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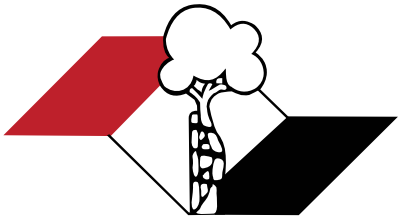

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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed March 2021)

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ACKNOWLEDGEMENTS

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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

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Original Article

HEALTH SCIENCES

HIP

KNEE

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THE IMPACT OF COVID-19 ON THE ORTHOPEDIC CARE SYSTEM IN A PRIVATE HOSPITAL

O IMPACTO DA COVID-19 NO SISTEMA DE ATENDIMENTO ORTOPÉDICO EM UM HOSPITAL PRIVADO

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2. Brazilian Society of Orthopedics and Traumatology, São Paulo, SP, Brazil.
3. Federal University of São Paulo, Escola Paulista de Medicina, Department of Orthopedics and Traumatology, São Paulo, SP, Brazil.

ABSTRACT

Objective: To evaluate and compare the patient flow in the emergency department and the number of surgeries performed, as well as to determine the incidence of diseases due to the impact generated by the pandemic in April, May, June, and July 2020. Methods: This is a retrospective cross-sectional study that analyzed medical records using the TASY Phillips software. The 2019 information was compiled and served as a basis accomplish our comparative analyses. The ICD-10 was used to determine the different conditions considering the highest incidence of them. Results: there was a reduction in attendance of 49.3%; the reduction in the number of surgeries was 34.39%; among the main diagnoses in decreasing order were: Pain in the Lumbar Spine (18.76%), Joint Pain (14.82%), Neck Pain (7.7%), Ankle Sprain (4.2%) and Pain in the Limb (3.54%). Conclusion: There was a decrease in the number of visits and the overall incidence of surgeries in our service. ***Level of Evidence II, Retrospective Study.***

Keywords: Coronavirus. Epidemiology. Epidemiology, Descriptive. Demography. Traumatology. Emergency Medical Services.

RESUMO

Objetivo: Avaliar e comparar o fluxo de pacientes no pronto-socorro e o número de cirurgias, bem como determinar a incidência das doenças pelo impacto gerado pela pandemia nos meses de abril, maio, junho e julho de 2020. Métodos: Trata-se de estudo retrospectivo transversal que analisou prontuários médicos por meio do software TASY Phillips. Foram compiladas as informações do ano de 2019, que serviram como base para realizar as análises comparativas. Foi utilizado o CID-10 para determinar as diferentes afecções de maior incidência. Resultados: Houve redução nos atendimentos de 49,3%; a redução do número de cirurgias foi 34,39%; os principais diagnósticos em ordem decrescente foram: dor na coluna lombar (18,76%), dor articular (14,82%), cervicalgia (7,7%), entorse de tornozelo (4,2%) e dor no membro (3,54%). Conclusão: Houve decréscimo do número de atendimentos e da incidência global de cirurgias em nosso serviço. ***Nível de Evidência II, Estudo Retrospectivo.***

Descritores: *Coronavírus. Epidemiologia. Epidemiologia Descritiva. Demografia. Traumatologia. Serviços Médicos de Emergência.*

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INTRODUCTION

Coronavirus has a high spread, and viral transmission from person to person through droplets of saliva, coughing, phlegm, sneezing, through the contact of infected objects and surfaces with the mouth, nose and eyes causes Covid-19.[1-11]

Due to its severity and the high speed of virus propagation, the World Health Organization declared the disease caused by SARS-Cov-2 as a pandemic, since its worldwide spread could cause an intense outbreak, spreading in a sustained way, from person to person, across all continents of the planet.[7,8,12,13]

Faced with this unprecedented situation, government authorities began to adopt strategies to reduce the rate of spread of the disease, including social distancing, the use of masks and quarantine, which is the most restrictive measure, where there is an express prohibition for holding events that bring together a large number of individuals. Soon, activities in schools, universities, concerts, shopping malls, cinemas, sports academies, sporting events were deliberately canceled.[9,14,15,19]

In the state of São Paulo, the government decreed quarantine on March 24, 2020, keeping only essential food, health, supply, banking, cleaning, security and transport services open. These measures caused a considerable and sensitive decrease in the flow of people on the streets and, especially, in emergency services throughout the country.

Among the measures adopted by the government, there was the creation of protocols to provide services safely for patients and health professionals.

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

The study was conducted at Hospital IFOR Rede D'Or.
Correspondence: Henrique Von Rondow de Queiroz. Avenida Jamaris, 543, ap. 176, Jardim Planalto, São Paulo, SP, Brazil, 04078-000. vonrondow@hotmail.com.br

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The collective fear of the population determined a considerable reduction in consultations, where many of them were no longer considered priorities, which prevented patients from going to the emergency room for fear of contamination within the hospital.[7,20]
The assistance in emergency medical services is crucial for any health system, where the premise is to offer the population immediate emergency care and treatment, safely and efficiently.
The reduction in the number of consultations in other pandemic outbreaks resulted in a noticeable reduction in visits and hospitalizations, for example, in primary coronary interventions.[15,16,17]
The scarcity and novelty on this topic encouraged researchers to carry out this study. Therefore, the primary objective of this article is to evaluate the effects of Covid-19 on the frequency of patients seen in our emergency room service, and compare it with the flow of visits in the same period in the previous year (2019).
Among the secondary objectives, we shall analyze: the influence of the pandemic on the number of surgeries in orthopedic traumatology, and the incidence of diseases according to the International Code of Diseases (ICD 10) considering the same period defined for the study.

MATERIAL AND METHODS

This research project was submitted for analysis by the Research Ethics Committee of Plataforma Brasil under registration CAEE 39593320.4.0000.5625, and approved for execution by opinion 4,367,294.
This is a retrospective longitudinal study where the analysis of digital records of patients seen in the emergency room of our Service was performed. Information obtained from the Medical Archive and Statistics Service of patients who underwent surgical treatment in the area of Orthopedic Trauma was also compiled.
The diagnoses of conditions of the patients treated were cataloged, and the search considered the diseases coded by ICD 10.
The period of our evaluation study comprised the months of April, May, June and July 2020, when the pandemic occurred, and the same months of 2019 that were used so that the appropriate comparisons could be made.
For the selection of patients and medical records, the following inclusion criteria were used:
1. Patients of both sexes;
2. All ages;
3. With care in the emergency room for complaints related to disorders of the locomotor system;
4. Patients undergoing surgical procedures from the emergency room.

We consider the following criteria for non-inclusion of patients:
1. Patients with incomplete medical records;
2. Patients with emergency room care without locomotor disorders;

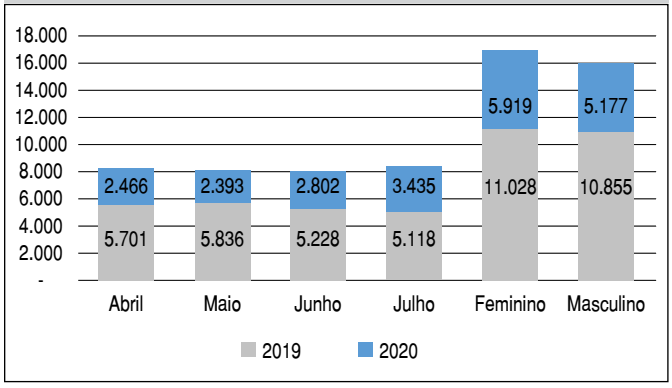
Quantitative analyses, comparisons and the necessary data collected were compiled and tabulated for further analysis, considering: age, sex, diagnosis and surgery.
We use the TASY PHILIPS – HEALTH MANAGEMENT SYSTEM medical record management program to extract information that is used in all registration processes.

RESULTS

The total number of patients seen in 2019 was 21,883. Of these, 10,885 (49.61%) patients were male and 11,028 (50.29%) were female. The average age was 41 years (minimum 1 and maximum 102 years). The distribution of care in the emergency room, according to the months of April, May, June and July was respectively 5,701 (26.05%), 5,836 (26.73%), 5,228 (23.89%) and 5,118 (23.44%). Information on the distribution of our material considering the control period is shown in Graph 1.

The total number of patients seen in 2020 during the pandemic period was 11,096. Of these, 5,177 (46.66%) patients were male and 5,919 (53.34%) were female. The average age in this period was 43 years (minimum of 1 and maximum of 99 years). The distribution of care in the emergency room, according to the months of April, May, June and July was respectively 2,466 (22.22%), 2,393 (21.56%), 2,802 (25.25%) and 3,435 (30.95%). The information on the distribution of our sample, considering the period of the pandemic, is shown in Graph 1.

Graph 1. Demographic profile of care provided at the IFOR Hospital between 2019 and 2020 (April to July).



Results on the comparison of the total number of patients seen in 2019 and 2020 showed a difference of 10,787 (49.29%).
The total number of patients operated for presenting injuries to the locomotor system resulting from orthopedic trauma in 2019 was 1,759. Of these, 934 (53.1%) patients were male and 825 (46.9%) were female. The average age was 44 years (minimum 6 years and maximum 98 years). The distribution of operated patients, according to the months of April, May, June and July was respectively 495 (28.14%), 418 (23.77%), 375 (21.31%) and 471 (26.78 %). Information on the distribution of our material considering the control period is shown in Table 1.

Table 1. Demographic profile of surgeries performed in 2019.

MALE	934	53.10%
FEMALE	825	46.90%
# Patients operated on	1,759	100%
Distribution of operated patients		
APRIL	495	28.14%
MAY	418	23.8%
JUNE	375	21.3%
JULY	471	26.8%
# Patients operated on	1,759	100%
44 year old average		

The total number of patients operated in 2020 was 1,154. Of these, 563 (48.75%) patients were male and 591 (51.25%) female. The average age was 44 years (minimum 6 years and maximum 98 years). The distribution of operated patients, according to the months chosen for the study, was respectively 178 (15.42%), 257 (22.27%), 274 (23.74%) and 445 (38.56%). The information on the distribution of our sample, considering the period of the pandemic, is shown in Table 2.

Table 2. Demographic profile of surgeries performed in 2020.

MALE	563	48.75%
FEMALE	591	51.25%
# Patients operated on	1,154	100%
Distribution of operated patients		
APRIL	178	15.4%
MAY	257	22.3%
JUNE	274	23.7%
JULY	445	38.6%
# Patients operated on	1,154	100%
44 year old average		

The overall reduction in the number of surgeries was 34.39%.
The results obtained, comparing month by month, in the period determined by the researchers, showed a decrease for the variable surgery, respectively: April 317 (64.04%), May 161 (38.51%), June 101 (26.93 %) and July 26 (5.52%).
In 2019 we observed the following diagnoses in descending order of frequency: lumbar spine pain with 3621 visits (16.55%), joint pain with 3569 visits (16.54%), neck pain with 1576 (7.2%), sprain of ankle with 1304 (6%) consultations, and limb pain with 863 (4%) consultations. The information on the distribution of the material in this research, considering the control period, is shown in Table 3.

Table 3. Demographic profile of surgeries performed in 2019.

Lumbar spine pain	3,621	16.55%
Arthralgia	3,569	16.54%
Neck pain	1,576	7.20%
Ankle sprain	1,304	6.00%
Limb Pain	863	4.00%

Among patients treated in 2020, we observed the following diagnoses in descending order of frequency: lumbar spine pain with 2,082 (18.76%) visits, joint pain with 1,645 (14.82%), neck pain with 855 (7.7%), ankle sprain with 467 (4.2%) and limb pain with 393 (3.54%). Information on the distribution of this sample is shown in Table 4.

Table 4. Demographic profile of surgeries performed in 2020.

Lumbar spine pain	2,982	18.76%
Arthralgia	1,645	14.82%
Neck pain	855	7.70%
Ankle sprain	476	4.20%
Limb Pain	393	3.54%

DISCUSSION

Researchers and health professionals face a constant and unprecedented challenge, caused by the lack of knowledge about Covid-19. The high speed of dissemination and the considerable rate of lethality, especially in vulnerable populations[8], generated uncertainties about what would be the best strategies to be used to face the consequences of its dissemination.[4,5,8,11,12]
Emergency medical care must be prompt, safe and effective, and provide the easy access provided by an effective health care system. And the installation of the pandemic could provide a marked change in the routines and patterns of consultation in the search for emergency units.[7]
The data obtained by the TASY Phillips System, which is the electronic system used in our service, showed that the comparative analysis between the years 2019 and 2020 of the patients treated, in general, showed a significant decrease in care during the Covid-19 pandemic period.[15,17,19]
This result was influenced by a drastic change in the behavior of the population that remained away from parks, fields, sports arenas, gyms and other environments, resulting in a reduction in exposure to traumatic accidents.
During the study period, there was a drop of 49.3% in emergency room visits during the current period of the pandemic, which significantly disrupted the routine, corroborating the findings found in the literature.[7] From the experience of previous pandemics, withdrawal behaviors included patients' reluctance to attend hospitals due to fear of contracting the disease. The hospital, object of study, has the characteristic of being essentially orthopedic, where consultations often result from complaints not related to trauma, where there was, notably, a drastic reduction, impacting this reduction in the total number of cases received.
Another aspect to consider is that there was also a reduction in visits for traumatic causes, although the decrease in frequency was less expressive (16%) when compared to those represented by diagnoses of non-traumatic disorders. However, we noticed that there was a change in the pattern of fractures diagnosed based on information collected from the hospital's database when we compared the most prevalent ICD 10 in the 2020 period during the pandemic. We believe that social isolation, adopted in most parts of the country, has changed the routine of the Brazilian population. Such behavior culminated in a higher rate of domestic trauma and a lower rate of injuries caused by recreational and sports activities, determined by the progressive reduction in social isolation.
Considering the fractures of patients who were admitted to the emergency room, we observed an increase in the number of cases of fractures of the toes, accounting for 1% of visits in 2019 and an increase to 3% in the same period in 2020. There was an increase in these cases, as in 2019 183 lesions were diagnosed and 371 in 2020. We noticed a decrease in the incidence of all other treated fractures. Domestic accidents, such as falling to the ground or direct trauma, became more prevalent in 2020.[18,19]
We observed that in a study carried out in Israel[7] data on emergency calls by ambulances during the period of the pandemic were collected in order to assess the diagnosis for such contacts. The authors of this study noticed a significant increase in calls for clinical situations such as cough, hemoptysis, sore throat and fever, with a reduction in limb and head injuries, for example, showing a reduction in demands of traumatic origin. Such data reflect a change in the care profile, in general, in the emergency units, which is in part consistent with what was observed in the emergency care analyzed in this work. However, in the studied hospital, the decrease in attendances was global, since it is an emergency room dedicated exclusively to orthopedic assistance, therefore, not expecting an increase in the demand for this unit due to non-orthopedic complaints.
As the care profile of our hospital is essentially for Orthopedics and Traumatology, performing surgeries is an important gateway for patients. We also found that the performance of elective

surgeries in general results in an increase in eventual visits to the emergency room.

Among the measures adopted by the federal and state government, it was determined that elective surgical interventions were systematically postponed or suspended[1] that actually occurred during the study period, which indirectly influenced the change in the volume of emergency room visits. However, this variable was not studied by this work.

In our service, patients who arrived at the emergency room with respiratory complaints were treated in a separate and isolated place, determined exclusively for this type of care. On the other hand, patients who were going to undergo surgical procedures were tested through the qualitative detection of Coronavirus by the PCR method (PCR-COVID) and underwent a chest tomography exam. In urgent surgeries, the PCR-negative cases occurred without the need for isolation from the operating room and without the patient leaving the post-anesthetic recovery room. In PCR-positive cases or in cases where the test result was not yet available, the operating room was isolated, the number of participants reduced to the minimum possible, and all members were instructed to wear appropriate clothing and N95 masks. Anesthetic recovery was performed in the room where each procedure took place.

Therefore, there was an impactful change in the flow of the operating room, since contingency measures were adopted with the installation of specific institutional protocols. In addition to the patients, the medical teams and collaborators were systematically submitted to the PCR test for Covid-19. The isolation of the operating room and the patient's release flow received attention from the time he left the anesthetic recovery room until he was taken to his room. Thus, the operating room included in its daily planning: the determination of the estimated time for release from each room and for each type of patient; anticipate the need for isolation.

The main limitations found in this study are: the hospital mostly meets orthopedic demands, which makes it difficult to compare the results found in this study with those carried out in institutions with a different care profile; the profile of the service with the same period of the previous year was evaluated, which for the authors may represent a short period for fostering more definitive conclusions; The study was carried out with data from only one health institution, which prevented the authors from concluding whether the change in the profile of care in the emergency room during the study period was a global trend or exclusive to this institution. This is a retrospective study of data analysis from medical records that by itself determines the production of an article of lesser scientific relevance despite using an adequate methodology.

CONCLUSIONS

In this retrospective cross-sectional study, we noticed a drop of 49.3% in the number of visits over the months due to the influence of Covid-19. This resulted in a decrease in the number of consultations, especially in the first three months of the pandemic, considering the consultations in the emergency room resulting from orthopedic trauma.

The reduction in the incidence of consultations was respectively in April 3,235 (56.8%), May 3,443 (59%), June 2,426 (46.4%) and July 1,683 (32.9%).

The overall reduction in the number of surgeries was 34.39%.

Among the main diagnoses found during the pandemic period in descending order according to the ICD-10 were:

- Pain in the Lumbar Spine with 2,082 (18.76%) visits;
- Joint Pain with 1645 (14.82%) visits;
- Neck pain with 855 (7.7%) visits;
- Ankle Sprain with 467 (4.2%) visits;
- Pain in the limb with 393 (3.54%) visits.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. HVRQ: writing, data acquisition and analysis, data interpretation and project design; NENT: writing, data acquisition and analysis and project design; BGPO: writing, project design; MVFS: review of the article and intellectual concept of the article; ETD: review of the article, intellectual concept of the article and final approval of the version of the manuscript to be published.

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EFFECTIVENESS OF DEEP VENOUS THROMBOSIS PREVENTION IN TOTAL HIP ARTHROPLASTY

EFICIÊNCIA DA PREVENÇÃO DA TROMBOSE VENOSA PROFUNDA NA ARTROPLASTIA TOTAL DO QUADRIL

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ABSTRACT

Objective: To determine the efficacy of Deep Venous Thrombosis (DVT) prophylaxis protocol in patients undergoing total hip arthroplasty (THA), and to verify differences in the rates of this complication when comparing primary replacement surgeries with revision surgeries. Methods: We conducted a retrospective study of patients operated between 2012 and 2018, with inclusion and non-inclusion criteria determined by the researchers. A protocol was created to compile data including 92 patients, amounting to 110 operated hips, divided by gender, age, laterality, among other criteria. For THA cases, low molecular weight heparin chemoprophylaxis was used, associated with the use of pneumatic and elastic compression, concomitant to deambulation as soon as possible. The detection of DVT was determined by clinical evaluation and imaging exams such as: simple radiographs, ultrasound, arterial and venous color doppler, and laboratory tests. Results: The use of the protocol was very effective in our study. Only one (1.09%) case of deep venous thrombosis was found. Conclusion: The use of thromboprophylaxis for DVT is indispensable, as was clearly demonstrated by these cases. We observed only one (1.09%) case of DVT in our series. ***Level of Evidence III, Retrospective Study.***

Keywords: Arthroplasty Replacement Hip. Venous Thrombosis. Diagnosis. Primary Prevention. Combined Modality Therapy.

RESUMO

Objetivo: Determinar a eficácia de protocolo de profilaxia contra a Trombose Venosa Profunda (TVP) em pacientes submetidos à artroplastia total do quadril (ATQ) e verificar diferenças nas taxas desta complicação ao comparar as cirurgias de substituição primária com as de revisão. Métodos: Realizamos um estudo retrospectivo de pacientes operados entre 2012 e 2018, com critérios de inclusão e não inclusão determinados pelos pesquisadores. Foi criado um protocolo para a compilação de dados no qual foram incluídos 92 pacientes, estes com 110 quadris operados divididos por sexo, idade, lateralidade, entre outros critérios. Para os casos de ATQ, utilizamos a quimioprofilaxia com heparina de baixo peso molecular associada ao uso de compressão pneumática e elástica, concomitante à deambulação assim que possível. A detecção da TVP foi determinada pela avaliação clínica e por exames de imagem como: radiografias simples, exame ultrassonográfico, doppler colorido arterial e venoso e exames laboratoriais. Resultados: A utilização do protocolo se mostrou bastante eficaz em nosso estudo. Foi encontrado apenas um (1,09%) caso de trombose venosa profunda. Conclusão: A utilização de tromboprofilaxia para a TVP é indispensável e consagrada nestes casos. Observamos apenas um (1,09%) caso de TVP em nossa casuística. ***Nível de Evidência III, Estudo Retrospectivo.***

Descritores: *Artroplastia de Quadril. Trombose Venosa Profunda. Diagnóstico. Prevenção. Tratamento Multimodal.*

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INTRODUCTION

Total hip arthroplasty (THA) is considered an undisputed modality as a therapeutic surgical option for patients with degenerative arthritis. Among the undesirable complications of this type of intervention are deep vein thrombosis (DVT) and pulmonary thromboembolism (PE).[1] As is well known, before the institution and application of protocols to combat and avoid such adversities, such as the use of anticoagulants, its incidence ranged from 55% to 80%.

Some factors, previously recognized by aspects such as family history, advanced age, cardiomyopathies, chronic edema of the lower limbs, immobilization, obesity, sedentary lifestyle, use of medication (oral contraceptives or hormones), excessive blood loss, transfusion, among others, increase the risk of developing thromboembolism. There is a greater risk of developing this condition between the second and third weeks of the postoperative period, as 29% of thrombi originate in the first 12 days, and 23% between 22 and

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

The study was conducted at the Ifor Hospital, Institute of Fractures, Orthopedics and Rehabilitation.
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24 days after surgery.[2] Ultrasonography with venous *Doppler* of the lower limbs and contrast venography assist the diagnosis.[3,4]
The routine administration of preventive methods for intravenous thrombosis in patients undergoing THA is consensual among all orthopedists; however, no universal protocol has been established, much less which medication to apply or the ideal time of use, as one may notice by the scarcity of studies on this subject.[5]
Mechanical methods of prophylaxis for DVT, such as the use of elastic compression stockings, can reduce its appearance by more than 50%, and the association with active and passive movement of the lower limbs and early ambulation would be considered auxiliary prophylactic measures.[6] Prophylactic drugs, such as vitamin K inhibitors and low molecular weight heparin, according to the orthopedic literature, also help to reduce the rates of these adversities.
Despite the undeniable importance of the benefit of using prophylactic methods for the prevention of DVT in patients who underwent THA, there is no consensus in the literature on which method has the best results. In a systematic review, through 26 trials with 2,600 individuals, we found that both low molecular weight heparin (LMWH) and unfractionated heparin (UFH) are effective in reducing DVT.[7] There are also reports that LMWH is significantly more effective and safer when compared to the use of UFH. Regarding the LMWH dose, 40mg applied subcutaneously once a day would be sufficient and effective.[8]
Therefore, our study has as its primary objective to determine the effectiveness of the prophylaxis protocol against DVT that we use in our service in patients undergoing THA. Secondarily, we will verify if there were differences in the rates of this complication when comparing primary replacement surgeries with revision ones.

MATERIAL AND METHODS

Firstly, the research project of this work was submitted to bioethical evaluation by the Research Ethics Committee of Plataforma Brasil under the CAEE registration and approved for completion under the opinion number 22051819.3.0000.5625.
A retrospective and observational study was conducted based on the analysis of medical records of patients who underwent total hip arthroplasty between 2012 and 2018 at the Institute of Fractures, Orthopedics and Rehabilitation – Hospital Ifor.
The following inclusion criteria were used:

1. Patients of both sexes; older than 18 years;
2. Postoperative follow-up of at least one year;
3. Carriers of unilateral or bilateral hip joint affection (primary or secondary);
4. No history of coagulopathies;
5. No DVT history;
6. Who present complete medical records;
7. Have been submitted to the institutional DVT prevention protocol.

The non-inclusion criteria used in this research were:

1. Patients with incomplete medical records;
2. Patients who did not adhere to the institutional protocol;
3. Patients who did not sign the free and informed consent form for the use of their medical records.

We devised an investigation protocol so that data could be collected and then tabulated using Excel (Microsoft), which consisted of the following information: order number; age at surgery; sex; affected side; ethnicity; weight and height; body mass index (BMI); nosological diagnosis; etiological diagnosis; comorbidities (diabetes, systemic arterial hypertension); continuous use medications; family history of deep vein thrombosis; determination of the degree of hip arthrosis according to the classification by Kellgren & Lawrence[9]; type of prosthesis used (primary or revision, cemented or cementless).
The methodology used to classify and assess the degree of degenerative hip osteoarthritis followed the methodology proposed by Kellgren & Lawrence[9] (Table 1).

Table 1. Kellgren-Lawrence Classification (1957)

Grade	Description
0	definite absence of x-ray changes of osteoarthritis
1	doubtful joint space narrowing and possible osteophytic lipping
2	definite osteophytes and possible joint space narrowing
3	moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends
4	large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends

According to the adopted criteria, 92 patients were included, of which 56 (60.87%) female and 36 (39.13%) male, 71 (77.17%) were white, nine (9.78%) of other ethnicities, seven (7.60%) black, and five (5.43%) asian. The mean age of patients was 57.42 years (minimum 26.75 years old and maximum 81.00). Of the total number of patients, 110 hips were operated, 55 (50.00%) of which underwent arthroplasty on the right hip and 55 (50.00%) on the left, and 18 (19.57%) patients underwent bilateral hip arthroplasty. According to the classification of Kellgren and Lawrence, 17 (18.47%) patients were classified as having type I degenerative arthritis, 06 (6.52%) type II, 26 (28.26%) type III, and 43 (46.73%) type IV. The mean weight of patients found was 75.2 kg (minimum of 50 kg and maximum of 110 kg) and the mean height of patients was 166 cm (minimum of 150 cm and maximum of 191 cm). The mean body mass index (BMI) found was 27.11 m^2/kg (minimum of 18.4 m^2/kg and maximum of 37.2 m^2/kg). As for the etiology, 64 (69.56%) had primary degenerative arthritis, nine (9.78%) other causes, eight (8.69%) had osteonecrosis, five (5.43%) hip developmental dysplasia, two (2.17%) had sickle cell anemia, two (2.17%) traumatic sequelae, and two (2.17%) were of infectious origin. Of the total, 64 (69.56%) patients had comorbidities and 28 (30.43%) did not have other diseases. Among patients with associated diseases, 44 (68.75%) had only one comorbidity, 18 (28.12%) had two and two (3.12%) had three or more. Of the comorbidities, we found 30 (46.87%) cases of hypertension, 23 (35.93%) of sedentary lifestyle, 20 (31.25%) other diseases (hemoglobinopathies, bronchitis, depression, hypothyroidism and previous local fractures), 10 (15.62%) cases of diabetes mellitus, five (8.06%) of cardiomyopathies and one (1.56%) of liver disease. There were no cases of previous DVT or family history of VTE. Our sample consisted of 28 (43.75%) patients who used antihypertensive drugs prior to the surgical procedure, 10 (15.62%) hypoglycemic agents, four (6.25%) anticoagulants, two (3.12%) hormones, one (1.56%) corticoid, one (1.56%) contraceptive, and one (1.56%) herbal. No prosthesis was cemented and, regarding the type of THA, 72 (65.45%) patients underwent THA with normal prosthesis, 25 (22.72%) of the metaphyseal type, and 13 (11.81%) were submitted to a prosthesis revision.
All 92 patients were adequately submitted to our institution's VTE and DVT prevention protocol (Figure 1). According to this protocol, THA are considered high risk procedures.

