18	7.4
	Total	242	100.0
Surgical margins	Not applicable	02	1.2
	negative	68	40.0
	positive	56	32.9
	unknown	44	25.9
	Total	170	100.0
Relapse	No	105	61.8
	Yes	65	38.2
	Total	170	100.0
Site First Relapse	Abdomen	15	23.1
	Head and neck	06	9.2
	Trunck	12	18.4
	Extremities	19	29.2
	Pelvis	13	20.0
	Total	65	100.0
Treatment first relapse	Surgery	42	55.3
	Radiotherapy	8	10.5
	Chemotherapy	12	15.8
	tamoxifen	10	13.1
	Observation	4	5.3
	Total	76	100.0
Treatment second relapse	Surgery	19	52.8
	Radiotherapy	5	13.9
	Chemotherapy	3	8.3
	Anti-inflamatory	3	8.3
	tamoxifen	5	13.9
	observation	1	2.8
	Total	36	100.0

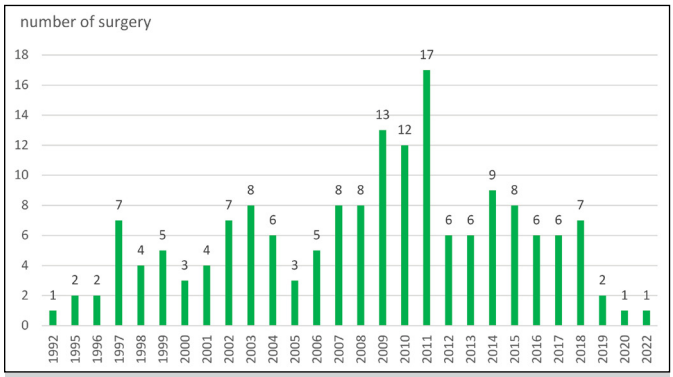

Figure 1. Distribution of surgical procedures to treat desmoid tumor over the years (1992-2022).

Table 3. Correlation of clinical variables with tumor relapse for patients treated with surgery (n = 170). São Paulo, 2023.

Variable	Relapse			p
	No	Yes	Total	
Age*				
<19	15	12	27	0.324
20-39	40	26	66	
40-59	24	9	33	
>60	6	1	7	
Total	85	48	133	
Sex**				
Male	33	21	54	0.868
Female	74	42	116	
Total	107	63	170	
Health Care System ***				
Public health care	25	6	31	0.001
Health Insurance	80	47	127	
Privaste (Out of pocket)	2	10	12	
Total	107	63	170	
Signs and symptoms**				
No pain	75	48	123	0.496
Pain	32	15	47	
Total	107	63	170	
Previous trauma******				
No	89	49	138	0.701
Yes	4	3	7	
Total	93	52	145	
Site***				
Abdomen	48	16	64	0.001
Head and Neck	12	6	18	
Dorsum	3	7	10	
Extremities	21	20	41	
Pelvis	5	10	15	
Trunk	18	4	22	
Total	107	63	170	
Size***				
< 5 cm	44	11	55	0.024
5 - 10 cm	37	11	48	
> 10 cm	13	12	25	
Total	94	34	128	
Biopsy**				
No	42	13	55	0.687
Yes	53	21	74	
Total	95	34	129	

*Fisher-Freeman-Halton exact test;**Continuity Correction; ***Pearson chi-square test; ****Fisher Exact Test. O evaluate the association among qualitative variables we used the qui-squared test or the Fisher exact test and for the quantitative variables we used the t test for independent samples or the non-parametric Mann-Whitney test.

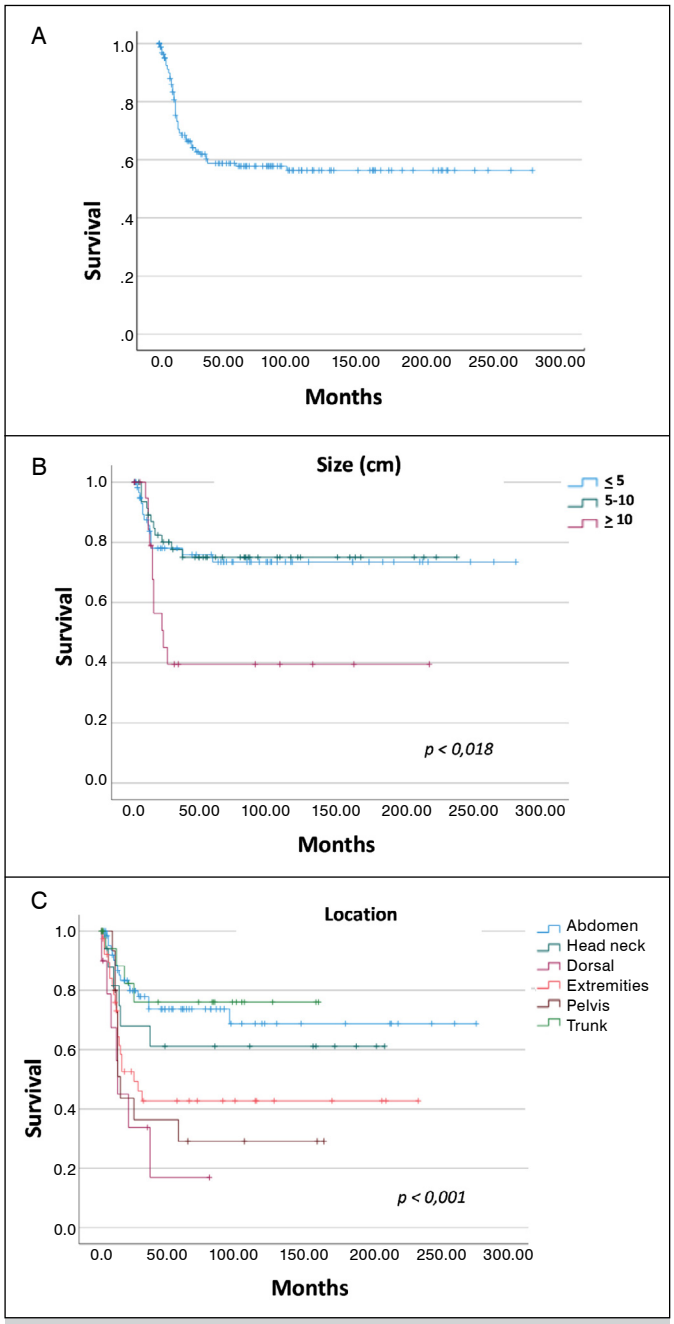

Figure 2. Disease-free Survival in months for patients treated with surgery (A), according to tumor size (B) and tumor location (C). Kaplan-Meier curves, log-rank test.

(HR 2.52, CI 95% 1.14-5.59, $p = 0.022$) and tumor located in the dorsum (HR 4.69, CI 95% 1.92-11.43, $p = 0.001$), extremities (HR 2.67, CI 95% 1.32-5.16, $p = 0.003$) and pelvis (HR 3.29, CI 95% 1.49-7.29, $p = 0.003$) increased risk of relapse as compared to the other tumor locations, as shown in Table 4.

DISCUSSION

The management of desmoid tumor is challenging and the therapeutic plan should be defined by a multidisciplinary team.[4] There are many barriers to deliver the best treatment for patients including physicians' awareness of tumor behavior. As a result, it is important to understand the socio-demographic characteristics of patients diagnosed with DT and to evaluate the patterns of diagnosis and

Table 4. Correlation of age, sex, tumor site and size with Disease-free survival. Cox regression model. São Paulo, 2023.

Variable	Category	HR	CI 95%		p
		Ref. (1)	Lower	Upper	
Age	<19	1			
	20-40	0.686	0.346	1.361	0.281
	>40	0.575	0.248	1.332	0.197
Sex	Female	1			
	Male	1.124	0.666	1.899	0.661
Site	Abdomen	1			
	Head and Neck	1.543	0.603	3.945	0.366
	Dorsum	4.693	1.926	11.438	0.001
	Extremities	2.671	1.382	5.162	0.003
	Pelvis	3.299	1.493	7.291	0.003
	Trunk	0.840	0.281	2.514	0.755
Size	< 5 cm	1			
	5 - 10 cm	0.888	0.403	1.957	0.769
	> 10 cm	2.528	1.142	5.595	0.022

Cox regression model.

treatment delivered. Our study characterized the clinical and sociodemographic aspects of 272 patients with DT, the largest series of DT treated at a Brazilian cancer center.

DTs are rare mesenchymal neoplasms with uncertain behavior. Patients can present with fast growing and symptomatic tumors, or the disease can remain stable for a long time.[6] Interestingly, some patients undergo spontaneous regression even without active treatment.[7] Thus, an active surveillance strategy is recommended for most newly diagnosed patients.[4,6] Our study showed that 70% of the patients underwent surgical tumor resection. This number appears to be elevated but, in accordance with the most recent guidelines,[4] we observed a trend in the decreasing number of surgeries over the years. After surgical resection, the disease recurrence is frequent. We observed a relapse rate of 38% and the 1,2,5 years disease-free survival rate was 75,3%, 64,2%, 57,8% respectively. Our data are in line with the literature showing that most of the events occurs in the first 2 years after surgery[6] and it could guide the follow up police after a tumor resection with more frequent medical visits and imaging in the first 2 years after surgery. There are no clear data regarding the best option for patients with tumor recurrence. The joint global consensus-based guideline focuses mainly on first diagnosis and reinforces the importance of active surveillance for most patients with asymptomatic and slow growing tumors.[4] In our study, a salvage surgery was performed in 42/76, 19/36 and 7/17 of patients with first, second and third relapse, respectively. On the other hand, only 10% of the patients received radiation therapy and tamoxifen and 15% received systemic therapy. There are many reasons to consider a non-surgical approach after a tumor relapse. First, there is a hypothesis that growth factors released after surgery, during the initial phase of wound healing, could transmit signals that promote the activation of β-catenin resulting in tumor growth.[11] Second, more recently prospective trials showed the activity of tyrosine kinase inhibitors to treat DT with objective response rate around 30 to 40% for pazopanib[7] and sorafenib,[8] respectively. Another important prospective, phase 3 trial, the DeFi trial[12] showed that the gamma secretase inhibitor Nirogacestat promoted tumor shrinkage in almost all the patients with objective response rate of 40% and the study demonstrated an improvement in the quality of life of patients treated with Nirogacestat. Disparity and inequity in treatment access is an important barrier that patients with cancer face,[13] especially in the Brazilian health system where there is no officially approved chemotherapy

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or target agent for DT. This data could partially explain the high frequency of surgery and less indication of systemic treatment. However, one the data of active systemic treatment was available only in recent years, a more detailed analysis should be carried out regarding the use of systemic treatment including tyrosine kinase inhibitors over the past 5 years.

Over the past decades, many prognostic factors, such as age, tumor size, tumor location, and surgical margins, have been associated with recurrence after surgical resection.[14,15] Our series showed that tumor location and size were the only 2 variables associated with inferior DFS. Patients with tumors larger than 10 cm had a median DFS of 21 months as compared to NR for $\leq$ 10 cm ($p = 0.018$) and tumors located in the dorsum, pelvis and limbs had median DFS of 12, 14 and 24 months, respectively and not reached in the head and neck, trunk and abdomen ($p < 0,001$). In the multivariate analysis, tumor size and location were independent prognostic factors related to risk of relapse. The addition of molecular profiling of DT with inclusion of CTNNB1 gene mutation status improves the accuracy of the predictive models of recurrence as demonstrated by our group in a recent study (data not published) and other authors.[16] Moreover, the better understanding of molecular factors related to disease behavior could predict tumor progression and better guide the therapeutic approach. More recently, circulating tumor DNA (ctDNA)[17] and circulating tumor cells[18] are under investigation and could become a valid biomarker of response/progression.

One important step in the management of patients with soft tissue tumors is the histopathological diagnosis. The strategy of "first treat and then diagnose" is not advised since the treatment plan can only be established based on the specific tumor subtype.[5,19] In our series, we observed a high number of patients (25%) that were treated without a previous biopsy. It may denote that patients were treated in non-reference centers for sarcomas and the suspicion of a benign lesion was made. Our data showed that growing mass and pain was present in 59% and 28% of the patients, respectively, both symptoms are not characteristics of a benign lesion. This data highlights the importance of medical education regarding initial approach of soft tissue mass and the importance of organized referral networks in the management of desmoid tumor and other sarcomas.[20]

There are some limitations in our study. First, it is a retrospective study and much information could not be retrieved from the medical records and a considerable ratio of missing information was detected. Second, important information regarding the use of hormotherapy and pregnancy was not available for most of patients. Our analysis could not detect the amputation ratio since many patients were treated with many surgical resections as well as the precise indication of surgery for recurrence. Of note, the analysis was carried out in a long period it may negatively impact the findings, but it may, on the other hand, be useful to illustrate the changes in the treatment over time. These limitations were mitigated by the large number of patients if we consider a single center analysis and for the long period of follow up.

CONCLUSION

Our study shows the characteristics of 240 patients with the diagnosis of desmoid tumor treated at a Brazilian center. Despite the high rate of surgery, we observed a decline in the recent years. In contrast to the good practice recommendations a large proportion of patients were treated without previous biopsy. Tumor size and location were correlated with the risk of disease relapse. Our data illustrate the scenario of DT approach in Brazil and could be helpful to guide future actions in the health police strategies.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. CS: intellectual concept of the article, writing the article, data analysis, data interpretation and review of the article; AL: review of the article and data interpretation; FFEP: review of the article and data interpretation; MPSA: writing the article, and data analysis; SAJ: review of the article and data interpretation; SAN: review of the article and data interpretation; CALM: intellectual concept of the article, writing the article, data analysis, data interpretation and review of the article.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e274533
ORTHOPEDIC TRAUMA

HOOK ASSISTED REDUCTION IN CEPHALOMEDULLARY NAILING WITHOUT TRACTION TABLE

REDUÇÃO ASSISTIDA POR GANCHO EM HASTE CEFALOMEDULAR SEM MESA DE TRAÇÃO

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ABSTRACT

Introduction: Proximal femoral nailing for intertrochanteric femur fracture is sometimes a challenging procedure without a traction table, especially if complicated fracture pattern. We aimed to overcome this difficulty with the hook. Materials and Methods: A retrospective study of 60 patients. 28 of the patients reduction was necessitated with a hook (group 1). The other patients did not need to use this technique (group 2, n=32). The collo-diaphyseal angle, lag screw placement, and tip-apex distance were measured using radiographs. Results: There were statistically significant differences between the two groups regarding the Garden Alignment Index, postoperative collo-diaphyseal angle measurements, and tip-apex distance. The Garden Alignment Index was found as 163.92 degrees (dg.) In the frontal plane in group 1, and 154.78 dg in group 2, respectively. In group 1, the tip-apex distance was 16.05 cm, whereas it was 25.32 cm in group 2. The collo-diaphyseal angle was 133.1º in group 1, and 128.65º in group 2. Conclusions: The hook-assisted reduction is beneficial when operating without a traction table; however, it can also be a part of the surgeons' equipment even when operating on a traction table. When difficulties in obtaining an ideal anatomical reduction in displaced intertrochanteric femoral fractures, we suggest using the hook-assisted reduction technique. ***Level of Evidence III; Case-control Study.***

Keywords: Femoral Fractures. Surgical Procedures, Operative. Surgical Hooks. Developing Countries.

RESUMO

Introdução: Frequentemente, a fixação do fêmur proximal para fratura intertrocantérica do fêmur sem uma mesa de tração é um procedimento desafiador, especialmente se o padrão da fratura for complicado. O objetivo foi superar essa dificuldade utilizando um gancho. Materiais e métodos: Trata-se de um estudo retrospectivo de 60 pacientes. Em 28 desses, a redução foi necessária com um gancho (grupo 1). Os outros pacientes não precisaram usar essa técnica (grupo 2, n=32). O ângulo colo-diafisário, a colocação do parafuso lag e a distância ponta-ápice foram medidos por meio de radiografias. Resultados: Houve diferenças estatisticamente significativas entre os dois grupos com relação ao Índice de Alinhamento de Garden, às medidas do ângulo colo-diafisário pós-operatório e à distância ponta-ápice. O índice de alinhamento de Garden foi de 163,92 graus (dg.) No plano frontal no grupo 1 e 154,78 dg no grupo 2, respectivamente. No grupo 1, a distância ponta-ápice foi de 16,05 cm, enquanto no grupo 2 foi de 25,32 cm. O ângulo colo-diafisário foi de 133,1 graus no grupo 1 e 128,65 graus no grupo 2. Conclusão: A redução assistida por gancho é benéfica quando se opera sem uma mesa de tração; no entanto, ela também pode fazer parte do equipamento do cirurgião mesmo quando se opera em uma mesa de tração. Quando houver dificuldades em obter uma redução anatômica ideal em fraturas femorais intertrocantéricas deslocadas, sugerimos o uso da técnica de redução assistida por gancho. ***Nível de Evidência III; Estudo de Caso-controle.***

Descritores: Fraturas do Fêmur. Procedimentos Cirúrgicos Operatórios. Ganchos Cirúrgicos. Países em Desenvolvimento.

Citation: Tekin C, Gunaydin B. Hook assisted reduction in cephalomedullary nailing without traction table. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 5. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Closed anatomical reduction of displaced intertrochanteric femur fractures (IFFs) has challenged orthopedic surgeons due to the broken medial hinge. The displacement of broken fragments by strong muscles may not allow the fracture to be reduced.[1,2] A fracture table is a part of the technique in most countries; however, limited centers in developing countries own a particular table. Limited surgical hints are available for intertrochanteric fractures.[3,4]

Some auxiliary techniques for reducing unstable IFFs such as Steinmann pins,[3] various types of bone clamps, and even some authors advised for open reduction after unsuccessful attempts. Additional surgeries can be anticipated if the reduction is not appropriately made.[5]

In this study, we aimed to evaluate the hook-assisted reduction technique, which we have used since 2015 in patients with IFFs if the reduction was difficult.

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

The study was conducted at the Istanbul Cam ve Sakura City Hospital, Orthopaedics and Traumatology Department, Turkey.
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Article received on 05/05/2023, approved in 02/15/2024.

PATIENTS AND METHODS

Patients selection

The Local Ethics Committee approved this study (Date: 24/09/2019, 2019/156/09/16).

Between December 2015 and March 2019, 66 patients with IFFs who underwent osteosynthesis with cephalomedullary nailing were identified. One patient died in the early postoperative period, and five did not attend outpatient follow-ups after discharge. Accordingly, 60 patients were included in the study and evaluated retrospectively. All patients provided written informed consent to participate. Fractures were classified according to the A.O. Foundation/Orthopaedic Trauma Association System. The inclusion criteria were as follows: patients over 18 years, treatment with cephalomedullary nail in the lateral decubitus position without a traction table, and at least six months of outpatient follow-up. Patients were excluded if they had A1.1 type proximal femur fractures, but 1.2 and 1.3 were included because of displacement of these type fractures whether they're stable or not collo-diaphyseal angle distortion less than 5 degrees from the opposite side, patients with pathologic fractures, patients with follow-up less than six months.

METHODS

The Integrated Compression Screw cephalomedullary nail (interTAN, Smith & Nephew, Memphis, TN) was used for internal fixation. All operations were performed in the lateral decubitus position without a traction table. If the reduction is appropriate, the nail is inserted. The hook-assisted reduction technique was initiated if the alignment was not acceptable despite three consecutive attempts. While one orthopedic surgeon used this technique, a control group was formed with the permission of the other surgeon, who did not use hook-assisted reduction but attempted any other auxiliary tools. He was able to use the hook through existing incisions. If the hook could not be utilized using previous incisions, an additional 2 cm incision was done laterally to provide access to the fracture (Figure 1). A case example showing hook-assisted reduction and surgical fluoroscopy images during the reduction and application of the nail can be found in Figure 2 a-g. Preoperative traction radiography, postoperative A.P., and lateral radiographs of the patient can be found in Figure 3 a-c.

Study Protocol

Age, sex, fractured side, follow-up, and fracture type were determined. Mobilization, weight-bearing, and union data of the patients were recorded. The collo-diaphyseal angle, Garden Alignment Index (frontal), tip-apex distance, the quadrant of the helical blade according to Cleveland and Bosworth,[6] and Ikuta's reduction subgroups were determined.[7] The Herman criteria were used for the quality of reduction.[8]

Figure 1. Application of the hook in hook-assisted reduction methods.

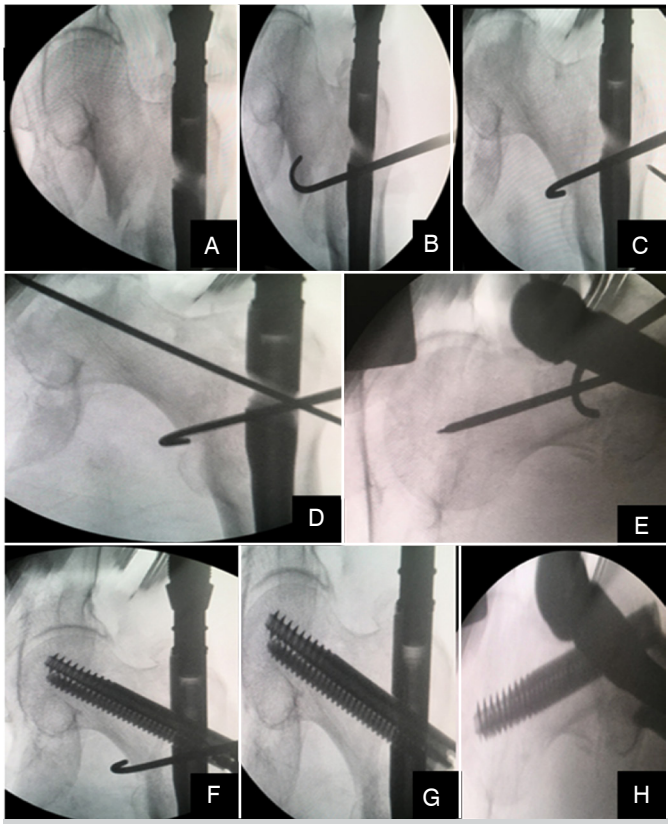

Figure 2. Fluoroscopic images: (A) Anteroposterior (AP) view showing fracture displacement prior to reduction; (B) AP view before hook-assisted reduction (C) AP view after hook-assisted reduction (D) AP view after proximal femoral nail guide wire was applied (E) Lateral (frog-leg) image after proximal femoral nail guide wire was applied (F) AP image when a two-screw cephalomedullary nail was applied (G) AP fluoroscopy image of two-screw cephalomedullary nail after removing the hook (H) Frog-leg image of two-screw cephalomedullary nail.

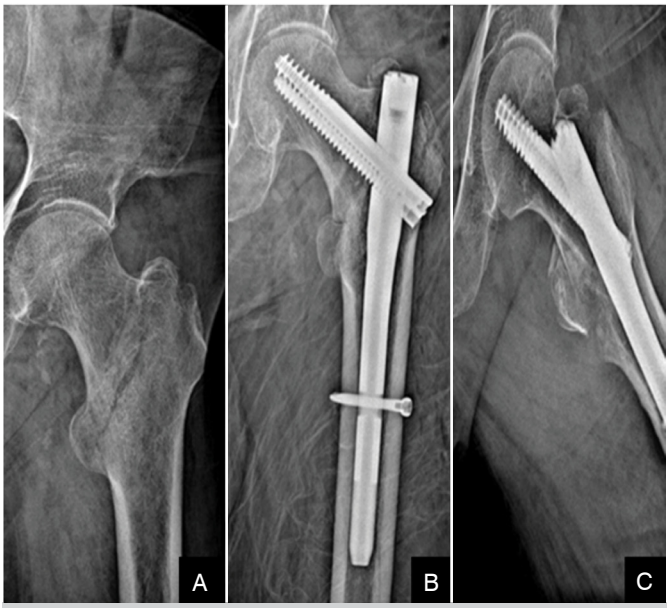

Figure 3. (A) 92-year-old patient in the hook-assisted reduction group, preoperative AP fracture radiograph in traction; (B) AP postoperative radiography of a patient with a two-screw cephalomedullary nail; (C) Postoperative frog-leg radiography of a patient with a two-screw cephalomedullary nail.

