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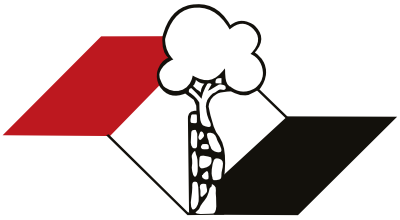

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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed April 2022)

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

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

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

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

CONCLUSION: The conclusion should be clear and concise, establishing a link between the conclusion and the study objectives. Avoiding conclusions not based on data from the study in question is recommended, as well as avoiding suggest that studies with larger samples are needed to confirm the results of the work in question.

ACKNOWLEDGEMENTS

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d) Summaries: Author(s). Title, followed by [abstract]. Journal year; volume (supplement and corresponding number, if applicable): page(s) Ex.: Enzensberger W, Fisher PA. Metronome in Parkinson's disease [abstract]. Lancet. 1996;34:1337.

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nov 8];21(3):197-205. Available from: http://periodicos.puc-campinas.edu.br/seer/index.php/transinfo/article/view/501

h) Data Sharing: Pavezi N, Flores D, Perez CB. Proposição de um conjunto de metadados para descrição de arquivos fotográficos considerando a Nobrade e a Sepiades. Transinf. [Internet]. 2009. Available at: https://doi.org/10.1590/S0103-37862009000300003. Write [dataset] immediately before the reference so we can identify it properly as a data reference. The identifier [dataset] will not appear in the published article.

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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

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FOOTWEAR PURCHASING PATTERN DURING THE COVID-19 PANDEMIC: A CROSS-SECTIONAL STUDY
PADRÃO DE COMPRA DE CALÇADOS DURANTE A PANDEMIA DE COVID-19: UM ESTUDO TRANSVERSAL
Fernando Gonzalez Correa, Lucas Plens de Britto Costa, Lucas Furtado da Fonseca, Leonardo Fernandez Maringolo, Caio Augusto Souza Nery, Tania Szejnfeld Mann
DOI: http://dx.doi.org/10.1590/1413-785220253302e285417

HIP

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FOOTWEAR PURCHASING PATTERN DURING THE COVID-19 PANDEMIC: A CROSS-SECTIONAL STUDY

PADRÃO DE COMPRA DE CALÇADOS DURANTE A PANDEMIA DE COVID-19: UM ESTUDO TRANSVERSAL

Fernando Gonzalez Correa[1], *Lucas Plens de Britto Costa*[1], *Lucas Furtado da Fonseca*[1], *Leonardo Fernandez Maringolo*[1], *Caio Augusto Souza Nery*[1], *Tania Szejnfeld Mann*[1]

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ABSTRACT

Introduction: The COVID-19 pandemic boosted the increase in online sales, however there is a lack of research on the shoe purchasing pattern among the Brazilian population. Objective: To investigate the shoe purchasing pattern. Method: This cross-sectional study comprises individuals from a Foot and Ankle Outpatient Clinic. A total of 500 individuals were invited to respond to a digital form using the Google Forms tool. Stata® software version 13.0 was used for statistical analyses. Results: 433 individuals were included, 86.37% of whom were women. Purchasing shoes online was reported by 44.34% (n=192/433) of individuals, and 13.39% (n=58/433) said that the choice of digital platforms was due to the practicality of purchasing online. There were differences in the shoe purchasing pattern according to female and male gender (p<0.001). Conclusion: Although most of the individuals surveyed are not used to buying shoes online, most purchases were made by women, mainly aiming for comfort and beauty. This study highlights the need to develop tools that help people purchase shoes online. ***Level of Evidence I; High-quality prospective study.***

RESUMO

Introdução: A pandemia de COVID-19 impulsionou o aumento das vendas on-line, contudo há uma carência de pesquisas sobre o padrão de compra de calçados na população brasileira. Objetivo: Investigar o padrão de compra de calçados. Método: Trata-se de um estudo transversal, composto por indivíduos de um Ambulatório de Pé e Tornozelo. Um total de 500 indivíduos foram convidados a responder um formulário próprio e digital através da ferramenta Google Forms. O software Stata®, versão 13.0, foi utilizado para as análises estatísticas. Resultados: Foram incluídos 433 indivíduos, sendo 86,37% mulheres. A compra de calçados pela internet foi relatada por 44,34% (n=192/433) dos indivíduos e 13,39% (n=58/433) disseram que a escolha de plataformas digitais deve-se a praticidade ao comprar on-line. Houve diferenças no padrão de compra de calçados conforme o gênero feminino e masculino (p<0,001). Conclusão: Embora grande parte dos indivíduos pesquisados não estejam acostumados a comprar sapatos online, a maior parte das compras foram realizadas pelas mulheres, visando principalmente o conforto e a beleza. Este estudo destaca a necessidade de desenvolvimento ferramentas que auxiliem para compra on-line de calçados. ***Nível de Evidência I; Estudo prospectivo de alta qualidade.***

Keywords: Habits; Shoes; e-Commerce; COVID-19.

Descritores: *Hábitos; Sapatos; Comércio Eletrônico; COVID-19.*

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INTRODUCTION

Footwear is the oldest fashion accessory and is considered a means of protecting the feet.[1-3] The fit of footwear is essential to ensure comfort and prevent or treat orthopedic pathologies affecting the lower limbs and spine.[2,4-7]

Shopping in physical stores allows you to choose a better shoe fit and comfort. However, e-commerce, mainly driven by the COVID-19 pandemic,[8] has made buying shoes online increasingly common. The increase in online research into the fit of footwear, especially for children, has been reported in the literature,[5,9] but there is a lack of studies exploring the footwear purchasing patterns of adults in the Brazilian population. Therefore, this study aimed to investigate the footwear purchasing patterns of the Brazilian population.

METHODS

This prospective cross-sectional study was carried out at the Orthopedics and Traumatology Department of the Universidade Federal de São Paulo – UNIFESP. It was approved by the UNIFESP Ethics Committee (CEP/UNIFESP/ n:0809P/2021) and complies with the Declaration of Helsinki.

A total of 500 individuals from the Orthopedics and Traumatology Outpatient Clinics at UNIFESP were invited to fill in a digital form

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

The study was conducted at Federal University of São Paulo (UNIFESP), a leading institution in orthopedics and traumatology, located at Sena Madureira Street, 1.500, Vila Clementino, São Paulo, Brazil. 04021-001.
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using the Google Forms tool. The data was collected between January 2021 and January 2023.

Subjects of both sexes over 20 years of age were included. Individuals who refused to take part in the study, had pain, foot deformities, inflammatory diseases, comorbidities, or previous surgery were excluded.

Participants were asked for their age (20-40 years, 40-60 years and >60 years) and gender (female and male). We asked about the habit of shopping online (yes or no); the number of shoe purchases [once a week (50 shoes/year), once a month (12 shoes/year), 3 times a year (4 shoes/year), twice a year (2 shoes/year) and only on specific occasions] and what you consider when choosing shoes (beauty/design, comfort, recommendation from someone else (friend, salesperson) and price).

They were also asked about buying shoes online (yes or no); about the use of digital platforms to buy shoes (Don't trust that the shoes will fit; If they don't fit, it will be a pain to exchange them; Prefer the experience of going to the store to choose; Prefer the convenience of buying online) and the choice of brand/store [I always buy the same brand; I look for the shoe, regardless of the store; I search for models on the internet, then go and try them on in the store; I follow the recommendation of a doctor or a friend]. They were also asked if they used any tools, such as a virtual shoe fitting room, when buying shoes (yes or no).

Participants were also asked how often they bought shoes that hurt during use and had to stop wearing them and whether they used any tools, such as a virtual shoe fitting room, when buying shoes (yes or no). Would you like to use a tool to help you buy shoes that don't hurt (yes or no)? What would be the ideal way to receive advice on how to choose the best shoes (app, information leaflet, video lesson, or instruction manual)?

The last question was about how much you would be willing to pay for an app to take measurements and recommend suitable shoes (R$10/month; R$120 once; R$10/every time you wear it; or I don't want to pay anything, the shoe store has to offer it).

Statistical analysis

Descriptive statistics were used to summarize the results. For descriptive analyses, we obtained absolute frequency (n) and percentage (%) values. Stata® software version 13.0 was used for the statistical analysis.

RESULTS

The sample consisted of 433 individuals (13.63% men and 86.37% women) (Figure 1). Of these, 32.33% (n=140) were aged between 20 and 40, 25.87% between 40 and 60, and 1.85% over 60. 39.95% of the participants chose not to answer their age (Figure 2).

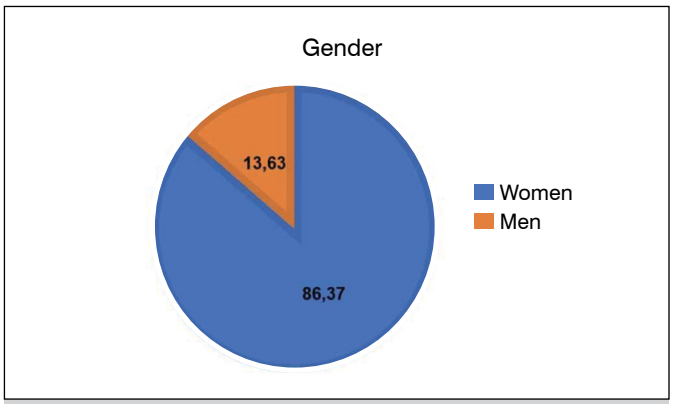

Figure 1. Gender graph of the survey participants: 86.37% women and 13.63% men.

More than half of the participants (n= 371/433 - 85.68%) reported that they are used to shopping online, and 44.34% (n=192/433) buy shoes through these channels (Figure 3).

Regarding the use of digital platforms to buy shoes, 16.16 % (n=70/433) don't trust that the shoes will fit; 34.64 % (n=150/433) think that if they don't fit, it will be a pain to exchange them; 35.79 % (n=155/433) prefer the experience of going to the store to choose the shoes; 13.39% (n=58/433) prefer the convenience of buying online. Most shoe purchases are made 3 times a year, 48.50% (n=210/433), and 2 times a year, 25.17% (n=109/433). 16.40% (n= 71/433) buy feathers on specific occasions.

The choice of footwear is mainly based on comfort (64.43%, n=279/433), followed by the beauty or design of the shoes (27.02%, n=117/433) and price (7.85%, n=34/433) (Figure 4). Most of the participants reported that they rarely or never buy shoes that hurt their feet (48.04%, n=208/433, and 6.47%, n=28/433, respectively). When asked how they choose their shoe brand/store, 36.49% (n=158/433) said that they always buy shoes from the same brand, 9.93% (n=43/433) research the models on the internet and then try them on in the store and only 1.62% (n=7/433) follow the recommendation of a doctor or a friend. The rest, 51.96% (n=225/433), look for shoes on the Internet, regardless of the store.

Most of the participants (93.76 % - 406/433) don't use digital fitting rooms or measurement tables to help them buy, although 88.68 % (n= 384/433) are interested in an online tool that could help them buy a shoe that doesn't hurt.

The preferred tool for guidance on how best to choose your shoes is apps on mobile devices (60.50 %, n= 262/433) and video lessons

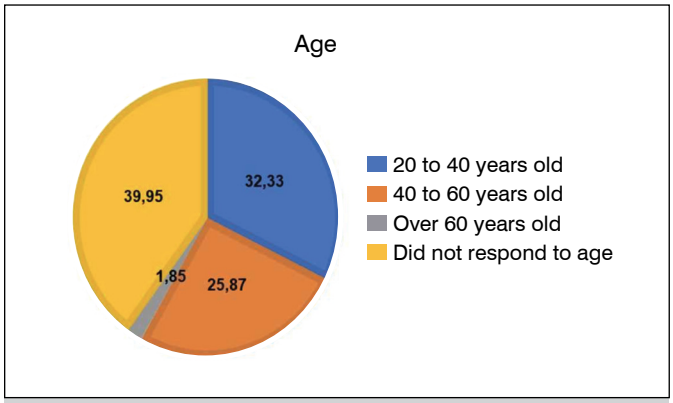

Figure 2. The age graph of the participants in the survey was 20-40 years, 32.33%; 40-60 years, 25.87%; over 60 years, 1.85%, and 39.95% did not choose to answer.

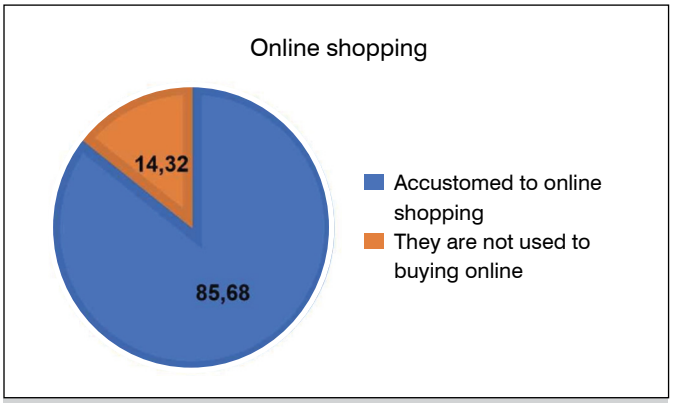

Figure 3. Online shopping chart: 85.68% of participants are used to shopping online, and 14.32% of participants are not used to shopping online.

(16.62%, n=72/433). However, 50.35% (n=218/433) said they didn't want to pay for an app. Table 1 shows information on internet shopping patterns according to gender.

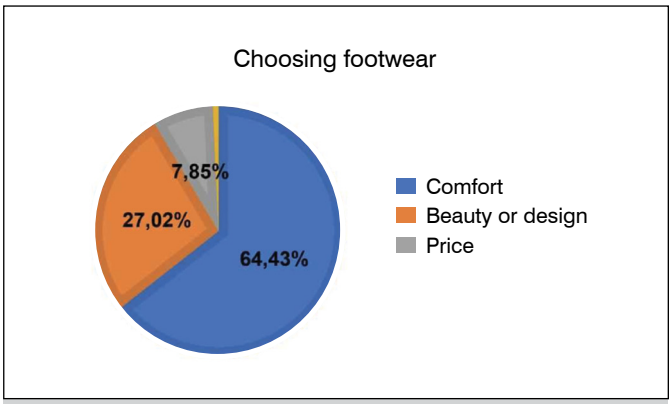

Figure 4. The age graph of the participants in the survey was 20-40 years, 32.33%; 40-60 years, 25.87%; over 60 years, 1.85%, and 39.95% did not choose to answer.

Table 1. Prevalence of footwear purchasing patterns according to gender (n = 433).

Variable	Gender		
	Female (n=374)	Male (n=59)	
	Prevalence n (%)		p
Internet shopping habits			**0.151**
Yes	324(93.27)	44(6.73)	
No	50(86.49)	15(13.51)	
Buying shoes online			**0.071**
Yes	171(95.65)	15(4.35)	
No	203(89.66)	44(10.34)	
Use of a virtual shoe fitting room			**1.000**
Yes	23(93.75)	2(6.25)	
No	351(92.21)	55(7.79)	

Fisher's exact test was used when the frequencies were less than five. $p < 0.05$ was considered statistically significant (bold).

DISCUSSION

This study analyzed the footwear purchasing patterns of adults during the Covid-19 pandemic. As far as we know, this is the first study carried out with adults in São Paulo, Brazil. Among the contributions of this article, the following results stand out: there was a high prevalence of online shopping, and less than half of the participants reported shopping for shoes. The choice of digital platforms was mainly due to the convenience of buying online. In addition, most of the individuals in this survey buy shoes three times a year, and their choice is made with comfort in mind. The use of apps on mobile devices is the preferred tool to help guide people on how to choose their shoes better. Women make the majority of internet purchases and online shoe purchases.

In this study, we identified a high prevalence of internet shopping, mainly due to the convenience of buying online. The COVID-19 pandemic has resulted in a general increase in online shopping (e-shopping), especially for supermarket products. There has also been an increase in teleworking, teleconferencing, e-learning, and telehealth compared to the pre-COVID-19 period.[8,10]

Our findings indicate that there were few purchases of shoes online and that those who did buy them chose comfort in particular. We didn't find any studies that reported on adults buying shoes online. However, the literature indicated increased searches for online resources on the fit of children's footwear.[5] The authors reported that choosing properly fitting footwear for children is challenging.[5] The correct footwear fit is recognized as vital for comfort and mainly because using inappropriate or ill-fitting shoes is responsible for increased falls, ankle and foot injuries, and pain, especially in the elderly.[7] Therefore, although online shopping has expanded to a variety of consumers, the choice and fit of footwear remains a challenge,[1] especially when shopping online, and specific interventions for advice and education regarding footwear are needed.[6,7]

There were no differences in the pattern of footwear purchases according to gender. However, the literature indicates that men generally favor buying electronic products and women consume more clothing and accessories.[11]

The possible limitations of this study are the low number of men in our sample. Among the strengths of this research, we highlight the sample size, which is representative of the population. Thus, the findings of this study are essential to stimulate the development of online shopping tools to help fit shoes. The development of these tools could reduce dissatisfaction with purchases and provide greater comfort for buyers, and the increase in online sales will have a positive impact on our country's economy.

CONCLUSION

Even with the great digitalization of shopping caused by the COVID-19 pandemic, many of the individuals surveyed are not used to buying shoes online. Even so, the majority of purchases are made by women, mainly for comfort and beauty. This study highlights the need to develop tools to help people buy shoes online.

AUTHOR'S CONTRIBUTION: Each author has made a personal and significant contribution to the development of this article. FGC: conceived and planned the activities that gave rise to the study, wrote the article, interpreted the results of the study, participated in the review process, and approved the final version; LPBC, LFF, LFM, CASN, and TSM: conceived and planned the activities that gave rise to the study, wrote the article, participated in the review process, approved the final version.

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DOI: http://dx.doi.org/10.1590/1413-785220253302e280114

COST AND QUALITY OF LIFE IN PATIENTS UNDERWENT HIP ARTHROPLASTY IN A BRAZILIAN HOSPITAL

CUSTO E QUALIDADE DE VIDA EM PACIENTES SUBMETIDOS À ARTROPLASTIA DO QUADRIL NUM HOSPITAL BRASILEIRO

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ABSTRACT

Introduction: There are few studies in Brazil evaluating the quality of life and costs of patients undergoing total hip arthroplasty (THA). Purpose: (1) To describe the total cost, quality of life and functional scores of patients undergoing THA in a Brazilian private hospital; (2) to determine preoperative factors associated with quality of life and total cost; and (3) to evaluate the association between cost and quality of life. Methods: Of the 1061 patients included, pre- and peri-operative data, total costs, pre- and post-operative functional scores (HOOS, WOMAC) and quality of life scores (EQ-5D) were collected over 2 years. Results: EQ-5D, HOOS and WOMAC improved from 0.492, 54.5 and 45.2, respectively, to 0.888, 90 and 5.9 at 1-year follow-up, and 0.892, 90.4 and 4.0 at 2-year follow-up. The average cost was R$43,324.22±11,323. Associations were observed between EQ-5D variation and male sex (RM=1.058; p=0.03) as well as age (RM=0.996; p<0.001). No association was found between total cost and EQ-5D. Conclusions: The average cost of patients undergoing THA was R$43,324.22. There was an improvement in quality of life and function, an association between quality of life and male sex and age, however no association was found between total cost and quality of life. ***Level of evidence IV; Case Series.***

Keywords: Arthroplasty; Hip; Quality of life; Hospital costs.

RESUMO

Introdução: Há escassez de estudos no Brasil que avaliem qualidade de vida e custos de pacientes submetidos à artroplastia total do quadril (ATQ). Objetivos: (1) Descrever custo total, escores de qualidade de vida e funcionais de pacientes submetidos à ATQ num hospital privado brasileiro; (2) determinar fatores pré-operatórios associados com qualidade de vida e custo total; e (3) avaliar associação entre custo e qualidade de vida. Método: Dos 1061 pacientes incluídos, foram coletados dados pré e peri-operatórios, custo total, escores funcionais (HOOS, WOMAC) e de qualidade de vida (EQ-5D) pré- e pós-operatórios ao longo de 2 anos. Resultados: EQ-5D, HOOS e WOMAC melhoraram de 0,492, 54,5 e 45,2, respectivamente, para 0,888, 90 e 5,9 com 1 ano de seguimento, e 0,892, 90,4 e 4,0 com 2 anos. O custo médio foi R$43.324,22±11.323. Observou-se associações da variação de EQ-5D com sexo masculino (RM=1,058; p=0,03) e idade (RM=0,996; p<0,001). Não observou-se associação entre custo total e EQ-5D. Conclusão: O custo médio de pacientes submetidos à ATQ foi R$43.324,22. Observou-se melhora da qualidade de vida e função, associação da qualidade de vida com sexo masculino e idade, porém não encontrou-se associação entre custo total e qualidade de vida. ***Nível de evidencia IV; Série de Casos****.*

Descritores: *Artroplastia; Quadril; Qualidade de Vida; Custos hospitalares.*

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INTRODUCTION

Total hip arthroplasty (THA) is considered one of the most successful and cost-effective surgeries when compared to other orthopedic surgeries.[1,2] It is estimated that, with an ageing population, there will be an increase in demand for THAs,[3,4] and there is concern about the impact on health system costs.

In Australia, based on the national arthroplasty registry, there was an increase in the annual cost of THA surgeries from 2003 to 2013, from 364 million to 625 million Australian dollars ($AUD), with the expectation that by 2030 this cost will rise to $AUD 953 million.[5] In Brazil, there are few studies on the costs of THA. Recently, Guimarães et al. evaluated the costs of THA in the public health system in the city of São Paulo and found average costs per patient of 1,345.15 and 1,840.42 dollars for cemented and uncemented/hybrid THA, respectively.[6]

Patients undergoing THA, due to arthrosis or other hip deformity pathologies in more advanced stages, evolve with significant improvement in pain, function and quality of life.[7] Quality of life in the

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

The study was conducted at Hospital Israelita Albert Einstein, Avenida Albert Einstein, 627, Morumbi, Sao Paulo, SP, Brazil. 05652-900.
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post-THA period can be measured using the *Euroqol-5 Dimensions* (EQ-5D), a questionnaire that assesses the individual's health in five domains: mobility, self-care, daily activities, pain and anxiety/depression.[8,9] In addition, there are functional questionnaires, such as the *Hip disability and Osteoarthritis Outcome* score (HOOS) and *the Western Ontario and McMaster Universities Arthritis Index* (WOMAC), which assess aspects related to pain and hip function in patients' daily activities.[10,11] These tools analyze the patient's perception of quality of life and restoration of function in relation to the treatment received over time. In Brazil, there is a scarcity of studies evaluating costs, associated or not with preoperative characteristics, clinical outcomes and quality of life of patients undergoing elective THA, both in private and public services. Thus, this study aims to (1) describe the quality of life and functional assessment scores over two years and total cost of patients undergoing elective primary THA in a private tertiary hospital in Brazil; (2) determine preoperative factors associated with quality of life and total cost; and (3) evaluate the association between total cost and quality of life.

METHODS

The present study is a retrospective cohort with data from patients who underwent elective primary THA in a private tertiary hospital in Brazil with an open clinical staff, considered to be one of the reference centers in orthopedics in Latin America. The study included 1061 patients over the age of 18 who underwent THA for osteoarthritis, osteonecrosis, rheumatoid arthritis or hip dysplasia between 2012 and 2019.

The hospital has been systematically collecting and recording data on all patients undergoing THA, such as demographic data, preoperative data, perioperative data, hospitalization data and the need for readmission, since 2009. However, data on clinical and functional outcomes over time began to be collected and recorded in 2012. Cost data is stored in another database in the hospital's administrative department, which can be consulted with institutional authorization.

For this study, the following pre- and peri-operative data was collected: gender, age, body mass index (BMI), comorbidities (hypertension, diabetes, heart disease, smoking), diagnosis of the hip pathology affected, preoperative quality of life using the EQ-5D,[8] preoperative functional scores using the HOOS[11] and WOMAC,[10] surgery time, length of hospital stay, place of hospitalization on the first postoperative day (ward, intensive care unit (ICU), semi-ICU), and need for readmission within 30 days. The total cost of the procedure was also collected, which involves the costs related to the hospitalization period directly related to the surgical procedure, such as hospitalization time, operating room use time, list of medications, surgical materials and implants used during surgery. In addition, postoperative data from the EQ-5D, HOOS and WOMAC scores at 1 and 2 years of follow-up were collected.

This study was approved by the institution's Research Ethics Committee (CAAE: 44554121.1.0000.0071, opinion number 4.704.702) and the informed consent form was waived.

Statistical analysis

The data was described using absolute and relative frequencies for the qualitative variables and means, standard deviation (SD), minimum and maximum values for the quantitative variables. The distribution of normality was checked using the Shapiro-Wilk test. To compare the questionnaire scores between the different assessment times, generalized mixed models were adjusted and Mann-Whitney parametric tests were used. Comparisons between gender and age group (up to 55 years, between 56 and 70 years and over 70 years) in relation to variations in preoperative and postoperative scores at one and two years of follow-up were assessed using linear mixed models, taking into account the dependence between assessments in the same patient. Associations between the variation in EQ-5D two years after surgery and the total cost with pre- and perioperative data were made using generalized linear models. The correlations between the total cost and the EQ-5D at the end of two years were measured using Spearman's correlation coefficients. The analyses were carried out using the SPSS program, considering a significance level of 5%.

RESULTS

Of the 1061 patients included, 531 were women (50%) and 530 men (50%) (Table 1). The average age was 62.0 ±14.0 years and the average BMI was 27.6 ±4.5. 72.9% of the patients were overweight or obese. The most frequent comorbidities were hypertension (n=392; 36.9%) and diabetes (n=149; 14.0%). The main diagnosis for the indication of THA was osteoarthritis (96.3%) and the average total cost per patient was R$43,324.22 ±11,323.

There was an improvement in all the quality of life and functional assessment scores 1 year after surgery and this improvement was maintained 2 years later (Table 2). At the end of two years, the average EQ-5D improved from 0.492 to 0.892, HOOS improved from 54.5 to 90.4 and WOMAC improved from 45.2 to 4.0.

Comparisons of score variations showed differences in the EQ-5D between the groups of patients aged up to 55 years and over 70 years in the one-year ($p<0.001$) and two-year ($p<0.001$) post-operative evaluations, and between the groups aged 56 to 70 years and over 70 years in the one-year ($p=0.003$) and two-year ($p=0.013$) post-operative evaluations (Table 3). There were no differences in

Table 1. Patients' pre- and peri-operative data (n=1061).

	n (%)
	Mean ± SD (Min-Max)
Female	531 (50.0%)
Age (years)	62.0 ± 14.0 (18-99)
IMC (kg/m2); n=1025	27.6 ± 4.5 (14.7-43.0)
Low weight (<18.5kg/m)	8 (0.8%)
Adequate (18.5 to 24.9 kg/m)	269 (26.2%)
Overweight (25 to 29.9 kg/m)	435 (42.4%)
Obesity (≥30 kg/m)	313 (30.5%)
Comorbidities	
Hypertension	392 (36.9%)
Diabetes	149 (14.0%)
Heart disease	105 (9.9%)
Smoking	51 (4.8%)
Diagnosis of hip pathology	
Osteoarthritis	1022 (96.3%)
Osteonecrosis	33 (3.1%)
Artrite Reumatóide	4 (0.4%)
Hip dysplasia	2 (0.2%)
Surgery time (hours); n = 1020	2.0 ± 0.8 (0.7-8.8)
Length of stay (days)	4.6 ± 3.8 (1.0-76.0)
Readmission within 30 days	3 (0.3%)
Place of hospitalization in the 1st PO	
Infirmary	531 (50.0%)
Semi-ICU	178 (16.8%)
ICU	352 (33.2%)
Total cost per patient (reais)	43.324,22 ± 11.323,00 (16.868,31-147.082,01)

SD, standard deviation; n, number of patients; BMI, body mass index; PO, postoperative; ICU, intensive care unit

<< SUMÁRIO

Table 2. Results of quality of life and functional assessment of patients.

	Mean (95% CI)	p-value
EQ-5D (n=651)		
Preoperative	0.492 (0.477-0.507)	
Post-surgery 1 year	0.888 (0.872-0.904)	*<0.001
Post-surgery 2 years	0.892 (0.874-0.910)	*<0.001
HOOS (n=244)		
Preoperative	54.5 (51.5-57.6)	
Post-surgery 1 year	90.0 (87.7-92.3)	*<0.001
Post-surgery 2 years	90.4 (87.3-93.7)	*<0.001
WOMAC (n=411)		
Preoperative	45.2 (42.9-47.6)	
Post-surgery 1 year	5.9 (4.9-7.2)	*<0.001
Post-surgery 2 years	4.0 (3.1-5.1)	*<0.001

* in relation to the preoperative score

the comparisons of the variations in the HOOS and WOMAC scores preoperatively and at one and two years of follow-up between sex and the age groups established.

The analysis of associations between EQ-5D variation two years after surgery and pre- and peri-operative data showed a significant association with male gender (RM=1.058; p=0.03) and age (RM=0.996; p<0.001) (Table 4).

When analyzing the association between total cost and pre- and perioperative data, a significant association was found with patients who smoked (RM= 0.914; p= 0.043) (Table 5). The other linear analyses showed no evidence of an association between the variation in EQ-5D two years after surgery or the total cost with pre- or peri-operative data.

There was no evidence of a correlation between total cost and scores for quality of life (EQ-5D) and function (HOOS and WOMAC) at the end of two years (Table 6).

DISCUSSION

In this study on THAs carried out in a private tertiary hospital with an open clinical body in Brazil, the most important results were to report an average total cost per patient of R$43,324.22, achieving satisfactory quality of life and functional results at one and two years of follow-up. Furthermore, there was no association between total cost and quality of life or functional outcomes. However, there was an association between the variation in EQ-5D two years after surgery and male gender and age.

The results of improved quality of life and function in patients undergoing THA were present at one and two-year follow-ups. At one-year follow-up, the EQ-5D showed an improvement of 0.396, which was greater than the 0.18 improvement one year after surgery in the study that analyzed more than 28,000 THAs in several European countries.[12] This difference exceeds the *minimally important difference* of 0.074 for the EQ5D.[13] There was also an improvement in the HOOS and WOMAC functional scores, similar to those found in other studies,[14-16] reinforcing the excellent results of THA.