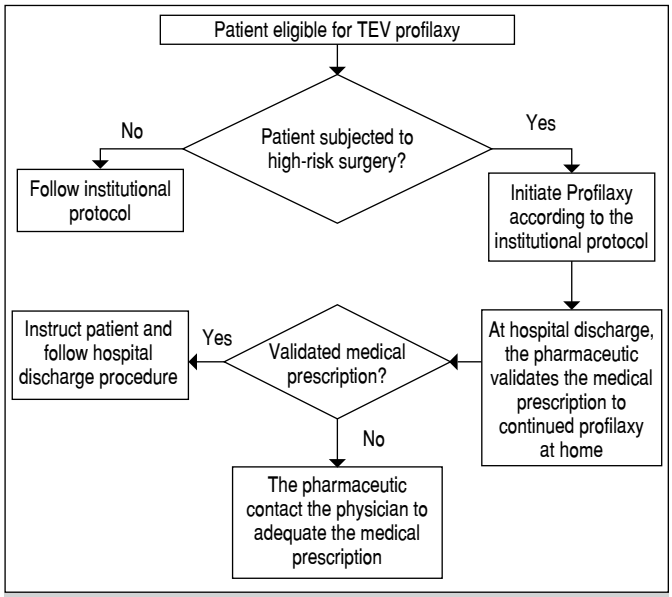

Figure 1. Prophylactic Scheme of Venous Thromboembolism.

The contraindication for the use of pharmacological methods was: active bleeding or active peptic ulcer, use of anticoagulation, heparin allergy or thrombocytopenia, coagulopathy (thrombocytopenia < 100,000/mm^3 or NR°> 1.5), uncontrolled systemic arterial hypertension (> 180 × 110 mmHg), persistent renal failure (clearance < 30 ml/min), recent intracranial or ocular surgery < 2weeks, CSF collection in the last 24 hours.

Contraindications to adjuvant methods were: concomitant open fractures, severe heart failure, peripheral arterial insufficiency of the lower limbs and infection or ulcer in the lower limbs.

As chemoprophylaxis with LMWH and UFH, we recommend enoxaparin 40 mg subcutaneously administered once a day or unfractionated heparin at a dose of 5,000 IU subcutaneously administered every 8 hours, associated with mechanical prophylaxis. The beginning of chemoprophylaxis is 12 hours before or 12 to 24 hours after the surgical procedure, lasting for seven to 10 days.

For cases of hip arthroplasty, we used chemoprophylaxis with LMWH for 28 to 35 days, associated with the use of pneumatic compression (at least 18 hours a day during the period in which the patient is hospitalized). The use of elastic compression stockings is recommended as soon as possible. Walking is initiated and supervised by the physiotherapy team on the first day of the postoperative period, considering the individual walking capacity of each operated patient.

For the detection of DVT, elements of clinical evaluation and imaging exams are used. Clinical analysis consists of: detection of lower limb pain; palpation of the affected region; observation of distal perfusion; palpation of peripheral pulses, observation of edema; positivity for specific propaedeutic maneuvers such as *Homan's* sign, flag sign, calf jamming; hyperemia, pallor or local heat.

Among the complementary exams, when thrombosis is suspected, the following are used: plain radiographs, ultrasonography, arterial and venous color Doppler, magnetic resonance and laboratory tests.

RESULTS

We observed only one (1.09%) patient with DVT in our sample.

Due to the fact that we found only one case of DVT, it was not possible to ascertain the relative risk of onset of this condition in relation to factors inherent to our patients such as age, use of medications, postoperative complications, use of medications, comorbidities and number of comorbidities.

It was not possible to contemplate our secondary objective of verifying whether the rates of this complication would be related to primary replacement surgeries or revision surgeries.

Regarding postoperative complications, only one case of late infection was reported, in which the prosthesis was removed and surgical revision was performed successfully.

DISCUSSION

The THA, an established orthopedic procedure, adequately solves hip affections in cases of primary or secondary degenerative arthritis. Its use is closely related to the general aging of the world population and the improvement of techniques and materials used in these salvage operations, making these patients' satisfaction higher, as well as increasing the durability of the effects of this technique.

The first adverse event on this list is considered the most common and is considered the leading cause of death in the first three months of the postoperative period. DVT is responsible for the large number of deaths, especially those that occur suddenly, resulting from pulmonary embolism and the sum of other injuries that are often undiagnosed.

Our study demonstrated that the protocol used was efficient. However, we know there are cases where DVT presents itself asymptomatically, where subclinical forms of this entity do not clearly expose the symptoms of its onset, which include venous obstructions between 10-40%. Therefore, this pathophysiological information could not manifest and, therefore, not be diagnosed.

In our view, an investigative protocol of this occlusion pattern should be carried out. Possibly, some of our patients may have developed this pattern of occlusion, which would justify our low incidence.

We believe that the best and lowest cost-benefit for VTE prevention is related to the systematic use of intermittent pneumatic compression. This finding is in line with the opinion of other authors who consider that the association with the use of acetylsalicylic acid (ASA) increases its preventive power,[10] especially if used within the first 24 hours after surgery.[11] We found divergent opinions regarding the use of this protocol, as there is a fear that its application will not be enough to prevent DVT.[12]

When consulting the literature, it is evident that it is not yet defined as to which drug agent actually has superiority in terms of collective efficacy and safety when compared to each other.[13] The use of enoxaparin (ENX), as well as other substances that act in the coagulation cascade, such as ASA, rivaroxaban (RVX),[14,15] Fondaparinux (FPX) or apixaban (APX), have been proven to reduce the incidence of VTE.[13,15,16] However, each of these substances has a series of complications, such as increased risk of massive bleeding. We know that ENX and ASA have similar bleeding risks, both of which had better results when compared with the use of RVX.[17]

Another factor to be considered in the use of these substances is the inherent cost of DVT. The financial impact of health policies, especially with regard to prevention, of the treatment of installed thromboembolic event and the cost of medications must be considered, as the use of THA has increased in the world population.[18]

One must emphasize that the effectiveness of these measures varies according to the patient's profile, surgical technique used, operative time,[16] patient compliance,[19] as well as their clinical evaluation, since the use of ENX causes laboratory alterations in liver function, in DHL, in 53% of the cases, albeit without clinical repercussions.[20]

Thus, an effective measure in preventing VTE and reducing hospital time, in addition to reducing other adverse events, is the early

mobilization of the patient associated with the use of intermittent pneumatic compression.[21]

It is worth emphasizing that the risk of VTE in revision arthroplasties is greater, as the magnitude and complexity of the procedure are considered to increase the risk of occurrence of this event.[12] We believe the use of the same protocol we used can determine the same positive results achieved in primary and revision THA. We did not observe any cases of DVT in the group of individuals undergoing revision THA.

At our institution, we value the following active factors that increase the risk of developing VTE: stroke, cancer, central venous catheter, inflammatory bowel disease, severe respiratory disease, smoking, peripheral arterial insufficiency, admission to a care unit intensive, BMI $\geq$ 30 kg/m^2, rheumatic disease, pregnancy, puerperium, class III or IV congestive heart failure in crisis, previous history of VTE, infection, paresis or paralysis of the lower limbs, chemotherapy, hormone therapy, hormone replacement, contraceptive, syndrome nephrosis, thrombophilias, varicose veins and venous insufficiency.

We believe that the combination of drug and physical methods determines favorable rates in the prevention of thromboembolic phenomena. In general, we found studies whose methods are similar to those adopted by Torres, Bautista and Lins, with incidences ranging from 0% to 3%.[10-12]

CONCLUSION

The use of thromboprophylaxis for DVT is essential against the appearance of this complication after performing procedures such as THA. The institution of different prevention protocols determined, according to the literature, a significant reduction in its incidence.

However, the most effective method for preventing DVT has not yet been determined in the orthopedic literature, as in several studies opinions are contradictory regarding the best protocol, medication or mechanical therapy.

The association of prophylaxis methods, whether mechanical or chemical, seems to be superior when compared to isolated therapies.

Our research detected only one case in one (1.09%) patient among the 92 that make up our sample, which presupposes that:

1. The protocol used was effective
2. The use of the same protocol, in cases of THA review, can determine similar positive results when compared to those of primary total hip arthroplasty.

It was not possible to determine whether the risk of DVT would be greater in revision THAs when compared to primary THAs.

We also could not possible to determine the relative risk of DVT onset in relation to patients' age, comorbidities, BMI, complications and revision surgeries.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. VMM: literature review, data collection and analysis, article writing; MBM: literature review, data collection, article writing; NGB: literature review, data collection, article writing; ETT: research project development, data analysis, review of the article to be published; ETB: review of the article to be published.

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POSTERIOR VERSUS ANTERIOR APPROACH TO TOTAL HIP ARTHROPLASTY: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

VIA POSTERIOR VERSUS VIA ANTERIOR PARA ARTROPLASTIA TOTAL DO QUADRIL: REVISÃO SISTEMÁTICA E METANÁLISE DE ESTUDOS CLÍNICOS RANDOMIZADOS

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ABSTRACT

Objective: To perform a systematic review and meta-analysis to compare clinical and surgical outcomes of posterior *versus* anterior approach to primary total hip arthroplasty (THA). Methods: This study followed the standard methodology established by the Cochrane Handbook and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Two independent reviewers searched for randomized controlled trials comparing posterior an anterior approach to primary THA with at least one quantifiable functional outcome published in the PubMed, Cochrane, and Virtual Health Library databases. Results: The analysis included ten randomized controlled trials conducted with 774 patients. The posterior approach was associated with shorter operative time (mean of 15.98 minutes shorter, 95% CI 11.21 to 20.76, $p < 0.00001$) while the anterior approach was associated with shorter length of hospital stay (0.31 days or about eight hours shorter, 95% CI 0.12 to 0.51, $p = 0.002$) and greater earlier improvement in functional outcomes up to six months from the procedure (mean Harris Hip Score of 4.06 points greater, 95% CI 2.23 to 5.88, $p < 0.0001$). Conclusion: Whereas the posterior approach to primary THA is associated with a shorter operative time, the anterior approach has the potential to decrease the length of stay and provide greater short-term functional restoration. ***Level of evidence I, Systematic Review and Meta-Analysis.***

RESUMO

Objetivo: Realizar uma revisão sistemática e metanálise para comparar os resultados clínicos e cirúrgicos entre a via posterior e via anterior para ATQ. Métodos: Este estudo seguiu as diretrizes Cochrane e PRISMA (Principais Itens para Relatar Revisões Sistemáticas e Meta-Análises). Dois investigadores independentes procuraram estudos randomizados controlados nas plataformas de busca PubMed, Cochrane e Biblioteca Virtual em Saúde. Estudos comparando a via posterior com a via anterior para ATQ primária com pelo menos um escore funcional de resultado clínico foram incluídos. Resultados: Dez estudos com 774 pacientes foram incluídos. A via posterior foi associada a um tempo operatório menor (média de 15.98 minutos menor, IC 95% 11.21 a 20.76, $p < 0.00001$), enquanto a via anterior foi associada a um tempo de internação hospitalar menor (0.31 dia ou cerca de oito horas a menos, IC 95% 0.12 a 0.51, $p = 0.002$) e melhora superior dos resultados funcionais em até seis meses após a cirurgia (Harris Hip Score médio de 4.06 pontos maior, IC 95% 2.23 a 5.88, $p < 0.0001$). Conclusão: A via posterior foi associada a um tempo operatório menor, enquanto a via anterior tem o potencial de diminuir o tempo de hospitalização e fornecer melhor recuperação funcional no curto prazo. ***Nível de Evidência I, Revisão Sistemática e Metanálise.***

Keywords: Hip. Arthroplasty, Replacement, Hip. Treatment Outcome. Complications. Meta-Analysis. Systematic Review.

Descritores: *Artroplastia do Quadril. Resultados de Tratamento. Complicações, Metanálise. Revisão Sistemática.*

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INTRODUCTION

When it comes to performing total hip arthroplasty (THA), there are controversies between anterior and posterior approach. Whereas the posterior is the most traditional and popular approach worldwide,[1,2] the anterior approach has gained prominence during the second half of the 20th century with the contributions of

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The study was conducted at the Universidade Federal de São Paulo, Department of Orthopedics and Traumatology, Sports Traumatology Center (CETE).
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Smith-Petersen.[3,4] The number of studies comparing different approaches and techniques for THA has increased in recent years, with a recent study highlighting the controversies over the evidence for clinical outcomes and economic factors favoring the anterior approach.[5] However, high-quality evidence evaluating the potential superiority of one method over another is limited. Considering that, this systematic review and meta-analysis of randomized controlled trials (RCTs) aimed to compare postoperative functional outcomes and complication rates following primary THA through the posterior and anterior approach, as well as to identify which approach was associated with shorter operative time and length of hospital stay, lower level of postoperative opioid use and pain, and shorter time to discontinuing walking aids.

METHODS

This study followed the standard methodology established by the Cochrane Handbook and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[6,7] The databases PubMed, Cochrane Library, and Virtual Health Library were searched for articles indexed up to June 2nd, 2020, using the terms "total hip arthroplasty", "posterior" and "anterior" in combination with "comparison of approaches". All RCTs comparing the posterior (control group) and the anterior approach to THA, with at least one quantifiable clinical outcome measured by a validated score (Table 1) were considered eligible. Articles were selected by two independent reviewers, whom also screened their titles and abstracts for eligibility criteria. After that, studies were fully read for exclusion criteria, which included: narrative review articles; biomechanical, animal, or cadaveric studies; investigations conducted with children; studies using double-incision approaches; studies reporting data from arthroplasty registries; studies on bilateral THA; studies involving surgical revision of failed primary hip arthroplasty or hemiarthroplasty; and studies with no abstract or written in non-English languages. Eventual disagreements between the two reviewers were solved by a third reviewer.

Table 1. Inclusion criteria for randomized controlled trials included in meta-analysis.

Domain (order)	Inclusion criterion
Study design (1)	Study comparing study posterior *versus* anterior approach.
Population (2)	18-year old or older individuals undergoing primary THA.
Intervention (3)	Anterior, single-incision, (modified-Heuter, Smith-Petersen) Approach THA, Direct Anterior approach.
Control (4)	Posterior (Moore or Southern) Approach THA, Posterolateral, MIS-posterior.
Outcome measures (5)	One quantifiable clinical outcome measured by a validated score.

THA: total hip arthroplasty, MIS: minimally invasive surgery.

Two independent reviewers performed the quality assessment of included studies according to the Gradings of Recommendations Assessment, Development, and Evaluation (GRADE) approach.[8] The risk of bias was assessed using the second version of the Risk-of-Bias (RoB 2) tool,[9] based on five domains: (1) randomization process, (2) deviations from the intended interventions, (3) missing outcome data, (4) outcome measurement, and (5) selection of the reported result. Table 2 shows data related to the included studies.

Table 2. Data related to the included Studies.

Continuous Variables
Number of patients undergoing THA
Age
BMI
Functional outcome scores
Pain scores
Follow-up time
Operative time
Length of hospital stay
Surgeon's experience
Time for discontinuing walking aid
Postoperative opioid use
Categorical Variables
Gender
Major complications
Minor complications
Country of study

Statistical analysis

Continuous variables were extracted from the selected articles and expressed as means and standard deviations (SD), medians and ranges, or interquartile ranges (IQR). Data reported as medians and ranges or interquartile ranges were transformed into mean and SD according to the method described by Hozo et al.[10] Pooled outcomes were expressed as weighted mean differences (WMD) or standardized mean differences (SMD) and 95% confidence intervals (CI) using the inverse variance analysis and random effects model. Dichotomous variables including complications were extracted as absolute numbers for each cohort. Intraoperative fractures and postoperative dislocations were considered as major complications, whereas neuropraxia and deep vein thrombosis,[11] hematoma, trochanteric bursitis, persistent pain, wound dehiscence, heterotopic ossification, superficial wound infection, and iliopsoas tendinopathy were considered as minor complications. Table 3 shows complications occurrence.

Heterogeneity (I^2) between the studies was assessed by the Cochran's Q test, whereby a p-value < 0.05 was considered statistically significant, and by Higgins I^2 statistics,[12] whereby an I^2 value below 30% was considered as low heterogeneity; between 30% and 60% as moderate heterogeneity; and higher than 60% as substantial heterogeneity. The RevMan 5.3 software (Cochrane Community, London, UK) was used to create forest plots and display the effect size of each study together with the pooled result.[13] Sources of heterogeneity for function (measured with Harris Hip Score – HHS) were investigated by subgroup analysis, to which case a new categorical covariate was created, named as short- and mid- to long-term. A follow-up period < 6 months was categorized as short-term, while a follow-up period ≥ 6 months was categorized as mid- to long-term. When deemed necessary, sensitivity analysis with recalculation of the pooled primary outcome was performed. Secondary outcomes included operative time, length of hospital stay, opioid use, pains scores, and time to discontinue any walking aid.

RESULTS

In total, 1882 eligible articles were identified in the database searches, 1810 of which were excluded after abstract and title screening. The remaining 72 articles underwent full-text reading for inclusion criteria, leading to a sample of nine peer-reviewed

randomized control trials (RCTs)[14-22] (Figure 1a and Table 2). After updating the literature search, one additional study (*in press)* was included.[23] Thus, this meta-analysis included 10 peer-reviewed RCTs conducted with 774 patients, being 372 men and 402 women, of mean age ranging from 59 to 70.4 years, and mean body mass index (BMI) ranging from 24 to 31 kg/m^2. Of these, 385 were randomized to the posterior approach and 389 to the anterior approach. Maximum duration of follow-up ranged from six weeks to 60 months. Groups showed no significant differences regarding mean age and BMI, but two studies verified differences in gender distribution.[18,23]

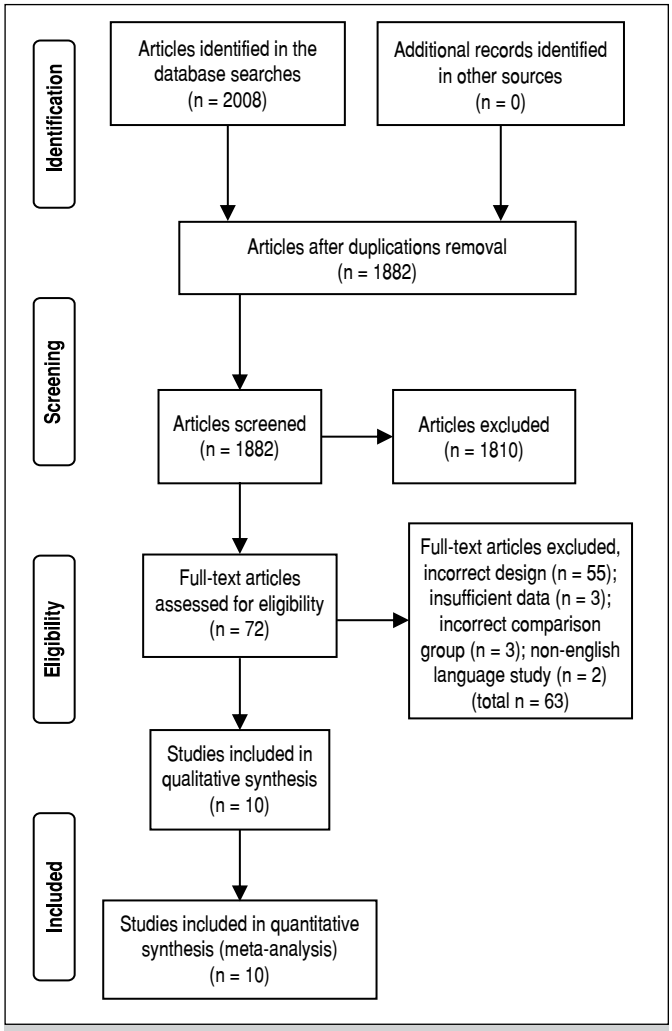

Figure 1a. PRISMA Flowchart.

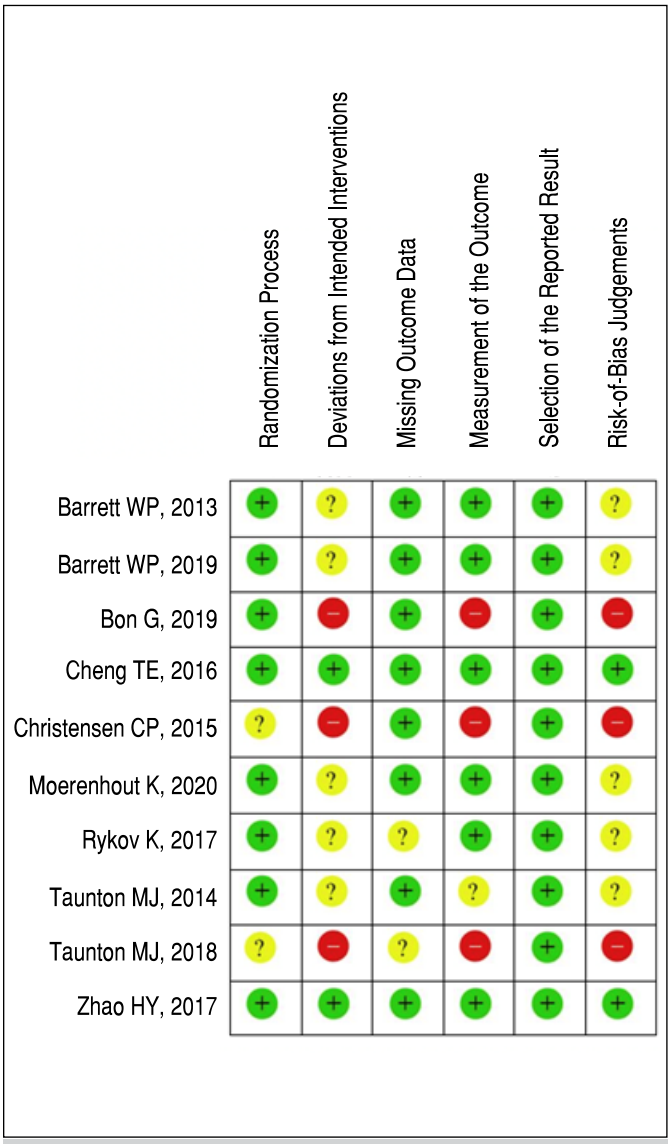

Figure 1b. Revised Risk-of-Bias tool.

Risk of Bias and Quality of Evidence for Included Studies

Two of the studies included in the meta-analysis presented a low risk of bias, whereas the other eight presented uncertain or high risk. The domains presenting higher risk of bias were "deviations from the intended intervention" and "outcome measurement" (Figure 1b).[14-16,18-21] Seven studies informed that all procedures were performed by a single surgeon, six of which also reported that surgeons had sufficient experience for performing either posterior or anterior approach to total hip arthroplasty (THA).[14-16,18,19,21,22] All studies showed low level of certainty for methodological quality based on the GRADE classification, whereas operative time and length of stay showed a high-quality level.

Primary and secondary outcomes

Although different scores were used to evaluate function (Table 3), eight of the ten studies adopted the Harris Hip Score (HHS) at six weeks and two, three, six, 12 and 60 months postoperatively.[14-16,18,20-23] Patients who underwent the anterior approach to THA reached greater scores at the HHS in the short-term follow-up when compared to those who underwent the posterior approach (mean HHS 90.2 ± 9.97 versus 85.7 ± 9.97, respectively; WMD 4.06, 95% CI 2.23 to 5.88, I^2 = 41%, p < 0.0001), as well as in the mid- to long-term follow-up (mean HHS 93.9 ± 8.81 versus 92.5 ± 9.71, respectively; WMD 1.52, 95% CI 0.48 to 2.56, I^2 = 0%, p = 0.004; Figure 2).

Six studies reported the occurrence of major complications,[14,17,18,21-23] being intraoperative fractures the most common, with 11 cases – five of which (45%) occurred in the anterior approach and six (55%) in the posterior approach (OR 0.83, 95% CI 0.25 to 2.74, I^2 = 42%, p = 0.76). Postoperative dislocations occurred in five cases: three (60%) in the posterior approach and two (40%) in the anterior approach (OR 0.68, 95% CI 0.12 to 3.94, I^2 = 0%, p = 0.66).[17,18,21]

Table 3. Summary of characteristics of included studies and primary outcomes.

Lead author / Country	AA/PA (N)	Maximum follow-up (months)	HHS[32,33] mean SD at maximum follow-up AA/PA	Other functional scores reported in included studies	Major complications AA/PA F = Fractures D = Dislocations (N)	Minor complications AA/PA NX = Neuropraxia V = DVT (N)
Moerenhout et al. 2020[23]/Canada	28/27	60	82 19.8/ 80 20.4	NR	F. 0/2 D. 0/0	NX. 0/0 V. 0/0
Barret et al.2019[15] /U.S.	39/40	60	NR	UCLA[34,35] HOOS Jr	F. 0/0 D. 0/0	NX. 0/0 V. 0/1
Bon et al. 2019[16]/France	50/50	3	89.95 12.73/ 91.3 9.48	OHS[36,38]	F. 0/0 D. 0/0*	NX. 8/0 V. 1/0
Taunton et al. 2018[21]/U.S.	52/49	12	97 4/ 95 7	HOOS[37,39]	F. 0/2 D. 1/1	NX. 0/0 V. 0/1
Rykov et al. 2017[20]/ Netherlands	23/23	1.5	93 10.87/ 90 9.14	HOOS	NR	NR
Zhao et al 2017[22]/China	64/64	6	92.2 13.25 89.9 11.74	UCLA	F. 1/0 D. 0/0	NX. 0/0 V. 0/0
Cheng et al. 2016[17]/Australia	35/38	3	NR	OHS WOMAC[39]	F. 2/0 D. 1/1	NX. 29/0 V. 0/1
Christensen et al. 2015[19]/U.S.	28/23	1.5	NR	NR	NR	NR
Taunton et al 2014[14]/U.S.	27/27	12	97.5 1.70/ 95.5 3.73	WOMAC	F. 2/1 D. 0/0	NX. 0/0 V. 0/0
Barrett et al. 2013[18]/U.S.	43/44	12	97.5 5.7/ 97.3 5.5	HOOS	F. 0/1 D. 0/1	NX. 0/0 V. 0/0
N total Mean follow-up Total complications	361/358	12.34	94.52 8/ 93.2 7.76	-	F. 5/6 D. 2/3	NX. 37/0 V. 1/3

PA: posterior approach; AA: anterior approach; N: number of cases; NR: non-reported; SD: standard deviation; HHS: Harris Hip Score; UCLA: University of California Los Angeles Score; HOOS: Hip Disability and Osteoarthritis Outcome Score; OHS: Oxford Hip Score; WOMAC: Western Ontario and McMaster Universities Arthritis Index; * One case of traumatic hip dislocation after a fall was not included.