Accordingly, for the reduction to be considered appropriate, it was assumed that there was no varus position, and displacement between the medial cortices measured on A.P. and lateral radiographs should be less than 5 mm or near at sight. If two of these conditions were met, the reduction was assessed as "good," if one was completed, as "acceptable," if no criteria were met, as "poor." The union was determined by a single surgeon with radiographs taken in the follow-up of patients. Sectra UniView (Sweden, version 20.2.14.3442) was used in the measurements. The presence of union was defined as the presence of callus formation as a result of bridging at least three cortices on A.P. and lateral radiographs. Complications and mortality were recorded in outpatient clinic follow-up.

Statistical Analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS, Chicago, Illinois, USA), version 23.0 software. A standard distribution test was performed on all data. For the comparison of quantitative data, Student's t-test was used for those with normal distribution, and the Mann-Whitney U test was used for non-parametric data. Fisher's Chi-square test was used to compare qualitative data. Statistical significance was set as $p < 0.05$.

RESULTS

The patients were divided into two groups: those who underwent the hook method (group 1, n=28) and those without the hook method (group 2, n=32). Average values of age, follow-up time, sex, and side (Table 1) were summarized.

Fractures were classified according to type 31. Groups in Table 2 summarize A.O. Fracture types. Patients with 31AO-A1-1 fractures were excluded from the study.

The Garden Alignment Index in the frontal plane was 163.92 degrees in group 1, and 154.78 degrees in group 2 (p<0.001). The tip-apex distance was determined as 16.05 mm in group 1 and 25.32 mm in group 2 (p=0.001). The mean collo-diaphyseal angle was 133.1 degrees in group 1 and 128.65 degrees in group 2 (p=0.032) (Table 3).

Table 1. Average values of age, follow-up time, sex, side distribution by groups.

		Group 1 n=28	Group 2 n=32	p
Age (Year) mean ± SD, (Min-Max)		72.25 ± 18.91 (27-92)	77.03 ± 14.14 (32-95)	0.553
Follow-up time (month) mean ± SD, (Min-Max)		16.53 ±11.60 (6-45)	16.65 ± 11.35 (6-40)	0.97
Sex (%)	Female	16 (57.1%)	13 (40.6%)	0.3
	Male	12 (42.9%)	19 (59.4 %)	
Side (%)	Left	16 (57.1%)	18 (56.3%)	0.576
	Right	12 (42.9%)	14 (43.8%)	

Table 2. OTA / AO fracture classification by groups.

	Group 1 n=28 (%)	Group 2 n=32 (%)	p
31AO-A1-2	8 (28.6%)	8 (25%)	0.91
31AO-A1-3	5 (17.9%)	3 (9.4%)	
31AO-A2-1	3 (10.7%)	2 (6.3%)	
31AO-A2-2	4 (14.3%)	6 (18.8%)	
31AO-A2-3	1 (3.6%)	2 (6.3%)	
31AO-A3-1	3 (10.7%)	4 (12.5%)	
31AO-A3-2	0 (0%)	1 (3.1%)	
31AO-A3-3	4 (14.3%)	6 (18.8%)	

The quadrant of the helical blade, which was advanced to the femoral neck, is shown in Figures 4 a-b. The percentage of patients in the recommended quadrants in the postoperative radiographs was 32.1% for group 1 and 31.3% for group 2. The implant was in the superior-posterior quadrant in 3.6% of patients in group 1, the quadrant in which the implant should not be placed, whereas this ratio was 12.5% in group 2. Patients who underwent arthroplasty with cut-out complications were those whose implants were in the superior-posterior and central-posterior quadrants in group 1. However, it was in the superior-posterior quadrant in all patients in group 2.

According to Herman's criteria, we accepted 130 degrees as a cut-off value for varus alignment; a good reduction was seen in 20 patients, and an acceptable reduction was seen in six patients (varus alignment in four patients, fracture interval over 5 mm in two patients) in group 1. A good reduction was observed in 20 patients, and an acceptable reduction was observed in 10 patients (varus alignment in six patients, fracture interval over 5 mm in four patients) in group 2. The poor reduction was detected in two patients in both groups (Table 4).

According to the Ikuta classification, 12 patients were typical subtypes, six were posterior, and 12 had anterior subtypes in group 1. In group 2, 14 patients were typical subtypes, four were posterior

Table 3. The mean collo-diaphyseal angle, Garden Alignment Index (frontal plane) measurements, and tip-apex distance measurements according to the groups.

	Group 1, mean ± SD, (Min-Max)	Group 2, mean ± SD, (Min-Max)	p
Collo-diaphyseal angle (degrees)	133.1 ± 6.96 (116-145)	128.65 ± 7.36 (103-138)	0.032
Garden Alignment Index frontal (degrees)	163.92 ± 5.49 (147-171)	154.78 ± 6.35 (135-165)	<0.001
Tip-apex distance (mm)	16.05 ± 7.23 (3-25)	25.32 ± 12.23 (2-62)	0.001

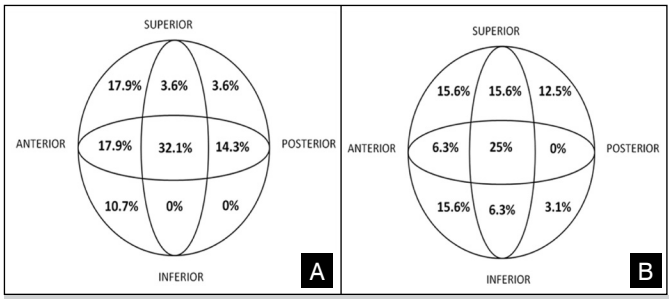

Figure 4. The positions of the helical blade on the quadrant of the helical blade according to Cleveland and Bosworth (A) group 1 (hook method) (B) group 2 (no hook).

Table 4. Distribution of groups according to the Herman criteria and Ikuta classification.

			Group 1 n=28 (%)	Group 2 n=32 (%)	p
Herman Criteria	Good Reduction		20 (71.4%)	20 (62.5%)	0.849
	Acceptable	Varus alignment	4 (14.3%)	6 (18.8%)	
		Fracture range	2 (7.1%)	4 (12.5%)	
	Poor reduction		2 (7.1%)	2 (6.3%)	
Ikuta Classification	Normal		12 (42.9%)	14 (43.8%)	0.619
	Posterior		6 (21.4%)	4 (12.5%)	
	Anterior		12 (34.7%)	14 (43.8%)	

subtypes, and 14 were anterior subtypes (Table 4). All those with cut-out complications were classified in the posterior subtype according to the Ikuta classification.
Mean mobilization, weight-bearing, and fracture union times were summarized in Table 5. General complications and mortality distribution of the Groups can be found in Table 6. No deep infections or vascular and nerve lesions were detected in any patients.
A statistically significant difference was found in the Garden Alignment Index, tip-apex distance, and collo-diaphyseal angle measurements.

DISCUSSION

Displaced IFFs are not uncommon fractures and several methods were described.[9] The critical point for the successful treatment of IFF, so hip fractures in the elderly, is to obtain stable geometry and rigid internal fixation for treatment and encourage patients to mobilize as early as possible.
IFFs are the most common type of proximal femoral fractures and can face various stress rates due to body weight and muscles around the hip. In this region, the reduction can occasionally be difficult due to the push-pull forces caused by the muscles. For the same reason, some surgeons experience reduction problems. The hook-assisted reduction is used, especially in cases where reduction is challenging. Internal fixation is the preferred surgical treatment for IFFs.[10] However, performing and maintaining a proper alignment before placing the implant can be difficult for displaced IFFs. Techniques have been described to prevent this complication.[11] Chun et al. described a method in which they reduced with one or two Steinmann pins used in the sagittally unstable IFFs.[3] In this study, hook-assisted reduction was used in cases where reduction could not be achieved with traction and rotation maneuvers.
Short intramedullary nails can be applied with or without a fracture table. Although most surgeons prefer to use a traction table, there are instances where it is not available. Availability problems make surgeons find alternative ways, especially in developing countries.[12] In 2016, Sahin et al. compared femoral nailing procedures in unstable IFFs using a traction table or manual traction. As a result, they determined that despite the increase in the number of surgical assistants required for manual traction, the preparation and the total anesthesia times were shorter using manual traction.[13]
In the surgical treatment of IFFs, the appropriate reduction must be achieved before starting nailing.[14] In some cases, although all means of reduction are being used, such as increased traction and the addition of rotational maneuvers, a sufficient reduction cannot be achieved. We used the "hook-assisted method" in these cases to provide an acceptable reduction.
Ikuta classification was used in the postoperative lateral radiographs to evaluate the head-neck segment's alignment according to the distal fracture fragment. It is divided into standard (central), posterior, and anterior subtypes.[3] It was in a normal position in 42.9% in group 1 and 43.8% of patients in group 2. The cut-out complication was seen in patients with Ikuta posterior subtype.
In group 1, the cut-out rate was 7.1% (n=2), whereas in group 2, it was 9.4% (n=3). The literature shows that the cut-out ratio of intramedullary implants is 8%.[15] Our series observed an 8.3% overall complication rate when all patients were included.
The study has some limitations, such as being a retrospective study. No functional score has been added, and the last one limited number of patients and short follow-up can also be counted.
In displaced intertrochanteric femoral fractures, difficulties in obtaining an ideal anatomical reduction that sometimes may lead to malreduction have been challenging for orthopedic surgeons. This challenge can get more complicated when assisting apparatus such as a traction table is unavailable, which may be the case in developing countries. The hook-assisted reduction is beneficial when operating without a traction table[16]; however, it can also be a part of the surgeons' equipment even when operating on a traction table.

Table 5. Mean mobilization, weight-bearing, and fracture union times by groups.

	Group 1 mean ± SD, (Min-Max)	Group 2 mean ± SD, (Min-Max)	p
Mobilization	1.82 ± 0.81 (1-4)	1.96 ± 0.78 (1-4)	0.425
Weight bearing	3.46 ± 1.52 (2-6)	3.96 ± 1.44 (2-6)	0.180
Union	7.03 ± 2.48 (4-12)	7.31 ± 2.46 (4-12)	0.503

Table 6. General complications and mortality distribution by groups.

Complications	Group 1 n=28 (%)	Group 2 n=32 (%)	p
Mortality	2 (7.1%)	2 (6.3%)	0.89
DVT	2 (7.1%)	2 (6.3%)	0.89
Cut-out	2 (7.1%)	3 (9.4%)	0.755
Varus collaps*	1 (3.6%)	1 (3.1%)	0.923
Re-operation	3 (10.7%)	4 (12.5%)	0.830
Superficial infection	1 (3.6%)	0 (0%)	0.467

*Excluding patients with cut-out.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. CT: conceptualization, data analysis and article writing B.G.: data analysis, study supervision and article review; M.K. data analysis and review and conclusion of the article.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e278581
ORTHOPEDIC TRAUMA

RISK FACTORS AT NON-UNION OF TIBIAL FRACTURE TREATED WITH INTRAMEDULLARY NAIL

FATORES DE RISCO PARA NÃO-UNIÃO DA FRATURA DE TÍBIA TRATADA COM HASTE INTRAMEDULAR

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ABSTRACT

Objective: Identify the predictors associated with delayed union at 6 months and non-union at 12 months in tibial shaft fractures treated with intramedullary nailing (IMN). Methods: This retrospective longitudinal study included a cohort of 218 patients who sustained tibial shaft fractures and received IMN between January 2015 and March 2022. We gathered data on a range of risk factors, including patient demographics, trauma intensity, associated injuries, fracture characteristics, soft tissue injuries, comorbidities, addictions, and treatment-specific factors. We employed logistic bivariate regression analysis to explore the factors predictive of delayed union and non-union. Results: At the 6-month follow-up, the incidence of delayed union was 28.9%. Predictors for delayed union included flap coverage, high-energy trauma, open fractures, the use of external fixation as a staged treatment, the percentage of cortical contact in simple type fractures, RUST score, and postoperative infection. After 12 months, the non-union rate was 15.6%. Conclusion: the main predictors for non-union after IMN of tibial shaft fractures are related to the trauma energy. Furthermore, the initial treatment involving external fixation and postoperative infection also correlated with non-union. ***Level of Evidence III; Retrospective Longitudinal Study.***

Keywords: Tibial Fracture. Fracture Healing. Fractures, Ununited.

RESUMO

Objetivo: identificar os fatores preditivos associados ao atraso de consolidação em 6 meses e à não união em 12 meses em fraturas da diáfise da tíbia tratadas com haste intramedular (HIM). Métodos: O estudo longitudinal retrospectivo de coorte incluiu 218 pacientes, que apresentaram fraturas da díafise da tíbia e receberam HIM entre janeiro de 2015 e março de 2022. Os desfechos principais pesquisados foram atraso de consolidação em 6 meses de acompanhamento, e não união em 12 meses. Coletou-se dados de uma variedade de fatores de risco. Utilizou-se análise de regressão logística bivariada para explorar os fatores preditivos de atraso de consolidação e não união. Resultados: Aos 6 meses, a incidência de atraso de consolidação foi de 28,9%. Os preditores de atraso de consolidação incluem cobertura de retalho, trauma de alta energia, fraturas expostas, uso de fixação externa como tratamento estagiado, porcentagem de contato cortical em fraturas simples, escore RUST e infecção pós-operatória. Após 12 meses, a taxa de não união foi de 15,6%, com fatores preditivos sendo necessidade de cobertura por retalho, lesão vascular, trauma de alta energia, fraturas expostas, uso de fixação externa como tratamento estagiado, porcentagem de contato cortical em fraturas simples e infecção pós-operatória. ***Nível de Evidência III; Estudo Longitudinal Retrospectivo.***

Descritores: *Fraturas da Tíbia. Consolidação da Fratura. Fraturas não Consolidadas.*

Citation: Puccetti VLYA, Miranda FL, Figueiredo CCN, Medeiros KAA, Leonhardt MC, Silva JS, Kojima HE. Risk factors at non-union of tibial fracture treated with intramedullary nail. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 8. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Tibial shaft fractures are the most prevalent type of long bone fracture, demonstrating a bimodal distribution. Intramedullary nailing (IMN) stands as the primary treatment for displaced tibial shaft fractures[2]. Despite its effectiveness, complications such as delayed union and non-union continue to pose a substantial challenge, with reported incidence rates ranging from 4% to 48%[3,4].

The consequences of delayed union and non-union extend beyond statistics. These complications impose additional burden on patients, necessitating revision surgeries and prolonging pain and disability.

Numerous previous studies have endeavored to shed light on the factors influencing non-union development, including patient demographics, injury and fracture characteristics, and aspects

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

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Article received on 09/15/2023, approved in 01/24/2024.

related to treatment[5,6]. However, the current body of literature remains marked by uncertainties and inconclusive findings regarding the precise risk factors for fracture healing disturbances[7,8].
The primary objectives of this study are to elucidate the risk factors and predictors associated with delayed union at 6 months and non-union at 12 months following the intramedullary nailing treatment of tibial shaft fracture.

METHODS

This retrospective study was conducted at urban university-based level one trauma center. Data were collected through a retrospective chart review and the review of existing radiographs from patients with tibial shaft fractures who underwent fixation with IMN, between January 2015 and March 2022. Ethical approval was granted by the Scientific and Ethical Committee (SEC) of the University under the protocol number 24061. Given the retrospective nature of the study, a request was submitted to the SEC to waive the need for the informed consent from the patients, and it was approved.
The inclusion criteria were as follows: age over 18 years, fracture of the tibia shaft, closed or open, treated with intramedullary nailing, follow up radiographs at six months and 12 months, and availability of all necessary data in the patient's charts.
The exclusion criteria included pathologic fractures, proximal or distal fractures of the tibia, diaphyseal bone loss, prior injury to the same tibia, and treatments other than IMN.
Data were collected on patient's preoperative, intraoperative, and postoperative information. All the relevant data potentially influencing the healing process were collected. These factors were considered to establish their association as risk factor for delayed or non-union.
Patient characteristics: age, sex, and race.
Trauma energy: high-energy (e.g., car accidents, firearm injuries, fall from height, motorbike accident and vehicle collision) and low energy (e.g., fall from standing height, sports injuries, blunt trauma).
Associated injuries: chest and abdominal injuries, neurovascular damage, and fractures in other segments. These injuries were classified according to the Abbreviated Injury Scale (AIS), and subclassified into AIS ≤ 2 and AIS ≥ 3[9].
Fracture characteristics: side, shaft segment (proximal, middle, distal), AO/OTA (AO Foundation / Orthopedic Trauma Association) classification[10], open fractures (Gustilo classification)[11], in AO/OTA simple type fractures the percentage of cortical contact (< 25%, 25% to 50%, 50% to 75%, > 75% and 100%), for the type B fractures more or less than 50% of contact.
Soft tissue injury: flap reconstruction, vascular injury and compartment syndrome.
Comorbidities and addictions: obesity, diabetes mellitus, and any other relevant comorbidity, as well as smoking, alcoholism, use of illicit drugs.
Treatment: treatment with external fixator, time to conversion into IMN, time between the fracture and the IMN fixation in non-staged cases, reaming or not reaming, gap > 2 mm between the fragments.
Radiographic evaluation: Radiographic Union Scale in tibial fracture (RUST) was used to assess the bone healing. A score of 1 indicated no callus, 2 indicated initial callus with the fracture line still visible, 3 indicated callus with no fracture line visible. It was based on the sum of the four cortical scores (two in the anteroposterior and two in the lateral view)[12].
Healing: fracture was considered healed when patients had no pain in the fracture site, no limping and showed callus involving at least three of the four cortices and required additional surgical intervention beyond definitive fixation[13]. Lack of healing in 6 months was classified as delayed union and absence of healing at 12 months was classified as non-union.
Follow up: assessment of screw breakage and deep infection.

Qualitative parameters assessed were described for all patients using absolute and relative frequencies and the qualitative characteristics were described using summary measures (mean and standard deviation). The occurrence of delayed union at 6 months and non-union at 12 months was described according to the qualitative characteristics using absolute and relative frequencies and the association was verified using chi-square tests or exact test (Fischer's exact test or likelihood ratio tests). The quantitative characteristics were described according to each outcome using summary measures and compared using Student's t-test. Unadjusted odds ratios (OR) were estimated with the respective 95% confidence intervals for each variable of interest for non-union in each period using bivariate logistic regression and joint models were created with the characteristics that had a descriptive level of less than 0.10 ($p < 0.10$) in the unadjusted analyzes, with the characteristics being present for all the patients in the study and whose numbers of patients in the categories were in agreement to be included in the analyzes, with the models being carried out using multiple logistic regression with full models, i.e., all the variables included in the models were kept in the final models[14,15].
The IBM-SPSS for Windows version 22.0 software was used to carry out the analysis and Microsoft Excel 2013 was used to tabulate the data and create the graphs. The tests were carried out at a 5% significance level.

RESULTS

From January 2015 to March 2022, our cohort encompassed a total of 218 patients. The cohort exhibited a mean age of 36.2 ± 14.2 years, with a male predominance comprising 180 patients (82.6%). High-energy trauma constituted the etiological factor in 84.9% of the cases, and 50.5% of these cases presented with associated injuries, of which 52.7% were classified as AIS >3. (Table 1)
The prevailing fracture type was the AO/OTA type A, accounting for 57.3% of the cases. The majority of the fractures were characterized as open injuries (63.3%), with 49.1% classified as Gustilo IIIA and 9.2% as Gustilo IIIB. Compartment syndrome occurred in only 5 (2.3%) cases. (Table 1)
For a more comprehensive dataset of the patients' characteristics, please refer to Table 1.
The average interval between fracture occurrence and IMN fixation was 8.5 ± 5.7 days. Among the patients who underwent the staged treatment with the external fixator 135 (61.9), the average time to conversion into IMN was 6.1 ± 6.1 days. Reaming was performed in 146 (67%) cases. (Table 1)
A fracture gap greater than 2 mm was observed in 132 cases (60.6%) following IMN. The final reduction revealed less than 50% contact in 61% of type A fractures and 41.8% of type B fractures. (Table 2)
Regarding the radiographic assessment of the healing process, the RUST at the 6-month follow up was 8.2 ± 2.2. Fracture healing was observed in 155 patients (71.1%) at the 6-month mark, increasing to 184 patients (84.4%) at the 12-month follow up leading to a non-union rate of 15.6%. (Table 2)
Locking bolt breakage occurred in 10 patients (4.6%) and deep infection emerged as complication in 29 patients (13.3%). (Table 2)
At the six-month follow-up evaluation, several factors exhibited statistically significant correlations with delayed union. These included the need for flap reconstruction ($p < 0.001$), high-energy trauma ($p < 0.001$), open fractures ($p < 0.001$), staged treatment involving initial external fixation ($p < 0.001$), the number of days to convert the external fixator to IMN ($p = 0.006$), cortical contact in type A fractures less than 50% ($p < 0.001$), RUST ($p < 0.001$), and deep infection ($p < 0.001$). (Table 3)
In the 12-month follow-up assessment, factors that remained statistically significant in their correlation with non-union included the need for flap reconstruction ($p = 0.001$), high-energy trauma ($p = 0.007$),

Table 1. Demographic data.

Variable	Description (n = 218)
Age (years), mean SD	36.2 ± 14.2
Sex (male), n (%)	180 (82.6)
Race (white), n (%)	172 (78.9)
High energy trauma, n (%)	185 (84.9)
Associated injuries, n (%)	
No	108 (49.5%)
AIS < 3	58 (26.6)
AIS ≥ 3	52 (23.9)
AO/OTA classification, n (%)	
Type A	125 (57.3)
Type B	55 (25.2)
Type C	38 (17.4)
Gustilo classification, n (%)	
Closed	80 (36.7)
Type I	4 (1.8)
Type II	2 (0.9)
Type IIIA	107 (49.1)
Type IIIB	20 (9.2)
Type IIIC	5 (2.3)
Side, n (%)	
Right	92 (42.2)
Left	123 (56.4)
Bilateral	3 (1.4)
Shaft segment, n (%)	
Proximal	10 (4.6)
Middle	129 (59.2)
Distal	79 (36.2)
Obesity, n (%)	3 (1.4)
Smokers, n (%)	23 (10.6)
Alcoholism, n (%)	11 (5)
Illicit drugs, n (%)	12 (5.5)
Diabetes, n (%)	6 (2.8)
Other comorbidities, n (%)	24 (11)

n = number, SD = standard deviation.

Table 2. Results related to the treatment.

Variable	Description (n = 218)
Flap reconstruction, n (%)	29 (13.3)
Vascular injury, n (%)	5 (2.3)
Compartment syndrome, n (%)	5 (2.3)
Staged external fixator, n (%)	135 (61.9)
Days to convert, mean SD	6.1 6.1
Days to definitive IMN, mean SD	8.5 5.7
Gap > 2 mm, n (%)	132 (60.6)
Type A cortical contact, n (%)	
< 25%	44 (35.2)
25% - 50%	32 (25.6)
50 - 75%	37 (29.6)
100%	12 (9.6)
Type B cortical contact, n (%)	
< 50%	23 (41.8)
> 50%	37 (29.6)
Reamed nail, n (%)	146 (67)
RUST 6m, mean SD	8.2 2.2
Healed 6 months, n (%)	155 (71.1)
Healed 12 months, n (%)	184 (84.4)
Locking bolt breakage, n (%)	
No	208 (95.4)
Proximal	6 (2.8)
Distal	4 (1.8)
Deep infection, n (%)	29 (13.3)

n = number, SD = standard deviation.

open fractures ($p < 0.001$), staged treatment involving an external fixator ($p = 0.003$), cortical contact less than 50% in type A fractures ($p < 0.001$), RUST ($p < 0.001$), and deep infection ($p = 0.002$). Additionally, vascular injury showed correlation ($p = 0.029$) in this group. (Table 4) Multiple logistic regression analyses encompassing all risk factors revealed that, at the 6-month mark, patients who used an external fixator had a 5.99 times higher chance of experiencing delayed union compared to those who did not use one ($p = 0.016$). Furthermore, with each 1-point increase in RUST, the chance of delayed union decreased by 79% ($p < 0.001$), irrespective of other patient characteristics. Patients requiring flap reconstruction had a 2.99 times higher chance of non-union at 12 months compared to those without the need for a flap ($p = 0.027$). Patients subjected to prior external fixation had a 4-fold higher chance of non-union at 12 months compared to those who did not undergo external fixation ($p = 0.031$). Lastly, patients with postoperative deep infections had a 2.87 times higher chance of experiencing non-union, regardless of other patient characteristics. (Table 5)

DISCUSSION

Non-union, a distressing complication, may ensue after a fracture, imposing considerable physical and economic burdens. This phenomenon not only inflicts substantial pain, discomfort and functional impairment to the patient but also necessitates additional medical interventions, incurring in substantial expenses[13,16].

