

Volume 27 – Number 5 – Year 2019

ISSN 1413-7852

Acta Ortopédica Brasileira



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

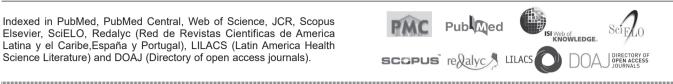
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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed January 2016)

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Original	Structured, up to 200 words	2.500 Excluding abstract, references, tables and figures	20	10	6	6
Update / Review*	Non-structured, up to 200 words	4.000 Excluding abstract, references, tables and figures	60	3	2	2
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*These contributions shall be published at the Editors' criteria, with due replica, when applicable

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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.)

		The second stand			
		Types of study	1	1	
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 Mode	
1	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	
	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective ⁴ 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	
Ш	Prospective ^d comparative study ^e	Untreated controls from an RCT	Systematic review ^b of Level II studies	Systematic review ^b of Level II studies	
n	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			
	Case control study ^g	Case control study ^a	Study of non consecutive patients; without consistently applied reference "gold" standard	Analyses based on limited alternatives and costs; and poor estimates	
ш	Retrospective ^r 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	
		1	1	1	

^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.

⁹ 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.



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CHRONIC MONTEGGIA FRACTURE-DISLOCATION IN CHILDREN SURGICAL STRATEGY AND RESULTS

FRATURA-LUXAÇÃO DE MONTEGGIA CRÔNICA EM CRIANÇAS: ESTRATÉGIA CIRÚRGICA E RESULTADOS

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ABSTRACT

Objective: To report surgical techniques and results in the treatment of chronic Monteggia fracture-dislocation in children. Methods: Six pediatric patients who had undergone a procedure involving the following 6 crucial surgical steps were retrospectively evaluated: 1- extended lateral approach, 2- fibrotic removal, 3-proximal ulnar osteotomy, 4- reduction of the radial head and transcapitellar temporary fixation, 5- ulnar fixation with a straight plate shaped according to the deformity generated by temporary fixation, and 6- transcapitellar Kirschner wire removal. Results: Four patients were women, and four showed the right-sided compromise. The mean age of patients was 8 years, and the minimum follow-up period was 12 months. The mean time from the onset of fracture to treatment was 6 months. Six patients underwent complete flexo/extension, and one patient had a complete prono-supination. In four patients, we observed loss of pronation (by 10° in two, 15° in one, and 20° in one), and one patient had a 15° decrease in supination. We did not observe any redislocation of the radial head in the follow-up evaluation. No complications were observed; the only complaint was salience of the ulnar plate. Conclusions: Our results demonstrated an effective option for the treatment of chronic Monteggia fracture-dislocation in children, even with a small study sample, following the presented technical and surgical strategies. Level of evidence IV, Therapeutic Studies.

Keywords: Monteggia fracture/pathology, Monteggia fracture/ surgery, Monteggia fracture/complications.

RESUMO

Objetivo: Relatar a técnica cirúrgica e os resultados no tratamento da fratura-luxação de Monteggia crônica nas crianças. Métodos: Análise retrospectiva de seis pacientes submetidos à técnica com seis passos cirúrgicos, a saber: acesso único lateral estendido para o bordo lateral da ulna; capsulotomia e retirada da fibrose e do tecido interposto; osteotomia proximal transversa da ulna; redução da cabeça radial no capítulo e fixação temporária transcapitelar; fixação da ulna com placa reta moldada a deformidade gerada da ulna; retirada do fio de Kirschnner transcapitelar. Resultados: Quatro pacientes eram do sexo feminino, e em quatro o lado direito foi o acometido. O seguimento mínimo foi de 12 meses, e o tempo médio entre a fratura e o tratamento foi de 6 meses. Os seis pacientes obtiveram flexo/extensão completa; em quatro deles, foi observada perda da pronação (dois 10°, um 15° e um 20°) e um paciente teve diminuição de 15° da supinação. Em todos os pacientes, foi obtida redução da cabeça do rádio sem reluxação até o seguimento avaliado. Conclusões: Mesmo considerando uma pequena amostra, nossos resultados, pela técnica e pelas estratégias cirúrgicas apresentadas, demonstraram opção eficaz no tratamento da fratura-luxação de Monteggia crônica em crianças. Nível de evidência IV, estudo do tipo terapêutico.

Descritores: Fratura de Monteggia/patologia. Fratura de Monteggia/ cirurgia. Fratura de Monteggia/complicações.

Citation: Valenza WR, Matsunaga CU, Faria FF, Costa ACP, Soni JF. Chronic monteggia fracture-dislocation in children - surgical strategy and results. Acta Ortop Bras. [online]. 2019;27(5):244-7. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Monteggia fracture-dislocation was described by Giovanni Batista Monteggia in 1814, as an ulnar fracture, usually in the proximal edge associated to a dissociation of the proximal radioulnar joint, with consequent dislocation of the radiocapitellar joint (dislocation of the head).¹ Bado has proposed a classification that helps on a better understanding of the injury and its correct management, describing the mechanisms of the fracture, its displacement and angulation presented on a ulnar fracture and the direction of the dislocations deviation of the radial head² and the direction of the radial head dislocation.

Monteggia fracture-dislocation is usually seen between 4yrs to 10yrs, uncommonly incident (it's a rare injury), corresponding to less than 1% of all pediatric fractures.³

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

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Article received in 10/11/2018, approved in 04/03/2019



Despite its rarity, its greatest importance lies in the fact that the diagnosis is not correctly carried out, being missed in up to 50% of cases, especially in cases of radial head dislocation associated with a plastic deformation or a greenstick fracture of the ulna.^{4,5} Another situation that increases the number of cases of chronic Monteggia is the loss of the initial reduction, what may occur in 20% of patients.⁶

Due to inaccurate diagnosis of the initial trauma, neglected Monteggia fracture-dislocation may proceed with pain, mobility limitations loss of motion (especially flexion and supination), elbow stiffness, deformity, loss of strength, late neuropathy and osteoarthritis.⁷

Several surgical techniques have been described to approach and correct chronic Monteggia fracture dislocation, such as: opened reduction and reconstruction of the annular ligament^{8,9}, opened reduction and ulnar osteotomy¹⁰⁻¹³, ulnar osteotomy and progressive correction with external fixator^{14,15}, radial osteotomy¹⁶⁻¹⁷ and radial head excision^{18,19}. Usually, the described series are composed by small samples with no consensus or standardization on the most appropriate treatment.

Our goal is to demonstrate the clinical and radiographic results of our standardized surgical strategy for chronic Monteggia fracture-dislocation type I of Bado in children.

MATERIALS AND METHODS

The study was approved by the Research Ethics Committee (CAAE 55157016.9.0000.5225), according to Resolution 196/96 e 251/97, of the National Health Council.

A retrospective analysis was performed on six pediatric patients presenting Monteggia fracture-dislocation type I of Bado by the authors' group of Pedriatric Orthopedics. The patients were submitted to the same standardized surgical technique (6 steps), with mean follow-up of 3 years. In the post- operative clinical evaluation we accessed the presence of pain and flexo-extension or prono-supination loss of movement. The congruency of the radial epiphysis with the capitellum on the x-ray exams at the last follow-up lateral radiography at the last follow-up was considered adequated. We included in our study patients admitted between 2006 and 2015 according to the inclusion ? criteria: children or teenagers less than to 16 years presenting Monteggia fracture-dislocation. Patients with less than six months of follow up, older than 16 yrs, congenital dislocation of the radial head diagnosis, chronic dislocation / teratological radial head associated with syndromes and patients who had records with incomplete data were excluded from the study.

All patients underwent to the same surgical strategy of 6 basic stages, as described below:

- Single approach side extended to the lateral edge of the ulna (Figure 1)
- Radiocapitellar and humeroulnar capsutolomy, with fibrosis removal and tissue interposition with tissue interposition and fibrosis removal.
- Ulnar transverse proximal osteotomy
- Radial head anatomic reduction in the capitullum and temporary transcapitellar fixation from posterior to anterior with Kirschnner 2mm wire(Figure 2).
- Ulnar fixation with straight plate of 3,5 mm or 2,7 mm shaped according to the deformity generated in the ulna after the beginning of transcapitellar temporary fixation, usually in dorsal deviation and lengthening (Figure 3)
- Transcapitellar Kirschnner wire removal with flexo-extension and prono-supination stability test.

This post-operative procedure was followed in all cases, keeping immobilization by an elbow cast splint in neutral position for 4 weeks.



Figure 1. Single approach side extended to the lateral edge of the ulna.



Figure 2. Radial head anatomic reduction in the capitullum and temporary transcapittellar fixation from posterior to anterior with Kirschnner 2mm wire.



Figure 3. Ulnar Fixation with straight plate of 3,5mm or 2,7mm shaped according to the deformity generated in the ulna after the beginning of transcapitellar temporary fixation, usually in dorsal deviation and lengthening.

RESULTS

The sample was based on the analysis of clinic and radiographic treatment results of 4 males and 2 females. Three fractures were on the right side. The mean age of the patients included in the study was 8 yrs and 1 month and the minimum follow-up was 12 months. Five of the six patients were treated with primary cast (Table 1). Two of them underwent to closed reduction under general anesthesia. The other three patients were also submitted to immobilization with cast without reduction (diagnosis of ulnar fracture, radial head dislocation was missed) and 1 patient had no primary treatment due to lack of diagnosis. The mean time between the trauma and the proposed surgical treatment was 6 months.

After the proposed treatment all the 6 patients showed complete flexo-extension of the elbow joint. Four of the children involved in the study presented decrease in pronation and 1 patient presented limitation on supination. Limitation on pronation of 20° was identified in 1 patient, 15° in another, and 10° in two patients. One patient presented decrease in supination of 15°. All patients maintained the reduction of the radial head at the follow-up radiography, showing no evidence of redislocation (Figure 4 and 5). We have not found major postoperative complications. The only complaint reported by all patients was the salience of plate and screws used for ulnar fixation. All patients had the removal of the osteosynthesis plate after the bone healing (Table 2).

DISCUSSION

Chronic Monteggia fracture-dislocation may occur after a missed fracture dislocation, as well as after an injury where there was loss of the primary reduction. We find no consensus in literature defining the time to consider it as chronic injury, so the most accepted period is after four weeks^{5,20}.

Table 1	Table 1. Demographic data.									
Pcte	Gender	Age	Side	Primary cast	Time up to diagnosis	Follow-up				
J.G.C	М	3a6m	R	No	24 Months	4 Years				
J.G.R	М	6a2m	L	Yes (missed)	3 Months	2 Years				
L.C.S	F	7a1m	R	Yes (missed)	6 Months	6 Years				
B.C.C.	М	8a5m	R	Yes (bad reduction)	3 Months	1 Year				
M.C.S	F	9a8m	L	Yes (bad reduction)	4 Months	5 Years				
R.R.P	М	14a1m	L	Yes (missed)	1 Month	1 Year				
Media		8a1m			6.8 Months	3 Years				

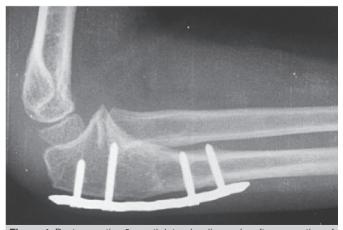


Figure 4. Post-operative 6 month lateral radiography after correction of chronic Monteggia fracture-dislocation.



Figure 5. Post-operative 6 month lateral radiography after correction of chronic Monteggia fracture-dislocation.

Table 2. Results and complicatio

Pcte	Reduction of radial head	Prono/ supina	Flexo/ extent	Complications	Plate salience	Satisfaction		
J.G.C	Yes	90/0/90	0/140	No	Yes	Yes		
J.G.R	Yes	80/0/90	0/140	No	Yes	Yes		
L.C.S	Yes	90/0/75	0/140	No	Yes	Yes		
B.C.C.	Yes	80/0/90	0/140	No	Yes	Yes		
M.C.S	Yes	70/0/90	0/140	No	Yes	Yes		
R.R.P	Yes	75/0/90	0/140	No	Yes	Yes		

As the result of the evolution of the lesion, the patient may present pain, joint mobility limitation, elbow stiffness, deformity, and loss of strength, late neuropathy and osteoarthritis. Surgical treatment for correction is indicated to prevent further complications.⁷

The most important point to obtain radial head reduction is to create the ulnar deformity and lengthening and to achieve the consequent maintenance of radialcapitellar congruence. The created deformity was in the opposite direction to the radial head dislocation.^{12,13}

Hirayama and cols²¹ and Inoue and cols¹², showed better results, lower index of re-dislocation and better mobility, when hipper-corrected the ulna post-osteotomy, compared to a simple ulnar osteotomy. We agree with the literature that the ulna is the key to radial head reduction. Our strategy of treatment after the removal of joint fibrosis is to perform ulnar transverse osteotomy and to reduce radial head by temporarily fixing it with Kirschnner 2,0 mm wire in the capitullum. This way it is achieved an ulnar lengthening and the necessary dorsal deviation to post reduction stability.

Ulnar fixation can be performed with flexible intramedullary rods or Kirschnner wires. In some situations, this fixation can promote the correction or rectification of deformity created on the ulna . Another option is the stabilization with external fixation, having the advantage to make any adjustments during treatment. However, a common disadvantage is the infection in the path of pins and the inconvenience for the patient, making it difficult to tolerate.¹⁴⁻¹⁵ Nowadays, the most used method of fixation is by plate and screws. This implant provides greater stability with less loss on the obtained correction. Another advantage is that the plate may be shaped adapting to the ulnar position.^{10,19-23}

In our series we routinely fixed the ulna with plate and screws, shaping the plate to fit to the ulnar position (elongated and dorsal angulations). After the reduction, it was performed a temporary transcapitellar fixation, as proposed by Bae.⁷ After the ulnar stabilization by plate and screws we removed the temporary fixation and test the stability. It should be avoided the fixation with transcapitellar wire to add stability during the postoperative period, since it is related to a common limitation on range of motion, especially of prono-supination, besides the risk of intrarticular broken of this wire. In all our cases such fixation was used temporarily.

It is a controversial subject in literature if the annular ligament must or not be reconstructed. Rahbek and cols in their study¹¹, reconstructed the ligament in 10 patients and did not do it in six patients, having no difference on the final result. In our sample we did not reconstructed the annular ligament in any of the six treated patients.

As a standard postoperative pattern we chose to immobilize with braquiopalmar splint cast in neutral position for four weeks, avoiding supination, because the greatest functional loss described is from pronation. Our results confirm this trend, despite the loss of pronation of only 10° in 2 patients, 15° and 20° in 2 other patients.

Another important aspect not yet well determined is the time limit to treat aiming to reduce chronic Monteggia fracture-dislocation. Several authors propose the time limit of two, three, four and up to seven years. Other authors consider that the most important fact, despite the time of dislocation to the treatment, would be if the radial head and/or the capitullum would be deformed. None of our patients presented radial head deformity, and in our opinion these amendments could lead to poor results, due to new dislocation, mobility limitation or post-operative pain.^{8,17,21,24-26}

The complications described in the literature are loss of reduction (re-dislocation), radioulnar synostosis, nerve damage, limitations of flexo-extension and prono-supination. In our series we did not observe any case of re-dislocation of the radial head. Regarding the range of the movement we observed limitation of pronation in four patients (discussed above), the supination (15°) in a patient who did not change the ability to manage daily activities. We have not observed any redislocation of radial head in the accessed follow-up, as well as no other complication as the ones described in the literature. All our patients have reported a mild discomfort caused by the plate, matter solved after its removal.