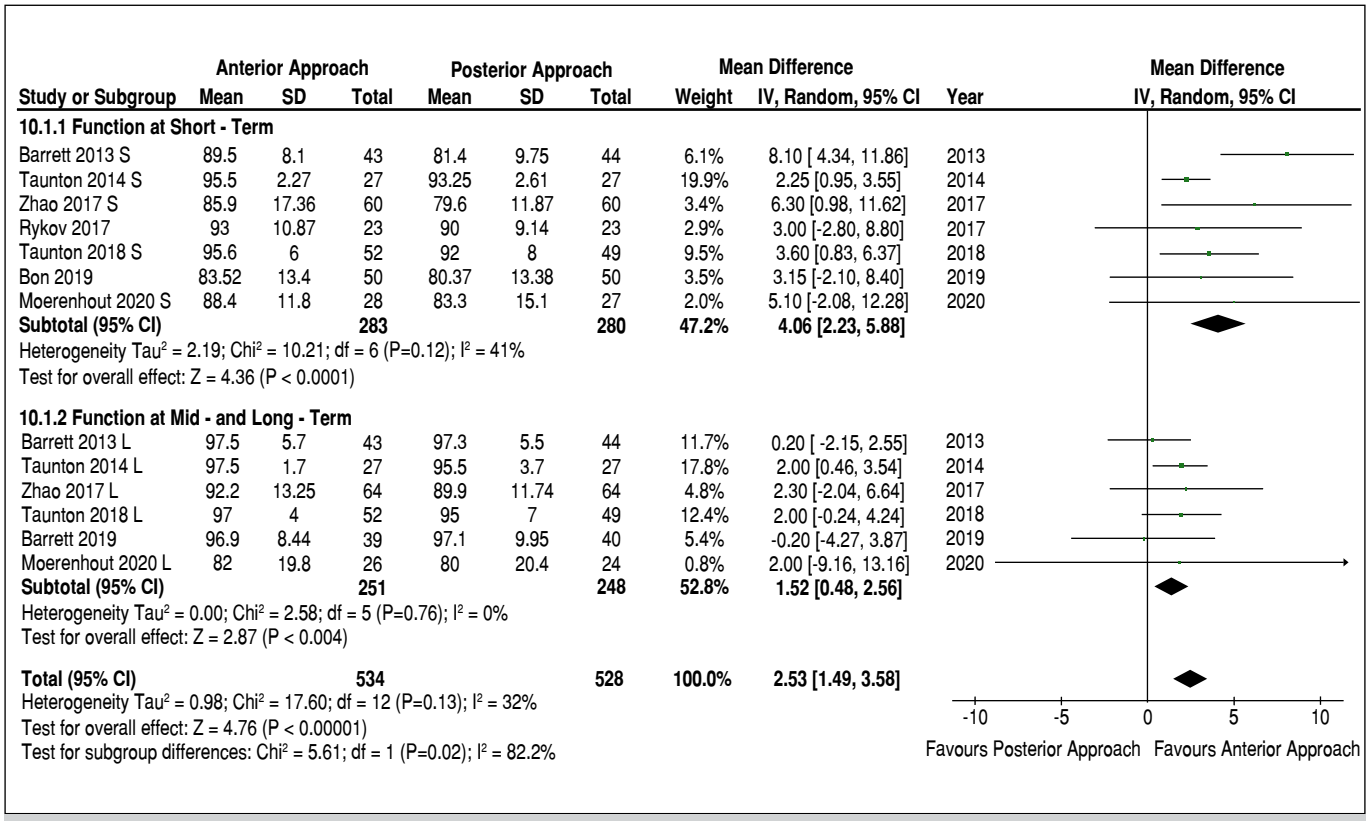

Figure 2. Subgroup analysis (short-term *versus* mid- and long-term) for mean function measured with Harris Hip Score after posterior *versus* anterior approach THA.

Five studies reported the occurrence of minor complications,[15-18,21] being neuropraxia the most common – observed only in patients that underwent the anterior approach (37 cases) and involving only the lateral femoral cutaneous nerve (LFCN).[16,17] In one study, most patients from the anterior approach group (29/35; 82%) presented with LFCN neuropraxia.[17] Due to this particular high proportion, we performed a sensitivity analysis excluding this study, resulting in no differences between groups regarding the occurrence of all minor complications (OR 2.16, 95% CI 1.01 to 4.63, I^2 = 58%, p = 0.05).[15,16,18,21] As shown in Table 3, four cases of deep vein thrombosis (DVT) were reported in the studies, three of which (75%) occurred in the posterior approach and one (25%) in the anterior approach (OR 0.52, 95% CI 0.05 to 4.98, I^2 = 25%, p = 0.57).[15,16,17,21]

Seven studies included reports on operative time.[16-18,20-23] When compared to the anterior approach, the mean operative time was shorter in patients undergoing the posterior approach (80.47 ± 10.51 minutes *versus* 64.69 ± 12.31, respectively; mean of 15.98 minutes shorter, 95% CI 11.2 to 20.7, I^2 = 87%, p < 0.00001, Figure 3a). Eight studies reported length of hospital stay,[16-23] indicating that hospital discharge was faster among patients submitted to the anterior approach when compared to those submitted to the posterior approach (0.31 days or 7.44 hours shorter for anterior approach, 95% CI 0.12 to 0.51, I^2 = 60%, p = 0.002, Figure 3b).[16-23] Only four studies included reports on postoperative opioid intake,[14,17,18,21] two of which verified a lower intake of opioids in early postoperative care among patients who underwent the anterior approach than among those who underwent the posterior approach (100 mg *versus* 145 mg, p = 0.01; 300 mg *versus* 413 mg, p = 0.04, respectively).[17,21] Eight studies assessed postoperative pain, measured at time-points ranging from 24 hours to 24 months.[14-18,21-23] However, due to the variability in pain scores, our meta-analysis included only three studies reporting pain as a component of the HHS [14,16,18] and one study reporting pain as a component of the hip disability and osteoarthritis outcome score HOOS [21].

Studies showed no difference regarding postoperative pain at short-term follow-up between the posterior and anterior approach (SMD 0.20, 95% CI -0.01 to 0.42, p = 0.06). Only three of the ten studies reported time for discontinuing walking aids,[14,19,21] with shorter periods for patients from the anterior approach groups when compared to patients from the posterior approach group, with a mean difference of 9.8 days (33 *versus* 43 days, p = 0.03; 23 *versus* 35 days, p = 0.04; 17 *versus* 24 days, p = 0.04, respectively).

DISCUSSION

Total hip arthroplasty (THA) is considered as one of the most important procedures in the field of Orthopaedic surgery; however, evidence on the most common approaches to this procedure still stirs controversies. Considering that, this study sought to investigate possible differences in the posterior and anterior approach to THA regarding functional and surgical outcomes by means of a systematic review and meta-analysis of randomized controlled trials (RCTs)

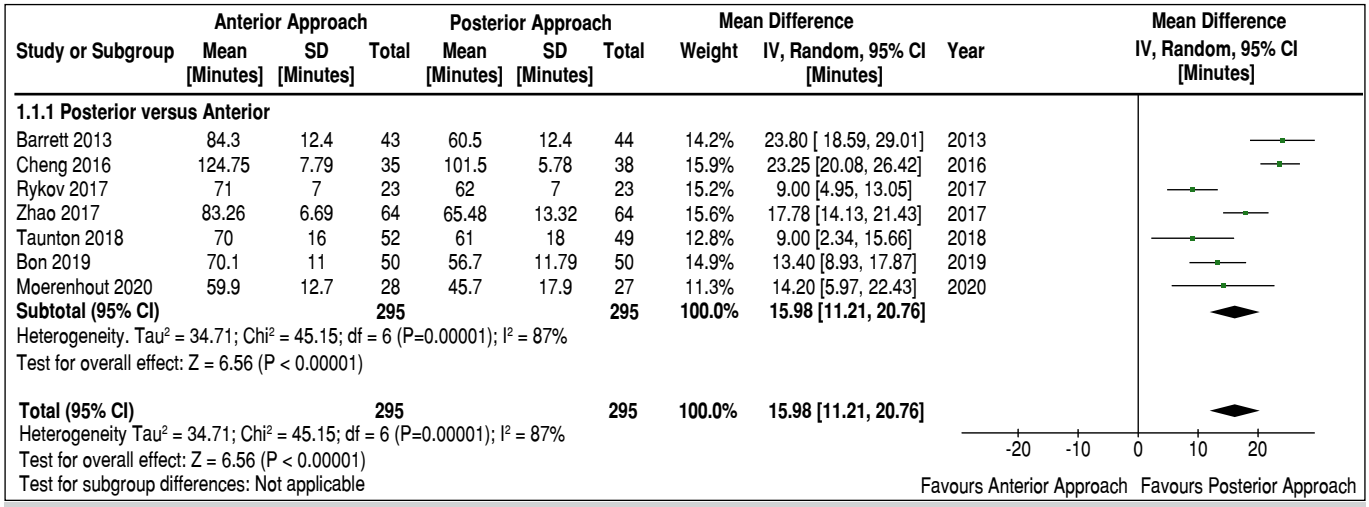

Figure 3a. Operative time during posterior *versus* anterior approach to THA.

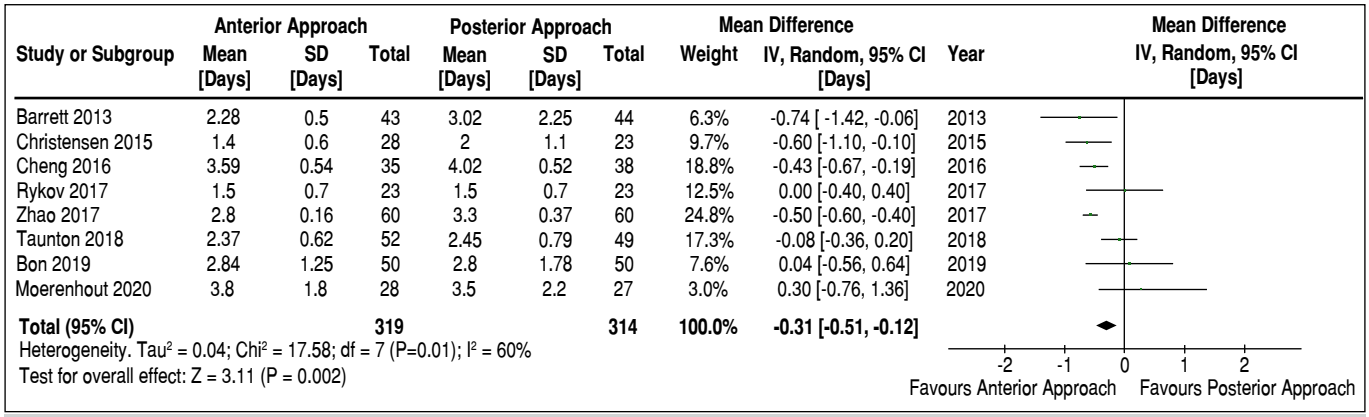

Figure 3b. Length of hospital stay for posterior *versus* anterior approach to THA.

comparing these approaches. Our results indicate an association between shorter operative time and the posterior approach. We also verified no differences regarding complications arising from both procedures, including fractures and dislocations.

Several studies found the anterior approach to achieve superior clinical outcomes when compared with the posterior approach.[18,22,23,25,27] In a systematic review of randomized and non-randomized studies comparing both approaches, Higgins et al.[25] found that the anterior approach showed superior clinical outcomes at short-term follow-up in four studies. Conversely, Taunton et al. [14] reported superior outcomes at early postoperative assessment following THA through the posterior approach when compared with the anterior approach, but no further differences in functional outcomes remained at 12 months after surgery. In comparison with the posterior approach, the anterior approach was associated with superior pooled HHS (mean of 4.06 points for short-term and 1.52 points for mid and long-term follow-up), but such difference did not reach the minimal 16-point clinical importance for the HHS.[24] Thus, the clinical superiority attributed to the anterior approach over the posterior approach to THA remains unclear.

Corroborating our findings, one systematic review reported a similar rate of major complications for both approaches, including intraoperative fractures.[26] A recent study found dislocations to be more prevalent among patients submitted to the posterior approach, with no differences in intraoperative fracture rates.[40] Another systematic review on early postoperative complications following THA also reported no differences in complication rates between anterior and posterior approach.[25] Regarding minor complications, one single cohort found high rates of LFCN neuropraxia in patients submitted to the anterior approach,[17] which lead us to perform a sensitivity analysis for minor complications that showed no differences between the approaches. However, this specific analysis resulted in an underpowered comparison ($p = 0.05$).

The operative time was about 16 minutes shorter for the procedure performed through the posterior approach when compared with the anterior approach. Considering that a primary THA takes on average 100 minutes, with a standard deviation (SD) of 26 minutes, a difference of 16 minutes in operative time may represent a procedure 15 to 20% faster.[27] As the posterior approach has historically been performed prior to the anterior approach, both surgery centers and surgeons may be more familiarized with its performance, indicating an expertise bias that favors this most traditional approach. Patients who underwent the anterior approach stayed in healthcare facilities 0.31 days (about eight hours) less than those who underwent the posterior approach. This may be explained by the fact that the surgical technique adopted in the anterior approach causes minimal muscle damage, thus allowing for a faster gait training and hospital discharge.[29] Three studies reported that patients operated through the anterior approach were able to walk without the aid of crutches within a shorter period after surgery.[14,19,21] However, the lack of sufficient knowledge on physical therapy protocols adopted during postoperative care hampers any strong inferences on this topic. Moreover, patients submitted to the anterior approach presented lower opioid intake, corroborating previous findings in the literature.[30]

Our initial plan was to compare the posterior with the anterior and the lateral approach. However, the database search identified only three RCTs comparing the posterior with the lateral approach, which would hinder most comparisons due to insufficient data. The heterogeneity and variability of clinical scores were yet another limitation inherent to this study, affecting the ability to pool several outcomes. Although the overall mean follow-up period was superior to 12 months, when considering RCTs individually, most studies have not completed a mid to long-term follow-up (more than six months). With that, we could not determine the complication rate at 12 months postoperatively. Most studies were conducted either in the U.S. or in Europe, which may preclude attempts to generalize our results. On the other hand, the inclusion of RCTs or Level 1 studies according to the Wright classification strengthens this systematic review.[31] Whenever possible, we adopted robust methodologies and protocols to ensure accuracy in data acquisition and pooling.

CONCLUSIONS

This systematic review denoted the scarcity of high-quality studies comparing clinical and surgical outcomes between the posterior and anterior approach to total hip arthroplasty, possibly assisting surgeons and patients in determining the preferable surgical approach. The anterior approach was associated with a potential faster rehabilitation at short-term, higher functional scores, shorter length of hospitalization, and faster discontinuing of walking aids such as crutches and walkers. On the other hand, the posterior approach may provide shorter operative time, with no increase in complications rates and similar long-term function.

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THE USE OF ANTIFIBRINOLYTICS IN HIP TRAUMA SURGERY IN A PUBLIC HEALTH SYSTEM: A PROSPECTIVE STUDY

O USO DE ANTIFIBRINOLÍTICOS EM CIRURGIA DE TRAUMA DE QUADRIL EM UM SERVIÇO PÚBLICO DE SÁUDE: ESTUDO PROSPECTIVO

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ABSTRACT

Objective: To evaluate the use of tranexamic acid (TXA) and ε-aminocaproic acid (EACA) in reducing blood loss in hip and proximal femur trauma surgery. Methods: Prospective study with 49 patients surgically treated in a trauma hospital between Nov/2015 and Feb/2017. The patients were divided in two groups: TXA (n = 24) and EACA (n = 25). The comparison was made according to gender, age at the time of surgery, ASA, fracture and surgery type, estimated blood loss during surgical approach, hemoglobin and hematocrit levels pre and post-operative, and pharmacological cost. The data was processed using SPSS 22.0 with significance level of p < 0,05. Results: No significant difference was found in the variables age, gender, ASA and estimated blood loss during surgical approach. No patient needed blood transfusion. When evaluated post-operatively, the hemoglobin and hematocrit values decrease had no significant difference between the antifibrinolytics (p > 0.05). When analyzing total cost for both pharmacological agents, higher cost was observed in EACA than in TXA (US$ 16.09 – US$ 2.73), resulting in a US$ 13.36 addition per patient. Conclusion: Antifibrinolytic use was efficient on lowering the total blood loss, without the need of blood transfusion. ***Level of evidence II, Prospective Comparative Study.***

Keywords: Anti-Fibrinolytic. Hip Fractures. Surgery.

RESUMO

Objetivo: Avaliar o uso do ácido tranexâmico (ATX) e aminocaproíco (AEAC) na redução da perda sanguínea em cirurgias para trauma do quadril e femur proximal. Métodos: Estudo prospectivo com 49 pacientes operados em hospital de trauma entre nov./15 e fev./17. Pacientes divididos em dois grupos: ATX (n = 24) e AEAC (n = 25). Comparações feitas de acordo com o sexo, idade na cirurgia, ASA, tipo de fratura e cirurgia, perda sanguínea estimada durante a cirurgia, níveis de hemoglobina e hematócrito pré e pós-operatório e o custo das medicações. Dados processados no SPSS 22.0 com nível de significância de p < 0,05. Resultados: Não foram encontradas diferenças significativas entre as seguintes variáveis: idade, sexo, ASA e perda sanguínea estimada durante a cirurgia. Nenhum paciente necessitou de transfusão sanguínea nos dois grupos. Na avaliação pós-operatória, não houve diferença significativa entre os grupos nos valores de queda da hemoglobina e hematócrito (p > 0,05). Analisando os custos de ambos as medicações, observou-se um custo mais elevado do AEAC em relação ao ATX (R$ 90,00 – R$ 15), resultando em R$ 75, 00 a mais por paciente. Conclusão: O uso dos antifibrinolíticos foi eficiente na redução da perda sanguínea, sem a necessidade de hemotransfusões. ***Nível de evidência II, Estudo Prospectivo Comparativo.***

Descritores: *Antifibrinolíticos. Fraturas de Quadril. Cirurgia.*

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INTRODUCTION

Blood loss is one of the main complications in major trauma surgeries, and, depending on how much is lost, it needs to be treated with transfusion, under the risk of immune and non-immune adverse reactions.[1-3]

Aiming to reduce the need for transfusion in surgeries with high blood loss, several techniques for blood management are used,

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The study was conducted at Instituto Dr. José Frota.
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being the administration of antifibrinolytics one of them. The usage of tranexamic acid (TXA), and ε-aminocaproic acid (EACA) antagonize fibrinolytic activity, and therefore reduce the amount of lost blood.[4-7] Studies have been demonstrating that the use of these medications in patients who had undergone orthopedic surgery, has led to a significant reduction in the total blood loss, without the increase of thromboembolic events.[6,8] However, research comparing the cost-effectiveness between these two drugs are limited in hip trauma surgery.

This study intents to evaluate the use of tranexamic acid and ε-aminocaproic acid in reducing blood loss in hip and proximal femur trauma surgery.

This study was approved by the Ethics in Research Committee of the aforementioned institution with the statement number 1.539.629.

MATERIAL AND METHODS

Prospective cohort study with a sample of 49 patients that underwent hip and/or proximal femur surgery, at a single metropolitan level 1 regional trauma center between November 2015 and February 2017.

Exclusion criteria were refusing participate, and the ones who presented renal insufficiency, allergies to TXA and/or EACA, or had a history of hemostasis disorders, low blood platelet count (< 100,000), altered prothrombin time (PT)/international normalized ratio (INR), activated partial thromboplastin time (APTT); thromboembolic events before the surgery, or family history of thromboembolism; ASA (American Society of Anesthesiologists) score > 3, infection at the puncture point of the subarachnoid block, blood in urine, clinical signs of acute hypovolemia, and pregnant or lactating women.

No patient has made use of previously donated autologous blood, isovolemic hemodilution in the intraoperative stage, intraoperative blood salvage, and erythropoietin (EPO) during the pre and postsurgical stages.

The sample was chosen by convenience, and the patients were divided into two groups, the first one was the tranexamic acid group (TXA) and the second was the ε-aminocaproic acid group (EACA). The TXA group had 1 g of tranexamic acid administered, and the EACA group was medicated with 4 g of ε-aminocaproic acid, both diluted in 100 ml of saline solution 0.9% received via intravenous infusion at the beginning of the surgery, right after the neuro-axis blockage, with no maintenance dose.

There was no blinding in the study, therefore the surgical team had knowledge of the administered medication. The team had four orthopedic trauma surgeons, with expertise in hip surgery, and two anesthesiologists.

For hip surgery, patients were placed onto the operating table on lateral decubitus position for the Kocher Langenbeck approach, whereas for the proximal femur surgery they were placed on dorsal decubitus position. For the acetabular approach, they were positioned either in dorsal decubitus or lateral decubitus, depending on the acetabular wall/column that was affected. Proximal femur conformation and the cortical index, as described by Dorr et al.,[9] was employed in the total arthroplasty of the hip (A, B, C) for the femoral component cementation, or not.

The parameters for blood transfusion included hemoglobin below 7 g/dl in the gasometry analysis, or hemoglobin below 8 g/dl with signs and symptoms of anemia: tachycardia (> 100 bpm) and hypotension (< 100 mmHg of systolic blood pressure) refractory to volume expansion. Both the surgeon and the anesthetist made a cooperative decision for the blood transfusion during the surgery.

The patients underwent deep vein thrombosis and pulmonary embolism prophylaxis with low molecular weight heparin (enoxaparin), 40 mg/day, subcutaneously, initiated in the hospital admission, suspended 12 hours before the procedure and reinitiated 12 hours after surgery until hospital discharge. Subsequently, the patients had a prescription of an oral Xa inhibitor factor, used during 21 days after osteosynthesis and 30 days after hip arthroplasty.

The blood loss was quantified by counting and weighing the medical dressings used during, before and after the surgery, as well as counting all the amount of saline solution and other liquids during the intraoperative stage of the surgery – used for basal patient hydration. The weight of the medical dressings after the surgery was subtracted from their original weight, and the result provided an estimated blood loss for the intraoperative stage. The conversion of the weight difference between the medical dressings used before and after the surgery considered the blood density of 1.05 g/ml. The suction drain was not used during the post-surgical stage.

The groups were compared according to the following data on their medical history; gender; age at the time of the surgery; ASA Score (I, II, or III); intraoperative volume of blood loss and pre and postsurgical levels of hemoglobin (Hb), hematocrit (Ht). The cost of medication used per patient in the surgery was described.

The patients were followed up during surgery and six months post-operatively for possible adverse reactions to the medication, such as conjunctivitis, diarrhea, urticaria, headache, nausea, vomiting, delirium, convulsive crises, hypotension, arterial fibrillation, renal failure and thromboembolic events.

Data was processed at the SPSS 22.0, license number 10101131007, when the average, medium and standard-deviation measures were estimated. The general characteristics of TXA and EACA groups were compared with Qui-Square and Fisher Exact Tests, whereas the average measures of the hematimetric levels (Hb and Ht) were compared in accordance with the Tukey test. Trust level was set as 0.05.

RESULTS

From 60 patients, 11 were excluded, the others were divided into two groups: TXA (24 patients) and EACA (25 patients). For the acetabular fractures, the first group (TXA) had a double approach (anterior + posterior) for two patients, anterior for one patient and posterior for another; in the second group posterior approach was performed in three patients and ilioinguinal approach in one patient. For the femoral neck fractures, the EACA group had 4 patients subjected to posterolateral approach and one to lateral approach, whereas, in the TXA group, the approaches were performed, respectively, in ten and one patients. When mentioning the transtrochanteric fractures (15 in EACA and 8 in TXA), all had lateral approach. The EACA group had one subtrochanteric fracture resolved by lateral approach, and the TXA group had a pelvic ring (pubic symphyses) approached previously.

The average age ranged from 68.38 ± 18.92 years old in the TXA group and 67.85 ± 22.13 years old in the EACA group ($p > 0.05$). No significant difference was observed between the groups regarding the variables gender, the ASA scores I/II/III, or by quantifying the perioperative blood loss of the studied subjects (Table 1).

Table 1. Comparison of clinical and surgical characteristics among the groups.

	TXA (N = 24)	EACA (N = 25)	P
Age (years)	68.38 18.92	67.85 22.13	0.180[1]
Gender			0.740[1]
Male	21 (34.42%)	19 (31.16%)	
Female	5 (29.41%)	7 (41.17%)	
ASA			0.300[2]
I	6	6	
II	14	12	
III	4	7	
FRACTURES (AO Classification)			
31A1	2	5	
31A2	7	10	
31B2	5	4	
31B3	4	1	
32A1	1	–	
32B1	–	1	
61B1	1	–	
62A1	1	1	
62A3	1	1	
62C2	2	2	
SURGERY			
Acetabulum			
Plate + Screw	4	4	
Femoral neck			
Canulated screws	1	1	
Non-cemented total hip arthroplasty	8	4	
Hemiarthroplasty	2	–	
Transtrochanteric			
DHS	8	15	
Subtrochanteric			
DCS	–	1	
Pubic Symphyses **Intraop. Blood Loss (ml)**	1 225.30 123.56	– 241.65 102.42	0.190[1]

[1] Qui-Square Test; [2] Fisher Exact Test.
TXA: Tranexamic Acid Group, EACA: Ɛ-Aminocaproic Acid Group.

The hemoglobin values observed in the pre-surgical stage were similar in all studied groups. In the post-surgical stage, however, these values were higher in the TXA group compared to the EACA group, but the differences were not significant ($p > 0.05$) (Table 2). When evaluating the percentage of hematocrit decrease, no differences between the TXA and EACA groups were observed ($p > 0.05$). We emphasize that there was no need for blood transfusion in either group.
Analyzing the cost of the medication, it was found that each patient spent approximately US$ 16 with the aminocaproic acid, almost 5 times more than tranexamic acid (US$ 2.73) (Table 3).

Table 2. Comparison of hemoglobin and hematocrit values during the pre and post-surgical stages between the groups.

		TXA	EACA	p
HEMOGLOBIN (g/dl)				
Pre-surgical		11.20 1.51	11.05 1.38	0.46
1st post-surgical		10.36 1.39	9.87 1.06	0.39
Reduction		0.83 0.49	1.12 0.71	0.33
HEMATOCRIT (%)				
Pre-surgical		33.16 4.49	33.10 3.92	0.99
1st post-surgical		30.33 4.07	29.99 3.15	0.94
Reduction		2.93 2.01	3.26 2.04	0.87

P by Tukey Test.
TXA: Tranexamic Acid Group, EACA: Ɛ-Aminocaproic Acid Group.

Table 3. Cost-effectiveness evaluation of tranexamic acid usage versus ε-aminocaproic acid.