The importance of this issue is further exacerbated when it pertains to non-union arising from tibia shaft fractures, given their status as the most prevalent long bone fractures in adults[1,2], thereby amplifying the magnitude of the problem.

This is the first to study a population in Brazil and Latin America with a substantial sample size. Notably, the average age of our patient cohort stood at 36.2 ± 14.2, signifying a youthfulness in comparison to analogous studies such as Kawasaki N et al.[4] and Makaram NS et al.[17], which reported mean ages of 45.6 and 46 years, respectively. This deviation may be explained to the unique characteristics of our institution - a tertiary trauma center entrusted with the most severe cases within the city's rescue system.

Given the prominence of high-energy trauma, one might anticipate a concomitant prevalence of associated injuries. However, our study diverges from this expectation, revealing that nearly half of our patients (49.5%) presented without any associated injuries. Among those who did, the injuries tended to be minor in nature (AIS < 3). This phenomenon can be explained by the preponderance of motorcycle accidents within our city. Such incidents frequently result in extremity injuries while sparing the abdomen or thorax from trauma, thus accounting for this distribution of injury pattern.

Among the 138 patients in our study, representing 63.3% of the total cohort, 107 patients (77.5%) presented with Gustilo IIIA lesions, while 20 patients (14.5%) exhibited type IIIB lesions, necessitating attention to soft tissue reconstruction with flap coverage. However, it is noteworthy that 29 patients underwent flap reconstruction, that is explained by the fact that nine patients from the Gustilo IIIA group encountered postoperative soft tissue complications, requiring debridement and subsequent soft tissue reconstruction. Both open fracture and need for flap had association with the incidence of delayed union at 6 months of 28.9% and non-union at 12 months of 15.6% (($p < 0.001$).

Despite the predominance of high-energy mechanism as the primary etiological factor, the incidence of vascular injuries was relatively low, observed in only five patients (2.3%). A similar trend was noted for compartment syndrome, affecting only five patients (2.3%).

On average, fractures that did not necessitated staged treatment with external fixation were stabilized using IMN approximately 8.5 ± 5.7 days post-fracture. Importantly, this delay in fixation did not

Table 3. Statistical analyzes of healing with 6-month follow up.

Variable	Healing in 6 m		OR	IC (95%)		p
	Yes	No		Inferior	Superior	
Age (years), mean SD	36,8 14,6	34,8 13,2	0,99	0,97	1,01	
Sex						0,117
Female	31 (81,6)	7 (18,4)	1,00			
Male	124 (68,9)	56 (31,1)	2,00	0,83	4,81	
Race						0,765
White	122 (70,9)	50 (29,1)	1,00			
Brown	19 (67,9)	9 (32,1)	1,16	0,49	2,72	
Black	14 (77,8)	4 (22,2)	0,70	0,22	2,22	
Flap reconstruction						<0,001
No	143 (75,7)	46 (24,3)	1,00			
Yes	12 (41,4)	17 (58,6)	4,41	1,96	9,90	
Vascular injury						0,146*
No	153 (71,8)	60 (28,2)	1,00			
Yes	2 (40)	3 (60)	3,83	0,62	23,26	
Compartment syndrome						0,628*
No	152 (71,4)	61 (28,6)	1,00			
Yes	3 (60)	2 (40)	1,66	0,27	10,20	
Obesity						>0,999*
No	153 (71,2)	62 (28,8)	1,00			
Yes	2 (66,7)	1 (33,3)	1,23	0,11	13,89	
Smoker						0,753
No	138 (70,8)	57 (29,2)	1,00			
Yes	17 (73,9)	6 (26,1)	0,85	0,32	2,28	
Alcoholism						0,517*
No	146 (70,5)	61 (29,5)	1,00			
Yes	9 (81,8)	2 (18,2)	0,53	0,11	2,53	
Illicit drugs						>0,999*
No	146 (70,9)	60 (29,1)	1,00			
Yes	9 (75)	3 (25)	0,81	0,21	3,10	
Diabetes						>0,999*
No	151 (71,2)	61 (28,8)	1,00			
Yes	4 (66,7)	2 (33,3)	1,24	0,22	6,94	
Other comorbidities						0,324
No	140 (72,2)	54 (27,8)	1,00			
Yes	15 (62,5)	9 (37,5)	1,56	0,64	3,76	
Trauma energy						<0,001
Low	33 (100)	0 (0)	1,00			
High	122 (65,9)	63 (34,1)	&			
Associated injury						0,179
No	83 (76,9)	25 (23,1)	1,00			
AIS < 3	38 (65,5)	20 (34,5)	1,75	0,87	3,52	
AIS ≥ 3	34 (65,4)	18 (34,6)	1,76	0,85	3,64	
Gustilo						<0,001#
Closed	64 (80)	16 (20)	1,00			
I	4 (100)	0 (0)	&			
II	2 (100)	0 (0)	&			
IIIA	78 (72,9)	29 (27,1)	1,49	0,74	2,98	
IIIB	5 (25)	15 (75)	12,00	3,80	37,93	
IIIC	2 (40)	3 (60)	6,00	0,92	38,98	
Side						0,356#
Right	65 (70,7)	27 (29,3)	1,00			
Left	87 (70,7)	36 (29,3)	1,00	0,55	1,80	
Bilateral	3 (100)	0 (0)	&			
Bilateral						0,558*
No	152 (70,7)	63 (29,3)	1,00			
Yes	3 (100)	0 (0)	&			
Segment in the shaft						0,056#
Proximal	4 (40)	6 (60)	1,00			
Middle	90 (69,8)	39 (30,2)	0,29	0,08	1,08	
Distal	61 (77,2)	18 (22,8)	0,20	0,05	0,77	
Staged with external fixator, n (%)						<0,001

No	73 (88)	10 (12)	1,00			
Yes	82 (60,7)	53 (39,3)	4,72	2,24	9,90	
Reamed IMN						0,099
No	46 (63,9)	26 (36,1)	1,00			
Yes	109 (74,7)	37 (25,3)	0,60	0,33	1,10	
Days to convert to IMN, mean SD	5,4 6,2	7,9 5,6	1,07	1,02	1,12	0,006**
Days to IMN, mean SD	8,4 5,7	8,9 5,5	1,02	0,97	1,07	0,488**
Gap between fragments						0,383
< 2mm	64 (74,4)	22 (25,6)	1,00			
> 2mm	91 (68,9)	41 (31,1)	1,31	0,71	2,41	
AO/OTA classification						0,120
A	94 (75,2)	31 (24,8)	1,00			
B	39 (70,9)	16 (29,1)	1,24	0,61	2,53	
C	22 (57,9)	16 (42,1)	2,21	1,03	4,72	
Type A cortical contact						<0,001#
< 25%	23 (52,3)	21 (47,7)	4,57	0,90	23,29	
25% - 50%	26 (81,3)	6 (18,8)	1,15	0,20	6,70	
50% - 75%	35 (94,6)	2 (5,4)	0,29	0,04	2,29	
100%	10 (83,3)	2 (16,7)	1,00			
Type B cortical contact						0,431
< 50%	15 (65,2)	8 (34,8)	1,60	0,50	5,17	
> 50%	24 (75)	8 (25)	1,00			
RUST 6 m, mean SD	9,3 1,4	5,6 1,5	0,21	0,14	0,33	<0,001**
Locking bolt breakage						0,081#
No	151 (72,6)	57 (27,4)	1,00			
Yes (Proximal)	3 (50)	3 (50)	2,65	0,52	13,51	
Yes (Distal)	1 (25)	3 (75)	7,94	0,81	76,92	
Deep infection						<0,001
No	143 (75,7)	46 (24,3)	1,00			
Yes	12 (41,4)	17 (58,6)	4,41	1,96	9,90	

Chi-square test; * Fisher exact test; # Likelihood ratio test; ** unpaired Student t test; & Not enough case to estimate.

Table 4. Statistical analyzes of healing with 12 months follow up.

Variable	Healing in 6 m		OR	IC (95%)		p
	Yes	No		Inferior	Superior	
Age (years), mean SD	36,8 14,3	34,8 14,7	0,99	0,96	1,02	0,462**
Sex						0,058
Female	35 (94,6)	2 (5,4)	1,00			
Male	142 (82,1)	31 (17,9)	3,82	0,87	16,67	
Race						0,571#
White	136 (82,9)	28 (17,1)	1,00			
Brown	25 (89,3)	3 (10,7)	0,58	0,16	2,07	
Black	16 (88,9)	2 (11,1)	0,61	0,13	2,79	
Flap reconstruction						0,001*
No	161 (88)	22 (12)	1,00			
Yes	16 (59,3)	11 (40,7)	5,03	2,07	12,20	
Vascular injury						0,029*
No	175 (85,4)	30 (14,6)	1,00			
Yes	2 (40)	3 (60)	8,77	1,40	55,56	
Compartment syndrome						0,578*
No	173 (84,4)	32 (15,6)	1,00			
Yes	4 (80)	1 (20)	1,35	0,15	12,50	
Obesity						>0,999*
No	174 (84,1)	33 (15,9)	1,00			
Yes	3 (100)	0 (0)	&			
Smoker						>0,999*
No	159 (84,1)	30 (15,9)	1,00			
Yes	18 (85,7)	3 (14,3)	0,88	0,24	3,18	
Alcoholism						>0,999*
No	167 (83,9)	32 (16,1)	1,00			
Yes	10 (90,9)	1 (9,1)	0,52	0,06	4,22	
Illicit drugs						>0,999*
No	167 (83,9)	32 (16,1)	1,00			

Yes	10 (90,9)	1 (9,1)	0,52	0,06	4,22	
Diabetes						>0,999*
No	172 (84,3)	32 (15,7)	1,00			
Yes	5 (83,3)	1 (16,7)	1,08	0,12	9,52	
Other comorbidities						0,549*
No	158 (84,9)	28 (15,1)	1,00			
Yes	19 (79,2)	5 (20,8)	1,49	0,51	4,31	
Trauma energy						0,007
Low	33 (100)	0 (0)	1,00			
High	144 (81,4)	33 (18,6)	&			
Associated injury						0,428
No	91 (87,5)	13 (12,5)	1,00			
AIS < 3	46 (82,1)	10 (17,9)	1,52	0,62	3,73	
AIS ≥ 3	40 (80)	10 (20)	1,75	0,71	4,33	
Gustilo						<0,001#
Closed	69 (88,5)	9 (11,5)	1,00			
I	4 (100)	0 (0)	&			
II	2 (100)	0 (0)	&			
IIIA	91 (89,2)	11 (10,8)	0,93	0,36	2,36	
IIIB	9 (47,4)	10 (52,6)	8,52	2,73	26,56	
IIIC	2 (40)	3 (60)	11,50	1,69	78,39	
Side						0,596#
Right	74 (84,1)	14 (15,9)	1,00			
Left	100 (84)	19 (16)	1,00	0,47	2,13	
Bilateral	3 (100)	0 (0)	&			
Bilateral						>0,999*
No	174 (84,1)	33 (15,9)	1,00			
Yes	3 (100)	0 (0)	&			
Segment in the shaft						0,252#
Proximal	6 (75)	2 (25)	1,00			
Middle	103 (81,7)	23 (18,3)	0,67	0,13	3,53	
Distal	68 (89,5)	8 (10,5)	0,35	0,06	2,05	
Staged with external fixator, n (%)						0,003
No	76 (93,8)	5 (6,2)	1,00			
Yes	101 (78,3)	28 (21,7)	4,22	1,56	11,36	
Reamed IMN						0,899
No	57 (83,8)	11 (16,2)	1,00			
Yes	120 (84,5)	22 (15,5)	0,95	0,43	2,09	
Days to convert to IMN, mean SD	5,8 6,2	7,7 5,9	1,05	0,99	1,11	0,105**
Days to IMN, mean SD	8,5 5,7	9 5,8	1,02	0,95	1,08	0,613**
Gap between fragments						0,238
< 2mm	73 (88)	10 (12)	1,00			
> 2mm	104 (81,9)	23 (18,1)	1,62	0,73	3,60	
AO/OTA classification						0,067
A	106 (87,6)	15 (12,4)	1,00			
B	46 (85,2)	8 (14,8)	1,23	0,49	3,10	
C	25 (71,4)	10 (28,6)	2,82	1,14	7,04	
Type A cortical contact						<0,001#
< 25%	31 (72,1)	12 (27,9)	&			
25% - 50%	28 (90,3)	3 (9,7)	&			
50% - 75%	36 (100)	0 (0)	&			
100%	11 (100)	0 (0)	1,00			
Type B cortical contact						>0,999*
< 50%	19 (86,4)	3 (13,6)	0,85	0,18	4,01	
> 50%	27 (84,4)	5 (15,6)	1,00			
RUST 6 m, mean SD	8,9 1,7	5,2 1,3	0,33	0,23	0,46	<0,001**
Locking bolt breakage						0,142#
No	171 (85,5)	29 (14,5)	1,00			
Yes (Proximal)	4 (66,7)	2 (33,3)	2,95	0,52	16,95	
Yes (Distal)	2 (50)	2 (50)	5,88	0,80	43,48	
Deep infection						0,002*
No	161 (87,5)	23 (12,5)	1,00			
Yes	16 (61,5)	10 (38,5)	4,37	1,77	10,75	

Chi-square test; * Fisher exact test; # Likelihood ratio test; ** unpaired Student t test; & not enough case to estimate.

Table 5. Multiple regression logistic analyzes of the healing in 6 and 12 months and the risk factors.

Outcome	Risk factor	OR	IC (95%)		p
			Inferior	Superior	
Healing in 6 months	Flap reconstruction	0,85	0,21	3,46	0,817
	Shaft segment				
	Proximal (ref.)	1,00			
	Middle	0,23	0,02	3,15	0,273
	Distal	0,41	0,03	5,65	0,506
	External fixator	5,99	1,40	25,64	0,016
	Reamed IMN	0,30	0,09	1,06	0,061
	RUST 6 months	0,21	0,13	0,33	<0,001
	Deep infection	4,15	0,88	19,61	0,071
Healing in 12 months	Flap reconstruction	2,99	1,14	7,94	0,027
	Vascular injury	4,00	0,49	32,26	0,194
	External fixator	3,12	1,11	8,77	0,031
	Deep infection	2,87	1,08	7,63	0,034

Multiple regression logistic analyzes.

exhibit any significant association with disturbance in the healing process ($p = 0.488$).

The staged treatment protocol was indicated for 135 patients, comprising 61.9% of our study cohort. Notably, prior use of external fixation demonstrated a strong association with both delayed and non-union outcomes ($p < 0.001$). This phenomenon can be attributed to the specific indication for external fixation, which is typically reserved for patients with systemic compromise, like polytrauma, or severe soft tissue injuries. Both these factors are known to significantly influence the healing process, potentially delaying, or impeding it.

Interestingly, the time to conversion to the IMN, with an average of 6.1 ± 6.1 days, did not exhibit a significant association with disruption in the healing process.

In our research, the utilization of reaming or on-reaming procedures exhibited no statistically significant association with non-union incidence ($p = 0.899$). The debate surrounding the advantages of reamed nail insertion in the context of fracture healing remains ongoing. A comprehensive systematic review conducted by Clark DR et al.[18], which included six relevant studies, leans towards endorsing the use of reamed nails. However, it is worth noting that the overall quality of these studies falls within a moderate range. Conversely, Xia L et al.[19], in their meta-analysis, suggest that reamed nailing may lower the risk of non-union in closed fractures, in a different perspective, Schemitsch EH et al.[20] reported findings that indicate neither reaming nor non-reaming significantly affects reoperation rates. Notably, our series primarily includes open fractures, and this fact seems to align with the argument that reaming may not significantly impact open fracture outcome.

The RUST serves as valuable scoring system for assessing progress through radiographic imaging. Our study strongly supports the utility of RUST as a reliable predictor of delayed union at 6-month follow up. Remarkably, for each one-point increase in RUST score, there is in 79% reduction in the likelihood of delayed union ($p < 0.001$). To ensure the quality of our results, we deliberately excluded cases involving tibial shaft fractures with significant bone loss. It is self-evident that in absence of a contiguous cortical segment, fracture consolidation is unattainable without a reconstructive procedure. Our data underscores a observation: when cortical contact falls below 50% in simple type fractures, a significant association with non-union becomes evident ($p < 0.001$). however, in the case of B type fractures, proximal-to-distal segment contact does not exhibit a statistically significant association ($p = 0.999$). This discrepancy can likely be attributed to the overriding importance of the size and height of the wedge fragment in influencing the outcome.

In accordance with our expectations, a discernible correlation between postoperative deep infection and non-union has been established ($p = 0.002$). our observed infection incidence stands at 13.3%, and this is intrinsically linked to the substantial representation of patients afflicted with high-energy trauma and open fractures within our cohort.

Our study aligns with the findings of Ford et al.[21], who reported a 27.9% non-union rate and an 11.5% incidence of deep infection. They identified high-energy trauma, open fractures, and early postoperative complications, including deep. Comorbidities play a diminishing role, whereas open fractures and staged external fixation become more critical.

Our study underscores that having less than 50% cortical contact is a significant non-union risk factor, corroborated by Bhandari et al[22]. and Fong et al[3].

The clinical implications is, while these predictors are beyond a surgeon's control, they offer valuable insights for postoperative monitoring and intervention strategies. Although the choice of reaming has minimal impact, achieving a satisfactory reduction with more than 50% cortical contact is crucial, Furthermore, rigorous measures should be taken to prevent deep infection, as they strongly correlate with non-union risk.

CONCLUSION

Our study identifies several key factors associated with heightened risk of non-union following IMN of tibial shaft fracture: high-energy trauma, open fracture, the need for flap procedures, staged external fixation treatment, less than 50% cortical contact, and deep infection.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. MFL, FCCN, and MKAA: data acquisition, analysis, and interpretation; writing the paper. LMC: interpretation of the data and critical revision of its intellectual content. SJS: critical review of its content and final approval of the manuscript version. KKE: interpretation of the data, critical revision of its content, drafting of the manuscript, and final approval.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e278639

FRACTURE-DISLOCATIONS OF THE ELBOW: CAN THEY INFLUENCE THE PATTERN FRACTURE OF RADIAL HEAD?

AS FRATURAS-LUXAÇÕES DO COTOVELO PODEM INFLUENCIAR NO PADRÃO DE FRATURA DA CABEÇA DO RÁDIO?

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ABSTRACT

Introduction: Radial head fractures are consistently part of a terrible triad of the elbow and can occur in association with Monteggia fracture-dislocations, transolecranon fractures, and their variations. Understanding the degree of comminution of the radial head fracture and the location of fragments determines the course of action to be taken. Objectives: To correlate fracture-dislocations with the pattern of radial head fracture (number of fragments) and involvement in the proximal radioulnar region. Materials and Methods: A retrospective study (level II) of patients undergoing surgery for radial head fractures associated with fracture-dislocations. Patients had radiographs in anteroposterior and lateral views, as well as tomography. The number of radial head fracture fragments and the presence of fractures in the proximal radioulnar region were correlated with the type of fracture-dislocation and demographic variables. Conclusion: Elbow fracture-dislocation types could not predict the number of fragments and the location of radial head fractures. However, most injuries presented three or more fragments in the radial head, and many had involvement of the proximal radioulnar region, suggesting high-energy trauma. ***Level of Evidence II; Retrospective Study.***

Keywords: Radial Head and Neck Fractures. Elbow Fractures. Fracture Dislocation.

RESUMO

Introdução: As fraturas da cabeça do rádio estão sempre presentes em uma tríade terrível do cotovelo e podem ocorrer associadas a uma fratura-luxação de Monteggia, fratura transolecraniana e suas variações. Conhecer o grau de cominuição da fratura da cabeça do rádio e a localização dos fragmentos determinam a conduta a ser tomada. Objetivos: Correlacionar as fraturas-luxações com o padrão da fratura da cabeça do rádio (número de fragmentos) e o acometimento na região radioulnar proximal. Material e Métodos: Estudo retrospectivo (nível II) de pacientes submetidos a cirurgia devido fraturas de cabeça de rádio associadas às fraturas-luxações. Os pacientes possuíam radiografia nas incidências anteroposterior e perfil e tomografia. O número de fragmentos da fratura da cabeça do rádio e a presença de fratura na região radioulnar proximal foram correlacionadas com o tipo de fratura-luxação e as varáveis demográficas. Conclusão: Os tipos de fratura-luxação do cotovelo não foram capazes de predizer o número de fragmentos e a localização da fratura da cabeça do rádio. Entretanto, a maioria das lesões apresentaram três ou mais fragmentos na cabeça do rádio e muitos apresentaram acometimento da região da radioulnar proximal sugerindo traumas de alta energia. ***Nível de Evidência II; Estudo Retrospectivo.***

Descritores: *Fraturas da Cabeça e do Colo do Rádio. Fraturas do cotovelo. Fratura-Luxação.*

Citation: Silva TA, Malaquias AM, Cruz MA, Kikuta FK, Mouraria GG, Etchebehere M. Fracture-dislocations of the elbow: can they influence the pattern fracture of radial head? Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Fractures of the radial head are common and account for one-third of elbow fractures, often caused by falls with the elbow in a pronated and partially flexed position, mainly affecting patients between 20 and 60 years of age .[1,2] Radial head fractures are always part of a terrible triad of the elbow and can occur in association with a Monteggia fracture-dislocation, transolecranon fracture, and their variations.[3] These injuries are related to high-energy traumas.[4] One of the most commonly used classifications for radial head fractures is the Mason classification modified by Broberg and Morrey, defined as follows: type 1 - marginal fractures without displacement; type 2 - fragments involving at least 30% of the articular surface with more than 2mm displacement; type 3 - comminuted fracture involving the entire head, and type 4 when the radial head fracture is associated with elbow dislocation.[3] Complementary exams such as X-rays and computed tomography assist in confirming the diagnosis and studying the patterns of radial head fractures. The correlation of the trauma mechanism (direction of dislocation) and the types

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

The study was conducted at the Hospital Estadual de Sumaré, Sumaré, SP, Brazil.

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Article received on 09/18/2023, approved in 01/19/2024.

of elbow fracture-dislocation with the pattern of radial head fracture can aid in therapeutic decision-making.[4] The management of radial head fractures in elbow dislocations is complex and generally requires surgical treatment.[3] Treating radial head fractures is crucial to achieve elbow stability after fracture-dislocation.[5] Knowing details of the Radial Head fracture, such as involvement of the radioulnar joint, number of fragments, and direction of the main fragment, is essential in making surgical decisions. Fractures with three or more fragments and radioulnar involvement are prone to be treated with arthroplasty to achieve a stable and pain-free elbow. On the other hand, fractures with fewer than two fragments and no radioulnar involvement can be reconstructed with osteosynthesis with a good outcome.[6] Thus, knowledge of the degree of comminution of the radial head fracture and the location of the fragments determines the course of action. There are few studies in the literature that correlate the type of elbow fracture-dislocation with radial head fracture patterns.

The primary objective of this study was to correlate the various types of fracture-dislocations with the pattern of radial head fracture (number of fragments).

The secondary objective was to correlate the presence of radial head fracture fragments in the proximal radioulnar region with the various types of elbow fracture-dislocation.

MATERIALS AND METHODS

A retrospective study was conducted by reviewing medical records at a referral hospital between the years 2018 and 2023.

Inclusion criteria were as follows: patients undergoing surgical treatment for radial head fractures associated with Terrible Triad, Monteggia fracture, or transolecranon fracture. All patients should have had preoperative radiographs in anteroposterior and lateral views as well as preoperative tomography.

Patients who did not sign the informed consent form (ICF) or those with inadequate medical records/imaging for evaluation were excluded from the study.