A small number of cases could be seen as a limitation to our study, but that can be justified partially by the rarity of the presented injury.

CONCLUSION

The surgical strategy based on the 6 demonstrated steps aiming the reduction and stability of radial head by the capitullum, demonstrating to be applicable on planning and surgically correct chronic Monteggia fracture dislocation in children.

AUTHORS' CONTRIBUTIONS: Each author individually and significantly contributed to the development of this article. WRV (0000-0001-7358-819X)*: study design, manuscript drafting, review and critical analysis of the data, besides the execution of surgeries, data analysis, and statistical analysis; CUM (0000-0001-9921-3337)*: study design, manuscript drafting and review, survey and data analysis, and statistical analysis; JFS (0000-0002-9448-7352)*: execution of surgeries, manuscript review, data analysis, and final approval of the manuscript to be published; FFF (0000-0001-6163-5147)*: execution of surgeries and manuscript drafting and review; ACCP (0000-0003-1055-9601)*: execution of surgeries and final approval of the manuscript to be published. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

PLATELET-RICH PLASMA (PRP) AND TRANEXAMIC ACID (TXA) APPLIED IN TOTAL KNEE ARTHROPLASTY

PLASMA RICO EM PLAQUETAS (PRP) E ÁCIDO TRANEXÂMICO (ATX) APLICADOS NA ARTROPLASTIA TOTAL DO JOELHO

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ABSTRACT

Objective: To evaluate the efficacy of platelet-rich plasma (PRP) and tranexamic acid (TXA) applied in total knee arthroplasty. Methods: We selected and randomized 84 patients. TXA was applied in 23 patients, PRP in 20, and PRP in combination with TXA in 20. Hemoglobin was measured preoperatively and 24 and 48 hours postoperatively. The function questionnaire, pain scale and gain of knee flexion were monitored until the second postoperative year. Results: There was a difference (p < 0.01) in the decrease in hemoglobin 48 hours after surgery between the TXA group and the control and PRP groups. In terms of pain, the TXA group at 24 and 48 hours after surgery and the PRP group at 48 hours after surgery showed advantages (p < 0.01). Knee flexion gain in the first 24 hours postoperatively was better in the TXA group (p < 0.05). Conclusion: TXA was effective in lowering the drop in hemoglobin level, reducing pain and improving movement gain 48 hours after the procedure. PRP was not effective in reducing bleeding or improving knee function after arthroplasty, but provided better control of postoperative pain. Level of Evidence I, Randomized, blinded, prospective clinical trial.

Keywords: Arthroplasty, Replacement, Knee. Tranexamic Acid. Platelet-Rich Plasma. Hemorrhage. Pain.

RESUMO

Objetivo: Avaliar a eficácia do plasma rico em plaquetas (PRP) e do ácido tranexâmico (ATX) aplicados na artroplastia total do joelho. Métodos: Selecionamos e randomizamos 84 pacientes. ATX foi aplicado em 23 pacientes, PRP em 20, e PRP associado a ATX em 20. A hemoglobina foi medida no pré-operatório e nas 24 e 48 horas após a cirurgia. O questionário de função, a escala de dor e o ganho de flexão do joelho foram verificados até o segundo ano de pós-operatório. Resultados: Houve diferença(p < 0,01) na diminuição da hemoglobina 48 horas após a cirurgia entre o grupo ATX e os grupos controle e PRP. Na dor, o grupo ATX 24 e 48 horas após a cirurgia e o grupo PRP 48 horas após a cirurgia apresentaram vantagens (p < 0,01). O ganho de flexão do joelho nas primeiras 24 horas de pós-operatório foi melhor no grupo ATX (p < 0,05). Conclusão: O ATX foi eficaz na diminuição da queda da hemoglobina, reduzindo a dor e melhorando o ganho de movimento em 48 horas após o procedimento. O PRP não foi eficaz na redução do sangramento ou na melhora da função do joelho após a artroplastia, mas proporcionou melhor controle da dor pós-operatória. Nível de Evidência I, Randomizado, duplo cego, ensaio clínico prospectivo.

Descritores: Artroplastia do Joelho. Ácido Tranexânio. Plasma Rico em Plaquetas. Hemorragia. Dor.

Citation: Guerreiro JPF, D Lima, G Bordignon, MV Danieli, AO Queiroz, DC Cataneo. Platelet-rich plasma (prp) and tranexamic acid (TXA) applied in total knee arthroplasty. Acta Ortop Bras. [online]. 2019;27(5):000-0. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

In 2000, during the American Academy of Orthopedics meeting, for the first time, Mooar et al.¹ demonstrated the use of autologous platelet gel in the postoperative period following total knee prosthesis with good results. Since 2006, studies on the use of PRP after TKA have presented conflicting results, and there is no consensus on its effectiveness.²⁻⁵ Similar to sealants such as fibrin, thrombin and PRP, antifibrinolytics have also been used to reduce bleeding.⁶⁻⁸Tranexamic acid (TXA) is the most commonly used.⁹⁻¹¹ The demonstrated results of intra-articular

administration of TXA in TKA include effectively decreasing the reduction in hemoglobin (Hb), blood loss due to drainage and the need for transfusion within 48 hours after surgery.¹² Currently, TXA seems to be the most effective method to reduce bleeding. Nonetheless, TXA is not directly related to healing, and its efficacy in pain control and postoperative knee function improvement has not been demonstrated. The hypothesis of this study is that PRP combined with TXA is effective in controlling bleeding and pain and improves healing and function after TKA.

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

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Article received in 11/09/218, approved in 04/22/2019.



OBJECTIVE

To evaluate the effectiveness of PRP and TXA in TKA in relation to the decrease in Hb levels, postoperative pain control, knee flexion gain and lower limb function gain.

MATERIAL AND METHODS

Study design

Randomized, blinded, prospective clinical trial Sample size Eighty-four patients

Follow-up time

Two years

Study stages

a) The project was approved by the Institution's Ethics and Research Committee under protocol number 634815 and clinical trial number RBR-9b4qqq.

b) Patient selection:

Inclusion criteria: three-compartment osteoarthritis of the knee; both sexes; indication for total knee prosthesis surgery and awaiting scheduling of the procedure; no diagnosis of inflammatory disease; and no history of atrial fibrillation, deep vein thrombosis or previous pulmonary embolism.

Exclusion criteria: a diagnosis of inflammatory disease; use of anticoagulant medications up to seven days before surgery; previous surgeries in the same knee; inadequate closure of the joint capsule; and no possibility of postoperative clinical follow-up.

All selected patients signed an informed consent form.

c) Randomization:

Random numbers were used for randomization. The patients were not informed of the group to which they were assigned until the end of the study.

d) Definition of groups:

Control (21 patients): total knee prosthesis and intra-articular application of saline only.

Experimental TXA (23 patients): total knee prosthesis and intra-articular TXA application.

Experimental PRP (20 patients): total knee prosthesis and intra-articular PRP application.

Experimental PRP + TXA (20 patients): total knee prosthesis and intra-articular application of PRP and TXA.

e) PRP preparation:

PRP was prepared by a duly trained professional. A total of 20 mL of blood was collected from patients in 5-mL vacuum tubes with 10% sodium citrate for anticoagulation. The tubes were centrifuged (FANEM®, Guarulhos, Sao Paulo, Brazil) at 1200 rotations per minute (RPM) for 10 minutes at room temperature in a 6.5-cm radius centrifuge. This centrifugation allowed the separation of the blood into the following components: red blood cells (tube bottom), white cells (thin layer over red blood cells) and plasma (superficial layer). The plasma was transferred to another 10-mL sterile tube and was centrifuged in the same centrifuge at the same speed for five minutes. At the end of this second centrifugation, the upper plasma layer (approximately 50%) was discarded because of the small amount of platelets present. The lower portion, which is rich in platelets and called PRP, was placed in a sterile Petri dish on a surgical drape and placed in a syringe for application by the surgeon. (Figure 1) Every five patients, part of the prepared PRP was separated and subjected to platelet count analysis in automatic counters (ADVIA 120 Siemens[®], Berlim and Munique, Germany).

f) Tranexamic acid:

The TXA treatment dose used was 1 g (four ampoules with 5 mL each and 50 mg/mL concentration) and was administered topically based on previous studies.¹³ After cleaning the joint cavity, 20 mL TXA was applied and maintained for 5 minutes before the joint capsule and wound were closed. (Figure 2) Data collection (Table 1)

Statistical analysis

The statistical power of the sample was calculated using the sampsicommand of STATA software (version 11, 2011, College Station, Texas, USA), based on the method proposed by Frison and Pocock¹⁴ for a comparative design of groups with repeated measures and using the reduction in Hb levels as the parameter. By adopting a significance



Figure 1. PRP Application in the Joint Cavity.



Figure 2. Application of TXA in the Joint Cavity.

 Table 1. Model of the Worksheet Used to Collect Data on the Analyzed
 Parameters at the Different Time Intervals (before and after Surgery).

	Before	24 h	48 h	7 days	21 days	2 months	6 months	1 year	2 years
Hb	Х	Х	Х						
Knee flexion		Х	Х	Х	Х	Х	Х	Х	Х
Pain		Х	Х	Х	Х	Х	Х	Х	Х
WOMAC	Х					Х	Х	Х	Х
Transfusion		Х	Х						
Wound		Х	Х	Х	Х	Х			
Signs of infection				Х	Х	Х	Х	Х	Х

Hb: hemoglobin; pain: numerical pain scale; WOMAC: Western Ontario and McMaster Universities Index; transfusion: assessed the need for blood transfusion; wound: observed healingdelay; signs of infection: serum tests were collected, and the need for antibiotic therapy, surgical debridement or removal of the implant was evaluated.

level of 5% and varying the power of the test, it was concluded that 20 patients per group would ensure at least 95% power for the comparisons. Comparisons among the groups in relation to the variable Hb reduction were performed through analysis of variance (ANOVA). Tukey's posttest for multiple comparisons was used when relevant.¹⁵

RESULTS

Demographic Data (Table 2) and Preoperative and Prepared PRP Platelet Counts (Table 3).

Table 4 shows that there was a significant difference (p < 0.01) in decreased Hb at 48 hours after surgery among the groups.

Table 2. Demographic Data.							
	Control	TXA	PRP	PRP+TXA			
	group	group	group	group			
Number of operated patients	21	23	20	20			
Number of patients	21	22	19	20			
followed up to 1 year	21	22	19	20			
Number of patients	21	13	16	18			
followed up to 2 years	21	13	10	10			
Mean age	69.14	68.3	66.4	68.75			
Mean age	(55-81)	(55-86)	(50-79)	(56-79)			
Sex (male/female)	7/14	5/18	6/14	8/12			
Preoperative hemoglobin value	12.19	12.4	11.61	12.41			
(mean and standard deviation)	(1.6)	(1.26)	(1.41)	(1.67)			
Preoperative WOMAC score	73.52	77.48	73.2	75.4			
(mean and standard deviation)	(5.25)	(7.77)	(5.94)	(8.69)			

Table 3. Preoperative and Prepared PRP Platelet Counts.

Platelet count	Serum platelet amount	PRP platelet amount	Fold increase in concentration
Patient 1 PRP group	200,000	550,000	2.75
Patient 6 PRP group	277,000	620,000	2.23
Patient 11 PRP group	155,000	480,000	3.1
Patient 16 PRP group	416,000	880,000	2.11
Patient 1 PRP + TXA group	183,000	450,000	2.45
Patient 6 PRP + TXA group	238,000	513,000	2.15
Patient 11 PRP + TXA group	295,000	834,000	2.82
Patient 16 PRP + TXA group	174,000	621,000	3.56
Total	1,938,000	4,948,000	2.55

The TXA groupswere compared with the control group and PRP group, and there were no differences between the TXA group and TXA + PRP group. In the pain evaluation, compared with the control group, the TXA groups showed significant advantages in the evaluations at 24 and 48 hours after surgery, and the PRP group showed advantages in the evaluation at 48 hours after surgery (p <0.01). The flexion gains in the first 24 hours after surgery were better in the TXA groups than in the PRP and control groups (p < 0.05), with no difference between the TXA group and TXA + PRP group. In the evaluations of the decrease in Hb in the first 24 hours, pain in the first week, flexion gain in the first 48 hours and WOMAC function questionnaire scores in the second month, there were no differences among the four groups up to 2 years after surgery. (Table 4) During the follow-up of the 84 patients, five cases (5.9%) of wound dehiscence and superficial infection were successfully treated with dressings and oral antibiotics (two in the control group, two in the TXA and one in the PRP + TXA group). Two cases (2.4%) of acute deep infection were treated, which required debridement, removal of the implant and two-step review of TKA with good progression (both in the PRP group). Two cases (2.4%) of late deep infection (after the third postoperative month) were also treated, with a two-step review of TKA with good progression (one in the TXA group and one in the PRP). In one case (1.2%), a review was indicated for patellar replacement, which was not performed in any of the primary surgeries. In total, five (5.9%) reviews were performed over a two-year period. Three manipulations were performed to treat arthrofibrosis (one in the TXA group, one in the PRP group and one in PRP + TXA group). No cases required a blood transfusion (the transfusion criterion was a Hb value less than

DISCUSSION

To the best of our knowledge, no studies have yet evaluated the simultaneous use of TXA and PRP in TKA. Thus, in this study, we sought to combine the healing and anti-inflammatory effects of PRP with the hemostatic effect of TXA. This discussion is based on previous studies in which these substances were used alone in TKA. Administration of 1 g topical TXA alone or in combination with PRP is effective at reducing bleeding, based on the reduction in the Hb

7 mg/dL in symptomatic patients). There were no diagnosed cases of

thrombosis or thromboembolism. The identified complications were not significantly associated with PRP or TXA among the groups. (Table 5)