	Presentation	Volume	Value (US$)	Vial/ Patient	Final Cost/ Patient (US$)	Total Cost (US$)
EACA	50mg/ml	20 ml	4.02	4	16.09	418.30
TXA	50mg/ml	5 ml	0.68	4	2.73	70.98
Δ	–	–	3.34	–	13.36	347.32

DISCUSSION

The perioperative stage in hip surgery involves an extensive tissue damage, the activation of the coagulation and fibrinolysis systems. In these cases, the use of antifibrinolytics is clearly beneficial to the reduction of perioperative blood loss and the demand for blood components,[10] and, currently, TXA and EACA are the most used in clinical practice.[11-13]
Benoni and collaborators[11] have shown that tranexamic acid had not significantly reduced the blood loss in the primary hip arthroplasty, despite more patients in the control group (26 *vs* 21) needing blood transfusion, such difference was not significant.
Yamasaki et al.[12] elaborated a study with 40 patients that suffered from hip osteoarthritis and have undergone a non-cemented total hip arthroplasty. They were sorted randomly into two distinct groups: one used 1 g of tranexamic acid five minutes before the procedure, and the other that did not use the drug. The previously medicated group showed a significant reduction of blood loss than the other group which had not used any antifibrinolytic.
This study shows that reduction in hemoglobin and hematocrit was lower in the TXA group than by the EACA group, but the difference between them was not significant. These results are reinforced by other studies.[7,13]
Lee et al.[14] evaluated 270 patients who had undergone hip hemiarthroplasty surgery and concluded that the tranexamic acid is advantageous to the patient's health due to the lower intraoperative and post-surgical blood loss. Besides, according to them this advantage extends to cost-effectiveness, since the administration of TXA saves up to £6,300 yearly, per patient, with blood transfusions avoided by using this drug.
Hobbs et al.[15] conducted a study with patients that had undergone knee or hip, total arthroplasty. They had two different groups, one that used EACA and other that used TXA as antifibrinolytic. And, besides showing that this type of medication is beneficial to patients, they also observed that using them costs less for the public health system, since the price of blood transfusion is higher than the price of antifibrinolytics.[15]
In a meta-analysis study with polytraumatized patients, Pinto et al.[16] concluded that the cost-effectiveness of tranexamic acid is $ 14.96 per year lived. According to these authors, TXA is highly cost-effective, and should be used in protocol for polytrauma patients.
In this study, both antifibrinolytic agents used were beneficial. However, when comparing the total cost of these medication in both groups, a higher cost of $ 347.32 was observed in the group using ε-aminocaproic acid. This difference shows a simple cost analysis in favor of using tranexamic acid.
Regarding unfavorable results, no adverse reactions with the 1 g TXA dose, and 4 g EACA dose, such as thromboembolic events, allergic reactions, or low renal function were observed during the trans-operative period, or even in 180 days after the surgery. These results were similar to revision studies previously carried out.[8,10]
Unfortunately, given the resource-limited setting in which this study was performed. The single-centered nature, lack of a control group and the small sample size may be the cause of bias. However, for the choice of treatments in public health system, the decisions need be based on the costs, benefits, and likelihoods of all potential consequences of treatments.

CONCLUSION

Our study stated that the use of antifibrinolytics (tranexamic acid and ε-aminocaproic acid) is an effective procedure to lower the reduction of the hematimetric levels, since no significant difference was observed between the two drugs used, the one with the lowest cost can be chosen, which, in this study, was the tranexamic acid.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. JAAO: writing, statistical analysis, intellectual concept, and preparation of the entire research project; GCCB: writing, review and intellectual concept; FMPB: writing, review, intellectual concept and surgeries; CACN: writing and review; JBAN: writing, review and surgeries; RCPI: writing, review and surgeries.

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DOES PARTIAL MENISCECTOMY AFFECT ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION RESULTS?

A MENISCECTOMIA PARCIAL AFETA OS RESULTADOS DA RECONSTRUÇÃO DO LIGAMENTO CRUZADO ANTERIOR?

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ABSTRACT

Objective: To compare the application of partial meniscectomy concomitant with primary ACL reconstruction, using the graft from the patellar tendon with individuals who underwent only ACL reconstruction, in clinical functional criteria and degree of osteoarthritis (OA), after 10 years of the surgical process. Methods: This is a retrospective cross-sectional study with 37 patients who underwent ACL reconstruction with a graft from the patellar tendon, associated or not with partial meniscectomy, divided into 2 groups: with meniscal injury (n = 22) and without meniscal injury (n = 15). Anthropometric data and four outcome measures were used to analyze the results: SF-36 questionnaire, arc of motion assessment, Knee injury and Osteoarthritis Outcome Score (KOOS), and Ahlbäck Radiographic Classification. Results: No differences were found for health-related quality of life, arc of motion, functional condition and knee OA severity/grade in patients who underwent partial or no meniscectomy in conjunction with ACL reconstruction ($p > 0.05$). Conclusion: Participants who underwent partial meniscectomy in conjunction with primary ACL reconstruction with a graft from the patellar tendon, after 10 years of the surgical process, showed no significant differences in the clinical functional criteria and severity of knee OA, compared to individuals who underwent only ACL reconstruction. ***Level of Evidence II, Prognostic study.***

Keywords: Anterior Cruciate Ligament. Knee. Meniscectomy. Osteoarthritis.

RESUMO

Objetivo: Comparar a realização da meniscectomia parcial concomitante à reconstrução do LCA (RLCA) primária, utilizando o enxerto do tendão patelar, com indivíduos que realizaram apenas a RLCA, em critérios clínico-funcionais e grau de osteoartrite (OA), após 10 anos do processo cirúrgico. Métodos: Trata-se de um estudo retrospectivo transversal, com 37 pacientes que realizaram a RLCA com enxerto do tendão patelar, associada ou não à meniscectomia parcial, divididos em dois grupos: com lesão meniscal (n = 22) e sem lesão meniscal (n = 15). Dados antropométricos e quatro medidas de desfecho foram utilizados para análise dos resultados: questionário SF-36, avaliação do arco de movimento, Knee Injury and Osteoarthritis Outcome Score (KOOS) e Classificação Radiográfica de Ahlbäck. Resultados: Não existem diferenças em termos de qualidade de vida relacionada à saúde, amplitude de movimento, condição funcional e severidade/grau de OA do joelho em pacientes que realizaram ou não meniscectomia parcial em conjunto com a RLCA ($p \geq 0.05$). Conclusão: Os participantes que realizaram meniscectomia parcial em conjunto com a RLCA primária com enxerto do tendão patelar, após 10 anos do processo cirúrgico, não demonstraram diferenças significativas nos critérios clínico-funcionais e gravidade da OA do joelho, comparados aos indivíduos que realizaram apenas a RLCA. ***Nível de Evidência II, Estudos prognósticos.***

Descritores: *Ligamento Cruzado Anterior. Joelho. Meniscectomia. Osteoartrite.*

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INTRODUCTION

Anterior cruciate ligament (ACL) rupture is the most common injury in the knee joint.[1] However, isolated damages to this structure are rare, with a high prevalence (40-70%) of involvement of the meniscus.[2] Many studies investigated the consequences of ACL reconstruction on knee joint function and structure;[3,4] however, the additional effect of partial meniscectomy on long-term postoperative outcomes remains controversial and little investigated.

Osteoarthritis (OA) risk is believed to increase with ACL and meniscus injury compared to either of these isolated injuries.[2,5] Although ACL reconstruction was widespread for many years as a preventive factor against the development of OA, recent studies found no

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The study was conducted at Hospital Ortopédico e Medicina Especializada, Instituto de Pesquisa e Ensino.
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protective capacity.[6] Likewise, meniscectomy has been considered one of the most important outcomes for knee OA development, being dependent on the amount of meniscus removed.[7,8] However, previous studies show that joint ligament and meniscal injuries are not significant predictors of subjective (e.g., quality of life) and functional outcomes of patients,[9,10] whereas others report worse functional capacity in individuals who underwent joint meniscal surgery with ACL reconstruction.[11]

Such inconsistency in the information available and the importance of the subject raise the need for more studies on the topic. To the best of our knowledge, the investigation of functional clinical outcomes and long-term OA severity in this comparison scenario remains scarce.

This study aimed to compare functional clinical outcomes and the OA grade between individuals who underwent primary ACL reconstruction with graft from the patellar tendon accompanied by partial meniscectomy and individuals who underwent only ACL reconstruction 10 years after the surgical process. We believe that individuals who also underwent partial meniscectomy will present worse knee function, quality of life and more severe OA.

MATERIALS AND METHODS

Study design and participants

This is a retrospective cross-sectional study performed with 75 patients who underwent ACL reconstruction with a graft from the patellar tendon, associated or not with partial meniscectomy and operated by the same surgeon in 2009.

The exclusion criteria were patients who fractured the operated knee before or after the procedure, underwent a revision ACL surgery or of other associated ligament injuries, had previous arthrosis, under 18 years of age and older than 50 years, had asymmetric varus and valgus deformities, had rheumatologic diseases, underwent ACL reconstruction surgery in both knees, and who could not be contacted. In total, 37 patients participated; they were divided into two groups: patients with associated meniscal injury (MI) (n = 22) and without associated meniscal injury (WMI) (n = 15) (Figure 1).

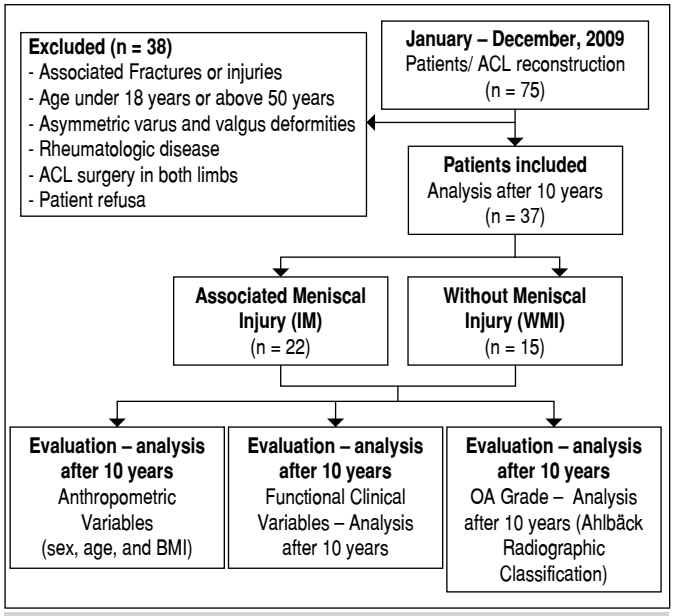

Figure 1. Flowchart of the patient selection process. ACL reconstruction: reconstruction of the anterior cruciate ligament; BMI: body mass index; SF-36: health status questionnaire; AoM: arc of motion; KOOS: Knee injury and Osteoarthritis Outcome Score.

Ethical Considerations

This study was submitted and approved by the Research Ethics Committee through Plataforma Brasil, under CAAE 18484919.3.0000.0023. All participants signed an Informed Consent Form before the study.

Surgical procedure and rehabilitation

All surgical procedures were performed by one of the authors of the present study. The technique was standardized for all patients. Intra-articular anatomical reconstruction with a single arthroscopic band with graft from the patellar tendon was used. All patients with meniscal injury underwent partial meniscectomy (no more than half of the meniscus was resected). Meniscal injuries were between 2.5 and 3.5 cm in length. The medial meniscus was involved in 15 cases and the lateral in 7.

For all patients, the same scientifically-proven and worldwide widespread rehabilitation protocol was applied.[12]

Analysis outcomes

The patients included in this study were evaluated after 10 years of the surgical procedure. The participants were invited by phone for a face-to-face evaluation at the *Hospital Ortopédico e Medicina Especializada* (HOME) – Brasília/DF.

Anthropometric data were initially collected using a questionnaire. Four outcome measures were used for analysis and divided into functional clinical outcomes (a) and OA grade (b): A1) physical and general health through the Short Form-36 – Health State Questionnaire (SF-36); only the two most relevant subdomains were selected for objectivity purposes: SF-36: Physical functioning (PF SF-36) and SF-36: General Health (GH SF-36). SF-36 is considered an effective measure for assessing health-related quality of life;[13] A2) functional evaluation of the arc of motion (AoM) of both knees, verified by goniometry; A3) patient's opinion about their knee, associated problems, and functional limitations through the Knee injury and Osteoarthritis Outcome Score (KOOS). The KOOS questionnaire demonstrated a high correlation with structural knee changes associated with OA in previous studies;[14] B1) grade of knee OA involvement, verified by bilateral radiography with load in anteroposterior and profile incidences, evaluated by the Ahlbäck Radiographic Classification. To determine the score of each patient, radiography images were evaluated independently by two experienced evaluators. In cases of divergence, a third more experienced evaluator determined the definitive classification.

Statistical analysis

Univariate descriptive analysis was used to analyze the individual behavior of each variable: absolute and relative frequencies, quartiles, mean, median, and standard deviation. The Wilcoxon-Mann-Whitney nonparametric test was applied to compare means between the two independent groups (with and without meniscal injury). The statistical software R version 3.6.1 was used for data analysis and the significance level adopted was 5%.

RESULTS

Comparison of functional demographic and clinical variables between groups after 10 years

ACL reconstruction was performed in 75 patients, associated or not with meniscal injury. Of these, 49.3% (37/75) participated in the study and completed the 10-year follow-up, being 20 men and 2 women in the MI group and 15 men in the WMI group (Figure 1). Demographic and functional clinical variables

were similar between the MI versus WMI groups ($p \geq 0.05$) groups (Table 1). No significant differences were found for age (42.41 ± 8.29 vs 46.07 ± 9.73), BMI (27.07 ± 3.92 vs 26.76 ± 2.46), SF-36 scores for physical functioning (94.09 ± 06.66 vs. 90.33 ± 11.09) and general health (85.91 ± 12.87 vs 85.67 ± 8.20), contralateral knee flexion AoM (127.10 ± 11.06 vs 127.50 ± 11.04), AoM of the operated knee (123.80 ± 13 vs 125.60 ± 11.95) and the KOOS score (93.10 ± 5.34 vs 92.61 ± 5.21).

Table 1. Characterization of the sample. Demographic and clinical functional variables of the Meniscal Injury (MI) and Without Meniscal Injury (WMI) groups. Age, BMI, SF-36 scores, contralateral and operated knee flexion ROM and the score obtained in the Knee injury and Osteoarthritis Outcome Score (KOOS) were expressed as mean, standard deviation (SD), minimum and maximum. Data referring to gender by frequency (n).

Variable: mean SD (minimum - maximum)	Meniscal Injury (MI) group	Without Meniscal Injury (WMI) group
Female (n)	2	0
Male (n)	20	15
Age (years)	42.41 8.29 (29 – 50)	46.07 9.73 (31 – 50)
BMI (kg/cm)	27.07 3.92 (21 – 39.3)	26.76 2.46 (22.8 – 31.4)
SF-36: Functional capacity (score)	94.09 6.66 (80 – 100)	90.33 11.09 (55 – 100)
SF-36: General Health (score)	85.9 12.87 (50 – 100)	85.67 8.20 (70 – 100)
Knee flexion ROM (degrees)	127.10 11.06 (110 – 157)	127.50 11.04 (108 – 145)
Operated knee flexion ROM (degrees)	123.80 13 (110 – 150)	125.60 11.95 (104 – 145)
KOOS: mean SD (minimum – maximum)	93.10 5.34 (81.50 – 100)	92.61 5.21 (82.10 – 98.20)

Comparison of osteoarthritis severity between the groups after 10 years

Based on Ahlbäck's Radiographic Classification, no significant difference was found for the OA degree between groups (MI group: 64% of the sample obtained a score equal to 2, 27% equal to 3 and only 9% equal to 4; WMI group: 20% of the sample obtained a score equal to 1, 47% equal to 2, 20% equal to 3, and only 13% equal to 4) (Table 2).

Table 2. Comparative analysis of the results of the Ahlbäck radiographic classification between the Meniscal Injury (MI) and No Meniscal Injury (WMI) groups.

Raio-X Ahlback (n - %)	Meniscal Injury (MI) group	Without Meniscal Injury (WMI) group
Grade – 1	0 – 0%	3 – 20%
Grade – 2	14 – 64%	7 – 47%
Grade – 3	6 – 27%	3 – 20%
Grade – 4	2 – 9%	2 – 13%

DISCUSSION

The main objective of this investigation was to compare individuals who underwent a partial meniscectomy together with ACL reconstruction with the graft from the patellar tendon and patients who underwent only ACL reconstruction after 10 years of the surgical process. Our data suggest long-term similarity of the functional and severity clinical results of knee OA in patients who underwent or not meniscectomy in conjunction with primary ACL reconstruction in a cross-sectional retrospective investigation. This study is not the first to compare different outcomes among patients who underwent partial meniscectomy after primary ACL reconstruction; however, to the best of our knowledge, it is the first in which no differences between the groups were found regarding functional clinical criteria and OA grade after a long period (10 years after the surgical process).

The ACL is considered as the main stabilizer of the knee, restricting rotational and translational movements between the tibia and femur.[15] Its rupture increases joint instability, which may lead to functioning changes in most patients.[16] Likewise, anatomical and biomechanical studies show that menisci are vital structures for maintaining joint health.[17] The removal of a part of the meniscus may decrease the energy attenuation capacity from joint movement, promote constant pain and slow down the capacity to produce quadriceps strength, an important active stabilizer of the femorotibial joint.[18] Meniscectomy, performed separately, has already been shown to increase the risk knee OA development and decrease the functional capacity of patients.[7,19]

From these assumptions, greater impairment of functioning and higher OA grades would be expected when meniscectomy was performed in conjunction with ACL reconstruction. However, our results are not consistent with this hypothesis. The type of surgical treatment used is an important point to be considered. The highest OA rates are found in open total meniscectomy and the lowest in patients who underwent arthroscopic partial meniscectomy.[7] Moreover, previous studies have shown that lateral meniscectomy leads to a faster progression of OA compared to medial meniscectomy.[7,19] These findings may help to understand the results found in this study. Meniscal surgical procedures were partial meniscectomy and the highest prevalence of injuries was on the medial meniscus. Classic references such as Daniel et al.[20] show an increase in the incidence of knee OA after ACL reconstruction regardless of meniscectomy, evaluated by imaging tests. The authors explain that joint injuries from the surgical procedure, abnormal joint mechanics and inflammatory response after ACL reconstruction surgery seem to be the main factors linked to increased joint degeneration and not meniscal removal.[20] In a 5-year prospective analysis, Paradowski et al.[9] demonstrated that isolated ACL reconstruction showed no superiority in terms of lower limb function as evaluated by the KOOS questionnaire when compared to combined partial meniscectomy. Likewise, meniscal repair or partial meniscectomy did not affect the functional recovery of quadriceps muscle function and strength in the return to sport after ACL reconstruction.[10]

The fact that all surgical procedures were conducted by the same surgeon is an important aspect that should be highlighted in this study. Our research limitations should serve as guidance when designing future studies. The sample size is small, so our results should be interpreted with caution. Most of the analysis outcomes were not collected before the surgical procedure, making it impossible to conduct a prospective follow-up study.

CONCLUSION

Participants who underwent partial meniscectomy in conjunction with primary ACL reconstruction with graft from the patellar tendon 10 years after the surgical process did not demonstrate significant differences in the functional clinical criteria and severity of knee OA in comparison to individuals who underwent only ACL reconstruction.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. JHSB: preparation of the entire research project, intellectual conception of the article, data/statistical analysis, writing and review of the article; BSLC: preparation of the entire research project, intellectual conception of the article, data/statistical analysis, writing and review of the article; RAQA: preparation of the entire research project, intellectual conception of the article, data/statistical analysis, writing and review of the article; PA: preparation of the entire research project, intellectual conception of the article, data/statistical analysis, writing and review of the article; MSR: preparation of the entire research project, intellectual conception of the article, data/statistical analysis, writing and review of the article; PLJ: preparation of the entire research project, intellectual conception of the article, data/statistical analysis, writing and review of the article.

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INTRAARTICULAR EPSILON AMINOCAPROIC ACID VERSUS TRANEXAMIC ACID IN TOTAL KNEE ARTHROPLASTY

ACIDO ÉPSILON AMINOCAPROICO INTRA-ARTICULAR VERSUS ACIDO TRANEXÂMICO NA PRÓTESE TOTAL DO JOELHO

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ABSTRACT

Objective: To examine and compare the clinical efficacy of intraarticular epsilon aminocaproic acid (EACA) and tranexamic acid (TXA) in total knee arthroplasty (TKA). Methods: This study was a prospective, single-center, double-blinded randomized controlled trial, including sixty patients with osteoarthritis of the knee divided into two groups of 30 patients. In the TXA group, 1 g of TXA (0.05 g/ml) was applied intraarticularly, and in the EACA group, 4 g of EACA (0.2 g/ml) was applied intraarticularly. Serum hemoglobin (Hgb) and hematocrit (Htb) were measured during the preoperatively and 24 and 48 hours postoperatively. The range of motion and pain were evaluated by clinical examination. To evaluate knee function before and 2 months after surgery, the Western Ontario and McMaster Universities Index (WOMAC) questionnaire was used. Results: In total, 56 (93.3%) patients were evaluated up to the second postoperative month. No significant difference between the groups ($p > 0.05$) was found in the decrease in Hgb or Htb at 24 or 48 hours. Regarding assessment of the pain, WOMAC score and gain in knee flexion, no significant advantages up to 60 days after surgery ($p > 0.05$) were found. Conclusions: The decrease in Hgb and Htb during the first 48 hours postoperatively and the risk of transfusion were similar with the intraarticular use of 1 g of TXA and 4 g of EACA in TKA. The possible benefits regarding knee pain, gain in flexion and function were also similar for the two drugs. ***Level of Evidence II, Randomized, Double-Blinded, Single-Centre, Prospective Clinical Trial.***

Keywords: Total Knee Arthroplasty. Bleeding. Pain. Tranexamic Acid. Epsilon Aminocaproic Acid.

RESUMO

Objetivo: Avaliar e comparar a eficácia clinica do uso intra-articular do ácido épsilon aminocaproico (AEAC) versus o ácido tranexâmico (ATX) na prótese total do joelho. Métodos: Estudo clínico prospectivo, centro-único, duplo-cego e randomizado. Sessenta pacientes com osteoartrose de joelho foram incluídos. Os participantes foram divididos em dois grupos de 30 pacientes. No grupo ATX, foi aplicado 1 g de ATX (0.05 g/ml) intra-articular e, no grupo AEAC, foram aplicados 4 g de AEAC (0.2 g/ml) intra-articular. Valores séricos da hemoglobina (Hb) e hemtatócrito (Ht) foram dosados no pré-operatório e com 24 e 48 horas após a cirurgia. A amplitude de movimento e a dor também foram avaliadas no exame clínico. O índice WOMAC foi utilizado para avaliar a função do joelho antes e após dois meses da cirurgia. Resultados: Foram avaliados 56 (93.3%) pacientes até o segundo mês pós-operatório. Depois da cirurgia, não houve diferenças entre os grupos ($p > 0.05$) na queda do valor de Hb e Ht com 24 ou 48 horas. Com relação à avaliação da dor, WOMAC e ganho de flexão do joelho, não houve vantagem significativa para nenhum dos grupos até os 60 dias depois da cirurgia($p > 0.05$). Conclusão: A queda do valor da Hb e do Ht durante as primeiras 48 horas pós-operatórias e o risco de transfusão foram similares com o uso intra-articular de 1 g de ATX e 4 g de AEAC na artroplastia total do joelho. Os possíveis benefícios com relação ao controle da dor, ganho de flexão e função foram similares entre as duas drogas. ***Nível de Evidência II, Ensaio-Clínico Prospectivo, Randomizado, Duplo Cego, Centro-Único.***

Descritores: *Artroplastia Total do Joelho. Sangramento. Dor. Ácido Tranexâmico. Ácido Épsilon Aminocapróico.*

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INTRODUCTION

Antifibrinolytics have already been successfully used to reduce the need for transfusion in total knee arthroplasty (TKA).[1-3] TKA is associated with considerable blood loss.[3] Besides the risk of transfusion, excessive bleeding can impair the success of TKA through hematoma, swelling, stiffness, prolonged hospitalization, and delayed functional recovery and rehabilitation.[3] Epsilon aminocaproic acid (EACA) and tranexamic acid (TXA)

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The study was conducted at Hospital Evangélico de Londrina.
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are synthetic amino acid derivatives that interfere with fibrinolysis and promote hemostasis. Although the clinical efficacy of TXA in decreasing blood loss, improving the hemoglobin (Hgb) level and improving some functional parameters, such as pain and flexion, have been well demonstrated in TKA,[4] data on the effects of EACA in TKA have been reported in few published studies to date, and those studies have only investigated the intravenous use of EACA.[2,5,6] Due to the scarcity of this data, most surgeons prefer TXA over EACA, despite its higher cost in many countries.[1,6]

To our knowledge, this was the first trial of intraarticular EACA and TXA in TKA to determine if apparent differences in efficacy can be found.

The primary aim of this prospective, randomized trial was to examine and compare the clinical efficacy of intraarticular EACA and TXA in TKA. The study questions were if EACA and TXA were similar regarding blood conservation (defined by the transfusion rate and drop in Hgb and hematocrit [Htb]), postoperative pain control and postoperative gain in knee flexion; possible associations that have not yet been described were identified using a functional questionnaire.

Our hypothesis was that intraarticular TXA would be similar to intraarticular EACA in terms of antifibrinolytic effects after TKA.

MATERIALS AND METHODS

This study was a prospective, single-center, double-blinded randomized trial. The project was approved by Institution Ethics and Research Committee in July 2017 and was assigned the clinical trial in December 2017. All patients provided written informed consent to participate in the study.

Study population

During recruitment, between July 2017 and December 2018, patients (of both sexes) that had three-compartment osteoarthritis of the knee as an indication for TKA and were awaiting scheduling of the procedure, had no diagnosis of inflammatory disease, had no history of atrial fibrillation, pulmonary embolism, deep vein thrombosis, or surgery on the same knee, had no coagulopathy and were not using anticoagulant medications were eligible for inclusion. The TKA procedures were performed between October 2017 and July 2019. Inadequate closure of the joint capsule at the end of surgery, with identified leakage of the drug applied to the joint, was considered an exclusion criterion. The last follow-up was in September 2019.

Interventions

The blood of the patients was collected for serum Hgb and Htb measurements before surgery, in the operating room. Knee arthroplasty was performed with a standard medial parapatellar approach by two surgeons from the same hospital. A tourniquet was used in all subjects during the surgery until the wound was dressed. Cemented cruciate-substituting implants without patellar resurfacing were used in all procedures. After joint capsule closure, the surgeon left the operating room, and the random group assignment of the patient, determined using an electronic randomization program to divide the participants into 2 groups of 30 patients, was revealed. No patient was informed of the group assigned. In the TXA group, the auxiliary surgeon applied 1 g of TXA (0.05 g/ml) intraarticularly using a 20 ml syringe and a 40 × 1.2 mm needle before the operative wound was sutured (Figure 1). In the EACA group, the auxiliary surgeon applied 4 g of EACA (0.2 g/ml) intraarticularly using a 20 ml syringe and a 40 × 1.2 mm needle before the operative wound was sutured (Figure 1).

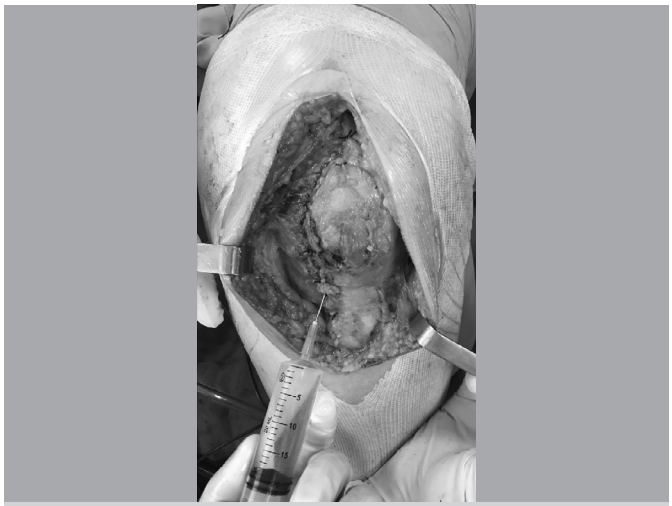

Figure 1. Application of drug in the joint cavity after joint capsule closure.

Data collection

Data were collected before and after surgery, as follows (Table 1):

Table 1. Model of the worksheet used for data collection at the different time points (before and after surgery).

	Before	24 h		48 h	20 days	60 days
Hgb	x	x		x		
Htb	x	x		x		
Knee flexion		x		x	x	x
Pain		x		x	x	x
WOMAC	x					x
Transfusion		x		x		
Surgical site		x		x	x	x
Signs of infection					x	x

Hgb: hemoglobin; Htb: hematocrit; pain: evaluation of pain on a numerical scale; WOMAC: evaluation of the Western Ontario and McMaster Universities Index; transfusion: assessment of the need for blood transfusion; surgical site: observation of the healing status; signs of infection: assessment of serum test results and the need for antibiotic therapy, surgical debridement or implant removal.