Demographic data such as gender, age, and the affected side were analyzed. Radiological assessment was performed using the SynapseR program. The number of fragments and whether the fracture affected the proximal radioulnar region were analyzed. A fragment was considered present when there was a displacement greater than 2 mm, as calculated in the tomography examination (Figure 1). It was considered that the fracture affected the radioulnar joint when the radial head fragment was located in the area of the greater sigmoid notch of the ulna, as analyzed in the axial cut of the tomography (Figure 2). The direction of elbow dislocation was assessed in the lateral radiograph and the sagittal cut of the tomography.

The number of fragments in the radial head fracture and the presence of a fracture in the proximal radioulnar region were correlated with the type of fracture-dislocation and demographic variables. Categorical variables were tested using the chi-square test or Fisher's exact test. Non-categorical variables were tested using the Kolmogorov-Smirnov test. Therefore, both unpaired t-tests (parametric variables) and Mann-Whitney tests (non-parametric) were used in the study of these variables. All analyses were conducted using PASW Statistics 18.0 software (SPSS Inc., Chicago, USA), with a significance level of 5% ($P < 0.05$). The study was approved by the local ethics committee under number 66748122.6.0000.5404.

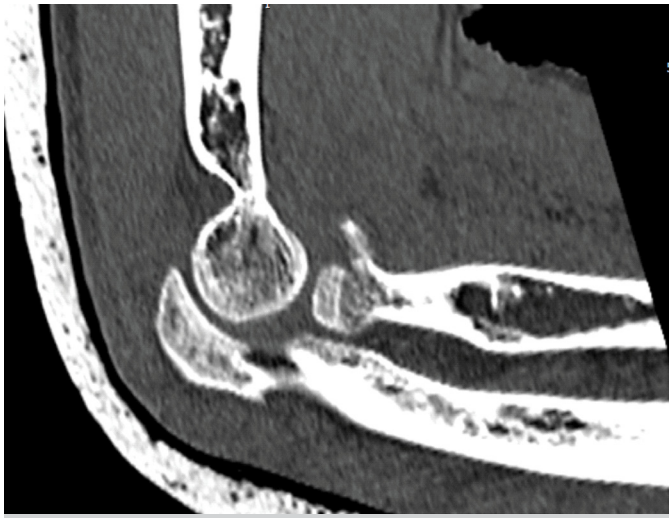

Figure 1. Method for considering a fragment in the radial head.

RESULTS

Initially, 113 medical records were evaluated, but only 59 met all the inclusion criteria. The mean age was 43.8 ± 15 years (ranging from 21 to 80 years). There was a higher prevalence of males (64%). There was no difference in terms of the affected side of the body, with 50.8% on the right side and 49.2% on the left side. The most frequent injury was the terrible triad of the elbow (72.9%), followed by Monteggia fracture-dislocation (22%). Demographic data are described in Table 1.

Figure 2. Fracture affecting the proximal radioulnar region.

Table 1. Demographic data.

Variable	Value
Age [Average (± SD)] (years)	43,83 ± 15,21
Ses[nº (%)]	
Man	38 (64,4%)
Woman	21 (35,6%)
Type of injury[nº (%)]	
Terrible elbow triad	43 (72,9%)
Monteggia fracture-dislocation	13 (22%)
Transolecranial fracture	3 (5,1%)
Affected side[nº (%)]	
Right	30 (50,8%)
Left	49,2%)

Regarding the number of fragments in the radial head fracture, it was observed that no patient had only one fragment (median of 3), as presented in Table 2.

The type of fracture-dislocation (p=0.94) and the direction of elbow dislocation (p=0.71) did not influence the number of fragments in the radial head. In 17 patients, the radial head fracture affected the region of the proximal radioulnar joint. Despite the majority of patients having two or more fragments, the number of fragments did not influence the frequency of fractures affecting the radioulnar proximal region (p=0.80). Furthermore, the type of fracture-dislocation and the direction of dislocation did not influence the presence of a fracture in this region (Table 3).

Table 2. Number of radial head fracture fragments.

Number of fragments	Value N (%)
2	14 (23,7%)
3	27 (45,8%)
4	13 (22%)
5	4 (6,8%)

N = number; % = porcentage.

Table 3. Incidence of fracture in the proximal radioulnar region compared with type of fracture, dislocation and direction of dislocation.

Type of injury	Fracture affecting the radioulnar region	Fracture not affecting the radioulnar region	Value of p[(a)]
Classification			
Terrible elbow triad (44)	10	34	0,077
Monteggia (12)	5	7	0,271
Transolecranial (3)	2	1	0,137
Dislocation direction			
Posterior (45)	13	32	0,268
Anterior (3)	2	1	0,137
Lateral (11)	2	9	0,388

N= total number ; (a) Fischer's exact test.

DISCUSSION

Fractures of the radial head are often accompanied by other elbow injuries, which can be fractures and/or dislocations. Haasters et al.[7] describe that radial head fractures are associated with concomitant injuries in the elbow joint, which may be underdiagnosed in radiological examinations.

In this study, we investigated a correlation between the number of fragments in radial head fractures, the presence of an articular fragment (radioulnar joint), and the direction of dislocation, as these are important prognostic factors and surgical planning considerations.[7] A 2009 study by Rinner (3) involving 296 patients with radial head fractures found associated injuries in 49% of cases, with the most common being the terrible triad of the elbow (19.9%), followed by posterior olecranon fractures-dislocations at 13.9%, and Monteggia lesions at 4.4%. Our results corroborate the literature data. We found only 3 cases (5.1%) of concomitant radial head fracture with transolecranon fracture, indicating it to be an infrequent association. In a study by Ditsios et al.[8] involving 15 cases over 5 years of study, it was considered a rare association by the authors.

The average age of patients was 42.9 ± 10.9 years, and 64% were male. An epidemiological study conducted by Kodde et al.[6] Showed similar data with an average age ranging from 44 to 47.9 years and gender ratios ranging from 1:1, 2:3, and 3:2 (male-female). Female patients are significantly older compared to male patients. The peak incidence in men occurs between 30 and 40 years, while in women, it is between 50 and 60 years. Therefore, the incidence peak is bimodal: young male patients and older female patients.[6] Elbow fractures-dislocations, especially the terrible triad, often involve significant comminution of the radial head. Our results are consistent with the literature, as 74.6% of cases had 3 or more fragments. This result is similar to studies by Gonçalves et al.[9] and Miyazaki et al.[10]

Understanding the specific characteristics of elbow fracture-dislocations is important because they influence treatment and prognosis. Gonzalez et al.[11] Compared complication profiles and outcomes in patients associated with these two distinct patterns over a 12-year period. The authors evaluated 105 patients, 58 with Monteggia injuries and 47 with terrible triad injuries, and identified elbow stiffness as the main complication. Elbow contractures requiring surgical release were more commonly associated with terrible triad injuries.[11] Hockmann et al.[12] Emphasized that Monteggia-type fractures are complex injuries with high rates of complications, sequelae, and functional limitations. One possible cause of reduced range of motion may be related to fractures affecting the proximal radioulnar joint, which were not described in previous studies. We observed that 27% of cases had fractures in this region. Therefore, even if a radial head arthroplasty is performed, potential chondral damage to the ulna may be established, leading to functional limitations and/or pain.

This study has some limitations. The first is related to the small number of patients, although these are relatively rare injuries compared to isolated radial head fractures. Another bias is related to determining the location of the fracture and the possible involvement of the proximal radioulnar region, as this location is influenced by forearm pronation and supination. Despite the limitations of this study, the proposal to analyze the characteristics of radial head fractures and correlate them with the types of elbow fracture-dislocations was important. Most studies do not mention the number of fragments and whether they involve the radioulnar joint.

CONCLUSION

The types of elbow fracture-dislocations were not able to predict the number of fragments and the location of the radial head fracture. However, the majority of injuries showed three or more fragments in the radial head, and many of them involved the proximal radioulnar region, suggesting an association with high-energy trauma.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. TAS: Writing and data collection; AMM: Data collection and analysis; MAC: Fracture classification and data analysis; FKK: Data analysis and writing; GGM: Intellectual concept of the article, data analysis, writing; ME: Revision of the article.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e274209

SHORTENING OF CLAVICLE FRACTURES: PHYSICAL *VERSUS* IMAGE EXAMINATIONS

ENCURTAMENTO DE FRATURAS DE CLAVÍCULA: EXAME FÍSICO *VERSUS* EXAME DE IMAGEM

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ABSTRACT

Objective: Determine the reliability of three different methods of evaluating bone shortening in displaced midshaft clavicle fractures (DCMF). Method: A cross-sectional analytical study evaluated bone shortening by metric tape (MT), radiography (X-ray), and computed tomography (CT). Twenty-six men had been evaluated and used clavícula not broken as control. The collection of data was of the blind type for three specialists. Differences and reliability were analyzed with the Friedman and Kappa tests and validated with the T-test (CI: 95%; significance index $p<0.05$; Software "R" version 3.2.2). Results: The MT measurements (control) showed abnormal distribution and significant statistical difference concerning the imaging tests ($p=0.000008$). There was a similarity between X-ray and CT and Kappa agreement of 0.65. The fractured clavicles presented similar measurements between the three methods ($p=0.059$), and the T-tests proved that the similarity was caused by chance or possible measurement errors. Conclusion: Measurement by metric tape showed a tendency to overestimate bone shortening. The CT showed more reliable results for the diagnosis; however, the X-ray was sufficient for decision-making by surgeons, and therefore, it is not possible to rule out the importance of this resource for DCMF. ***Level of Evidence IV; Case-Control Study.***

Keywords: Fractures, Bone. Clavicle. Physical examination. Radiography. Tomography, X-Ray Computed.

RESUMO

Objetivo: Determinar a confiabilidade de três diferentes métodos de avaliação do encurtamento ósseo em fraturas deslocadas do eixo médio da clavícula (FDEMC). Método: Estudo analítico transversal que avaliou o encurtamento ósseo por fita métrica (FM), radiografia (X-Ray) e tomografia computadorizada (TC). Foram avaliados 26 homens utilizando a clavícula não fraturada como controle. A coleta de dados foi do tipo cega por três especialistas. As diferenças e a confiabilidade foram analisadas com os testes de Friedman e Kappa e validados com o teste T (IC:95%; índice de significância $p<0,05$; Software "R" versão 3.2.2). Resultados: As medidas de FM (controle), apresentaram distribuição anormal e diferença estatísfica significativa em relação aos exames de imagem ($p=0,000008$). Houve semelhança entre radiografia e TC, concordância Kappa 0,65. As clavículas fraturadas apresentaram medidas semelhantes entre os três métodos ($p=0,059$) e os testes-T comprovaram que a semelhança foi provocada casualmente ou possíveis erros de medição. Conclusão: A medição por fita métrica apresentou tendência em superestimação do encurtamento ósseo. A TC apresentou resultados mais confiáveis para o diagnóstico, contudo, a radiografia foi suficiente para tomada de decisão dos cirurgiões e por isso, não é possível descartar a importância deste recurso para FDEMC. ***Nível de Evidência IV; Estudo Caso Controle.***

Descritores: *Fraturas Ósseas. Clavícula. Exame Físico. Radiografia. Tomografia Computadorizada por Raios X.*

Citation: Beraldo RA, Silva CIB, Paiva Junior HH, Galdeano EA, Moraes R. Shortening of clavicle fractures: physical versus image examinations. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Fractures of the clavicle represent between 5 and 10% of all fractures,[1] it is predominant for the young population whose trauma mechanism is medium to high energy and due to sports and motor vehicle accidents.[2] The involvement of the midiaphyseal third is present in 70% to 80% of cases, [3] and is often associated with bone displacement.[4]

The traditional literature shows a good evolution in non-surgical treatment in fractures of the middle third of the clavicle. [5] While surgical treatment was recommended for cases with bone exposure, associated neurovascular injury, floating shoulder, scapulothoracic dissociation, polytraumatized,[6] and presence of bone shortening equal to or greater than 15 to 20 millimeters,[7,8] the latter being the main predisposing factor for non-bone union, identified in 15% to 21% of cases.[9]

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

The study was conducted at the Hospital São Vicente de Jundiaí, Nucleus of Education and Research, Jundiaí, São Paulo, Brazil.
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Article received on 04/24/2023, approved in 07/14/2023.

However, current studies have shown failures in non-operative treatment for this type of fracture, especially in those with shortening greater than 20 millimeters.[10] Therefore, it is essential to standardize the evaluation of clavicle fractures in the therapeutic decision. Bone shortening of the clavicle can be measured through physical examination and imaging tests such as radiography and computed tomography (CT),[11] the latter resource is considered the "gold standard".[12] However, CT generates additional costs to care,[13] and greater exposure of the patient to radiation.

The objective of this study is to analyze the bone shortening in displaced midshaft clavicle fractures (DCMF) and identify the reliability of three different evaluation methods, recommended by physical examination with the aid of a metric tape, digital radiography with anteroposterior incidence and caudocranial axial projection at 20° and CT with 3D reconstructions.

METHOD

A cross-sectional analytical study was carried out between 2019 and 2020, which evaluated 26 patients seen in a highly complex hospital unit in Orthopedics and Traumatology, who presented unilateral fracture of the middle third of the clavicle with deviation, identified as type II by Robson's classification.[14] Individuals with bilateral fractures; fractures of the proximal or distal thirds; history of contralateral clavicular fracture were excluded.

Participants were included in the study by signing the Informed Consent Form (ICF) and the study was duly approved by the Research Ethics Committee, under CAAE number: 10751919.8.0000.5412.

Evaluations

All examinations were bilateral and performed by three experienced examiners. Participants were positioned in orthostatic for evaluation by metric tape.

The imaging tests used in the study were radiography and computed tomography with reconstruction in three dimensions 3D. Imaging tests were carried out with the volunteers in dorsal decubitus, shoulders resting on the table, arms relaxed and parallel to the trunk, and hands positioned on the abdomen. The digital images were evaluated with the aid of the "ruler" tool of the Web Viewer software.

For the three evaluation methods, the anatomical measurement points were standardized, considering: Center of the most proximal projection of the sternal end and the center of the most distal projection of the acromial end, forming a rectilinear line.

For the measurements of bone shortening, we considered the differences in length between the clavicles obtained by the three expert examiners, who were blinded and did not have access to each other's data.

Physical examination with a metric tape (MT)

A metric tape (MT) with a millimeter scale was used for bilateral evaluation of clavicle length, for further analysis of differences. The examination was performed with palpation of the sternoclavicular and acromioclavicular joints to identify the acromial and sternal extremities of the clavicles. Then the metric tape, staggered in millimeters (mm), was positioned using the predefined anatomical points and in a rectilinear manner. The tape was malleable to allow adaptation to the contour of the bone deviation (Figure 1A). Surgeons were asked to disregard the joint spaces, requiring more vigorous palpation. Dermographic markings were also not used since this procedure could influence the inter-examiner analyses.

Digital radiographic examination (X-Ray)

It was performed with anteroposterior incidence with a caudocranial axial projection of 20°, with the patient positioned in horizontal dorsal decubitus and an X-Ray beam oriented to an intermediate point of the clavicles. The distance between the ampoule of the equipment and the patient has been standardized to 1 meter away (Figure 1B).

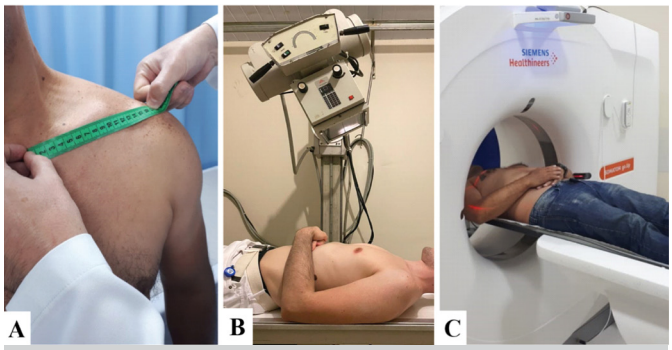

Figure 1. Methods of measuring clavicular length. (A) Physical examination using the metric tape; (B) Radiographic examination with anteroposterior incidence with a caudocranial axial projection of 20°; (C) Examination by computed tomography.

Computed Tomography (CT)

Performed in a Siemens device model Somatom Spirit, whose clavicular length was measured by a line between the standardized anatomical points, with the aid of Web Viewer software in 3D axial reconstruction (Figure 1C).

Statistical Analyses

Initially, the principal components of the non-fractured clavicles (Control) were analyzed to identify the data distribution pattern. Then Friedman's test was applied to analyze the differences in length, with significance index $p<0.05$ and Kappa coefficient (k) with a confidence interval of 0.95%, to determine the agreement between the evaluation methods from the clavicles without anatomical changes, being considered: $k \leq 0.2$ = poor; $0.2 < k \leq 0.4$ = reasonable; $0.4 < k \leq 0.6$ = good; $0.6 < k \leq 0.8$ = very good; $0.8 < k \leq 1$ = excellent.

After that, the tests were replicated to the bone shortening data present in the fractured clavicles. Finally, data validation occurred through T-tests ($p<0.05$) for each of the participants, to determine the reliability of the methods. The statistical analyses had been carried through with aid of software "R" version 3.2.2.

RESULTS

The descriptive analysis of the main components of the non-fractured clavicles (Control) allowed the identification of the data distribution pattern between the three evaluation methods. The radiographic measurements had presented changeable standards between the three examiners, but if they had approached the measures gotten for the computed tomography, whose examination of the image presented greater uniformity of the distribution of the data. The results of the metric tape did not present normal distribution, even after the logarithmic transformation of data by the Box-Cox method (Figure 2).

The non-parametric comparative analysis of the control clavicles by Friedman's test identified a significant difference for MT ($p=0.000008$), and statistical similarity between X-Ray and CT. The Kappa test demonstrated agreement enters the data of the image examinations (Table 1).

Measurement by metric tape showed a tendency to overestimate bone length (Figure 3)

After identifying the pattern of distribution, agreement, and differences between the evaluation methods in clavicles without biological changes (Control), the study directed the analysis to

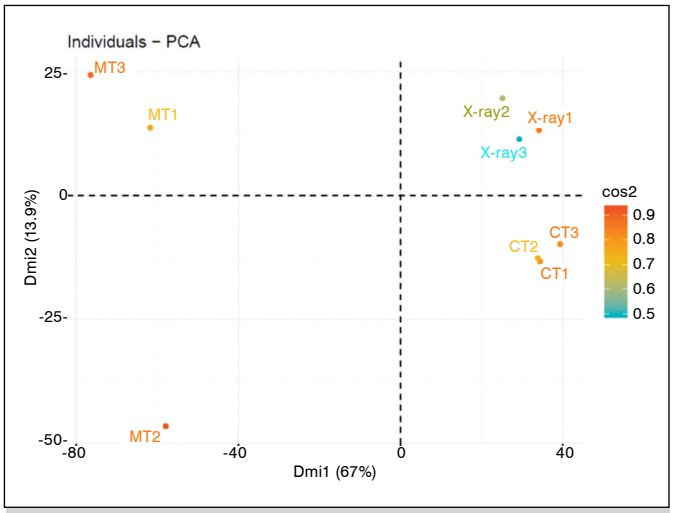

Figure 2. Analysis of main components of the control clavicles in two dimensions (dim) for data distributions of the three examiners. Color patterns indicate the variability of inter-examiner results.

Table 1. Statistical comparison between the methods of evaluating the length of the control clavicles. (ns) Not significant.

Comparison between methods	Statistical test	
	Friedman	Kappa
MT versus X-Ray	<0.05	0.45
MT versus CT	<0.05	0.34
X-Ray versus CT	ns	0.65

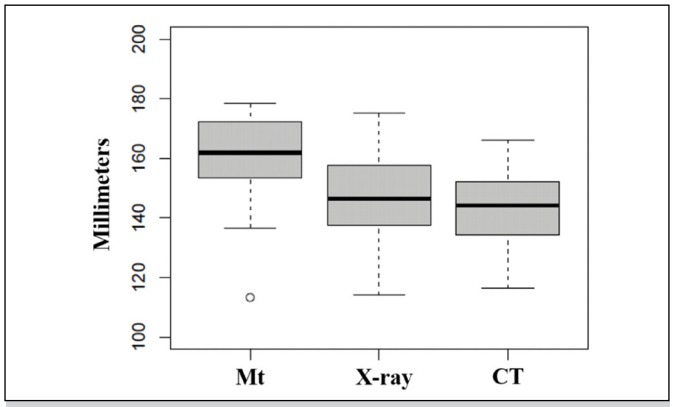

Figure 3. Distribution of mean clavicle lengths controlled for the three assessment methods.

the differences in bone length identified in the fractured clavicles compared to the control side.

The descriptive analysis of the main components of the differences in bone length showed a different distribution pattern, approximating the radiographic measurements to the measurements of the metric tape (Figure 4).

When comparing differences in bone length between the three methods of measurement, the test of Friedman did not identify significant differences (p=0,059). The average clavicular length and bone shortening are shown below (Table 2).

Although bone shortening was similar among the clinical evaluation methods, great variability of the results was found for the computed tomography examination (Figure 5).

The variability was caused by a higher incidence of elongation of the clavicle present in both imaging exams and especially in CT. This result generated the hypothesis that the use of the control side to measure the difference in clavicular length might not be a good alternative.

This preliminary result required an individual statistical evaluation for each of the 26 study participants with the application of T-tests to determine whether the differences between the clavicles were caused by biological factors, by chance, or measurement error. From this point, the relative frequencies of the presence of bone shortening before and after statistical validation were analyzed (Table 3).

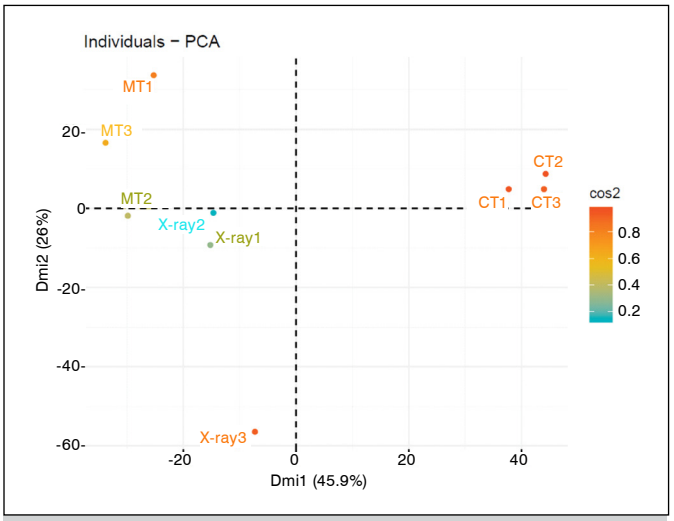

Figure 4. Analysis of main components of bone shortening of fractured clavicles, in two dimensions (dim) for data distributions of the three examiners. Color patterns indicate the variability of inter-examiner results.

Table 2. Averages of clavicular length and absolute (millimeters) and relative (percentage) bone shortening.

Exam	Non-fractured clavicle (mm)	Fractured clavicle (mm)	Bone shortening (mm)	Relative bone shortening (%)
MT	165.5±16.3	154.7±15.2	10.8±6.4	6.4
X-Ray	151.5±16.5	144.5±16.0	7.1±7.2	4.5
CT	145.2±13.2	139.1±14.2	6.1±9.9	4.1

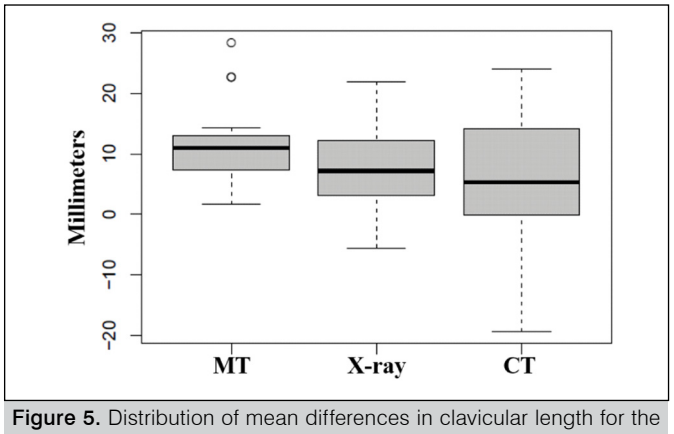

Figure 5. Distribution of mean differences in clavicular length for the three assessment methods.

Table 3. Frequency of bone shortening after statistical validation.