The total cost per patient at the end of hospitalization ranged from R$16,868.31 to R$147,082.01, with an average cost of R$43,324.22. The variation in cost is related to the different values of implants, materials inherent in the procedure and hospitalization costs. In an Italian public hospital, Fidanza et al[17] cited an average value of €5,754.00 euros, relatively lower than the cost found in the present study, which was carried out in a private tertiary hospital. In the scenario of private American hospitals, Robinson et al[18] and Gardezi et al[19] reported a cost of between $2,391.00 and $12,651.00 dollars, comparable to the cost resulting from the present study. In England,

Table 3. Comparisons of variations in EQ-5D, HOOS and WOMAC scores preoperatively and at one and two years of follow-up, according to age group.

	Age		
	Up to 55 years old	**56 to 70 years old**	**Over 70**
EQ-5D scale			
1 year	0.45 (0.41; 0.49)	0.42 (0.39; 0.45)	0.34 (0.30; 0.38)
2 years	0.47 (0.43; 0.51)	0.42 (0.39; 0.45)	0.35 (0.31; 0.39)
	Contraste	**p-value**	
Evaluation 1 year			
Up to 55 years old - 56 to 70 years old	0.03 (-0.02; 0.08)	0.305	
Up to 55 years old - over 70 years old	0.11 (0.04; 0.18)	<0.001	
56 to 70 years old - over 70 years old	0.08 (0.02; 0.14)	0.003	
Evaluation 2 years			
Up to 55 years old - 56 to 70 years old	0.05 (0.00; 0.10)	0.06	
Up to 55 years old - over 70 years old	0.12 (0.05; 0.19)	<0.001	
56 to 70 years old - over 70 years old	0.07 (0.01; 0.13)	0.013	
HOOS scale			
1 year	31.2 (23.9; 38.5)	40.9 (35.1; 46.8)	34.6 (27.0; 42.1)
2 years	34.4 (24.1; 44.8)	39.7 (32.6; 46.8)	35.1 (25.2; 45.0)
	Contraste	**p-value**	
Evaluation 1 year			
Up to 55 years old - 56 to 70 years old	-9.7 (-21.1; 1.8)	0.127	
Up to 55 years old - over 70 years old	-3.3 (-13.8; 7.2)	0.534	
56 to 70 years old - over 70 years old	6.4 (-4.5; 17.3)	0.378	
Evaluation 2 years			
Up to 55 years old - 56 to 70 years old	-5.3 (-20.6; 10.0)	>0.999	
Up to 55 years old - over 70 years old	-0.6 (-15.2; 13.9)	>0.999	
56 to 70 years old - over 70 years old	4.6 (-9.5; 18.8)	>0.999	
WOMAC scale			
1 year	-45.5 (-50.1; -40.9)	-40.3 (-44.0; -36.7)	-44.6 (-48.8; -40.4)
2 years	-47.1 (-51.4; -42.8)	-42.6 (-46.0; -39.1)	-45.0 (-48.9; -41.0)
	Contraste	**p-value**	
Evaluation 1 year			
Up to 55 years old - 56 to 70 years old	-5.1 (-12.3; 2.1)	0.264	
Up to 55 years old - over 70 years old	-0.9 (-7.1; 5.4)	0.785	
56 to 70 years old - over 70 years old	4.2 (-2.1; 10.6)	0.272	
Evaluation 2 years			
Up to 55 years old - 56 to 70 years old	-4.5 (-11.3; 2.3)	0.331	
Up to 55 years old - over 70 years old	-2.1 (-8.5; 4.3)	0.745	
56 to 70 years old - over 70 years old	2.4 (-3.6; 8.4)	0.745	

Values expressed as estimated means (95% CI)

Table 4. Associations of EQ-5D variation two years after surgery with pre- and peri-operative data.

	Estimated means (95% CI)	RM (IC 95%)	p-value
Male (n=156)	0.447 (0.411; 0.483)	1.058 (1.005; 1.113)	0.03
Female (n=162)	0.391 (0.355; 0.426)	1	
Age (years) (n=318)		0.996 (0.995; 0.998)	<0.001
IMC (kg/m2) (n=310)		1.003 (0.997; 1.009)	0.399
Smoker (n=18)	0.440 (0.333; 0.548)	1.024 (0.917; 1.143)	0.676
Non-smoker (n=300)	0.417 (0.391; 0.443)	1	
Hypertensive (n=127)	0.412 (0.372; 0.452)	0.990 (0.940; 1.043)	0.696
Not hypertensive (n=191)	0.422 (0.390; 0.455)	1	
Diabetic (n=53)	0.403 (0.341; 0.466)	0.982 (0.917; 1.052)	0.603
Non-diabetic (n=265)	0.421 (0.393; 0.449)	1	
Heart disease (n=40)	0.384 (0.312; 0.456)	0.961 (0.890; 1.038)	0.314
Non-cardiac (n=278)	0.423 (0.396; 0.450)	1	
Surgery time (hours) (n=303)	1.008 (0.975; 1.042)	0.621	
Length of stay (days) (n=318)	0.991 (0.980; 1.002)	0.097	
1st PO in Infirmary (n=155)	0.432 (0.396; 0.469)	1.019 (0.961; 1.079)	0.531
1st PO in Semi-ICU (n=61)	0.390 (0.332; 0.448)	0.977 (0.908; 1.051)	0.53
1st PO in ICU (n=102)	0.414 (0.369; 0.459)	1	

BMI, body mass index; MR, ratio of means; 95% CI, 95% confidence interval for the estimated ratio of means; reference categories have 1 in place of the odds ratio; PO, postoperative; ICU, intensive care unit.

from the national arthroplasty registry, between 2008 and 2017, around 400,000 THAs were registered, and an average cost of 6,208 pounds per patient was estimated,[20] relatively lower than the average cost of this study.

The improvement in quality of life was associated with the preoperative factors age and gender. These associations have been found in other studies, but other factors such as previous surgeries, ASA, comorbidities and BMI have also been shown to be associated with clinical-functional outcome.[21,22] This study found no association between these factors and quality of life, possibly due to the characteristics of the population and the number of patients included.

The increase in total cost has already been described as being associated with age, complication rate and fate after discharge,[18] but in the present study there was no significant association with any preoperative factor, except smoking. Although patients who smoked had lower total costs than non-smokers, the interpretation of this finding is limited, as the frequency of smokers is small (N= 51; 4.8%), and there are no studies reporting this association. Furthermore, the lack of association between preoperative factors and total cost at an individual level, such as patient characteristics, seems to have a minimal influence on the final cost, with intra-hospital characteristics being most responsible for this variation, which could include materials and the particular preferences of each surgical team.[18] This is corroborated by Fidanza et al,[17] who cite that approximately half of the total cost is attributable to the value of the prosthesis alone. Given that the assessment of quality of life by predetermined scores limits the possible range of improvement and that hip arthroplasty is already recognized as a surgery of excellent effectiveness, regardless of the primary cause for surgery, it is not surprising that no associations were observed between total cost and quality of life or functional results up to 2 years after surgery.

Table 5. Associations between total cost and pre- and peri-operative data.

	Estimated means (95% CI)	RM (IC 95%)	p-value
Male (n=309)	43269.11 (42175.87; 44390.70)	0.997 (0.961; 1.035)	0.888
Female (n=286)	43383.77 (42244.97; 44553.26)	1	
Age (years) (n=595)		1.001 (0.999; 1.002)	0.318
IMC (kg/m2) (n=575)		1.000 (0.995; 1.004)	0.927
Smoker (n=28)	39762.59 (36532.12; 43278.71)	0.914 (0.838; 0.997)	0.043
Non-smoker (n=567)	43500.11 (42688.67; 44326.97)	1	
Hypertensive (n=214)	42949.94 (41473.06; 44479.41)	0.987 (0.944; 1.031)	0.545
Not hypertensive (n=381)	43534.45 (42407.63; 44691.21)	1	
Diabetic (n=83)	43124.57 (41046.96; 45307.34)	0.995 (0.943; 1.049)	0.843
Non-diabetic (n=512)	43356.59 (42503.16; 44227.15)	1	
Heart disease (n=65)	41731.07 (39469.84; 44121.85)	0.959 (0.904; 1.017)	0.163
Non-cardiac (n=530)	43519.61 (42678.80; 44376.99)	1	
Surgery time (hours) (n=580)		0.995 (0.971; 1.020)	0.685
Length of stay (days) (n=585)		1.002 (0.994; 1.010)	0.586
1st PO in Infirmary (n=327)	43222.52 (42161.01; 44310.75)	1.003 (0.960; 1.047)	0.902
1st PO in Semi-ICU (n=108)	43957.63 (42096.25; 45901.31)	1.020 (0.964; 1.079)	0.493
1st PO in ICU (n=160)	43104.54 (41599.18; 44664.38)	1	

BMI, body mass index; MR, ratio of means; 95% CI, 95% confidence interval for the estimated ratio of means; reference categories have 1 in place of the odds ratio; PO, postoperative; ICU, intensive care unit

Table 6. Correlation coefficients of the total cost with the EQ-5D, HOOS and WOMAC scores at the end of two years.

		Total cost*
EQ-5D - 2 years	n=292	-0.079 (p=0.179)
HOOS score - 2 years	n=70	-0.041 (p=0.734)
WOMAC score - 2 years	n=223	0.093 (p=0.164)

*Spearman's correlation coefficient (p-value)

This study has some limitations that should be taken into account. This is a retrospective study, which used an institutional database, without access to the medical records by the researchers, so that gaps in the data, sometimes incomplete, reduced the study's sample number for the different analyses carried out. However, the n used in each analysis is reported in the tables. Furthermore, as this was a single-center study in a single private tertiary hospital, its results cannot be extrapolated to the entire Brazilian population. However, it is a reference hospital in Latin America and open to external surgeons, whose profile, surgical technique and level of experience vary considerably.

CONCLUSION

Patients who underwent THA in a private Brazilian hospital with an open clinical practice had improved quality of life and functional scores at one and two years' follow-up and an average total cost per patient of R$43,324.22. In addition, there was an association between the increase in the EQ-5D score two years after surgery and male gender and age. There was no association between total cost and quality of life score.

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EFFECTIVENESS OF CEMENTLESS PROSTHESIS IN PATIENTS OVER 70 YEARS OF AGE

EFETIVIDADE DA PRÓTESE DE QUADRIL NÃO CIMENTADA EM PACIENTE ACIMA DE 70 ANOS DE IDADE

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ABSTRACT

Introduction: Hip replacement in the elderly is challenging due to their unique clinical conditions. Choosing the prosthesis requires an evaluation of risks and benefits, considering the implant's durability, postoperative recovery, and patient longevity. Uncemented prostheses have emerged as a viable alternative, offering osseointegration, as well as mechanical and biological stability. Methods: A retrospective observational study analyzed the medical records of patients aged 70 years or older who underwent total hip arthroplasty (THA) with an uncemented prosthesis between 2013 and 2022. Age, sex, diagnosis, procedures performed, and postoperative follow-up time were evaluated. Results: Of the 231 patients analyzed, women predominated (62%), with an average age of 78.5 years for men and 79.1 for women. There was a consistent preference for the uncemented technique across all age groups, with less than 20% of cases requiring cerclage. Complications were minimal, with over 90% of cases being complication-free, highlighting the technique's efficacy. Conclusion: The technique reduces complications, including inflammatory reactions and long-term bone loss. The low rate of surgical revision and return to recreational activities reinforce its efficacy. Although cemented prostheses have historically been preferred, uncemented prostheses offer advantages in the elderly population, as they preserve bone and facilitate revisions. ***Level of evidence III; Therapeutic Studies - Investigation of Treatment Outcomes.***

Keywords: Hip Replacement Arthroplasty; Aged; Treatment Outcome.

RESUMO

Introdução: A substituição do quadril em idosos é desafiadora devido às suas condições clínicas singulares. A escolha da prótese requer avaliação de riscos e benefícios, considerando a durabilidade do implante, a recuperação pós-operatória e a longevidade do paciente. As próteses não cimentadas surgiram como alternativa viável, oferecendo osseointegração e estabilidade mecânica e biológica. Métodos: Estudo retrospectivo observacional, analisando prontuários de pacientes com mais de 70 anos submetidos à artroplastia total de quadril (ATQ) com prótese não cimentada entre 2013 e 2022. Foram avaliados idade, sexo, diagnóstico, procedimentos realizados e tempo de acompanhamento pós-cirúrgico. Resultados: Dos 231 pacientes analisados, predominaram mulheres (62%), com média de idade de 78,5 anos para homens e 79,1 para mulheres. Houve uma preferência consistente pela técnica não cimentada em todas as faixas etárias, com menos de 20% dos casos requerendo cerclagem. Complicações foram mínimas, com mais de 90% dos casos sem complicações, destacando a eficácia da técnica. Conclusão: A técnica reduz complicações como reações inflamatórias e perda óssea a longo prazo. A baixa taxa de revisão cirúrgica e retorno à atividade recreativa reforçam sua eficácia. Embora as próteses cimentadas tenham sido historicamente preferidas, as não cimentadas oferecem vantagens na população idosa, preservando osso e facilitando revisões. ***Nível de Evidência III; Estudos Terapêuticos - Investigação dos Resultados do Tratamento.***

Descritores: *Artroplastia de Substituição de Quadril; Idoso; Resultado do Tratamento.*

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INTRODUCTION

The choice of prosthesis type used in hip replacement surgeries for the elderly requires careful evaluation of risks and benefits, considering the implant's durability, postoperative recovery, and patient longevity.[1] Surgery relieves pain and improves quality of life, especially in the elderly with osteoarthritis. With the increase in longevity, the number of hip replacements is rising. Uncemented prostheses are a viable alternative to cemented ones, benefiting patients over 70 years old.[2]

Uncemented prostheses are popular due to their osseointegration, which provides greater mechanical and biological stability, better load transfer, and reduced aseptic loosening, crucial factors for the longevity of the implant in elderly patients with extended life expectancy.[3]

Bone quality compromised by osteoporosis and anatomical deformities can complicate the fixation and stability of the implant. The choice of size and design for the prosthesis should consider individual anatomical characteristics to ensure a proper fit and minimize complications.[4]

By analyzing clinical outcomes, revision rates, and complications in patients over 70 years old, the aim is to inform treatment decisions and promote better outcomes in hip replacement for the elderly.

MATERIALS AND METHODS

The study was approved under CAAE No: 80917524.7.0000.0237. All participants signed the informed consent form (ICF).

This retrospective observational study was conducted using data collected from electronic medical records spanning the years 2013-2022 in a private clinic located in a Brazilian capital city. The following were analyzed: age, sex, laterality, injury diagnosis, procedures performed, and time elapsed between diagnosis and revision surgery.

Patients who were at least 70 years old at the time of their surgery, who underwent hip arthroplasty using an uncemented hip prosthesis, who had the surgery in a private clinic located in a Brazilian capital city, and who have medical follow-up in the same hospital for at least 6 months post-surgery for post-operative supervision were selected. Patients who did not meet the sociodemographic criteria of the study, who abandoned treatment, or who failed to comply with the established follow-up criteria for the study (i.e., loss to follow-up) were excluded.

RESULTS

A total of 144 female patients and 87 male patients were identified, aged between 70 and 107 years, with an average age of 78.5 years for men and 79.1 years for women, a global median of 77 years, and a standard deviation (σ) of 7.1 years. According to the data presented in Table 1, there was a general predominance (62%) of the female sex, and as shown in Figure 1, the predominance remains consistent across all age groups evaluated. For all statistics involving the study parameters, patients without data were excluded from the analysis.

The data obtained are consistent with the epidemiology of patients affected by the main indications for THA, including femur fracture and hip osteoarthritis.

The sampling was divided between patients undergoing cemented THA and non-cemented, regardless of laterality or gender. Patients who were bilaterally prosthetized or who received hybrid fixation techniques (cemented and non-cemented prostheses) were also included among the surgeries. Figure 2 shows a heterogeneous distribution of the techniques employed; however, there is a consistent predominance of the non-cemented technique across all age groups.

Of the patients in this group who met the inclusion criteria, only 13.51% underwent dissimilar techniques. With the available data, it was not possible to establish a direct correlation between the indication of alternating techniques in the same patient and other parameters, given the homogeneous distribution of these patients in gender, age group, and the proximity of the THA dates.

Among the patients in whom the technique was repeated, non-cemented prosthesis stood out at 75.7%. Hybrid techniques were not described in the sampling. In 13 patients, it was necessary to perform cerclage concurrently with THA, and, as indicated in Figure 2, less than 20% of the cases involved cemented prostheses.

Due to the known correlation between chronological age and bone fragility, the reduction of fixation is a significant obstacle to consider when selecting a prosthesis.

There is a clear trend towards a progressive increase in the use of non-cemented prostheses over time. Contrary to the observations of John Chanrley, a pioneer in the development of the first joint prostheses in the 1960s, who concluded in his studies conducted over 50 years ago that the success of the surgery was closely linked to an effective cementation technique.

Figure 3 illustrates the complications observed in patients undergoing uncemented THA.

It is noted that in more than 90% of the analyzed cases, no complications were observed, thus highlighting the effectiveness of the cementless technique.

Despite various modifications to THA techniques over the decades, cementation remains a benchmark standard. It is essential to emphasize that the advancements aimed primarily to minimize

Table 1. Gender predominance.

Gender	Sample	Percentage
Female	144	62.33%
Male	87	37.66%
Total	231	100%

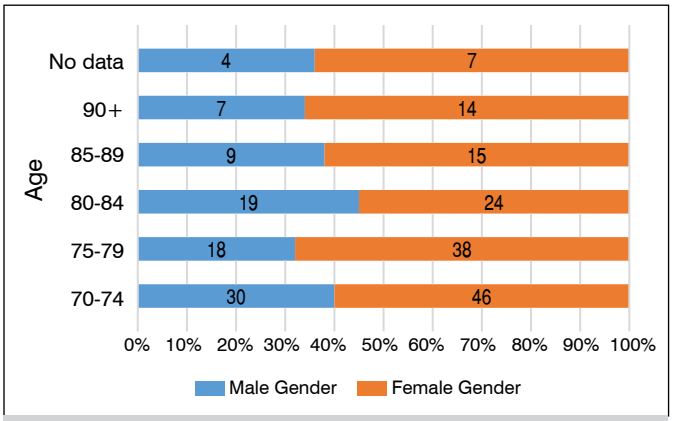

Figure 1. Gender by age group.

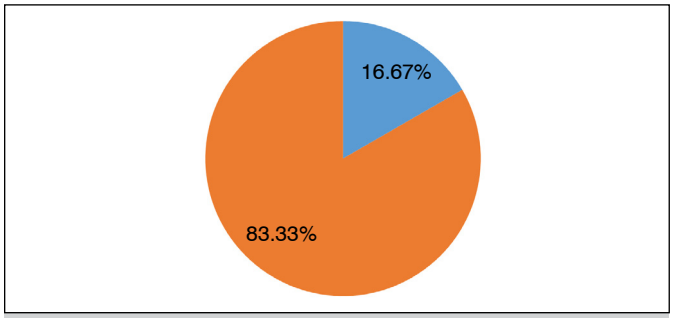

Figure 2. Distribution by method of patients undergoing cerclage.

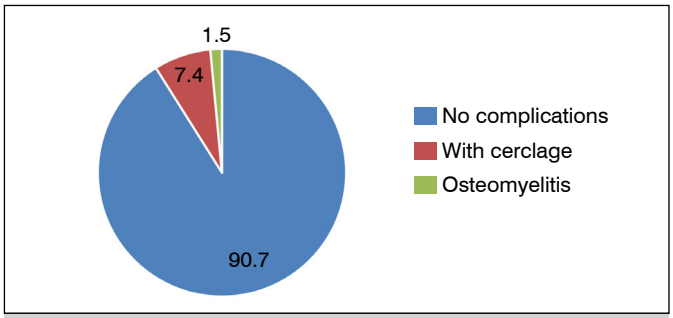

Figure 3. Complications in patients undergoing uncemented THA.

complications arising from the interaction of the cemented material with the bone; this interaction does not exist in the uncemented technique, avoiding possible allergic, inflammatory, or infectious reactions. Preventing bone degradation and reducing the chances of needing surgical revisions.

DISCUSSION

Over the last 20 years, cementless prostheses have gained significant ground in most Brazilian orthopedic centers, as observed in the clinic where the study was conducted. However, the discussion regarding the possible superiority of one of the techniques still lacks a definitive conclusion.

The choice of a qualitative-quantitative approach to analyze the research data was based on the need to understand both quantitative and qualitative aspects related to total hip arthroplasty (THA). This allowed for a more detailed analysis of the variables involved, including not only numerical and statistical data but also qualitative considerations regarding surgical methods, patient characteristics, and trends over time.

The selection of a sample of 231 patients aged 70 years and older who underwent THA between 2013 and 2022 was motivated by the need to obtain a representative and specific sample for the study. This demographic group was chosen due to the clinical relevance of surgical interventions on the hip in elderly patients, considering the prevalence of conditions such as femoral fractures and osteoarthritis in this age group.

The observed age range and sex are consistent with the data obtained by Brüggemann et al.,[1] who analyzed cases treated from 1987 to 2020 in Norway. In this study, the cemented technique was used in 61% of the surgeries, but the uncemented technique gained popularity starting in 2008. In addition to this similarity, the study by Brüggemann et al.,[1] observed that only 1% of the cases presented intraoperative periprosthetic femoral fracture, a remarkably low percentage considering the study period and the number of patients included. These results clearly relate to those obtained in this study.

The increased risk for uncemented stem fixation versus cemented stem fixation was relatively stable across different age and sex strata; thus, the uncemented total hip arthroplasty (THA) technique presents better prognoses, especially when considering the interaction of the material with the patient's body.

There is a heterogeneous distribution of the techniques employed, with a consistent predominance of the uncemented technique across all age groups. Even among patients aged 90 years or older, the preference for uncemented prostheses reaches 69%. The study by Delmonte et al.,[3] analyzes the effectiveness of uncemented hip prosthesis in managing hip dysplasia; in this study, about 86% underwent uncemented THA surgery between 1999 and 2021, with patients aged between 26 and 77 years. Consolidation of all femoral osteotomies was noted, with no delays in consolidation or pseudarthroses observed in any patient. Delmonte et al.,[3] present concurrent results with those obtained in this study, with a low incidence of the need for re-surgical intervention (one patient).

Another study that also reports on uncemented THA intervention in managing rheumatoid arthritis was conducted with a sample of 24 patients; throughout the study development period, no cases of prosthesis loosening were evidenced, nor was there vertical migration of the stem, only one case of distal perioperative fracture at the calcaneus, treated with cerclage, without affecting the quality of clinical and radiographic results for the patient, and no cases of dislocations or infections were reported. In the clinic, the need for additional procedures, such as cerclage, was relatively low, with only 16.67% of cases requiring cerclage.[4]

Patients over 80 years in the sample were significant (88 patients, among both women and men); the study by Yuasa et al.[5] analyzed the results of uncemented total hip arthroplasties (THA) in patients aged 80 years or older, where none of the THAs required a re-surgical approach due to poor initial fixation or early loosening. In this study, conducted in Japan, all analyzed patients were female; this age group is associated with a known history of greater bone fragility due to age and reduced calcium absorption after menopause.

The overall predominance (62%) of females in the sample corroborates the epidemiology of indications for THA, such as femur fracture and hip osteoarthritis. This trend remains isolated across all age groups evaluated. Talking with other studies.[6,7]

Solarino et al.,[6] highlight that men and women have significant anatomical differences in the hip, which may influence the results of THA. Women tend to have a wider pelvis and a larger femoral neck angle, which can affect the biomechanics of the prosthesis and the wear of the components. The authors do not present the percentage data for each sex; however, it is noted that women tend to be more prevalent due to the higher incidence of osteoarthritis and osteoporosis, conditions that often lead to the need for THA.

The study by Liu et al.,[7] compares the long-term results of patients undergoing total hip arthroplasty (THA) using cemented versus uncemented femoral components. The study reveals a higher revision rate in the group with uncemented components (5.2%) compared to the group with cemented components (3.8%). This difference was not statistically significant. Patients with cemented components had a higher incidence of perioperative complications, such as pulmonary embolism and intraoperative fractures, compared to the uncemented group. It is emphasized that uncemented prostheses are designed to allow direct bone growth on the surface of the implant, promoting a more natural and solid integration. This osseointegration can lead to greater long-term stability and reduce the need for revisions. Liu et al.[7] emphasize that cementing can lead to bone necrosis around the cement, compromising bone quality in the long term. Uncemented prostheses better preserve bone structure, facilitating possible revision procedures in the future.

Following the technique chosen to develop the case study at the Clinic, the study by Li et al.[8] (2020) shows better results in procedures where the uncemented technique was employed. A total of 8 studies involving 1,577 hips (782 uncemented and 795 cemented) were included in this meta-analysis. The meta-analysis indicates that the operation time for cemented hemiarthroplasty was longer than for uncemented hemiarthroplasty. This study notes that the cemented technique resulted in a longer hospitalization time and a higher rate of pulmonary embolism. It is also emphasized that the uncemented procedure has a shorter operating room time.

A study conducted in Europe has shown that, in recent years, there has been an increase in the use of uncemented prostheses among the elderly population. This study highlighted trends in the use of uncemented fixation, particularly in patients over 75 years old. The

study included countries such as Australia, Denmark, England and Wales, Finland, the Netherlands, New Zealand, Norway, Romania, Sweden, and Switzerland, all of which have high completeness rates. Through this study, it was noted that in Scandinavian countries, the percentage of total hip arthroplasties (THAs) performed with uncemented fixation gradually increased, with a notable increase in the use of uncemented fixation in patients over 75 years old.[9] It was again observed that there was a shorter hospitalization time and fewer postoperative complications.

That said, the uncemented technique still showed a clear advantage in the study when used in men up to 75 years old. Stabilization and lower fall rates in patients aged 75 or older were also attributed; however, the hypothesis of better awareness methods is raised.[9]

Rassir et al.,[10] (2021), when analyzing THAs performed with bone cement, discuss a study on the bone cement implantation syndrome (BCIS), which is characterized by hypoxia, hypotension, and loss of consciousness during cemented THA and can result in death. This study also reports that BCIS occurred in 26% of arthroplasties in general, and the incidence in hemiarthroplasties was 31%. Specifically, in hip hemiarthroplasties, a 28% occurrence of BCIS was recorded, which is a relatively high percentage considering the study population. In surgical re-approach procedures, BCIS was present in 20% of cases. Among patients who experienced severe BCIS, a higher probability of death was noted within 30 days after the procedure. Among the factors independently associated with the development of severe BCIS, age over 75 years and chronic renal failure were the most prevalent specifics. The uncemented technique does not use surgical cement. Thus, this serious complication is completely ruled out as a possible occurrence.

The study by Jämsen et al.[11] shows that periprosthetic fracture was the primary mode of failure for uncemented hip replacements, indicating that the most serious complication observed could be treated with cerclage, a relatively straightforward procedure. After 1 year, there were no differences in survival rates, once again showing favorable patterns for the cementless technique.

Zimmerer et al.[12] conducted a cohort study with 96 patients aged between 76 and 84 years who underwent cementless total hip arthroplasty (THA), with 79 patients completing a comprehensive questionnaire on postoperative recreational activities, including sports. After surgery, 71% of patients were active in at least one recreational activity, 72% of patients returned to recreational activities within one month after surgery, and 26% resumed sports activities within three months. The main findings of the study are that the vast majority of patients could return to any type of recreational behavior after cementless THA.

Finally, the study by Yuasa et al.,[6] reports that among the 30 cementless THAs performed in patients over 80 years old, no patient required surgical revision due to poor fixation or early loosening of the prosthesis. Thus, it was possible to conclude in this context that cementless THA is safe and durable in this population.

CONCLUSION

Cementless prostheses offer greater bone preservation and facilitate revision procedures, when necessary, which can be beneficial for individuals facing mobility issues and fragile health. The hip arthroplasty procedure is significantly safer than other techniques, as demonstrated in our analysis of the elderly population and that of other authors. The surgical revision rate is expressively low, comparable to the same procedure frequently performed in the United States of America, where the revision rate is only 1%. Thus, considering the benefits in terms of longevity and quality of life, cementless prostheses emerge as a highly advantageous option for this age group.

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COMPARATIVE STUDY BETWEEN ATK 1ª WITH CONSTRICTED POLYETHYLENE VERSUS POSTERO-STABILIZED

ESTUDO COMPARATIVO ENTRE ATJ 1ª COM POLIETILENO CONSTRITO VERSUS PÓSTERO-ESTABILIZADO

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ABSTRACT

Objective: The objective of the article was to do a comparative study between Smith & Nephew ® prosthesis with constricted polyethylene against the standard in patients submitted to total knee arthroplasty surgery during a short-term follow-up. The aim was to analyze the survival of the related implants due to the range of movement and radiographic aspect. Methods: The sample was divided into two different groups: constricted polyethylene and standard polyethylene. A clinical analysis of the patients was carried out, and it was verified whether implant loosening had occurred. Results: This study evaluated 61 patients in a period of 2 years, 29 in the constricted polyethylene group. The pre-operative deformities were predominantly considered severe. In the postoperative, the tibial-femoral angle varied on average between 5 – 6° of valgus. The total range of movement in the post-operative was above 101° in both groups. One loosened implant in the constricted polyethylene group was observed. Conclusion: The patients treated with constricted polyethylene had the same range of movement as the control group. There was no significant difference between both groups related to loosened implants in short-term follow-up. ***Level of evidence III; Retrospective study.***

Keywords: Arthroplasty; Replacement, Knee; Knee; Postoperative Complications.