1. Serum Hgb and Htb were measured during the preoperative period and also 24 and 48 hours after surgery. The need for transfusion was evaluated for patients with values below 7 mg/dL and clinical signs of acute anemia.
2. The patients underwent clinical examinations at the following postoperative time points: 24 hours, 48 hours, between 15 and 25 days, and 2 months after surgery. a) Range of motion was evaluated using a goniometer. b) Pain was evaluated using an 11-point (0-10) numerical scale, on which zero indicated no pain, and 10 indicated the most intense pain ever felt. Each patient selected a single number that best represented the intensity of their pain at the time of the evaluation. c) The surgical site was evaluated by clinical examination.
3. To evaluate knee function before and 2 months after surgery, the Western Ontario and McMaster Universities Index (WOMAC) questionnaire was used.

Postoperative protocol used

1. During hospitalization, the following analgesics were prescribed: 1 g of intravenous dipyrone every 6 hours and 50 mg of tramadol hydrochloride every 8 hours.
2. Patients with pain equal or above 7 on the numerical pain scale received 4 mg of intravenous morphine every 4 hours, and this grade was considered in the evaluation for that period.
3. At the time of discharge, 1 g of dipyrone was given orally every 6 hours if there was pain, and 50 mg of tramadol hydrochloride

was given orally every 8 hours if pain persisted despite the use of dipyrone.
4. All patients received 40 mg of subcutaneous enoxaparin as prophylaxis for deep venous thrombosis in the hospital at 8, 24 and 48 hours after surgery, and 10 mg of rivaroxaban daily was prescribed for another 10 days at home.
5. Antibiotic prophylaxis was performed with 2 g of intravenous cefazolin during anesthetic induction, and 1 g of cefazolin was administered every 8 hours for 24 hours.

Statistical analysis

The statistical power of the sample was calculated using the sampsi command of STATA software (version 11, 2011, College Station, Texas, USA) for a comparative design of groups with repeated measures and using the reduction in Hgb as the parameter, and we found that 20 patients per group would guarantee a power of at least 95% for comparisons.
Comparisons between the two groups at all times with respect to all variables were performed using mixed-effects (random and fixed effects) linear regression models. Post-test orthogonal contrasts were used for comparisons. Intergroup comparisons regarding changes in Hgb and Htb at certain times were performed using Student's *t*-test. The significance level adopted for all comparisons was 5%.

RESULTS

In this study, 60 patients, including 30 in the TXA group and 30 in the EACA group, were followed until the second postoperative day (Figure 2). In total, 56 (93.3%) patients were evaluated up to the second postoperative month, including 27 (90%) in the TXA group and 29 (96.6%) in the EACA group. The mean patient age was 67.97 (41-85) years in the TXA group and 68.67 (46-83) years in the EACA group. In total, 22 women in the TXA group and 20 women in the EACA group were included. The two groups were statistically similar preoperatively regarding Hgb, Htb, knee flexion and WOMAC score (Table 2).

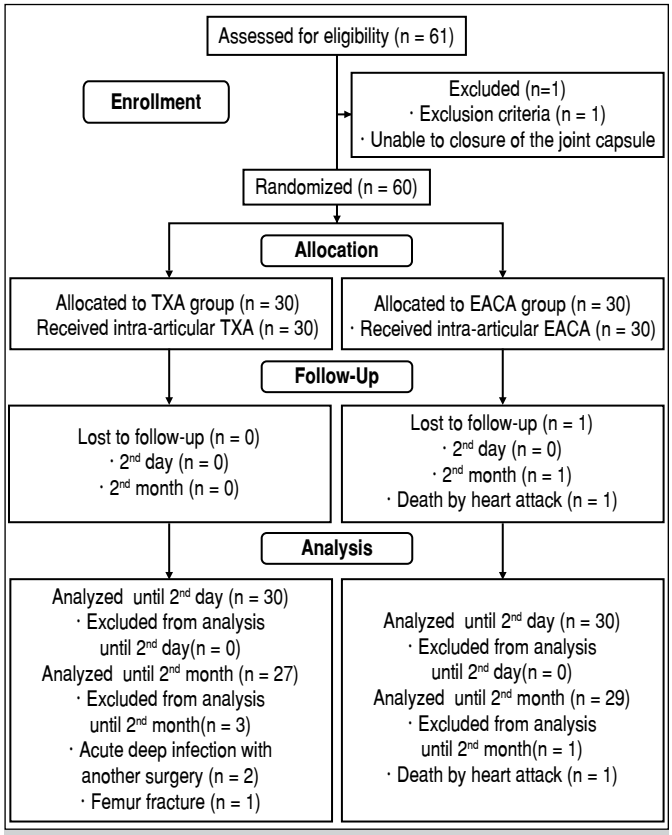

Figure 2. CONSORT flowchart.

Table 2. Demographic data.

	TXA group	EACA group	P value
Number of surgical patients	30	30	> 0.05
Number of patients followed to the 2nd day	30	30	> 0.05
Number of patients followed to the 2nd month	27 (90%)	29 (97%)	> 0.05
Mean age	67.97 (41-85)	68.67 (46-83)	> 0.05
Sex (man/woman)	8/22	10/20	> 0.05
Preoperative hemoglobin value (mean and standard deviation)	13.24 (1.48)	12.47 (1.6)	> 0.05
Preoperative hematocrit value (mean and standard deviation)	38.49 (4.15)	37.95 (5.34)	> 0.05
Preoperative knee flexion (mean and standard deviation)	106.5 (13.84)	98.33 (10.77)	> 0.05
Preoperative WOMAC score (mean and standard deviation)	66.93 (19.96)	68.57 (20.72)	> 0.05

Table 3 shows that no significant difference ($p > 0.05$) was found in the Hgb or Htb decrease at 24 or 48 hours after surgery between the groups.

Table 3. Hgb and Htb.

	TXA group (mean and standard deviation)	EACA group (mean and standard deviation)	P-value
Hgb drop at 24 hours	1.59 (1.11)	1.19 (0.82)	> 0.05
Hgb drop at 48 hours	2.54 (1.18)	2.48 (1.22)	> 0.05
Htb drop at 24 hours	4.82 (3.37)	3.68 (3.01)	> 0.05
Htb drop at 48 hours	7.29 (3.42)	7.04 (4.05)	> 0.05

Table 4 shows that no significant advantage was detected in either group regarding either pain or gain in knee flexion at 24 hours, 48 hours, 20 days or 60 days after surgery ($p > 0.05$).

Table 4. Evaluation of pain and flexion gain.

	TXA group (mean and standard deviation)	EACA group (mean and standard deviation)	P value
Mean pain at 24 hours	3.37 (2.58)	4.07 (3.17)	> 0.05
Mean pain at 48 hours	3.1 (2.75)	3.31 (3)	> 0.05
Mean pain at 20 days	2 (1.82)	2.24 (2.47)	> 0.05
Mean pain at 60 days	1.36 (1.81)	1.59 (1.86)	> 0.05
Flexion gain at 24 hours	66.17 (18.37)	74.17 (24.74)	> 0.05
Flexion gain at 48 hours	74.83 (17.88)	76 (24.26)	> 0.05
Flexion gain at 20 days	91.67 (12.89)	91.55 (15.18)	> 0.05
Flexion gain at 60 days	97.96 (17)	98.1 (12.57)	> 0.05

Regarding the WOMAC score, no differences between the two groups were found up to 2 months after surgery (Table 5).

Table 5. Comparison of WOMAC score between groups.

	TXA group (mean and standard deviation)	EACA group (mean and standard deviation)	P-value
WOMAC score at 2 months	19.96 (8.5)	20.72 (11.71)	> 0.05

During the follow-up of the 60 patients, four cases (6.7%) of wound dehiscence and superficial infection were successfully treated with dressings and oral antibiotics (two in the TXA group and two in the EACA group). Two cases (3.3%) of acute deep infection were treated; one required debridement, and one required implant removal (both in the TXA group). One (1.7%) manipulation was performed to treat arthrofibrosis (in the EACA group). In total, one (1.7%) diagnosed case of thrombosis in the TXA group was identified. One (1.7%) case of mortality due to a heart attack in the EACA group were detected. No patients required a blood transfusion (the transfusion criterion was an Hgb value less than 7 mg/dL in symptomatic patients). The identified complications were not significantly associated with EACA or TXA use (Table 6).

Table 6. Complications.

	TXA group	EACA group	Total
Wound dehiscence and superficial infection	2 (3.3%)	2 (3.3%)	4 (6.7%)
Acute deep infection	2 (3.3%)	0	2 (3.3%)
Manipulation due to arthrofibrosis	0	1 (1.7%)	1 (1.7%)
Thrombosis	1 (1.7%)	0	1 (1.7%)
Death	0	1 (1.7%)	1 (1.7%)
Transfusion	0	0	0
Total patients	5 (8.3%)	4 (6.7%)	9 (15%)

DISCUSSION

EACA and TXA function by a similar mechanism. Supported by robust scientific evidence, TXA is widely routinely used in TKA at many orthopedic surgery centers, reducing the risk of transfusion and costs.[7] However, fewer studies have analyzed EACA or compared the two drugs.[3]

We found only two clinical prospective studies in the literature, both of which were small trials showing similar efficacy for TXA and EACA.[1,5] We found only a prior retrospective study including a large number of patients that showed the same results.[6] The doses of EACA were at least 5 times higher than the doses of TXA in these studies, and EACA was administered intravenously in all of them.[1,5,6] This study was the first to compare 1 g of TXA with 4 g of EACA administered intraarticularly in TKA. In some situations, EACA is less expensive than TXA[1,6]; proving that the effects are comparable providing additional justification for its use, and this justification becomes even more robust if an even lower dose can be used with the same efficacy. Several publications have shown the noninferior effect of topical TXA over intravenous TXA.[8,9] When given intravenously, minor gastrointestinal symptoms, such as nausea and vomiting, have been reported.[10] Antifibrinolytic drugs are known to decrease perioperative bleeding and prevent premature clot dissolution.[11] Surgeons can apply the drug by themselves when administering it intraarticularly, and lower doses can be used with less risk of systemic side effects.[12,13]

We determined pain control, knee flexion gain and knee function by the WOMAC questionnaire in the groups up to two months postoperatively, in addition to evaluating the drop in Hgb and Htb. This study also shows that the possible benefits in pain control, flexion gain and knee function demonstrated in some previous studies using TXA were similar when using EACA.[12,14]

This study has some limitations. First, although we performed a power analysis to determine the size of the study population, our study was a small clinical trial at a single center. Second, we estimated bleeding using only serum Hgb and Htb levels without calculating the blood volume using the weight and height of the patients. Third, since we did not use drains because we considered that a portion of the drug applied intraarticularly could be lost through the drain, we could not directly measure bleeding. Fourth, we did not determine the serum drug levels achieved in the patients, and therefore, although we did not observe any clinically evident side effects, we cannot determine a difference in the safety of these drugs administered intraarticularly.

CONCLUSIONS

The drop in Hgb and Htb in the first 48 hours postoperatively and the risk of transfusion were similar for 1 g of TXA and 4 g of EACA administered intraarticularly in TKA. The possible benefits regarding knee pain, flexion and function were also similar for the two drugs.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. JPFG: drafted and reviewed the article, performed statistical analysis and contributed to the intellectual concept of the study and the entire research project; JRMB: drafted the article, sought volunteers and analyzed the data; BPR: drafted the article, sought volunteers and analyzed the data; MVD: reviewed the article and contributed to the intellectual concept of the study; AOQ: reviewed the article and contributed to the intellectual concept of the study; DCC: reviewed the article and contributed to the intellectual concept of the study.

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ORIGINAL ARTICLE
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THE EFFECTS OF NEUROMUSCULAR ELECTRICAL STIMULATION IN ASSOCIATION WITH WHEY PROTEIN SUPPLEMENTATION AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

EFEITOS DA ESTIMULAÇÃO ELÉTRICA NEUROMUSCULAR ASSOCIADO À SUPLEMENTAÇÃO COM WHEY PROTEIN APÓS RECONSTRUÇÃO DO LIGAMENTO CRUZADO ANTERIOR

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ABSTRACT

Objective: To analyze the effects of neuromuscular electrical stimulation of the femoral quadriceps associated or not with whey protein supplementation on the electromyographic activity and body mass distribution in volunteers undergoing anterior cruciate ligament reconstruction. Methods: 24 volunteers were randomly divided into three groups: basal control, whey protein in association with neuromuscular electrical stimulation, and neuromuscular electrical stimulation alone. Results: In the postoperative evaluation, during the mini squat, the basal group showed a decrease in the electromyographic activity of the vastus medialis ($p = 0.005$, eyes open; $p = 0.003$, eyes closed), vastus lateralis ($p = 0.005$, eyes open; $p = 0.020$; eyes closed) and rectus femoris ($p = 0.075$, eyes open; $p = 0.074$, eyes closed) and of body mass distribution in the injured limb ($p < 0.001$, eyes open; $p < 0.001$, eyes closed), and in the healthy limb ($p < 0.001$, eyes open; $p < 0.001$, eyes closed). Conclusion: The early use of neuromuscular electrical stimulation of the quadriceps femoris maintained the electromyographic activity of the vastus medialis and vastus lateralis muscles and prevented asymmetries in body mass distribution 15 days after anterior cruciate ligament reconstruction. ***Level of Evidence I, High quality randomized trial.***

Keywords: Anterior Cruciate Ligament Reconstruction. Electric Stimulation. Whey Proteins.

RESUMO

Objetivo: Analisar os efeitos da estimulação elétrica neuromuscular do quadríceps femoral associado ou não à suplementação com whey protein na atividade eletromiográfica e distribuição de massa corporal em voluntários submetidos à reconstrução do ligamento cruzado anterior. Métodos: 24 voluntários foram divididos em três grupos: controle basal, whey protein associado com estimulação elétrica neuromuscular e estimulação elétrica neuromuscular isolada. Resultados: Na avaliação pós-operatória, durante o miniagachamento, o grupo controle basal demonstrou diminuição da atividade eletromiográfica do vasto medial ($p = 0,005$, olhos abertos; $p = 0,003$, olhos fechados), vasto lateral ($p = 0,005$, olhos abertos; $p = 0,020$, olhos fechados) e reto femoral ($p = 0,075$, olhos abertos; $p = 0,074$, olhos fechados) e da distribuição de massa corporal no membro operado ($p < 0,001$, olhos abertos; $p < 0,001$, olhos fechados) e membro lesionado ($p < 0,001$, olhos abertos; $p < 0,001$, olhos fechados). Conclusão: O uso precoce de estimulação elétrica neuromuscular do quadríceps femoral, independentemente do uso de whey protein, foi eficaz para manter a atividade eletromiográfica dos músculos vasto medial e vasto lateral, e prevenir assimetrias na distribuição de massa corporal 15 dias após a reconstrução do ligamento cruzado anterior. ***Nível de Evidência I, Ensaio randomizado de alta qualidade.***

Descritores: *Reconstrução do Ligamento Cruzado Anterior. Estimulação Elétrica. Proteínas do Soro do Leite.*

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INTRODUCTION

Anterior cruciate ligament (ACL) rupture is a common lesion, occurring mainly in young people who participate in physical activity.[1,2] This lesion can be treated conservatively or through surgery.[3] The reconstructive surgery of this ligament is one of the more common orthopedic surgical procedures.[4,5,6]

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

The study was conducted at Federal University of Alfenas.
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Patients undergoing ACL reconstruction surgery have persistent atrophy and loss of quadriceps femoris strength.[7] The main factors for the dysfunction of this quadriceps muscle are the period of immobilization, disuse, decreased overload,[8] deficits in the ability to activate muscle fibers, muscle atrophy,[8] and muscle arthrogenic inhibition.[9]
Quadriceps arthrogenic muscle inhibition is an inhibitory reflex of the musculature of the knee region that occurs when there is joint damage, pain, edema and inflammation.[10] This inhibition is considered a protective mechanism for avoiding injury; however, this same inhibition may limit rehabilitation.[11] Interventions aimed at improving the voluntary activation of the quadriceps femoris are important because the early restoration of quadriceps femoris strength positively influences the following phases of rehabilitation.[12]
In this context, one effective and safe intervention that can be used early to improve quadriceps femoris strength is neuromuscular electrical stimulation (NMES).[9,13] In patients undergoing ACL reconstruction, NMES can be used to decrease arthrogenic muscle inhibition, help restore strength and minimize quadriceps femoris atrophy.[9,13,14]
To help maintain muscle mass, muscle stimulation is very important, but dietary intake should also be considered, especially protein intake, which stimulates the synthesis of muscle proteins.[15] Therefore, one intervention that may be used in association with NMES to help minimize strength loss and muscular atrophy due to short-term disuse is the administration of whey protein.
Whey protein is a nutritional supplement rich in essential amino acids, which are important for assisting in the stimulation of muscle protein synthesis and thus improve muscle strength and aid in the muscle hypertrophy process.[16] However, its use is not exclusive to those who are seeking muscular hypertrophy and its effect in regard to rehabilitation has only recently been studied.[17,18]
The aim of this study was to analyze the electromyographic activity of the rectus femoris, vastus lateralis and vastus medialis muscles and body mass distribution during a bipodal mini squat movement in volunteers who had undergone ACL reconstruction surgery and had taken NMES of the quadriceps femoris associated or not with whey protein. The authors hypothesized that the group receiving the whey protein intervention in association with NMES would obtain better results than the other groups of the study.

METHODS

This is a controlled randomized, blinded clinical trial that was approved by the Research Ethics Committee for research on human beings at the Federal University of Alfenas (opinion number: 1.940.399). This study was also registered in the Brazilian clinical trial registry (REBEC). Before participating in the study, all volunteers signed an informed consent form.
The volunteers were recruited at orthopedic clinics located in Alfenas-MG. Participants were recruited from October 2016 to June 2018. Eligibility candidates were those who presented rupture of the ACL and who were scheduled to undergo ACL reconstruction surgery. The inclusion criteria were: male volunteers aged 18 to 50 who presented a unilateral rupture of the ACL as verified by magnetic resonance imaging and who were scheduled to undergo ACL reconstruction. The exclusion criteria were: those with a history of lower limb surgery, renal disease, lactose intolerance or diabetes.
After an interview, the block randomization of eight volunteers was performed using a random number application by a trained researcher who was responsible for the interventions. Other researchers were responsible for assessing and analyzing the data early on when volunteers were allocated to their respective groups. However, due to the nature of the interventions, it was not possible to blind the therapist and the patients.
The sample consisted of 24 male volunteers who were divided into three groups: basal control (BC), whey protein supplementation in association with the NMES of the quadriceps femoris (WE), and the NMES of the quadriceps femoris alone (ES). The BC group was composed of volunteers who participated in evaluations only twice: a preoperative evaluation and a reassessment 15 days after surgery. The WE group was composed of volunteers who underwent both NMES and whey protein supplementation, taking a dose of 20 grams of whey protein in 250 ml of water as a vehicle. The ES group consisted of volunteers who underwent the NMES of the quadriceps femoris with only 250 ml of preintervention water administered. One researcher was responsible for performing the NMES intervention and giving whey protein or water to the volunteers. All groups were verbally oriented for immediate postoperative care, such as the use of cryotherapy and the initiation of gradual weight-bearing where the surgery was performed.
All groups underwent two evaluations performed at two different periods: a prior evaluation, approximately 7 days before the surgery (preoperative); and a reevaluation, 15 days after the surgical procedure (postoperative). For all groups, the evaluations were performed using an evaluation card, surface electromyography (sEMG) and baropodometry.

Evaluation procedures

Initially, an evaluation form was used where data such as age, body mass, height, body mass index (BMI) and mean time of injury were collected.

Surface electromyography (sEMG)

The sEMG is a non-invasive method for assessing skeletal muscle activity that verifies the electrical power of muscles.[19] This method can be used to evaluate the effectiveness of rehabilitation or physical exercise.[20]
For the electromyographic evaluation of the rectus femoris, vastus medialis and vastus lateralis muscles, the Trigno 8 Channel Wireless device (EMGworks, Delsys Inc., Boston, MA, USA) equipped with EMGworks 4.0 acquisition software was used.
The mode of acquisition of the electromyographic signals was calibrated at a sampling frequency of 1000 Hz with 1000-fold gain, a 20 Hz high-pass filter, 500 Hz low-pass filter and 60 Hz filter to prevent grid interference.
To reduce possible interference in the acquisition of the electromyographic signal, trichotomy and the cleaning of the skin with 70% alcohol were performed in the areas where the electrodes were placed, which were fixed to the volunteers' skin with double-sized tape. The electrodes were placed on the muscles as recommended by the European Society of Surface Electromyography (SENIAM).[21]
The electromyographic evaluation of the muscles was performed during a maximum voluntary isometric contraction (MVIC) and during a bipodal mini squat with eyes open and posteriorly with eyes closed. Five acquisitions were made for each condition lasting six seconds each and, between each collection, a 30-second interval was inserted. The electromyographic signal for the MVIC collected from the previously mentioned musculatures was taken against manual resistance, which was performed each time by the same evaluator. For the electromyographic collection of the MIVC, joint position was standardized for all volunteers, and they were seated with a 60-degree knee flexion.[22]
After the collection of the MVIC, data on the bipodal mini squat were collected. The volunteers were instructed how to perform the bipodal mini squat to reach a 30-degree knee flexion, and this angulation was demonstrated using a goniometer.
For the analysis and interpretation of the records, EMGWorks 4.0 analysis software was used to obtain root mean square (RMS) and peak parameters, which excluded the first and last second of the collection for a total of four seconds.
Gross sEMG data are often sensitive to a number of extrinsic and intrinsic factors.[23,24] Thus, the interpretation of gross sEMG data is subject to different challenges, indicating the need for a normalization process for these data.[22] For the normalization of the sEMG data during the bipodal mini squat, the value during the squat was considered with an sEMG reference value from the MVIC of same muscle, which was as follows:[25]

$$\text{Normalization} = \frac{\text{RMS bipodal mini squat}}{\text{RMS of MVIC}} \times 100$$

Baropodometry

A FootWork Pro baropodometer (IST-Informatique, France) was used to observe the distribution of body mass during the bipodal mini squat with eyes open and closed.
The volunteers were positioned in orthostatism on the platform with their feet equidistant. Static balance was assessed with eyes open and gaze focused on a wall two meters away to the front. Then, the mini squat movement was performed. Five repetitions were done with eyes open and then five with eyes closed. The collection time for each repetition was six seconds and, between each collection, a 30-second interval was given to avoid possible fatigue. The body mass data were acquired at an acquisition frequency of 100 Hz and then analyzed by the software FootWork Pro v. 3.2.2.0 (IST-Informatique, France).
Body mass distribution was analyzed on the anterior, posterior and injured and healthy limb regions as shown in Figure 1.

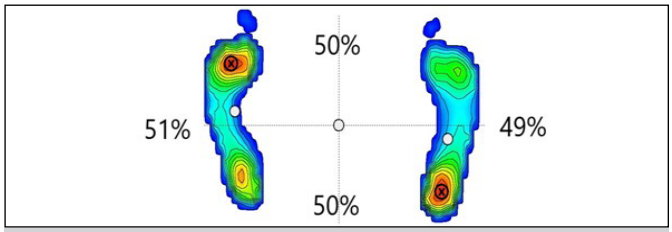

Figure 1. Distribution of body mass in the anterior, posterior, injured and healthy limbs.

Neuromuscular electrical stimulation (NMES)

For NMES, the Neurodyn High Volt device from Ibramed was used. The procedure was performed individually under the supervision of a trained researcher. The following parameters were used: a frequency of 50 Hz, 4-second rise time, 4-second descent time, ton of 5, and toff of 15. The current intensity in milliamperes was initially adjusted to the maximum tolerance of the individual that produced a contraction, which was increased according to the accommodation of the current. The total application time was 20 minutes. All volunteers performed three weekly applications with a one-day interval between for two consecutive weeks for a total of six procedures. The volunteers were seated, with a 90-degree flexion of the hips and knees. Four electrodes were placed on the quadriceps femoris muscle and two proximal and two distal to the muscle were positioned according to the previous location of the motor points of the vastus medialis and vastus lateralis muscles.

Whey protein supplementation

In total, 20 grams of whey protein of the Hilmar Ingredients® brand was dissolved in 250 ml of water. The volunteers ingested the whey protein after the NMES intervention. This 20-gram dose of whey protein is sufficient to stimulate the synthesis of muscle proteins in young individuals.[26,27]

Statistical analysis

The statistical analysis of the data was performed using SPSS software (IBM Corp., Chicago, IL, USA), version 20.0.
Initially the data were analyzed with descriptive statistical methods, obtaining values for mean and standard deviation. All data sets were tested for their normality using Shapiro-Wilk tests.
Then the variables of age, body mass, height, BMI and time of injury were analyzed using a one-way analysis of variance (ANOVA) test. For the categorical variable, the type of graft, a chi-square test was used. The other data from the study were submitted to a general linear model procedure using the repeated measures of ANOVA test followed by a Bonferroni test to verify the interaction between the groups (BC, WE and ES) with the pre- and postoperative evaluations. A 5% significance level was considered for all analyses. To calculate the effect size in ANOVA, f^2 Cohen was used as well as values from 0.02 to 0.15 (small effect), 0.15 to 0.35 (median effect), and above 0.35 (large effect).

RESULTS

Between October 2016 and June 2018, 47 volunteers were assessed for eligibility. Of these, 23 were excluded. The reasons for exclusion were being female (n = 3), over 50 years old (n = 2), less than 18 years old (n = 2), having a history of lower limb surgery (n = 3) and living in a different city (n = 13). At the end of the selection, 24 volunteers fulfilled the selection criteria and accepted to participate in the study. Then they were randomized and received an allocation into one of the three research groups. Figure 2 illustrates the flowchart of the study.

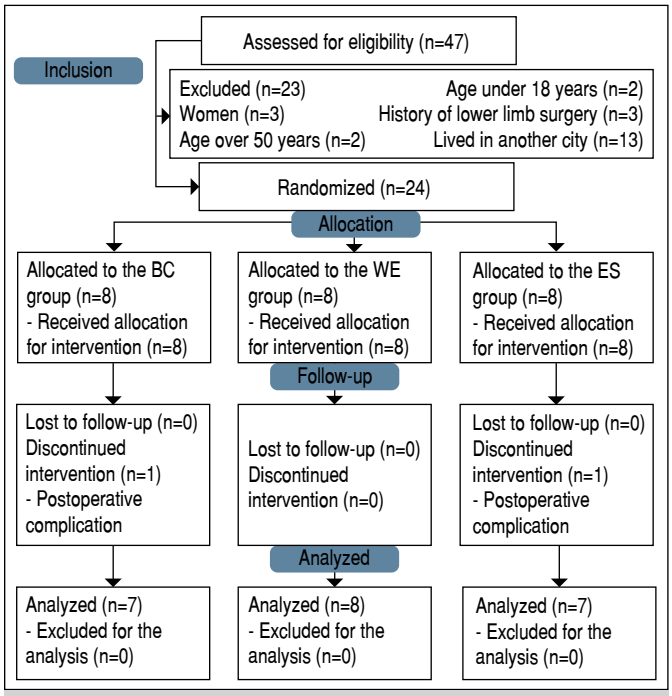

Figure 2. Abbreviations: BC, basal control group; WE, whey protein and neuromuscular electrical stimulation (NMES) group. ES, NMES group.