Exam	Before validation of test	After the validation test	Variation Percentage
MT	26	5	80.8%
X-Ray	20	13	65.0%
CT	19	17	10.5%

The only method that kept valid from the initial analysis was the CT results. Both the measurements with measuring tape and radiographs showed significant changes, indicating that the difference was caused by the chance or lower accuracy of the method.
The evaluation of bone shortening by measuring tape, in addition to underestimating the measurements, made the examiners present a tendency to always seek bone shortening.

DISCUSSION

In this study, different measurement methods for bone shortening in FMD were compared, using physical examination with the aid of a tape measure and two other methods composed of imaging exams, with anteroposterior axial radiographs at 20° with caudocranial projection and CT with 3D reconstructions.
As described by Smekal *et al*,[13] low reliability was identified for evaluation with metric tape for bone length measurement, which can be influenced by soft tissue coverage, while radiographs and tomography showed comparable repeatability. In total, the 26 individuals evaluated in this study showed more bone shortening when evaluated by measuring tape than by imaging exams.
A variety of techniques for the evaluation of the DMCF exists, but it does not have a consensus on an optimum method or standardization for the accomplishment of the image examinations.[14,15] Two concepts are more accepted to evaluate the shortening: measurement of the difference in bone length between the clavicles or overlapping the fragments.[15] Although the first concept is described as more reliable,[4] it is also subject to anatomical differences between the clavicles, present between 28.5% and 30% of the population and which may be greater than 5 mm in length,[16] in addition to the influence of radiographic incidence,[13] and patient positioning.[17,18] In this study, we recommend the method of evaluating the differences between the fractured clavicle and the contralateral one, as it is the only method that could be reproduced in evaluations by metric tape.
The study of Archer *et al*,[11] had been evaluated 22 patients with DMCF and although the excellent correlation between the examiners, did not have agreement enters the measures gotten for conventional x-rays AP and TC, in virtue of the error of measurement of 6,96 centimeters identified in the x-rays. It is also described that radiographic films can favor the overestimation of bone shortening on average 8.2 mm concerning CT.[12] Corroborating these results, the present study also noted the tendency of examiners to quantify greater bone shortening, however, an average difference of only 1 mm was found between digital radiographic images and CT with 3D axial reconstructions, evidencing the importance of standardization of radiographic examination in clinical practice.
When evaluating initially the methods of measurement from the measures of clavicle control, we do not evidence significant differences between the image examinations. The statistical similarity was also present for bone shortening measurements of fractured clavicles. However, the confirmation of the results with the application of T-tests for each individual showed that the frequency of shortenings on tomographic examination remained similar before and after statistical validation, while the same did not occur for the X-Ray. Despite the very good agreement between the imaging tests, the radiographic evaluation was more subject to differences because it was less accurate.
It is important to highlight that of the twenty six individuals evaluated, sixteen should receive conservative treatment according to the evaluations by metric tape and radiographs, and in only one case CT was able to change the opinions of surgeons to a surgical approach, due to the complexity and comminution of the fragments. For this reason, we cannot say whether the differences in shortening observed between both imaging exams are relevant in clinical practice by experienced surgeons.
Some limitations to this study must be taken into consideration: a limited number of literature on the use of the metric tape to quantify bone shortening in DMCFs; the absence of different radiographic projections for comparison purposes; impossibility of intra-examiner evaluation, since it is an emergency care service for orthopedic trauma, which made it impossible to collect measurements at different times; antalgic position of patients and the difficulty of palpation of bone structures in individuals with overweight or presence of swelling and abrasions in the anatomical areas used as reference points; comparison of the physical examination performed in the orthostatic position against the image evaluations that were performed with the patient in dorsal decubitus, generating variability in the results.

CONCLUSION

The evaluation of bone shortening with the aid of MT showed less reliability, greater variability and a tendency to overestimate measurements. Although measurements maked by radiography also showed variability, concordance was verified with the data obtained by 3D computed tomography, whose differences were not influence the orthopedic surgeons' treatment decision. For this reason, the importance of radiographic evaluation for the evaluation of DMCF cannot be ruled out. Statistical validation proved that the measurement of bone shortening by means of CT with 3D image reconstructions is less subject to measurement errors and overestimation of bone shortening, being the most reliable resource in this study.

AUTHORS' CONTRIBUTION: EAG, RAB, and RM: Significant contribution to the conception and design of the work, acquisition, analysis, and interpretation of the study data; writing of the work and critical review of its intellectual content. CIBS and HHPJr: Writing of the paper and critical review of its intellectual content.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e270051

SPINE

COMPARISON OF DYNESYS AND HYBRID SYSTEM FOR MULTI-SEGMENTAL LDD

COMPARAÇÃO ENTRE DYNESYS E SISTEMA HÍBRIDO PARA LDD MULTISSEGMENTAL

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ABSTRACT

Objective: To compare effectiveness of Dynesys and hybrid system in treating patients with multi-segmental lumbar degenerative disease (LDD). Methods: Patients involved in this retrospective study were divided into Dynesys (n = 22) and Hybrid (n = 13) groups. Clinical outcomes were evaluated using Oswestry Disability Index (ODI), and Visual Analogue Scale (VAS). Radiologic evaluations included X-ray, MRI, and CT. Furthermore, different complications were analyzed. Results: At the last follow-up, ODI and VAS of each group were improved ($p < 0.05$), and the range of motion (ROM) of operating segments decreased. However, Dynesys group preserved a larger extent of ROM at the final follow-up ($p < 0.05$). ROM of the upper adjacent segment was increased in both groups ($p < 0.05$), while the disc heights were decreased at the final follow-up ($p < 0.05$). Besides, Dynesys group had a more obvious decrease in the disc height of dynamic segments ($p < 0.05$). No significant difference existed in complications between both groups ($p > 0.05$). Conclusion: In our study, similar satisfactory results were obtained in both groups. Both surgical procedures can be employed as effective treatments for middle-aged and physically active patients with multi-segmental LDD. ***Level of Evidence III; Retrospective Comparative Study.***

Keywords: Intervertebral Disc Degeneration. Surgical Procedures, Operative. Comparative Study.

RESUMO

Objetivo: Comparar a eficácia do Dynesys e do sistema híbrido no tratamento de pacientes com doença degenerativa lombar multissegmentar (DLD).Métodos: Os pacientes envolvidos neste estudo retrospectivo foram divididos em grupos Dynesys (n = 22) e Híbrido (n = 13). Os desfechos clínicos foram avaliados por meio do Oswestry Disability Index (ODI) e da Escala Visual Analógica (EVA). As avaliações radiológicas incluíram radiografia, ressonância nuclear magnética (RNM) e tomografia computadorizada. Ademais, diferentes complicações foram analisadas. Resultados: No acompanhamento final, o ODI e a EVA de todos os grupos melhoraram ($p < 0,05$), e houve diminuição da amplitude de movimento (ADM) dos segmentos operacionais. No entanto, o grupo Dynesys preservou uma maior extensão da ADM no acompanhamento final ($p < 0,05$). A ADM do segmento superior adjacente foi ampliada em ambos os grupos ($p < 0,05$), enquanto as alturas dos discos foram reduzidas no acompanhamento final ($p < 0,05$). No entanto, o grupo Dynesys apresentou uma redução mais evidente na altura do disco dos segmentos dinâmicos ($p < 0,05$). Não houve diferença significativa nas complicações entre esses dois grupos ($p > 0,05$). Conclusão: Neste estudo, resultados satisfatórios semelhantes foram obtidos em ambos os grupos. Ambos os procedimentos cirúrgicos podem ser empregados como tratamentos eficazes para pacientes de meia-idade e fisicamente ativos com LDD multissegmentar. ***Nível de Evidência III; Estudo Retrospectivo Comparativo.***

Descritores: *Degeneração do Disco Intervertebral. Procedimentos Cirúrgicos Operatórios. Estudo Comparativo.*

Citation: Zhang X, Xiao X, Wang H, Wang S, Yang D, Peng S. Comparison of dynesys and hybrid system for multi-segmental LDD. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 8. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Of all the spinal diseases, lumbar degenerative disease (LDD) is the most common disease. It often develops into multi-segmental LDD over time. This disease generally responds well to conservative treatments, but some patients may need surgery due to severe back and leg pains. Spinal fusion are considered as the best surgical option for LDD, but most fixation devices are presently made of titanium alloy, which could cause many issues such as surgical site infection (SSI) and adjacent segment degeneration (ASD).[1-3] Additionally, as the number of fused segments increases, so does the likelihood of ASD.[4] Aside from that, physically active patients would have to give up their favorite sport after fusion surgery for limited lumbar spine mobility.

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

The study was conducted at the Shenzhen People's Hospital.
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Article received on 12/01/2022, approved in 07/14/2023.

In light of these issues, researchers designed Dynesys to replace rigid fusion for treating LDD. It could preserve the mobility of the operated segment and lessen the pressure on the adjacent discs and facet joints.[5] And studies have supported the beneft of Dynesys in preserving range of motion (ROM) and preventing ASD in LDD patients,[6]which means that it can be installed in middle-aged patients with single- or multi-segmental LDD. However, other study argued that Dynesys failed to achieve that beneficial effect.[7]

When the patient suffers from multi-segmental LDD yet wishes to retain some spinal mobility for sports and other recreational activities, the surgeon has to carefully consider the surgical protocol. Hybrid fixation have been utilized in LDD patients with at least two affected segments because the degree of degeneration of each segment varies. Currently, there are two types of hybrid fixation systems in clinical practice. The Dynesys-Transition-Optima system with Dynesys Screw, Transition Screw, and Optima Screw, effectively treats multi-level LDD. Yet, its internal structure may lead to operational failure.[8] In hybrid fixation, the dynamic segment is only fixed by the Dynesys device, whereas the fusion segment is fixed by both the Dynesys device and an intervertebral cage. Our team demonstrated in a previous study that the hybrid fixation device has comparable efficacy as rigid fusion in treating multi-segmental LDD within one year. However, hybrid fixation preserves spinal mobility better than rigid fusion.[9]

Researchers have primarily compared hybrid fixation to rigid fusion or Dynesys fixation to rigid fusion, neglecting a comprehensive comparison between Dynesys fixation and hybrid fixation. This study analyzed LDD patients undergoing multi-segmental hybrid fixation, contrasting them with a control group receiving Dynesys fixation. Our retrospective analysis aimed to assess clinical and radiological outcomes and complications of both techniques, shedding light on the most effective surgical approach for physically active middle-aged LDD patients.

Patients and Methods

Patient selection

The studies involving human participants were reviewed and approved by the Scientific Research Ethics Committee of Shenzhen People's Hospital (KY-LL-2021586-02). Informed consent was obtained from all subjects and/or their legal guardians.

Patient data were collected from January 2015 to August 2019. The inclusion criteria were: (1) diagnosed with lumbar disc herniation or lumbar spinal stenosis or both, via imaging; (2) had two or more affected segments; (3) symptoms persisted after six months of conservative treatment; (4) received Dynesys or Hybrid fixation. The exclusion criteria were: (1) severe osteoporosis (bone mineral density T-score < -2.5) in the lumbar spine; (2) severe spinal deformities such as Meyerding Grade II or higher spondylolisthesis, Cobb angle $> 30°$, and spinal rotation; (3) vertebral fracture, infection, tumor, and ankylosing spondylitis; (4) systemic connective tissue disease; (5) less than one year of recorded follow-up or incomplete follow-up records. A total of 35 patients with multi-segmental LDD were included.

Operating technique

Dynesys fixation

After disinfection and draping, a midline incision was made on the back. Bilateral muscles were dissected along the supraspinous ligament. Dynesys pedicle screws (Zimmer, Switzerland) were implanted at the intersection of the lateral facet of the articular process and the root of the transverse process. Following laminectomy and removal of the ligamentum flavum, discectomy relieved impinged nerve roots. The cord was inserted through the spacer and the second pedicle screw sequentially. The LIS Cord Tensioner Set was placed over the Guide Wire atop the screw head. The cord was threaded through the LIS Cord Tensioner, snapping the spacer. Finally, the surgical site was irrigated and closed by layers.

Hybrid fixation

A longitudinal incision was made bilaterally along the supraspinous ligament, separating the muscle groups. Dynesys pedicle screws (Zimmer, Switzerland) were implanted on both sides of the operative segments. Laminectomy and discectomy were performed on non-fusion segments to decompress the spinal canal and nerve roots. For fusion segments, inferior and superior facet joints were removed. After further decompression, foraminotomy, and discectomy, cartilage endplates and discs were removed for ideal bone-to-bone surface. Bone tissues were inserted into appropriately sized cages (Johnson & Johnson, USA), then into intervertebral space. Connector and spacer installation followed the Dynesys group procedure. Finally, the surgical site was irrigated and closed by layers.

Clinical and radiographic evaluations

The following perioperative data were collected: operating duration, blood loss, drain volume, length of hospital stay, and postoperative length. The Oswestry Disability Index (ODI) and the Visual Analogue Scale (VAS) were assessed for clinical outcomes.

The patient's disc height (DH) was measured from standing lumbar spine X-ray images before surgery, one week after surgery, and at the final follow-up. The anterior intervertebral space height (AH), the central intervertebral space height (CH), and the posterior intervertebral space height (PH) were measured at the affected and upper adjacent segments. The DH was calculated: $DH=(AH+CH+PH) / 3$.

Before surgery and at the last follow-up, lumbar spine X-ray images were taken to determine the range of motion (ROM) of the operative and upper adjacent segments. ROM was defined as the amount of change in the Cobb angle in the flexion and extension views.

The lumbar spine MRI was taken prior to surgery and at the last follow-up, showed the Pfirrman grade of the operative and upper adjacent segments. The rate of intervertebral disc degeneration was evaluated using the following formula: the number of patients who had Pfirrmann grade degeneration after surgery/the number of the total patients$\times$ 100%.[9]

Surgical complications

The criteria described by Liu were used to diagnose SSI during the follow-up.[10]

In standing lumbar spine X-ray images and CT scans, screw loosening appears as a "double halo sign", described as a radiolucent rim surrounding the screw encircled by dense bone trabeculae. ASD is defined either radiographically or symptomatically as Zhang and Xiao's studies described.[6,9]

Statistical Analysis

Statistical analysis was performed using SPSS version 26.0 (IBM, USA). The data were tested for normal distribution using the Kolmogorov-Smirnov test. Mann-Whitney U test, Wilcoxon signed-rank test, Kruskal-Wallis H test, and Friedman M test were used for continuous variables, while the Chi-square test was applied for categorical variables. $P < 0.05$ was considered a statistically significant difference.

RESULTS

A total of 35 patients with multi-level LDD were enrolled in this retrospective study, of which 22 received Dynesys fixation, and 13 received hybrid fixation. There was no significant difference in age, gender, BMI, follow-up time, operating levels, disease types, preoperative VAS, and preoperative ODI between the two groups ($p > 0.05$, Table 1).

Table 1. Demographic Characteristics.

	Dynesys group (n=22)	Hybrid group (n=13)	p
Age (years)	48.0 ± 10.0	56.5 ± 15.4	0.053
Gender (male/female)	15/7	9/4	1
BMI (kg/m^2)	23.8 ± 2.8	24.7 ± 3.9	0.448
Follow-up time (months)	21.0 ± 7.3	18.0 ± 8.7	0.113
Operating levels (n)			0.541
Two levels	21	11	
More than two levels	1	2	
Diseases (n)			0.851
Spinal stenosis	1	1	
Lumbar disc herniation	5	4	
Spinal stenosis combined with lumbar disc herniation	16	8	

Clinical outcomes

Perioperative data

There was no significant difference between the two groups concerning the length of hospital stay, Post-operation length of hospital stay, and drainage volume. However, the Hybrid group lost significantly more blood than the Dynesys group and had significantly longer surgical operations ($p < 0.05$, Table 2).

ODI and VAS

The ODI and VAS of both groups were significantly improved at the final follow-up than pre-operation ($p < 0.05$). There was no significant difference in ODI between the two groups at each time point ($p > 0.05$). However, the difference in VAS at the final follow-up between the two groups was statistically significant ($p < 0.05$, Table 3).

Radiologic outcomes

ROM of affected segments and the upper adjacent segment

In both groups, the ROM of affected segments decreased at the last follow-up ($p < 0.05$). However, it was significantly higher in the Dynesys group than in the Hybrid group at the last follow-up ($p < 0.05$). The ROM of the upper adjacent segment increased in both groups ($p < 0.05$). There was no significant difference in the ROM of the upper adjacent segment between the two groups at each time point ($p > 0.05$, Table 4).

DH of operating segments and the upper adjacent segment

In the Dynesys group, the DH of the operating segments dropped at the final follow-up ($p < 0.05$). In the Hybrid group, the DH of the dynamic segment increased one week after surgery ($p < 0.05$), then decreased at the final follow-up ($p < 0.05$). Also, in the Hybrid group, the DH of the fusion segment did not change significantly from pre-operation to one-week post-operation ($p > 0.05$) but did drop at the final follow-up ($p < 0.05$).

The DH of the upper adjacent segment in both groups one-week post-operation was significantly improved than pre-operation ($p < 0.05$). The DH in both groups significantly declined at the final follow-up than one-week post-operation ($p < 0.05$, Table 5).

Pfirrmann grade

At the final follow-up, the Dynesys group reported an average disc degeneration rate of 9.09%, while the Hybrid group reported 15.38%, without a significant difference between them ($p > 0.05$, Tables 6 and 7).

Complications

One-week post-operation, SSI occurred in two patients in the Dynesys group. In the Hybrid group, only one patient experienced dysuria six days after surgery. It was believed that the patient had developed a urinary tract infection. Until the last follow-up, there was one case of screw loosening in the Dynesys group, but none in the Hybrid group. There were no symptomatic ASD cases. There were 5 cases of radiographic ASD in the Dynesys group and 3 cases in the Hybrid group (Table 8).

Table 2. Perioperative Data.

	Dynesys group (n=22)	Hybrid group (n=13)	p
Operating duration (min)	192.6 ± 60.0	236.0 ± 55.3	0.012
Blood loss (mL)	174.0 ± 52.6	373.1 ± 164.1	0.001
Drainage volume (mL)	274.5 ± 248.1	357.7 ± 190.7	0.067
Length of hospital stay (days)	17.0 ± 8.1	18.0 ± 5.1	0.229
Post-operation length of hospital stay (days)	12.1 ± 7.1	12.3 ± 3.0	0.448

Table 3. ODI and VAS.

	Dynesys group	Hybrid group	p
ODI (%)			
Pre-operation	62.5 ± 10.5	62.9 ± 10.7	0.933
Final follow-up	23.5 ± 15.0*	18.1 ± 2.8*	0.775
VAS			
Pre-operation	6.8 ± 0.8	7.2 ± 0.9	0.257
Final follow-up	2.0 ± 2.2*	0.7 ± 0.9*	0.015

*Significant difference between pre-operation and final follow-up in each group, $p < 0.05$.

Table 4. ROM of operating segments and the upper adjacent segment.

	Dynesys group	Hybrid group	p
ROM of operating segments (°)			
Pre-operation	9.2 ± 6.1	11.5 ± 9.6	0.428
Final follow-up	6.4 ± 3.4*	4.4 ± 1.7*	0.029
ROM of the upper adjacent segment (°)			
Pre-operation	3.7 ± 2.1	3.3 ± 1.9	0.257
Final follow-up	6.4 ± 3.5*	5.4 ± 2.8*	0.169

*Significant difference between pre-operation and final follow-up in each group, $p < 0.05$.

Table 5. DH of operating segments and the upper adjacent segment.

	Dynesys group	Hybrid group		p
		Dynamic segment	Fusion segment	
Disc height of stabilized segment (mm)				
Pre-operation	11.2 ± 2.0	9.5 ± 1.4	9.9 ± 2.4	0.006
one week after surgery	12.1 ± 3.4	10.2 ± 1.9†	11.5 ± 2.1	0.064
Final follow-up	9.9 ± 1.9*#	8.7 ± 1.8*	9.7 ± 1.4*	0.175
Disc height of the upper adjacent segment (mm)				
Pre-operation	11.7 ± 1.9	9.8 ± 1.2		0.001
one week after surgery	12.6 ± 1.1†	10.6 ± 1.9†		0.002
Final follow-up	11.0 ± 0.9*#	9.4 ± 1.3*		0

†Significant difference between pre-operation and one-week post-operation in each group, $p < 0.05$. *Significant difference between one-week post-operation and final follow-up in each group, $p < 0.05$. #Significant difference between pre-operation and final follow-up in each group, $p < 0.05$.

Typical Cases

Patient 1 was a male, aged 47 years, diagnosed with L4/5 and L5/S1 lumbar disc herniation and spinal stenosis. Dynesys fixation was performed (Figure 1).

Patient 2 was a female, aged 58 years, diagnosed with L3/4, L4/5, and L5/S1 lumbar disc herniation and spinal stenosis. hybrid fixation was performed (Figure 2).

Table 6. Pfirrmann grade.

Preoperative	Final follow-up							
	Dynesys group (n)				Hybrid group (n)			
	II	III	IV	V	II	III	IV	V
II	-	-	-	-	-	-	-	-
III	-	15	2	-	-	7	2	-
IV	-	-	5	-	-	-	3	-
V	-	-	-	-	-	-	-	1

Table 7. Disc degeneration rate.

	Dynesys group (n)	Hybrid group (n)	Total
No degeneration	20	11	31
Degeneration	2	2	4
Total	22	13	35

P =0.618

Table 8. Complication.

	SSI (n)	Screw loosening (n)	Radiologic ASD (n)	Symptomatic ASD (n)
Dynesys group	2	1	5	0
Hybrid group	0*	0*	3*	0*

*No significant difference between both groups, $p > 0.05$.

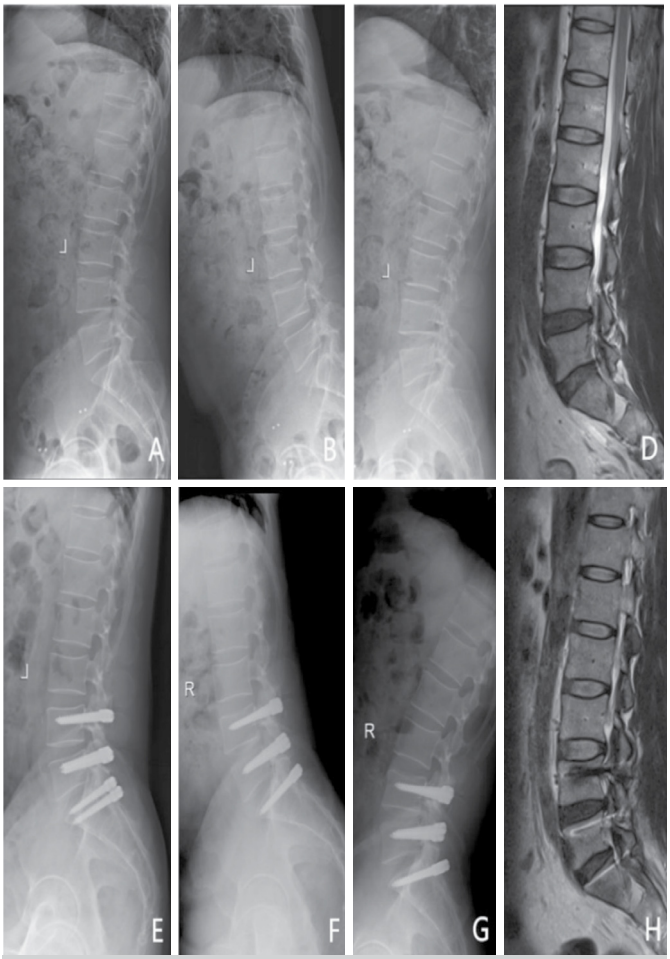

Figure 1. A 47-year-old male patient underwent surgery with Dynesys system due to lumbar disc herniation and spinal stenosis in L4/5 and L5/S1. (A) Pre-operation lateral X-ray. (B–C) Pre-operation flexion and extension X-ray, the ROM of operating segments was 6.5°, and that of the upper adjacent segment was 1.7°. (D) Pre-operation T2WI MRI demonstrated L4/5 and L5/S1 disc herniation. E: Lateral X-ray at 32 months after surgery. (F–G) Flexion-extension X-ray at 32 months after surgery, the ROM of operating segments was 1.7°, and that of the upper adjacent segment was 4.7°. (H) T2WI MRI at 32 months after surgery.