Table 4. Comparison among Groups.									
	Control group	TXA group	PRP group	PRP + TXA group	Divolue				
	(mean and standard deviation)	P value							
Hb drop 24 hours	1.38 (0.95)	0.97 (0.54)	1.33 (1.18)	0.71 (0.63)	>0.05				
Hb drop 48 hours	2.28 (1.15) ^a	1.5 (0.66) ^b	2.01 (1.02)	1.29 (0.81) ^b	< 0.01				
Mean pain 24 hours	6.33 (1.11) ^a	5.3 (1.92) ^b	5.45 (1.47)	4.9 (2.43) ^b	<0.01				
Mean pain 48 hours	3.81 (1.08) ^a	2.48 (0.95) ^b	2.7 (1.26) ^b	2.65 (1.46) ^b	< 0.01				
Mean pain 1 week	2.38 (0.67)	1.83 (0.94)	1.65 (0.88)	1.8 (1.58)	>0.05				
Mean pain 3 weeks	1.67 (0.8)	1.35 (0.98)	0.9 (1.02)	1.15 (1.04)	>0.05				
Mean pain 2 months	1.33 (0.73)	0.96 (1.07)	0.5 (0.83)	0.65 (1.04)	>0.05				
Mean pain 6 months	0.95 (0.8)	0.48 (0.9)	0.55 (0.83)	0.25 (0.55)	>0.05				
Mean pain 1 year	0.29 (0.56)	0.36 (1.05)	0.63 (1.38)	0.15 (0.49)	>0.05				
Mean pain 2 years	0.14 (0.36)	0.77 (1.48)	0.24 (0.97)	0.39 (0.7)	>0.05				
Flexion gain 24 hours	62.86 (11.89)a	70.87 (10.41)b	58 (10.05)a	67.75 (12.4)b	< 0.05				
Flexion gain 48 hours	80 (8.37)	80.43 (9.28)	76.5 (6.71)	78.75 (9.16)	>0.05				
Flexion gain 1 week	86.67 (7.13)	88.04 (8.49)	87.5 (8.96)	89 (9.12)	>0.05				
Flexion gain 3 weeks	95.48 (8.2)	94.57 (9.16)	93 (10.81)	97.5 (10.58)	>0.05				
Flexion gain 2 months	97.38 (9.17)	99.13 (11.35)	100.25 (14.55)	103.5 (13.48)	>0.05				
Flexion gain 6 Months	96.9 (6.61)	105.65 (14.17)	101.25 (13.07)	111 (11.65)	>0.05				
Flexion gain 1 year	109.05 (9.44)	109.55 (12.53)	108. 68 (13.93)	117.5 (9.67)	>0.05				
Flexion gain 2 years	113.1 (10.43)	112.31 (10.92)	112.5 (11.83)	118.89 (10.65)	>0.05				
WOMAC 2 months	36.05 (4.59)	42.74 (12.12)	41.45 (8.75)	39.9 (6.32)	>0.05				
WOMAC 6 months	20.9 (5.16)	20.57 (5.87)	20.9 (9.36)	18.55 (4.72)	>0.05				
WOMAC 1 year	14.1 (4.41)	14.73 (7.5)	14.53 (9.16)	9.95 (5.42)	>0.05				
WOMAC 2 years	10.05 (4.25)	11 (7.31)	8.94 (6.57)	10.17 (5.93)	>0.05				

Legend: TXA: tranexamic acid, PRP: platelet-rich plasma, Hb: hemoglobin, WOMAC: Western Ontario and McMaster Universities Index.

Table 5. Complications.								
	Control group	TXA group	PRP group	PRP+TXAgroup	Total			
Wound dehiscence and superficial infection	2 (9.5%)	2 (8.7%)	0	1 (5%)	5 (5.9%)			
Acute deep infection (up to 3 months)	0	0	2 (10%)	0	2 (2.4%)			
Late deep infection (after 3 months)	0	1 (4.3%)	1 (5%)	0	2 (2.4%)			
Needed review	0	1 (4.3%)	4 (20%)	0	5 (5.9%)			
Manipulation due to arthrofibrosis	0	1 (4.3%)	1 (5%)	1 (5%)	3 (3.5%)			
Transfusion	0	0	0	0	0			
Thromboembolism	0	0	0	0	0			
Total patients	2 (9.5%)	4 (17.3%)	5 (25%)	2 (10%)	13 (15%)			

value, and this finding was once again confirmed in the present study.¹¹⁻¹³ In published studies on TKA, the most common route of administration for TXA application is intravenous. In this study, PRP was not effective in reducing bleeding or enhancing the effect of TXA. Mochizuki et al.³ conducted a prospective, controlled, randomized clinical study with 315 knees that showed less bleeding through the drain and smaller decreases in Hb levels in patients in whom PRP was applied intra-articularly after capsule suture and activated with thrombin and calcium chloride. In the present study, PRP was applied with the joint still open and exposed with the intention of obtaining a better distribution of the substance. This more natural way may be beneficial for pain control. Moreover, this method may have delayed the effect of PRP at the time of major bleeding shortly after reperfusion as the substance had not reached its maximum effect for hemostasis. The preparation and application of PRP vary in the literature, constituting the main limitation for any systematic review or meta-analysis. Additionally, the results are conflicting. In a recent meta-analysis of 12 studies and 1,333 knees, no significant difference was found for the decrease in Hb in patients treated with PRP.⁴ In this meta-analysis, there was also no evidence of improvements in knee range of motion or function, but pain was reduced with the use of PRP. Another meta-analysis published after the aforementioned one showed an improvement in the range of motion in cases where PRP was used but without advantages for pain control or function gain.⁵

The present study demonstrates that in addition to reducing bleeding, a good result can be achieved in the first 48 hours after the procedure with regard to pain and range of motion gain, but this finding did not remain in the outpatient evaluations performed in the first 2 months. Moreover, knee function gain analyzed using the WOMAC questionnaire did not increase within this time frame. Despite demonstrating that TXA was effective in reducing pain and promoting better movement gains in the first hours after the procedure, this study was performed in a single center with a relatively limited number of patients. Because this is the first prospective study demonstrating this result, other studies should be performed to better understand this effect.

The limitations of the present study include its design, which allowed the surgeon to know which patient belonged to each group during the surgery. The loss of TXA group presented more than 40% lost follow-up. It did not happen in the other groups and can create a huge bias. The loss of patients who did not complete the 2-year follow-up (19%) and the lack of quantification of growth factors and the number of residual leukocytes in PRP samples are also aspects that may have limited the impact of our results.

CONCLUSION

In the first 48 hours after the procedure, TXA applied topically in TKA reduced the decrease in Hb levels, reduced pain and promoted better movement gain.

In this study, compared with the control, PRP was not effective in reducing bleeding or improving knee function after arthroplasty but provided better control of postoperative pain as measured by the pain scale in the first 48 hours after surgery.

Compared to their use individually, the combination of PRP and TXA led to a smaller decrease in Hb and better pain control in the first 48 hours after surgery, but their use in combination was not synergistic and did not enhance their individual effects.

AUTHORS' CONTRIBUTIONS: Each individual author contributed individually and significantly to development of this work. JPFG (0000-0002-2026-9176)*: drafted and reviewed the article, performed statistical analysis and contributed to the intellectual concept of the study and the entire research project; DRL (0000-0002-0307-2582)*:drafted the article, sought volunteers and analyzed the data; GB (0000-0001-5273-4303)*:drafted the article, sought volunteers and analyzed the data; AOQ (0000-0003-2808-7892)*:reviewed the article and contributed to the intellectual concept of the study; MVD (0000-0001-7547-7557)*:reviewed the article and contributed to the intellectual concept of the study; MVD (0000-0001-7547-7557)*:reviewed the article and contributed to the intellectual concept of the study; NVD (0000-0001-7547-7557)*:reviewed the article and contributed to the intellectual concept of the study; NCD (0000-0001-7547-7557)*:reviewed the article and contributed to the intellectual concept of the study; NCD (0000-0001-7547-7557)*:reviewed the article and contributed to the intellectual concept of the study; NCD (0000-0001-7547-7557)*:reviewed the article and contributed to the intellectual concept of the study; NCD (0000-0002-3400-2309) reviewed the article and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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REVIEW OF TOTAL KNEE ARTHROPLASTY AND THE BRAZILIAN UNIFIED HEALTH SYSTEM: A NATIONAL PROBLEM

REVISÃO DE ARTROPLASTIA TOTAL DE JOELHO E O SISTEMA ÚNICO DE SAÚDE: UM PROBLEMA NACIONAL

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ABSTRACT

Objectives: To analyze, through DATASUS data, the historical trend of revision of total knee arthroplasty (TKA) in the period between 2008-2016 and to relate them to demographic, regional and national aspects. Methods: Elaboration of a historical series between the period 2008-2016, using the database of DATASUS, in the area of Health Information (TABNET). In order to calculate the incidence, the total number of TKA revisions and as denominator the total national, regional or state population for the period studied was used as numerator. Results: The national rate of procedures per 100,000 inhabitants varied between 0.41 and 0.48 in the analyzed period (mean of 0.44). The Southeast region, with 69% of the SBCJ accredited services and 61% of the SBCJ members, was responsible for 60% of the absolute number of procedures performed in Brazil. Conclusions: In absolute numbers, the Southeast region has the highest volume of procedures. However, the highest rate is found in the South region. The North, Northeast and Central-West regions presented unsatisfactory results, well below the others. Level of evidence IV, Economic and decision analysis - development of economic model or decision.

Keywords: Reviews. Arthroplasty. Knee. Public Health. Osteoarthritis.

RESUMO

Objetivos: Analisar, através dos dados do DATASUS, a tendência histórica das revisões de artroplastia total de joelho (ATJ) no período entre 2008-2016 e relacioná-las com aspectos demográficos, regional e nacionalmente. Métodos: Elaboração de uma série histórica entre o período de 2008-2016, utilizando-se do banco de dados do DA-TÁSUS, na área de Informações de Saúde (TABNET). Para calcular a incidência, foi usado como numerador o total de revisões de ATJ e como denominador a população total nacional, da região ou do estado pelo período estudado. Resultados: A taxa nacional de procedimentos por 100.000 habitantes apresentou variação entre 0,41 e 0,48 no período analisado (média de 0,44). A região Sudeste, onde estão 69% dos serviços credenciados à SBCJ e 61% dos membros titulares da SBCJ, foi responsável por 60% do número absoluto de procedimentos realizados no Brasil. Conclusões: Em números absolutos, a região Sudeste possui o maior volume de procedimentos. Entretanto, a taxa mais alta é encontrada na região Sul. As regiões Norte, Nordeste e Centro-Oeste apresentaram resultados insatisfatórios, bem abaixo das demais. Nível de evidência IV. Análises econômicas e de decisão - desenvolvimento de modelo econômico ou de decisão.

Descritores: Revisão. Artroplastia. Joelho. Saúde Pública. Osteoartrose.

Citation: Melo LP, Losso GA, Costa GHR, Pécora JR, Demange MK, Helito CP. Wei TH. Review of total knee arthroplasty and the brazilian unified health system: a national problem. Acta Ortop Bras. [online]. 2019;27(5):252-6. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

The progressive aging of the population is a worldwide phenomenon. As a result, there is an increase in the prevalence of osteoarthritis (OA) and, consequently, in the number of total knee arthroplasties (TKA) performed, a cost-effective procedure with good clinical results.¹

With the greatest number of TKA, invariably, there is a growing need for review procedures,¹ which are technically more difficult and more costly, with an estimated cost of \$ 75,000 per procedure in the United States.² There are no published current epidemiological studies in Brazil that quantify the number of surgeries performed for TKA revision. The survival rate and clinical outcomes of revision of arthroplasties are lower than the primary TKA, so that their performance should preferably be in specialized centers and with experienced surgeons.³ However, it is known that there is no such distinction by specialized centers in our environment, so that any service is authorized to perform these procedures.

According to studies of published TKA indications, the main causes of failure are aseptic loosening, instability and infection. Lombardi Jr et al,³ in a multicentric analysis of 844 cases of TKA revision, found aseptic loosening (31.2%) as the predominant mechanism of failure in primary TKA, followed by instability (18.7%) and infection (16.2%), with mean time to failure of 5.9 years. These data are in agreement with those published by Khan et al,⁴ with aseptic loosening (29.8%), infection (14.8%) and pain (9.5%) as the main indications for revision.

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

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Article received in 10/04/2018, approved in 04/24/2019



Unfortunately, because of the difficulty in dealing with bone loss and the lack of soft tissues present in these cases, the results of the revisions are not as predictable as in cases of primary arthroplasties,⁵ and may lead to catastrophic evolutions, such as arthrodesis and, in the last case, amputations, which greatly impairs patients' quality of life. Unlike trauma-related amputations, the outcome of transfermoral amputations after uncontrolled TKA infection is not satisfactory, with few patients resuming the ability to ambulate. Helito et al,⁶ in a series of cases, showed that only 25% of the patients undergoing amputation in this context were able to maintain the ability to ambulate.

Thus, trying to establish a national epidemiological profile, in order to understand how we deal with revisions of arthroplasty in our country, the objective of the present study is to evaluate the historical trend of revision of TKA performed by the Public Healthcare Service (Sistema Único de Saúde - SUS), analyzing regional differences and comparing findings with existing data from other countries. In addition, as a secondary objective, to establish a parallel between the number of reviews of TKA performed and the number of services accredited to the Brazilian Society of Knee Surgery (Sociedade Brasileira de Cirurgia do Joelho - SBCJ).

OBJECTIVE

To analyze, through DATASUS data, the historical trend of revision total knee arthroplasty (TKA) in the period between 2008-2016 and to relate it to demographic aspects, at a regional and national level.

MATERIALS AND METHODS

A research was performed using the DATASUS database, in the area of Health Information (TABNET). After definition of the period between

Table 1. Hospital procedures of the Brazilian Unified Health System (SUS) - by admission facility location - Brazil.

2008 and 2016, the procedure "0408050055 ARTROPLASTIA TOTAL DE JOELHO - REVISAO / RECONSTRUCAO" was selected as a filter.⁷ To calculate the incidence, the total of revisions of TKA was used as numerator and the total national, regional or state population for the period studied was used as denominator. Population data were obtained by the National Census of the Brazilian Institute of Geography and Statistics (Instituto Brasileiro de Geografia e Estatística - IBGE) and the projections for the other years. The number of accredited services by region/state is available on the SBCJ website.⁷

The obtained results were allocated in tables, according to the studied questions. The main objective of the study was to describe the incidence of TKA review in Brazil.

For the statistical analysis, the data related to the TKA revisions were presented in absolute and percentage values, with a total for Brazil and stratified according to the Region or Federal Unit, in relation to the year of the procedure. The surgery rate was presented by groups of 100,000 inhabitants. Finally, a statistical analysis was performed to allow a descriptive evaluation of the results obtained.

RESULTS

Between 2008-2016, the nine-year period used for the study, 7,844 TKA revision surgeries were recorded. We highlight the significant contribution of the Southeast region, with 60% of the absolute number of procedures performed in Brazil, with the state of São Paulo accounting for 37% of the total national amount (Tables 1, 2, 3). The national rate of procedures per 100,000 inhabitants presented a variation between 0.41 and 0.48 in the analyzed period (mean of 0.44) (Figure 1).