Table 1 shows data related to age, anthropometric characteristics, time of injury and the type of graft used in the surgeries. At the beginning of the study, we observed there were no significant differences between the groups for these variables.

Table 1. Mean values ± standard deviation of age, body mass, height, body mass index (BMI), time of injury, and type of graft used in the different study groups.

Variable		BC (n = 7)	WE (n = 8)	ES (n = 7)	P Value
Age (years)		27.71 ± 6.73	35.13 ± 8.77	32.29 ± 9.14	0.487
Body Mass (kg)		75.51 ± 4.96	85.50 ± 6.65	77.36 ± 10.50	0.070
Stature (m)		1.73 ± 0.05	1.79 ± 0.07	1.76 ± 0.05	0.180
BMI (kg/m^2)		25.32 ± 2.12	26.79 ± 1.41	25.18 ± 3.71	0.226
Mean Time of Injury(months)		10.71 ± 8.69	7.25 ± 6.25	13.00 ± 16.85	0.621
Type of Graft	GF(%)	5 (71.42%)	7 (87.5%)	6 (85.71%)	0.686
	GP(%)	2 (28.58%)	1 (12.5%)	1 (14.83%)	

Abbreviations: BC, basal control group; WE, whey protein and neuromuscular electrical stimulation (NMES) group; ES, NMES group; GF, graft with flexor tendon; GP, graft with patellar tendon.

Table 2 shows the normalized data from the electromyographic evaluation of the muscles in the injured lower limb during the bipodal mini squat with eyes open and closed.

Table 2. Normalized electromyographic analysis of the muscles of the injured knee during the bipodal mini squat with eyes open (EO) and closed (EC) among the different groups of the study in the pre- and postoperative evaluations.

Variable	Groups	PRE	POST	ANOVA p value			f^2
				Evaluation	Group	Evaluation*Group	
VM-EO	BC	45.85 ± 25.32*	16.37 ± 13.57	0.005	0.506	0.435	0.342
	WE	46.32 ± 23.45	32.86 ± 20.26				
	ES	50.96 ± 39.66	32.02 ± 27.10				
VL-EO	BC	52.42 ± 41.20*	23.30 ± 16.39	0.005	0.718	0.362	0.343
	WE	44.19 ± 24.92	31.55 ± 19.07				
	ES	54.75 ± 30.03	35.31 ± 26.78				
RF-EO	BC	55.01 ± 31.68	34.64 ± 25.29	0.075	0.146	0.349	0.157
	WE	57.39 ± 49.28	55.72 ± 47.70				
	ES	26.11 ± 16.03	18.96 ± 11.76				
VM-EC	BC	44.80 ± 22.65*	16.37 ± 13.57	0.003	0.251	0.526	0.385
	WE	44.82 ± 22.17	29.98 ± 21.71				
	ES	50.62 ± 38.46	33.14 ± 25.96				
VL-EC	BC	45.72 ± 41.43*	23.53 ± 16.28	0.020	0.559	0.722	0.254
	WE	44.72 ± 29.60	31.36 ± 19.09				
	ES	53.87 ± 30.63	35.25 ± 26.82				
RF-EC	BC	55.28 ± 37.60	30.49 ± 26.75	0.074	0.826	0.256	0.308
	WE	38.90 ± 28.84	35.43 ± 20.15				
	ES	44.89 ± 33.03	21.54 ± 16,92				

Abbreviations: f^2, effect size; VM, vastus medialis muscle; BC, basal control; WE, group that received whey protein in association with neuromuscular electrical stimulation (NMES) in the femoral quadriceps; ES, group that received only NMES in the femoral quadriceps; VL, vastus lateralis muscle; RF, rectus femoris muscle; * versus pre-evaluation, differs significantly based on the Bonferroni test ($p < 0.05$).

Based on these results, it is possible to verify that during the bipodal mini squat with eyes open, the BC group showed a decrease in the electromyographic activity of the vastus medialis ($p = 0.005$) and vastus lateralis ($p = 0.005$) muscles as compared to the initial evaluation. In the closed-eye analysis, the BC group also had a decrease in the electromyographic activity of the vastus medialis ($p = 0.003$) and vastus lateralis ($p = 0.020$) muscles in the postoperative evaluation as compared to the initial evaluation. The WE and ES groups did not demonstrate a significant decrease in the electromyographic activity of the vastus medialis and vastus lateralis muscles. It is possible to infer that NMES was effective in maintaining the electromyographic activity of these muscles during the mini squat movement. The other variables did not show significant differences.

Table 3 shows the normalized data from electromyographic evaluation of the muscles of the healthy lower limb during the bipodal mini squat with eyes open and closed. It can be observed there were no significant differences in the electromyographic activity of the evaluated muscles of the healthy limbs.

Table 3. Normalized electromyographic analysis of muscles of the healthy lower limb during the bipodal mini squat with eyes open (EO) and closed (EC) among the different groups of the study in the pre- and postoperative evaluations.

Variable	Groups	PRE	POST	ANOVA p value			f^2
				Evaluation	Group	Evaluation*Group	
VM-EO	BC	34.85 ± 24.34	41.15 ± 22.68	0.053	0.647	0.377	0.182
	WE	46.97 ± 21.48	59.12 ± 40.01				
	ES	39.99 ± 26.77	56.22 ± 29.47				
VL-EO	BC	38.12 ± 25.00	41.98 ± 26.34	0.250	0.547	0.259	0.069
	WE	48.26 ± 23.40	54.54 ± 24.32				
	ES	36.66 ± 26.47	53.31 ± 25.62				
RF-EO	BC	48.76 ± 43.49	73.53 ± 64.01	0.054	0.074	0.831	0.202
	WE	22.44 ± 13.14	38.79 ± 25.68				
	ES	23.83 ± 13.67	30.98 ± 20.63				
VM-EC	BC	34.72 ± 25.81	43.55 ± 21.29	0.087	0.777	0.241	0.241
	WE	48.28 ± 30.21	51.72 ± 35.44				
	ES	35.06 ± 31.09	54.58 ± 30.04				
VL-EC	BC	42.85 ± 30.90	39.47 ± 19.84	0.211	0.721	0.118	0.086
	WE	48.11 ± 25.59	52.03 ± 25.62				
	ES	27.97 ± 19.27	54.65 ± 35.04				
RF-EC	BC	29.41 ± 15.24	37.43 ± 18.25	0.080	0.618	0.685	0.160
	WE	36.62 ± 34.24	42.46 ± 31.11				
	ES	28.81 ± 15.51	46.97 ± 35.95				

Abbreviations: f^2, effect size; VM, vastus medialis muscle; BC, basal control; WE, group that received whey protein in association with neuromuscular electrical stimulation (NMES) in the femoral quadriceps; ES, group that received only NMES in the femoral quadriceps; VL, vastus lateralis muscle; RF, rectus femoris muscle.

Table 4 shows data regarding body mass distribution during the bipodal mini squat with eyes open and closed.

Table 4. Body mass distribution (%) of the injured and healthy limbs during the bipodal mini squat with eyes open (EO) and closed (EC) among the different groups of the study in the pre- and postoperative evaluations.

Variable	Groups	PRE	POST	ANOVA p value			f^2
				Evaluation	Group	Evaluation*Group	
IL-EO	BC	54.57 ± 6.90*	36.83 ± 11.62	< 0.001	0.178	0.533	0.610
	WE	45.60 ± 5.22	34.32 ± 8.77				
	ES	46.34 ± 5.68	34.45 ± 10.92				
HL-EO	BC	45.53 ± 6.90*	63.17 ± 11.62	< 0.001	0.173	0.499	0.603
	WE	54.92 ± 6.05	65.67 ± 8.77				
	ES	53.65 ± 5.68	65.54 ± 10.92				
ANT-EO	BC	46.96 ± 8.91	44.09 ± 12.64	0.334	0.002	0.781	0.049
	WE	61.60 ± 4.68†	58.37 ± 6.20†				
	ES	52.65 ± 8.64	52.68 ± 6.44				
POS-EO	BC	53.34 ± 8.91	55.91 ± 12.64	0.353	0.002	0.788	0.045
	WE	38.40 ± 4.68†	41.62 ± 6.20†				
	ES	47.34 ± 6.50	47.31 ± 6.44				
IL-EC	BC	53.62 ± 7.00*	37.20 ± 11.54	<0.001	0.312	0.653	0.594
	WE	48.00 ± 7.80	35.25 ± 9.35				
	ES	45.31 ± 6.50	34.68 ± 9.95				
HL-EC	BC	46.38 ± 7.00*	62.80 ± 11.54	< 0.001	0.694	0.677	0.690
	WE	52.00 ± 7.80	64.75 ± 9.35				
	ES	54.68 ± 6.50	65.60 ± 10.06				
ANT-EC	BC	50.25 ± 9.82	45.48 ± 11.42	0.224	0.023	0.787	0.077
	WE	60.07 ± 6.06†	58.15 ± 7.62†				
	ES	54.51 ± 9.28	53.20 ± 7.43				
POS-EC	BC	49.75 ± 9.82	54.52 ± 11.42	0.135	0.015	0.789	0.114
	WE	39.25 ± 5.45†	41.85 ± 7.56†				
	ES	45.58 ± 9.28	46.80 ± 7.43				

Abbreviations: f^2, effect size; BC, basal control group, WE, whey protein and neuromuscular electrical stimulation (NMES) group. ES, NMES group. IL; mass on the injured limb; HL, mass on the healthy limb; ANT, mass in the anterior region; POS, mass in the posterior region;
* versus pre-evaluation, differ significantly based on the Bonferroni test ($p < 0.05$).
† significant difference in relation to the BC group based on the Bonferroni test ($p < 0.05$).

Considering the results, we can observe that the volunteers in the BC group experienced a decrease in the body mass distribution of the injured limb during the bipodal mini squat with eyes open ($p < 0.001$) and closed ($p < 0.001$) in the postoperative evaluation as compared to the preoperative evaluation. This group also showed an increased body mass distribution in the healthy limb during the bipodal mini squat both with eyes open ($p < 0.001$) and closed ($p < 0.001$). The WE and ES groups showed no asymmetries in body mass distribution between the injured and healthy limbs, thus it is possible to infer that NMES was effective in treating this variable.
We observed in the pre- and postoperative evaluations that the WE and CB groups showed differences in the body mass distribution of the anterior and posterior regions during the bipodal mini squat with eyes open and closed. As compared to the BC group, the WE group showed a greater body mass distribution in the anterior region during the bipodal mini squat with eyes open ($p = 0.002$) and closed ($p = 0.023$) in the preoperative and postoperative evaluations and a lower body mass distribution in the posterior region during the bipodal mini squat with eyes open ($p = 0.002$) and closed ($p = 0.015$). Thus, we can verify that, for the anterior and posterior variables, the BC and WE groups differed in both evaluations.

DISCUSSION

This study evaluated the effects of the use of whey protein supplementation in association with NMES of the quadriceps femoris in patients who underwent ACL reconstruction surgery. Our hypothesis is that the group receiving the whey protein supplementation in association with NMES would obtain better results, since such interventions would stimulate muscle protein synthesis.
There are few studies that have considered the synergism use of NMES and protein supplementation. In the literature, only two studies considering these interventions together were found,[18,28] but neither evaluated the effect of NMES alone. Zange et al.[28] found that NMES in the soleus muscle in association with whey protein supplementation was effective in preserving leg muscle volume and, to a lesser extent, in maintaining the strength of the plantar flexors in healthy individuals who had used a brace in one leg 8–16 hours per day. Reidy et al.[18] found that NMES and protein supplementation were able to maintain lean mass, but there was no attenuation in the decline of muscle function and strength in resting older patients who remained in bed for five days. Although these studies have used interventions similar to those of our work, a comparison of the results is difficult due to differences in methodology and target populations.
Weakness of the quadriceps femoris muscle is a factor that negatively influences knee function and pain.[29] During the bipodal mini squat with eyes open, we observed that the volunteers of the BC group had a significant decrease in the electromyographic activity of the vastus medialis and vastus lateralis muscles of the injured limb, which did not occur in the other study groups. The use of NMES in association with rehabilitation during the initial phase after ACL reconstruction is effective in preventing atrophy,[9,14]

reducing loss of muscle strength in the quadriceps femoris,[9,13,24] assisting in strength recovery and quadriceps femoris symmetry,[14] and decreasing muscle inhibition.[11,9] NMES has been effective in maintaining the electromyographic activity of the vastus medialis and vastus lateralis muscles during voluntary activities such as the bipodal mini squat since it is capable of acting as a disinhibitory and activating tool for the quadriceps femoris muscle.[11]

Although there are many studies related to the use of NMES in patients after ACL reconstruction, there has been a great variability in the parameters and protocols used, making it difficult to compare results.[9,13] However, most studies agree on the intensity used, which has been described as the maximum that may be tolerated by the patient.[9,13] Thus, this parameter was adopted in this study.

The evaluation of body mass distribution in dynamic movements provides important information about the asymmetry of loads in injured and healthy limbs.[30] In the analysis of the bipodal mini squat with eyes open and closed, the BC group demonstrated a higher concentration of mass on the healthy limb and a consequent decrease in the injured limb. We believe = this compensatory mechanism was due to kinesiophobia, but we did not evaluate this variable. Other groups did not present this same mechanism. It is probable that NMES alone or in association with whey protein supplementation favored the obtained responses since it is capable of acting as a source of disinhibition by restoring the function of the quadriceps femoris muscle.[11]

When analyzing the anterior and posterior body mass concentrations of the volunteers, we observed that those belonging to the BC and WE groups differed significantly in both evaluations. This may have occurred due to the randomization process adopted by the study randomly selecting subjects with higher body mass distribution concentrations in the anterior region for the WE group. It is important to emphasize that body mass distribution should be established as soon as possible, as patients undergoing ACL reconstruction surgery tend to show a reduction in bone mineral density in the hip region, and this is a risk factor for other lesions.[31]

This study has some limitations that should be considered. First, it has a relatively small sample, so care must be taken when interpreting and generalizing the data. Another limitation is that there was no diet control for the volunteers. The dose and frequency of protein supplementation may also be considered a limitation. In addition, it was not possible to blind the volunteers.

CONCLUSION

In conclusion, in the sample of this study, we observed the early use of NMES of the quadriceps femoris muscle, regardless of whey protein supplementation, maintained the electromyographic activity of the vastus medialis and vastus lateralis muscles of the injured limb during the mini squat movement and prevented asymmetries in body mass distribution approximately 15 days after ACL reconstruction surgery.

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TREATMENT OF TRIPLANE FRACTURE ANKLE FRACTURES ASSOCIATED WITH IPSILATERAL TIBIAL FRACTURES USING A NOVEL APPROACH

FRATURA TRIPLANAR DO TORNOZELO CONCOMITANTE A FRATURA IPSILATERAL DA TÍBIA. UMA NOVA ABORDAGEM

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ABSTRACT

Objective: The aim of this study is to purpose a novel approach to the concomitant triplanar and tibial shaft fracture. Methods: Retrospective study between 2001 and 2019. We collected the patients' general information, clinical and radiographic data, and complications after the following three-step treatment: (1) fixation of the Salter-Harris II fracture of the triplane fracture, (2) fixation of the Salter-Harris II/IV fracture with cannulated screws, and (3) fixation of the tibial fracture with flexible titanium nails. Results: The study included seven patients (six males) with a mean age of 14 years and a mean follow-up of 6.4 years (minimum two years). Five triplane fractures had two fragments and two had three fragments. Five fractures were classified as Salter-Harris II and two as Salter-Harris IV. Three tibial fractures were long oblique, three were spiral, and one had a third fragment. Six fractures affected the middle third and one affected the distal third of the tibia. All triplane and tibial fractures consolidated without significant displacement. No physeal damage was identified. Conclusions: This study described the association of tibial fractures with triplane ankle fractures managed by our proposed treatment, which proved to be effective for this fracture association. ***Level of Evidence IV, Case Series.***

Keywords: Tibial Fracture. Ankle Fracture. Fracture Fixation, Internal. Salter- Harris Fractures.

RESUMO

Objetivo: Propor uma nova abordagem para fraturas concomitantes da diáfise da tíbia e triplanares do tornozelo. Métodos: Estudo retrospectivo entre 2001 e 2019. Foram coletadas informações gerais: dados clínicos, radiográficos e complicações. As fraturas seguiram três passos no tratamento: (1) fixação do fragmento Salter-Harris tipo III da fratura triplanar; (2) fixação do fragmento Salter-Harris II/IV com parafuso canulado; e (3) fixação da fratura diafisária da tíbia com hastes flexíveis. Resultados: O estudo incluiu sete pacientes (seis homens) com idade média de 14 anos e seguimento médio de 6.4 anos (mínimo de dois anos). Cinco fraturas triplanares tinham dois fragmentos principais e duas tinham três fragmentos. Cinco fraturas na radiografia em perfil foram classificadas como Salter-Harris II e duas como Salter-Harris IV. Três fraturas diafisárias tibiais tinham traço obliquo longo, três traço espiral e uma fratura com terceiro fragmento. Seis fraturas eram do terço médio e uma fratura do terço distal da tíbia. Todas as fraturas triplanares e tibiais consolidaram sem desvio significativo e não tivemos nenhuma lesão fisária. Conclusão: O estudo descreveu a associação da fratura da tíbia com a fratura triplanar do tornozelo e nossa proposta de tratamento, que se mostrou uma boa opção no tratamento dessa fratura especial. ***Nível de Evidência IV, Série de casos.***

Descritores: *Fratura Tibial. Fratura de Tornozelo. Fixação interna de Fraturas. Fratura Salter Harris.*

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INTRODUCTION

The tibia is the third long bone most frequently affected by fractures at any age during childhood and adolescence. The distal third is the most commonly involved tibial portion, followed by the middle third. Regarding the type of fracture line, the most prevalent is the oblique line, followed by multifragmented fractures and fractures with transversal lines; the spiral fracture line is the least common. The most frequent fractures associated with tibial fractures are ankle fractures.[1]

Most tibial fractures are adequately treated with a conservative approach using long-leg casting, but closed reduction may be required in the presence of displacement. Surgical treatment is recommended in open fractures, polytrauma patients, "floating"

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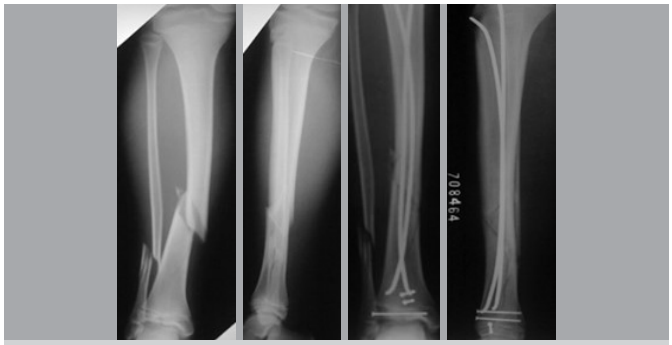
knee, loss of reduction, irreducible fractures, or in cases associated with other fractures in the same segment.
Triplane ankle fractures are infrequent, corresponding to 7% of all ankle fractures according to Spiegel et al.[2] These fractures occur during adolescence, due to the characteristic asymmetric closure of the tibial physeal plate in this age group, which starts from the central portion of the plate and extends to the posteromedial and anterolateral aspects of the plate.
Cooperman et al. described the mechanism of trauma involved in triplane fractures as "twisting in external rotation".[3] These fractures are usually characterized by the presence of Salter-Harris type III epiphyseal fracture-detachment in anteroposterior radiographic views and type II or IV fractures in lateral views. Triplane fractures have several subtypes with two, three, or four fragments and are described as intramalleolar or extramalleolar; however, all subtypes follow the same configuration pattern described above.[4] Fractures with a displacement of up to 2 mm are generally treated conservatively, whereas those with larger displacements must be reduced and, if possible, undergo fixation.[5]
The association of triplane fractures with ipsilateral tibial fractures is uncommon, occurring at an incidence of 8.5%, according to Rapariz et al.[6]
This study aims to report the infrequent association of triplane fractures and ipsilateral tibial fractures and analyze the outcomes after treatment with a novel protocol adopted at our institution.

MATERIALS AND METHODS

This was a retrospective analysis of medical records level IV, of patients with triplane ankle fractures associated with ipsilateral tibial fractures, treated at a tertiary trauma hospital between January 2001 and January 2019, and with a minimum follow-up of 2 years. We collected information regarding the patients' sex and age, mechanism of trauma, fracture classification (with the triplane fractures described considering the number of fragments and the tibial fractures according to the fracture line and location) and initial deviation of the triplane fracture by axial computerized tomography. Data regarding clinical and radiographic results and complications were obtained from the patients' medical records.
All patients underwent surgery following the same three-step technique protocol:
First step: treatment of the triplane fracture with closed reduction and percutaneous fixation of the Salter-Harris III fracture visualized in the anteroposterior view with a cannulated screw from a lateral to a medial direction to correct the joint deviation.
Second step: fixation of the Salter-Harris II or IV fragment visualized in the lateral view with one or two percutaneous screws positioned from an anterior to posterior direction.
Third step: fixation of the tibial fracture with two titanium flexible intramedullary nails from a proximal to a distal direction, C-shaped, one introduced laterally and the other medially at the proximal tibial metaphysis (Figures 1, 2, 3, 4).



Figures 1, 2, 3 e 4: Pre and postoperative x-rays, association of tibial and triplane fracture treated with titanium elastic nail for tibial and cannulated screws for triplane fractures.

Post-operative care: No orthesis such as splint or cast were used in any case. The patients could parcial weight bear (touchdown) during the first four weeks. Progressive weight bearing was allowed from the fourth week to total weight bearing after fracture union. The exclusion criteria were patients with incomplete medical records or tibial physeal closure, and those treated with a different surgical technique than the one described above.
The study was approved by the Research Ethics Committee (CAAE: 13435519.4.0000.5525) according to the National Health Council Resolutions 196/96 and 251/97.

RESULTS

Between January 2001 and January 2019, seven skeletally immature patients with triplane fractures associated with ipsilateral tibial fractures were treated following the steps detailed in the proposed protocol.
Six patients were males, and one was female, and the mean age of the cohort was 14 years old (range 13 to 16 years old). The fractures resulted from trauma associated with car (three cases) and bicycle (one case) accidents, and soccer (two cases) and basketball (one case) activities. The mean follow-up was 6.4 years (range 2 to 12 years).
Among the triplane fractures, five had two fragments (one of which was intramalleolar) and two had three fragments. On lateral x-rays, five fractures were classified as Salter-Harris II and two as Salter-Harris IV.
Among the tibial fractures, three were long oblique, three were spiral, and one had a third fragment. Six fractures were in the middle third and one in the distal third of the tibia (Table 1).

Table 1: General dates from pacients in this study.

Patient	Gender	Age	Mechanism of trauma	Tibial fracture type	Triplane fracture	Follow up
1	Male	13	Soccer	Long oblique	2 fragments	3 years
2	Male	15	Bicycle accident	Spiral	2 fragments	5 years
3	Male	13	basketball	Long oblique	3 fragments	7 years
4	Male	14	Car accident	Spiral	3 fragments	2 years
5	Male	14	Car accident	Third fragment	2 fragments	6 years
6	Female	13	Soccer	Long oblique	2 fragments	12 years
7	Male	16	Car accident	Spiral	2 fragments	10 years

All triplane and tibial fractures consolidated. The final radiographic control showed no varus, valgus, antecurvatum, or recurvatum deformities greater than 5 degrees in the tibial fractures. In triplane fractures, we identified no physeal injuries or ankle joint deviations. During follow-up, one patient complained of ankle pain and edema during physical activities.
All flexible nails were removed as soon as the fractures were completely consolidated in at least three cortical surfaces and the integrity of the medullary cavity was recovered. No refractures of the tibial diaphysis were observed. The cannulated screws of the triplane fractures were not removed in any of the patients.

DISCUSSION

Isolated triplane ankle fractures are not common in childhood, but are well established and described. In contrast, their association with ipsilateral tibial fractures, which is quite unusual, has been reported in few studies. In our literature search, we found only five studies describing this association, with the largest

series, including six patients.[7-11] Despite the infrequency of this association, more studies are needed to compare treatments and establish the best approach.

Kasture and Azurza,[12] in a case report and literature review, described that those tibial fractures may be oblique or spiral (suggesting a twisting injury), while triplane fractures also result from traumas with this type of mechanism, postulating that the trauma extends distally from the leg to the ankle. These authors also point out that if the trauma started at the ankle and continued to the tibia, the displacement of the triplane fracture would be greater than that usually observed. The authors also suggest that the trauma involves greater energy to result in fracture of both the tibia and ankle. The fractures found in our patients confirms the description of these authors.

The same authors recommend that a concomitant ankle fracture should be excluded with radiographic evaluation in adolescents with spiral or oblique tibial fractures, an important precaution to ensure that no injury is left unnoticed.

The first treatment step was the fixation of the Salter-Harris type III fragment visualized in the anteroposterior view; if the patients had a displacement of 2 mm or more, this initial displacement could be treated with closed reduction and percutaneous fixation with a cannulated screw.

The option to start the treatment at the ankle instead of the tibia was based on our concern that the manipulation or fixation of the tibial fracture could increase the displacement of the triplane fracture, transforming a fracture with little displacement into a displaced fracture requiring open reduction.

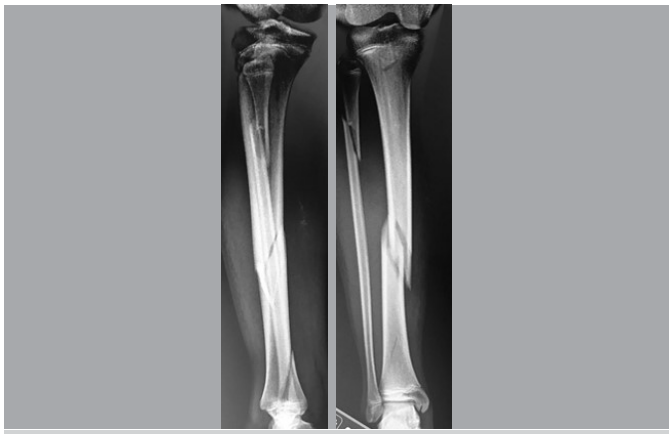
The second step was the fixation of the Salter-Harris II or IV fragment, with one or two cannulated screws from an anterior to a posterior direction, as customarily done in the treatment of isolated triplane fractures.

The third step included closed reduction and fixation of the tibial fracture with flexible titanium nails, a step that could be performed without risk of affecting the ankle fracture.