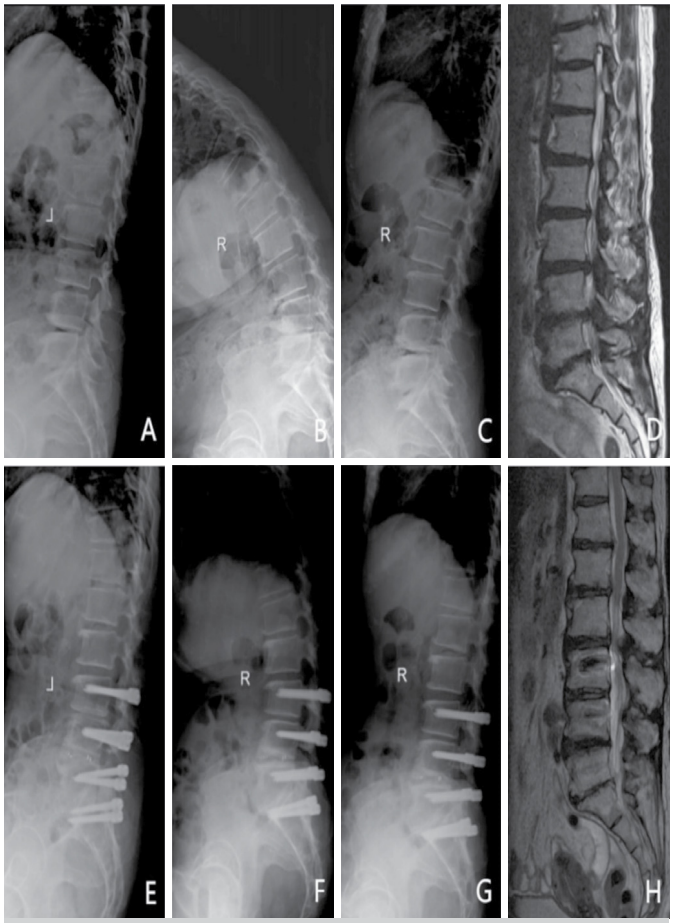

Figure 2. A 58-year-old female patient underwent surgery with a hybrid fixation system due to lumbar disc herniation and spinal stenosis in L3/4, L4/5, and L5/S1. (A) Pre-operation lateral X-ray. (B–C) Pre-operation flexion and extension X-ray, the ROM of operating segments was 40.0°, and that of the upper adjacent segment was 7.9°. (D) Pre-operation T2WI MRI demonstrated L3/4, L4/5, and L5/S1 disc herniation. (E) Lateral X-ray at 43 months after surgery. (F–G) Flexion-extension X-ray at 43 months after surgery, the ROM of operating segments was 2.6°, and that of the upper adjacent segment was 10.5°. (H) T2WI MRI at 43 months after surgery.

DISCUSSION

Symptomatic relief, and functional improvement of LDD patients

All patients revealed appreciable symptomatic relief and functional improvement during the follow-up period. Although there were much fewer Dynesys fixation and hybrid fixation surgeries than fusion surgeries, the clinical efficacy of Dynesys fixation and hybrid fixation for multi-level LDD has been proven by several studies. Hu et al. compared Dynesys fixation and rigid fusion after five years of follow-up and demonstrated that both groups experienced equally improvement in ODI and VAS.[11] In a two-year study, similar results were found.[12] Hu et al. also compared hybrid fixation and fusion surgery in their study and found that both groups reported comparable decline in ODI and VAS.[13]

Influence on ROM and DH in the operating segments

In the present study, the ROM in the operating segments of both groups was preserved. However, the Hybrid group reported smaller ROM at the final follow-up. The height of the intervertebral space of the operating segments in the Dynesys group stayed constant from pre-operation to one-week post-operation while continually decreasing afterward, correlating to the ROM of the operating segments. The Hybrid group experienced a similar progression

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in the DH of the fusion segment and dynamic segment as the Dynesys group. However, there was no statistically significant change in the DH of the Hybrid group between the final follow-up and the baseline. At the same time, our findings demonstrated that the DH of dynamic segment of the Hybrid group had a significantly smaller change from one-week post-operation to final follow-up than the Dynesys group. It could be due to the more limited ROM in the Hybrid group.

Other studies have also reported similar results. Five years after the surgery, the intervertebral space height in the Dynesys group was lower than pre-operation.[11] An analogous outcome was reported by other researchers.[14] A total of 27 patients who received hybrid fixation were included in the study by Hu et al.[13] They also utilized Dynesys devices and interbody cages. Their report claimed that the DH of the fusion segment increased at the last follow-up than pre-operation, while it appeared to decrease in the dynamic segment. However, our study did not find any DH difference between pre-operation and final follow-up in either the fusion or the dynamic segment. The continuous degeneration in dynamic segment may take time to show in X-ray. Therefore, we may get a result similar to Hu et al. had we extended the follow-up duration.

The prevalence of ASD

It remains controversial whether Dynesys fixation and hybrid fixation can prevent ASD. Theoretically, the Dynesys system can reduce the stress on the adjacent disc above the operating segment by moderating the movement of the adjacent segment, thereby staving off ASD. Under the restriction of the Dynesys device, however, there is no doubt that the ROM of the upper adjacent segment will grow.[15] In our study, the ROM of the upper adjacent segment in both groups increased than baseline, and there was no significant difference between the two groups. Simultaneously, the height of the upper adjacent intervertebral space also decreased due to the extra stress. ASD may develop over time as a result of persistently exceeding the physiological limits of the upper adjacent segment.[16] Sven et al. reported a 28.2% incidence of ASD in their study after a 7.2-year follow-up.[17] Hu reported that the incidence of ASD in the Hybrid fixation group was 18.5%.[13]

In this study, there was no difference in ASD between both groups. It is certain that ASD inevitably develops in patients after the two surgical procedures.

The prevalence of other complications

SSI is not a rare complication for patients who received Dynesys fixation. A study reported wound infection rates of 2.22% after Dynesys fixation.[10] The difference between the Hybrid group and the Dynesys group was not statistically significant in this study. Since hybrid fixation also used the Dynesys device, the surgeon should watch for SSI post-operation and react appropriately and promptly. Screw loosening is also a common complication of Dynesys fixation. In different retrospective studies, the incidence of screw loosening ranged from 18% to 19.8%.[18,19] In our study, there was no significant difference in screw loosening between the two groups.

CONCLUSION

We observed a significant improvement in VAS and ODI in each group. Both of them could preserve the ROM of stabilized segments, although Dynesys fixation allows a larger ROM, whereas hybrid fixation is better at maintaining the disc height of the dynamic level. The authors feel that both surgical procedures are effective treatments for middle-aged and physically active patients with multi-segmental LDD.

ACKNOWLEDGEMENTS

This study was supported by grants from the National Natural Science Foundation of China (No.82272488, 82272458) and Shenzhen Key Laboratory of Musculoskeletal Tissue Reconstruction and Function Restoration (ZDSYS20200811143752005).

AUTHORS' CONTRIBUTION: Each author made significant individual contributions to the development of this manuscript. SP and DY performed surgeries; HW, XXo, and SW performed data analysis; and XZ wrote, reviewed the article, and conceptualized the article.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e275070
WRIST AND HAND

RADIOGRAPHIC EVALUATION OF CONSERVATIVE TREATMENT OF DISTAL RADIUS FRACTURES

AVALIAÇÃO RADIOGRÁFICA DO TRATAMENTO CONSERVADOR EM FRATURAS DISTAIS DO RÁDIO

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ABSTRACT

Objective: This article aims to evaluate the evolution of radiographic parameters (radial tilt, volar tilt, and radial height) of distal radius fractures in patients indicated for conservative treatment at three different times: date of diagnosis, first outpatient visit within 2 weeks after closed reduction, and last outpatient visit. Methods: We included 84 patients seen at the emergency department of Hospital Municipal Odilon Behrens, with a diagnosis of distal radius fracture and an indication for conservative treatment. We considered only those patients who had serial radiographs taken at least three different times (n=69) in this analysis. Results: There was an improvement in radiographic parameters of volar tilt after closed reduction and immobilization, which was maintained until the last outpatient visit. Radial inclination and radial height showed increased values from the first to the second radiographic evaluation and both values had regression when comparing the second to the third (last) evaluation. Conclusion: Universal classification stable fractures tend to evolve well with conservative therapy. ***Level of Evidence II; Development of Diagnostic Criteria in Consecutive Patients (with Gold Standard of Reference Applied).***

Keywords: Fracture, Distal Radius. Conservative Treatment. Radiography.

RESUMO

Objetivo: O objetivo deste artigo foi avaliar a evolução dos parâmetros radiográficos (inclinação radial, inclinação volar e altura radial) das fraturas da extremidade distal do rádio em pacientes com indicação de tratamento conservador em três momentos diferentes: data do diagnóstico, primeira consulta ambulatorial dentro de duas semanas após a redução fechada e última consulta ambulatorial. Métodos: Incluímos 84 pacientes atendidos no departamento de emergência do Hospital Municipal Odilon Behrens, com diagnóstico de fratura distal do rádio e indicação de tratamento conservador. Consideramos nesta análise apenas os pacientes que tiveram radiografias seriadas realizadas pelo menos três vezes diferentes (n=69). Resultados: Houve uma melhora nos parâmetros radiográficos da inclinação volar após a redução fechada e a imobilização, que foi mantida até a última consulta ambulatorial. A inclinação radial e a altura radial apresentaram valores aumentados da primeira para a segunda avaliação radiográfica e ambos os valores tiveram regressão quando comparados da segunda para a terceira (última) avaliação. Conclusão: As fraturas estáveis de classificação universal tendem a evoluir bem com a terapia conservadora. ***Nível de Evidência II; Desenvolvimento de critérios diagnósticos em pacientes consecutivos (com aplicação de referência padrão ouro).***

Descritores: *Fraturas Distais do Rádio. Tratamento Conservador. Radiografia.*

Citation: Cangussu BL, Baldanza HC, Carmo RL, Nobre DM, Estanislau AR, Barros TSV. Radiographic evaluation of conservative treatment of distal radius fractures. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 8. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Defined as those that occur up to 3 cm from the radius carpal joint, fractures of the distal end of the radius account for 17% of all fractures seen in emergency rooms.[1] Middle-aged women are the most affected, with a significant increase in incidence over the age of 50. [2]

In order to define the best type treatment it is fundamental to initially classify them in relation to the parameters of instability, reducibility, the fracture mechanism and associated injuries, as well as the patient's age and comorbidities.[2]

Among the classifications most widely used today, we highlight three that have greater practical applicability because they provide contributions to the treatment and prognosis of fractures: the AO classification, the Universal classification described by Raylock in 1990, modified by Cooney in 1993, and the Fernandez classification, described in 1994 (Board 1, 2 and 3).

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

The study was conducted at the Hospital Municipal Odilon Behrens, Belo Horizonte, Minas Gerais, Brazil.
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Article received on 05/24/2023, approved in 09/01/2023.

Board 1. Universal Classification (COONEY).

Universal Classification (COONEY)
I. Extra-articular without deviation
II. Extra-articular with deviation
A. Stable reducible
B. Unstable reducible
C. Irreducible
III. Intra-articular without deviation
IV. Intra-articular with deviation
A. Stable reducible
B. Unstable reducible
C. Irreducible
D. Complex

The Universal classification described by Raylock in 1990, modified by Cooney in 1993.

Board 2 . Fernandez Classification.

I. fractures produced by angulation of the distal metaphysis of the radius, in which a cortical suffers a degree of comminution, as seen in Colles' and Smith's fractures;
II. fractures produced by shear mechanism, such as Barton's fractures and those of the radial styloid apophysis;
III. compression of the articular surface with impaction of the subchondral bone and the epiphysis. Current terms used for this fracture are complex articular fracture or radial pilon fracture;
IV. avulsion mechanism, includes radial and ulnar styloid fractures associated with carpal displacement;
V. fractures produced by high-energy trauma, translated by the combination of the four previous mechanisms, that means, angulation, shear, compression, and avulsion.

Board 3. AO Classification – Distal Radius Fractures.

AO classification - distal radius - 2R3
Extra articular - 2R3A
Radial styloid avulsion - 2R3A1
Single line - 2R3A2
Wedge or multifragment 2R3A3
Partial articular - 2R3B
Sagittal 2R3B1
(Barton) dorsal rim 2R3B2
(Reverse Barton) volar rim2R3B3
Complete articular 2R3C
Simple articular and metaphysis - 2R3C1
Multifragmentary Metaphyseal - 2R3C2
Multifragmentary articular, simple or multifragmentary metaphyseal - 2R3C3

AO/OTA international classification of fractures and dislocations.

In a conservative approach, closed reduction of the fracture is performed when necessary and cast immobilization for approximately six weeks. The objective of this intervention is the anatomical restructuring and return of its functionality as close as possible to the physiological one.[3]

This study, carried out at Hospital Municipal Odilon Behrens - Belo Horizonte - MG, was performed through periodic patient follow-up at the orthopedics/hand surgery outpatient clinic. Radiographic parameters in distal radius fractures were evaluated.

MATERIALS AND METHODS

The study included 84 patients who sought emergency care at the Odilon Behrens Municipal Hospital and whose diagnosis was distal radius fracture. After diagnosis and conservative treatment of the fractures, the patients were followed up as outpatients, performing radiographic control.

Cooney's Universal Classification (Board 1) was used to evaluate the fractures and plan inclusion or exclusion of patients in the study, by means of radiographic criteria.

For analysis in our study, only patients who had undergone outpatient follow-up in our service, with radiographic control in at least three distinct times (n=69), such as: day of diagnosis and immobilization, first outpatient visit (two weeks) and last visit.

There were excluded patients who had deviated and irreducible extra-articular (Cooney IIC), deviated and irreducible articular (Cooney IVC), complex fractures (Cooney IVD), and fractures with more than two criteria of instabilities defined by Lafontaine (Board 4).

There were excluded patients who did not have adequate follow-up, did not have radiographic control or did not attend return visits.

Two patients who were referred to surgery after two weeks of immobilization due to fracture deviation, were excluded from the study. These two were previously classified as Cooney IVB (intra-articular with deviation and unstable reducible).

We take into account three radiographic parameters: radial tilt/ulnar tilt of the radius, volar tilt, and radial height.

All patients in the study were made aware of the risks and benefits of participating in the research through the Free and Informed Consent Form (TCLE), having signed this document.

The present study was approved by the ethics and research committee through the brasil platform under number 5.113.627.

RESULTS

Out of the total 84 patients initially selected in the study, 55 (65%) participants required closed reduction in the emergency room.

Most patients (n=68; 81%) used axillopalmar cast, 10 patients (12%) used antebrachiopalmar cast, 2 patients (2%) used long splint and 2 patients (2%) used short splint immobilization. Out of the total 69 patients included in the study 54 were women (78%), 47 patients were aged 50 years or older (68.11%).

The patients had UNIVERSAL classification information at the date of diagnosis (pre-reduction).Out of this total, 14.2% were classified as Cooney I; 19% Cooney IIA, 8.3% Cooney IIB, 10.7% Cooney III, 4.7% Cooney IVA, 8.3% Cooney IVB.

It was observed a significant increase in volar tilt values during the evaluations, after closed reduction, immobilization, and a new radiography in a return visit (-3.8º , 2.0º) P<0.001. (Table 1) The radial tilt and radial height showed increased values from the first to the second radiographic evaluation. Both values had regression when comparing the second to the third (last) evaluation (17.2º / 18.6º / 17.6º) P<0.001, (9.8 mm/ 11.1 mm/ 10.1 mm) P<0.001. (Figure 1) Data presented on average (standard deviation). * statistically significant difference compared to the first evaluation in the One-Way ANOVA test (p<0.05).

Board 4. Lafontaine Criteria.

Lafontaine Criteria
Dorsal deviation > 20°, dorsal comminution, radial shortening > 9 mm, radiocarpal and distal radioulnar articular involvement, associated ulnar fractures, intra-articular fragment spacing > 2 mm, and age > 60 years.

Criteria of instabilities defined by Lafontaine in 1989. Type 1: 0-1 criterion (stable); Type 2: 2-3 criteria (potentially unstable); Type 3: ≥4 (unstable).

Table 1. Variables with the changes presented by each variable in the three evaluation moments.

Variable	1º	2ª	3ª	F-value	p-value	n
Volar	-3,8 (16,6)	2,1 (8,6)*	2,0 (9,2) *	10,92	<0,001	0.05 (Small)
Radial	17,2 (4,6)	18,6 (5,2)*	17,6 (5,1)	6,723	<0,001	0.01 (Small)
Radio	9,8 (2,9)	11,1 (2,9)*	10,1 (2,9)	11,45	<0,001	0.03 (Small)

Data presented on average (standard deviation). * statistically significant difference compared to the first evaluation in the One-Way ANOVA test (p<0.05).

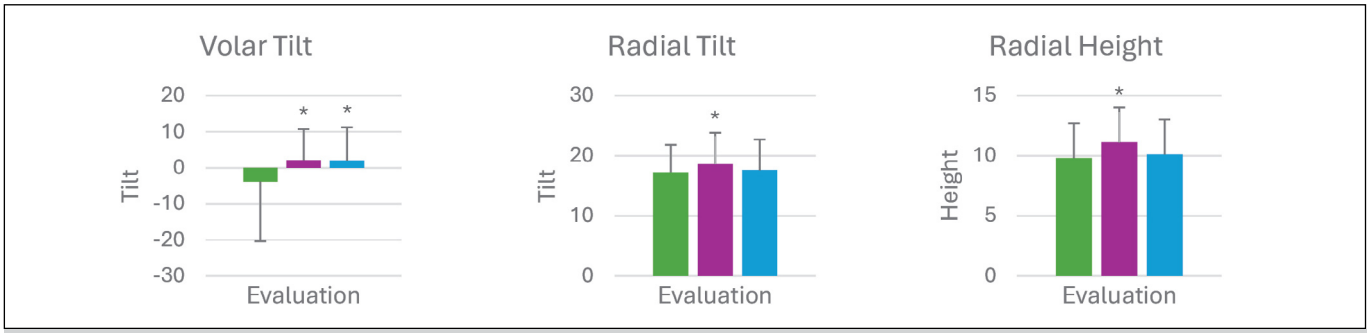

Figure 1. Changes shown by each variable in the three evaluation moments.

DISCUSSION

Wrist fractures involving the distal radius are frequent injuries in emergency care, affecting mostly middle-aged women. With n=54 (78%), they were also predominant in our study.[4]

With this research it was possible to observe through radiographic criteria, the evolution of the non-surgical treatment of distal radius fractures, using the criteria cited previously.

From the 3 different forms of immobilization (axillopalmar circular cast, antebrachiopalmar circular cast, and short plaster cast), no significant discrepancy was observed in the outcome (loss of measurements obtained in closed reduction at the first and third visits). However, although this was not a randomized study, it was observed a tendency of the use of short splint/plaster for reducible and stable fractures.[5-7]

In this study, there was an improvement trend in the radiographic parameters from the first to the second moment (after reduction), followed by a slight loss of the values obtained when analyzed at the third moment.

The measurements and angulations of the distal radius are predictors of success in choosing non-surgical treatment. They are: radial height, volar tilt, and radial slope. In a treatment that can vary from 4 to 8 weeks, these values of measurements and angulations classically are responsible for defining the continuation or discontinuation of the therapeutic method, resulting in maintenance of reduction or loss of fracture reduction.[8]

Radiographic parameters such as volar tilt and radial height correlate closely with clinical outcomes in conservative therapy, so they must be carefully evaluated at well-defined intervals.[9]

Most distal radius fractures can be treated with non-surgical therapies, even if it is only the first choice. If after a period of radiographic control it is possible to find other treatment options. The exception is for comminuted, intra-articular fractures, and those with significant deviation. For example, 2 patients who were excluded from the study due to a change in treatment: after a conservative approach, were referred to surgery for deviation of a fracture after two weeks of cast immobilization.[10]

A limiting factor in the study concerns the radiographic indicators, although commonly used, there is no consensus or well-established guidelines as to which descriptors should actually be used and how they should be performed to guide the course and choice for conservative therapy.[2]

It was possible to analyze the primary outcome: analysis of the radiographic parameters radial height, radial tilt and volar tilt, which have a strong relationship with the primary outcomes.

CONCLUSION

The good follow-up of the conservative treatment is closely linked to a good technique of closed reduction and immobilization with a correctly positioned external imobilization, either short/long or splint. Stable fractures by the Universal classification tend to evolve well with conservative therapy. A change of treatment to the surgical option was observed in two patients who initially had a classification (intra-articular BVI with deviation and unstable reducible).

Indicators such as volar tilt, radial tilt and radial height were the points of important radiographic analysis and divided into three moments, making it possible to infer the evolution of the non-surgical management and predict the clinical results of the conservative choice.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. CLB wrote the Introduction, the abstract in English, and the article review. BCH wrote the abstract in Portuguese and wrote the Discussion and Conclusion. LCR Wrote the materials and methods and the statistical analysis of data. EAR Wrote the materials and methods and the statistical analysis of data. NDM Wrote the materials and methods and the statistical analysis of data. BVST was the professor's Advisor and reviewer of the article.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e278586
ORTHOPEDIC TRAUMA

LOW INFECTION AND NON-UNION RATES IN POLYTRAUMA FEMORAL FRACTURES: A RETROSPECTIVE STUDY

BAIXAS TAXAS DE INFECÇÃO E NÃO UNIÃO EM FRATURAS FEMORAIS EM POLITRAUMATIZADOS: UM ESTUDO RETROSPECTIVO

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ABSTRACT

Objective: Assess complications and risks in staged femoral shaft fracture treatment using external fixation and intramedullary nailing (DCO). Methods: Analysis involved 37 patients with 40 fractures, mostly male (87.5%), average age 32.9 years. Data included ASA score, AO/OTA and Gustilo classifications, Glasgow Coma Score, Injury Severity Score, times to external fixation and conversion, ICU duration, nail type, and reaming status. Complications tracked were mortality, deep infection, and non-union. Results: Predominant fracture type was AO/OTA A (45%), with 40% open (Gustilo A, 93.8%). Average ISS was 21; GCS was 12.7. Median ICU stay was 3 days; average time to conversion was 10.2 days. Retrograde nails were used in 50% of cases, with reaming in 67.5%. Complications included deep infections in 5% and non-union in 2.5%. Conclusion: DCO strategy resulted in low infection and non-union rates, associated with lower GCS and longer ICU stays. ***Level of Evidence III; Retrospective Cohort Study.***

Keywords: Multiple Trauma. Femoral Fractures. Intramedullary Nailing. Postoperative Complications.

RESUMO

Objetivo: Analisar taxa de complicações e riscos no tratamento estagiado de fraturas diafisárias do fêmur com fixador externo e conversão para haste intramedular (DCO). Métodos: Estudo com 37 pacientes, 35 masculinos, idade média de 32,9 anos, abordando escores ASA, classificação AO/OTA, Gustilo, Glasgow e ISS, tempo até a fixação externa, na UTI e tipo de haste. Complicações como mortalidade, infecção profunda e não união foram registradas. Resultados: Fraturas tipo AO/OTA A foram as mais comuns (45%), com 40% expostas (Gustilo A, 93,8%). ISS médio de 21 e ECG de 12,7. Média de 3 dias na UTI e 10,2 dias até a conversão. Uso de haste retrógrada em 50% dos casos e fresagem em 67,5%. As complicações incluíram infecção profunda em 5% e não união em 2,5%. A não união correlacionou-se com baixo ECG e tempo prolongado na UTI. Conclusão: A estratégia de DCO mostrou-se eficaz com baixas taxas de infecção e não união, associada a baixo ECG e tempo na UTI. ***Nível de Evidência III; Estudo de Coorte Retrospectivo.***

Descritores: Traumatismo Múltiplo. Fraturas do Fêmur. Haste Intramedular. Complicações Pós-Operatórias.

Citation: Freitas MTB, Martins GBV, Santiago MAM, Silva IR, Leonhardt MC, Silva JS, Kojima KE. Low infection and non-union rates in polytrauma femoral fractures: a retrospective study. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 5. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Polytraumatized patients often experience a systemic immunologic response due to their multiple injuries and associated hemorrhagic shock. When this response is not well-balanced, it can lead to acute complications, including respiratory distress syndrome and multiple organ failure.[1,2] Among the factors that significantly impact the clinical course of these patients, major fractures, particularly femoral shaft fractures, stand out due to their potential for causing substantial bleeding and soft tissue damage.