Although the absolute number is much higher in the Southeast region, we highlight that the highest rate of TKA revision is found

Hospital admissions by Region/State and Year of processing Procedure:0408050055 total knee arthroplasty - revision/reconstruction - Period:2008-2016															
	. <u> </u>		ure:040	08050055 t		thropla	asty - revis		ruction	1 - Period:2					
Region/State		2008			2009			2010			2011			2012	
v		Population			Population		Surgeries	Population		Surgeries	Population			Population	
Acre	19	705.635	2.69	13	720.132	1.81	1	733.559	0.14	1	746.375	0.13	3	758.786	0.40
Amapá	0	651.977	0.00	0	669.360	0.00	0	669.526	0.00	0	684.301	0.00	0	698.602	0.00
Amazonas	10	3.463.562	0.29	10	3.534.456	0.28	6	3.483.985	0.17	2	3.538.359	0.06	1	3.590.985	0.03
Pará	36	7.402.515	0.49	15	7.521.656	0.20	46	7.581.051	0.61	9	7.688.531	0.12	8	7.792.561	0.10
Rondônia	0	1.616.992	0.00	0	1.640.607	0.00	0	1.562.409	0.00	1	1.576.423	0.06	1	1.590.011	0.06
Roraima	0	440.533	0.00	0	450.969	0.00	0	450.479	0.00	0	460.157	0.00	0	469.524	0.00
Tocantins	8	1.376.898	0.58	1	1.398.334	0.07	6	1.383.445	0.43	1	1.400.813	0.07	3	1.417.694	0.21
Alagoas	4	3.177.975	0.13	1	3.205.791	0.03	5	3.120.494	0.16	3	3.143.338	0.10	3	3.165.472	0.09
Bahia	10	14.558.148	0.07	17	14.665.810	0.12	12	14.016.906	0.09	15	14.097.333	0.11	16	14.175.341	0.11
Ceará	77	8.412.055	0.92	59	8.493.155	0.69	13	8.452.381	0.15	6	8.530.058	0.07	3	8.606.005	0.03
Maranhão	11	6.458.789	0.17	4	6.533.027	0.06	3	6.574.789	0.05	0	6.645.665	0.00	3	6.714.314	0.04
Paraíba	0	3.751.507	0.00	2	3.785.598	0.05	3	3.766.528	0.08	3	3.791.200	0.08	4	3.815.171	0.10
Pernambuco	16	8.825.549	0.18	19	8.906.488	0.21	7	8.796.448	0.08	12	8.864.803	0.14	16	8.931.028	0.18
Piauí	0	3.106.597	0.00	1	3.125.918	0.03	4	3.118.360	0.13	5	3.140.213	0.16	1	3.160.748	0.03
Rio Grande do Norte	6	3.186.891	0.19	3	3.226.259	0.09	7	3.168.027	0.22	7	3.198.572	0.22	9	3.228.198	0.28
Sergipe	0	2.066.358	0.00	0	2.093.507	0.00	0	2.068.017	0.00	4	2.089.783	0.19	1	2.110.867	0.05
Espírito Santo	7	3.598.524	0.19	13	3.648.075	0.36	20	3.514.952	0.57	11	3.547.013	0.31	25	3.578.067	0.70
Minas Gerais	62	19.794.278	0.31	65	19.967.560	0.33	68	19.597.330	0.35	47	19.728.252	0.24	74	19.855.332	0.37
Rio de Janeiro	40	15.859.866	0.25	67	15.969.092	0.42	69	15.989.929	0.43	63	16.112.637	0.39	74	16.231.365	0.46
São Paulo	334	41.651.651	0.80	325	42.075.716	0.77	456	41.262.199	1.11	385	41.586.892	0.93	74	41.901.219	0.18
Paraná	33	10.540.407	0.31	67	10.636.065	0.63	68	10.444.526	0.65	80	10.512.151	0.76	74	10.577.755	0.70
Rio Grande do Sul	90	10.906.958	0.83	88	10.965.071	0.80	88	10.693.929	0.82	111	10.732.770	1.03	74	10.770.603	0.69
Santa Catarina	29	6.164.049	0.47	33	6.257.173	0.53	36	6.248.436	0.58	35	6.316.906	0.55	74	6.383.286	1.16
Distrito Federal	8	2.483.669	0.32	6	2.541.434	0.24	4	2.570.160	0.16	4	2.609.997	0.15	74	2.648.532	2.79
Goiás	1	5.957.260	0.02	4	6.057.367	0.07	3	6.003.788	0.05	3	6.080.588	0.05	74	6.154.996	1.20
Mato Grosso	1	2.956.496	0.03	1	3.003.310	0.03	3	3.035.122	0.10	1	3.075.862	0.03	74	3.115.336	2.38
Mato Grosso do Sul	0	2.417.300	0.00	4	2.452.039	0.16	2	2.449.024	0.08	2	2.477.504	0.08	74	2.505.088	2.95

	Procedure:0408050055 total knee arthroplasty - revision / reconstruction -Period:2008-2016											
Degion/Otata		2013			2014		2015			2016		
Region/State	Surgeries	Population	Rate	Surgeries	Population	Rate	Surgeries	Population	Rate	Surgeries	Population	Rate
Acre	2	776.463	0.26	1	790.101	0.13	2	803.513	0.25	1	816.687	0.12
Amapá	0	734.996	0.00	0	750.912	0.00	0	766.679	0.00	0	782.295	0.00
Amazonas	2	3.807.921	0.05	7	3.873.743	0.18	4	3.938.336	0.10	1	4.001.667	0.02
Pará	5	7.969.654	0.06	10	8.073.924	0.12	13	8.175.113	0.16	14	8.272.724	0.17
Rondônia	1	1.728.214	0.06	0	1.748.531	0.00	0	1.768.204	0.00	3	1.787.279	0.17
Roraima	0	488.072	0.00	0	496.936	0.00	0	505.665	0.00	0	514.229	0.00
Tocantins	3	1.478.164	0.20	0	1.496.880	0.00	1	1.515.126	0.07	0	1.532.902	0.00
Alagoas	5	3.300.935	0.15	4	3.321.730	0.12	1	3.340.932	0.03	2	3.358.963	0.06
Bahia	22	15.044.137	0.15	13	15.126.371	0.09	18	15.203.934	0.12	25	15.276.566	0.16
Ceará	6	8.778.576	0.07	21	8.842.791	0.24	15	8.904.459	0.17	10	8.963.663	0.11
Maranhão	3	6.794.301	0.04	4	6.850.884	0.06	0	6.904.241	0.00	3	6.954.036	0.04
Paraíba	11	3.914.421	0.28	9	3.943.885	0.23	3	3.972.202	0.08	2	3.999.415	0.05
Pernambuco	18	9.208.550	0.20	9	9.277.727	0.10	14	9.345.173	0.15	6	9.410.336	0.06
Piauí	2	3.184.166	0.06	3	3.194.718	0.09	15	3.204.028	0.47	9	3.212.180	0.28
Rio Grande do Norte	5	3.373.959	0.15	7	3.408.510	0.21	7	3.442.175	0.20	2	3.474.998	0.06
Sergipe	0	2.195.662	0.00	2	2.219.574	0.09	2	2.242.937	0.09	3	2.265.779	0.13
Espírito Santo	33	3.839.366	0.86	40	3.885.049	1.03	59	3.929.911	1.50	37	3.973.697	0.93
Minas Gerais	77	20.593.356	0.37	89	20.734.097	0.43	119	20.869.101	0.57	144	20.997.560	0.69
Rio de Janeiro	97	16.369.179	0.59	107	16.461.173	0.65	147	16.550.024	0.89	85	16.635.996	0.51
São Paulo	281	43.663.669	0.64	330	44.035.304	0.75	261	44.396.484	0.59	225	44.749.699	0.50
Paraná	82	10.997.465	0.75	91	11.081.692	0.82	111	11.163.018	0.99	102	11.242.720	0.91
Rio Grande do Sul	133	11.164.043	1.19	95	11.207.274	0.85	89	11.247.972	0.79	88	11.286.500	0.78
Santa Catarina	60	6.634.254	0.90	86	6.727.148	1.28	84	6.819.190	1.23	71	6.910.553	1.03
Distrito Federal	10	2.789.761	0.36	8	2.852.372	0.28	6	2.914.830	0.21	4	2.977.216	0.13
Goiás	6	6.434.048	0.09	2	6.523.222	0.03	5	6.610.681	0.08	2	6.695.855	0.03
Mato Grosso	2	3.182.113	0.06	3	3.224.357	0.09	9	3.265.486	0.28	3	3.305.531	0.09
Mato Grosso do Sul	2	2.587.269	0.08	1	2.619.657	0.04	3	2.651.235	0.11	4	2.682.386	0.15

Table 2. Hospital procedures of the Brazilian Unified Health System (SUS) - by admission facility location - Brazil.

Hospital admissions by Region/State and year of processing

Table 3. Hospital procedures of the Brazilian Unified Health System (SUS) - by admission facility location - Brazil.

Hospital admissions by Region/State and Year of processing Procedure:0408050055 total knee arthroplasty - revision/reconstruction - Period:2008-2016 2008 2009 2010 2011 2012 Region/State Surgeries Population Rate North 15.658.112 0.47 39 15.935.514 0.24 59 15.864.454 0.37 16.094.959 0.09 16.318.163 0.10 73 14 16 Northeast 124 53.543.869 0.23 54.035.553 53.081.950 53.907.144 106 0.20 54 0.10 55 53.500.965 0.10 56 0.10 Southeast 443 80.904.319 0.55 470 81.660.443 0.58 80.364.410 0.76 506 80.974.794 0.62 502 81.565.983 613 0.62 South 152 27.611.414 0.55 188 27.858.309 0.67 192 27.386.891 0.70 226 27.561.827 0.82 252 27.731.644 0.91 Midwest 10 13.814.725 0.07 15 14.054.150 0.11 12 14.058.094 0.09 10 14.243.951 0.07 13 14.423.952 0.09 193.946.886 0.43 802 Total 191.532.439 0.42 818 193.543.969 0.42 930 190.755.799 0.49 192.376.496 0.42 839 811 2014 2016 2013 2015 **Region/State** Surgeries Population Rate Surgeries Population Rate Surgeries Population Rate Surgeries Population Rate North 13 16.983.484 0.08 18 17.231.027 0.10 20 17.472.636 0.11 19 17.707.783 0.11 Northeast 72 55.794.707 0.13 72 56.186.190 0.13 75 56.560.081 0.13 62 56.915.936 0.11 Southeast 488 0.58 566 85.115.623 0.66 586 85.745.520 0.68 491 0.57 84.465.570 86.356.952 275 0.96 272 0.94 284 0.97 261 29.439.773 South 28.795.762 29.016.114 29.230.180 0.89 Midwest 20 14.993.191 0.13 14 15.219.608 0.09 23 15.442.232 0.15 13 15.660.988 80.0

202.768.562

in the South region, with a mean in the studied period of 0.82 per 100,000 inhabitants (Figure 2). Rio Grande do Sul (0.90) and São Paulo (0.75) are the states of the federation with the highest average revision rate of TKA.

201.032.714

0.43

942

868

On the other hand, the performance of the North (0.19), Northeast (0.14) and Midwest (0.10) regions, evaluated by the average rate in the studied period, is well below the South and Southeast regions, showing a worrying scenario at national level.

After a trend of growth between 2011-2015, the year 2016 presented a national fall in the revision rate of TKA (15%), with the Center-West region showing the most intense fall (44%).

The rate of accredited services and associate members in the SBCJ in 2017 per 10,000,000 population group is shown in table 4.

DISCUSSION

988

204.450.649

0.46

The analysis of the official data provided by the SUS presents a worrisome national scenario regarding the revision of TKA. The national average rate of 0.44/100,000 inhabitants is well below international indicators. In the state of New York, Bansal et al⁸ showed a growth of 246% between 1993 and 2010, with the rate increasing from 4.9 to 16.8 / 100,000 inhabitants. Bozic et al⁹ using the NIS (Nationwide Inpatients Sample) between 2005 and 2010 demonstrated a 39% increase in the number of TKA revisions in the American population.

0.48

846

This trend of growth, also observed in several other series in Europe, Australia and Canada,¹⁰⁻¹³ contrasts with the decrease in the number

206.081.432

0.41

Total

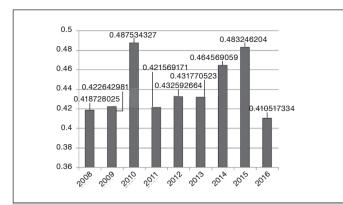


Figure 1. Rate of revision of total knee arthroplasty performed by the Brazilian Unified Health System from 2008 to 2019 (per 100,000 inhabitants).

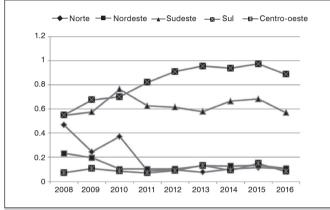


Figure 2. Rate of revision of total knee arthroplasty performed by the Brazilian Unified Health System from 2008 to 2019 (per 100,000 inhabitants).

Table 4. Rate of accredited services and associated members of the Brazilian Knee Surgery Society (SBCJ), by regions of Brazil, in 2017 (per 10,000,000).

Region	Accredited services	Associated members
North	2	36
Northeast	7	194
Southeast	58	867
South	14	222
Midwest	3	96

of TKA revisions made in Brazil in 2016, when there was a reduction of 15% compared to 2015, which may eventually be related to a worsening of the country's economic indicators in this period, with a direct impact on the public health system.

In England and Wales, it is estimated that 332% increase in the number of revisions of TKA between 2012 and 2030.¹⁴ In the United States, a 601% increase in TKA revision demand is estimated in 2030 when compared to 2005.² Although there are no national estimates of the number of TKA revisions in 2030, the chronological

evolution shown in figure 1 shows that public health policies are needed for an attempt to reverse this situation.

A recent national publication brought a picture of the primary TKA in the SUS. Between 2008 and 2015, there was an average annual increase of 8.7% in the number of primary TKA.¹⁵ Comparing with our study, after compiling the data in a linear regression curve, we found a growth of only 12.78 procedures per year. Although we use different parameters in this comparison, there appears to be a lag in the number of revisions, which can not grow analogously to the primary procedures.

The delay in performing the TKA review procedure, after its indication, is associated with an increase in complications and technical difficulties. Unresolved loosening tend to provoke a positive feedback in the process of osteolysis and bone loss. The need for endoprosthetic reconstruction, as an alternative to rescue the limb, has worse results, with higher infection rates and a greater need for further revisions.¹⁶ In cases of prolonged use of the cement spacer, late follow-up showed mechanical failure in 87%, with supracondylar fractures and spacer dislocation being the most common complications.¹⁷

As shown in table 4, there is a large regional disparity in the rate of accredited services and members associated with SBCJ, with more than 50% of services and members of society being in the Southeast region. This reflects a national lack of reference centers for conducting a revision of TKA. Jeschke et al,¹⁸ showed a clear association between the need for revision after a primary TKA and the surgical volume of the hospital where the procedure was performed. These data allow extrapolations for cases of TKA revisions. Because it is a high-cost, large-scale procedure with many complications, it is important to create regional centers of excellence, with professionals trained to perform this procedure, seeking better results and optimizing public health policy.

We know that underreporting makes it difficult to interpret the Brazilian TKA revisions more reliably. With use in the United States and the United Kingdom, the American Joint Replacement Registry¹⁹ and the National Joint Registry²⁰ are important tools for the prospective monitoring of performed arthroplasties and implant surveillance, generating a broader national perspective, rather than a purely institutional view. This reinforces the need to create a brazilian registry of implants, facilitating control and helping to guide decisions about investments and improvements to be made in the SUS network care.