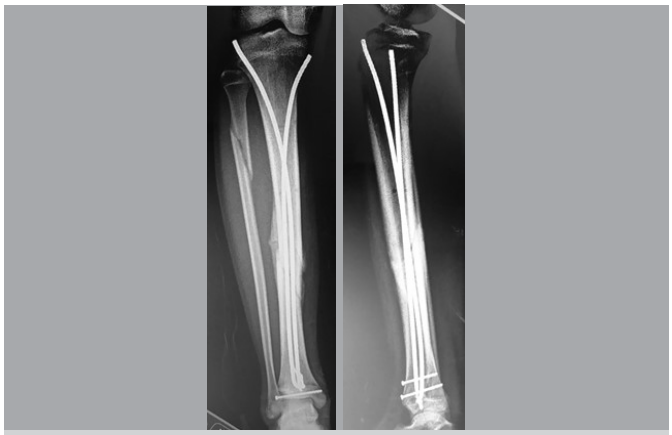
In general, tibial fractures in children are treated conservatively. However, there is a trend in the literature towards the surgical approach in cases of fractures affecting teenagers, open fractures, highly dislocated fragments, polytrauma and concomitant or associated fractures. There is no gold-standard method of fixation of tibial fractures in children. Several options have been described in the literature, each one presenting their own advantages and downsides. Reports show shorter operative times and lower rates of wound complications when the tibial shaft fracture is fixed with a titanium flexible intramedullary nail.[13,14]

In cases of tibial fractures associated with triplane ankle fractures, studies in the literature describe many treatments for the tibial fracture, and fixation of cannulated screws for the triplane fractures. Holland et al. treated four tibial fractures with closed reduction and casting and one with external fixation[15] Kasture and Azurza performed a minimally-invasive percutaneous 3.5 mm locking plate fixation to treat the tibial fracture.[12] Sprenger De Rover et al. treated the tibial fracture with closed reduction and fixation with plate and screws,[16] whereas Jarvis and Miyanji treated tibial fractures with cast immobilization.[17] Cuzmar-Grimalt et al. treated both the tibial and fibular fractures with locking plates.[7]

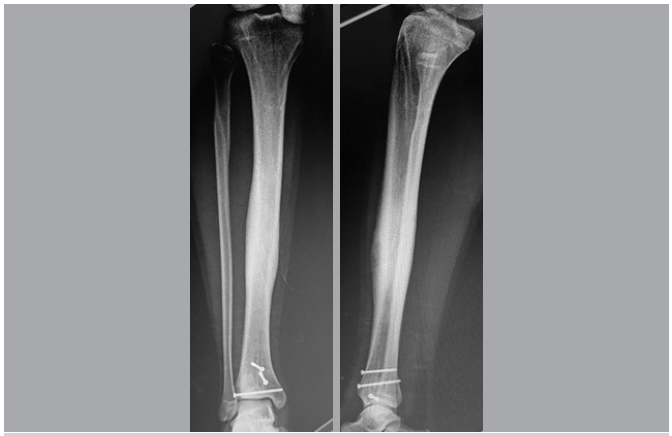
Different than the approach in these five studies, we treated the tibial fractures in our patients with flexible titanium nails. Advantages of these nails include percutaneous insertion, good stability and alignment, satisfactory cosmetic results, and facilitation of soft tissue care. However, removal of the nails is usually required, and in our study, all nails were removed (Figures 5, 6, 7, 8, 9, 10).



Figures 5, 6: Association of tibial and triplane fracture.



Figures 7, 8: One month after titanium elastic nail for tibial and cannulated screws for triplane fractures.



Figures 9, 10: After titanium elastic nail removal.

As limitation, we cite the retrospective nature of our study and the small size of the sample. As a major strength, the fact that all patients were treated following the same protocol.

CONCLUSIONS

Our study described the association of tibial fractures with triplane ankle fractures treated with a novel protocol comprising initial fixation of the triplane ankle fracture with cannulated screws followed by fixation of the tibial fracture with flexible titanium rods. This approach proved to be effective in the treatment of this fracture association.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. WRV: study conception and design, study writing, review and critical review, surgeries, data and statistical analysis; JCB: study conception and design, study writing and review, data collection and analysis, statistical analysis; JFS: surgeries, study review, data analysis, final approval of the manuscript to be published; CSU: surgeries, study writing and review; CUM: study writing and review, data collection and analysis, statistical analysis.

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KNEE INJURIES PREVALENCE IN BRAZILIAN JIU-JITSU: EPIDEMIOLOGICAL STUDY

PREVALÊNCIA DE LESÕES DO JOELHO NO JIU-JITSU BRASILEIRO: ESTUDO EPIDEMIOLÓGICO

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ABSTRACT

Objective: To evaluate the epidemiological and clinical characteristics of knee injuries in Brazilian Jiu-Jitsu (BJJ) practitioners. Methods: Cross-sectional study, using a mixed questionnaire, based on the Referred Morbidity Index. Results: 198 amateur and professional BJJ fighters, of both sexes, aged between 18 and 60 years, participated in the study. The majority (88%) of the fighters had only one knee injury ($p < 0.001$). In total, 29.8% proportion of knee injuries ($p < 0.001$) was identified, which were mainly from the medial collateral ligament (38%), caused by a sprain mechanism (86%) and conservative treatment (65%). Conclusion: A high prevalence of knee injuries in JJB fighters was found, compared to other sports that also perform rotational movements and have great body contact, such as mixed martial arts (MMA), judo, soccer, basketball and handball. Some JJB strikes, such as the key and the projection, can cause greater knee joint stress, both in the attacking fighter and in the opponent. The knowledge of the epidemiological characteristics of sports injuries is important in the elaboration of prevention and training protocols more specific to the sport and for the understanding of the complex mechanisms involved with this outcome in sport. ***Level of Evidence IV, Case Series.***

Keywords: Martial Arts. Knee. Injuries to Athletes. Knee Injuries.

RESUMO

Objetivo: Avaliar as características epidemiológicas e clínicas das lesões no joelho de praticantes de jiu-jitsu brasileiro (JJB). Métodos: Estudo de desenho transversal, por meio de questionário do tipo misto, baseado no Índice de Morbidade Referida. Resultados: Participaram 198 lutadores amadores e profissionais de JJB, de ambos os sexos, com idades entre 18 e 60 anos. A grande maioria (88%) dos lutadores apresentou apenas uma lesão no joelho ($p < 0,001$). Observou-se proporção de 29,8% de lesões no joelho ($p < 0,001$), que foram principalmente do ligamento colateral medial (38%), causadas por mecanismo de entorse (86%) e de tratamento conservador (65%). Conclusões: Observou-se alta prevalência de lesões no joelho em lutadores de JJB, comparativamente a outros esportes que também realizam movimentos rotacionais e têm grande contato corporal, como as artes marciais mistas (MMA), o judô, o futebol, o basquetebol e o handebol. Alguns golpes do JJB, como a chave e a projeção, podem causar maior estresse articular no joelho, tanto no lutador que ataca quanto no oponente. O conhecimento das características epidemiológicas das lesões esportivas é importante na elaboração de protocolos de prevenção e treinamento mais específicos à modalidade e também para a compreensão dos mecanismos complexos envolvidos com esse desfecho no esporte. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Artes Marciais. Joelho. Traumatismos em Atletas. Traumatismos do Joelho.*

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INTRODUCTION

Jiu-Jitsu is a martial art that has undergone an important development process since it started in Brazil, just over a century ago, which culminated in the emergence of Brazilian Jiu-Jitsu (BJJ).[1] These modifications were mainly based on stimulating of ground fighting through submission strategies characteristic of this modality.

In BJJ combat, athletes perform intermittent efforts and complex body movements, such as arm lock (Figure 1a) and projection (Figure 1b).[2] During the execution of these maneuvers, greater

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

The study was conducted at Federal University of Triângulo Mineiro, Research Group on Human Performance and Sport.
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joint stress can occur in the different axes of movement, especially in the knees, and this may be one of the triggering factors in the appearance of injuries.

Therefore, BJJ practitioner needs specific physical aptitudes[3,4] and biomechanical components suitable for their joint homeostasis.[5] These requirements are also present in other sports, especially those involving rotational movements and great body contact, such as soccer, handball and basketball.[6-8]

Studies have shown that sports injuries occur due to factors that interact through complex biological systems.[9] Initially, to understand these interactions, studying the epidemiological factors involved in sports injuries is essential. Through this, it is possible to understand the interactions between these factors and, consequently, the adoption of more specific protocols for the prevention of injuries in the sports field.

This study aimed to evaluate the epidemiological and clinical characteristics of knee injuries in BJJ fighters and to compare these segment injuries in other sports.

Figure 1: BJJ strikes, known as arm lock (A) and projection (B).

MATERIAL AND METHODS

This is a Cross-sectional study approved by the Research Ethics Committee of the Federal University of Triângulo Mineiro (nº 3636261/2019; CAAE 22824619.1.0000.5154). In the period from December 2019 to March 2020, 217 professional athletes and amateurs practicing BJJ answered a mixed questionnaire, based on the concepts of the Referred Morbidity Instrument.[10] All participants signed an informed consent form.

The study included participants of both sexes, aged 18 to 60 years, who have been practicing BJJ for at least six months and linked to academies registered at the Brazilian Confederation of Jiu-Jitsu. The exclusion criterion was filling out the questionnaire incorrectly or incomprehensibly.

Musculoskeletal injury was considered as any loss or traumatic event that results from a JJB training or competition and causes total removal from training or other external routines for more than one week, changes from normal training activities in volume or intensity for more than two weeks, and/or any physical complaint severe enough for seeking medical attention to diagnose or treat an injury.[11]No upper limit on the number of injuries reported by the fighter was imposed. The period of three years prior to the study was used to analyze the injuries presented by the participants.

The injuries reported in the knee segment were divided according to the fighter's epidemiological characteristics, the mechanism of trauma, the types of injuries, the degree of severity and the treatment performed.

Statistical analysis

Data were processed using Excel® and SigmaStat® 2.0 (GraphPad Software Jandel, SPSS, Chicago, IL, USA). The data were reported using descriptive and analytical statistics. For the analysis of qualitative bivariate or multivariate variables, the chi-square test was used, and for the equality test of two proportions, univariate qualitative variables was used. Values of $p < 0.05$ were considered significant.

RESULTS

In total, 198 fighters participated in the study (9% exclusion rate). Among the participants, 50 (25%) had some knee injury; the most (88%) had only one injury. The prevalence of knee injuries in training was 0.26 injuries per hours of BJJ workout / athlete / year (Table 1).

Table 1. General characteristics of injuries among the JJB fighters participating in the study.

		n/%	p-value
Injured JJB fighters	Yes No	105/53% 93/47%	0.23
JJB fighters with knee injuries	1 injury 2 injuries ≥ 3 injuries	44/88% 5/10% 1/2%	Ref. < 0,001 < 0,001
Prevalence of knee injuries (1.000 training hours/ athlete/year)	Training hours/year Total knee injuries in training Prevalence (1.000 training hours/athlete/year)	63.128 hours 49 0.26	–

No significant differences in knee injuries were found regarding some characteristics of the fighter, such as sex, age, graduation level, training floor, injury moment, practice of another sport, BJJ training time, BJJ weekly workout and acting as BJJ teacher. The absence time due to these injuries was over four weeks ($p < 0.001$) (Table 2).

Table 2. Qualitative characteristics of knee injuries in JJB fighters.

		Knee injuries (n/%)	Total injuries (n/%)	p-value
Sex	Male Female	54/95% 3/5%	177/93% 14/7%	0.5
Age group (years)	18-29 ≥ 30	18/32% 39/68%	52/27% 139/73%	0.37
Tracks	White Blue Purple Brown Black	5/9% 14/24% 9/16% 13/23% 16/28%	24/12% 54/28% 41/21% 32/17% 40/22%	0.16
Training floor	Synthetic Canvas	35/61% 22/39%	128/67% 63/33%	0.16
Injury timing	Training Competition	49/86% 8/14%	173/90% 18/10%	0.15
Fighter practices another sport?	Yes No	40/70% 17/30%	133/70% 58/30%	0.87
JJB practice time (years)	< 2 2-4 ≥ 4	7/12% 11/19% 39/69%	23/12% 33/17% 135/71%	0.87
Number of training sessions/week (days)	≤ 3 > 3	16/28% 41/72%	63/33% 128/67%	0.32
BJJ Teacher	Yes No	13/23% 44/77%	44/23% 147/77%	0.95
Time off sport (weeks)	≤ 1 ≤ 2 ≥ 4	1/2% 9/16% 47/82%	38/20% 42/22% 111/58%	< 0.001
Total	–	57/100%	191/100%	–

Regarding the main musculoskeletal injuries shown by fighters, 29.8% of them occurred in the knee joint ($p < 0.001$) (Table 3).

Table 3: Location of the four main sites of musculoskeletal injuries of JJB fighters.

Injury Site	n	%	p-value
Knee	57	29.8%	Ref.
Shoulder	34	17.8%	0.006
Ankle/Foot	25	13.1%	< 0.001
Wrist/hand	18	9.4%	< 0.001

The main mechanism of knee injuries in BJJ fighters was the sprain (86%) (Table 4). On the other hand, the most common ligament injury was the medial collateral ligament (MCL), with 38% of cases, followed by the lateral collateral ligament, with 19% of cases ($p = 0.02$) (Table 5). In 65% of the cases, the injuries were conservatively treated ($p < 0.001$) and, for the cases that required surgery, the most performed was simple knee arthroscopy (Figure 2).

Table 4. Mechanism of knee injuries in JJB fighters.

Injury mechanism		n/%	p-value
Sprain		49/86%	Ref.
Bruise		1/2%	< 0.001
Anterior knee pain	– Patellofemoral syndrome – Patellar tendinopathy	2/3% 4/7%	< 0.001
Fracture		1/2%	< 0.001
Total		57/100%	–

Table 5. Types of injuries after knee sprain, in JJB fighters.

Lesion	n/%	p-value
MCL	19/38%	Ref.
Meniscal/Condral	17/34%	0.76
LCL	9/19%	0.02
ACL	3/6%	< 0.001
PCL	1/3%	< 0.001
Total	49/100%	–

MCL: Medial collateral ligament; LCL: Lateral collateral ligament; ACL: Anterior cruciate ligament; PCL: Posterior cruciate ligament.

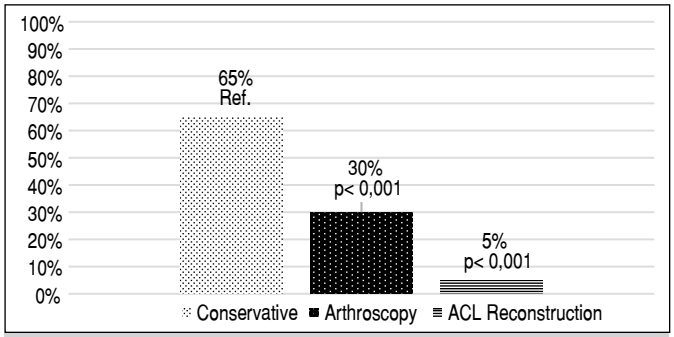

Figure 2. Treatment of injuries that occurred in the knee joint (in percentage).

DISCUSSION

This study showed a high proportion of knee injuries (29.8%) in BJJ practitioners, compared to other sports.[6-8,12,13] We emphasize the auxiliary nature of this measure for the elaboration of prevention protocols increasingly specific, based on the technical characteristics of the modality and the epidemiological nature of the injuries. The factors knowledge involved with the appearance of sports injuries, through epidemiological studies, is the first step towards understanding the complex interactions that involve this outcome in sport.[9]

This study indicates that the BJJ presented greater prevalence of injuries when compared with other martial arts and in other sports. Lystad et al.,[12] in a systematic review that assessed injuries in mixed martial arts (MMA), found an average proportion of 5.7% of knee injuries, over an average period of 3.5 years of evaluation. Akoto et al.[13] analyzed the injuries (which required more than a three-week leave) that occurred in 4,659 athletes practicing of judo, by an online questionnaire available for 90 days and found a frequency of 22.4% for the knee segment. Regarding other sports, which also involve rotational knee movements and great body contact, average proportions of 16% are observed in soccer,[6] 12% in handball[7] and 17% in basketball.[8]

Regarding BJJ, we identified varied data, mainly due to the different methodologies these studies. Moriarty et al.,[14] in a study with 1,287 adult athletes practicing Jiu-Jitsu, of both sexes, with a six-month follow-up, considered the concept of injury similar to that adopted in this study, in addition to not considering the skin as lesion topography. However, they considered injuries to the skull and face and analyzed a period of six months, with the finding of a 20.8% incidence of knee injuries.

McDonald's et al.[15] found a 9.2% proportion of knee injuries in a study with 140 Jiu-Jitsu practitioners of both sexes, over a 12-month period. However, this author was less comprehensive regarding the definition of injury and also considered injuries in regions of the skull, face and skin. If we considered only orthopedic injuries, this prevalence would be 10.8%.

Machado et al.[16] performed a study with 265 male competing athletes and evaluated the injuries that occurred in both training and in competition, with 28.4% of them on the knee. However, a very comprehensive criterion for the concept of injury was used, without even considering the need to withdraw from sport, which obviously causes an increase in this prevalence.

Scoggin et al.,[17] in a study that evaluated the incidence of injuries that occurred in world specialty championships (2,511 fights), all through medical diagnosis, over a period of seven years, observed a proportion of 19.4% of injuries in the knee (ranked second in the prevalence of injuries in this study).

The technical characteristics of the BJJ are represented by strokes that cause increased knee joint stress, both rotational and translational, and this is a major factor for the occurrence of injuries in this joint. These strokes are characterized mainly by blocking the joint in extension, through the articular keys, which cause high rotational torque according to the increase of the lever arm in the movement.

The leg lock is a submission maneuver in which the opponent suffers a high stress in knee hyperextension, which can predispose mainly to the occurrence of ligament injuries (anterior cruciate ligament and posterior cruciate ligament). On the other hand, when the fighter performs the arm lock attack, he gets high knee rotational stress. Another very common blow in the BJJ are the projections, which are also very likely to trigger knee injuries, either when the strike by the attacking fighter (lower support member) occurs or at the time of the defense attempt by the opposing athlete (at the moment of the fall, when performing ground support with the lower limb). All of these strokes are characterized mainly by the sprain injury mechanism, as was identified in this study and in others with similar methodologies.[17,18]

The projections are characterized by a predominance of stress in the valgus of the knee, with an increased chance of lesions of the MCL and medial meniscus. In this study, a predominance of injuries to the medial compartment of the knee (38%) was detected. However, varus stresses are also prominent among knee injuries in the JJB. Scoggin et al.[17] found a 57% prevalence of injuries to the lateral compartment, among the knee injuries observed in their study. Temponi et al.,[19] in a study that evaluated 27 athletes in the acute phase after knee sprain in the JJB practice, found a proportion of 25.9% with combined injuries of the lateral collateral ligament and anterolateral ligament complex.

In this study, most knee injuries occurred in isolated episodes and were of conservative treatment, however they demanded a high recovery time and return to sport (period equal to or greater than four weeks). Regarding of MCL injuries, which were the most common in this study, it is known that those originating from sports practice are characterized mainly by being of low or moderate degrees, conservative treatment and requiring an average recovery time of four weeks to six weeks, according to the rehabilitation protocol.[20]

In general, studies that address the occurrence of injuries in sports have different methodologies, such as regarding the concept of injury, the specific type, the analyzed period, among other factors that hinder the comparison between studies. In our study, we decided to use a questionnaire with a limit of three years, aiming to reduce the recall bias and, at the same time, not being a very short period of analysis. Moreover, the average time of BJJ practice of the athletes analyzed was 5.02 years, which is a factor favorable to the period of analysis that was stipulated in the study.

The cross-sectional design and the potential recall bias are the major limitations of the study. Besides, not all participants had their injuries diagnosed by a specialist doctor and/or by imaging exams. Another fact that deserves to be emphasized is the gender bias, which occurs in practically all studies with martial arts, which are practiced by a great predominance of male athletes.

CONCLUSION

The proportion of knee injuries observed in this study was higher than that of other sports that perform movements similar to those of the JJB. This knowledge is important in the elaboration of injury prevention and training prescription protocols that are increasingly specific to the sport, as already adopted in other sports, such as football.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. JMJE: writing, drafting the database, carrying out the statistical analysis, reviewing and approving the final version of the manuscript; ALR: sending the questionnaires and preparing the database; PD: writing the work and reviewing the intellectual content; CCK: essay writing and review of intellectual content; OBN: review and approval of the final version of the manuscript. All authors reviewed and approved the final version of the manuscript.

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HETEROTOPIC OSSIFICATION IN ACETABULAR FRACTURES: SYSTEMATIC REVIEW AND META-ANALYSIS OF PROPHYLAXIS

OSSIFICAÇÃO HETEROTÓPICA NAS FRATURAS DO ACETÁBULO: REVISÃO SISTEMÁTICA E METANÁLISE DA PROFILAXIA

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ABSTRACT

Objective: Heterotopic ossification is defined as the formation of trabecular bone in soft tissues. It is a common complication after surgical treatment of acetabular fractures. However, its prophylaxis and treatment are still controversial. The objective of this research is to evaluate the effectiveness of actions to prevent the development of heterotopic ossification after surgical correction of acetabular fractures. Methods: A systematic review was carried out with research in the databases PubMed/MEDLINE, Embase, LILACS and Cochrane until August 4, 2020, without restrictions on language and year of publication. Only randomized clinical studies carried out in humans without restrictions based on the dosage of treatments, use and duration of prophylaxis were included in this review. Results: Two studies compared the use of radiotherapy and indomethacin and three compared the use of indomethacin with a placebo or non-indomethacin group. The meta-analysis calculations did not indicate statistical differences between radiotherapy versus indomethacin (RR 1.45, IC 95% 0.97 to 2.17, p = 0,55) and indomethacin versus placebo or not indomethacin (RR 0.85, IC 95% 0.68 to 1.06, p = 0,59). Conclusion: There is insufficient evidence to affirm that the use of radiotherapy or indomethacin are effective to prevent the formation of heterotopic ossification after surgery for fractures of the acetabulum. In addition, the number of complications was higher in the indomethacin group when compared to placebo or no intervention. ***Level of Evidence I, Systematic Review.***

Keywords: Bone Fractures. Disease Prevention. Ossification. Heterotopic. Therapeutics. Clinical Trial.

RESUMO

Objetivo: A profilaxia e o tratamento da ossificação heterotópica ainda são controversos. O objetivo desta pesquisa foi avaliar a efetividade das intervenções para prevenir o desenvolvimento da ossificação heterotópica após a fixação cirúrgica das fraturas do acetábulo. Métodos: Foi realizada uma revisão sistemática com pesquisa nas bases de dados PubMed/MEDLINE, Embase, LILACS e Cochrane até 4 de agosto de 2020, sem restrições quanto ao idioma e ano de publicação. Foram incluídos apenas ensaios clínicos randomizados realizados em humanos sem restrições com base na dosagem dos tratamentos, no uso e na duração da profilaxia. Cálculos de metanálise foram realizados utilizando o software Review Manager desenvolvido pela Cochrane. Resultados: Dois estudos compararam o uso de radioterapia e indometacina e três compararam o uso de indometacina com um grupo placebo ou não indometacina. Os cálculos de metanálise não indicaram diferenças estatísticas entre radioterapia versus indometacina (RR 1.45, IC de 95% 0.97 a 2.17, p = 0,55) e indometacina versus placebo ou não indometacina (RR 0.85, IC de 95% 0.68 a 1.06, p = 0,59). Conclusão: Não há evidências suficientes para afirmar que a utilização da radioterapia ou da indometacina é efetiva para prevenir a formação da ossificação heterotópica após cirurgias por fraturas do acetábulo. Além disso, o número de complicações foi maior no grupo indometacina quando comparado ao placebo ou à não intervenção. ***Nível de Evidência I, Revisão Sistemática.***

Descritores: *Fraturas Ósseas. Prevenção. Ossificação Heterotópica. Terapêutica. Ensaio Clínico.*

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INTRODUCTION

Acetabular fractures are injuries that affect young and elderly individuals and commonly result from trauma with high kinetic energy, as in car accidents, falls from height and extreme sporting events.[1] Most of these injuries require open reduction surgery and stable internal fixation, which aim to restore the normal anatomy of the

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The study was conducted at Departamento de Ortopedia e Traumatologia, Universidade Federal de São Paulo, Escola Paulista de Medicina.
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hip.[2] Acetabular fractures have high morbidity due to damage to articular cartilage, and they can lead to future complications such as disabling osteoarthritis, infection, iatrogenic nerve injury, deep vein thrombosis and heterotopic ossification (HO).[1] The latter is a common orthopedic surgery complication, especially when considering the surgical treatment of acetabular fractures, occurring in approximately 40% of operated patients. It can cause limitations to mobility and impair their quality of life.[3-5]

Heterotopic ossification is a pathological process in which an anomalous bone formation occurs in an extra-bone site, including skeletal muscle tissue and other soft tissues such as fascia, tendon, ligament, subcutaneous skin, and any other connective tissue.[4] Current recommendations for the prevention of HO include the application of gentle exercises for maintaining and gaining range of motion, non-steroidal anti-inflammatory drugs (NSAIDs) and external beam radiation, which are mainly used after fractures and arthroplasty of the hip joint.[6,7]

However, it is known that the literature still remains inconclusive as to the definition of the best prophylactic treatment, the recommended dosages and the ideal time for its utilization.[7-10] A systematic review with meta-analysis of observational studies showed no significant difference in the effectiveness of the use of radiation or NSAIDs in the prevention of HO.[9] The authors also noticed that there was a high level of heterogeneity associated with a low quality in the observational studies included in their investigation.[9] Faced with the controversies pointed out in observational studies,[5,9] the aim of this research was to evaluate the effectiveness of interventions to prevent the development of heterotopic ossification after surgical fixation of acetabular fractures investigated in randomized clinical trials.

METHODS

This systematic review was conducted in accordance with the guidelines of the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses – PRISMA*[11] and was registered in *International Prospective Register of Systematic Reviews (PROSPERO)*. The registration number is CRD42020202676.

Data sources and studies

A researcher (T.S.P.B) elaborated the search strategies and the electronic search in the databases PubMed / MEDLINE, Embase, LILACS and *Cochrane Central Register of Controlled Trials*. Reference lists of eligible studies were also researched.

To guide the search for scientific publications of intervention studies, a discriminated clinical question was elaborated based on the strategy defined by the acronym PICO.[12] Thus, we determined that: P = persons with acetabular fractures; I = interventions to prevent heterotopic ossification; C = control group or another intervention; and O = expected outcomes, which includes the presence or absence of HO detected by imaging tests. In addition, other outcomes were investigated, with the presence of adverse effects arising from the interventions, the presence or absence of pain, the assessment of range of motion, quality of life and economic impacts.

The search terms were used in combination with the Boolean operators AND and OR, which are presented in Table 1.

Table 1. Search Terms.

1	Acetabulum [MeSH Terms]
2	Fractures, Bone OR Fracture Fixation OR Fracture Healing
3	Ossification, Heterotopic
4	Myositis Ossificans
5	pathologic* OR ectopic or heterotopic
6	extraosseous OR heterotopic OR metaplastic OR para-articular OR paraarticular OR pathologic* OR periarticular
7	myositis OR dystrophic OR ectopic OR heterotopic OR metaplastic OR para-articular OR paraarticular OR pathological OR periarticular
8	myo-osteosis OR neurogenic osteoma OR osseous heteroplasia OR ossifying fibromyopathy OR synostosis
9	3 or 4 or 5 or 6 or 7 or 8
10	1 AND 2 AND 9

The criteria used for inclusion of the papers were: (1) studies conducted in humans; (2) in adults who underwent fixation surgery for acetabular fractures; and (3) randomized or quasi-randomized clinical trials of any preventive intervention for heterotopic ossification after open reduction and internal fixation of acetabular fractures; (4) any preventive method, either local or systemic, for HO after acetabular surgery, compared with non-intervention, placebo intervention, or alternative preventive scheme; (5) no restrictions based on dosage, utilization and duration of prophylaxis; (6) no restrictions on language and publication year. The exclusion criteria were as follows: case reports or narrative review articles, conference abstracts, animal or in vitro experiments, and studies using replacement arthroplasty.