RESUMO

Objetivo: O objetivo da pesquisa foi realizar um estudo comparativo entre as próteses Smith & Nephew ® com polietileno constrito contra o standard, em pacientes submetidos à artroplastia total do joelho, durante um seguimento de curto prazo. Dessa forma, objetivou-se analisar a sobrevida dos implantes em questão sob o arco de movimento e o aspecto radiográfico. Métodos: A amostra foi dividida em grupos de polietileno constrito e polietileno standard. Foi realizada análise clínica dos pacientes e verificado se ocorreu soltura dos implantes. Resultados: No total, foram avaliados 61 pacientes pelo período de 2 anos, sendo 29 no grupo do polietileno constrito e 32 no polietileno standard. As deformidades pré-operatórias foram predominantemente consideradas graves. No pós-operatório o ângulo tíbio-femoral oscilou na média entre 5 e 6° de valgo. O arco de movimento total no pós-operatório foi acima de 101° nos dois grupos. Foi observada uma soltura do implante no grupo com polietileno constrito. Conclusão: Os pacientes tratados com o polietileno constrito apresentaram o mesmo arco de movimento do grupo controle. Não há diferença significativa na soltura dos implantes nos dois grupos nesse seguimento de curto prazo. ***Nível de evidência III; Estudo retrospectivo.***

Descritores: *Artroplastia do Joelho; Joelho; Complicações Pós-Operatórias.*

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INTRODUCTION

Osteoarthritis of the knee associated with complex deformity has been a challenge for orthopedists. The integrity of the envelope of soft parts, in the case of sharp valgus and varus deviations, is usually compromised. Correction of these axial deformities is often associated with severe contractions in flexion or recurvation, requiring extensive ligament releases.[1,2] This may result in elevation of the joint line, low patella, and possible residual instability, resulting in implant overload and premature release.[3-5]

In total knee arthroplasty surgery (TKA), instability is a major cause of prosthesis failure.[6] According to Maynard & Sauber,[7] acceptance of instability and implantation of non-constricted components can result in patient dissatisfaction and early review in a short-term follow-up. With its inherent stability, the poster-stabilized semi-constrict

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The study was conducted at Center for Knee Surgery of the National Institute of Traumatology and Orthopedics. Brasil Ave., 500, São Cristóvão, Rio de Janeiro, RJ, Brazil. 20940-070. Correspondence: Rodrigo Sattamini Pires e Albuquerque. Ataulfo Coutinho Street, 200, Rio de Janeiro, RJ, Brazil, 22793520. rodalbuquerque19@gmail.com

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prosthesis with polyethylene constrict (MLC) has been an acceptable solution for complex cases of primary knee arthroplasties.[8] With this, increasing the constriction of the prosthesis should reduce instability. However, it can also lead to increased transmission forces to the interface between the prosthesis and the bone, when compared to implants with the standard polyethylene, which can cause early aseptic release and a reduction in the knee arc movement.[9]

In addition to this option, the increase in constriction can also be achieved through the use of the rotary hinge prosthesis, having the advantage of being used in cases of severe bone loss, complete insufficiency of one of the collateral ligaments, ligament hyperfroxidism with excessive flex/extension spaces, neuromuscular diseases, severe rheumatoid arthritis and fixed axis deviation greater than 20 degrees.[10] This prosthesis is an evolution of the fixed hinge models, combining flex-extension movement with rotation and thus improving movement mechanics and reducing the transmission of stress in fixation. However, in addition to presenting a greater stress transmission to the implant-bone interface, the volume of the implants requires a greater bone resection and presents a less physiological pattern of movement, with these additional disadvantages.[10]

Due to this, several authors advocate using polyethylene constricted in this type of PS prosthesis to theoretically improve the implant's stability.[8-9,11-14]

The Smith & Nephew® type prosthesis with constricted polyethylene is an implant that, with the increase of the pole, restricts the movements in varicose varus and valgus, and is used in some cases in our institution, which has more serious cases because it is a reference tertiary hospital in the orthopedic area (Figure 1).

The main objective of the research is to conduct a comparative study between Smith & Nephew® polyethylene-constricted prostheses and the standard in patients undergoing primary total knee arthroplasty during a short-term follow-up. Thus, the objective is to analyze the survival of the implants in question under the motion arc and radiographic aspects.

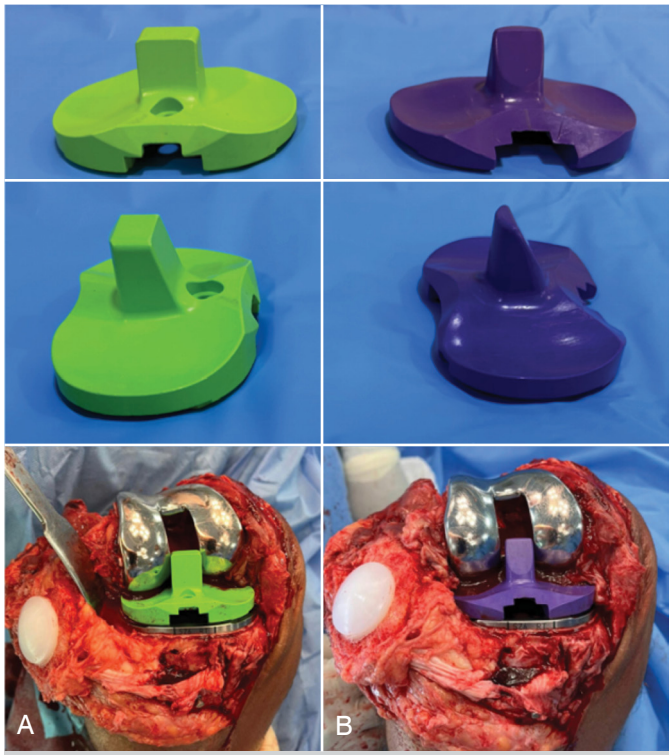

Figure 1. Image comparing constrained polyethylene (A) and standard (B).

MATERIAL AND METHODS

This study is an observational, transversal, and retrospective study. The identification of participants was carried out using data from our hospital's implant sector. Identifying the patients linked to the specific implant, it was possible to access the records of those submitted to post-stabilized primary TKA (PS) with constricted polyethylene and standard. Thus, a comparative study was conducted, observing the radiographic analysis of patients undergoing primary PS TKA, the Smith & Nephew ® brand during a follow-up of at least 2 years postoperative. The sample was divided into groups 1 with constricted polyethylene and 2 with standard polyethylene.

The sample consisted of 61 patients of both sexes and of all ages who had undergone primary TKA in the hospital with the Smith & Nephew® brand prosthesis and were admitted for treatment from 2017 to 2021. The number of patients was determined based on the observer's vision as a control case study.

The Smith & Nephew® prostheses, during this study period, were the implants offered at our hospital. Thus, the choice of the prostheses for analysis is justified, not presenting any type of conflict of interest in the evaluation.

The group was formed by 14 surgeons and doctors from the Brazilian Society of Knee Surgery, all of whom perform a minimum of 100 primary knee arthroplasties per year.

The inclusion criteria were: patients undergoing primary arthroplasty performed in the research hospital with Smith & Nephew® PS type prosthesis with constricted or standard polyethylene and knee osteoarthritis. The exclusion criteria are: rheumatic diseases, failure to document medical data, use of another model of prosthesis and non-acceptance to participate in the research. The research was approved by the Institutional Ethics Council (51589621.2.0000.5273) according to the established ethical standards.

In the postoperative, with a minimum of two years of follow-up, clinical evaluations were performed by a single doctor, a Brazilian Society of Knee Surgery member. The study consisted of two experienced observers with a postgraduate (doctoral) degree in their specialty, one of whom evaluated the radiography and the other the motion arc, and no response time was stipulated to try to reproduce a more accurate evaluation.[15]

During the evaluation, the patients' demographic data were collected, and the movement arc of the operated knee was evaluated. Angulation measurements were determined using a single goniometer with the patient naked and barefoot. The measurements were performed with the Trident® brand goniometer and by the same doctor trying to reduce biases. The interval between the goniometer measurements was two degrees. The references used to measure the clinical evaluation were the center of the patella and the membrane of the femur and tibia, respectively, in frontal vision. The center of the goniometer was positioned at the center of the patella. In the sagittal analysis, the patient was diagnosed with dorsal decubitus in the examination table. The fixed arm of the goniometer was aligned with the femur diaphysis and the moving arm with the tibia diaphysis. The goniometer's joint center was positioned to coincide with the femorotibial joint center.

The radiographic analysis of the implants was performed by another orthopedist doctor with a graduate degree in radiology, who had no prior knowledge of the functional indices obtained during the initial evaluation. The X-rays were performed with bipodal support in the anteroposterior profile and axial incidences of the patella. The radiographic analysis evaluated the release of the implant using the criteria used by the *Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System.*[16] The evaluation of osteolysis consisted of observing the presence of a radiolucent line in the area of the prosthesement-cement or cement-bone interface, which was quantified in millimeters of thickness and subsequently

analyzed in each radiographic incidence for comparison purposes. The intraoperative surgeon decided to implant with constricted polyethylene. Patients with large bone deformities or ligamental instabilities and large release of soft parts required the use of polyethylene constricted. The control group (standard polyethylene) was structured to be similar in gender and average age composition to the study group. In addition, the type of deformity of the lower limb was analyzed, and the tibio-femoral angle was measured. This angle was calculated by tracing lines between the anatomical axes of the femur and the tibia, in the pre- and postoperative period.[17]
The analysis of the radiographic data was performed using the software mDicomViewer 3.0 (Microdata, RJ-Brasil, 2007).
The medical records were analyzed, and the patients' demographic data were collected, as well as the movement arc, body mass index (BMI), and American Society of Anesthesiology Classification (ASA). The body mass index was calculated by dividing body mass by height elevated to the square. This ratio was recorded in kilograms per square meter (kg/m^2), as described by Adolphe Quelet.[18]
The statistical analysis was performed using Microsoft Excel 2016 and GraphPad Prism 5. Implant survival was defined as the need for revision for any cause, and release was determined by analyzing the Fischer test with a confidence interval of 95%. In addition, the Student T test of variance equality was used to calculate the outcomes analyzed with the two population-independent samples, with a significance level of 0.05.

RESULTS

A total of 61 patients were evaluated in postoperative primary knee total arthroplasty from 2017 to 2021. They were divided into two groups: constrained polyethylene and standard polyethylene (Table 1). All patients were diagnosed with primary knee osteoarthritis. Regarding the complications, the standard polyethylene group showed no complications. In contrast, the constricted polyethylene group presented a TKA failure with more than 2 years of follow-up, requiring a revision for a hinge-type implant (Fig. 2-4). There is no statistically significant difference between the groups (p = 0.475).

DISCUSSION

There is no study in Brazil that evaluates the polyethylene-type constricted MLC and that correlates with the movement arc of primary TKA and the survival of the implant. In addition, there are few studies in the literature on this subject. In this study, it was observed that the movement arc, the postoperative axis, the survival of implants, and the complications did not present a statistically significant difference between the groups.

It is believed that there is no waiting line for surgery in developed countries, so these patients are operated on in earlier stages of knee osteoarthritis and, consequently, are cases of less complexity. This fact makes the study extremely relevant.
When evaluating the preoperative deformities and the postoperative axis, similarity was observed between the groups, with no statistical difference.
When comparing the MLC-type implants with the PS standard prostheses, one observed a polyethylene with a higher and thicker pole, theoretically enabling a greater restriction of the implant.[12] The prostheses with intermediate constriction MLC limit the rotation in the varus and valgus; as an advantage, they have a lower degree of constriction when compared to the knee constriction implants (CCK).[12] The research demonstrates a positive result in the short-term follow-up with the MLC-type implant.
The decision to use the standard polyethylene or MLC was the surgeon's responsibility at the time of the operation. Other studies also conducted a similar analysis.[11,12] It is important to emphasize that 14 surgeons and doctors from the Brazilian Society of Knee Surgery

Table 1. Characteristics of participants.

	Constricted Polyethylene (n = 29)	Polyethylene Standard (n = 32)	P
Sex (male)			
Male	6 (20.7 %)	9 (28.2 %)	0.707
Female	23 (79.3 %)	23 (71.8 %)	
Age (years)	69 [64 : 73]	69 [61 : 73]	0.452
Laterality (right)	15 (51.7 %)	14 (43.7 %)	0.714
BMI	29.7 ± 5.6	32.2 ± 6.9	0.129
ASA			
Grade I	2 (6.9 %)	2 (6.2 %)	0.091
Grade II	23 (79.3 %)	30 (93.8 %)	
Grade III	4 (13.8 %)		
Deformity			
Valgus	12 (41.4 %)	9 (28.1 %)	0.413
Varus	17 (58.6 %)	23 (71.9 %)	
Articular axis			
Preoperative	19.4 ± 9.6	15.3 ± 8.5	0.087
Postoperative	5.7 ± 0.9	6.0 ± 1.2	0.321
ROM			
Preoperative	110 [80 : 112]	95 [85 : 110]	0.461
Postoperative	100 [90 : 115]	105 [90 : 117]	0.580

BMI: Body mass index, ASA: American Society of Anesthesiologists risk score, ROM: Range of movement. Categorical variables are expressed as absolute occurrence (percentage occurrence). Numerical variables with normal distribution are expressed as average ± standard deviation, and the rest as median (inter-quartile interval). The p-value refers to the comparison between groups.

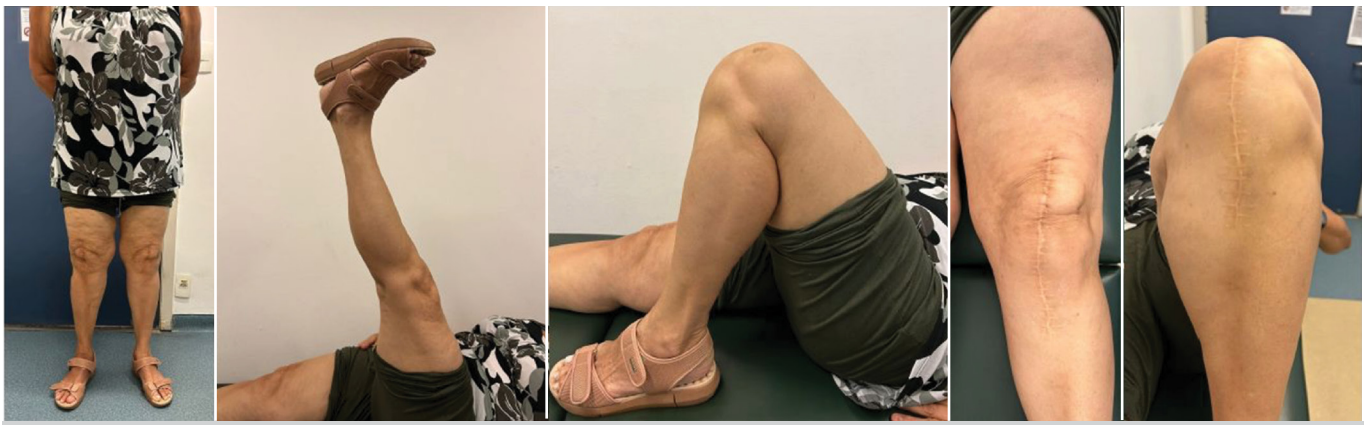

Figure 2. Clinical analysis with 2 years of implant evolution with constricted polyethylene.

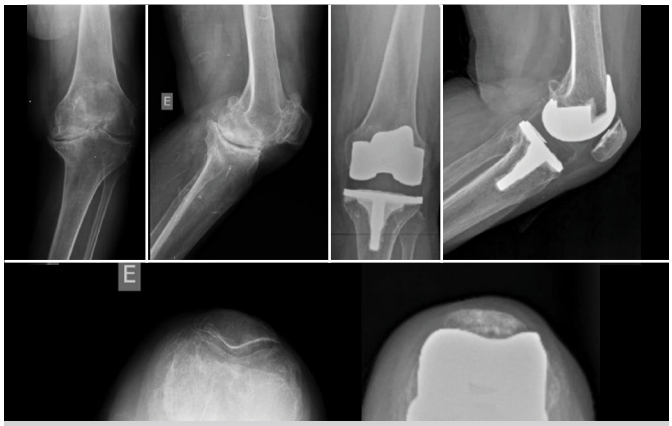

Figure 3. X-ray analysis with 2 years of implant evolution with constricted polyethylene.

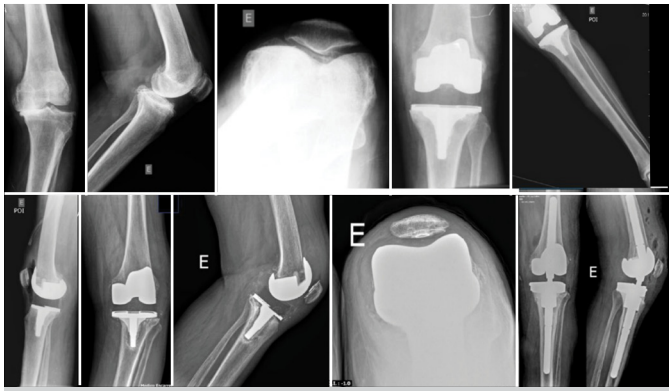

Figure 4. The X-ray shows the failure of the implant with constricted polyethylene, evolving with revision with a hinge-type implant.

were involved in this study. With this, the intraoperative analysis under anesthesia associated with the previous radiographic examination was considered the best tool for accurately assessing each case.
The study consisted exclusively of patients with osteoarthritis of the knee. Thus, we try to uniformize the groups. Patients with rheumatoid arthritis and other rheumatic diseases were excluded from the study. Dublin and collaborators corroborated the research.[12]
This study had a short-term follow-up (> 2 years) based on other studies.[11,12]

The results show that patients in both groups have a movement arc greater than 101° in this short-term follow-up. For this reason, the MLC implant is an option in more complex cases. King et al. also observed a similar result with a one-year follow-up.[9]
All radiographic analyses were performed by a single evaluator with more than twenty years of knee surgery and a graduate degree in radiology. With this, we tried to reduce the bias of inter-observation analysis. Vivalta et al.[19] verified that experienced observers generated individual variabilities, causing differences in the result and confusion in the literature.
In the evaluations of clinical follow-up after TKA, three parameters are considered important: the alignment of the limb, the implant positioned appropriately, and the balance of the flexion and extension spaces.[11] This research corroborates these claims and obtains, in a general way, a postoperative alignment within normality, an implant release considered small, and an adequate movement arc.
The revision rate with the MLC implant was low, corroborating the results of other authors.[11,12] Thiengwittayaporn et al. recommend the use of the MLC type implant when there is a varus > 19,8° or extensive release of the medial collateral ligament.[13] This study was composed of patients with varus- or valgus deviation and a MLC type group with an average deformity of 19°.
Some studies cite the procedure of joint manipulation in patients with MLC-type implants.[11,12] In contrast, this study did not require joint manipulation in any case. Early physiotherapeutic rehabilitation and regular postoperative control in the initial phase are believed to be fundamental for good outcomes.
The limitations of the research were: being a retrospective study, due to this, no sample calculation was made, and a small number of patients; however, the inclusion criteria were strict, and the experience of the surgeons generated a study with little index of complications. In addition, the control group comprised patients with deformities with an average of 15° in the preoperative period. Thiengwittayaporn et al. consider a severe knee deformity > 15°.[13] Thus, this study has, in its majority, a casuistic with patients presenting severe frames in both groups.

CONCLUSIONS

In general, the preoperative deformities were considered serious. In the postoperative period, the total amplitude of the movement arc was above 101º. The postoperative tibiofemoral angle obtained an average of between 5 and 6º valgus. There was no significant difference in the release of implants in the two groups.

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IMPACT OF PEDIATRICIAN TRAINING ON DIAGNOSIS OF DEVELOPMENTAL HIP DYSPLASIA

IMPACTO DO TREINAMENTO DO PEDIATRA NO DIAGNÓSTICO DE DISPLASIA DO DESENVOLVIMENTO DO QUADRIL

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ABSTRACT

Objective: This research aims to promote the development of diagnosis and training of pediatricians using the simulated model "baby hips" and to evaluate the impact on the knowledge and skills of participants about the diagnosis. Method: An ecological study was employed using the tool the International Institute of Hip Dysplasia provided. Results: The World Health Organization considers developmental hip dysplasia (HD) a public health problem, and Brazil has no national policy for neonatal screening for HD. Delayed diagnosis impacts public resources with hospitalizations and surgeries, while early diagnosis promotes the opportunity for conservative treatment with good results and low cost. The pediatricians are essential for neonatal screening with Barlow and Ortolani tests, which have high specificity and sensitivity during this period of the child's life. Conclusions: A positive impact on diagnostic competence was obtained, indicating the need to promote training programs for pediatricians and stimulate public health authorities to include HD in the neonatal screening practiced in Brazil. ***Level of evidence II; Analytic observational cross over study.***

Keywords: Developmental Dysplasia of the Hip; Teaching; Diagnosis.

RESUMO

Objetivo: Esta pesquisa pretende promover o desenvolvimento diagnóstico e treinamento de médicos pediatras utilizando o modelo simulado "baby hips" e avaliar o impacto sobre o conhecimento e habilidades dos participantes a respeito do diagnóstico. Método: Foi empregado um estudo ecológico utilizando a ferramenta cedida pelo instituto internacional de displasia do quadril. Resultados: A Organização Mundial de Saúde considera a displasia do desenvolvimento do quadril (DDQ) um problema de saúde pública e o Brasil não possui política nacional para triagem neonatal interessando a DDQ. O atraso diagnóstico impacta negativamente os recursos públicos com internações e cirurgias enquanto o diagnóstico precoce promove a oportunidade do tratamento conservador que demonstra bons resultados e baixo custo. O pediatra é fundamental para a triagem neonatal com os testes de Barlow e Ortolani, que apresentam elevada especificidade e sensibilidade nesse período da vida da criança. Conclusão: Observou-se um impacto positivo sobre a competência diagnóstica o que indica a necessidade da promoção de programas de treinamento ao pediatra e reforça que as autoridades de saúde pública adicionem a DDQ na triagem neonatal praticada no Brasil. ***Nível de evidência II; Estudo observacional analítico cruzado.***

Descritores: *Displasia do desenvolvimento do quadril; Ensino; Diagnóstico.*

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INTRODUCTION

Hip instability is one of newborns' most common alterations during routine physical examination, diagnosed by the Barlow and Ortolani tests.[1]

Described as a morphological alteration that ranges from an unstable joint to an installed dislocation, it is characterized by the anatomical anomaly between the femoral head and the acetabulum.[2]

The late diagnosis of HD directly implies a decrease in the child's quality of life, impacts on high health costs, and makes HD a public health problem, according to the World Health Organization, which determines the need for routine neonatal screening.[3]

The exact cause of this alteration is unknown, but several factors are involved, such as family history, female gender, oligohydramnios, twin babies, macrosomic babies, and intrauterine pelvic positioning, the latter standing out as the most important, increasing the incidence of HD.[4]

The number of new cases of HD in children without risk factors is estimated at 11.5/1,000 live births, based on meta-analysis and multiple logistic regression protocols, but this figure varies according to the geographical area studied. The relative risk in the case of a positive family history is 1.7 times higher (6.4/1,000 boys and

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<< SUMÁRIO

32/1,000 girls) and the pelvic presentation at birth, compared to the cephalic position, increases this risk by 6.3 times.[5,6]
When diagnosed early, conservative treatment for typical HD, i.e., without teratological changes, is effective, using suspenders and/or orthoses, and when late, the need for interventions increases the cost of treatment, increases morbidity, and has fewer effective results than conservative treatment.[7,8] The American Academy of Pediatric Orthopaedics recommends evaluating all newborns with Ortolani and Barlow tests, which show high specificity and sensitivity up to the third month of age.[8]
There has been a lack of knowledge among health professionals in Brazil, especially pediatricians and pediatric residents responsible for clinical screening, resulting in late referral of patients for treatment.[9]
Continuous education and training of health professionals using the simulated *"baby hips®"* model show effective results in early diagnosis.[10]
Brazil currently has no neonatal screening strategy and the main instrument, the Caderneta da Criança, has neglected this care.[11]
This failure leads to more tests being requested and unnecessary medical referrals, increasing the costs of this disease and making the surgical treatment of HD in Brazil more frequent, with significant costs to the Unified Health System.[12,13]
This study evaluated the impact of training pediatricians on their knowledge and skills in diagnosing developmental dysplasia of the hip using a simulated *"baby hips®"* model.

MATERIAL AND METHODS

A total of 312 pediatricians took part in this analytical, analytic observational cross over study. They received training in diagnosing HD using the simulated "*baby hips*" model and were assessed on their knowledge and skills in neonatal clinical diagnosis at two points in time, pre-and post-training.
The pre-training assessment consisted of collecting data on the participants' prior knowledge of HD and its early diagnosis by answering a questionnaire provided by the International Hip Dysplasia Institute using Google Forms® and on their ability to perform the Barlow and Ortolani tests on a simulated "*baby hips®*" model. (Figure 1)
The data collection questionnaire contained 18 questions, and the number of correct answers each participant provided classified them into three different groups: insufficient (zero to 5 correct answers), satisfactory (6 to 11 correct answers), and *good* (12 to 18 correct answers).
After this, a video with instructions for training in clinical diagnosis was shown, followed by a post-test containing the same questionnaire and simulated model applied previously.
The pre-and post-training scores were statistically analyzed with GraphPad Prism® software using the non-parametric data T-test, which was considered significant when $p < 0.05$.

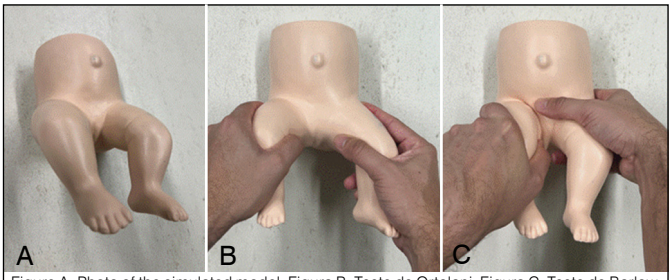

Figure A. Photo of the simulated model. Figura B. Teste de Ortolani. Figura C. Teste de Barlow. Source: author's photos.

Figure 1. A simulated model was used for the physical examination of pediatric hips with developmental hip dysplasia.

For the evaluations relating to the 18-question questionnaire, the groups were divided into 3 groups, analyzed by the scatter plot, and these groups were called: *unsatisfactory* - between 0 and 5 hits; *fair* - between 6 and 11 hits and *good* - between 12 and 18 hits. The raw values analyzed the Ortolani and Barlow tests as right and wrong, and their representation in the percentage of participants analyzed.
All participants signed the informed consent form (ICF), and the research was approved by the ethics committee under C.A.A.E. No. 3462343.

RESULTS

About the collection instrument

The impact of pediatrician training on the diagnosis of hip dysplasia showed positive results with improvement in all categories in response to the questionnaire.
Those with unsatisfactory success rates fell from 26% to 9%. Those in the regular category improved from 13% to 35%, and those in the good category increased significantly applying the unpaired t-test, showing statistical significance with a *p-value of* <0.05 between the values obtained pre- and post-training in all groups. (Table 1)
The analysis of the overall score obtained in the questionnaire by the participants showed an increase in the average from 7.52 correct answers to 10.33 correct answers after the training, giving a higher concentration of participants classified as regular and percentages before and after, respectively from 41.7% to 57.3%, and a significant improvement in the group classified as good, containing 41 pediatricians pre-training, increased to 110 pediatricians post-training.

About the Ortolani test

Analysis of the data on the Ortolani test performed by the participants was carried out using the ANOVA test and showed a significant difference between the variables before and after training, with a *p-value of* <0.05.
The number of errors decreased from 198 to 55 participants, while the number of correct answers increased from 114 participants before the training to 257 participants after the training, as shown in (Table 2).

About the Barlow test

The Barlow test was the most unfamiliar among pediatricians, and 274 participants made mistakes. After training, the number of errors dropped to 150, and the number of correct answers rose from 38 to 162, as shown in Table 3. When treated by the ANOVA test, these data were statistically significant with a *p-value of* <0.05.

Table 1. The table shows the number of participants per group according to the number of correct answers to the questionnaire. The groups are unsatisfactory (0 to 5 hits), fair (6 to 11 hits), and good (12 to 18 hits).

Classification of the questionnaire evaluation by the number of correct answers	Number of hits of the participants pre-training	Number of correct answers post-training
Group Unsatisfactory hits 0 - 5	82	28
Group Regular 6 - 11 hits	189	174
Group Good Hits 12 - 18	41	110

Table 2. The table shows the number of participants and the percentage distribution on the Ortolani test. (*)

Simulated physical examination test	Distribution of participants with error pre-training	Distribution of participants with error post-training	Distribution of participants correctly pre-training	Distribution of participants correctly post-training
Ortolani	n (198) % (63)	n (55) % (18)	n (114) % (37)	n (257) % (82)

(*) all pre- and post-training conversion rate values showed statistical significance with a value of $p<0,05$.

Table 3. The table shows the number of participants and the percentage distribution on the Barlow test. (*)

Simulated physical examination test	Distribution of participants with error pre-training	Distribution of participants with error post-training	Distribution of participants correctly pre-training	Distribution of participants with post-training success
Barlow	n (274) % (88)	n (150) % (48)	n (38) % (12)	n (162) % (52)

(*) all pre- and post-training conversion rate values showed statistical significance with a value of $p<0.05$.

DISCUSSION

Developmental hip dysplasia (HD) affects 1% to 3% of newborns worldwide, is graded from hip instability to complete dislocation of the joint, and most often occurs in healthy children in isolation, masking the diagnosis.[14]

The ideal method for early diagnosis of HD has yet to be defined in several countries, ranging from clinical aspects to different and controversial radiological methods.[15]

However, it has been established that the physical examination is effective and universally accepted in the neonatal period through the Barlow and Ortolani tests, with specificity of up to 95%.[9]

According to the recommendations of the Pediatric Orthopaedic Society of North America (POSNA), the physical examination is fundamental and should be carried out first by the pediatrician. If positive, the patient is referred for an orthopedic evaluation to clarify or confirm the diagnosis of HD.

In Brazil, knowledge of HD among health professionals who perform newborn screening is poor, as 81% of professionals have never made an HD diagnosis. In this sense, mannequins can be useful for training students and healthcare staff.[13]

Therefore, continuing education and measures that are easy to apply and cost-effective could benefit many newborns.

This study carried out in Amazonas, provided pediatricians with theoretical and practical training on diagnosing developmental dysplasia of the hip using a simulated model and verified the impact of the training on the participants' knowledge and skills.

We found that 86% of the participants had a fair or insufficient knowledge of HD prior to the training, as assessed by a questionnaire. The Ortolani and Barlow tests in a simulated model showed errors of 63% and 87%, respectively, indicating poor clinical diagnostic skills.