The fact that we use data only from the SUS generates a limitation to our study, since we can not size the impact of the revision of TKA in the supplementary health system, which is responsible for an important portion in the total amount of cases. In addition, a statistical analysis based on numbers alone may not reflect the presence of good services, which certainly exist in all regions of the country, with a qualified team that, although perform a low number of procedures.

CONCLUSIONS

In Brazil, an average rate of TKA revisions was 0.44 per 100,000 inhabitants between 2008 and 2016. In absolute numbers, the Southeast region has the highest volume of procedures. However, the highest rate found is in the South region. 69% of the services accredited to the SBCJ and 61% of the SBCJ members are in the Southeast region.

AUTHORS' CONTRIBUTIONS: Cada autor contribuiu individualmente e significativamente para o desenvolvimento do artigo intitulado "Panorama das revisões de artroplastia total de joelho no contexto do Sistema Único de Saúde: um problema nacional": LPM (0000-0002-1965-2100)*: pesquisa, levantamento de dados, análise estatística; GAL (0000-0002-9484-7717)*: pesquisa, levantamento de dados, análise estatística, redação do texto, revisão bibliográfica; GHRC (0000-0002-1409-3178)*: pesquisa, análise estatística, redação do texto, revisão bibliográfica; GHRC (0000-0003-1409-3178)*: idealização, orientação da pesquisa, orientação da escrita do texto; CHP (0000-0003-1139-2524)*: idealização, orientação da pesquisa, orientação da pesquisa, orientação da escrita do texto. *ORCID (Open Researcher and Contributor ID).

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ASSESSING PSYCHOSOCIAL DISTRESS IN BONE METASTASES TREATED WITH ENDOPROSTHESIS

AVALIAÇÃO DA ANGÚSTIA PSICOSSOCIAL NA METÁSTASE ÓSSEA TRATADA COM ENDOPRÓTESE

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ABSTRACT

Objective: To compare preoperative and early postoperative levels of psychosocial distress in patients undergoing bone metastasis treatment with endoprosthesis, evaluating its impact on quality of life. Methods: Thirteen patients undergoing endoprosthetic treatment of bone metastasis were assessed at two time points: preoperatively and 30 days postoperatively. The tool used was the Distress Thermometer, a questionnaire for psychosocial screening developed by the National Comprehensive Cancer Network. Distress is considered moderate or severe if the patient scores 4 or higher. Results: The most frequent problems in the preoperative period were "bathing and dressing". At 30 days, "fatigue" and "nervousness" prevailed. There was a significant improvement in distress when preoperative and 30-day assessments were compared. Conclusion: The surgical treatment of bone metastasis with endoprosthesis results in an early improvement of psychosocial distress as measured by the Distress Thermometer. Level of evidence II, Prospective and comparative therapeutic study.

Keywords: Quality of Life. Bone Neoplasms. Neoplasm Metastasis. Surgical Oncology.

RESUMO

Objetivo: Confrontar o nível de angústia psicossocial (distress) entre o pré-operatório e o pós-operatório precoce de pacientes submetidos ao tratamento de metástase óssea com endoprótese, avaliando seu impacto na qualidade de vida. Métodos: Foram avaliados 13 pacientes submetidos ao tratamento de metástase óssea com endoprótese em dois momentos: pré-operatório e pós-operatório de 30 dias. A ferramenta utilizada foi o termômetro de Distress, guestionário de triagem psicossocial desenvolvido pela National Comprehensive Cancer Network. É considerado distress moderado ou grave se o paciente somar 4 ou mais pontos. Resultados: No pré-operatório, os problemas mais frequentes foram "tomar banho e vestir-se". Com 30 dias, os itens mais prevalentes foram "cansaço" e "nervosismo". Houve melhora significativa do distress quando foram comparadas as avaliações pré-operatória e após 30 dias. Conclusão: O tratamento cirúrgico com endoprótese para metástase óssea reduz precocemente o nível de angústia psicossocial aferido pelo termômetro de Distress. Nível de evidência II, Estudo terapêutico, prospectivo e comparativo.

Descritores: Qualidade de Vida. Neoplasias Ósseas. Metástase Neoplásica. Oncologia Cirúrgica.

Citation: Filon MC, Anzuatégui PR, Ribeiro JPA, Santiago L, Mello GJP, Rigolino AVB. Assessing psychosocial distress in bone metastases treated with endoprosthesis. Acta Ortop Bras. [online]. 2019;27(5):257-60. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

According to the most recent global estimates, the three most common types of tumor in the population have a high prevalence of metastatic bone disease as they progress. Factors such as comorbidities associated with the underlying disease, risk of surgical treatment, and great variability in patient survival make bone metastasis treatment a challenge to the orthopedic oncologist.¹⁻³ There are two main types of surgical treatment for this type of neoplastic lesion: open reduction with internal fixation or endoprosthetic replacement. Both are effective when the bone neoplasm has high risk or presence of fracture, and lead to an important improvement in pain, quality of life, and function. However, there is no consensus

in the literature regarding which technique is superior.³⁻⁵ This study assesses the surgical treatment using endoprosthetic replacement, which is the method of choice at our Service.

Most authors consider improvement in pain and function to be a determinant factor for a successful surgery, but few of them focus on quality of life.^{3,6} When assessing quality of life, one of the parameters that can be included is psychosocial distress, which refers, in general terms, to all types of stress faced by the patient with cancer during treatment, being considered the sixth vital sign in cancer care.⁷

There are many tools that can be used to assess level of distress, such as the Beck Depression Inventory, the Hospital Anxiety and

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

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Article received in 01/04/2019, approved in 06/06/2019.

Depression Scale, the Short-Form General Health Survey (SF-36), and the National Cancer Comprehensive Cancer Network (NCCN) Distress Thermometer. The latter was the one chosen by the researchers.^{7,8}

Studies investigating the association of surgical treatment of bone metastasis in the appendicular skeleton with patients' level of distress were not found in the literature, even though its influence on treatment adherence and duration is known.^{9,10,11}This knowledge gap prompted us to perform the present study, whose aim was to determine the impact of endoprosthetic treatment on the level of distress of patients with bone metastasis.

MATERIALS AND METHODS

A prospective analysis of a series of consecutive patients with metastatic bone disease who were surgically treated with endoprosthesis was made. The study was approved by the relevant ethics committee (CAEE: 65673317.9.0000.0098), and all participants were properly informed about the study methodology and provided consent by signing an informed consent form.All procedures were in accordance with the ethical standards of the 1995 Helsinki Declaration.

Inclusion criteria

(1) Patients with appendicular skeletal metastasis undergoing surgical treatment with endoprosthesis; (2) presence of postoperative pathology study confirming the diagnosis of bone metastasis.

Exclusion criteria

(1) Death before 30 days of surgery; (2) loss to follow-up; (3) incomplete data.

SCREENING TOOLS FOR MEASURING DISTRESS

The DT questionnaire

The DT questionnaire was developed by the NCCN to evaluate the level of distress faced by the patient with cancer during treatment. This tool consists of two parts:the first one shows a visual analogue scale (VAS) of the patient's level of distress at the time of the evaluation, and the second contains a list of problems. (Figure 1) Research participants completed the questionnaire before surgery and 30 days after surgery, during outpatient follow-up. The questionnaire was administered in electronic format, using GoogleForms[®], and researchers assisted patients during its application.

Distress assessment

The patients graded their perception about their level of distress with the visual aid of a thermometer ranging from 0 to 10. A score higher than 4 was considered moderate/severe distress. Values below that were considered mild distress.

Problem list

The problem list consisted of 39 problems divided into five areas as follows: practical problems; family problems; physical problems; emotional problems; and spiritual concerns. Patients answered each problem from the list with "yes" or "no", and the prevalence of each of the problems and their distribution by area were measured.

Statistical analysis

Epidemiological data were detailed through descriptive statistics. The level of distress reported in the VAS was described as mean value and standard deviation.Statistical significance of the intergroup analysis was determined using one-way analysis of variance (ANOVA). Variation in level of distress (mild or moderate/severe)

Second, please indicate if any of the following has been a problem

for you in the past week including today. Be sure to cheek Yes or No for cach. Yes No Practical problems Yes No Physical problems Instruction: First please circle the number (0-10) that best describes Child care □ □ Appearance how much distress you have been experiencing in the past week Housing Bathing/dressing including today. П □ Insurance/financial Breathing □ Transportation П □ Changes in urination П □ Work/scholl П Constipations П Treatment decisions D Diarrhea Extreme distress Eating Family problems Fatique 9 Dealing with children □ □ Feeling swollen Dealing with partner 8 Fevers □ □ Ability to have children □ Getting around 7 □ Family health issues П □ Indigestion 6 □ Memory/concentration **Emotional problems** Mouth sores 5 □ □ Depression П Nausea □ Fears 4 Nose dry/congested п Nervousness Pain 3 □ Sadness Sexual п Worry 2 Skin dry/itchy п Loss of interest in □ Sleep п usual activities 1 □ □ Substance abuse No distress Ô □ □ Spititual/religious concerns □ □ Tingling in hands/feet Other problems:

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Figure 1. The Distress Thermometer questionnaire.

was analyzed as dichotomous variable and its significance was determined by the McNemar test.

The variables corresponding to the problems reported by the patients were described as mean value for each item and absolute number of marked items. The total number of problems in each category was presented as mean value, and the intergroup analysis significance was determined using one-way ANOVA.

The confidence interval used was 95%, and data were tabulated with Microsoft Excel 2018[®]. Statistical analysis was performed using MedCalc[®].

RESULTS

The initial sample consisted of 21 patients. Five patients died before 30 days of surgery (one due to pulmonary sepsis; one due to urinary sepsis; three due to natural disease progression). There were two losses to follow-up (both patients continued treatment in another institution) and in one case the pathology study showed no bone metastasis. After inclusion and exclusion criteria were observed, 13 patients remained in the study. Table 1 shows the general characteristics of the sample.

Level of distress

The mean distress score obtained preoperatively was 5.92, reducing to 4 postoperatively (at 30 days) (p=0.67). Figures 2 and 3 show the distribution of the participants' scores in each assessment. There was a reduction in the number of patients with severe/moder-

ate distress from 11 (84%) to 6 (46%), with p=0.06. (Figure 4) Only two participants performed worse, both with moderate/severe distress.

 Table 1. General characteristics of the patients undergoing surgery with endoprosthesis due to appendicular skeletal metastasis.

Characteristics	n (%)
Total sample size	13
Female sex	8 (62%)
Age (years)	45.8 (12), 39-87
Primary tumor	
Breast	7 (53.8%)
Kidney	2 (15.3%)
Lung	2 (15.3%)
Prostate	1 (7.7%)
Squamous cell carcinoma (oropharynx)	1 (7.7)
Lesion site	
Proximal femur	10 (76.9%)
Distal femur	1 (7.6%)
Proximal humerus	1 (7.6%)
Humeral diaphysis	1 (7.6%)

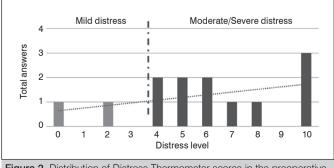


Figure 2. Distribution of Distress Thermometer scores in the preoperativeassessment of patients with appendicular skeletal metastasis. The most prevalent problems in each assessment are presented in Table 2.The proportion of problems by area is shown in Figure 5. Regarding the mean number of problems, there was a reduction from 9 to 7,8, without statistical significance (p=0.6). In the analysis by area, emotional, family, spiritual, and practical problems had little variation, as observed in Figure 5 (p>0.05).

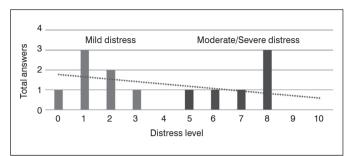
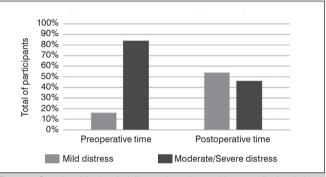


Figure 3. Distribution of Distress Thermometer scores in the 30-day postoperative assessment of patients with appendicular skeletal metastasis treated with endoprosthesis.



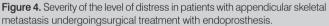


Table 2. Prevalence of problems reported by patients with appendicular skeletal metastasis in preoperative and 30-day postoperativeassessments.

Preoperative	30-daypostoperative
Pain - 76.9%	Getting around – 61.5%
Skin dry/itchy – 69.2%	Fatigue – 53.8%
Bathing/dressing - 61.5%	Skin dry/itchy – 46.2%
Worry - 53.8%	Worry- 38.5%
Constipation – 53.8%	Bathing/dressing - 30.8%

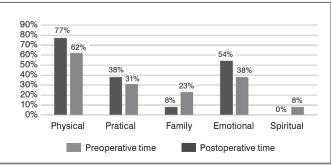


Figure 5. Prevalence of problems by category in patients with appendicular skeletal metastasis.

DISCUSSION

Bone metastasis is part of the natural history of the disease in a large proportion patients with cancer, ranging from one third to one fifth of ill patients in total.¹² The presence of the lesion is usually associated with pain and reduced mobility, which strongly impact patient's independence, capacity to perform daily activities, and, consequently, quality of life.¹³The reconstruction of bone metastases with endoprosthesis is one of the main treatment options for this condition. However, the procedure is not performed frequently, as most tumors are treated conservatively and not all patients are clinically stable enough to undergo a major surgery. Maybe because of that, even in the largest prospective studies found, the total number of surgeries was not superior to 20 a year.^{6,13}

Regarding the tool used, the DT was developed in the late 1990s similarly to the pain scale, with scores ranging from 0 to 10, where values equal to or below 4 indicate need of referral to a psychosocial care service.¹⁴Over the years, hospitals included the DT in their clinical protocols. In 2004, the Canadian public health agency recognized distress as the sixth vital sign, along with heart rate, respiration, blood pressure, temperature, and pain.⁷In the present study, the administration of DT was easy and fast, with good acceptance both by the researchers and by the patients. The use of a broad problem list provides guidance about the measures which may be taken to reduce patients' level of distress. As it encompasses many different areas, the DT also favors the patient, contributing to an interdisciplinary and comprehensive treatment.¹⁵

The participants of this study obtained a 30% reduction in the mean distress scoreas well as a lower frequency of moderate/severe distress in a short time after surgery, showing that reconstruction with endoprosthesis leads toan early improvement in quality of life. (Figures 2, 3, and 4) Such findings are of great importance in individuals that often have low estimated survival.

Direct comparison of our results was not possible because of a lack of similar studies. When we compared groups of patients with different profiles, we found that our preoperative distress score was higher than those found by Tuinman et al.¹⁶ and Lera et al.¹⁷However, scores were similar after surgical intervention, close to a grade 4 distress. Conversely, those authors did not stratify patients according to surgical treatment, which could have provided better grounds for comparison. There was a predominance of pain among the problems reported by the participants preoperatively, when almost 80% of the sample provided a positive answer to this item. After the reconstruction surgery the percentage reduced to a little less than half of the patients. Both results were above those found in the literature,¹⁸ which shows that pain is an important component both in preoperative care and in recovery after surgery. Another important finding was the prevalence of physical and emotional problems as reported by the patients in the two assessments. These two categories of problems had the strongest correlation with the reported level of distress,¹⁹ and in our study more than one third of the patients showed at least one problem in each of these areas.