All stages of the screening of articles were carried out using the Rayyan *software*, which enables rapid exploration and filtering of eligible studies.[13] The analysis of titles and abstracts and full reading were carried out by two researchers independently (T.S.P.B and G.P.G), where any disagreements were resolved between the members of the research team. After the studies were read in their entirety, the following information was collected: authors and year of publication, study design, country where the study was conducted, sample size, average age, participants and intervention time, intervention, outcomes and results (presence or absence of HO detected by imaging tests; data on adverse effects; presence of pain and range of motion; quality of life and economic impacts when this information was available in the studies).

Risk of bias and quality evaluation

The risk of bias in the included studies was assessed by two authors independently (T.S.P.B and G.P.G). As recommended by *The Cochrane Collaboration*[14] "risk of bias" tool, the following six methodological domains were evaluated: (1) *Sequence generation,* (2) *Allocation concealment*, (3) *Blinding of participants, personnel and outcome assessors*, (4) *Incomplete outcome data*, (5) *Selective outcome reporting* e (6) *Other sources of bias.* For each domain, a judgment was assigned as follows: "*low risk*" of bias; "*high risk*" of bias; or "*unclear risk*" of bias; the latter reflecting lack of information or uncertainty about the potential for bias. Disagreements between authors regarding the risk of bias for each domain were resolved by consensus.

The quality evaluation of the studies was performed using the *Grading of Recommendations, Assessment, Development, and Evaluations* (GRID).[15,16] The quality of study evidence was classified into four categories: high, moderate, low or very low.[16]

Statistical analysis

We performed the meta-analysis according to the recommendations of the *Cochrane Collaboration*.[17] We used the Review Manager software (RevMan Web).[17] We calculated the *risk ratio* with 95% confidence interval using the random effects model. We examined heterogeneity using statistics I,[2] where a statistic of 75% or more indicates a considerable level of inconsistency between the studies.[14]

Compliance with ethical guidelines

This article is a secondary study based on previously published studies. Therefore, there is no direct involvement of, nor exposure of direct data extracted from, study participants.

RESULTS

The surveys were conducted until August 4, 2020. We identified a total of 215 articles in the databases and an additional article was collected by manual search on *Google Scholar*. Then, we removed 41 duplicates and deleted 156 articles by screening titles and abstracts. We read 18 full articles, of which 13 were excluded: twelve studies had another type of design than a clinical trial,[18-29] and one presented patients from another research published and included in this article.[30] Of the total, five met the inclusion criteria (Figure 1).[31-35]

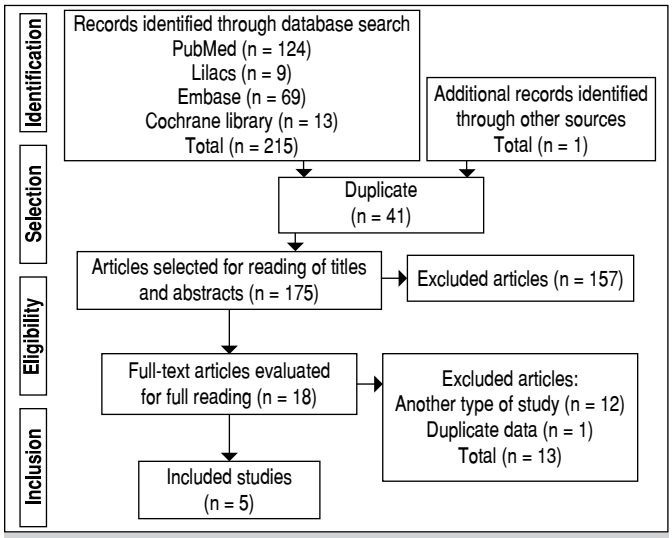

Figure 1. Flowchart of study selection.

The characteristics of the five studies included[31-35] are presented in Table 2 and 3. All studies were classified as randomized clinical trials[31-35] and performed in the United States. A total of 557 participants, including men and women, participated in the studies.

Table 2. Characteristics of the included studies on prevention of heterotopic ossification in patients with acetabular fractures.

Author, year	Type of study	Sample size / gender / average age	Country	Participants and intervention time	Intervention	Comparison or control	Outcome	Results	GRADE Quality of evidence
Burd et al., 2001[31]	Randomized clinical trial.	N = 150 105 M 45 F (Group *Radiation* – average age 44) (Group *Indomethacin* - average 41 years old)	USA	Patients with operative stabilization of acetabular fractures by open reduction and internal fixation. Dose: 800 cGy of local radiation therapy in the hip within seventy-two hours after the operation. Indomethacin (25 mg three times daily) starting within twenty-four hours after surgery for 6 weeks. Duration of follow-up: average thirteen and sixteen months.	*Radiation* (n = 78)	*Indomethacin* (n = 72)	HO classified according to *Brooker** None (grade 0) Mild (grade I and grade II) Severe (grade III and grade IV)	Brooker Grade III or IV heterotopic ossification developed in eight (11%) patients randomized for treatment with indomethacin and three (4%) patients randomized for treatment with radiation therapy. There were no differences between the treatment groups regarding heterotopic ossification (p = 0.22). Local radiation therapy and indomethacin were considered effective prophylaxis against heterotopic ossification after surgical treatment of acetabular fractures.	⊕⊕⊕⊕ DISCHARGE

Table 2. Characteristics of the included studies on prevention of heterotopic ossification in patients with acetabular fractures.

Author, year	Type of study	Sample size / gender / average age	Country	Participants and intervention time	Intervention	Comparison or control	Outcome	Results	GRADE Quality of evidence
Karunakar et al., 2006 [32]	Clinical trial. prospective, randomized double-blind controlled	N = 127 100 M 27 F Indomethacin group: average age 37 years old Placebo group: average age 39 years old	USA	Patients with operative stabilization of acetabular fractures through a subsequent *Kocher-Langenbeck* approach. Dose: 75 mg *Indomethacin* a single daily dose. Intervention time: 6 weeks	*Indomethacin* (*Merck Inc., Whitehouse Station, New Jersey*) Before (n = 63) After (n = 59)	Placebo Before (n = 64) After (n = 62)	HO classified according to *Brooker** None (grade 0) Mild (grade I and grade II) Severe (grade III and grade IV)	Grade III to IV occurred in nine of 59 patients (15.2%) in the indomethacin group and 12 of 62 (19.4%) who received placebo. There is no statistically significant difference between the two groups (chi-square test, p = 0.722). Fisher's exact test showed no significant association between Brooker categories (none, mild, severe) and treatment groups (p = 0.334).	⊕⊕⊕⊕ DISCHARGE
Matta e Siebenrock 1997 [33]	Randomized clinical trial.	N = 107 Gender NR Indomethacin group: average age 40,3 years old *Non-indomethacin* group: average *age* 45.7 years old	USA	Patients with acetabular fractures underwent surgery by Kocher-Langenbeck (KL), ilioinguinal (II) or extended iliofemoral approach. Dose: 100 mg per suppository at the end of the operation, then 25 mg orally or rectally. Intervention time: three times a day for six weeks.	*Indomethacin* Before (n = 61) After (n = 57)	*No indomethacin* Before (n = 46) After (n = 44)	HO evaluated by AP radiograph of the pelvis and classified as grade 0 (none), grade 1 (minimum) or grade 2 (moderate to severe) ROM	Of the patients receiving indomethacin, 30 (52.6%) did not develop ossification assessed by simple radiograph compared to 19 (43.2%) in the untreated group. Two patients (1.9%) developed clinically significant ossification (grade 2) with loss of hip motion greater than 20% compared to the non-involved side. Both received indomethacin and the operation was by a KL approach.	⊕⊕⊕ MODERATE

Table 2. Characteristics of the included studies on prevention of heterotopic ossification in patients with acetabular fractures.

Author, year	Type of study	Sample size / gender / average age	Country	Participants and intervention time	Intervention	Comparison or control	Outcome	Results	GRADE Quality of evidence
Moore et al., 1998[34]	Clinical trial, prospective, randomized, blind	N = 75 52 men 23 women Indomethacin group: average age 43 years old Radiation group: average age 47 years old	USA	Adult patients who underwent open reduction and internal fixation of acetabular fractures by means of a Kocher-Langenbeck, a combined ilioinguinal and Kocher-Langenbeck, or an extended iliofemoral approach. Dose: 25 mg of *Indomethacin* Intervention time: three times a day for six weeks. Duration of follow-up: 12 months. Radiation with 800 cGy three days after the operation	*Indomethacin* Before (n = 20) After (n = 39)	Radiation therapy Before (n = 46) After (n = 33)	HO evaluated by simple X-rays and classified according to *Brooker** None (grade 0) Mild (grade I and grade II) Severe (grade III and grade IV)	Cochran-Armitage analysis showed no significant difference between the two treatment groups regarding the formation of HO (p = 0.089). Indomethacin and single-dose radiation therapy are safe and effective in preventing HO after the operation of acetabular fractures.	⊕⊕⊕ MODERATE
Sagi et al., 2014[35]	Clinical trial, prospective double-blind randomized	N = 98 70 men 28 women Indomethacin group: average age 43 years old Radiation group: average age 47 years old	USA	Patients who suffered an acetabular fracture underwent open reduction and internal fixation of their acetabular fracture by a Kocher-Langenbeck approach. Dose: 75 mg PO daily. Intervention time: 6 weeks	*Indomethacin* Before Group 1-3 days (n = 24) Group 2 – one week) (n = 25) Group 3 - six weeks (n = 23) After Group 1 - (n = 17) Group 2- (n = 17) Group 3- (n = 13)	Placebo Before (n = 26) After (n = 21)	HO evaluated by simple X-rays and classified according to *Brooker** None (grade 0) Mild (grade I and grade II) Severe (grade III and grade IV) EVA: pain assessment.	A six-week long treatment with indomethacin does not appear to have a therapeutic effect to decrease the formation of HO after acetabular fracture surgery, and appears to increase the incidence of nonunion. A one-week long treatment with indomethacin may be beneficial to decrease the volume of HO formation without increasing the incidence of pseudoarthrosis. Visual analog scales for pain (VASs) were significantly higher for patients with radiographic nonunion (VAS 4 vs. VAS 1, P = 0,002).	⊕⊕⊕ MODERATE

HO: heterotopic ossification.
* Brooker AF, Bowerman JW, Robinson RA, Riley LH Jr. Ectopic ossification following total hip replacement. Incidence and a method of classification. J Bone Joint Surg Am. 1973;55(8):1629-1632.
ROM: range of motion.
AP: Antero-posterior
VAS: Visual analog scale for pain.

Table 3. Characteristics of the included studies on prevention of heterotopic ossification in patients with acetabular fractures.

Summary of findings:

Interventions to prevent heterotopic ossification in patients with acetabular fractures

Patient or population: Patients with surgical stabilization of acetabular fractures
Setting: Hospital
Intervention: Indomethacin
Comparison: Placebo

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with [Placebo/ no intervention]	Risk with [Indomethacin]				
Heterotopic ossification assessed with: Placebo versus Indomethacin follow up: average 6 weeks	598 per 1.000	497 per 1.000 (395 to 622)	RR 0.83 (0.66 to 1.04)	256 (3 RCTs)	⊕⊕⊕ MODERATE	No differences were found between the studies regarding the outcome
Range of motion	0 %	20 %	–	101 (1 study)	⊕⊕⊕ MODERATE	Two patients (1.9%) developed clinically significant ossification (grade 2) with loss of hip movement greater than 20% compared with the uninvolved side. The moderate quality of the studies is a result of the small sample size and because there is no available study protocol.
Pain (VAS) in Patients with Nonunion versus Patients with Union	4	1	–	34 (1 studies)	⊕⊕⊕ MODERATE	Pain as reported by VAS was significantly greater in the patients with radiographic nonunion at both the 6-month and 1-year follow-up intervals (P = 0.002). The moderate quality of the studies is a result of the small sample size.

Summary of findings:

Interventions to prevent heterotopic ossification in patients with acetabular fractures

Patient or population: Patients with surgical stabilization of acetabular fractures
Setting: Hospital
Intervention: Indomethacin
Comparison: Placebo

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with [Placebo/ no intervention]	Risk with [Indomethacin]				

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Risk of bias in the included studies

The results of the risk of bias assessment of the included studies are presented in Figures 2 and 3. Although the risk of bias in general was considered low, we identified a high risk of bias in some studies, as shown in Figure 2, because the studies did not meet the following criteria: *sequence generation, allocation concealment, blinding of participants and personnel, selective outcome reporting* and *other bias*.

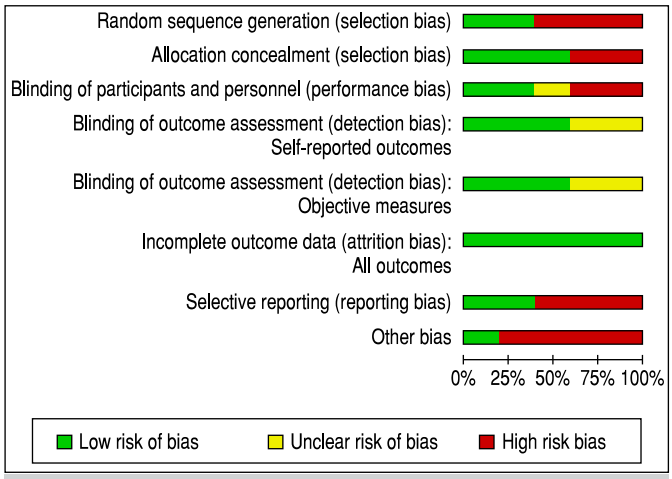

Figure 2. Risk of bias chart

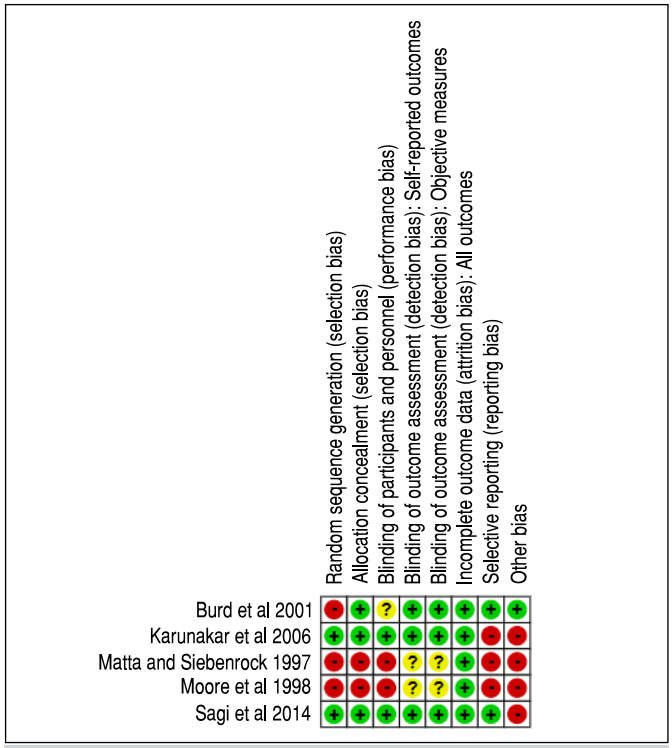

Figure 3. Summary of risk of bias for each trial (the plus sign denotes low risk of bias; the minus sign denotes high risk of bias; the question mark denotes uncertain risk of bias).

Quality evaluation

The individual analysis of the methodological quality of the studies, using the GRADE criteria, showed high quality[31,32] in two studies. In three studies comparing the use of Indomethacin versus Placebo, the GRADE evaluation was grouped according to Table 2. In addition, we present results for the outcome range of motion and pain. The result indicated moderate methodological quality.[33-35] The moderate quality of the studies is a result of the small sample size and because there is no available study protocol.

Intervention and group control or comparison

The interventions for preventing HO in patients with acetabular fractures included: radiotherapy compared to indomethacin (non-steroidal anti-inflammatory drug)[31,34] and the use of indomethacin compared to a placebo group[32,35] or non-indomethacin.[33]

Intervention time and dosages

Indomethacin was used with application of a single daily dose of 75 mg,[32,35] with intervention time of six weeks.[32,35] There was also application of 25 mg of indomethacin[31,34] three times a day for six weeks[31,34] with 100 mg of indomethacin per suppository at the end of the operation, and 25 mg orally or rectally three times a day for six weeks.[33] Moore et al.[34] administered 25 mg indomethacin orally or rectally before the operation and 25 mg three times a day for six weeks. The time and dosage of radiation therapy are described in Table 1.

Presence or absence of pain and range of motion

Only one study reported pain assessment[35] and four studies analyzed range of motion.[31,33-35] The instrument utilized for pain assessment was the Visual Analog Pain Scale.[35] Pain scores were significantly higher for patients who exhibited pseudoarthrosis, diagnosed by radiographic control images at follow-up intervals of 6 months and one year ($p = 0.002$).[35]

About range of motion, data (flexion, extension, internal rotation, external rotation, abduction and adduction) were collected, recorded and compared to the contralateral hip.[35] Joint mobility evaluated by clinical examinations performed at a six-month interval was similar to those performed during the one-year follow-up.[35] Matta and Siebenrock[33] reported that patients with loss of mobility greater than 20% were followed for more than one year. However, this study did not report how many individuals achieved such a loss.[33] In the study by Moore et al.,[34] hip range of motion improved slowly after surgery, but of the total subjects included in this study, 19 patients had a loss greater than 20°. In the study by Burd et al.,[31] the differences in range of motion between the injured side and non-injured side were, on average, 7° in flexion, 9° in external rotation, 8° in internal rotation, and 7° in abduction. Only hip flexion had a significant relationship with the degree of heterotopic ossification ($p = 0.011$), but there was no significant relationship with the treatment group (indomethacin or radiotherapy) ($p = 0.40$).[31]

Quality of life and economic impacts

The studies did not report the impacts of the intervention on quality of life and economic aspects.

Effect of interventions

The results of the interventions to prevent HO in patients with acetabular fractures are presented in Table 1.

Radiation therapy versus indomethacin

Burd et al.[31] concluded that local radiation therapy and indomethacin were effective prophylaxes for preventing heterotopic ossification after surgical treatment of acetabular fractures. However, they found no significant difference in efficacy between the two interventions. Moore et al.[34] reported that the use of indomethacin and single dose radiation therapy are safe and effective in preventing heterotopic ossification after surgical approach for acetabular fractures. However, the authors highlighted that radiation therapy is approximately 200 times more costly than indomethacin therapy.[34] Meta-analysis of randomized clinical trials[31,34] showed no statistical difference in the prevention of HO between radiotherapy and indomethacin (RR 1.45, 95% CI 0.97 to 2.17, $p = 0.07$), and there was no evidence of heterogeneity ($I^2 = 0\%$; $Chi^2 = 0.36$) (Figure 4).

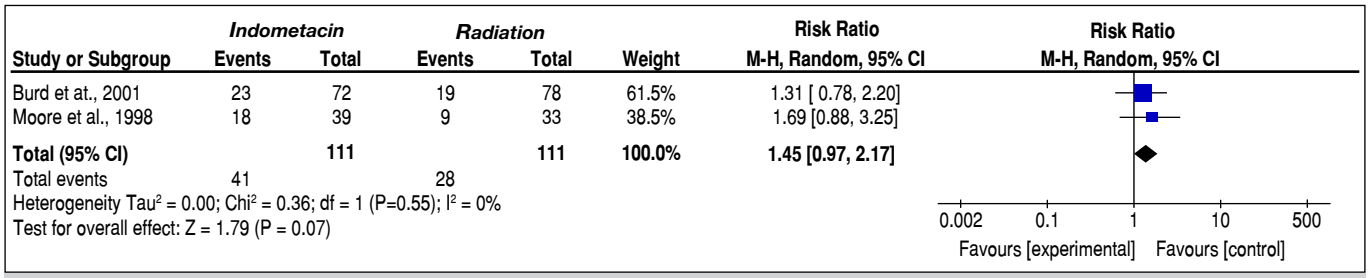

Figure 4. *Forest plot* comparing the risk of heterotopic ossification with radiation therapy and indomethacin.

Indomethacin versus control (placebo or non- intervention)

About the use of indomethacin, two studies reported that this intervention was not effective.[32,33] In addition, Matta and Siebenrock[33] pointed out that the number of patients studied was very small. Karunakar et al.[32] also found no statistical differences in the reduction of the incidence of severe HO with the use of indomethacin compared to the use of placebo. Sagi et al.[35] indicated that using indomethacin for 6 weeks does not appear to have a therapeutic effect to decrease the formation of HO after acetabular fracture fixation surgery. However, they indicated the possibility of increased incidence of pseudoarthrosis associated with this therapy. A one-week long treatment using indomethacin can be beneficial to decrease the volume of HO formation without increasing the incidence of pseudoarthrosis.[35] Meta-analysis of randomized clinical trials[32,33,35] showed no differences for HO results comparing indomethacin with placebo or non-use of indomethacin (RR 0.85, 95% CI 0.68 to 1.06, p = 0.14), and there was no evidence of heterogeneity (I^2 = 0%; Chi^2 = 1.07) (Figure 5).

Adverse effects due to the interventions

Only one study reported increased incidence of pseudoarthrosis.[35] Karunakar et al.[32] reported complications such as deep vein thrombosis, infection in the surgical wound, pseudoarthrosis of the tibia, gastrointestinal bleeding and perforated ulcer in the group that received indomethacin. Six patients who received placebo evolved with deep vein thrombosis and one presented infection of the surgical wound.[32] No complications were reported in the study by Burd et al.[31] No patients using indomethacin had to stop treatment due to gastrointestinal symptoms, although several patients had their treatment stopped by other doctors who did not understand the purpose of the drug. No problems with the healing of surgical wounds were found in patients treated with radiation.[31] Analyzing the complications, meta-analysis[32,35] indicated differences between the indomethacin and placebo groups, indicating statistical evidence that the number of complications was lower in the placebo group (RR 2.04, 95% CI 1.01 to 4.56, p = 0.05). Low heterogeneity was observed between the studies (I^2 = 23%) (Figure 6).

DISCUSSION

This review included five studies involving 557 participants.[31-35] These studies reported on the utilization of radiation therapy and indomethacin for preventing the development of heterotopic ossification after acetabular fractures. The analysis of the studies indicates that the available evidence for the utilization of both radiation therapy and indomethacin, as well as other interventions, is scarce and limited. The evidence on the use of radiation therapy compared to indomethacin, as well as indomethacin compared to placebo, indicated that there were no differences between the interventions. We consider that most studies had a low risk of bias, in addition to moderate and high methodological quality.

A notable finding of this review was the fact that all included studies were conducted in the United States. Another finding concerns the differences found in the studies with regard to the interventions and dosages and intervention time. Certainly, these observations highlight that new interventions should be explored in future studies. In addition,

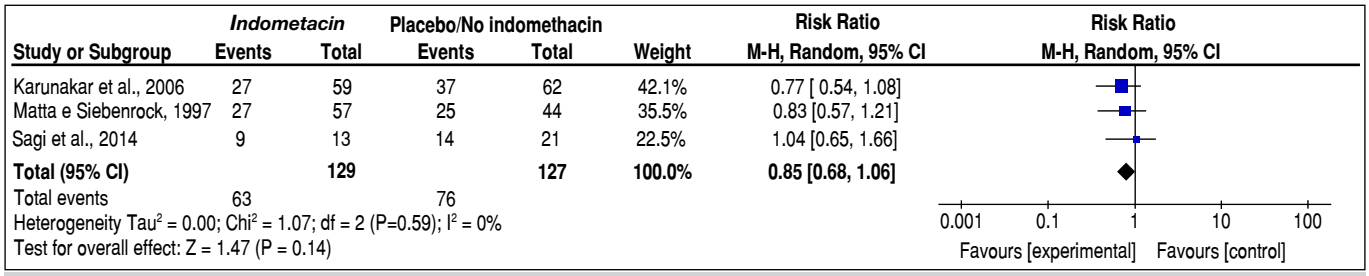

Figure 5. *Forest plot* comparing the risk of heterotopic ossification with radiation therapy and indomethacin.

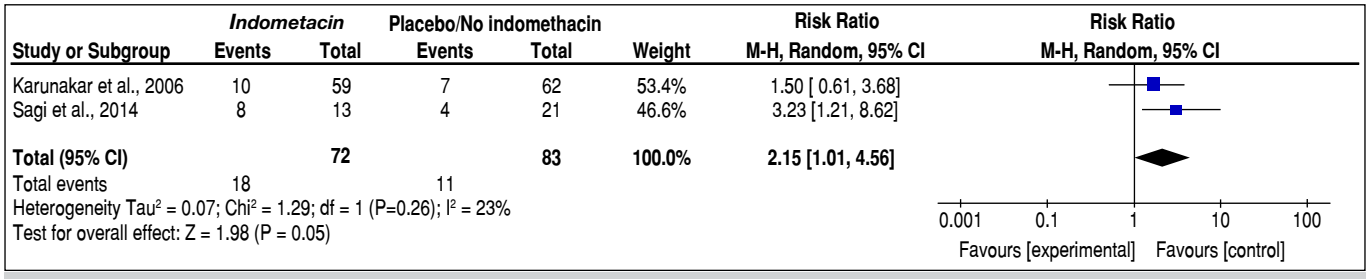

Figure 6. *Forest plot* comparing complications with the use of indomethacin and placebo.

<< SUMÁRIO

it is important to note that not all studies reported the presence of adverse effects or complications arising from the use of radiation therapy and indomethacin. There were reports of pseudoarthrosis[35] and complications such as deep vein thrombosis, infection in the surgical wound, pseudoarthrosis of the tibia, gastrointestinal bleeding and perforated ulcer when using indomethacin.[32]

Despite the limitation of few published clinical trials on the subject, radiation therapy and indomethacin have been investigated in many observational and longitudinal studies.[18-25] However, we observed that the results of these studies were also contradictory and should be interpreted with caution regarding the benefits and the risks of possible adverse effects, such as the risk of cancer when using radiation therapy and the risk of death from bleeding or gastric perforation, as well as pseudoarthrosis when using indomethacin.[18-25]

As a strength of this review, we highlight the conduct of a comprehensive survey of randomized clinical trials in any language and with no restrictions on year of publication. However, we consider that this systematic review and meta-analysis present some limitations. Firstly, the small number of studies found means that the results of this review cannot be considered definitive. Secondly, considerable heterogeneity was observed by the different comparison methods, dosages and intervention time to prevent the formation of heterotopic ossification. Some interventions were not cited or evaluated as a preventive method, such as the use of corticosteroids and bisphosphonates, suggesting a weakness in the studies performed. In addition, using the GRADE approach (Schunemann 2011), we evaluated the degree of evidence for each outcome reported as moderate in quality. We downgraded the evidence one level because of the risk of bias, reflecting that all five studies presented risk of detection and description of bias. The evidence is not robust for the comparison of indomethacin and placebo found in the evaluation of methodological quality. Therefore, we can state that the numerical results of this review should be interpreted with caution, and require confirmation by future studies with good methodological quality and adequate power.

Therefore, we infer that new randomized and controlled clinical trials need to be conducted to evaluate the effectiveness of the different interventions. Preferably, these studies will have a representative sample size so as to adequately determine the application time and the dosages of the interventions. Robust studies with standardized interventions will be useful to determine changes in clinical practice and to direct future research. Moreover, it is important that future studies analyze the adverse events arising from each intervention and the changes in quality of life, pain control and improvement of the arc of joint motion.

CONCLUSION

In conclusion, there is insufficient evidence to assert that the use of radiation therapy or indomethacin is effective in preventing the formation of heterotopic ossification after acetabular fracture surgery. Also, the number of complications was higher in the indomethacin group when compared to the placebo or non-intervention groups.

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