The study participants' profiles showed low diagnostic capacity, with an average of 24% correctly diagnosing HD in the simulated model.

The positive impact on theoretical knowledge was seen post-training, with indices showing a significant improvement in the number of correct answers to the questionnaire, demonstrated by the increase in the good group.

The participants' correct answers to the Barlow and Ortolani tests increased from 24% before training to 43% after training.

The data collection instrument used in this research was developed and supplied by the International Hip Dysplasia Institute and, like any other questionnaire-type data collection instrument, although it is a viable and pertinent technical tool to be used when dealing with problems whose objects of research correspond to empirical questions, involving the opinion, perception, position, and preferences of those surveyed, it can also be criticized when there are issues that compromise its construction and interpretation.[16,17]

Critically, the questionnaire drawn up by the International Hip Dysplasia Institute is difficult to interpret, with questions that could be improved by its authorial source to become a more accurate tool for assessing knowledge perception.

The participants' responses to the data collection instrument averaged 7.5 and 10.3 correct answers before and after training, respectively. Despite the increase in correct answers, it cannot be said that the data collection instrument is free from criticism and whether the data shows a gain in scores due to acquired learning or recent memory, since the data was collected in the same training session.

This research was carried out in Amazonas, where the distances between municipalities prevent their inhabitants from traveling quickly. In this sense, telemedicine, regulated by the Federal Council of Medicine, can be used for continuing education on the diagnosis of HD, facilitating access to health information, and integrating regions of Brazil. Providing remote locations with contact with hospitals and specialized professionals regarding prevention, diagnosis, and health education has proved possible, making it possible to identify and track public health problems.[18]

The current situation in Brazil regarding neonatal screening for HD is flawed and does not provide the care that newborns need concerning the early diagnosis of HD.

In recent years, Brazil has made progress with public neonatal screening policies, such as the expanded search for the heel prick test offered by the SUS, including new rare disease screening groups, a high-cost measure that is very important for the health care of newborns.[19]

Despite current public health efforts in Brazil, simpler and less costly measures have been abandoned. The removal of hip assessment, which was available in previous editions of the child's booklet, demonstrates a step backwards in the care of newborns in Brazil.

The Ministry of Health (MoH) recommends the Ortolani test in the first two days of life and at subsequent childcare appointments. Ultrasound is recommended when the Ortolani test result is positive, a family history is present, the newborn has intrauterine positioning of the pelvic presentation type, or associated clinical manifestations such as congenital torticollis or foot malformations.[14]

Research has verified the need to improve pediatricians' ability to diagnose HD, and technology tools should be employed to facilitate this. One example is the QR code with the acronym "Quick Response," which was developed by Masahiro Hara in 1994.[20] Its application in the new editions of the Children's Booklet could provide information on the diagnosis of HD.

The training of pediatricians proved to be successful, with a positive impact on the practical context of the neonatal physical examination, increasing from 37% to 82% of participants being correct about the Ortolani test using the *"baby hips®"* model.

On the other hand, the Barlow test, which is less well known among pediatricians, was only 12% correct before training and reached 52% correct after training. This makes it clear that neonatal diagnosis can be improved with instruction and practical training for professionals who care for children in the neonatal period.

Screening, when carried out by pediatricians who suspect the diagnosis of HD, can lead to an increase in demand for specialized outpatient clinics. Once the diagnosis is confirmed, these clinics begin treatment appropriately, with a better outcome and lower costs for the public health system.

Many studies confirm the effectiveness of clinical screening alone in reducing late cases of HD. A simple and low-cost measure to implement and apply.[21]

Some countries, such as Australia, France, and the United Kingdom, have seen an increase in the number of children diagnosed late. This fact has been attributed to low knowledge of hip physical examination maneuvers before walking.[15]

In the UK, a competency program in neonatal clinical diagnosis has been launched to ensure that all doctors involved in the screening program receive training, periodic assessments, and adequate competencies to make the diagnosis of HD.[22,23]

In Brazil, Ordinance No. 1,130 of August 5, 2015, which establishes the national policy for comprehensive care for children (PNAISC) within the scope of the Unified Health System (SUS), in its article 7, deals with strategic actions of the axis of humanized and qualified care for pregnancy, childbirth, birth, and the newborn, referring, in paragraph VII, to neonatal screening. Therefore, we believe there are mechanisms already in place to update future editions of the children's booklet, improving the diagnosis of developmental dysplasia of the hip in newborns.

The authors, concerned about the current scenario due to the absence of a neonatal screening tool for HD in Brazil and understanding that the pediatrician is fundamental to the diagnostic search, point out that continued training is important and positively impacts diagnostic capacity.

At the same time, it is recommended that the Child Handbook be rectified, including a diagnostic field for the Barlow and Ortolani tests and the addition of a *QR code* for further instructions to health professionals.

CONCLUSION

The pediatricians from the state of Amazonas who took part in the research showed a positive impact after the theoretical-practical training, improving their knowledge and skills in the neonatal diagnosis of developmental hip dysplasia.

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EVALUATION OF TENDON HEALING AFTER ARTHROSCOPIC REPAIR OF ISOLATED SUPRASPINATUS TEARS

AVALIAÇÃO DA CICATRIZAÇÃO TENDINOSA APÓS REPARO ARTROSCÓPICO DAS RUPTURAS ISOLADAS DO SUPRAESPINHAL

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ABSTRACT

Objective: To evaluate the healing of supraspinatus tendon lesions after arthroscopic repair, with analysis of intra- and inter-observer agreement by two experienced evaluators for the same lesions. Materials and Methods: A study was conducted with patients evaluated in the postoperative period of arthroscopic surgery to repair isolated supraspinatus tendon ruptures, with a minimum follow-up of one year. Tendon healing was evaluated using magnetic resonance imaging by two independent evaluators at two time points, with a seven-day interval between them. Categorical data were presented in absolute and relative frequencies, and mixed linear regression models were used to analyze intra- and inter-observer agreement, with a probability of rejecting the null hypothesis of 5%. Results: Twenty-three patients (26 shoulders) were evaluated, with a mean age of 61.5 years. At both evaluation times, most patients presented a healing grade between I and III in the Sugaya classification for both observers. The interobserver agreement was good, and the intraobserver agreement was excellent. Conclusion: The mean tendon healing rate for arthroscopic repair of isolated supraspinatus ruptures was 81.7%. Intra-observer agreement ratings were considered excellent, while inter-observer agreement was good, demonstrating reliability in the evaluations performed. ***Level of Evidence II; Cross-sectional study.***

Keywords: Rotator Cuff Injuries; Arthroscopy; Wound Healing; Magnetic Resonance Spectroscopy; Shoulder; Tendons.

RESUMO

Objetivo: Avaliar a cicatrização de lesões do tendão supraespinhal após reparo artroscópico, com análise da concordância intra e interobservador por dois avaliadores experientes para as mesmas lesões. Materiais e Métodos: O estudo foi realizado com pacientes avaliados no pós-operatório de cirurgia artroscópica para reparo das rupturas isoladas do tendão supraespinhal, com seguimento mínimo de um ano. A avaliação da cicatrização tendinosa foi realizada por meio de ressonância magnética, por dois avaliadores independentes, em dois momentos, com intervalo de sete dias entre eles. Dados categóricos foram apresentados na forma de frequências absolutas e relativas e modelos lineares de regressão mista foram utilizados para análise de concordância intra e interobservador, com probabilidade em rejeitar a hipótese nula em 5%. Resultados: Foram avaliados 23 pacientes (26 ombros), com idade média de 61,5 anos. A maioria apresentou grau de cicatrização entre I e III na classificação de Sugaya para ambos os observadores, nos dois momentos de avaliação. A concordância interobservador foi boa e a intraobservador foi excelente. Conclusão: A média da cicatrização tendinosa do reparo artroscópico das rupturas isoladas do supraespinhal foi de 81,7%. As concordâncias das avaliações intraobservador foram consideradas excelentes, enquanto a interobservador foi boa, demonstrando confiabilidade nas avaliações. ***Nível de Evidência II; Estudo Transversal.***

Descritores: *Lesões do Manguito Rotador; Artroscopia; Cicatrização; Espectroscopia de Ressonância Magnética; Ombro; Tendões.*

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INTRODUCTION

Rupture of rotator cuff (RC) is more common in the elderly due to aging and tissue degeneration and in athletes due to repetitive shoulder movements.[1-3] Risk factors for these lesions include aging, genetic predisposition, and lifestyle. The disease is multifactorial, with tendon degeneration involving structural changes, characterized by a noticeable change in collagen concentration, especially for a higher prevalence of type III compared to type I.[4] Muscle atrophy and fat infiltration occur in these chronic lesions and can be observed by imaging techniques, such as magnetic resonance imaging (MRI).[5,6] There are several surgical techniques for treating tendon ruptures of the RC, each suitable for specific types and severity of lesions,

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and the choice of the technique is influenced by factors such as the size and retraction of the lesion, tissue quality, and functional needs of the patient.[5,7] In arthroscopic surgeries, different types of anchors, with various techniques of single or double-row fixation (suture bridge or speed bridge), are recommended to repair broken tendons, and single-row tendons have a higher rate of rupture compared to double-row surgeries, especially in cases of large or extensive ruptures.[7] The addition of rich plasma in platelets and pluripotentiary cells originating from the bone marrow (speed bridge) during the repair of the RC can favor healing and decrease the index of post-surgical re-ruption.[8]

The healing of the tendon is a complex process, influenced by factors such as age, gender, hyperlipidemia, diabetes mellitus, smoking, fat atrophy/infiltration of the affected muscle, and retraction of the tendon, which can negatively affect this phenomenon.[6,9,10] The chronicity and size of the injury and the technique used in arthroscopic repair also affect the healing process of the affected tendon and can lead to a re-rupture.[8]

It is observed that there is a divergence in the literature as to the rate of tendon re-rupture of RC, which can reach up to 94.0%.[1,6] It is also observed that most studies evaluated the healing process of the arthroscopic repair of the ruptures of two or more tendons and not only of the isolated lesion of the supra-spinal, both in single and double rows.[1] In addition, evaluating the inter and intra-observative agreement of these lesions at different times is of paramount importance for verifying the reliability of the investigated outcome.[11-13] Thus, the objectives of the present study were to evaluate the healing of arthroscopic repair of isolated ruptures of the supraspinal tendon and verify the agreement between intra- and inter-observative measurements.

MATERIAL AND METHOD

Design and location of the study

This cross-sectional study was conducted from June 2022 to February 2024 in a private diagnostic center specializing in orthopedics. The Institute's Research Ethics Committee approved the study under the CAAE number 59403922.2.0000.5078.

Sampling

The patients were evaluated in the pre-and postoperative video arthroscopic surgery to repair the complete and isolated ruptures of the supra-spinal tendon of the shoulder.

Eligibility criteria

Patients over the age of 18 were included, with complete and isolated ruptures of the supra-spinal tendon by MRI, operated by arthroscopic technique, by the same surgeon, and with post-operative follow-up of at least one year.

Exclusion criteria were considered: partial ruptures of the RC; the presence of arthrosis or instability in the operated shoulder; involvement of other RC tendons associated with the supra-spinal; performing two or more surgeries to repair the RC in the ipsilateral shoulder; incomplete repair of the rotary sleeve; use of other surgical techniques in the treatment of these lesions, whether muscle transfers, upper capsule reconstruction or reverse shoulder prosthesis.

Data Collection

A single researcher collected the patients' sociodemographic and clinical data in a reserved environment after signing the Terms of Free and Informed Consent (TCLE). Subsequently, a Magnetic Resonance Examination of each study participant's operated shoulder was performed. Other preoperative and intraoperative data relevant to the study were listed after verification in medical records.

Used Classifications

SUGAYA was used to evaluate the structural integrity of the tendon of the supra-spinal muscle of the operated shoulder. It presents five categories in which types I, II, and III refer to the whole sleeve, and types IV and V determine sleeves with re-rupture.[14]

GOUTALLIER was used to evaluate the degree of fat infiltration in the supra-spinal muscle in the preoperative period. It is categorized into different stages that stratify the extension of fat in the muscle in five levels, from the absence of fat (stage G0) to fat predominance (stage G4).[15]

Image Examination

All operated shoulder MRI tests were performed on the same Siemens brand device, Model Essenza Dot® and Power of 1.5 Tesla. The evaluators were trained on the classification of Sugaya used in the study so that there was a standardization in the analysis of the images in the coronary T2 and sagittal T2 / fat DP sequences. This evaluation was carried out by two professional radiologists with experience in images of the musculoskeletal system, independently and blinded between them, each evaluator being in two distinct moments, with an interval of seven days between them.

Closures

The study outcome evaluated by the Sugaya classification highlighted above was the tendon healing.

Independent variables

The following independent variables were assessed: age (in years lived); gender (male / female); side (right / left); smoking (yes / no); diabetes mellitus (yes / no); dominance (right-handed / sinister); postoperative follow-up time (in months); preoperative pseudoparalysis (yes / no); degree of preoperative fatty infiltration (G0/G1/G2 or G3/G4); size of the lesion (small / medium / large); shape of the lesion (crescent / "V" / "U" / "L" / inverted "L" / other); presence of delamination (yes / no); tendon retraction (no retraction / lateral to the glenoid / at the edge of the glenoid / medial to the glenoid); biceps long head tendon (normal / ruptured / degenerated / unstable / degenerated and unstable); biceps tendon procedure (no / tenotomy / tenodesis); type of anchor (non-absorbable / bio-absorbable); number of anchors (in Arabic numerals); type of repair (single lateral row / single medial row / double row); convergence of margins (yes / no); number of stitches (in Arabic numerals); acromioplasty (yes / no); suction cups (yes / no); type of immobilization (simple / abduction); length of immobilization (in weeks).

Data analysis

The categorical data were presented in the form of absolute and relative frequencies, while the continuous data were presented in the form of averages. The linear mixed regression models were used for intra- and inter-observative concordancy analysis by incorporating the variation between observers and the evaluation moments. From the models, the Intraclass Correlation Coefficients (ICC) were extracted. Random effects models were created, including both the effect of the observers and the evaluation moments for each outcome, plus models for each evaluator, to verify the agreement between their evaluations between the two moments. The following values were adopted as reference for the ICC cutting points: ICC≤0.4 as weak; 0.59≥ICC>0.4 as regular; 0.74≥ICC>0.59 as good and 1.0≥ICC>0.74 as excellent.[16]

The analyses were conducted in the statistical program R, version 4.3.2 (2023, R Core Team, Vienna, Austria). The probability of rejecting the null hypothesis was 5%.

RESULTS

Of a total of 73 patients with isolated ruptures of the supra-spinal tendon of the shoulder operated by arthroscopy, seven were unavailable for the post-operative MRI examination; 14 were not interested in participating in the study; four had died, and 24 could not be contacted. There was the loss of the MRI images of a patient due to a failure in the data storage system of the diagnostic center, resulting in a final sample of 23 participants and 26 shoulders.
The average age of the participants was 61.0 years (DP: ±7.6). They were all right. There were no patients with pseudoparalytic shoulder. In all procedures, acromioplasty was performed. The average postoperative follow-up time was 50.4 months (DP: ±34.2). The other sociodemographic, clinical/preoperative, and surgical data are shown in Tables 1 and 2.

Table 1. Descriptive analysis of the socio-demographic and clinical/pre-operative characteristics of the study participants.

Variables	n	%
Sex		
Female	19	82.6
Male	4	17.4
Side		
Right	18	69.2
Left	8	30.8
Smoking		
Yes	4	17.4
No	19	82.6
Diabetes		
Yes	2	8.7
No	21	91.3
Grade of preoperative fatty infiltration		
G0/G1/G2	24	92.2
G3/G4	1	3.9
S/D	1	3.9
Injury size		
Small	3	11.5
Average	18	69.3
Grande	2	7.7
S/D	3	11.5
Injury format		
Rising	15	57.7
U	3	11.5
V	5	19.2
Others	1	3.9
S/D	2	7.7
Presence of Delamination		
Yes	1	3.9
No	25	96.2
Retreat		
Lateral to Glenoid	9	34.5
On the edge of the Glenoid	1	3.9
No retraction	15	57.7
S/D	1	3.9
Biceps Long Head Tender		
Normal	17	65.4
Degenerated	2	7.7
Instable and degenerated	2	7.7
Roto	3	11.5
S/D	2	7.7

S/D – no data. DP – standard deviation.

The Kolmogorov-Smirnov test showed an abnormal distribution for the continuous variables.
Table 3 shows the degree of healing after surgery verified by Sugaya classification of the study participants.
MRI images of the operated shoulders showed that tendons were healing 84.6% in the first moment and 84.7% in the second moment

Table 2. Descriptive analysis of the surgical characteristics of the study participants.

Variables	n	%
Procedure in the tendon CLB		
Tenodesis	2	7.7
Tenotomy	2	7.7
No	20	76.9
S/D	2	7.7
Anchor Type		
Bio-absorbable	11	42.3
Inabsorbable	14	53.8
S/D	1	3.9
Number of anchors		
One	17	65.4
Duas	9	34.6
Repair types		
Simple lateral filer	5	19.2
Simple medial filer	21	80.8
Convergence of margins		
Yes	5	19.2
No	21	80.8
Number of points (average)	3 (DP: ±0.9)	
Ventures		
Yes	5	19.2
No	20	76.9
S/D	1	3.9
Types of immobilization		
Simples	14	53.8
Abduction	11	42.3
S/D	1	3.9
Immobilization time (average) – in weeks	4.2 (DP: ±0.7)	

S/D – no data. DP – standard deviation.

Table 3. Evaluation of the degree of healing of the supra-spinal tendon of the shoulder (n=26).

Grade of healing	Evaluator 1		Evaluator 2	
	n	%	N	%
Grade I				
Moment 1	8	30.8	2	7.7
Moment 2	8	30.8	3	11.5
Grade II				
Moment 1	9	34.6	4	15.4
Moment 2	8	30.8	5	19.2
Grade III				
Moment 1	5	19.2	13	50.0
Moment 2	6	23.1	14	53.8
Grade IV				
Moment 1	1	3.8	4	15.4
Moment 2	0	0.0	1	3.8
Grade V				
Moment 1	3	11.5	3	11.5
Moment 2	4	15.4	3	11.5

for Evaluator 1, while for Evaluator 2, it was 73.1% in the first moment and 84.5% in the second moment.
Table 4 demonstrates the intra- and inter-observative agreement regarding the degree of tendon healing of the supraspinal tendon.

Table 4. Inter- and intra-observational agreement on the degree of healing of the supra-spinal tendon of the shoulder (n=26).

Model	ICC	p-value	Classification
Inter-observers agreement (moment)			
Evaluator 1	0.895	<0.001*	Excellent
Evaluator 2	0.887	<0.001*	Excellent
Inter-observer concordance (evaluator x moment)	0.740	0.018*	Good

DISCUSSION

The present study showed that there was healing of the supra-spinal tendon in most of the participants when the arthroscopic repair of the complete and isolated ruptures of the supra-spinal tendon was performed by simple row technique, either medial or lateral, with variation between 73.1% and 84.7%, with the average of the first observer being 84.7% and the average of the second observer being 78.8%. We obtained a healing rate of 81.7% if we consider the averages of the evaluators.
The literature points to a higher rate of tendon re-rupt in postoperative follow-up, which can reach up to 94,0%, depending on the group studied.[1,6,17] It is therefore highlighted that most previous studies jointly evaluated lesions that did not involve only the supra-spinal tendon of the shoulder, resulting in pre-operative ruptures of two or more tendons and greater potential for re-ruption, compared to those presented in this study.
Fat muscle infiltration before surgical repair and age, especially after age 65, are other important factors in predicting new ruptures.[3,10] Considering that in this study, we had an average age of 61 years and that most subjects presented low degrees of preoperative fat infiltration, we understand that such risk factors favored the good healing found. Another point to be discussed is the repair technique used, being in the simple queue for all participants. This data differs from the findings of some studies, which showed better healing in repairs, in which the double row or *suture bridge* technique was used when compared to the simple row.[7,18,19]
MRI is recognized as the gold standard in evaluating postoperative healing of RC lesions and provides detailed images of the insertion and tendon structure in addition to the health of the evaluated muscles,[6,11-13] having high specificity and sensitivity.[20] The reliability of the operated shoulder MRI images evaluated in our study demonstrated excellent agreement between the evaluations of the same observer at different analysis times and good between them. This inter and intra variability over a short time suggests some difficulty in using the Sugaya classification in evaluating the structural integrity of the tendon lesion repair. It demonstrates the need for continuous improvement by the evaluating professionals to create more ease in the analyses and, therefore, discussion among peers. Other studies that used similar inter and intra-observation comparison methodologies to evaluate tendinosis RC ruptures found similar concordancy rates.[11-13]
As a positive factor of the study, the evaluation of the healing of arthroscopic repair of isolated lesions of the supra-spinal cord is highlighted, associated with the analysis of the agreement of these evaluations made by two experienced professionals for the same lesion at different times. This happened blindly, and the evaluators of the MRI images did not know what had been performed in the intraoperative and independently, without any interference between them.
Despite its retrospective nature, the study collected data in a prospective manner, which increased its level of evidence. In addition, the patients were operated on by the same surgeon and evaluated using the same MRI device, which allowed us to remove the operator's bias and measurement. The surgical technique was similar in all cases, varying depending on the form and size of the injury. Among the study's limitations, we can cite that, due to the broad exclusive criteria that selected the isolated lesions of the supra-spinal tendon repaired by a specific arthroscopic technique, we had an even reduced sample. The case capture was carried out in a single center, which may indicate a bias in the selection of patients. In addition, the study's design did not allow us to have another comparative surgical group.

CONCLUSION

The study reveals that healing occurred in most cases, 84.7% on average for Observer 1 and 78.8% on average for Observer 2. If we consider the average of the two observers, the arthroscopic repair tendon healing of isolated supra-spinal rupture was 81.7%. It can also be concluded that the agreements of the intra-professional evaluations were considered excellent and the inter-observation was good, demonstrating reliability in the evaluations performed in the surveyed outcome.

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30 YEARS OF BONE GIANT CELL TUMOR IN THE KNEE: A BRAZILIAN PERSPECTIVE

30 ANOS DE TUMOR DE CÉLULA GIGANTE ÓSSEO NO JOELHO: PERSPECTIVA BRASILEIRA

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ABSTRACT

Objective: To analyze the evolution of patient/tumor characteristics and treatments for GCTB in the knee in Brazil over 30 years and assess changes in local recurrence rates. Methods: Retrospective study of 335 patients (1989-2021) from 16 Brazilian centers. Data on patient/tumor characteristics, recurrence, metastasis, and treatment trends were evaluated. Results: Campanacci grade 3 tumors, pulmonary metastasis, and local recurrence rates were 56.7%, 5.3%, and 15.8%, respectively. Recurrence was 21.4% for curettage and 9% for resection. Curettage with denosumab showed 23.8% recurrence, versus 21% for curettage alone. Overall, local recurrence decreased from 22.9% (1989-2005) to 15.1% (2006-2021), with a significant drop after en bloc resection (23% to 7.8%), while curettage-related recurrence remained stable. Conclusions: Despite an increase in aggressive tumors, local recurrence decreased, especially after en bloc resection. These findings emphasize the challenges of managing rare diseases in emerging economies. ***Level of evidence: III; Retrospective Cohort Study.***

Keywords: Neoplasms, Bone Tissue; Giant Cell Tumors; Curettage; Denosumab; Recurrence.

RESUMO

Objetivo: Analisar a evolução das características dos pacientes/tumores e dos tratamentos para GCTB no joelho no Brasil ao longo de 30 anos, avaliando as mudanças nas taxas de recorrência local. Métodos: Estudo retrospectivo de 335 pacientes (1989-2021) de 16 centros brasileiros. Foram avaliados dados sobre características dos pacientes/tumores, recorrência, metástases e tendências de tratamento. Resultados: As taxas de tumores Campanacci grau 3, metástase pulmonar e recorrência local foram de 56,7%, 5,3% e 15,8%, respectivamente. A recorrência foi de 21,4% para a curetagem e 9% para a ressecção. A associação de denosumabe e curetagem apresentou 23,8% de recorrência, contra 21% para a curetagem isolada. A recorrência local reduziu de 22,9% (1989-2005) para 15,1% (2006-2021), com uma queda significativa após a ressecção em bloco (23% para 7,8%), enquanto a recorrência após curetagem permaneceu estável. Conclusões: Apesar do aumento de tumores agressivos, a taxa de recorrência local diminuiu, especialmente após a ressecção em bloco. Esses achados destacam os desafios no manejo de doenças raras em economias emergentes. ***Nível de evidência: III; Estudo de Coorte Retrospectivo.***

Descritores: *Neoplasias de Tecido Ósseo; Tumor de Células Gigantes; Curetagem; Denosumabe; Recorrência.*

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INTRODUCTION

Giant cell tumor of bone (GCTB) is a locally aggressive tumor predominantly presenting in the bones around the knee joint of adults between the ages of 20 and 50 years. GCTB represents 20% of benign bone tumors and up to 5% of all primary bone tumors, and the primary therapeutic approach is surgical, predominantly via curettage or *en bloc* resection. However, when there is an elevated risk of functional impairment, pain, or pulmonary involvement, alternative treatments, such as the RANK-L inhibitor Denosumab and bisphosphonates, may be considered. While curettage tends

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to yield better functional outcomes than resection, it is associated with a higher risk of local recurrence. Therefore, it is imperative to undertake a comprehensive risk stratification approach in order to ensure the selection of the most appropriate treatment and to minimize the probability of local recurrence.[1-4]

The knee's role as a crucial joint for movement and weight-bearing means that GCTB's presence can notably affect a patient's quality of life. The tumor's high recurrence risk post-curettage has been well-documented, with older studies indicating rates from 20 to 50%, although recent findings suggest a decline to closer to 11%.[5,6] Such relapses can lead to severe complications, including loss of function, bone stock depletion, pathological fractures, and, on rare occasions, pulmonary metastasis, which is most prevalent post-recurrence, appearing in 2 to 5% of cases.[7] Finally, given its proximity to essential structures, the management of GCTB in the knee remains a challenge, emphasizing the importance of appropriate and effective surgical management.[8]

In this study, we reviewed a large multicenter cohort of patients treated for GCTB of the knee in national tumor centers in Brazil over a 30-year period. The aim of the study was to assess patient and tumor characteristics and to describe the treatment outcomes of GCTB located around the knee in the context of an emerging economy in South America. We asked the following questions: (1) What are the patient/tumor characteristics of surgical cases of GCTB in the knee in Brazil over the past 30 years, and how have treatment methods, including surgical approaches, evolved during this period? (2) What was the rate of local recurrence, and did this change over time?

METHODS

This study is a retrospective review of cases of GCTB of the knee identified in the databases of 16 specialized Brazilian institutions dedicated to the treatment of musculoskeletal tumors. Before the study began, we received ethical approval from the coordinating center and all participating institutions (REB# 94280918.0.0000.5327).

Outcome-related data were gathered from both electronic and paper medical records by all participating centers. To safeguard participant confidentiality, each individual was designated a numerical code. Data were transmitted to the coordinating center using an encrypted email system. Upon receipt, the data underwent meticulous examination to address any discrepancies or inconsistencies. Cases with conflicting variables were returned to the respective centers for clarification and then re-examined by the coordinating center. The collected data were stored in MS Excel and SPSS version 27.0 software programs.

Variables extracted were categorized into (1) demographic variables including gender, age, region within the country where the patient received treatment, and the timeframe of primary tumor diagnosis and treatment; (2) clinical variables at presentation including pulmonary metastasis, pathological fracture, and Campanacci grade[9] based on radiographic appearance: Grade I (latent) characterized by well-defined borders, Grade 2 (active) with less distinct borders, and Grade 3 (aggressive) with a breached cortex and soft tissue extension; (3) treatment-related variables detailing the type of surgery (curettage, *en bloc*, amputation), type of filling (cement, bone graft, or none), surgical adjuvants used (single, combined, or none), and denosumab usage; and (4) the primary outcome of local recurrence. The sample was divided into two 15-year groups (1989 – 2005 and 2006 – 2021) based on the availability of magnetic resonance imaging (MRI) in Brazil. Advanced imaging modalities such as MRI have resulted in improved pre-operative planning for musculoskeletal neoplasms, potentially impacting local disease control.

The inclusion criteria were: (1) Pathological diagnosis of GCTB in the distal femur, proximal tibia, and proximal fibula; (2) Primary tumor treatment administered at one of the participating centers; (3) Availability of comprehensive medical records for analysis at the coordinating center. Fifty-five patients were excluded due to incomplete records. A total of 335 patients met the inclusion criteria (Figure 1). Collaborative efforts among participating entities identified and rectified data discrepancies and voids. Nonetheless, of the 335 patients evaluated, instances of missing information were noted in 4% regarding pulmonary metastases, 12% concerning pathological fractures, 0.3% on the type of cavity filling, and 0.9% related to denosumab utilization. These data deficiencies were predominantly due to the loss of historical medical records, as well as inconsistencies in documentation procedures across various participating institutions. The primary outcome examined was the rate of local recurrence and its change over time. Secondary outcomes analyzed included the rate of local recurrence based on the type of surgery, use of denosumab before curettage, number of adjuvants used prior to surgery, and tumor aggressiveness according to the Campanacci classification.

RESULTS

Patient and tumor characteristics

In this analysis of 335 patients with GCT of the knee, 183 (54.6%) were females, and 152 (45.4%) were males, with a median age of 33 years (range 14-74 years, standard deviation 12.6 years). The median follow-up duration was 89.6 months. Patients were mainly from the Southeast region of Brazil (55.5%), followed by the South (26.9%), Northeast (13.7%), and North (3.9%). The distal femur was the most affected site, comprising 52.2% of cases, followed by the proximal tibia (38.5%) and proximal fibula (9.2%). Notably, 56.7% of the tumors were classified as aggressive Campanacci grade 3. Pathological fractures were present in 16.7% of patients, mostly in the distal femur, and pulmonary metastases were detected in 5.3% at diagnosis. The recent cohort exhibited more aggressive tumors, evidenced by a rise in Campanacci grade 3 cases from 43% to 58%. Instances of pathological fractures remained relatively unchanged between the time periods (Table 1).