The decision regarding how to stabilize femoral shaft fractures in polytraumatized patients is of paramount importance, as it can influence the final outcome. Early intramedullary nailing is the preferred approach for hemodynamically stable patients with good physiological reserves. In cases involving borderline hemodynamic stability or patients with limited physiological reserves, rapid stabilization using an external fixator, known as Damage Control Orthopedics (DCO), is an essential lifesaving measure that can also improve functional outcomes.[3,4]

However, the initial use of external fixation before definitive intramedullary nailing poses a potential risk of increased fracture complications, such as deep infections and non-union.

The objective of this retrospective study is to analyze the complication rate and identify the risk factors associated with femoral shaft fractures in polytraumatized patients who were initially treated with DCO (external fixation) and subsequently underwent intramedullary fixation. By investigating these complications and

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

The study was conducted at the Universidade de São Paulo, Faculdade de Medicina, Hospital das Clínicas (HC-FMUSP), Institute of Orthopedics and Traumatology, São Paulo, SP, Brazil. Correspondence: Kodi Edson Kojima. 333, Dr. Ovidio Pires de Campos Street, Cerqueira César, Sao Paulo, SP, Brazil. 05403-010. kodikojima@uol.com.br

Article received on 09/15/2023, approved in 01/24/2024.

their contributing factors, we aim to provide valuable insights that can inform clinical decision-making and enhance patient care in this challenging population.

CASUISTIC AND METHODS

This retrospective study has been performed at an urban university-based level one trauma center, between January 2019 and December 2021. Data were collected through a retrospective chart review and review of existing radiographs. Ethical approval was provided by the Scientific and Ethical Committee of the University under the protocol 12091. Written informed consent was obtained from all patients.

The inclusion criteria were as follows: age between 18 and 65 years, with femoral shaft fracture, Injury Severity Score (ISS) ≥ 16,[5] submitted to damage control with external fixation, followed by definitive fixation with intramedullary nail, either closed or open Gustilo type I, II, IIIA and IIIB ,[6] minimum of 12 months of follow-up, and signed informed consent.

The exclusion criteria included pathologic fractures, proximal or distal femoral fractures, polytrauma without femoral shaft fracture, previous injury to the same limb, associated vascular injury, submitted to a different treatment protocol, open Gustilo type IIIC.

Demographic data on the following were collected: age, sex, body mass index (BMI), smoking habit, comorbidity, American Society of Anesthesiology score (ASA), fracture side, fracture classification according to the AO/OTA classification,[7] location of the fracture in the shaft area, Gustilo classification for open fracture, Glasgow coma score (GCS), serum lactate, number of blood units transfused. Regarding the treatment the data collected were time to the external fixation, time to the definitive fixation, number of days in the intensive care unit (ICU), time with mechanical ventilation, respiratory complications (pneumonia, thromboembolism and acute respiratory distress syndrome), total days in the hospital, type of intramedullary nail, reamed or unreamed, post-operative infection, non-union and mortality.

Infection was defined according to the fracture-related infection criteria published by Metzemakers et al in 2018,[8] and non-union was defined if the fracture was not healed within 6 months of follow-up.

The qualitative parameters assessed were described for all patients using absolute and relative frequencies and the quantitative characteristics were described using summary measures (mean and standard deviation or median and quartiles). The occurrence of infection, non-union and poor outcomes (infection or non-union) were described according to the qualitative characteristics using absolute and relative frequencies and verified the association using Fisher's exact tests or likelihood ratio tests, the quantitative characteristics were described according to each outcome using summary measures and compared using Student's t-tests or Mann-Whitney tests according to the normality distribution of the data evaluated using Kolmogorov-Smirnov tests.[9]

The IBM-SPSS for Windows version 22.0 software was used to perform the analyzes and Microsoft Excel 2013 software was used to tabulate the data and make the graphs. The tests were performed with a significance level of 5%.

RESULTS

During the observation period spanning from 2019 to 2021, a total of 37 patients presented with 40 femoral shaft fractures, all of which met the criterion of an Injury Severity Score (ISS) ≥ 16. These patients initially received damage control orthopedic treatment followed by definitive fixation with an intramedullary nail. Among the 37 patients included in this study, 35 (87.5%) were male, with an average age of 32.9 ± 9.4 years. Notably, three patients exhibited bilateral fractures, resulting in a total of 40 femoral shaft fractures. (Table 1)

Table 1. Demographic characteristics of the patients.

Variable	Description (n = 40)
Age (years)	
Mean ± SD	32.9 ± 9.4
Median (min.; max.)	32.5 (19; 60)
Gender, n (%)	
Female	5 (12.5)
Male	35 (87.5)
Body mass index (BMI) Kg/m^2	
Mean ± SD	26.6 ± 4
Smoker	
n (%)	8 (20)
ASA score, n (%)	
I	24 (60)
II	14 (35)
III	2 (5)
Comorbidity	
n (%)	10 (25)
Fracture side, n (%)	
Right	22 (55)
Left	15 (37.5)
Bilateral	3 (7.5)
AO/OTA classification	
A	18 (45)
B	14 (35)
C	8 (20)
Gustilo classification, n (%)	
IIIA	15 (93.8)
IIIB	1 (6.3)
Injury Severity Score	
Median (range)	21 (16 - 50)
Glasgow Coma Score	
Mean ± SD	12.7 ± 4.1
Serum lactate (mmol/L)	
Mean ± SD	32.2 ± 20.2

The average Body Mass Index (BMI) among the participants was 26.6 ± 4 Kg/m^2, with only 8 individuals (20%) being smokers. The American Society of Anesthesiology (ASA) score distribution was as follows: ASA I in 24 patients (60%), ASA II in 14 patients (35%), and ASA III in 2 patients (5%). Ten patients (25%) had associated comorbidities. (Table 1)

Regarding the location of the fractures, 22 (55%) were on the right side, and 3 (8.1%) were bilateral. In accordance with the AO/OTA classification, 18 (45%) were classified as type A, 14 (35%) as type B, and 8 (20%) as type C. Among the 40 fractures, 16 (40%) were open; within this subset, 15 (93.8%) were categorized as Gustilo type A, and 1 (6.3%) as type B. The fractures were situated in the mid-portion of the shaft in 27 cases (67.5%), in the distal part of the shaft in 7 cases (17.5%), and in the distal shaft in 6 cases (15%). (Table 1)

The mean Injury Severity Score (ISS) was 21, ranging from 16 to 50. The average Glasgow Coma Score (GCS) was 12.7 ± 4.1, and the mean lactate level upon initial assessment in primary care was 32.2 ± 20.2 mmol/L. (Table 1)

The median duration of stay in the Intensive Care Unit (ICU) was 3 days, ranging from zero to seven days. Among the 40 patients, 13 (32.5%) required mechanical ventilation, with an average duration of 2.8 ± 2.9 days. Total hospitalization duration ranged from 9 to 58

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days, with an average of 35.4 ± 29.9 days. Respiratory complications, including pneumonia, thromboembolism, and acute respiratory distress syndrome, were observed in 20 patients (50%). (Table 2)
The average time interval between external fixation and intramedullary nailing was 10.2 ± 4.5 days, with a range of 3 to 24 days. All procedures were performed as one-stage interventions, involving the removal of the external fixator and subsequent fixation with an intramedullary nail. Among the 40 fractures, retrograde nails were utilized in 20 cases (50%), antegrade nails in 15 cases (37.5%), and cephalomedullary nails in 5 cases (12.5%). Reaming was performed in 27 fractures (67.5%). (Table 2)
Deep infection was observed in two cases (5%), and non-union was identified in one case (2.5%) during the six-month follow-up. Notably, the latter case occurred in a patient who experienced paraplegia subsequent to a spinal cord injury. One fracture (2.5%) exhibited both deep infection and non-union. (Table 2)
Statistical analyses revealed that none of the patient or fracture characteristics exhibited a significant correlation with infection ($p < 0.05$). Furthermore, the time elapsed from external fixation to intramedullary nailing, although averaging 10 days, did not correlate significantly with the incidence of deep infection ($p = 0.492$).
Regarding non-union, statistical analyses indicated a correlation with a lower Glasgow Coma Score ($p = 0.041$) and an extended duration of stay in the ICU ($p = 0.023$). However, no significant correlations were observed between non-union and reaming ($p = 0.242$) or the type of nail employed ($p = 0.452$).

DISCUSSION

Polytrauma constitutes a multifaceted and potentially life-threatening condition, necessitating a comprehensive and integrated approach. Traumatic injuries affecting the head, chest, abdomen, or pelvis often carry significant physiological repercussions. When coupled with a femoral shaft fracture, these cases become even more intricate due to soft tissue damage, hemorrhage, and the ensuing systemic inflammation, which elevate the risk of complications such as pulmonary infections, thromboembolic events, morbidity, and mortality.[10,11] It is noteworthy that the presence of associated injuries escalates the 30-day mortality rate, reaching 12.8% when multiple injuries are present.[12]
In an effort to mitigate the exacerbation of the patient's systemic condition, damage control orthopedics (DCO) is employed as an effective strategy. DCO involves the initial application of external fixation for femoral shaft fractures, followed by definitive fixation once the patient's overall systemic condition, particularly the respiratory aspect, stabilizes. This approach has demonstrated its merit in reducing both morbidity and mortality.[13-16]
Our study corroborates the safety and efficacy of DCO in the management of polytraumatized patients with femoral shaft fractures. Importantly, none of the 37 patients in our cohort experienced mortality. However, it is crucial to recognize that while external fixation serves as an effective primary intervention, its continued application as the definitive treatment is not without risks and potential complications. These include loss of stability, mal-union, pin-track infections, and non-union.[17] To mitigate these complications, the conversion to intramedullary fixation is recommended,[18,19]
A primary concern when transitioning to intramedullary nailing is the risk of infection. This risk is compounded by the presence of Schanz screws traversing soft tissues and breaching the cortex, thereby exposing the medullary canal to the external environment. Prolonged external fixation durations, in particular, elevate the risk of infection, as the trajectory of the Schanz screw may become susceptible to pin-track infection.[17]
Notably, while much literature emphasizes the life-saving benefits of DCO, there is a paucity of recent research focused on the long-term outcomes and complications in patients treated with this approach, especially in the context of femoral shaft fractures initially managed with external fixation and subsequently converted to intramedullary nailing.
In our study, three fractures (7.5%) developed deep infections, and notably, this did not correlate with several variables, including BMI, open fracture status, type of nail, reaming, or time to definitive fixation. Of significance is the lack of correlation between deep infection (Table 3) and the time to definitive fixation, which averaged 13 days in this subgroup.
Comparatively, the rate of deep infection in closed femoral shaft fractures among non-polytrauma patients without a staged treatment approach has been reported as low in previous studies: 1% by Wolinsky et al.,[20] 1% by Brumback et al,[21] and 3% by Hammacher et al..[22] Infection in nailing open femoral shaft fracture ranges from 2.4% and 4.8%.[23,24] The staged treatment with conversion of external fixation to internal fixation with intramedullary nailing has historically shown higher infection rate: Taeger et al. 6.6%,[25] Malik et al.,[26] and Parekh et al 16%.[27]
Our findings further suggest that prolonged time for conversion may elevate the risk of infection, aligning with recommendations to keep the conversion period under two weeks.[28]
In our series, 2 fractures (5%) resulted in non-union, with correlations identified between non-union and lower GCS, longer ICU stays, and marginally with the time to conversion. These observations challenge the notion that cranial trauma promotes bone formation and subsequent healing. Importantly, we found no correlation between non-union and the type of nail or the reaming process. (Table 4)
Our non-union rate is consistent with rates reported in previous studies: 3% shown by Nowotarski et al.,[29] 6% by Malik et al.[26] and 9% by Parekh et al.[27]
Due the tight inclusion criteria of polytraumatized patient with ISS ≥ 16 with femoral shaft fracture treated initially with DCO the number of patients in our study was 37. Other studies also have

Table 2. Results of the treatment.

Variable	Description (n = 40)
Time to external fixation (DCO), minutes	
Median (min.; max.)	30 (5; 54)
Time in the ICU, days	
Median (min.: max.)	3 (0; 7)
Mechanical ventilation, days	
n (%)	13 (32.5)
days (mean ± SD)	2.8 ± 2.9
Time in hospital, days	
Mean ± SD	35.4 ± 29.9
Time to definitive fixation, days	
Mean ± SD	10.2 ± 4.5
Type of nail, n (%)	
Retrograde	20 (50)
Antegrade	15 (37.5)
Cephalomedullary	5 (12.5)
Reaming, n (%)	
Reamed nail	27 (67.5%)
Deep infection	
n (%)	2 (5%)
Non-union	
n (%)	1 (2.5%)
Deep infection and non-union	
n (%)	1 (2.5%)

Table 3. Deep infection statistical analyzes.

Variable	Deep infection		p
	No	Yes	
Age (years), mean ± SD	33.3 ± 9.7	28.8 ± 6.5	0.423
Sex, n (%)			
Female	4 (80)	1 (20)	0.338*
Male	33 (94.3)	2 (5.7)	
BMI (Kg/m^2), mean ± SD	26.8 ± 4	24 ± 2.7	0.253
Smoker, n (%)			
No	29 (90.6)	3 (9.4)	> 0.999*
Yes	8 (100)	0 (0)	
ASA, n (%)			
I	23 (95.8)	1 (4.2)	0.469#
II	12 (85.7)	2 (14.3)	
III	2 (100)	0 (0)	
Respiratory complication			
No	18 (90)	2 (10)	> 0.999*
Yes	19 (95)	1 (5)	
Fracture side, n (%)			
Right	21 (95.5)	1 (4.5)	0.498#
Left	13 (86.7)	2 (13.3)	
Bilateral	3 (100)	0 (0)	
Comorbidities, n (%)			
No	27 (90)	3 (10)	0.560*
Yes	10 (100)	0 (0)	
AO/OTA classification, n (%)			
A	17 (94.4)	1 (5.6)	0.349#
B	12 (85.7)	2 (14.3)	
C	8 (100)	0 (0)	
Gustilo classification, n (%)			
IIIA	14 (93.3)	1 (6.7)	> 0.999*
IIIB	1 (100)	0 (0)	
Glasgow coma score, n (%)			**0.461£**
Serum lactate, median (min., max.)	29 (18; 43)	12 (6, 40)	0.136£
ISS, median (min., max.)	21 (17.5, 26.5)	22 (16, 28)	0.885£
Fracture location in the shaft, n (%)			
Proximal	5 (83.3)	1 (16.7)	0.439#
Median	25 (92.6)	2 (7.4)	
Distal	7 (100)	0 (0)	
Type of nail, n (%)			**0.452#**
Retrograde	19 (95)	1 (5)	
Antegrade	13 (86.7)	2 (13.3)	
Cephalomedullary	5 (100)	0 (0)	
Reaming, n (%)			**0.242***
No	11 (84.6)	2 (15.4)	
Yes	26 (96.3)	1 (3.7)	
Time to definitive fixation, days	10 (6, 13)	13 (8, 15)	0.492£
Time in the ICU, days median (min., max.)	3 (0, 6)	7 (0, 10)	0.626£
Time in the hospital, days median (min., max.)	24 (16, 37)	41 (23, 54)	0.251£

Student t test (£), Mann-Whitney test (*), Fischer exact test (#), Likelihood ratio test.

Table 4. Non-union statistical analyzes.

Variable	Non-union		p
	No	Yes	
Age (years), mean ± SD	32.4 ± 8.7	44.5 ± 21.9	0.577
Sex, n (%)			
Female	5 (100)	0 (0)	> 0.999*
Male	33 (94.3)	2 (5.7)	
BMI (Kg/m^2), mean SD	26.5 4.1	27.5 1.2	0.743
Smoker, n (%)			
No	30 (93.8)	2 (6.3)	> 0.999*
Yes	8 (100)	0 (0)	
ASA, n (%)			
I	23 (95.8)	1 (4.2)	0.834#
II	12 (85.7)	2 (14.3)	
III	2 (100)	0 (0)	
Respiratory complication			
No	19 (95)	1 (5)	> 0.999*
Yes	19 (95)	1 (5)	
Fracture side, n (%)			
Right	20 (90.9)	2 (9.1)	0.290#
Left	15 (100)	0 (0)	
Bilateral	3 (100)	0 (0)	
Comorbidities, n (%)			
No	29 (96.7)	1 (3.3)	0.560*
Yes	9 (90)	1 (10)	
AO/OTA classification, n (%)			
A	18 (100)	0 (0)	0.266#
B	13 (92.9)	1 (7.1)	
C	7 (87.5)	1 (12.5)	
Gustilo classification, n (%)			
IIIA	14 (93.3)	1 (6.7)	> 0.999*
IIIB	1 (100)	0 (0)	
Glasgow coma score, median (min., max.)	15 (3, 15)	6 (3, 9)	0.041£
Serum lactate, mean ± SD	29.5 ± 2	14.5 ± 2.5	0.085£
ISS, median (min., max.)	20.5 (16, 50)	25.5 (22,29)	0.885£
Fracture location in the shaft, n (%)			
Proximal	5 (83.3)	1 (16.7)	0.094#
Median	27 (100)	0 (0)	
Distal	6 (85.7)	1 (14.3)	
Type of nail, n (%)			
Retrograde	19 (95)	1 (5)	0.744#
Antegrade	14 (93.3)	1 (6.7)	
Cephalomedullary	5 (100)	0 (0)	
Reaming, n (%)			
No	12 (92.3)	1 (7.7)	>0.999*
Yes	26 (96.3)	1 (3.7)	
Time to definitive fixation, days	9.5 ± 4.5	34 ± 20	0.051£
Time in the ICU, days	3.0 ± 9.9	37.5 ± 17.5	0.021£
Time in the hospital, days	24.5 ± 25.4	80.5 ± 57.5	0.369£

Student t test (£), Mann-Whitney test (*), Fischer exact test (#), Likelihood ratio test.

shown a limited number of patients included: Nowotarski et al. 59 patients,[29] Mallik et al, 12 patients,[26] Taeger et al. 75 patients[25] and Parekh et al. 16 patients.[27]

However, it is essential to acknowledge the inherent limitations in our study, including the relatively small sample size and the retrospective nature of data collection, which may introduce bias and imprecision. The absence of a control group for comparison further underscores the need for cautious interpretation of our results.

In conclusion, our study underscores the life-saving benefits of DCO in polytrauma patients with femoral shaft fractures. The conversion to internal fixation with intramedullary nailing emerges as a safe strategy, characterized by low infection and non-union rates. Nevertheless, the limitations inherent to our study, including its small sample size and retrospective design, necessitate the exercise of caution in interpreting and generalizing our findings. Further research, incorporating larger cohorts and prospective methodologies, is warranted to validate and refine our observations and treatment protocols.

CONCLUSIONS

In our series the indication of damage control orthopedics in patients with femoral shaft fracture and ISS ≥ 16 lead to zero mortality. The conversion from the external fixation to the intramedullary nailing, done in average after 10 days, hasn't shown increase in infection and non-union rate. Non-union had correlation with lower GCS and longer stay in the ICU.

AUTHORS' CONTRIBUTION: IRS, MTBF, GBVM and MAMS: Data collection and manuscript preparation; MCL and JSS: Text review; KEK: preparation of the manuscript, adaptation of the text and language.

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DOI: http://dx.doi.org/10.1590/1413-785220243202e263176
ORTHOPEDIC TRAUMA

TIME UNTIL THE START OF ANTIBIOTIC PROPHYLAXIS AND THE RISK OF OPEN FRACTURE INFECTION: A SYSTEMATIC REVIEW

TEMPO ATÉ O INÍCIO DA ANTIBIOTICOPROFILAXIA E O RISCO DE INFECÇÃO EM FRATURAS EXPOSTAS: UMA REVISÃO SISTEMÁTICA

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ABSTRACT

Open fractures are highly incident injuries closely related to the modern life, in which accidents caused by motor vehicles or other machines impart high energy to bone tissue. Individual morbidity is represented by the functional impairment resultant of infection, nonunion, or vicious healing. In terms of public health, there are huge costs involved with the treatment of these fractures, particularly with their complications. One of the critical issues in managing open fractures is the use of antibiotics (ATB), including decisions about which specific agents to administer, duration of use, and ideal timing of the first prophylactic dose. Although recent guidelines have recommended starting antibiotic prophylaxis as soon as possible, such a recommendation appears to stem from insufficient evidence. In light of this, we conducted a systematic review, including studies that addressed the impact of the time to first antibiotic and the risk of infectious outcomes. Fourteen studies were selected, of which only four found that the early initiation of treatment with antibiotics is able to prevent infection. All studies had important risks of bias. The results indicate that this question remains open, and further prospective and methodologically sound studies are necessary in order to guide practices and health policies related to this matter. ***Level of Evidence II; Therapeutic Studies Investigating the Results Level of Treatment.***

Keywords: Antibacterial Agents. Fractures, Bone. Infection Control.

RESUMO

As fraturas expostas são lesões altamente incidentes, intimamente relacionadas à vida moderna, na qual os acidentes causados por veículos automotores ou outros aparatos transmitem alta energia ao tecido ósseo. A morbidade individual é representada pelo comprometimento funcional resultante de infecção, não-união ou cicatrização viciosa. Há enormes custos envolvidos no tratamento dessas fraturas em termos de saúde pública, principalmente quanto as complicações. Uma das questões críticas no tratamento de fraturas expostas é o uso de antibióticos, incluindo as decisões sobre quais agentes específicos devem ser administrados, a duração e o momento ideal para a primeira dose profilática. Embora as diretrizes recentes tenham recomendado o início da profilaxia antibiótica o mais rápido possível, essa recomendação parece se basear em evidências insuficientes. Em vista disso, realizamos uma revisão sistemática, incluindo estudos que abordaram o impacto do tempo até o primeiro antibiótico e o risco de resultados infecciosos. Foram selecionados 14 estudos, dos quais apenas quatro concluíram que o início precoce do tratamento com antibióticos é capaz de prevenir infecções. Todos os estudos tinham riscos importantes de viés. Os resultados indicam que essa questão permanece em aberto, sendo necessários mais estudos prospectivos e metodologicamente sólidos para orientar as práticas e políticas de saúde relacionadas a esse assunto. ***Nível de Evidência II; Estudos Terapêuticos que Investigam o Nível de Resultados do Tratamento.***

Descritores: *Agentes Antibacterianos. Fraturas Ósseas. Controle de Infecções.*

Citation: Marchiori JGT, Nunes APF. Time until the start of antibiotic prophylaxis and the risk of open fracture infection: a systematic review. Acta Ortop Bras. [online]. 2024;32(2): Page 1 of 8. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

An open fracture is defined as a traumatic injury leading to exposure of a broken bone to external environment, with consequent contamination by microorganisms. There is always an associated soft tissue injury, the severity of which is directly related to the risks of complications, such as lack of consolidation and infection[1] The ever-increasing incidence of open fractures reflects developments in technology in the industry, military and transport fields. Only in the US, it is estimated that up to 180.000 open fractures occur every year.[2] Industrial accidents, gunshot wounds and, mostly, motor vehicle accidents represent the main causes of open fractures, whose incidence approaches 30 cases per 100.000 persons per year. [3-5] Open fractures inevitably lead to bacterial contamination of deep compartments, including subfascial soft tissues and bone. The subsequent risk of proliferation and infection is dependent on

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

The study was conducted at the Universidade Federal do Espírito Santo, UFES, Espírito Santo, Brazil.
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Article received on 04/18/2022, approved in 07/05/2022.

the interaction of variables such as the inoculum, host vulnerability and the lesion seriousness itself.[6]

Current paradigms in management of open fractures have included completion of bony e soft tissue reconstruction in the first 48-72 hours. Inoculum size limitation has been achieved with modernization of initial fracture management, including lavage, debridement, fixation and antibiotic prophylaxis. The infectious complication worsens the prognosis, reduces probabilities that the fracture will consolidate, increases the risk of sequelae and dysfunction, including amputation and death. In the social realm, open fractures entail exorbitant costs with hospitalizations, surgical procedures, medication, physical therapy and rehabilitation, in addition to insurance and social security costs.[7-9]

In this context, it is of great relevance to improve methods or strategies that provide a reduction in the incidence of infections associated with open fractures. Particular attention has been paid to the study of the relationship between early antibiotic (ATB) prophylaxis and the risk of infection. However, evidence is conflicting in this topic, mainly due to poor methodological quality of most studies published by now. This systematic review seeks to synthesize the body of evidence regarding this topic, in order to support relevant clinical decisions that may inform protocols and health policies addressing open fractures management.