Because of the severe condition of the evaluated patients, there was a significant number of deaths in less than 30 days of follow-up. This led to a small final sample, which is the main limitation of this study. Our study shows how the treatment of appendicular skeletal metastasis with endoprosthesis may result in an early reduction in the level of distress reported by patients. Knowledge of the most common problems at different times may also better guide the team regarding the pre- and postoperative care of the patient, besides favoring a comprehensive treatment.

CONCLUSION

Patients undergoing treatment of appendicular skeletal metastasis with endoprosthesis tend to show a reduction inlevel of distress as demonstrated by the DT tool.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. MCF (0000-0002-4402-8895)*: substantial contribution in the conception and design of the work and acquisition of data for the study; PRA (0000-0002-1813-2242)*: surgeries; acquisition and analysis of data for the study; critical review of the article and participation in the intellectual concept of the article; JPAR (0000-0001-6238-3041)*: acquisition of data for the study; LS (0000-0001-7903-3996)*: acquisition, analysis and interpretation of data for the study, writing of the manuscript and critical review of its intellectual content; GJPM (0000-0002-5877-6472)*: surgeries; critical review of the article and participation in the intellectual concept of the article; AVBR (0000-0002-8492-4774)*: surgery; critical review of the article. *ORCID (Open Researcher and Contributor ID).

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DISTAL HUMERAL FRACTURE: AN EPIDEMIOLOGICAL ANALYSIS OF ORTHOPEDIC PATIENTS FOR CHILDREN

FRATURA DE ÚMERO DISTAL: UMA ANÁLISE EPIDEMIOLÓGICA DE PACIENTES ORTOPÉDICOS INFANTIS

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ABSTRACT

Objective: To analyze the epidemiological profiles of children with orthopedic distal humerus fractures. Methods: An analytical descriptive study was conducted with a retrospective approach using medical records of 665 orthopedic children who attended the Jesser Amarante Faria Children's Hospital, a reference hospital in the city of Joinville, Santa Catarina, between June 2012 and December 2016. Results: The results showed a predominance of male patients (64.2%), with a mean age of 7 years, and the age group of 6–10 years being the most frequent with 319 patients (48%). The main mechanism of trauma was fall of height in 59.7% of patients, Gartland type 1 fracture in 57.1%, and absence of vascular injury in 99.7%. Conservative management was implemented in 64.7% (95%) of patients. Absence of neurological lesion (95.6%) and closed lesion (99.4%) were the main epidemiological characteristics of patients in the study. A low complication rate was observed, with reduction losses in 1.7% of patients, followed by infections in 1.1%. Conclusion: We can conclude that the cases studied presented epidemiological characteristics similar to those described in the literature. Level of evidence IV, Description of a case series, with analysis of results, without a comparative study.

Keywords: Humeral fractures, Supracondylar, Elbow fracture, Pediatric.

RESUMO

Objetivo: Analisar o perfil epidemiológico de pacientes ortopédicos infantis com fratura de úmero distal. Método: Estudo analítico-descritivo, com abordagem retrospectiva dos prontuários médicos de 665 pacientes ortopédicos infantis, atendidos no Hospital Infantil Dr. Jeser Amarante Faria, referência no município de Joinville (SC), do período de junho de 2012 a dezembro de 2016. Resultados: Os resultados mostraram um predomínio de pacientes do sexo masculino (64,2%), com idade média de 7 anos, sendo a faixa etária de 6 a 10 anos a mais frequente, com 319 (48%) pacientes. O principal mecanismo do trauma foi por queda da própria altura (59,7%), com Gartland 1 em 57,1% dos casos e ausência de lesão vascular (99,7%). A conduta conservadora foi observada em 64,7% dos pacientes, além de ausência de complicações imediatas (97,1%), complicações tardias (95,3%) e lesão neurológica (95,6%). Lesão fechada (99,4%) foi a principal característica epidemiológica dos pacientes estudados. Uma baixa frequência de complicações foi observada, sendo mais prevalentes as perdas de reduções (1,7%), seguidas de infecções, em 1,1% dos casos. Conclusões: Os casos estudados apresentaram características epidemiológicas semelhantes àquelas descritas na literatura. Nível de evidência IV, Descrição de série de casos, com análise de resultados, sem estudo comparativo.

Descritores: Fratura do úmero. Supracondiliana. Fratura do cotovelo, pediatrica.

Citation: Fernandes Jr JCF, Milan TV, Ribeiro HAMF, Stein HE, Filho HCR, Carula BC. Distal humero fracture: an epidemiological analysis of orthopedic patients for children. Acta Ortop Bras. [online]. 2019;27(5):261-4. Available from URL: http://www.scielo.br/aob.

INTRODUCION

Within the fractures of the elbow in infancy, supracondylar fractures represent the majority with 55%, being the second most common fracture in infancy, accounting for 15% of all childhood fractures. There is a predominance in males where the right upper limb is the most affected. The mean age of children affected by this pathology is 5-7 years¹.

Supracondylar humeral fractures in children are divided into extension or flexion. Those in extension correspond to up to 95% of the cases, while in flexion they occur from 5 to 10%. Falls are the main mechanism of trauma of this pathology varying according to the attitude of the limb at the time of the trauma, or in the extension or flexed. Due to the proximity to noble structures this type of fracture

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

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Article received in 10/26/2018, approved in 03/18/2019.

presents important complications, being the lesion of the brachial artery and the radial nerve the most common lesions¹.

The most used classification is Gartland, which subdivides them into 3 types, namely type I: the displacement is minimal or non-existent where the fracture can be visualized on radiographs, and the sign of the fat pad may be observed, type II: Although the fracture has posterior displacement, the posterior integrity of the bone cortex is preserved and type III: there is displacement and interruption in the posterior cortical bone with loss of contact between fragments. The distal fragment is shifted posteriorly and proximally by triceps contraction in extension fractures. In the flexural fractures, the displacement of the distal fragment occurs anteriorly¹.

Some studies report that the age and severity of the fracture, identified by the Gartland criteria, have a prognostic value in the final range of motion of the elbow. The recover after these fracture, but they have long-term complications. It was observed that the majority of Gartland type I fractures presented good results, and types II and III were varied according to the personality of each fracture.

During the bibliographic research on the topic, it was verified the existence of several studies involving fractures of the distal humerus in children, some analyzing the epidemiology and others evaluating the surgical technique of approach, pointing out that it is necessary a regional study that provides reliable data.

Having knowledge about the affected population and its particularities, as the age group with the highest incidence, as well as of greater severity, can assist in the assembly of specific strategies for each group, providing better assistance to these Patients both in intra and extra-hospital environment.

Thus, patients benefit from adequate and optimized guidance and follow-up, aimed at their age group and associated conditions, avoiding not only outcomes such as death, but also sequelae, resulting in a better quality of life post-intervention.

This research aimed to perform an epidemiological analysis of pediatric orthopedic patients, with fracture of the distal humerus, attended in the emergency room of the Pediatric Hospital Dr. Jesser Amarante Faria in the period from June 2012 to December 2016.

MATERIAL AND METHODS

Analytical-descriptive and retrospective study of 665 medical records of patients attended at the Pediatric Hospital Dr. Jesser Amarante Faria -HJAF, reference in the municipality of Joinville - Santa Catarina, from June 2012 to December of 2016.

Patients with distal humeral fracture treated at the HJAF in the aforementioned period were included in this project, which information from their medical records responded to at least 6 questions of the established protocol. Patients with other types of fracture were excluded from the research and also those who did not present information that answered at least 6 questions of the research protocol. Descriptive and inferential statistical methods were applied to analyze the data of orthopedic patients seen in the HJAF, being presented as graphs and tables and interpreted from the descriptive statistics with the help of the program BioEstat version 5.3.

All the patients involved in the research were evaluated according to the precepts of the Declaration of Helsinque and the Nuremberg code, respecting the norms of research involving human beings (resolution No. 196/96) of the National Health Council, guaranteeing the Confidentiality of patient identification. This work was submitted to the ethics committee, being approved on 06/14/17 (caae: 66741317.3.0000.5363)

RESULTS

The present study analyzed data from n = 665 trauma patients, attended at a children's hospital. These patients are 64.2% male (415 patients) and 37.6% female (250 patients). The age distribution

of the patients had a mean of 7.2 years with a standard deviation of 3.6 years, being the age group of 6 to 10 years the most frequent with 319 patients (48%), as you can see in Table 1.

The sample distribution according to the patient's age range shows that the expected values are as follows: from 0 to 2 years (4.1%), from 3 to 5 years (31.7%), from 6 to 10 years (47.8%) and adolescents (16.4%). These are the main characteristics found in the medical records: mechanism of trauma due to fall of own height (59.7%), with Gartland I (57.1%), absence of vascular injury (99.7%), being found only in 2 patients with vascular injury, conduct Conservative 64.7%, absence of immediate complications 97.1%, absence of late complications 95.3%, absence of neurological injury 95.6% and closed lesion 99.4%.

Table 1. Epidemiological profile of patients with distal humeral fracture, attended at the Pediatric Hospital Dr. Jesser Amarante Faria - HJAF, in the city of Joinville - Santa Catarina, from June 2012 to December 2016.

	Ma	ale	Fen	nale	То	tal	- · ·
Socio-demographic profile	n	%	n	%	n	%	P-value ¹
Age							0.0015**
0 to 2 years	14	3.4	13	5.2	27	4.1	
3 to 5 years	113	27.2	99	39.6	212	31.9	
6 to 10 years	210	50.6	109	43.6	319	48.0	
Uninformed	78	18.8	29	11.6	107	16.1	
Trauma Mechanism							0.5779 ^{ns}
Running over injuries	6	1.4	2	0.8	8	1.2	
Fall from own height	244	58.8	153	61.2	397	59.7	
Agression	2	0.5	0	0	2	0.3	
Fall/Height	133	32.0	77	30.8	210	31.6	
Uninformed	30	7.2	18	7.2	48	7.2	
Diagnostic							0.0025**
GARTL I	220	53.0	160	64.0	380	57.1	
GARTL II	65	15.7	42	16.8	107	16.1	
GARTL III	130	31.3	48	19.2	178	26.8	
Vascular injury							0.7143 ^{ns}
Present	2	0.5	0	0	2	0.3	
Absent	413	99.5	250	100	663	99.7	
Conduct							0.0129*
Conservative	253	61.0	177	70.8	430	64.7	
Surgical	162	39.0	73	29.2	235	35.3	
Immediate Complications							0.3287 ^{ns}
Absent	401	96.6	245	98	646	97.1	
Compartment Syndrome	0	0.0	1	0.4	1	0.2	
Infection	5	1.2	2	0.8	7	1.1	
Loss of reduction	9	2.2	2	0.8	11	1.7	
Late Complications							0.7798 ^{ns}
Absent	393	94.7	241	96.4	634	95.3	
Infection	7	1.7	3	1.2	10	1.5	
Vicious consolidations	1	0.2	0	0	1	0.2	
Angular deformities	4	1.0	1	0.4	5	0.8	
Joint Stiffness	10	2.4	5	2	15	2.3	
Neurological Injury							0.3007 ^{ns}
Absent	394	94.9	242	96.8	636	95.6	
Radial	12	2.9	2	0.8	14	2.1	
Median	4	1.0	3	1.2	7	1.1	
Ulnar	5	1.2	3	1.2	8	1.2	
Closed or Exposed							0.9986 ^{ns}
Closed	413	99.5	248	99.2	661	99.4	
Exposed	2	0.5	2	0.8	4	0.6	

Source: Medical records of the Pediatric Hospital Dr. Jesser Amarante Faria - HJAF (2018).¹ Pearson's chi-squared test for trend. ** Highly significant values; *Significant values; ^{NS} Non significant values. H₁: There is a significant trend in the level 0.05 (p<0.05). On the other hand, the variables that presented real association with the sex of the patient were these. Age (P = 0.0015 *, statistically significant) in the range of 3 to 5 years: male (27.2%) and female (39.6%). Gartland III (p = 0.0025 *, statistically significant): male (31.3%) and female (19.2%). The surgical procedure (p = 0.0129 *, statistically significant): male (39%) and female (29%).

It was found that both in the immediate complications (P < 0.0001 *) and in the late complications (P < 0.0001 *) There was a statistically significant predominance for conservative conduct with no complications.

The evaluation of the diagnosis showed A highly significant tendency (P < 0.0001 *) to: Gartland I Conservative conduct 87.2% and surgical Conduct-Gartland III 74.2% (Table 2).

The evaluation of Gartland according to the immediate complications resulted in the P-value < 0.0001 * (highly significant) indicating that in Gartland I absence of complication is more frequent in conservative conduct (99.8%). The evaluation of the conduct according to the late complications resulted in the P-value < 0.0001 * (highly significant) indicating that the absence of complication is more frequent in the conservative conduct (99.8%). The evaluation of the conduct according to the late complication frequent in the absence of complication is more frequent in the conservative conduct (99.8%). The evaluation of the conduct according to Gartland resulted in the P-value < 0.0001 * (highly significant) indicating that Gartland III is more frequent in the surgical conduct (74.0%), and its demonstrated in Table 3.

Table 2. Distribution of patients with distal humeral fracture, attended atPediatric Hospital Dr. Jesser Amarante Faria - HJAF, in the municipalityof Joinville - Santa Catarina, in the period from June 2012 to December2016, according to the type of conduct and the presence of complicationsand diagnosis.

Olinia Drafila		C	onduc	t			D Valua1
Clinic Profile	Conse	rvative	Sur	gical	Ger	eral	P-Value ¹
	n	%	n	%	n	%	
Immediate Complications							<0.0001**
Absent	428	99.8	218	92.4	646	97.1	
Compartmental Syndrome	0	0.0	1	0.4	1	0.2	
Infection	0	0.0	7	3.0	7	1.1	
Loss reduction	1	0.2	10	4.2	11	1.7	
Late Complications							<0.0001**
Absent	428	99.8	205	86.9	633	95.2	
Infection	0	0.0	10	4.2	10	1.5	
Vicious consolidations	0	0.0	1	0.4	1	0.2	
Angular deformities	1	0.2	4	1.7	5	0.8	
Joint Stiffness	0	0.0	15	6.4	15	2.3	
Diagnostic							<0.0001**
GARTL I	374	87.2	6	2.5	380	57.1	
GARTL II	52	12.1	55	23.3	107	16.1	
GARTL III	3	0.7	175	74.2	178	26.8	

Source: Medical records of the Pediatric Hospital Dr. Jesser Amarante Faria - HJAF (2018).¹ Pearson's chi-squared test for trend. ** Highly significant values; *Significant values; ^{NS} Non significant values. H_i: There is a significant trend in the level 0.05 (p<0.05).

DISCUSSION

In our series, the most significantly affected age are between 6 and 10 years old, with an average of 7.2 years, similar to other studies in which the described media age is around 7.9 years as found in Houshian's work. In relation to gender, the highest prevalence in boys was 64.2% of males in relation to 37.7% of females, which corresponds with the study of Houshian⁶, but diverges from the work of Barr¹ that found a higher prevalence in girls.