Treatment characteristics

Surgical approaches were most commonly curettage (57%), followed by resection (38.5%), and amputation (3.9%). Among those undergoing curettage, 16.2% were managed without intraoperative adjuvant therapy, 40.8% with one adjuvant, and 42.9% with two or more adjuvants. In terms of cavity filling after curettage, cement filling was the most common (95.8%) approach, either alone or combined with bone graft, while bone graft alone (1.0%) and no filling (3.1%) were less common approaches. The surgical approaches were similar in the two time periods of 1989-2005 and 2006-2021. Curettage procedures comprised 60.0% and 57.0% in the respective time periods, with *en bloc* resections 37.1% and 38.9%. Amputation rates were also stable at 2.9% and 4.0% (Table 2).

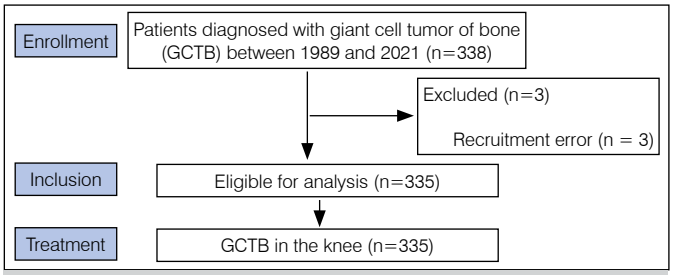

Figure 1. Flow diagram of patient selection.

<< SUMÁRIO

Table 1. Patients and tumor characteristics from 1989 to 2021.

Characteristics, %(n)	All patients (n=335)	1989-2005 (n=35; 10.4%)	2006-2021 (n=300; 89.6%)
Age (years)	33.0 (± 12.6)	29.7 (± 10.9)	33.4 (± 12.8)
Sex			
Male	45.4 (152)	37.1 (13)	46.3 (139)
Female	54.6 (183)	62.9 (22)	53.7 (161)
Site of lesion			
Distal femur	52.2 (175)	45.7 (16)	53.0 (159)
Proximal fibula	9.2 (31)	8.6 (3)	9.3 (28)
Proximal tibia	38.5 (129)	45.7 (16)	37.7 (113)
Campanacci grade			
1/2	43.3 (145)	57.1 (20)	41.7 (125)
3	56.7 (190)	42.9 (15)	58.3 (175)
Regions			
South	26.9 (90)	22.9 (8)	27.3 (82)
Northeast	13.7 (46)	0.0 (0)	15.3 (46)
Southeast	55.5 (186)	74.3 (26)	53.3 (160)
North	3.9 (13)	2.9 (1)	4.0 (12)
Pathological fracture	19 (56)	14.3 (5)	17.0 (51)
Pulmonary metastasis	5.3 (17)	2.9 (1)	5.3 (16)

Categorical variables are presented as frequencies and percentages, and continuous variables are presented as the mean and SD.

Table 2. Treatment characteristics and surgical approach from 1989 to 2021.

Characteristics % (n)	All patients (n=335)	1989-2005 (n=35; 10.4%)	2006-2021 (n=300; 89.6%)
Type of surgery			
Curettage	57.0 (191)	60.0 (21)	57.0 (170)
En bloc resection	38.5 (129)	37.1 (13)	38.9 (116)
Amputation	3.9 (13)	2.9 (1)	4.0 (12)
Adjuvant			
None	16.2 (31)	0.0 (0)	18.2 (31)
Simple	40.8 (78)	28.6 (6)	42.4 (72)
Combined (>2)	42.9 (82)	71.4 (15)	39.4 (67)
Types of adjuvants			
Extensive curettage	49.2 (94)	76.2 (16)	45.9 (78)
Phenol/alcohol	18.8 (36)	23.8 (5)	18.2 (31)
Fulguration	66.0 (126)	76.2 (16)	64.7 (110)
Filling type			
Cement	95.8 (183)	90.5 (19)	96.4 (164)
Bone graft	1.0 (2)	0.0 (0)	1.2 (2)
No filling	3.1 (6)	9.5 (2)	2.4 (4)
Denosumab	9.5 (32)	0.0 (0)	10.8 (32)

Categorical variables are presented as frequencies and percentages.

Local recurrence rates

The overall local recurrence rate was 15.8% (53/335). Curettage led to a 21.4% recurrence rate, whereas *en bloc* resection resulted in a 9.3% recurrence rate. There was a 25% recurrence rate among patients with a single surgical adjuvant and 14% among those with multiple adjuvants, compared to 29% with no adjuvants. Post-curettage recurrence was least common in the proximal tibia at 19%, followed by the distal femur at 22.5%, and 40% in the proximal fibula. *En bloc* resection recurrence rates were lower in all three anatomical locations. No recurrences were reported post-amputation. Curettage combined with denosumab indicated a slight increase in recurrence (23.8%) compared to curettage alone (21%). The overall recurrence rate decreased from 22.9% in the period 1989-2005 to 15.1% in 2006-2021. While the recurrence rates for curettage remained relatively stable at 23.8% for 1989-2005 and 21.2% for 2006-2021, there was a notable reduction in recurrence after *en bloc* resection, dropping from 23% to 7.8% over the same periods (Table 3).

DISCUSSION

In this study we report on 335 GCTB cases of the knee treated in Brazil over a 30-year period, featuring insights into demographic distribution, tumor localization, and aggressiveness, as well as treatment strategies and their corresponding outcomes. The overall local recurrence rate was 15.8%, with a discernible higher risk associated with curettage (21%) compared to *en bloc* resection (9%). Notably, despite variations in adjuvant therapy use, recurrence rates post-curettage remained significantly high, particularly emphasizing the concern for patients without surgical adjuvant therapy (29%). A time-based analysis showed a reduction in the overall local recurrence rate. While recurrence rates after curettage remained consistent across the study periods, there was a considerable decrease in recurrences after *en bloc* resections, dropping from 23% to 7.8%. This decline is likely attributed to the use of MRI for preoperative planning. Furthermore, the period comparison underscored an increased presence of more aggressive tumors in recent years, with Campanacci grade 3 cases rising from 43% to 58%. In relation to the use of denosumab prior to curettage, cases that received denosumab exhibited a slight increase in the rate of local recurrence compared to those undergoing isolated curettage. Recently, do Brito et al.[5] published a systematic review encompassing studies from 2005 to 2019, highlighting that curettage, particularly when supplemented with adjuvants, typically yields acceptable local recurrence rates, often under 15%. This contrasts the higher rates (20-50%) often reported in earlier literature.[10,11] We report a local recurrence rate of 21% post-curettage, with a substantial drop to 14% with the integration of multiple adjuvants. These adjuvants also generally included extended tumor removal with a high-speed burr (extended curettage). Similarly, Niu et al.[12] reviewed 283 patients with GCTB (60% in the knee region), reporting a local recurrence of 12.4%, with 8.6% for extended curettage and 56.1% for curettage alone. Capanna et al.[13] supported these findings, showing a 16% local recurrence when adjuvants were used, versus 37% for standalone curettage. This suggests that variations in local recurrence are evident across different studies, and adjuvants appear to aid in reducing the recurrence rate of GCTB.

In 2016, Lin et al.[14] reported on a series from a multicenter nationwide GCTB registry, encompassing 268 patients treated for GCTB around the knee, with an overall recurrence rate of 21.4% and a high incidence of Campanacci grade 3 tumors at 44%. Similarly, our study reflected comparable trends in local recurrence, yet it highlighted an even more pronounced prevalence of Campanacci grade 3 tumors, accounting for 56.7% of cases. The elevated incidence of Campanacci grade 3 tumors, typically anticipated to be around 20%, could be associated with deferred medical care in developing nations such as Brazil.[15]

Table 3. Overall and overtime (1989-2005 and 2006-2021) local recurrence rates.

Local recurrence %(n)	All patients (n=335)	1989-2005 (n=35)	2006-2021 (n=300)
Overall	15.8% (53/335)	22.9% (8/35)	15.1% (45/300)
Curettage	21.4% (41/191)	23.8% (5/21)	21.2% (36/170)
En bloc	9.3% (12/129)	23.1% (3/13)	7.8% (9/116)
Amputation	0/13	0/1	0/12
Curettage after denosumab	23.8% (5/21)	0	23.8% (5/21)

Categorical variables are presented as frequencies and percentages.

It is important to emphasize the potential ramifications of delayed treatment, underlining the impact of timely clinical evaluations and interventions in the management of GCTB. Errani et al.[16] in their study of 349 patients with GCTB highlighted that more aggressive tumors, particularly those graded as Campanacci 3, correlated with *en bloc* resections and a heightened risk of lung metastasis. Similarly, Medellin et al.[17] reported higher rates of pathological fractures in Campanacci 3 tumors compared to Campanacci 2 tumors among a cohort of 107 patients. While a meta-analysis by Salunke et al.[18] indicated that the presence of a fracture did not increase the risk of local recurrence in GCTB cases, other studies[6,19,20] have documented an elevated recurrence rate in stage 3 tumors.

Building on this, our research reaffirms the necessity of meticulous tumor management strategies to minimize GCTB recurrences. Our approach endorses the systematic application of adjuvants during curettage and meticulous planning for achieving optimal margins in *en bloc* resections. Recognizing the implications, we also advocate for enhancing healthcare policies to facilitate patient access to medical services. This strategy is crucial for musculoskeletal malignancies, which mirror the challenges seen in GCTB, often marked by late presentations and high-risk patients. One approach would be the establishment of a national database and the standardization of clinical protocols and best practices.

An inherent limitation of our GCTB study is its retrospective nature, which can introduce potential systematic biases. This is a common challenge in retrospective research, where the risk of selection bias, information bias, and confounding variables are heightened. It is crucial to approach our findings with caution, recognizing that while they offer valuable insights, they are based on historical data from 30-year time period, and there might be factors not accounted for that could influence the outcomes.[21]

CONCLUSIONS

In summary, we report on a large multicenter cohort of GCTB of the knee in Brazil over a 30-year period. There was a high incidence of Campanacci grade 3 tumors, particularly in the more recent 15-year time period; however, the overall local recurrence rate of 15.8% is consistent with previous literature. Over time, the overall local recurrence rate declined, particularly following *en bloc* resection. Our findings highlight the challenges of treating rare diseases in the context of an emerging economy.

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IMPACT ON PULMONARY FUNCTION AFTER SPINAL FUSION IN CONGENITAL SCOLIOSIS

IMPACTO NA FUNÇÃO PULMONAR APÓS ARTRODESE DE COLUNA NA ESCOLIOSE CONGÊNITA

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ABSTRACT

Purpose: To evaluate the effect, in long-term postoperative follow-up (more than 15 years), of combined spinal fusion (anterior and posterior) and only posterior on the pulmonary function of patients with congenital scoliosis. Methods: Case series with five patients, operated on from 03/1997 to 12/2009, groups: dual approach with anterior arthrodesis through thoracotomy versus only posterior arthrodesis. Data processed in SPSS 20.0. Comparison of means (Student's t-test and Anova, or Mann-Whitney and Kruskal-Wallis/Dunn) with p = 0.05. Results: There was no difference in the absolute and predicted percentage values of pulmonary function FVC (Forced Vital Capacity) and FEV1 (Forced Expiratory Volume in 1 Second), Cobb of the main thoracic curve and thoracic kyphosis between the groups, in the preoperative and last follow-up (p>0.05).Conclusion: There were no significant differences in preoperative and postoperative pulmonary function parameters between the groups, after an average follow-up of 17 years, and there were also no significant differences in relation to the radiographic variables evaluated. ***Level of evidence IV; Serie Cases.***

Keywords: Scoliosis; Respiratory Function Tests; Vital Capacity; Forced Expiratory Volume; Spinal Fusion.

RESUMO

Objetivos: Avaliar o efeito, em acompanhamento pós-operatório de longo prazo (maior que 15 anos), da fusão vertebral combinada (anterior e posterior) e somente posterior sobre a função pulmonar de pacientes com escoliose congênita. Materiais e Métodos: série de casos com cinco pacientes, operados de 03/1997 a 12/2009, grupos: artrodese anterior por toracotomia mais artrodese posterior versus somente artrodese posterior. Dados processados no SPSS 20.0. Comparação das médias (teste t de Student e Anova, ou Mann-Whitney e Kruskal-Wallis/Dunn) com p de 0,05. Resultados: sem diferença dos valores absolutos e percentuais previstos da função pulmonar: CVF (Capacidade Vital Forçada) e VEF1 (Volume Expiratório Forçado no 10 Segundo), do Cobb da curva torácica principal e da cifose torácica entre os grupos, no pré-operatório e pós-operatório (p>0,05). Conclusões: não se visualizou diferenças significativas dos parâmetros pré-operatórios e pós-operatórios da função pulmonar entre os grupos, após tempo de seguimento em média de 17 anos, não havendo também em relação às variáveis radiográficas avaliadas. ***Nível de evidência: IV Série de Casos.***

Descritores: *Escoliose; Testes de Função Respiratória; Capacidade Vital Forçada; Volume Expiratório Forçado; Fusão Vertebral.*

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INTRODUCTION

Lung development is characterized by the growth of new alveoli until 5 to 8 years of age, but thoracic development and lung function continue until 17 to 23 years of age, depending on variables such as sex and growth speed, with a reduction from 35 years old.[1]
The etiology of scoliosis is an important risk factor for the development of postoperative pulmonary complications, as well as the difficulty in recovering lung function after correction of the deformity.[2]
Some authors report that the minimum value of 65% for forced vital capacity (FVC) and forced expiratory volume in one second (FEV1), as, above this value, there is no impairment of lung function in patients with congenital scoliosis in adult life.[3]
There are few data on long-term follow-up, longer than 10 years, of changes in respiratory function in patients after surgery for scoliosis, especially for cases that are not idiopathic. As a result, this research aims to evaluate the impact of combined (anterior and posterior) and posterior-only spinal fusion on pulmonary function in patients with congenital scoliosis in long postoperative follow-up.

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

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MATERIAL AND METHODS

A series case study was carried a spinal surgery reference center to assess the lung function of 168 patients with scoliosis who underwent surgery from 1997 to 2009. The inclusion criteria were as follows: patients of both sexes with congenital scoliosis who underwent instrumented spinal fusion only with 3rd generation implants (hooks and pedicle screws or only pedicle screws) without thoracoplasty and/or halo traction. The exclusion criteria were a history of heart disease, pulmonary illnesses, infection, cognitive changes that influenced the understanding of the tests, and inability to perform the proposed evaluation. Eligible patients underwent an assessment during the last follow-up period with radiography and spirometry tests.

The information was obtained, after approval by the Institutional Ethics and Research Committee (06671719.9.0000.5257 and 06671719.9.3001.5273) with signed written informed consent, through medical records. During last follow-up, patients underwent pulmonary function tests (PFT) and radiographs (in anteroposterior and lateral), which were reviewed by two independent physicians who were not involved in the study. The same levels of the final vertebrae were used to calculate the preoperative and postoperative Cobb angle. The following data were collected: gender; age (at diagnosis and surgery); corrected height by wingspan; body mass index (BMI); type of approach (dual or only-posterior); duration of surgery (minutes); estimated blood loss (cc.); follow-up time until last postoperative appointment (years); pulmonary and implant-related complications, preoperative and postoperative Cobb angle of the main thoracic curve and thoracic kyphosis (T5 to T12); number of instrumented levels; absolute and predicted percentages values of Forced Vital Capacity (FVC) and Forced Expiratory Volume in the 1st second (FEV1).

Pulmonary function tests were performed with patients sitting. No patient reported a history of smoking. At least three acceptable curves were obtained, two of which were reproducible, with parameters classified according to ATS/ERS 2005 guidelines.[4]

The patients were divided into two groups: thoracotomy and posterior arthrodesis versus only posterior arthrodesis. The option for a dual approach was based on the surgical team's experience with the technique and on radiographic criteria (rigid curves, flexibility less than 40% and/or curves greater than 80°). The procedure was carried out in two stages. Interbody spinal fusion was performed during the anterior approach. In the posterior approach, PCOs (Posterior Column Osteotomies) were performed at three to four levels. During all procedures, the awakening test was used, as there was no intraoperative neurophysiological assessment with somatosensory and motor evoked potentials at the institution during this period.

The postoperative immediate pulmonary complications identified were: the presence of pleural effusion, atelectasis and respiratory failure. Regarding implant-related complications no were recorded from the immediate postoperative period until the last postoperative evaluation.

Statistical analysis

Quantitative data were expressed as mean and standard deviation, subjected to the Kolmogorov-Smirnov normality test and compared between groups using Student's t or ANOVA/Bonferroni tests (parametric data) and Mann-Whitney or Kruskal-Wallis/ Dunn (non-parametric data) and intragroup analysis included the paired t (parametric data) and Wilcoxon (non-parametric data) tests. Categorical data were expressed as absolute and percentage frequencies and associated using Fisher's exact or Pearson's chi-square tests. All analyses were performed in SPSS version 20.0 for Windows, adopting a confidence level of 95%.

RESULTS

This study included an initial sample of 22 patients eligible for the study obtained after meeting the inclusion and exclusion criteria, and 5 patients with spirometry at the last follow-up appointment. It was verified, when analyzing the preoperative values of clinical and radiographic variables, as well as the pulmonary function test of patients with congenital scoliosis with and without follow-up, that there were no significant differences between them (Table 1). It was found that there was no significant difference between patients undergoing combined arthrodesis and those with only posterior arthrodesis in relation to the variables: age at surgery, sex, preoperative corrected height by wingspan, preoperative BMI, fused levels, estimated blood loss and follow-up time until last postoperative appointment, which was approximately 19 years in the posterior approach group. Regarding surgical time, although surgeries with a dual approach (anterior and posterior) lasted longer, this difference was not significant (Table 2).

Table 1. Comparison between preoperative clinical and radiographic parameters of patients with and without follow-up.

	Follow-up		
	Yes	No	P
Age at last preoperative PFT (yrs)	13.2±3.1	15.1±6.1	0.515[a]
Gender (F/M)	4/1	10/7	0.613b
Corrected height by wingspan (cm)	149.2±9.2	147.4±17.9	0.834[a]
BMI	15.9±3.6	18.2±4.2	0.302[a]
FVC (L)	1.6±0.7	1.6±0.8	0.973[a]
% FVC	59.0±20.7	59.7±19.7	0.945[a]
FEV1 (L)	1.4±0.6	1.4±0.7	0.950[a]
% FEV1	57.8±18.6	58.0±19.9	0.984[a]
Cobb angle of main thoracic curve (0)	77.0±48.4	68.6±19.1	0.619[a]

*p<0,05, [a] Student´s T Test; [b] Fisher´s Exact Test. FVC, Forced Vital Capacity; FEV1, Forced Expiratory Volume in 1Second.

Table 2. Comparison of preoperative clinical and surgical parameters between different procedures.

	Surgery		
	Thoracotomy and posterior arthrodesis	Posterior arthrodesis	P
Age at surgery (yrs)	13.3±3.2	13.5±3.5	0.960[a]
Age at last follow-up (yrs)	31.8 ± 2.5	34.2 ± 4.2	0.48a
Gender (M/F)			0.40b
Male	3 (100.0%)	1 (50.0%)	
Female	0 (0.0%)	1 (50.0%)	
Corrected height by wingspan preoperative (cm)	146.7±6.7	153.0±14.1	0.530[a]
BMI preoperative	15.6±4.7	16.5±2.6	0.812[a]
Fused Levels	13.3±2.5	5.5±3.5	0.059[a]
Estimated Blood Loss (cc.)	2013.0±1345.5	882.0±138.6	0.343[a]
Surgical Time (min.)	491.7±235.3	227.5±3.5	0.229[a]
% FVC Preoperative			
<= 50%	2 (66.7%)	0 (0.0%)	0.082b
50-65%	0 (0.0%)	2 (100.0%)	
65-80%	1 (33.3%)	0 (0.0%)	
80-100%	0 (0.0%)	0 (0.0%)	
% FEV1 Preoperative			
<35%	0 (0.0%)	0 (0.0%)	0.172b
35 - 49%	2 (66.7%)	0 (0.0%)	
50-59%	0 (0.0%)	1 (50.0%)	
60 - 69%	0 (0.0%)	1 (50.0%)	
>70%	1 (33.3%)	0 (0.0%)	
Last Follow-up (yrs)	16.8 5.0	18.9 2.8	0.628a

*p<0,05, [a] Student´s T Test; [b] Fisher´s Exact Test. FVC, Forced Vital Capacity; FEV1, Forced Expiratory Volume in 1Second.

When evaluating the performance of preoperative pulmonary function between the groups, it can be seen that the majority of patients undergoing the dual approach have lower values of the FVC and the FEV1 in relation to the group with the only posterior approach, however, this difference was not significant (Table 2).
During the comparison between the groups regarding certain absolute and predicted percentages parameters of pulmonary function, as well as radiographic variables, it was noted that there were no significant differences between preoperative and postoperative values (Table 3).
In the analysis of the Odds Ratio between the type of surgery versus pulmonary complications, no greater chance of these was identified to the detriment of the surgical approach used, whether combined (anterior and posterior), or only posterior (Table 4).

Table 3. Analysis of pulmonary and radiographic parameters between different surgeries.

	Procedure		
	Thoracotomy and posterior arthrodesis	**Posterior arthrodesis**	**P**
FVC (L)			
Preoperative	1.4±0.6	2.0±0.8	0.417[a]
Postoperative	1.8±1.4	2.6±0.4	0.520[a]
P	0.468b	0.286b	
Postoperative – Preoperative	0.4±0.8	0.6±0.4	0.795[a]
FEV1(L)			
Preoperative	1.3±0.4	1.6±0.8	0.539[a]
Postoperative	1.5±0.9	2.1±0.4	0.418[a]
P	0.548b	0.353b	
Postoperative – Preoperative	0.2±0.5	0.5±0.4	0.542[a]
% FVC			
Preoperative	56.0±28.6	63.5±3.5	0.749[a]
Postoperative	55.7±33.4	73.5±3.5	0.526[a]
P	0.937b	0.295b	
Postoperative – Preoperative	-0.3±6.5	10.0±7.1	0.190[a]
% FEV1			
Preoperative	56.7±25.1	59.5±10.6	0.894[a]
Postoperative	80.0±35.6	72.0±0.0	0.783[a]
P	0.476b	0.344b	
Postoperative – Preoperative	23.3±46.5	12.5±10.6	0.778[a]
Cobb angle of main thoracic curve (0)			
Preoperative	99.0±53.4	44.0±5.7	0.262[a]
Postoperative	52.0±23.5	30.5±0.7	0.308[a]
P	0.181b	0.161b	
Postoperative – Preoperative	-47.0±40.3	-13.5±4.9	0.347[a]
Kyphosis Thoracic (T5 to T12) (0)			
Preoperative	53.3±14.4	20.0±0.0	0.184[a]
Postoperative	52.3±17.6	22.5±3.5	0.110[a]
P	0.923b	1.000b	
Postoperative – Preoperative	-1.0±15.9	+2.5±0.0	0.961[a]

*p<0,05, [a] Student´s T Test; [b] Paired T Test. FVC, Forced Vital Capacity; FEV1, Forced Expiratory Volume in 1Second.

Table 4. Analysis of Odds Ratio between the postoperative pulmonary complications and the type of surgery.

	Pulmonary Complications			
	Yes	**No**	**P**	**OR (CI95%)**
Surgery			1.00	2.00 (0.75-5.34)
Thoracotomy and posterior arthrodesis	2 (100.0%)	2 (66.7%)		
Posterior arthrodesis	0 (0.0%)	1 (33.3%)		

*p<0,05, Fisher´s Exact Test. OR = Odds Ratio; CI95% = Confidence interval 95%.

Pulmonary complications in the two patients who underwent dual approach were atelectasis and respiratory failure in one patient, pleural effusion and respiratory failure in the other.

DISCUSSION

Regarding the assessment of pulmonary function in patients with congenital scoliosis undergoing surgery, the present study compared the preoperative results and those of the last follow-up (greater than 15 years) between the combined approach and the posterior-only approach with materials of 3rd generation.
As reported in a study by Xue et al., patients who had FVC and FEV1 values above 65% would not have impaired lung function during adult life. On the other hand, those with clinically relevant pulmonary involvement have a lower BMI and a higher Cobb angle, among other characteristics.[3]
In the current research, in both groups, the preoperative mean percentage predicted values of %FVC and %FEV1 were less than 65% in patients aged around 13 years at the time of surgery. In the follow-up time until last postoperative appointment, an increase in %FEV1 values was noticed for both groups and %FVC for the posterior arthrodesis group, although without significant diferences.
In another study, which analyzed postoperative pulmonary function parameters in patients with congenital scoliosis undergoing arthrodesis, three by posterior approach and seven by combined approach, before the age of 10, an average FVC% and FEV1% were obtained around 64%. Furthermore, early surgery did not produce good radiographic results (Cobb of the main thoracic curve of 41.6°±19.2°), after seven years of follow-up.[5]
In the present series, patients who underwent the dual approach compared to the posterior approach presented, respectively, the following preoperative and postoperative Cobb angle values of the main thoracic curve (90°± 53.4°→52°± 23.5°) and (44° ± 5.7°→ 30.5° ± 0.7°). This, after a smaller number of fused levels in the posterior arthrodesis group compared to the combined (5.5 ± 3.5 versus 13.3 ± 2.5).
Other authors, when evaluating changes in lung function in patients with congenital scoliosis undergoing combined and posterior approaches, found a postoperative magnitude of the main thoracic curve of 47.6° ± 27.4° and FVC% of 68% with a mean follow-up 7.6 years ± 4.2 years. In patients with a vital capacity of less than 50% in the postoperative period, three operated by dual approach and two operated only by posterior approach, complications were pseudarthrosis in one patient and surgical wound infection in another.[6]
In the present study, the variation of Cobb angles coronal and sagittal (Kyphosis T5-T12) in the dual approach and posterior-only groups was, respectively, coronal (-47.0° ± 40.3° / 13.5° ± 5.0 °), sagittal (-1.0° ± 15.9° /2.50° ± 0°), but without significant differences.
Pulmonary complications were only seen in the group that performed the dual approach, with one patient having atelectasis and respiratory failure, undergoing orotracheal intubation and antibiotic therapy; in another, pleural effusion and respiratory failure, chest drainage and orotracheal intubation were performed. It should be noted that both progressed well clinically after the measurements taken.
There was no greater chance of pulmonary complications in these patients, considering the type of approach used, whether combined or only posterior. In addition, there are no records of complications related to implants.
The present research's strong point is that it is one of the few studies, if not one of the only ones, that compares preoperative and postoperative pulmonary function parameters in patients with congenital scoliosis, submitted to the combined approach versus the only posterior approach with long follow-up (greater than 15 years). However, caution must be taken when interpreting the results and in their external validation, due to the inherent limitations of this research.

While the limitations can be attributed to the fact that the study is retrospective; have been carried out in a single center; present a small sample; and not having evaluated the effect of skeletal traction, vertebral osteotomies and thoracoplasty on pulmonary function.

CONCLUSIONS

When evaluating the effect of combined spinal fusion (anterior and posterior) and only posterior on the pulmonary function of patients with congenital scoliosis, in long-term follow-up (greater than 15 years), it was found that there was no difference in the absolute and percentages predicted values of FVC and FEV1 between the groups, in the last follow-up. Furthermore, considering that %FVC and %FEV1 are more appropriate for comparing preoperative and postoperative values for a given surgical approach, it is suggested that the dual approach did not result in worse pulmonary involvement compared to the posterior-only approach.

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EPIDEMIOLOGICAL PROFILE OF PATIENTS WITH SYSTEMIC SCLEROSIS TREATED AT A QUATERNARY HOSPITAL IN THE STATE OF SÃO PAULO

PERFIL EPIDEMIOLÓGICO DE PACIENTES COM ESCLEROSE SISTÊMICA ATENDIDOS EM UM HOSPITAL QUARTENÁRIO DO ESTADO DE SÃO PAULO

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ABSTRACT

Objective: To report the profile of patients diagnosed with systemic sclerosis and monitored in a four-year hospital in São Paulo. Methods: Observational study with 51 patients, mostly composed of women. Descriptive statistics such as mean age, proportions (sex, ethnicity, form of the disease), and correlations between functional scores (HAQ, SHAQ, and Rodnan score) were extracted. Results: The average age found was 49.96 ± 12.01 years. The time since diagnosis was 11.19 ± 10.16 years. When separated by sex, 25% of men presented the limited form, while 65.9% of women presented the localized form. There was a statistically significant correlation (p-value<0.01) between the Rodnan score and the HAQ score, with a value of 0.36 (CI: 0.09-0.58), as well as with the SHAQ score (value of 0.33; CI: 0.05-0.55, p-value=0.01). When evaluating the correlation between the Rodnan score and the Cochin functional scale, there was a statistically significant correlation (p-value<0.01), with a value of 0.38 (0.12-0.58). Conclusion: According to the literature, this study showed the highest prevalence in women, and the predominant form is limited. ***Level of Evidence II; Cohort Study.***

Keywords: Epidemiology; Scleroderma, Systemic; Epidemiological Profile.

RESUMO

Objetivo: Relatar o perfil dos pacientes diagnosticados com esclerose sistêmica e acompanhados em um hospital quartenário paulista. Métodos: Estudo observacional com 51 pacientes, composto majoritariamente por mulheres. Foram extraídas estatísticas descritivas como idade média, proporções (sexo, etnia, forma da doença) e correlações entre escores funcionais (HAQ, SHAQ e escore de Rodnan). Resultados: A idade média encontrada foi de 49,96 ± 12,01 anos. O tempo desde o diagnóstico foi de 11,19 ± 10,16 anos. Quando separados por sexo, 25% dos homens apresentaram a forma limitada, enquanto 65,9% das mulheres apresentaram a forma localizada. Houve correlação estatisticamente significante (p-valor<0,01) entre o escore de Rodnan e a pontuação HAQ, com valor de 0,36 (IC: 0,09-0,58), bem como com a pontuação SHAQ (valor de 0,33; IC: 0,05-0,55, p-valor=0.01). Quando avaliada a correlação entre o escore de Rodnan e a escala funcional de Cochin, houve correlação estatisticamente significante (p-valor<0,01), com valor de 0,38 (0,12-0,58). Conclusão: De acordo com a literatura, este estudo evidenciou a maior prevalência em mulheres e a forma predominante sendo a limitada. ***Nível de Evidência II; Estudo de Coorte.***

Descritores: *Epidemiologia; Escleroderma Sistêmico; Perfil Epidemiológico.*

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INTRODUCTION

Scleroderma is defined as the presence of thickened and hardened skin (from the Greek "scleros"). This is a distinctive feature of systemic sclerosis (SSc), a chronic disease that affects multiple organs and is characterized by generalized vasculopathy associated with progressive fibrosis of the skin, as well as other organs. Its diagnosis is based mainly on characteristic clinical signs, such as stiffened fingers distal to the metacarpal-phalangeal joints, backed up by serological alterations, such as antinuclear antibodies. SSc is a complex disease with extensive organ involvement, varying progression, and severity, as well as a varied response to surgical procedures.