METHODS

Search strategy and information sources

We initially defined the review scope using PICO acronym[10,11] (Patient, Intervention, Comparison, Outcome), as follows: P: open fractures of any location and severity; I: early ATB after trauma; C: late ATB after trauma and O: superficial or deep infection.

Search process followed PRISMA guidelines[12] (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). An orthopedic surgeon and a microbiologist (JM and AN) independently searched the following databases: Cochrane, Embase, Pubmed, Google Scholar. Sources of gray literature were also searched, including ClinicalTrials.gov, WHO's International Clinical Trials Registry Platform (ICTRP), Networked Digital Library of Theses and Dissertations (NDLTD) and Dissertations and Theses Global. Disagreements were discussed and jointly solved. Search extended from June 2021 to February 2022, including the terms *open fractures* + *infection* + *antibiotic* + *timing or time or early*, with no date restriction.

Inclusion and exclusion criteria

Randomized or non-randomized clinical trials, case-control and cohort studies were eligible, since they provided quantitative information on time to first ATB and infection endpoint.

Data extracted was registered in a Microsoft Excel spreadsheet. Complementary items were antibiotic prophylaxis regimen and its duration, the time between the fracture and the first surgical debridement, what type of osteosynthesis was used, total length of hospital stay, at what point in the follow-up the outcome occurred, which bone was fractured, open fracture classification, general demographics, presence of clinical comorbidities and missing data information.

Studies without intervention or outcome data were excluded. Regarding the design, we excluded case series, ecological studies and reviews. Others exclusions applied to duplicate, preclinical or studies with no full-text available. Only studies published in English were evaluated.

Evaluation criteria of selected studies

We used the ROBINS-I[13] tool for risk of bias assessment, which covers 7 essential domains (confusion, selection, missing data, classification of intervention, detection and selection bias, and bias due to deviation from the intended intervention). We chose to describe the results by separating the articles that provided recommendations from those that only indicated that early antibiotics were a current practice in trauma center. Whenever possible, we choose to group fractures with similar prognosis with the aim of improving external validity of the systematic review, since, in practice, it makes more sense to reach clinical decisions about antibiotic prophylaxis based on groups of fractures whose prognosis are similar. The main objectives of the synthesis were the identification of the methodological aspects, biases and measures of effect related to the binomial antibiotic precocity and infection. Ultimately, we meticulously investigated the selected studies, aiming at providing recommendations for practice and health policies in this matter.

RESULTS

Our search initially identified 604 titles, 71 from Pubmed, 271 from Embase, 117 from Google Scholar, 138 from Cochrane and 7 from Clinicaltrials.gov. Twenty duplicate studies were automatically removed by the reference organization tool (Endnote). Of the remaining 584, 527 were excluded for not containing minimal quantitative data on the intervention or outcome. We then proceeded to a detailed analysis of 57 titles, of which 15 duplicates were additionally excluded. Others exclusions applied to 22, due to ineligible designs, 6 due to full-text unavailability and 2 for other reasons. Another 2 studies were included by handsearch. In the end, 14 studies composed the present review. (Figure 1)

Table 1. presents individual characteristics of the studies selected in the systematic review, with emphasis on results addressing the association between timing of first ATB and infectious outcome, including main author, year of publication, design, sample size, distribution of fractures by classification, risk of bias classification, information about time to first ATB and outcome.

Table 2. contains information on the analytical methods used, results and whether the authors made recommendations on this topic. Finally, we summarize some comments on strengths and limitations of the selected studies.

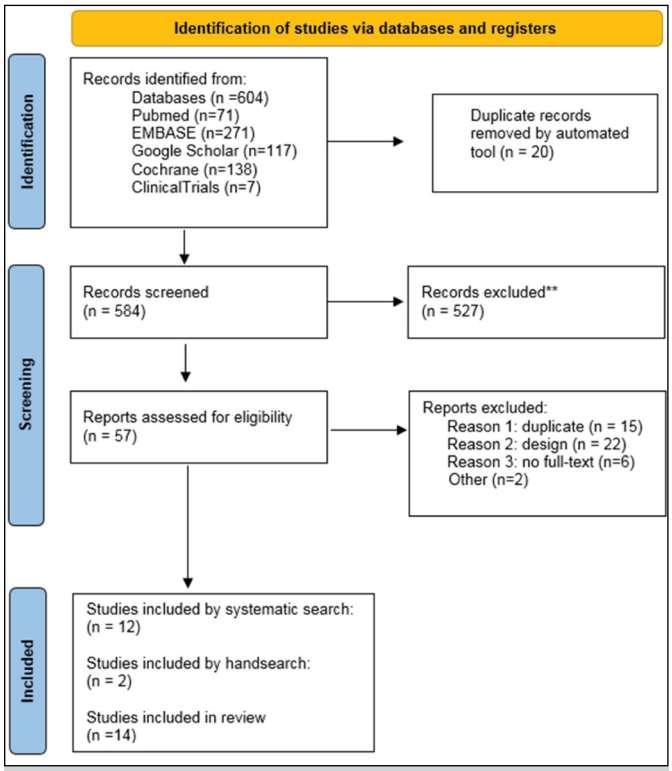

Figure 1. PRISMA flow diagram.

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Table 1. General characteristics of studies.

Study Year of publication Design	Inclusion	Sample data Timing to first ATB	Outcome definition	Risk of bias	Study risk of bias
Dellinger et al. 1988[15] Retrospective cohort	Femur, humerus, leg bones, forearm bones All classifications Multicentric > 14y No comorbidities	N= 240 (263 fx) Minimum follow-up 21d Gt I: 25% Gt II: 47% Gt IIIA: 19% Gt IIIB: 5% Gt IIIC: 5% Method of counting time to first ATB undefined	Clinical criteria	A=M B=L C=S D=L E=S F=S G=M	S
Patzakis et al. 1989[16] Prospective cohort	Any age Any bone	N= 1.104 or 1.390? Undefined follow-up Method of counting time to first ATB undefined	Clinical criteria, confirmed by microbiology	A=S B=S C=NI D=L E=C F=M G=M	C
Al-Arabi et al. 2008[17] Prospective cohort	Femur, humerus, leg bones, forearm bones All classifications	N=133 Undefined follow-up Method of counting time to first ATB undefined	Clinical criteria (edema, erythema, discharge, pain), cultures when possible	A=C B=C C=S D=L E=C F=S G=M	C
Enninghorst et. al 2011[18] Prospective cohort	> 18y, trauma center, all classifications of open diaphyseal tíbia fx	N=89 Gt I: 25% Gt II: 30% Gt IIIA: 20% Gt IIIB: 24% Gt IIIC: 1% Follow-up: 12m	Surgical debridement indication or long term systemic ATB	A=M B=L C=S D=L E=NI F=S G=M	S
Thomas et al. 2013[19] Prospective cohort	Any age, extremity open fractures	N= 138 Follow-up: 6m 60 patients: ATB pre-hospital (helicopter) 78 patients: ATB hospital Method of counting time to first ATB: time of admission and time of trauma	Composite Endpoint (superficial or deep infection or nonunion)	A=C B=L C=S D=L E=C F=C G=M	C
Leonidou et al. 2014[20] Prospective cohort	Open long bones fractures	N= 212 (220 fx) Analysis for first ATB included 139 patients Follow-up: until bone healing or a procedure for nonunion or infection Gt I: 36,6% Gt II: 19,9% Gt IIIA: 24,8% Gt IIIB: 18,6% Method of counting time to first ATB: time of admission and time of trauma	Purulent discharge from deep fascia, dehiscence; "radiological evidence" or cultures	A=C B=L C=S D=L E= C F=S G=M	C
Weber et al. 2014[21] Prospective cohort	Long bones open fx of adults. All classifications	N=686 (737 fx) Gt I: 29% Gt II: 37% Gt IIIA: 21% Gt IIIB: 12% Gt IIIC: 1% Follow-up: 90d or phone interview at 12m	Surgical debridement indication or long term systemic ATB	A=M B=L C=S D=L E=S F=S G=M	S

Zumsteg et al. 2014[22] Retrospective cohort	18y Radius and/or ulna open fx	N=200 Variable follow-up (max 6m) Gt I: 22% Gt II: 24% Gt III: 55% Data from medical records	Deep infection as an indication or surgical debridement, assessed from medical records or phone calls	A=S B=C C=S D=L E=S F=C G=M	C
Lack et al. 2015[23] Retrospective cohort	Type III open tibia fractures	N=137 Follow-up 90d Gt IIIA: 52% Gt IIIB/IIIC: 48% Method of counting time to first ATB: time of admission and time of trauma	CDC	A=M B=L C=S D=L E=L F=S G=M	S
Johnson et al 2017.[24] Cross-sectional	> 18y Limb and axial bones All classifications Data from medical records	N=100 1 group N= 50 before early ATB protocol. 1 group N=50 after protocol institution Undefined follow-up	Surgery indication	A=S B=C C=S D=L E=S F=S G=M	C
Assunção ALF, Oliveira de ST. 2020[25] Prospective cohort	> 18y, trauma center, data from medical records.	N=241 Gt I: 20% Gt II: 19% Gt III: 21,6% NC: 39,4% Time from admission to first ATB	NS	A=C B=C C=S D=C E=M F=S G=M	C
Hendrickson et al 2020[26] Retrospective cohort	Type IIIB open tíbia fx	N= 156 (159 fx) Minimum follow-up 1y Median 26 m (IQR 18-39) Method of counting time to first ATB: time of trauma	Deep infection confirmed by microbiology	A=M B=L C=L D=L E=L F=M G=M	M
Roddy et al. 2020[27] Retrospective cohort	Upper and lower limb open fx, all classifications, data from medical records	N= 230 Minimum follow-up: 30d, endpoint assessment at 90d	CDC NHSN	A=M B=L C=S D=L E=S F=S G=M	S
Zuelzer et al. 2021[28] Retrospective cohort	> 18y, trauma center, data from medical records, rescue sheets, Gustilo I, II, IIIA	N=127 Gt I: 27,6% Gt II: 48,8% Gt IIIA: 23,6% Minimum follow-up: 6w	CDC	A=M B=L C=S D=L E=M F=S G=M	S

A: bias due to confounding. B: selection bias. C: bias in classification of intervention. D: bias due to deviations from intended interventions. E: bias due to missing data. F: bias in measurement of outcomes. G: bias in selection of the reported result. L: low risk. M: moderate risk. S: serious risk. C: critical risk NI: no information. ATB: antibiotic. NC: not classified. NS: not specified. CDC: Centers for Disease Control. OR: Odds Ratio. ROC: Receiver Operator Characteristics. NHSN: National Healthcare Safety Network. Fx: fractures. Gt: Gustilo

DISCUSSION

Investigation of risk factors for infection in open fractures is extremely important, given the morbidity and health costs involved in treating such complications.[6,9] At the individual level, deep infections are difficult to treat, often incurable, with tendency to become chronic and to permanently compromise the quality of life and the work performance. This is particularly relevant when considering that open fractures are especially incident in younger and economically active age groups.[3-5] Even with the optimization of techniques, devices and treatment protocols, infection rates can still reach 27% for type III fractures, even in specialized trauma centers.[14]

In this context of high morbidity and functional impairment, a simple and inexpensive intervention able to avoid infectious complications becomes an attractive option to be tested. Still, contemporary literature does not give the intended answers, in the face of high heterogeneity and several methodological flaws of studies published by now. In our systematic review, we chose to list such limitations, or risk of bias, both in a descriptive way, as from a standardized tool, the ROBINS-I.[13] Bias risk assessment has shown has been especially useful in the internal comparison of studies included in the review. Generally, we observed a high risk of internal validity issues in the studies. In fact, of the 14 articles included in the systematic review, 6 were

Table 2. Main results of studies included.

Study	Analysis	Results	Comments	Earl ATB: recommendation x usual practice
Dellinger et. al. 1988[15]	Chi-square Fisher Student´s t Kaplan-Meier Logistic regression	Time to 1°ATB < 3h: 16% infected; > 3h: 17% infected. p=0,9784 Mean time to 1º ATB in infected: 2,0h (+-1,1h); non-infected: 2,2h (+-1,4h)	Method of counting the time to first ATB not informed 22% lost to follow-up at 6m	No mention about recommendation or practice
Patzakis et al. 1989[16]	Chi-square	Time to first ATB <3h (364 fx): 4,7% infected. . >3h (661 fx): 7,4% infected p= 0,087 (Yates 0,114)	No information on follow-up No control for confounding variables Method of counting the time to first ATB not informed. Dichotomization of time to first ATB variable. No information on time as a continuous variable Divergence regarding composition of the cohort (1.104 ou 1.390?) No apparent distinction between superficial and deep infection	Recommends ATB as soon as possible after lesion
Al-Arabi et al. 2007[17]	Fisher Linear Regression	Time to first ATB < 6h: 5,7% infected > 6h: 22,2% infected p=0,1144	No control for confounding variables No information regarding central tendency measures for follow-up Method of counting the time to first ATB not informed A non-specified number of more severe fx (IIIB and IIIC) lost to follow-up, with no information on their basal characteristics 80% statistical power for a reduction of 10% in infection rate	No mention about recommendation or practice
Enninghorst et al. 2011[18]	Means Student´s t Mann-Whitney U Chi-square Univariate, bivariate, multiple regression	Cohort mean: 1,2h (+-0,3h) Incidence of infection: 16,8% No difference in time to first ATB between infected and non-infected	Indefinition regarding classification of intervention and outcome No missing data information	No mention about recommendation or practice
Thomas et al. 2013[19]	Fisher Chi-square Kruskal-Wallis	Pre-hospital ATB group: 60 patients (13 completed follow-up) 1 outcome (infection or nonunion [7,7%]) Hospital ATB group: 78 patients. (70 completed follow-up) 9 outcomes nonunion [12,9%]) P=1,0 60,2% lost to follow-up	No control for confounding variables Inconsistencies in classification of intervention, without proper control (potentially affects internal validity) High losses to follow-up Meticulous statistical analysis and discussion about limitations	No mention about recommendation or practice
Leonidou et al. 2014[20]	Fisher	Time to 1°ATB < 3h: 14% infected; > 3h: 12,5% infected. p=1,0	No control for confounding variables No information regarding central tendency measures for follow-up 39,6% lost to follow-up Inconsistencies in classification of intervention, without proper control (potentially affects internal validity) Inconsistencies in information of sample composition and in records of losses	Usual practice: ATB in less than 3 hours from lesion
Weber et al. 2014[21]	Medians Mann-Whitney U Simple and multiple regression	6% of infection Median to 1° ATB among infected: 2h37min. Median to first ATB among non-infected: 3h5min p=0,67 Logistic regression: OR 1,0 (IC95% 0,95-1,05)	Sound methodology Method of counting the time to first ATB not informed Few losses to follow-up. Intervention not known in 15% of patients No definite conclusion on the association of early ATB and infection, as most patients received late ATB	Usual practice

Zumsteg et al. 2014[22]	Wilcoxon Fisher Chi-square Logistic Regression	32% lost to follow-up, with no information on their basal characteristics Mean time to 1° ATB: 1,6 +- 0,9h among infected; 2,6 +- 2,2 horas among non-infected ATB < 3h: 159 patients (6% infected). ATB > 3h: 41 patients (2% infected p=0,40 10 infections (5%), on average 118 days after first stabilization	Many confounders not controlled Inconsistencies in classification of intervention High losses to follow-up Upper limb open fractures have less risk of getting infected, so big samples may be needed to investigate such associations.	No mention about recommendation or practice
Lack et al. 2015[23]	Chi-square Student´s t Logistic Regression	Time to 1°ATB < 66min: 7% infected; > 66min: 25% infected p=0,0063 ROC: 66min (AUC=0,63 p=0,03) Logistic regression: ATB > 66min: OR = 3,78 (CI95% 1,26-14,11 p= -0,016)	Sound methodology and analysis Gives a cut-off time to first ATB Sample calculation for a power of 80% Late ATB is a independent predictor of infection Inconsistencies in classification of intervention, without proper control (potentially affects internal validity)	Recommends ATB as soon as possible, preferably at pre-hospital level
Johnson et al. 2017[24]	Chi-square Mann Whitney U Student´s t	Time to first ATB dropped from 123,1min to 35,7min (p=0,0003). Incidence of infection = 10% for both groups	Time to first ATB counted from admission time (risk of bias due to classification of intervention) Outcome defined as indication of surgery (not precise and subjective) Follow-up not defined Small sample (few outcomes, low power)	Usual practice: first ATB as soon as possible from admission
Assunção ALF, Oliveira de ST. 2020[25]	Frequencies Chi-square	Infection: ≤ 3h from admission: 15,7% >3h from admission: 26,1% p =0.0350	Confounders and co-interventions not listed	Usual practice (preoperative ATB)
Hendrickson et al. 2020[26]	Medians and IQR Logistic Regression	Time to 1° ATB: median 162 min (IQR: 120-207) Time to 1° ATB x Infection (regression analysis): Continuous: p=0,431 1h: p=0,099 3h: p=0,848	Sound methodology and analysis Main confounders accounted for, including multicollinearity tests Outcome assessed with objective criteria Potential risk of beta error, as most patients took late ATB (>2h)	Usual practice: early/pre-hospital ATB
Roddy et al. 2020[27]	Chi-square Mann Whitney U ROC Cox regression	Deep infection: 6% Median to 1° ATB in infected: 83min Median to 1° ATB non-infected: 61min p=0,053 Cut-off 120min ROC (AUC 0.62, 95% CI [0.50 - 0.75], p = 0.042) OR 2,4 [CI95% 1,1-5,7] p=0,036.	Sound methodology and analysis Gives a cut-off time to first ATB CI of AUC do not show a definitive benefit of cut-off found Small sample (low power) 130 patients missed (29%) e 78 with no information on time to first ATB (17%)	Recommends ATB as soon as possible
Zuelzer et al. 2021[28]	Chi-square Fisher ANOVA Binary regression Logistic regression ROC curve	Infection: ≤ 150 from admission: 3% >150 from admission: 20% Odds Ratio 5.6 [95% CI 1.4 to 22.2]; p = 0.01	Sound methodology, detection bias risk, risk of bias due to classification of intervention (non-standardized sources of data)	ATB as soon as possible after lesion (practice and recommendation)

ANOVA: Analysis of Variance. ATB: antibiotic. IQR: interquartile range. OR: Odds Ratio.

considered at serious risk of bias, 7 at critical risk and only 1 at moderate risk. The main problems encountered were substantial losses to follow-up, knowledge of the intervention at the time of assessing the outcome, and subjectivity in the classification of both the intervention and the outcome.

Regarding the follow-up, the main problems found were substantial losses, lack of definition or omission of measures of central tendency.[15,17,19,20,22,27] In view of their designs, all studies allowed knowledge of the intervention at the time of evaluating the outcome. In others, the way of measuring the outcome was not defined[25], or it was subjective,[15,17,18,21,22,24,27] or without distinction between superficial and deep planes,[16] or even taken as a composite endpoint.[19]

Another potentially serious question was the inconsistency in the way time to the first ATB was accounted for. In fact, some studies

started time counting from the time of trauma, others from hospital admission, and still others from both timepoints, without performing a separate analysis for each of these situations. [19,20,23] For example, patients whose first dose of ATB was administered after 30 minutes after admission and who became infected were mistakenly classified as early ATB takers, as the time elapsed between the trauma and hospital admission was not accounted for. So, eventual infections in this group are mistakenly associated with early ATB, when in fact should be attributed to late intervention. The net effect is a tendency to mitigate eventual contributions of early ATB in reducing the risk of infection.

Some studies classified timing to first ATB from trauma time, [26] while others did so from hospital admission. [15,24,25] The latter situation makes time registry of first ATB earlier than in fact it was. Some studies did not define the method of accounting time to first ATB.[15-18,21,22] We found situations of lack of balance between the comparison groups, with cases in which the vast majority of the sample either took ATB too early[18] or too late, [21,26] which tends to reduce statistical power and favor the null hypothesis.

Few authors performed comprehensive control of confounders,[19,21,27,28] and most samples were not large enough to confer adequate statistical power, or, even if there was a representative sample, the number of outcomes was small, introducing a risk of false negative associations between confounders and the endpoint. Although there were substantial limitations in all studies, we found, in the most recent publications, better methodological and analytical elaboration,[19,21,26-28] which reflects the growing interest in clarifying the real role of early antibiotic prophylaxis in the management of open fractures.

Due to great heterogeneity, low methodological robustness and absence of randomized clinical trials on this topic, it was not possible to build a meta-analytic study, which could inadvertently compromise validity of results. However, the present review was valuable in identifying methodological gaps that can be optimized in future investigations. So, we suggest that upcoming studies carry out separate (or adjusted) analyzes to patients whose exact time of trauma is known and for those whose hospital admission is the starting time point to the first ATB. The time interval to the first ATB should be, in principle, analyzed as a continuous variable, avoiding artificial categorizations. Construction of ROC curves, from the mentioned time analysis, should be encouraged, and the data related to them, including sensitivity, specificity, AUC and respective confidence intervals, must be informed. The minimum follow-up of 3 months seems reasonable, since the vast majority of infections concentrate in this period. However, measures of central tendency and dispersion related to follow-up must be recorded in all cohorts. Those individuals lost at follow-up should be analyzed for the available data, especially the time interval to the first ATB. This is because the risk of bias due to missing data will be mitigated if the losses are balanced between patients who took early ATB and those who took it later.

Regarding the classification of outcome, we suggest that validated and objective methods are used, including, whenever possible, information on subfascial origin and microbiological results. Creative ways to prevent outcome assessors from knowing about the intervention or exposure (early or late ATB) should be implemented. All these measures tend to increase the methodological homogeneity necessary for the elaboration of future meta-analyses, something not currently feasible.

Of the 14 studies included in our review, only 4 showed a positive correlation between the interval to the first ATB and the risk of infection. [23,25,27] However, even though the benefits of early antibiotic prophylaxis in preventing infection are still to be confirmed, there are already centers that recommend or incorporate such practices, demonstrating that it is possible to implement antibiotic prophylaxis at a pre-hospital level. [24,29]

It is important to consider that even studies that show benefits with a small size of effect justify efforts to implement antibiotic prophylaxis as early as possible, because it is a safe, simple and cheap intervention, so that even if the number necessary to treat (NNT) is large, the cost-risk-benefit ratio will be highly favorable. Implementation of pre-hospital systemic antibiotic prophylaxis tends to be straightforward, as first-generation cephalosporins are acceptable options for all types of fractures in the Gustilo classification[23,30-32] and do not produce considerable risks of severe allergic reactions. In fact, even in the rare cases of truly penicillin-allergic patients, the risk of cross-allergy is only 0.5%[33,34]

Of the articles included in this systematic review, even the negative ones, there is a tendency to recommend early antibiotic prophylaxis or to indicate that such a practice is routine at the trauma center, which was the case in 8 of the 14 studies. Although the evidence is inconsistent, the biological plausibility, low costs and safety of the intervention are already sufficient arguments to justify implementation of early ATB in public health policies that deal with the pre-hospital management of open fractures.[35]

CONCLUSION

Our study synthesized the current evidence regarding the association between time to onset of antibiotic prophylaxis and the infectious outcome, reaching the conclusion that the benefits of early use of antibiotics in open fractures are yet to be confirmed, given the low methodological quality and potential risk of bias in the studies carried out so far. However, given the safety of the intervention, the ease of its implementation, its very low cost and its biological plausibility, we believe, at least at this point, that it is reasonable to keep the trend to organize services in order to institute pre-hospital administration of ATB, and that public health policies embrace this paradigm. Well-conducted prospective studies with blinding of outcome assessors and results analysts, and with adequate statistical power, can draw definitive conclusions about the potential benefits of early antibiotic prophylaxis in the management of open fractures.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. JM and AN: initial databases searches; review, selection and analysis of articles, paper writing and critical review of its intellectual content; approval of the final version of the manuscript to be published.

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