It was not possible to define the most affected dominance due to the lack of data in the medical records, but a higher frequency of involvement of the left arm was verified in relation to the right **Table 3.** Distribution of patients with distal humeral fracture, attended at thePediatric Hospital Dr. Jesser Amarante Faria - HJAF, in the municipality ofJoinville - Santa Catarina, from June 2012 to December 2016, accordingto the Gartland classification and the presence of complications.

		GARTL	1				
Clinic Profile	GI		GII		G III		P-value ¹
	n	%	n	%	n	%	
Immediate Complications							<0.0001**
Absent	380	100.0	102	95.3	164	92.1	
Compartmental Syndrome	0	0.0	1	0.9	0	0.0	
Infection	0	0.0	0	0.0	7	3.9	
Loss of reduction	0	0.0	4	3.7	7	3.9	
Late Complications							<0.0001**
Absent	380	100.0	100	93.5	154	86.5	
Infection	0	0.0	3	2.8	7	3.9	
Vicious consolidation	0	0.0	0	0.0	1	0.6	
Rotation deformity	0	0.0	3	2.8	2	1.1	
Joint Stiffness	0	0.0	1	0.9	14	7.9	
Source: Medical records of the P	ediatric	Hospit	al Dr. J	esser A	marante	e Faria	- HJAF (2018).1

Source: Medical records of the Pediatric Hospital Dr. Jesser Amarante Farra - HJAF (2018). Pearson's chi-squared test for trend, ** Highly significant values; *Significant values; NS Non significant values. H,: There is a significant trend in the level 0.05 (p<0.05).

arm, which goes according to the findings of the work of Barr¹ that Reported an impairment of 59% on the left side, and Sinikumpu⁵, which found a higher prevalence on the right side.

It was observed a high prevalence of fractures resulting from the fall of the own height (59.7%), followed by falls of heights (31.6%), when compared to the work of Barr¹, we noticed a higher number of falls in height, and we related this fact to the period in which the study was carried out, coinciding with the school vacation period, which makes children more susceptible to falls from heights while they are in the external environment, our work has a longer scope of time not taking into consideration the month in which the trauma occurred. However, this research goes according the results found in the work of Omid, Choi and Skaggs³, which attributed the occurrence of falls from their own height to the locality, where there is a predominance of residences without recreational area. We found exposed fracture rates that are compatible with the literature (0.6% of all fractures) as well as nerve injury (4.4%) being the most prevalent of the radial nerve (2.1%) agreeing with Omid, Choi and Skaggs³ and Martini, the same occurs for vascular lesions, which in this research was identified injury in only 2 patients, consistent with the maximum number stipulated by Omid, Choi and Skaggs³ who observed that these lesions did not exceed 3%. Considering the total of 655 patients, it was found that 57.1% of the patients were classified as Gartland 1, according to Barr1 the most common, but diverges from the results presented by Martini⁶ and Omid, Choi and Skaggs³, it is believed that these discrepancies are related to kinematics and to the mechanism of trauma, since the patients in this research, as previously mentioned, were victims of low-energy falls, such as falling from their own height, and already in the cited references the mechanism of trauma most common would be the falls of the height, resulting in greater energy.

As for the treatment, there is a supremacy of conservative treatment in relation to surgery, 64.7% and 35.3% respectively, this due to the choice to treat type II fractures conservatively in a large number of cases, this way we found a divergence in relation to the data found by Martini⁶, since it had a media of 76% of the cases, being treated as surgical and correlated this divergence to the prevalence of Gartland III fractures in the cited study.

Regarding the immediate complications, there was a low number of complications in this study, with more prevalent losses of reductions (1.7%), followed by infections (1.1%), which is within the values described in the literature as shown by the review of Omid, Choi and Skaggs³.

Reduces losses were related to Gartland II and Gartland III fractures, 4 and 7 patients, respectively. As for the late complications, we found a small number of joint stiffness (15 patients), 14 of whom were initially classified as Gartland III, related to this the time of immobilization and initial severity of the lesion, but all showed improvement after physiotherapy. Considering the deformities, we found a "n" of 5 patients, representing 2.3% of the patients, within the limits presented by Omid, Choi and Skaggs³.

CONCLUSION

Analyzing the epidemiological profile of patients with distal humeral fracture, a predominance of males with a mean age of 7.2 years was

observed, the main mechanism of trauma was the fall of the own height and the most prevalent Gartland classification was Type I. The most accomplished treatment was the conservative with absence of immediate complications and absence of late complications in most cases. Analyzing the conducts according to the Gartland classification it was noted that the type I obtained 87.2% of the conservative conducts, while Gartland II obtained 23.3% of the surgical conducts together with type III with 74.2%. Among the immediate and late complications, the Gartland type I fracture did not present any alterations, whereas type II was the main immediate complication of loss of reduction with 3.7%, and 2.8% of infection and angular deviation as late complications, while observed that type III presented 3.9% of infection and loss of reduction in immediate complications and 7.9% of joint stiffness in late complications.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this manuscript. JCFFJ (0000-0002-5687-8774)* *: manuscript drafting and review; TVM (0000-0003-1891-5148)*: data analysis and manuscript drafting; HAMFR (000-0002-2633-2463) *: manuscript review; HES (0000-0003-0469-8605)*: study conception and design; HCRF (000-0002-2633-2463)*: manuscript review and the intellectual concept of the article; BCC (0000-0001-9739-4867)*: data collection. *ORCID (Open Researcher and Contributor ID).

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PREVALENCE OF POPEYE DEFORMITY AFTER LONG HEAD BICEPS TENOTOMY AND TENODESIS

PREDOMÍNIO DA DEFORMIDADE DE POPEYE APÓS TENOTOMIA E TENODESE DA CABEÇA LONGA DO BÍCEPS

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ABSTRACT

Objective: To evaluate whether body mass index (BMI) 30 can be used as a cut-off point in decisions about whether or not to perform long head biceps (LHB) tenodesis, leading to a low rate of esthetic complaints, and to compare two tenodesis techniques. Methods: Ninety-six patients underwent shoulder arthroscopy where tenotomy was performed separately in patients with a BMI \geq 30 and was followed by tenodesis when BMI <30. The patients were assessed on the basis of their personal perception of the deformity and by 3 independent observers. Results: The patient's perception of esthetic deformity in the arm was 15.6%. In the tenotomy group (12.5%) and in the tenodesis group (17.9%) -(p = 0.476). Patients with rocambole-like tenodesis perceived the deformity in 13.2% of cases, while patients with anchor tenodesis noticed the deformity 27.8% (p = 0.263) of the time. There was no statistical difference in the perception of deformity among the independent examiners. Conclusion: BMI 30 can be used as a cut-off point in decisions about whether or not to perform LHB tenodesis, leading to low rates of esthetic complaint by patients (12.5%). The rocambole-like tenodesis technique appears to be more able to avoid esthetic deformity of the arm after the LHB tenotomy according to the patients' observations. Level of evidence II, Prospective comparative study.

Keywords: Shoulder/surgery. Arthroscopy. Tenotomy. Obesity.

RESUMO

Objetivo: Avaliar se índice de massa corporal (IMC) 30 pode ser utilizado como ponto de corte nas decisões sobre realizar ou não a tenodese da cabeça longa do bíceps (CLB), levando a um baixo índice de queixa estética, e comparar duas técnicas de tenodese. Métodos: Foram submetidos à cirurgia artroscópica no ombro 96 pacientes, sendo a tenotomia realizada de forma isolada nos pacientes com IMC \geq 30 e seguida de tenodese quando IMC < 30. Os pacientes foram avaliados por sua percepção pessoal da deformidade e por três observadores independentes. Resultados: A percepção da deformidade estética no braço pelo paciente foi de 15,6%. No grupo tenotomia (12,5%) e no grupo tenodese (17,9%) - (p=0,476). Pacientes com tenodese rocambole perceberam a deformidade em 13,2% dos casos, enquanto os pacientes com tenodese em âncora a notaram em 27,8% das vezes (p=0,263). Não houve diferença estatística para a percepção da deformidade entre os examinadores independentes. Conclusão: IMC 30 pode ser usado como ponto de corte nas decisões sobre realizar ou não a tenodese da CLB, levando a baixos índices de queixa estética por parte dos pacientes (12,5%). A técnica de tenodese tipo rocambole parece ter mais capacidade de evitar a deformidade estética do braço após a tenotomia da CLB, conforme a observação dos pacientes (13,2%). Nível de evidência II, estudo prospectivo comparativo.

Descritores: Ombro/cirurgia. Artroscopia. Tenotomia. Obesidade.

Citation: Almeida A, Gobbi LF, Almeida NC, Agostini AP, Garcia AF. Prevalence of popeye deformity after long head biceps tenotomy and tenodesis. Acta Ortop Bras. [online]. 2019;27(5):265-8. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

The long biceps head (LHB) is a frequent source of pain in the shoulder joint.¹ The literature is controversial for the different forms of surgical approach of painful LHB in the failure of conservative treatment and the suggested procedures vary from the surgical debridement of LHB, the isolated tenotomy and tenotomy followed by tenodesis.¹⁻³ Arthroscopic debridement is indicated when there are signs of LHB tendonitis and involvement of less than 50% of tendon thickness.³

In the presence of lesions that compromise 50% or more of LHB thickness, in the presence of instability in the bicipital sulcus or degenerative SLAP lesion, tenotomy, whether or not followed by LHB tenodesis is necessary.³

Isolated LHB tenotomy is an excellent treatment alternative. It is a simple technique, with low morbidity and rapid rehabilitation, but it is not free of complications. Among the reported complications are fatigue, arm discomfort, Popeye's deformity, and loss of flexion

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

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Article received in 11/19/2018, approved in 05/23/2019.



and supination elbow strength.^{1,3,4} there are no valid criteria in the literature to define which patient will evolve well with an isolated tenotomy of LHB and which patient will require tenodesis.

The main objective of this research is to evaluate if the Body Mass Index (BMI) of 30 can be used as a cut-off point in decisions about whether or not to perform the LHB tenodesis, leading to a low rate of aesthetic complaint by the patients. As a secondary objective, we will compare two techniques of tenodesis, regarding the ability to avoid the aesthetic deformity of the arm.

METHODS

The study was prospective. We evaluated 96 patients submitted to arthroscopic surgery on one shoulder, from January 10, 2010 to July 27, 2017. The study was submitted to the institution's ethics committee (CAAE 40167714.8.0000.5331). Every patient received an informed consent form that was signed and filed with the institution. No revision surgeries and any patient presenting with a history of surgery, atrophy or any aesthetic modification in the contralateral upper limb that could compromise the visual comparison between the upper limbs were chosen for this study.

The mean age of the patients was 57 ± 8.5 years. With regard to sex, 63 patients (65.6% -ICC95%: 55.2% -75%) were female. The dominant side was affected in 78 (81.3% -ICC95%: 72% -84.5%) patients.

All patients underwent height and weight measurements in the immediate preoperative period. The values found were used to calculate the BMI through the specific equation.⁵ The result is obtained when dividing the weight (in kilos) by the square of the height (in meters). Its result is given in "kg / M2": BMI = Weight / Height² (Table 1).

The surgeries were always performed by the senior surgeon with the patient positioned in lateral decubitus, with the upper limb (UL) abducted at 30°, flexed at 20° and with longitudinal traction of 5 kg. Whenever a compromise of 50% or more of the LHB thickness, an intertubercular groove instability, or a degenerative SLAP lesion was found, the patient was elected to the study and the LHB tenotomy was performed with a Trimmer forceps in its insertion in the upper lip of the glenoid. It was performed in isolation in patients with a BMI \geq 30 kg/m² and was followed by tenodesis when BMI<30 kg/m².

In the group of patients with BMI<30 kg/m², two tenodesis techniques were used. The anchor tenodesis was used whenever was found an injury of the Subscapular or lesion of the medial pulley of the LHB and the "rocombole" tenodesis⁶ in the other cases. In the anchor tenodesis, a 5.0 Super-Revo[®] pre-loaded with two high strength wires was used in the bicipital groove. In the "rocombole" tenodesis⁶ the LHB is exteriorized through the anterior portal and rolled onto itself until it is about 3 times its normal thickness, then it is repositioned at the joint, preventing its sliding in the bicipital groove.

Patients were divided into 3 groups. The Tenotomy Group consisted of 40 patients, the "Rocombole" Tenodesis Group

Table 1.	
Classification	BMI
Very Low Weight	16 a 16,9 Kg/m ²
Low Weight	17 a 18,4 Kg/m ²
Normal	18,5 a 24,9 Kg/m ²
Overweight	25 a 29,9 Kg/m ²
Obesity Grade 1	30 a 34,9 Kg/m ²
Obesity Grade 2	35 a 40 Kg/m ²
Obesity Grade 3 (Morbid)	>40 Kg/m ²

Classification of the degrees of obesity according to the values of the Body Mass Index.

composed of 38 patients and the Anchor Tenodesis Group composed of 18 patients.

All patients were immobilized with a neutral rotation sling. Regardless of the procedure performed at the LHB, the patients received guidance to avoid forced elbow flexion as well as their full extension within the first four weeks postoperatively.

The patients were evaluated with a median of 8 months (IIQ 6-15.5 months) postoperative. At the evaluation, the attending physician informed each patient that he would be questioned about his aesthetic perception of the operated UL, and that other professionals would photograph him for the purpose of aesthetic evaluation. It was again clarified, according to the terms of the Informed Consent previously signed, that there would be no exposure of its identification.

Patients were asked about their perception of any aesthetic deformity in their operated arm.

The patients were photographed with an Apple-branded cell phone at a distance of 60 cm, with the UL adducted at the trunk, the elbow at 90 degrees and the forearm in maximal supination. The photographs were performed in ambient light, hiding the patient's face and exposing the arm with the shoulder and elbow joints.

Patient photographs of 8x5 cm were placed in a blue-and-green Microsoft PowerPoint presentation. The photo of the operated UL was on the left and the photo of the contralateral UL on the right. (Figures 1, 2, and 3) The Microsoft-Powerpoint presentation was examined by three professionals with specialization in shoulder surgery, where they were invited to observe each slide separately for a maximum time of 60 seconds and to mark in the response grid if he observed or not some aesthetic deformity that could result from a distal migration of the LHB. No descriptive patient data or clinical history was revealed.

The studied variables were: age, sex, operated side, dominance, perception of deformity by the patient, perception of the deformity by the professional specialist and degree of agreement among the specialists.

The data were analyzed with the statistical package SPSS 20.0 (IBM SPSS Inc., 2011). For the statistical analysis, the following were used: calculation of means, standard deviation, median, frequency and percentage. The t-student test for age assessment was used. The Chi-square test and Fisher's exact test were used when the variables were categorical. A one-digit numerical precision was used after the comma in the presentation of the data, except for the data of the value P where three digits remained. A 5% α (p <0.005) and a 90% β were considered statistically significant.



Figure 1. Examples of patient photos in the Microsoft-Powerpoint presentation.