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

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Previous studies have reported discrepant incidence and prevalence rates. This can be attributed, in part, to the different classifications, geographical discrepancies, and timing of the disease. The global incidence is estimated at between 8 and 56 new cases per million people per year, while the prevalence is estimated at 38 and 341 cases per million people.[1] Studies report a higher prevalence of SSc in females, with a ratio of affected women to men ranging from 3:1 to 8:1. The disease presents differently based on gender, with women tending to have a more limited form of the disease, an earlier age of onset and a higher frequency of peripheral vasculopathy and risk of pulmonary involvement. In males, there is a higher risk of diffuse skin disease, heart disease, and nephropathy. In addition, the interval between the first episode of Raynaud's phenomenon and the diagnosis of SSc tends to be longer in females.[2] Patients of African descent tend to have an earlier onset of the disease and more severe forms, with an increased risk of pulmonary fibrosis and renal involvement.[3]

Because of its heterogeneous presentation and evolution, there are different ways of assessing the limitations associated with the disease. The Health Assessment Questionnaire (HAQ) and its version adapted for scleroderma (SHAQ) are widely used tools in the functional and quality of life assessment of patients with rheumatological diseases such as systemic sclerosis. Composed of questions covering various aspects of daily life, the HAQ and SHAQ score the patient's perceived difficulty carrying out everyday activities such as dressing and walking. Its global scores provide a quantitative measure of functional disability and are valuable for clinical assessments and research.[4] The Rodnan score, or Rodnan Index, plays a crucial role in the clinical assessment of SSc by quantifying the extent of skin fibrosis in 17 specific areas of the body. The scores reflect the severity of skin thickening and are essential for monitoring disease progression and assessing treatment efficacy, contributing to comprehensive clinical management of systemic sclerosis.[5]

This study aims to describe the profile of patients with SSc who are followed up in a São Paulo orthopaedic hospital.

MATERIALS AND METHODS

An observational study was carried out on 51 patients, mostly women. The average age of the participants was 49.96 ± 12.01 years, with variations between 27 and 76 years. The average time since diagnosis was 11.19 ± 10.16 years, ranging from 1 to 42 years. Patients were diagnosed with systemic sclerosis using the criteria found in the American College of Rheumatology (ACR)/ European League Against Rheumatism (EULAR) 2013.[6] All patients were assessed using the Health Assessment Questionnaire (HAQ), Scleroderma Health Assessment Questionnaire (SHAQ), Cochin functional score and modified Rodnan score. The study was carried out after approval by the institution's research ethics committee (protocol number 23261013.8.0000.5404), under the Declaration of Helsinki. All the data in this study was obtained from the patient's clinical records after informed consent.

Statistical analysis

The data was statistically analyzed using the R language version 3.1 (R Foundation for Statistical Computing, Vienna, Austria). Quantitative data was characterized using descriptive statistics; qualitative data was characterized using frequency distributions and contingency tables, and comparisons between samples were made using the chi-square test. All P values were bidirectional with a significance level of 0.05%. The statistical correlation used Pearson's method with Yates' correction, considering p-values of less than 0.05 to be significant.

RESULTS

The majority of the sample population was made up of women (92.2%), and the most prevalent self-declared ethnicities were white (64.7%), brown (27.5%) and black (7.8%). The patients were classified into 2 types of disease: Limited form (62.7%) and diffuse form (37.3%). (Table 1)

When separated by gender, 25% of the men (1 patient) had the limited form, while 75% had the diffuse form (3 patients). In the group of women, 65.9% had the localized form (31 patients), while 34% had the diffuse form (16 patients). There was no statistically significant association between gender and the form of the disease (p-value=0.27). (Figure 1)

When separated by self-declared ethnicity, 100% of black patients had the limited form (4 patients). In brown people, the prevalence of the limited form was 64.3% (9 patients) and the diffuse form was 35.7% (5 patients). In whites, 57.6% of patients had the limited form (19 patients) and 42.4% had the diffuse form (14 patients). However, these differences were not statistically significant (p-value=0.25). (Table 2 and Figure 2).

There was a statistically significant correlation (p-value<0.01) between the Rodnan score and the HAQ score, with a value of 0.36 (CI: 0.09-0.58), as well as with the SHAQ score (value of 0.33;

Table 1. Frequency distribution of the sample by gender.

Sex	Absolute frequency	Relative Frequency
Female	47	92.2%
Male	4	7.8%
Total	51	100%

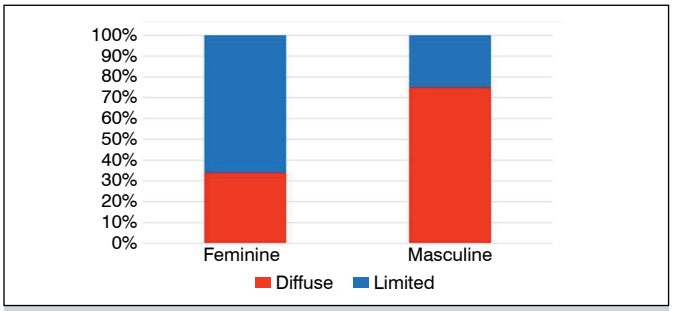

Figure 1. Distribution of forms of the disease by gender.

Table 2. Frequency distribution of the sample by self-declared ethnicity.

Ethnicity	Absolute frequency	Relative Frequency
White	33	64.7%
Brown	14	27.5%
Black	4	7.8%
Total	51	100%

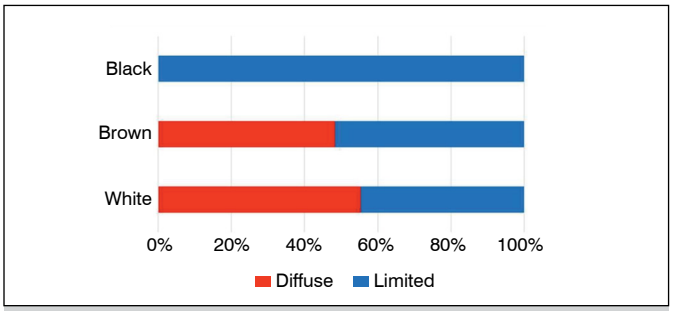

Figure 2. Distribution of forms of the disease, by self-declared ethnicity.

CI: 0.05-0.55, p-value=0.01). When the correlation between the Rodnan score and the Cochin functional scale was evaluated, there was a statistically significant correlation (p-value <0.01), with a value of 0.38 (0.12-0.58). (Table 3).

Table 3. Frequency distribution of the sample by form of the disease.

Form	Absolute frequency	Relative Frequency
Limited	32	62.7%
Diffuse	19	37.3%
Total	51	100%

DISCUSSION

This observational study reports on the epidemiological profile of patients with systemic sclerosis followed up as outpatients at a hospital in the state of São Paulo. The relatively high prevalence justifies the small number of patients recruited for the study. According to Horimoto et al. (2017),[7] the prevalence in a Brazilian municipality (Campo Grande/MS) was 105.6/million inhabitants. SSc is a rare disease, but its incidence has slightly increased in recent years.[8]

In this study, most patients were women, which aligns with the literature. Only 1 in 5 patients with systemic sclerosis is estimated to be male.[9]

The limited form was more prevalent, similar to other results found in the literature. In a multicenter European study, Della Rosa et al. (2001) showed the prevalence of 2/3 of the cases in its limited form.[10] Similarly, Jacobsen et al. (1998) reported that three-quarters of patients had a diffuse presentation of the disease in a study of Danish patients.[11] Similarly, Nagy and Czirjak (1997) diagnosed the limited form as the most prevalent in a study carried out in Hungary.[12] However, these results are not unanimous. Steen et al. (1988) and Bobeica et al. (2021) identified the diffuse form as the most prevalent in epidemiological studies.[9,13]

The limited form was the most prevalent in female patients, while the diffuse form was the most prevalent in men. However, no statistical significance was observed for these differences, which could be explained by the low number of men selected in the sample. The same rationale can be used for the prevalence of the limited form in blacks: although 100% of the patients in the study had this form, the number of participants was too low to be statistically significant. Morgan et al. (2017) showed contrasting differences in the severity and time of manifestation of symptoms when comparing an African-American cohort with European studies.[3] However, given the low number of patients who self-declared as black, the present study could not show such differences.

When the statistical correlations were analyzed, a weak correlation was observed between the Rodnan score, HAQ, and SHAQ. These measures, in general, limit patients' quality of life. Thus, despite using different questions, the increase in limitation observed in one questionnaire is expected to be reflected in the others, which was evidenced, albeit weakly.

CONCLUSION

This study describes the epidemiological profile of systemic sclerosis in a hospital in São Paulo. Similar to what has been found in other publications, the study showed a higher prevalence in women, and the predominant form is limited. The most prevalent form of the disease was limited, especially in women. When stratified by self-declared ethnicity, the most prevalent form in blacks, browns, and whites was limited, with no statistically significant difference. Due to the disease's low incidence and high heterogeneity, multicentre epidemiological studies are necessary for a better characterization and prognosis.

AUTHOR'S CONTRIBUTION: Each author has made an individual and significant contribution to the development of this article. PHMT: article writing, review, and statistical analysis; RC and MPPR: data collection and article writing; RAQ: data collection and statistical analysis; MFMA: article writing, statistical analysis, and intellectual concept of the article and preparation of the entire research project.

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EFFECTIVENESS OF ORAL MEDICATIONS IN THE PERIOPERATIVE PERIOD OF ROTATOR CUFF INJURIES - SYSTEMATIC REVIEW

EFETIVIDADE DAS MEDICAÇÕES ORAIS NO PERÍODO PERIOPERATÓRIO DAS LESÕES DO MANGUITO ROTADOR - REVISÃO SISTEMÁTICA

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ABSTRACT

Postoperative pain management remains a significant challenge in patient care, being particularly crucial in the context of arthroscopic or open rotator cuff repairs. Objective: To compare the effectiveness of different medications in controlling pain after this surgical intervention. Material and methods: A systematic review of the literature was carried out, conducting a data search in the Pubmed/Medline, Science Direct and Embase databases. Initially, 1,223 articles were identified where, after detailed analysis, eight studies were selected to compose this research. The total sample comprised 703 patients. Results: We observed a predominance of male participants in most studies, and the age range of those involved varied, on average, from 50.0 to 59.9 years old. The studies included cover a variety of pain management strategies after arthroscopic rotator cuff repair, highlighting the diversity of approaches in the literature, including analgesics, anti-inflammatories, anticonvulsants and opioids. Conclusion: In general, we showed that the interventions used were well tolerated. Some studies have demonstrated mild adverse effects, such as nausea, vomiting, dizziness, headache and other transient symptoms. This systematic review highlights that there is no well-established protocol for managing postoperative pain in arthroscopic rotator cuff repair, comparing the effectiveness of different medications. The diversity of approaches observed in the literature highlights the need for personalized strategies. Despite the good tolerance and positive results of the interventions, the choice of medication must consider the individuality of the patient and specific characteristics of the procedure. ***Level of Evidence II; Systematic Review.***

Keywords: Perioperative Period; Postoperative Care; Pain; Rotator Cuff Injuries; Drug Therapy.

RESUMO

O gerenciamento da dor pós-operatória permanece como um desafio significativo na prestação de cuidados ao paciente, sendo particularmente crucial no contexto do reparo artroscópico ou aberto do manguito rotador. Objetivo: Comparar a efetividade de diversas medicações no controle da dor após essa intervenção cirúrgica. Material e métodos: Realizou-se uma revisão sistemática da literatura, conduzindo a busca de dados nas bases Pubmed/Medline, Science Direct e Embase. Foram identificados 1.223 artigos, oito estudos foram incluídos. A amostra total compreendeu 703 pacientes. Resultados: Os participantes foram do sexo masculino na maioria dos estudos, e a faixa etária dos envolvidos variou, em média, de 50,0 a 59,9 anos. Os estudos incluídos abarcam uma variedade de estratégias de manejo da dor após o reparo artroscópico do manguito rotador, destacando a diversidade de abordagens existentes na literatura, incluindo medicamentos analgésicos, anti-inflamatórios, anticonvulsivantes e opioides. Conclusão: De maneira geral, evidenciamos que as intervenções empregadas foram bem toleradas. Alguns estudos demonstraram efeitos adversos leves, como náuseas, vômitos, tontura, cefaleia e outros sintomas transitórios. O uso pós-operatório de ibuprofeno reduz a necessidade de opioides e diminui os níveis de dor do paciente na primeira semana pós-operatória e sua utilização não aumentou o risco de rerrotura. ***Nivel de Evidência II; Revisão Sistemática.***

Descritores: *Período Perioperatório; Cuidados Pós-Operatórios; Dor; Lesões do Manguito Rotador; Terapia Medicamentosa.*

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INTRODUCTION

Rotator cuff injury is the leading cause of upper limb dysfunction related to the shoulder.[1] The symptoms of these injuries are characterized by pain, predominantly located in the front or lateral part of the shoulder, which may intensify with specific movements.[2]
The management of rotator cuff injuries is the subject of extensive discussion, encompassing both non-surgical and surgical approaches. Among the non-surgical options, we can mention modifications to daily activities, the use of medications for symptom relief, and participation in physical therapy programs.[3]
The number of patients undergoing rotator cuff repair (RCR) has increased, and postoperative pain control is considered a challenge in these cases. Some studies show an increase in this type of procedure ranging from 163% to 268%.[4]
A national study utilized the DataSUS table, which is based on population data from the Brazilian Institute of Geography and Statistics (IBGE). The rates presented per group of 100,000 inhabitants, from 2003 to 2017, regarding rotator cuff tear repair, recorded 50,207 surgeries, including decompression procedures. The rates were calculated using the total number of rotator cuff repairs as the numerator and the total population of the evaluated locality as the denominator. The rate of surgical interventions increased from 0.83 to 2.81, resulting in a 238% rise. In 2015, the South Region had the highest rate, at 6.32, followed by the Southeast, at 3.62, while the North had the lowest rate, at 0.13. The trend of this growing expansion is observed in the Southeast, South, and Midwest regions, while the index is stable in the North and Northeast regions.[5]
Despite being a minimally invasive surgical procedure, it is associated with significant pain observed in the immediate postoperative period, especially in the first 2-3 days after surgery. However, effective pain control at this time can help reduce hospital stays and improve patient satisfaction and functional recovery.[6]
There is no systematic review of postoperative pain control for rotator cuff repair managed solely with oral medications. In this perspective, the present study aims to investigate the influence of different medications on postoperative pain control and evaluate which medication would have the greatest effectiveness in patients undergoing RCR.
The importance of this work lies in the fact that, despite numerous therapeutic approaches having been described for pain control, this topic remains a significant issue for both patients and orthopedic surgeons.
The objective is to compare the effectiveness of different medications administered orally for pain control in patients undergoing RCR and the specific objectives are: To conduct a comprehensive literature analysis to evaluate the effectiveness of analgesics, anti-inflammatories, antidepressants, anticonvulsants, and opioids; to investigate and consolidate existing data addressing the effectiveness and adverse effects of oral medications used, and to perform a critical and comprehensive synthesis of existing evidence, contributing to a deeper understanding of this topic.

METHODOLOGY

This is a systematic literature review registered in the International Prospective Register of Systematic Reviews (PROSPERO) database. The review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.
The research was guided by the following question: "What is the most effective oral medication for postoperative pain control in patients undergoing rotator cuff repair?" This question was formulated according to the PICO strategy. (Table 1)
The following databases were used: PubMed, ScienceDirect, and Embase. The search strategy included terms related to rotator cuff repair, postoperative pain medications, and randomized clinical trials. The research strategy is presented in Table 2.
A comprehensive review of the literature was conducted to identify and include randomized clinical trials investigating oral pharmacological interventions for postoperative control in individuals undergoing rotator cuff repair. Covering all age groups and both sexes, with no ethnic or age restrictions, the review included various medications such as analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, opioids, antidepressants, anticonvulsants, and supplements. Studies whose interventions did not exclusively involve the use of oral medications in the postoperative period were excluded. The primary outcome is to assess pain intensity (using a VAS or another tool), and the secondary outcomes include assessing adverse effects, function, quality of life, use of rescue analgesics, and tendon rerupture.
Initially, two independent reviewers analyzed the titles and abstracts of the studies identified in the search. Those that met the inclusion criteria were selected for full review. Relevant data were extracted from the selected studies, including characteristics, population,

Table 1. The PICO strategy was adopted to define the guiding question of the research.

P – Population	Patients in the perioperative period of rotator cuff repair
I – Intervention	Oral medication
C – Comparison	Compare the effectiveness of medications
O – Outcome	Pain, function, adverse effects

Source: Author (2024).

Table 2. Search strategy for the review articles.

Pubmed Central	("rotator cuff"[MeSH Terms] OR ("rotator"[All Fields] AND "cuff"[All Fields]) OR "rotator cuff"[All Fields]) AND ("wound healing"[MeSH Terms] OR ("wound"[All Fields] AND "healing"[All Fields]) OR "wound healing"[All Fields] OR "repair"[All Fields]) AND ("pain, postoperative"[MeSH Terms] OR ("pain"[All Fields] AND "postoperative"[All Fields]) OR "postoperative pain"[All Fields] OR ("postoperative"[All Fields] AND "pain"[All Fields])) AND ("pharmaceutical preparations"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "medications"[All Fields]) AND ("pain management"[MeSH Terms] OR ("pain"[All Fields] AND "management"[All Fields]) OR "pain management"[All Fields] OR ("pain"[All Fields] AND "control"[All Fields]) OR "pain control"[All Fields]) AND ("randomized controlled trial"[All Fields] OR "randomized controlled trials as topic"[MeSH Terms] OR "randomized clinical trials"[All Fields] OR "randomized clinical trials"[All Fields])
Science Direct	('Rotator Cuff Repair') AND ('postoperative pain medications' OR (postoperative AND medications)) AND ('pain control'/exp OR 'pain control') AND ('randomized controlled trial' OR 'randomized controlled trials as topic')
Embase	('rotator cuff repair'/exp OR 'rotator cuff repair' OR (('rotator'/exp OR rotator) AND ('cuff'/exp OR cuff) AND ('repair'/exp OR repair))) AND ('postoperative pain medications' OR (postoperative AND ('pain'/exp OR pain) AND medications)) AND ('pain control'/exp OR 'pain control' OR (('pain'/exp OR pain) AND ('control'/exp OR control))) AND ('randomized clinical trials' OR (randomized AND ('clinical'/exp OR clinical) AND trials))

Source: Pubmed Central, Science Direct, Embase (2024).

interventions, and outcomes related to postoperative pain. Any disagreements between the reviewers were resolved by consensus or, when necessary, by consulting a third reviewer. This approach aimed to ensure consistency and reliability in the selection and analysis of studies, thereby strengthening the validity and accuracy of the results obtained in the systematic review, a process that has already been completed.

The methodological quality of the included randomized clinical trials was assessed through an evaluation of the risk of bias for each study using the ROB-2 tool, following the criteria described in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions.[7] Any discrepancies were resolved through discussion or by involving another author of the review. The risk of bias was assessed according to the following domains: (1) Random sequence generation (to determine if the method of randomization sequence generation was adequate, such as random number tables, computer-generated random numbers, minimization, drawing lots, etc.), (2) Allocation concealment (to determine if appropriate methods were used to conceal allocation, such as central randomization and opaque envelopes, sequentially numbered and sealed), (3) Blinding of participants and personnel, (4) Blinding of outcome assessors. Blinding was considered separately for self-reported subjective outcomes (pain, function, treatment success, quality of life) and objective outcomes (such as abstinences, adverse events, disability). For example, for a non-blinded assessment of outcomes, the risk of bias for mortality may differ from that for a pain scale reported by participants), (5) Incomplete outcome data, (6) Selective reporting of outcomes, (7) Other potential threats to validity, such as inadequate analyses in crossover trials, baseline imbalance in important factors, inappropriate or unequal application of co-interventions.

Each potential source was classified as high risk, low risk, or unclear risk regarding bias, taking into account the lack of information or uncertainty about the potential for bias. The numbers generated by the "Risk of Bias Tool" were presented in the "Risk of Bias" table, providing summarized assessments of the risk of bias, along with justifications for each judgment. A summary of the risk of bias across different studies was addressed for each listed domain.

Additionally, information regarding the risk of bias related to unpublished data or correspondence with researchers was recorded in the "Risk of Bias" table. In the context of analyzing the main results, the impact of missing data was taken into account.

When assessing the treatment effects, the risk of bias of the contributing studies for each outcome was taken into account. The numbers generated by the "Bias Risk" tool were presented to summarize the results of the evaluations.

The review was conducted in accordance with the published protocol, and any deviations from this protocol were reported in the "Differences between protocol and review" section of the study.

The results from each trial were presented as point estimates, along with the mean and standard deviation (SD) for continuous outcomes and risk ratios (RR) with corresponding 95% confidence intervals (CIs) for dichotomous outcomes.

Dichotomous data, such as RRs or odds ratios from Peto, were analyzed when the outcome was a rare event (approximately less than 10%), and 95% CIs were used.

For continuous data, when different scales were used to measure the same conceptual outcome (e.g., disability), standardized mean differences (SMDs) were calculated, along with corresponding 95% confidence intervals (CIs). The SMD was expressed as an MD on a typical scale (e.g., 0 to 10 for average pain) by multiplying the SMD by a typical SD among people (e.g., the SD of the control group at the baseline of the most representative trial).[7]

In the Comments column of the 'Summary of Results' table, the absolute percentage difference, the relative percentage change from baseline, and the number needed to treat for one additional beneficial outcome (NNTB), or the number needed to treat for one additional harmful outcome (NNTH) were reported (only NNTB and NNTH were provided when the outcome showed a statistically significant difference between treatment groups).

For dichotomous outcomes, such as adverse events, NNTB or NNTH was calculated from the event rate of the control group and the relative risk using the Visual Rx NNT calculator.[8] NNTB was calculated for continuous measures using the Wells calculator, available on RevMan Web. The minimum clinically important difference (MCID) was used in the calculation of NNTB or NNTH; an MCID of 1.5 points on a 10-point scale for pain was assumed, and 10 points on a 100-point scale for function or disability were used as input into the calculator.[9]

For dichotomous outcomes, the absolute risk difference was calculated using the risk difference statistic (in RevMan Web), and the result was expressed as a percentage. For continuous outcomes, the absolute benefit was calculated as the improvement in the intervention group minus the improvement in the control group (MD), in the original units. The results were then presented as percentages.

The relative percentage change was calculated for dichotomous data as Risk Ratio - 1. For continuous outcomes, the relative difference was calculated as the absolute benefit (MD) divided by the mean baseline of the control group.

Additionally, the combined analysis of the studies was conducted using R programming software, version 4.3.1, with the meta package. Six meta-analyses were performed: the first four used only studies with similar treatment methods, while the fifth used all works to estimate the results, and the sixth included studies that presented the average pain scores.

The researchers of the study were contacted by email to verify the main characteristics of the study and obtain missing numerical data from the results whenever possible (e.g., when a study is identified only as an abstract or when data are not available for all participants). Otherwise, considering that missing data introduces serious biases, the impact of including such studies in the overall assessment of results was explored through a sensitivity analysis.

For dichotomous outcomes (e.g., number of withdrawals due to adverse events), the withdrawal rate was calculated using the number of participants randomized in the group as the denominator.[7]

For continuous outcomes (e.g., mean change in pain score), the MD or SMD was calculated based on the number of participants analyzed at that time. If the number of participants analyzed was not presented for each time point, the number of participants randomized in each group at baseline was used.[7]

Whenever possible, the missing standard deviations of other statistics, such as standard errors, confidence intervals, or *p-values*, were calculated using the methods recommended in the Cochrane Handbook for Systematic Reviews of Interventions.[7] When it was not possible to calculate the standard deviations, they were imputed from other studies with meta-analysis. Any assumptions and imputations were described to handle missing data and explore the effect of imputation through sensitivity analyses.

Clinical and methodological diversity was assessed among the participants, interventions, and outcomes of the included studies to determine if the meta-analysis was appropriate, as observed in the data extraction tables. Statistical heterogeneity was assessed by visual inspection of the forest plot to identify clear differences in outcomes between studies, using the statistical tests I^2 and Chi^2. The interpretation of an I^2 value ranges from 0% to 40% as "not important", 30% to 60% as "moderate heterogeneity",

50% to 90% as “substantial heterogeneity”, and 75% to 100% as “considerable heterogeneity”. As noted in the Cochrane Handbook for Systematic Reviews of Interventions, the importance of I^2 depends on (i) the magnitude and direction of effects and (ii) the strength of evidence for heterogeneity.

The Chi^2 test where $p \leq 0.10$ indicates evidence of statistical heterogeneity. If substantial heterogeneity is identified, this was reported and possible causes were investigated.[7]

A funnel plot was created and examined to explore possible small-study biases. When interpreting funnel plots, the various possible reasons for the asymmetry of the plots were analyzed and related to the review's results.

To assess outcome reporting bias, the trial protocols were checked against the published reports. For studies published after July 1, 2005, the Clinical Trials Registry on the International Clinical Trials Registry Platform of the World Health Organization was examined.[10] It was assessed whether there is selective reporting of outcomes.

The following questions and main comparisons were considered: Are opioid analgesics more effective than placebo or no treatment? Do anti-inflammatory medications provide additional benefits when combined with other interventions (e.g., analgesics)? Are analgesics more effective than standard therapies such as the use of glucocorticoids, NSAIDs, or others? Is one analgesic more effective than another?

The main outcomes and comparisons of the review were presented in ‘Summary of Results’ tables that provide important information about the quality of evidence, the magnitude of the effect of the examined interventions, and the sum of available data on outcomes: reported by participants as pain relief of 30% or more; mean overall pain; function; participants' global assessment of treatment success; quality of life; number of participant dropouts due to adverse events; and number of participants who experienced an adverse event, as recommended by Cochrane.[7] The moments included were: pre and post-surgical approaches, after three weeks to six weeks in the tables, except for withdrawals (failures) and adverse events, which were reported at the end.

Two reviewers independently assessed the quality of the evidence. The five GRADE considerations (study limitations, effect consistency, imprecision, indirectness, and publication bias) were used to assess the quality of a body of evidence regarding studies contributing data for the pre-specified outcomes in meta-analyses, and to report the quality of evidence as high, moderate, low, or very low using GRADEpro GDT software.[11] All decisions to downgrade the quality of studies were reported using footnotes and comments to help the reader understand the review when necessary.

The following sensitivity analyses were conducted: assessment of the robustness of pain and function results for selection and detection biases, removal of trials in secondary analyses with inadequate or unclear allocation concealment to assess the effect of selection bias, and trials with unclear or inadequate blinding of participants to assess the effect of detection bias. Assessment of the effect of including imputed data and assumption-based data.

For the interpretation of the results, we were aware of distinguishing between a lack of evidence of effect and a true lack of effect. The conclusions were based solely on the results of the quantitative or narrative synthesis of the studies included in this review. Recommendations for practice and implications for future research were not addressed, and instead, the remaining uncertainties in the field were outlined.

RESULTS

Initially, 1,223 articles were identified in the initial search. The summary of the article selection process is presented in Figure 1. After evaluating the titles and abstracts, followed by the selection and detailed analysis of the articles, 11 studies were deemed eligible to be included in this systematic review.

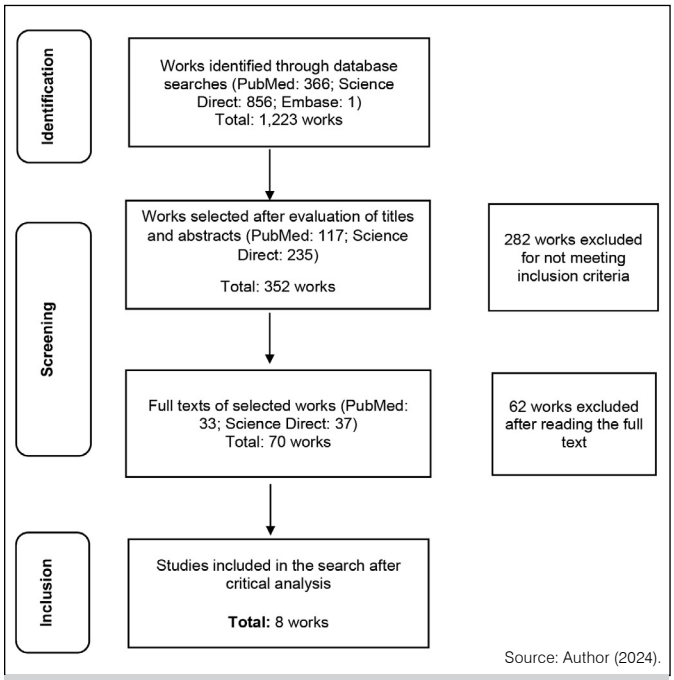

Figure 1. Flowchart illustrating the schematic representation of methods for identifying, screening, assessing eligibility, and including works in the review, adapted from the PRISMA protocol.

This systematic review was conducted in accordance with the PRISMA recommendations, as illustrated in Figure 1.

The studies included in this systematic review consisted of randomized clinical trials that investigated the effects of various medications on postoperative pain control after RCR.

The total sample comprised 703 patients. A predominance of male participants was observed in most studies, with an average age range of participants varying from 50.0 to 59.9 years. The methodological characteristics of the selected studies are detailed in Table 3.

The included studies encompassed a variety of pain management strategies following RCR, highlighting the diversity of existing approaches in the literature, including the use of analgesics, anti-inflammatory agents, specific medications, and multimodal protocols.

Table 4 highlights the adverse events and effects on pain observed in the studies.

Overall, we found that the interventions employed were well-tolerated, with some studies reporting only mild adverse effects, such as nausea, vomiting, dizziness, headache, and other transient symptoms. It is noteworthy that, despite the diversity of approaches, all investigated strategies showed positive results regarding effective postoperative pain control.

This consistency in favorable outcomes highlights the robustness of the available therapeutic options, providing not only analgesic efficacy but also a good safety margin in terms of tolerability. These observations reinforce the feasibility and clinical utility of the reviewed interventions for pain management in the context of rotator cuff repair.

Regarding methodological rigor, 50.0% of the studies presented a low risk of bias, while 50.0% presented a moderate or high risk of bias. (Figure 2)

Among the main factors related to this assessment, we found two studies that presented insufficient or inconsistent data in measuring

Table 3. Summary of demographic data and pharmacological intervention of all included studies.

Author/ Year	Study Type	Intervention Groups	Gender (M/F)	Age (years)	Doses
Chillemi et al., 2023.[12]	Randomized Clinical Trial	A: 38 B: 38 C: 38	62/52	59 9	A: Paracetamol 1000mg, 1 tablet as needed, maximum 3 times a day / 7 days B: Paracetamol 500 mg + Codeine 30 mg 1 tablet 3 times a day / 7 days C: Paracetamol 500 mg + Ibuprofen 150 mg 1 tablet 2 times a day / 7 days
Tangtiphaiboontana et al., 2021.[13]	Randomized Clinical Trial	Ibuprofen: 51 Placebo: 50	Ibuprofen: 29/22 Placebo: 29/21	Ibuprofen: 57.7 10.8 Placebo: 56.9 13.8	Ibuprofen: ibuprofen 400 mg every 8 hours / 14 days continuously + opioid Placebo: placebo + opioid
Yang et al., 2022.[14]	Randomized Clinical Trial	Pre-operative analgesia: 53 Post-operative analgesia: 53	Pre-operative analgesia: 31/22 Post-operative analgesia: 26/27	Pre-operative analgesia: 50.0 10.0 Post-operative analgesia: 52.4 9.0	Pre-operative analgesia: 400 mg of Celecoxib 2 hours before surgery, and then 200 mg of Celecoxib at 4 hours, 12 hours, 24 hours, 36 hours, 48 hours, 60 hours, and 72 hours after surgery Post-operative analgesia: 400 mg of Celecoxib 4 hours after surgery, and 200 mg of Celecoxib at 12 hours, 24 hours, 36 hours, 48 hours, 60 hours, and 72 hours after surgery
Singh et al., 2021[15]	Randomized Clinical Trial	G1: 21 G2: 18 G3: 18	G1: 10/11 G2: 03/15 G3: 07/11	G1: 56.67 11.45 G2: 57.11 8.51 G3: 59.72 8.23	G1: 5 mg of Oxycodone every 6 hours, and 1,000 mg of acetaminophen every 6 hours if necessary G2: 5 mg of Oxycodone every 6 hours if necessary G3: 1,000 mg of acetaminophen every 6 hours pre-surgery, and every 8 hours until the 5th post-operative day and 5 mg of oxycodone if necessary
Bang et al., 2010.[16]	Randomized Clinical Trial	Placebo: 23 Gabapentin: 23	Placebo: 18/08 Gabapentin: 14/09	Placebo: 59.5 6.2 Gabapentin: 56.3 8.5	Placebo: placebo identical in appearance to gabapentin Gabapentin: 300 mg of gabapentin 2 hours before surgery
Ahn et al., 2016[6]	Randomized Clinical Trial	Pregabalin: 30 Control: 30	Pregabalin: 13/17 Control: 13/17	Pregabalin: 55 9 Control: 51 12	Pregabalin: 150 mg of pregabalin Control: placebo capsules
Su et al., 2022[17]	Randomized Clinical Trial	Control: 60 Intervention: 60	NR	NR	Control: placebo Intervention: oral duloxetine
Alaia et al., 2022[18]	Randomized Clinical Trial	Control: 50 Experimental: 49	NR	18 to 75 years	Control: placebo Experimental: 25 mg of CBD 3 times a day if <80 kg, or 50 mg of CBD 3 times a day if >80 kg, for 14 days post-operative

Legend: NR: Not reported; M: male; F: female; PO: Post-operative; CBD: cannabidiol. Source: Author (2024).

Table 4. Summary of adverse effects and pain effects of medications in the post-operative period.

Author/ Year	Adverse Events	Effects on Pain
Chillemi et al., 2023.12	No adverse signs/symptoms were highlighted during the administration of the medication.	The use of oral anti-inflammatory is a viable strategy for controlling post-operative pain. The combination of paracetamol with ibuprofen reduces pain, as seen in the VAS, and promotes early recovery of passive range of motion.
Tangtiphaiboontana et al., 2021.[13]	No adverse signs/symptoms were highlighted during the administration of the medication.	The post-operative use of ibuprofen reduces the need for opioids and decreases the patient's pain levels in the first week post-operatively. The use of ibuprofen does not increase the risk of re-rupture.
Yang et al., 2022.[14]	The most commonly occurring adverse events were nausea, constipation, vomiting, drowsiness, and dizziness in both groups.	Pre-operative administration of celecoxib alleviates acute pain and improves perceived satisfaction.
Singh et al., 2021[15]	The commonly reported side effects associated with post-operative medication included nausea, constipation, and drowsiness.	The use of perioperative paracetamol significantly reduced opioid consumption and improved overall pain control.
Bang et al., 2010.[16]	The side effects associated with the medication were nausea, dizziness, and respiratory difficulty with no difference between the groups.	The use of 300 mg of gabapentin could reduce the post-operative VAS score with fewer side effects.
Ahn et al., 2016[6]	The occurrence of complications related to the multimodal analgesic regimen, including sedation, headache, dizziness, and blurred vision, was similar between the groups.	The numerically assessed pain scores were significantly lower in the Pregabalin group at 6, 24, and 48 hours postoperatively.
Su et al., 2022[17]	The incidence of nausea and vomiting in the duloxetine group was significantly higher than in the placebo group.	Duloxetine resulted in a significant reduction in pain in the first 2 postoperative days, but the reduction was not clinically significant.
Alaia et al., 2022[18]	NR	Orally absorbed cannabidiol demonstrated an acceptable safety profile and showed promise in reducing pain in the immediate perioperative period after RCR compared to the control.

Legend: RCR, rotator cuff repair; VAS, visual analog scale for pain; NR, not reported. Source: Author (2024).

	D1	D2	D3	D4	D5	General
Chillemi 2023[12]	+	+	+	!	+	!
Tangtiphaiboontana 2021[13]	+	+	+	+	!	!
Yang 2022[14]	+	+	+	-	+	-
Singh 2021[15]	+	+	+	+	+	+
Bang et al., 2010[16]	+	+	+	+	+	+
Ahn et al., 2016[6]	+	+	+	+	!	!
Su et al., 2022[17]	+	+	+	+	+	+
Alaia et al., 2022[18]	+	+	+	+	+	+

Legend: +: low risk of bias; !: uncertain risk; -: high risk of bias. D1: Randomization process; D2: Deviation from planned interventions; D3: Absence of outcome data; D4: Outcome measurement; D5: Selection of reported results.

Figure 2. Assessment of methodological risk of bias of the studies according to the Risk-of-bias assessment for randomized trials by Cochrane.[7]

the outcome (Chillemi et al.[12] Yang et al.[14]). Two other studies reported incomplete outcomes (Ahn et al,[6] Tangtiphaiboontana et al.[13]). Some items were rated as "uncertain risk" due to insufficient information that would allow a correct understanding of the methodological process. Figure 3 presents the graphical distribution of potential risks concerning the evaluated items.

In addition, five estimates were made using the same methodology regarding the number of patients who experienced any adverse effect during treatment, regardless of whether the patient presented only one or more symptoms. We employed a random-effects meta-analysis model for binary outcome data, which addresses the objective mentioned at the beginning of the paragraph. The first comparison was made with studies that used NSAIDs in the postoperative period, as shown in Figure 4.

In the analysis conducted, we observed a low level of heterogeneity (I^2 = 0%) among the included studies (Chillemi et al.[12] Yang et al.[14]) and (Tangtiphaiboontana et al.[13]), indicating a remarkable consistency in the results obtained. This uniformity was attributed to

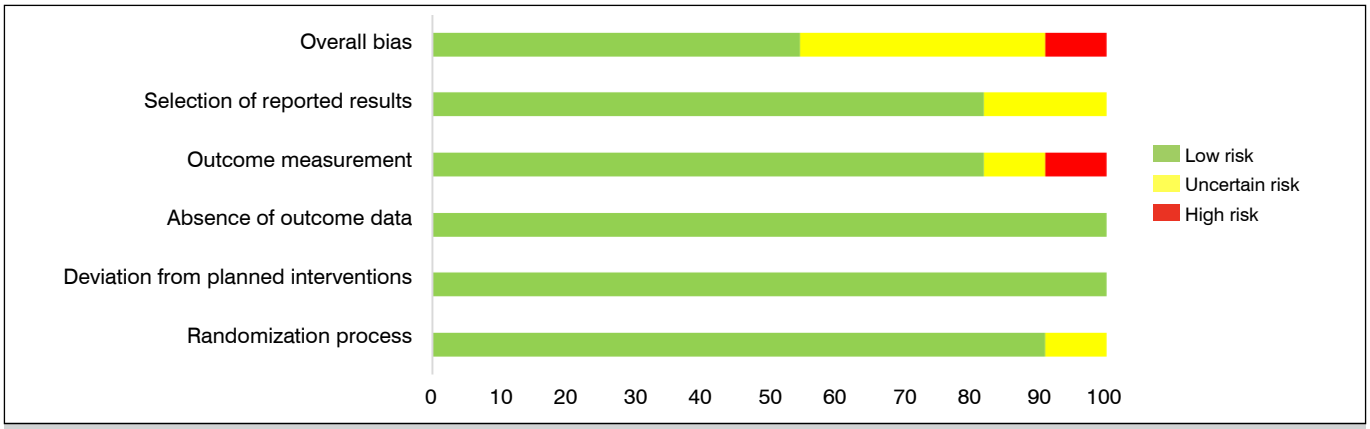

Figure 3. Assessment of risk of bias regarding the analysis categories of all grouped studies.

the clear cause identified: two studies reported the complete absence of adverse effects in the treated group, suggesting a disparity in the pain treatment methods adopted. Despite this discrepancy, when considering the common effect observed in all studies, it was found that only 4% of patients experienced some type of adverse effect. Notably, when adjusting for random effects, this percentage was reduced to 1%. Thus, although the variation in results was clarified by the lack of adverse effects in some studies, the overall analysis revealed a low incidence of those associated with treatment.

The second comparison was made with studies that used medications in the preoperative period, as shown in Figure 5.

The statistical analysis revealed moderate heterogeneity among the included studies, with an I^2 value of 47%, indicating considerable variation in the results. Despite this variation, when considering the common effect observed in all studies (Singh et al.[15] and Yang et al.[14]), it was found that approximately 13% of patients experienced some type of adverse effect with the medications administered in the preoperative period. This proportion remained unchanged at 13%, even after adjusting for random effects. Therefore, although there was moderate heterogeneity among the studies, the overall incidence of adverse effects remained consistent.

The third comparison was made with studies that treated patients with analgesics and opioids, as shown in Figure 6.

In the comparative analysis between the studies of Chillemi et al.[12] and Singh et al.[15], a remarkable consistency in results was observed, reflected by a low level of heterogeneity ($I^2 = 0\%$). This uniformity was attributed to the complete absence of adverse effects in the treated group in the study by Chillemi et al.[12], possibly due to differences in the pain treatment methods employed, which included the use of analgesics and opioids. Despite this discrepancy, when considering the common effect observed in all studies, it was found that only 7% of patients experienced adverse effects. After adjusting for random effects, this proportion was reduced to 3%. Therefore, despite the variations in results attributed to the lack of adverse effects in the study by Chillemi et al.,[12] the overall analysis suggests a low incidence of adverse events related to treatment.

The fourth comparison was made with studies that treated patients with anticonvulsants. (Figure 7)

In comparing the results of the studies by Bang et al.[16] and Ahn et al.[6], which investigated the use of anticonvulsants, low heterogeneity was observed ($I^2 = 0\%$). Notably, when considering the common effect among these studies, about 21% of patients experienced adverse effects. After random adjustments, this proportion remained stable at 21%.

The fifth analysis used all previous works for an overall meta-analysis of adverse effects, as shown in Figure 8.

When comparing the results of all included studies, significant heterogeneity was evidenced ($I^2 = 75\%$), with substantial statistical relevance ($p < 0.01$). Notably, when analyzing the shared effect among these studies, it was found that approximately 21% of patients experienced adverse effects. After random adjustments, this proportion stabilized at 7%, indicating a significant decrease in the incidence of adverse events.

Finally, the last meta-analysis employed a single means (Meta-analysis of single means) with random effects, as only three of the collected studies used a control group and reported the mean and standard error of the pain score for that group. The selected model enabled the computation of an overall average across all studies that reported the mean and standard error of the pain score, including those that did not use a control group. (Figure 9)

The I^2 statistic indicated low heterogeneity, which was statistically non-significant ($p = 0.60$), justifying the adoption of the random effects model in the analysis. We observed that the overall mean pain in the studies was 47.44, as demonstrated in Figure 9. he results of the meta-analysis corroborate the effectiveness of oral medications in reducing the mean pain of patients.

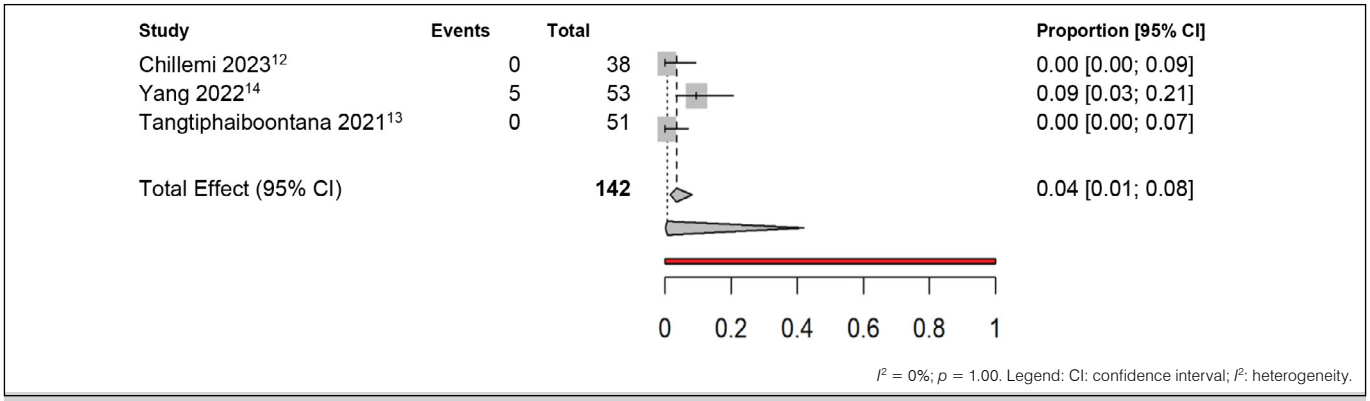

Figure 4. Meta-analysis of adverse effects outcomes in patients treated with NSAIDs in the postoperative period.

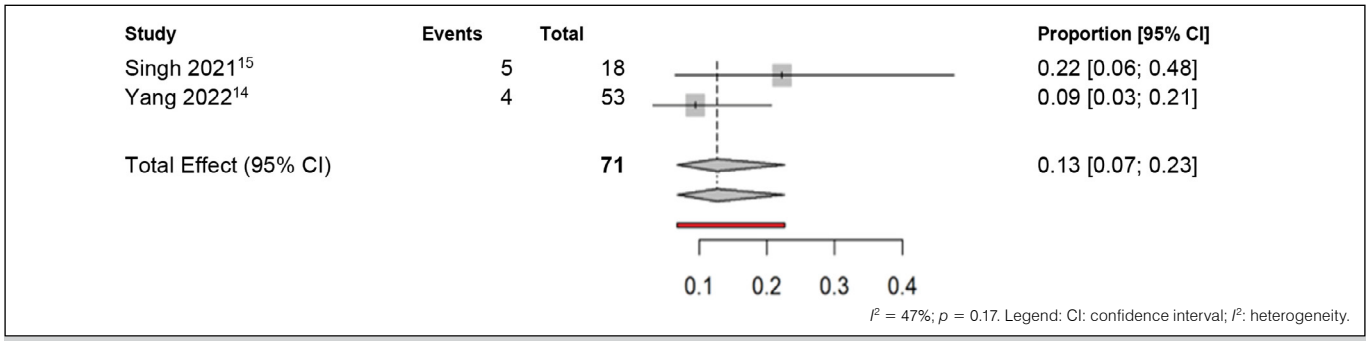

Figure 5. Meta-analysis of adverse effects outcomes in patients treated with medications in the preoperative period.

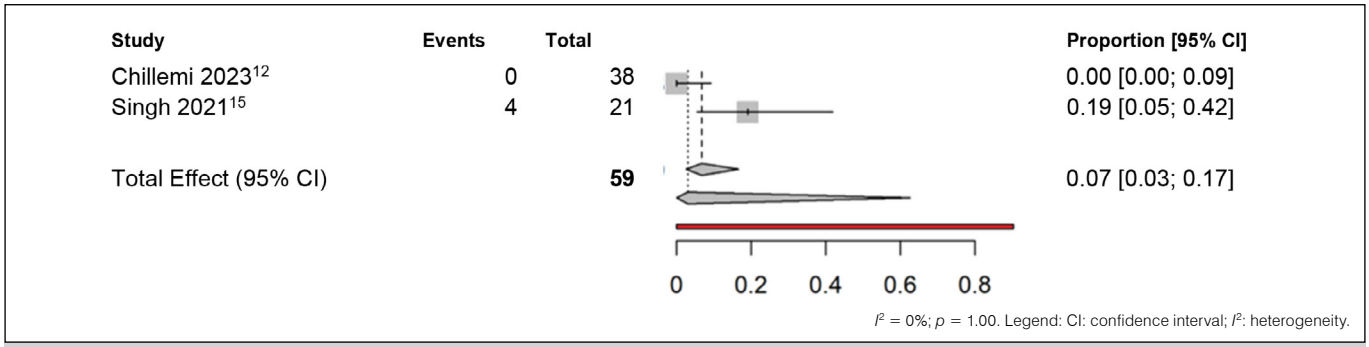

Figure 6. Meta-analysis of adverse effects outcomes in patients treated with analgesics and opioids.

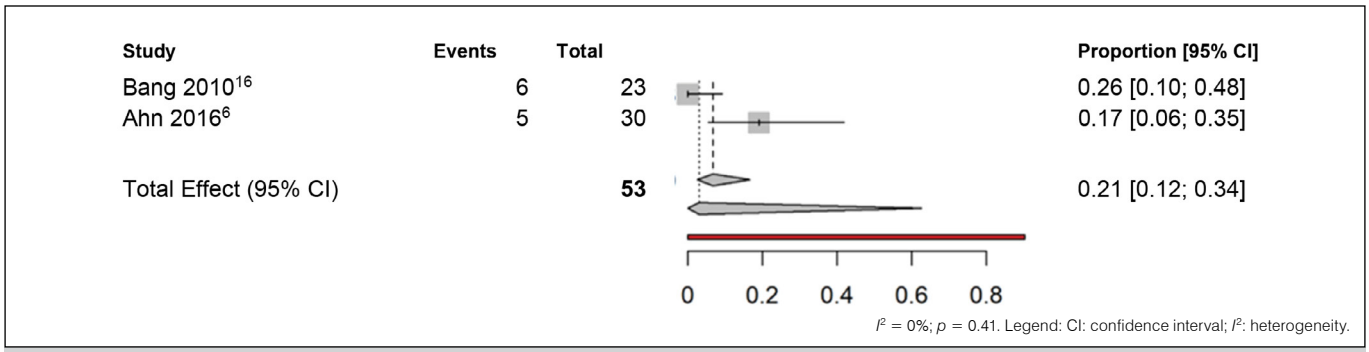

Figure 7. Meta-analysis of adverse effects outcomes in patients treated with anticonvulsants.

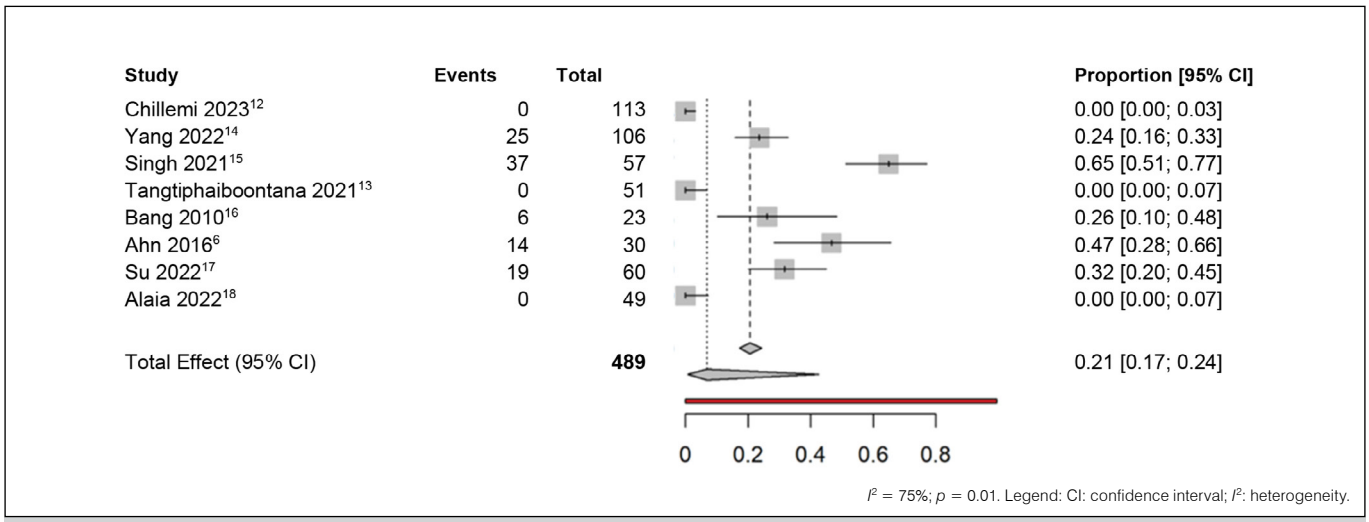

Figure 8. Meta-analysis of adverse effects outcomes in patients.

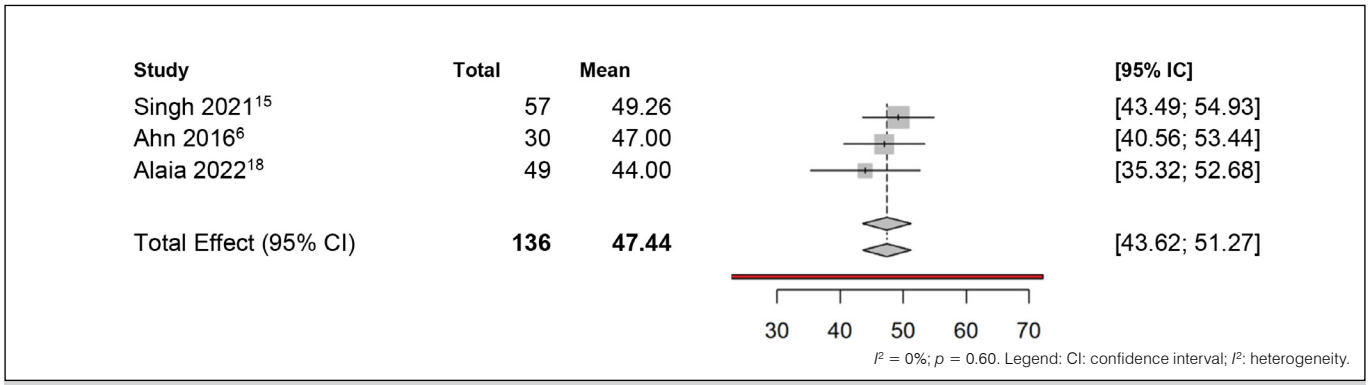

Figure 9. Meta-analysis of adverse effects outcomes in patients.

<< SUMÁRIO

DISCUSSION

The systematic review provides a comprehensive and comparative analysis of the effectiveness of various medications in managing postoperative pain in patients undergoing rotator cuff repair (RCR), which remains a significant challenge for the care team. In this context, effective management of postoperative pain remains a significant challenge in clinical practice, considering the diversity of available strategies.

Several factors contribute to pain in this context, and the review reflects this complexity by incorporating a range of approaches that involve different classes of medications. The examined literature emphasizes the importance of selecting medications carefully to optimize pain control, acknowledging that the superiority of one approach over another has not been conclusively established (Lee et al.[1]).

From this perspective, we agree with Chillemi et al.[12], who emphasize the use of a combination of paracetamol with codeine or ibuprofen as an effective strategy for controlling pain after RCR, resulting in better reductions on the Visual Analog Scale (VAS) and an earlier recovery of range of motion. This approach emphasizes the importance of selecting suitable medications to enhance patient comfort during the early stages of recovery.

Similarly, Tangtiphaiboontana et al.[13] explored the postoperative use of non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, highlighting the significant reduction in the need for opioids and the lower total consumption of morphine equivalents in the first postoperative week. In addition to pain control, the group that received ibuprofen showed short-term functional improvements, with a lower rate of re-rupture indicating safety in its use beyond pain relief.

The perioperative use of paracetamol in multimodal analgesia in patients undergoing RCR was utilized by Singh et al.[15] The significant reduction in opioid consumption, along with better overall pain control, is highlighted as a crucial role of paracetamol in postoperative management, providing comprehensive and sustainable relief.

In the study by Yang et al.[14] the authors focus on the preoperative administration of Celecoxib, demonstrating a significant reduction in pain scores in the first 12 hours and on the first day after surgery. This observation suggests that preoperative Celecoxib plays a crucial role in the immediate alleviation of pain, offering relief in the early stages of recovery.

Agreeing with these studies, a systematic review conducted by Toma et al.[15] highlighted that the analgesic protocol for RCR should encompass an arthroscopic approach, administration of paracetamol, use of NSAIDs, incorporation of dexamethasone, and application of regional analgesic techniques, with opioids considered as rescue analgesics. Furthermore, they emphasized that systemic analgesia should involve the administration of paracetamol and NSAIDs in both the preoperative and intraoperative periods, with continuity in the postoperative period.

Additionally, the efficacy of preoperative gabapentin is highlighted by Bang et al.[16] with a significant reduction in pain scores at 2, 6, and 12 hours postoperative. Gabapentin can be used as an alternative to cyclooxygenase-2 inhibitors. This result suggests that gabapentin used in the first 24 hours after rotator cuff repair contributes to a more comfortable postoperative experience, reducing pain intensity immediately after RCR.

Ahn et al.[6] have demonstrated the efficacy of pregabalin as an adjunct in postoperative analgesia following arthroscopic shoulder surgeries. Preoperative administration as an adjunct to patient-controlled analgesia (IV-PCA) resulted in lower fentanyl consumption during the first 48 hours postoperative, highlighting its role in reducing opioid consumption and improving the postoperative experience. In addition to improving postoperative pain, there was no increase in side effects related to the use of pregabalin and a lower need to resort to rescue opioids.

In 2022, Su et al.[17] analyzed the effects of duloxetine, demonstrating a significant reduction in pain in the first 48 hours postoperative, although its use did not reach clinical significance. This observation highlights the immediate efficacy of duloxetine, although its clinical relevance may be questioned. In contrast, Alaia et al.[18] investigated orally absorbed CBD, highlighting a significant reduction in pain scores on the first postoperative day, resulting in greater patient satisfaction. This finding suggests that CBD may play a beneficial role in perioperative pain management.

The findings of these studies offer a comprehensive and insightful perspective on pain management strategies following RCR. Furthermore, the choice between preoperative or perioperative medications has been shown to significantly influence immediate outcomes and patient satisfaction, emphasizing the need for a personalized approach.

The common trend of reducing opioid consumption reflects a growing search for safer strategies in postoperative pain management after RCR, aligned with concerns about the adverse effects associated with opioids. However, it is crucial to recognize the need to consider individual patient characteristics when selecting a pain management strategy, ensuring long-term safety and efficacy. Moreover, the importance of additional research is emphasized to validate these findings and provide more specific guidance for clinical practice, contributing to significant advances in the field of postoperative pain treatment after RCR.

CONCLUSION

This systematic review and meta-analysis showed that the postoperative use of ibuprofen reduces the need for opioids and decreases patient pain levels in the first week postoperative, and its use did not increase the risk of a new rupture. Specific medications, such as Celecoxib, Gabapentin, Duloxetine, and Pregabalin, have demonstrated efficacy in reducing opioid consumption without compromising functional outcomes. Duloxetine provided immediate pain relief, and orally absorbed cannabidiol proved to be promising. There is no definitively established oral protocol in the medical literature, and the choice of drug depends exclusively on the surgeon's preference. There is still a lack of evidence for a more robust routine recommendation of interventions related to perioperative analgesia in the surgical treatment of rotator cuff injuries.

AUTHOR'S CONTRIBUTION: Each author significantly contributed to the development of the manuscript. MJST, ETD, FTM, and MPS contributed significantly to the conception and design of the work. EMB and EFCJ contributed significantly to the acquisition, analysis, and interpretation of data for the work; MPS, FTM, ETD, and MJST reviewed and approved the final version of the manuscript.

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LOWER TRAPEZIUS TRANSFER FOR IRREPARABLE ROTATOR CUFF TEAR: SYSTEMATIC REVIEW

TRANSFERÊNCIA DO TRAPÉZIO INFERIOR PARA LESÃO IRREPARÁVEL DO MANGUITO ROTADOR: REVISÃO SISTEMÁTICA

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ABSTRACT

To evaluate functional results considering the final stages of function and postoperative pain in patients with irreparable rotator cuff tears undergoing surgical treatment by lower trapezius transfer. A systematic review of the literature was carried out following the PRISMA guidelines without restrictions on language and year of publication. The search was carried out in the following databases: MEDLINE/PubMed, EMBASE, Scopus and Cochrane Central Register of Controlled Trials. The main descriptors used were: "Rotator Cuff" OR "Rotator Cuff Injuries" OR Rotator Cuff Tear. The stages analyzed were pain, range of motion and function. We found 215 articles, of which 12 were included involving 374 participants. There was a statistically significant improvement comparing the pre and postoperative periods. The average intensity of pain was 7.1 and decreased to 2.4 according to the VAS. Using the ASES system, the result certainly improved, where the initial average was 49.5 (bad result) and the final average was 78.3 (good result). The results suggest that lower trapezius transfer is effective as a therapeutic option in patients treated by the surgical technique studied, according to the results found. ***Level of Evidence III; Systematic Review.***

Keywords: Shoulder; Rotator Cuff Tear; Shoulder; Shoulder Injuries; Systematic Review.

RESUMO

Avaliar os resultados funcionais de pacientes com rupturas irreparáveis do manguito rotador submetidos à transferência do trapézio inferior, considerando dor e função pós-operatória. Realizamos uma revisão sistemática seguindo as diretrizes PRISMA, sem restrições de idioma ou ano de publicação. As buscas foram feitas nas bases MEDLINE/PubMed, EMBASE, Scopus e Cochrane. Utilizamos os descritores: "Rotator Cuff" OR "Rotator Cuff Injuries" OR "Rotator Cuff Tear". Os desfechos analisados foram dor, amplitude de movimento e função. Foram identificados 215 artigos, dos quais 12 atenderam aos critérios de inclusão, totalizando 374 participantes. Houve melhora estatisticamente significativa entre os períodos pré e pós-operatório. A intensidade média da dor, medida pela Escala Visual Analógica (EVA), reduziu de 7,1 para 2,4. Pelo sistema American Shoulder and Elbow Score (ASES), a pontuação aumentou de 49,5 (ruim) para 78,3 (bom). A transferência do trapézio inferior demonstrou eficácia na melhora da dor e função dos pacientes estudados. A análise estatística evidenciou diferença significativa nos desfechos pós-operatórios. ***Nível de Evidência: III, Revisão Sistemática.***

Descritores: *Ombro; Ruptura do Manguito Rotador; Ombro; Lesões do Ombro; Revisão Sistemática.*

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INTRODUCTION

The topic involving the management of massive and irreparable rotator cuff tears is considered challenging, as surgical outcomes have not yet been definitively clarified. Some authors note a high failure rate in evaluating results.[1,2] However, in clinical practice, the therapeutic indication is based on the following criteria, such as the rupture of two or more tendons, the duration of symptoms being longer than 6 months, tendon retraction greater than 5 cm, and a fatty infiltration grade of 3 according to the Goutallier classification, to indicate surgical intervention.[3]

In irreparable tears of the subscapularis, supraspinatus, and infraspinatus muscles, patients present significant dysfunction and pain. Thus, functional restoration and pain reduction are considered paramount,[4] particularly in patients who are not candidates for shoulder arthroplasty due to age or high-level activity. Therefore, tendon transfers are considered surgical options with superior effects when performing reconstruction of the deficient rotator cuff.[2,5] Recently, the orthopedic literature has highlighted that the lower trapezius transfer (LTT) warrants attention in the treatment of posterosuperior rotator cuff tears, particularly when associated

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

The study was conducted at Hospital IFOR, Rede D'Or São Luiz. Américo Brasiliense, 596 - Centro, São Bernardo do Campo, São Paulo, SP, Brazil. 09715-021.
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with weakness in external rotation and signs of relapse in external rotation.[6] Therefore, researchers have shown increasing interest in investigating the effects of this transfer to treat deficiencies in degenerative shoulder conditions.[7] We know that, initially, LTTs were indicated to restore external rotation surgically in the treatment of brachial plexus paralysis.

A recent systematic review reported that LTT improves clinical outcomes in patients with irreparable rotator cuff tears. It presents a similar complication and reoperation rate when compared with other surgical alternatives in this group of patients.[7,8] What motivated the authors of this research was the absence of secondary studies evaluating the functional outcomes of surgical treatment. Therefore, this study aims to evaluate the functional results of LTT, considering functional aspects and pain in the pre and postoperative periods of patients with irreparable rotator cuff tears.

MATERIALS AND METHODS

This systematic review was conducted according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses – PRISMA.[9]

Data Sources and Searches

To assist in the search for scientific publications of intervention studies, a clinical question was formulated based on the strategy defined by the PICO acronym.[10] Therefore, we determined that: P = patients with irreparable rotator cuff injuries; I = interventions with the lower trapezius transfer ; C = intervention comparing preoperative and postoperative results; O: the outcomes analyzed were pain and function by the ASES system in the pre and postoperative periods.

For pain assessment, we considered studies that used the Visual Analog Scale (VAS).[11] For shoulder range of motion measurements, we considered studies that used a goniometer, and for shoulder function assessment, we considered studies that used the following questionnaires: Constant-Murley Score,[12] American Shoulder and Elbow Surgeons (ASES)[13] or Quick Disabilities of Arm, Shoulder & Hand (Quick DASH score).[14]

A researcher formulated the electronic search strategy in the databases MEDLINE/PubMed, EMBASE, Scopus, and Cochrane Central Register of Controlled Trials. Additionally, additional articles that could be included were searched in the reference lists of eligible studies.

The search terms used in the database searches were combined with the Boolean operators “AND” and “OR”. The terms for the searches were as follows: Arthroplasty; Coracohumeral Impingement; Coracohumeral Impingement Syndrome; Coracohumeral Impingement Syndromes; Cuff Injury; Glenoid Labral Tear; Glenoid Labral Tears; Glenoid, Rotator Cuff Injury; Injuries; Injury; Orthopedic Procedures; Replacement, Shoulder; Rotator; Rotator Cuff; Rotator Cuff Injuries; Rotator Cuff Tear; Rotator Cuff Tear Arthropathy; Rotator Cuff Tears; Rotator Cuff Tendinitides; Rotator Cuff Tendinitis; Rotator Cuff Tendinosis; Rotator Cuff Tendinosis; Rotator Cuff, Coracohumeral Impingement; Rotator Cuff, Labral Tear; Shoulder; Shoulder Fractures; Shoulder Impingement Syndrome; Shoulder Injuries; Shoulder Joint; Shoulder Pain; Shoulder Prosthesis; Tear, Glenoid Labral; Tear, Rotator Cuff; Tears, Glenoid Labral; Tears, Rotator Cuff; Tendinitis, Rotator Cuff; Tendinosis, Rotator Cuff; Tendinosis; Tendinosis, Rotator Cuff.

The inclusion criteria for the studies were: (1) studies with individuals who underwent LTT for irreparable rotator cuff injury; (2) individuals of both sexes; (3) studies in any language; (4) without restrictions regarding the year of publication. The criteria for exclusion of articles were: (1) studies conducted on cadavers; (2) publication in the form of conference abstract, letter, editorial, case report; (3) literature reviews; (4) systematic reviews; (5) LTT for brachial plexus injury; (6) studies comparing LTT with other techniques.

The screening of articles was conducted using the Rayyan software, which enables a rapid selection of eligible studies.[15] The evaluations of titles, abstracts, and the full reading of the articles were conducted by two researchers independently. Any discrepancies in the identification of articles were resolved among the research team members. After the full reading of the old ones, the following information was collected: authors and year of publication, study design, follow-up time, country where the study was conducted, sample size, average ages, intervention, and outcome results (pain, range of motion, and function).

The electronic search was conducted between January and February 2024.

Quality assessment of the studies

The analysis was performed by scoring the Methodological Index for Non-Randomized Studies (MINORS) score, which comprises eight items for non-comparative studies and 4 additional items for comparative studies.[16]

Compliance with Ethical Guidelines

This original article was based on previously published studies; therefore, it did not involve the direct extraction of data from study participants.

RESULTS

A total of 215 articles were identified in the databases used in this study, and three additional articles were selected through searches of the references of the included studies. 102 duplicate articles and 81 were excluded through the screening of titles and abstracts. Thus, we conducted a full reading of 35 articles, of which 12 were included in the qualitative synthesis.[17-28] (Figure 1 illustrates the flowchart for selecting studies).

Ten studies were classified as retrospective case series,[17,18,20-24,26-28], one retrospective cohort study,[25] and one study using a retrospective crossover design.[19] These studies were conducted in Brazil,[17] South Korea,[18-20] Turkey,[21] United States[22-26,28] and France.[27] The twelve

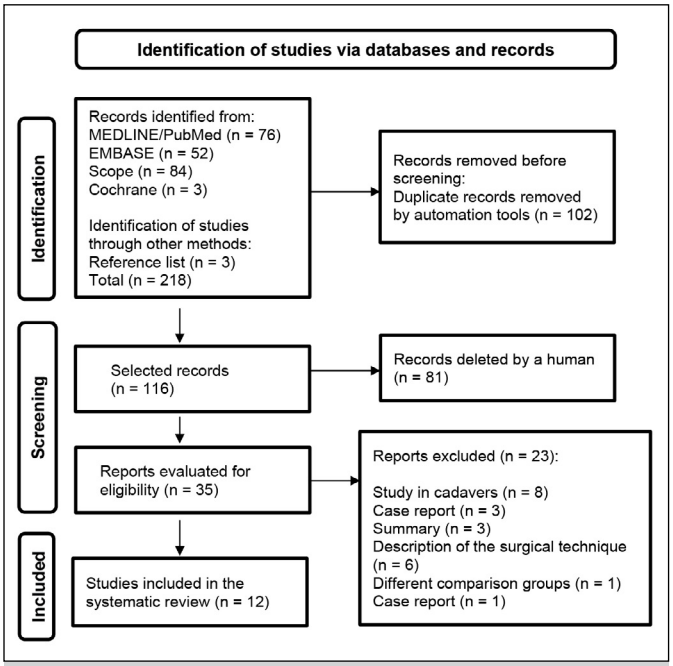

Figure 1. PRISMA flowchart of the study selection process.

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studies included a total of 374 participants, with an average age of 61 years (ranging from 40 to 73 years). The participant demographics were as follows: 241 (64.4%) were male, and 133 (35.6%) were female. The average postoperative follow-up time was 22 months, ranging from 6 to 70 months.

The main indications for surgery were persistent pain, failure of conservative treatment,[17-20,22] massive rotator cuff tear identified on MRI, association with fatty infiltration (Goutallier grade III or IV),[23-25,28] presence of intact subscapularis[28] and teres minor tendons, and limitation of active range of motion.[17-20,22] Other criteria found in the studies were: arthritic changes by Hamada criteria grade 0, 1, 2;[19,28] patients without neurological diseases;[19] absence of glenohumeral osteoarthritis on X-rays (Hamada <3); no limitation of passive range of joint movements;[21] and patients with deltoid muscle paralysis.[25]

The average MINORS score was 11.5 (range from 10 to 12) for non-comparative studies and 18 (range from 17 to 19) for the included comparative studies (Table 1).

Table 1. Characteristics of the included studies on lower trapezius transfer for rotator cuff injuries.

Author/ Year/ Country	Study design/follow-up	Sample size	Average age	Type of injury	Intervention	Comparison group	Type of graft	Instruments	MINORS Score
Almeida et al., 2023[17] Brazil	Retrospective case series Pre-operative, 6 and 12 months post-operative.	10 10 Men	40 and 62 years (mean 51.90)	Irreparable rotator cuff tears	Transfer of the lower trapezius	Pre and Post-operative	Knee flexor tendon grafts (semitendinosus and gracilis)	VAS ROM	16/12
Baek et al., 2023[18] Republic of Korea	Retrospective case series 58.2 5.3 months (48-70 months)	36 24 Men 12 Women	63.4 5.4 years	Irreparable postero-superior rotator cuff tears in the wrist	Lower trapezius transfer assisted by arthroscopy	Pre and Post-operative	Achilles tendon	VAS ROM	16/12
Baek et al., 2022[19] Republic of Korea	Cross-sectional retrospective study 2 years	42 27 Men 15 Women	63.3 5.8 years	Irreparable postero-superior rotator cuff tears in the wrist	Lower trapezius transfer	Pre and Post-operative	Achilles tendon	VAS ROM	18/24
Baek et al., 2022[20] Republic of Korea	Retrospective case series 2 years 26-49 months	36 22 Men 14 Women	63.1 65.5 years	Irreparable postero-superior rotator cuff tears	Lower Trapezius Transfer	Pre and Post-operative	Achilles tendon	VAS ROM	19/24
Bozoğlan al., 2023[21] Turkey	Retrospective case series 29 3 months (24-39)	16 12 Men 4 Women	62 9 years (42-73 years)	Large irreparable rotator cuff tears	Lower trapezius tendon transfer	Pre and Post-operative	Long fibular allograft combined with interpositional repair with fascia lata	VAS ROM	16/12
Chopra et al., 2023 EUA	Retrospective case series 14.6 (range 6 to 45) months	19 17 Men 2 Women	56.7 years (range 29 to 72 years)	Large irreparable rotator cuff tears	Lower trapezius tendon transfer	Pre and Post-operative	Achilles tendon	VAS ROM	16/12
Marigi et al., 2023[22] EUA	Retrospective cohort comparison 2.9 1.3 years (range 1.0 to 6.3 years)	104 58 Homens 14 Women	56.8 7.9 years	Irreparable rotator cuff tears	Assisted by Arthroscopy Trapezius transfer	Pre and Post-operative	Achilles tendon	VAS ROM Quick DASH score	17/24
Elhassan et al., 2020[23] EUA	Retrospective case series 14 months follow-up	41 30 Men 11 Women	52 years (range 37-71 years)	Massive and irreparable postero-superior rotator cuff tear	Transfer of the lower trapezius	Pre and Post-operative	Achilles tendon	(1) VAS (2) ROM (3) Quick DASH score	16/10
Stone et al., 2020[24] EUA	Retrospective case series 1 year follow-up	15 14 Men 1 Women	52 years (age range 31-62 years)	Irreparable posterior-superior rotator cuff tears	Lower trapezius tendon transfer	Pre and Post-operative	Achilles tendon	VAS ROM	16/11
Woodmass et al., 2020[25] EUA	Retrospective case series The average follow-up was 22 10 months	8 6 Men 2 Women	53 years	Chronic massive posterior-superior rotator cuff tear	Arthroscopy-assisted lower trapezius tendon transfer	Pre and Post-operative	Achilles tendon	VAS ROM ASES function	18/24
Valenti e Werthel et al., 2018[26] France	Retrospective case series 1 year follow-up	14 8 Men 6 Women	62 years (age range 50 to 70 years)	Irreparable posterior-superior rotator cuff tear	Transfer of the lower trapezius	Pre and Post-operative	Semitendinosus tendon	VAS ROM Constant-Murley score	16/12
Elhassan et al., 2016[27] EUA	Retrospective case series 47 months follow-up	33 27 Homens 6 Women	53 years (variation from 31 to 66 years)	Massive and irreparable postero-superior rotator cuff tear	Transfer of the lower trapezius	Pre and Post-operative	Achilles tendon	(1) VAS (2) ROM (3) Quick DASH score	16/11

Visual Analog Scale (VAS); Range of motion (ROM); Quick Disabilities of the Arm, Shoulder, and Hand (Quick DASH) score; MINORS score: Methodological Index for Non-Randomized Studies.

Ten studies assessed pain using the EVA scale in the pre and post-operative periods.[17-23,25,27,28] These studies indicated that there was a significant reduction in pain after surgical intervention. After evaluating the results, we observed a statistically significant improvement when comparing the pre and post-operative periods. The average pain intensity was 7.1 and decreased to 2.4 according to the EVA. Using the ASES system, the result improved positively where the initial average was 49.5 (poor result) and final was 78.3 (good result).

Table 2 summarizes the pre- and post-operative results, considering pain, ROM, and function, as assessed by ASES scales,[17-20,22,28] the Constant-Murley Score,[21,27] and the Quick DASH score.[23-25] There was a statistically significant improvement during outpatient follow-up ($p < 0.05$).

Table 2. Results of the included studies on lower trapezius transfer for rotator cuff injuries.

Study	Pre-operative			Post-operative		
	Pain	Range of motion	Function	Pain	Range of motion	Function
Almeida et al., 2023[17]	7,9	Mean lateral rotation 31° Flexion 84° Abduction 76°	ASES function 26.63±7.34	2.5 (p < 0.001)	Mean lateral rotation improved by 51° Flexion 122° Abduction 101° (p < 0.001)	ASES function 75.24±3.59 (p < 0.001)
Baek et al., 2023[18]	4,5±1,2	Forward elevation 134°±42° Abduction 116°±41° External rotation at 90° Abduction 48°±20° Lateral external rotation 25°±13° Internal rotation at the back 6.3°±1.6°	ASES function 57.1±13.4	1.4±0.7 (p < 0.001)	Frontal elevation 160°±30° (p=0.007) Abduction 149°±32° (p<0.001 *) External rotation at 90° Abduction 69°±17° (p<0.001) Lateral external rotation 43°±12° (p<0.001) Internal rotation on the back 6.5°±1.2° (p=0.283)	ASES Function 83.7 ± 8.2 (p <0.001)
Baek et al., 2022[19]	4,3 ± 1,6	Active frontal elevation 125,4°±34,9° Active external rotation with 0° abduction 22,3°±10,9°	ASES Function 55.8±16.7	1.7 ± 1.3 (p < 0.001)	Active frontal elevation 160.1°±19.5° (p < 0.001) Active external rotation with 0° abduction 54.8°±9.8° (p < 0.001)	ASES function 82.7 ± 8.6 (p < 0.001)
Baek et al., 2022[20]	4,5±61,8	Active frontal elevation 134,2°±653,6° Active external rotation 27,5°±614,3 °	ASES function 47.2±617.3	1.3±61.0 (p < 0.001)	Active front elevation. 165.7°±22.3° (p=0.003) Active external rotation 51.7°±10.9° (p=0.003)	ASES function 84,8±67,6 (p<0.001)
Bozoğlan et al., 2023[21]	6,1±1,1	Active forward flexion 109°±24.7° Active abduction 60°±16.3° Active external rotation 12°±16.9°	Constant - Murley score 24.00 ± 9.43	2.4±1.35 (p=0.007)	Active flexion advance 144°±22.21° in the postoperative period (p=0.005) Active abduction 135°±16.3° (p=0.005) Active external rotation 35°±14.3° (p=0.005)	Constant - Murley score 50.20 ± 14.28 (p=0.008)
Chopra et al., 2023	5,9±2	Elevation 139,5° ±26° External rotation 10,5° ±17° External rotation force 2,8/5° ±1°	ASES function 44.6 ± 18	1.8±2 (p<0.001)	Elevation 147.4°±29° (p=0.31) External rotation 40.5°±13° (p<0.001) External rotation force 4.7/5°±0.5° (p<0.001)	ASES function 71.2 ± 24 (p<0.001)
Marigi et al., 2023[22]	6,2±2,5	Front lift strength 4,0°±0,6° External rotation strength 3,4°±0,5° Internal rotation strength 4,3 °± 0,7 °	Quick DASH score 50.3 ± 14.0	1,1±2,0 (p < 0.00)	Front lift strength 4.5°±0.5° (p<0.001) External rotation strength 4.5°±0.5° (p<0.001) Internal rotation strength 4.8°±0.4° (p=0.005)	Quick DASH score 13,2±15,4 (p = <0.001)
Elhassan et al., 2020[23]	6	Forward flexion 67° External rotation 25°	Quick DASH score 49	2 (p<0.001)	Forward flexion 133° (p<0.001) External rotation 47° (p<0.001)	Quick DASH score 18 (p<0.001)
Stone et al., 202024	NR	Active elevation 98° Abduction 74° External rotation 23°	NR	NR (p < 0.05)	Active elevation 144° (P < 0.0001) Abduction 127° (P < 0.0001) External rotation 43° (P < 0.0001)	NR
Woodmass et al., 2020[25]	2,85	Forward flexion 101° External rotation 33°	ASES function 12.5	1.17 (p = 0.089)	Forward flexion 146° (p = 0.031) External rotation 44° (p = 0.27)	ASES function 24.4 (p = 0.0092)
Valenti e Werthel et al., 2018[26]	7	Flexion of 150° External rotation −20° External rotation with the arm at 90° abduction −10°	Constant - Murley score 35 (range) 20–50)	2 (p<0.001)	Flexion 160° External rotation 24° External rotation with the arm at 90° abduction improved from 40°	Constant- Murley score 60±9 (p<0.001)
Elhassan et al., 2016[27]	NR	Flexion of 70° Abduction of 40° External rotation of 20°	Quick DASH score 52±19	NR	Flexion of 120° Abduction of 90° External rotation of 50° (p < 0.01)	Quick DASH score 18±10

NR: Not reported.

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Statistical analysis

The population size and the mean and standard deviation values for EVA pre-intervention and post-intervention, as well as the ASES score pre-intervention and post-intervention, were subjected to meta-analysis, and the results were expressed as mean differences. The percentage of variability attributable to heterogeneity among the studies was estimated using the I^2 statistic, with a p-value of less than 0.05 considered statistically significant.

Heterogeneity was classified based on I^2 values as follows: 25% low heterogeneity, 50% moderate heterogeneity, and 90% high heterogeneity. A random effects model was used, and meta-analyses were performed with a 95% confidence interval (CI).

All statistical analyses were performed using the Cochrane Revman software.

Table 3 shows that there was a difference in the average ASES function before and after the intervention, indicating an improvement in function after treatment. Similarly, Table 4 also shows that there was a difference in the average pain levels before and after the intervention, indicating a reduction in pain after treatment.

DISCUSSION

This review included 12 studies,[17-28] compiling a total of 374 whose results showed a significant reduction in pain and improvement in joint mobility of the affected shoulders after LTT surgery, the subject of this study.

Initially, the first studies conducted using this technique employed experimental designs on the hemithorax of fresh-frozen cadavers. These studies mainly investigated the biomechanics of this intervention to assess the range of motion of the shoulder joint. This provides a greater restoration of external shoulder rotation compared to the transfer of the latissimus dorsi.[30] Moreover, the LTT determines a significant decrease in superior and anteroposterior translation. It also causes a peak of subacromial contact pressure at 0°, 30°, and 60° of shoulder abduction. The LTT efficiently prevents the loss of abduction movement and the superior migration angle of the humeral head. Therefore, we agree with the authors who argue that the LTT can sufficiently restore glenohumeral kinematics, potentially leading to better postoperative functional outcomes.

In 2016, a study conducted on 32 patients demonstrated that, after an average follow-up of 47 months, there was a significant improvement in pain, function, and range of motion of the shoulder. In patients with more than 60° of preoperative flexion, the gain in shoulder range of motion was significantly greater. External rotation improved in all patients, regardless of the loss of extension observed in the preoperative period.[24]

Overall, studies have shown good clinical and surgical results.[17-28] In patients with a notable reduction in rotation strength, tendon transfers have the ability to restore strength while safely preserving the joint.[22] After surgery, increases in forward flexion and external rotation are expected, as well as a reversal of the external rotation delay signal when present before surgery.[8]

We observe that with the inclusion of more studies on this topic, the surgical technique of LTT has undergone significant improvement. This has been used assistively with the aid of arthroscopy and is considered a promising option for the treatment of this condition.[18-20,22-26,28]

It is important to highlight that the transfer of the lower trapezius tendon should not be used in certain patients such as: those with arthropathy due to rotator cuff tear; combined loss of elevation and external rotation; irreparable tear of the subscapularis muscle; involvement of the teres minor muscle; and in elderly patients or those considered unable to comply with the strict rehabilitation guidelines.[6]

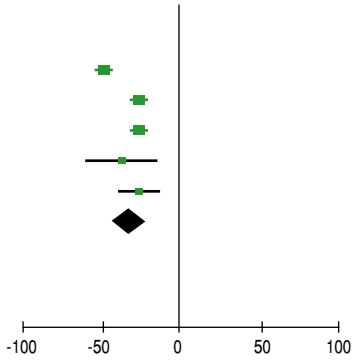
Table 3. Statistical analysis of pre and post-operative ASES score values of lower trapezius transfer.

	Pre ASES			Post ASES			Avarege difference	Avarege difference
Study or Subgroup	**Significant**	**SD**	**Total**	**Significant**	**SD**	**Total**	**IV, Aleatory, IC95%**	**IV, Aleatory, IC95%**
Almeida et al., 2023[17]	26.63	7.34	10	75.24	3.59	10	23.3% -48.61 [-53.67, -43.55]	
Baek et al., 2022[18]	57.1	13.4	36	83.7	8.2	36	23.2%-26.60 [-31.73,-21.47]	
Bael et al., 2022[19]	55.8	16.7	42	82.7	8.6	42	23.0%-26.90 [-32.58, -21.22]	
Baek et al., 2023[20]	47.2	17.3	36	84.8	67.6	36	12.3% -37.60 [-60.39, -14.81]	
Subtotal (95% CI)			124			124		

Heterogeneity: Tau = 138.61; Chi = 47.17, df = 4 (P <0.00001); I = 92%

Test for overall effect: Z = 5.70 (P<0.00001)

Test for subgroup differences: Not Applicable



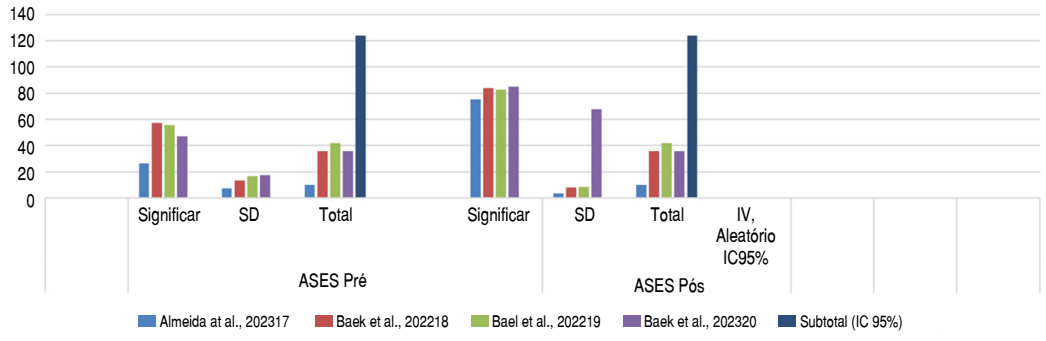


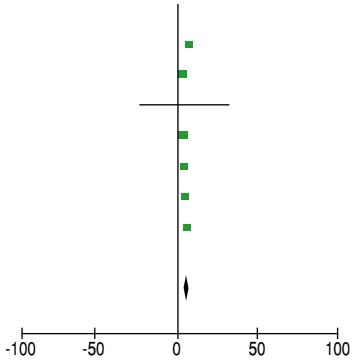
Table 4. Statistical analysis of pre and post-operative VAS values of lower trapezius transfer.

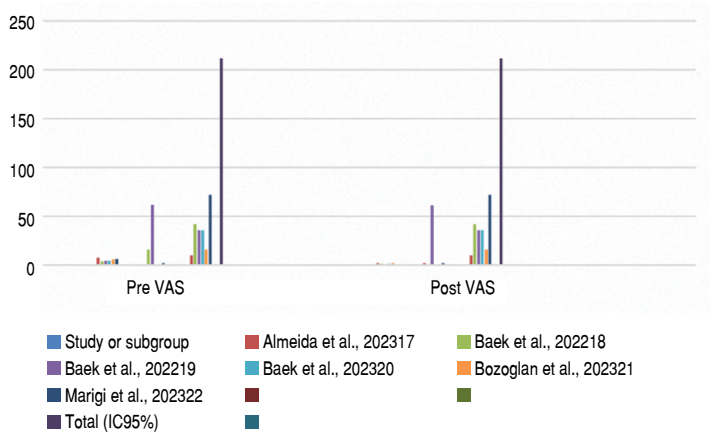
	Pre VAS			Post VAS				Avarege difference	Avarege difference
Study or Subgroup	**Significant**	**SD**	**Total**	**Significant**	**SD**	**Total**	**Weight**	**IV, aleatory, IC 95%**	**IV, aleatory, IC 95%**
Almeida et al., 2023[17]	7.9	0.74	10	2.2	2.2	10	13.20%	5.70 [4.26, 7.14]	
Baek et al., 2022[18]	4.3	16	42	1.7	1,3	42	18.30%	2.6 [1.98, 3.22]	
Baek et al., 2022[19]	4.5	61.8	36	1.3	61	36	0.10%	3.20 [-25.17, 31.57]	
Baek et al., 2023[20]	4.5	1.2	36	1.4	0,7	36	19.10%	3.10 [2.65 3.55]	
Bozoglan et al., 2023[21]	6.1	1.1	16	2.4	1,35	16	17.00%	3.70 [2.85, 4.55]	
Marigi et al., 2023[22]	6,2	2.2	72	1.1	2	72	18,00%	5.10 [4.41, 5.79]	
Total (95% CI)			**212**			**212**			

Heterogeneity: Tau = 1.04; Chi = 41.66, df = 6 (P < 0.00001); I = 86%

Test for overall effect: Z = 8.66 (P < 0.00001)

Test for subgroup differences: Not applicable





We highlight the sample value and observed results as relevant positive aspects of this secondary study. We cannot fail to point out some negative aspects of this systematic review where we highlight the low level of evidence of the compiled studies, with most being retrospective cohort studies. The homogeneity among the studies was not evaluated. Authors who used combinations of different surgical techniques, approaches (open versus arthroscopic), and types of grafts were excluded. Some studies presented biases when considering sample size and minimum follow-up time, which hindered the identification of more relevant considerations.

Thus, we emphasize that this interesting topic requires the pursuit of scientific work with the highest level of scientific evidence that can be achieved through randomized clinical trials and the performance of representative sample calculations.

CONCLUSION

The authors conclude that the results of the pre and postoperative evaluation of patients with irreparable rotator cuff injuries treated by the LTT technique showed:

Improvement of pain after the surgical intervention was performed. The average pain intensity was 7.1 to 2.4, as measured by the VAS. Improvement in function, as measured by the ASES system. The initial average value was 49.5 (a poor result) and subsequently improved to 78.3 (a good result).

The associated p-value indicated a statistically significant difference in pain levels before and after the intervention. The transfer of the lower trapezius is an effective therapeutic option for patients treated with the studied surgical technique, according to the results obtained.

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