Figure 2. Examples of patient photos in the Microsoft-Powerpoint presentation.



Figure 3. Examples of patient photos in the Microsoft-Powerpoint presentation.

RESULTS

The perception of the aesthetic deformity by the patient resulting from the bicipital shortening was 15.6% (15 patients). Two patients reported crackling in the bicipital sulcus (2%).

The perception of aesthetic deformity in the tenotomy group was 12.5% (ICC95%: 2.2% -22.7%) (5/40), whereas in patients who underwent tenodesis it was 17.9% (ICC95 % 7.8% -27.8%) (10/56) (p = 0.476). Patients who underwent rocambole-type tenodesis perceived the aesthetic deformity in 13.2% (ICC95%: 2.4% -23.9%) (5/38), while the patients submitted to tenodesis with anchor in 27.8% (ICC95%: 7.1% -48.5%) (5/18) (p = 0.263).

The specialists who analyzed the photos of the patients were named as examiner 1, 2 and 3.

Examiner 1 verified the aesthetic deformity in 3 patients (3/40) who underwent LHB tenotomy (7.5% -ICC95%: 1.6% -20.4%) and in 18 patients (18/56) who underwent tenodesis (32.1% -ICC95%: 20.3% -46.0%) (p = 0.004).

The examiner 2 verified the aesthetic deformity in 14 patients (14/40) who underwent LHB tenotomy (35% -ICC95%: 20.6% -51.7%) and in 19 patients (19/56) who were submitted to tenodesis (33.9% -ICC95%: 21.8% -47.8%) (p = 0.913).

The examiner 3 verified the aesthetic deformity in 12 patients (12/40) who underwent LHB tenotomy (30% -ICC95%: 16.6% -46.5%) and in 26 patients (26/56) who were submitted to tenodesis (46.4% -ICC95%: 33% -60.3%) (p = 0.105).

The examiner 1 verified the aesthetic deformity in 11 patients (11/38) who underwent "rocombole" tenodesis (28.9% -ICC95%: 15.4%

-45.9%) and in 7 patients (7/18) who underwent anchor tenodesis (38.9% -ICC95%: 17.3% -64.3%) (p = 0.457).

Examiner 2 verified the aesthetic deformity in 14 patients (14/38) who underwent "rocombole" tenodesis (36.8% -ICC95%: 21.8% -54%) and in 5 patients (5/18) who underwent anchor tenodesis (27.8% -ICC95%: 9.7% -53.5%) (p = 0.503).

The examiner 3 verified the aesthetic deformity in 17 patients (17/38) who underwent "rocombole" tenodesis (44.7% -ICC95%: 21.8% -54%) and in 5 patients (9 / 18) who underwent anchor tenodesis (50% -ICC95%: 9.7% -53.5%) (p = 0.712).

DISCUSSION

The surgical treatment of LHB pathologies is indicated when occurs failure of the conservative treatment.^{1,3,7} Khazamet al.¹ consider indications for the surgical treatment of LHB lesions are partial lesions affecting more than 25% of the tendon diameter, longitudinal lesions, instabilities in the pulley and association with the injury of the subscapularis muscle tendon. Boileau et al.⁷ add to the previous list hourglass lesions and the detachment of the superior glenoid lip. Among the modalities of treatment of pathologies of LHB recommended in the literature are: debridement, isolated tenotomy and tenotomy of LHB followed by tenodesis.¹ Arthroscopic debridement is indicated when there are signs of chronic tendonitis and for lesions with involvement from 25% of tendon thickness, for some authors. or from 50% for others.^{1,3} The literature is even more controversial in lesions where there is a need for LHB tenotomy, due to the possibility of aesthetic deformity, loss of muscle strength and residual pain when this technique is performed in isolation. In our study, we indicated tenotomy followed or not by tenodesis for lesions that compromised 50% or more of tendon thickness, for instability in the bicipital groove or for the finding of degenerative SLAP lesion. For the indication of tenodesis after the LHB tenotomy, the most diverse subjective criteria are used. Godinho et al.6 and some other authors recommend tenodesis in young, active patients less than 50 years of age. Walch et al.² recommend not to perform isolated LHB tenotomy in patients under 55 years of age. Szabó et al.8 suggest tenodesis for more active patients and those under 60 years of age. There are authors who suggest avoiding isolated tenotomy of LHB in young patients without mentioning age. Checchia et al.⁹, recommends the isolated LHB tenotomy only in elderly patients. In our study, the age criterion was not used.

The LHB isolated arthroscopic tenotomy has some advantages, among which the following are cited: the lower morbidity of the procedure, fewer complications, faster performance, less interference with rehabilitation, and lower cost.^{2,10} However, the technique presents as disadvantages the deficiency of tension control in LHB, muscle atrophy, flexion and supination strength deficit of the elbow, painful popping in the intertubercular groove and, the main one of them, the aesthetic deformity in the arm after the distal migration of the LHB tenotomy.

Concerned with the residual aesthetic deformity of the patients, some authors analyzed the frequency of aesthetic complaint where LHB had been tenotomized. Boileau et al.⁷ found 66.6% of aesthetic complaint in their patients after the isolated LHB tenotomy. Maynou et al.¹¹ noted only 5% of aesthetic complaint. Lim et al.¹² found 45%; Delle Rose et al.,¹³ 37.5%; De Carli et al.¹⁴ 17% and Checchia et al.⁹ 8.3%. Slenker et al.¹⁵ carried out a systematic review of the literature. They observed that the presence of aesthetic deformity occurred in an average of 43% of the patients with isolated LHB tenotomy. We published a study in 2008¹⁶ evaluating the aesthetic complaint after the isolated LHB tenotomy and we verified 35.1% of aesthetic complaint after the different ages evaluated. However, male patients with BMI below 30 kg/m² and operated on the dominant UL showed a significantly higher

prevalence of aesthetic complaint. Kelly et al.⁴ also found a higher frequency of aesthetic complaints among men. On the other hand, Osbahr et al.¹⁷ did not find difference between sexes.

The aesthetic deformity may also occur after tenotomy followed by tenodesis.¹⁸ Godinho et al.⁶ verified 11.1% of aesthetic complaint by the patient after tenotomy followed by "rocambole" tenodesis. Checchia et al.,¹⁹ suturing the LHB in the rotator cuff lesion, verified 6.6% of aesthetic complaint.

Some authors have studied the perception of aesthetic deformity by the medical professional. Walch et al.,² followed the results of 307 LHB tenotomies and reported the difficulty in evaluating the presence of deformity in obese or elderly patients with weak muscle tone, eventually classifying them as dubious. In general, they verified the aesthetic deformity in 50.2% of their casuistry. Godinho et al.6 demonstrated that the ability to verify the residual deformity of the Popeye deformity is more concise in the professional. They used an independent examiner to assess the presence of the deformity after performing the LHB tenotomy associated with "rocambole" tenodesis. The professional verified the aesthetic deformity in 31.8% of the patients. Almeida et al.²⁰ analyzed the perception of aesthetic deformity after LHB tenotomy by different categories of professionals. They found that professionals specialized in shoulder surgery perceived the aesthetic deformity more frequently than general orthopedists and fellow residents and that, when obese patients were analyzed (BMI>30 kg/m²), the greatest capacity of perception of the deformity by the specialists was lost.

The absence of standardization and criteria that define the patients who must present more or less complaints of the residual aesthetic deformity after LHB tenotomy motivated the study. Using as an objective criterion, the BMI>30 kg/m² to perform the isolated LHB tenotomy we verified a 12.5% of aesthetic complaint in our patients. The result is about 1/3 of the amount of aesthetic complaint perceived

in the study previously published in 2008 (35.1%) .¹⁶ We believe that this criterion can be used with a certain degree of safety leaving both the medical professional and the patient, satisfied with the aesthetic aspect of the upper limb after the treatment of the bicipital pathology. We have not found studies comparing different LHB tenodesis techniques with regard to the ability to avoid Popeye's aesthetic deformity. Godinho et al.⁶ verified the perception of aesthetic deformity by 11.1% of the patients using the "rocambole" technique, without relation to the age group, sports practice or associated injury of the subscapularis tendon and its repair.

In our study, although there was a reduction in the perception of aesthetic deformity by the patient in "rocambole" tenodesis, this was not significant. Also when we verified the difference of perception of aesthetic deformity by the medical professional, we did not find statistical significance.

We believe that it is extremely difficult to find objective criteria to avoid aesthetic complaint, due to subjectivity influenced by various personal, psychological and social factors. We considered bias of our study the limited number of the sample and the lack of randomization in the choice of patients.

CONCLUSION

The BMI 30 can be used as a cut-off point in decisions about whether or not to perform LHB tenodesis, leading to low rates of aesthetic complaint by patients.

The "rocambole" tenodesis technique seems to be more capable of avoiding the aesthetic deformity of the arm after LHB tenotomy, according to the observation of the patients, although the finding was not significant. The evaluation of aesthetic deformity by specialists in shoulder surgery did not show a difference between the two techniques of tenodesis.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. AA (0000-0002-6215-09) *: intellectual concept of the article and preparation of the entire research project. Writing and review of the article, and performing the surgeries. LFG (0000-0003-3173-4157)*: writing the article and data analysis. NCA (0000-0002-6251-1098)*: review of the article and data analysis. APA (0000-0001-7981-0521)*: data analysis, statistical analysis and review of the article. *ORCID (Open Researcher and Contributor ID).

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QUALITY OF LIFE IN PATIENTS WHO HAVE UNDERGONE REVERSE SHOULDER ARTHROPLASTY

QUALIDADE DE VIDA DE PACIENTES SUBMETIDOS À ARTROPLASTIA REVERSA DO OMBRO

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ABSTRACT

Objective: To evaluate the health-related quality of life (HRQoL) of patients who have undergone reverse shoulder arthroplasty (RSA) for rotator cuff arthropathy (RCA). Methods: A retrospective study with 35 patients who underwent RSA from August 2007 to July 2015. We collected clinical data and applied the 36-item Short Form Health Survey (SF-36). Results: Of the 35 patients, 29 (82.9%) were female, and mean age was 75.71 years, ranging from 50 to 89 years. The dominant side was frequently affected (68.6%), and most of the cases were Hamada type 3 (57.1%). The Mackenzie approach was used in 30 patients (85.7%). Physical and mental HRQoL was not associated with severity of RCA before RSA. Lower scores for Physical Functioning, Role Physical, Bodily Pain, and Physical Component Summary (PCS) were associated with other orthopedic comorbidities. Vitality, Role Emotional, Mental Health, and Mental Component Summary (MCS) were significantly higher in patients without depression. Orthopedic comorbidity and depression predicted lower PCS and longer follow-up time predicted better PCS scores. Depression was also a predictor of the MCS. Conclusion: Patients who had undergone RSA for RCA had good HRQoL. Longer follow-up time was associated with better HRQoL. Good results were maintained over the follow-up period. Level of evidence II, retrospective study.

Keywords: Rotator Cuff Tear Arthropathy. Shoulder. Arthroplasty. Quality of Life.

RESUMO

Objetivo: Avaliar a qualidade de vida relacionada à saúde (QVRS) de pacientes com artropatia do manguito rotador (AMR) submetidos à artroplastia reversa do ombro (ARO). Métodos: Estudo retrospectivo com 35 pacientes submetidos à ARO, de agosto de 2007 a julho de 2015. Foram coletados dados clínicos, e foi aplicado o guestionário 36-Item Short-Form Health Survey (SF-36). Resultados: Dos 35 pacientes, 29 (82,9%) eram mulheres, e a média de idade foi de 75,71 anos, variando de 50 a 89 anos. O lado dominante foi frequentemente afetado (68.6%). A maioria dos casos foi Hamada tipo 3 (57.1%). A abordagem Mackenzie foi utilizada em 30 pacientes (85,7%). A QVRS física e mental não foi associada à gravidade da AMR antes da ARO. Pontuações menores de Capacidade Funcional, Aspectos Físicos, Dor e Componente de Saúde Física (CSF) foram associadas a outras comorbidades ortopédicas. Vitalidade, Aspectos Emocionais, Saúde Mental e Componente de Saúde Mental (CSM) foram significativamente maiores nos pacientes sem depressão. Comorbidades ortopédicas e depressão foram preditores de menor PCS, e maior tempo de seguimento foi preditor de CSF. Depressão também foi preditor do CSM. Conclusão: Pacientes submetidos à ARO por AMR apresentaram boa QVRS. Maior tempo de acompanhamento foi associado à melhor QVRS. Bons resultados foram mantidos durante o acompanhamento. Nível de evidência II, estudo retrospectivo.

Descritores: Artropatia de Ruptura do Manguito Rotador. Ombro. Artroplastia. Qualidade de Vida.

Citation: Leite LMB, Lins-Kusterer L, Belangero PS, Patriota G, Ejnisman B. Quality of life in patients who have undergone reverse shoulder arthroplasty. Acta Ortop Bras. [online]. 2019;27(5):269-72. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Rotator cuff arthropathy (RCA) is defined as the combination of glenohumeral arthritis and extensive rupture of the rotator cuff tendons.¹ RCA affects approximately 4% of the population with rotator cuff rupture.² In RCA, patients present pain, weakness, muscular atrophy, reduction of strength, deficits in the shoulder active and passive movement. Posterosuperior and extensive anterosuperior ruptures of the rotator cuff lead to progressive loss of abduction force, anterior elevation and external rotation and eventually pseudoparalysis.³ Although there are a few other operative possibilities, the RSA seems to be an effective treatment in cases of RCA, allowing considerable clinical and functional improvement.⁴

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

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Article received in 04/20/2019, approved in 06/06/2019.



Health-related quality of life is a multidimensional and polysemic concept that usually comprises subjective assessments of positive and negative aspects of an individual's physical and mental health as well as aspects of self-perceived well-being related to or affected by diseases and treatments.⁵ Some studies report improvement of health-related quality of life (HRQoL) and functionality after RSA.⁶ However, most of them present a short follow-up period and did not evaluate the predictors of functional results after RSA. There are studies with long follow-up periods for cases with total shoulder prosthesis,⁷ but any study evaluated RSA. We aimed to evaluate the health-related quality of life and its predictors in patients submitted to RSA for RCA.

MATERIALS AND METHODS

Study design and population

We conducted a retrospective study. From August 2007 to July 2015, we performed 51 RSA in 38 patients with RCA refractory to conservative treatment. We used the ARROW® (FH France) prosthesis in all cases. Three patients were lost during follow-up. Thirty-five patients were available for final follow-up. Clinical data were collected and the 36-item Short Form Health Survey (SF-36)⁸ was applied during patient evaluation. The inclusion criteria were: follow-up greater than 2 years; RCA as the underlying disease; Hamada score greater than or equal to three^{9,10} and age greater than 50 years. (Figure 1)

The Hamada classification^{9,10} is a radiographic classification of extensive rotator cuff lesions. Such classification was mainly based on the acromiohumeral interval (AHI). In Grade 1 of Hamada, the AH1 was more than 6 mm, and in Grade 2, the AH1 was 5 mm or less. In Grade 3, acetabulization (a concave deformity of the acromion undersurface) was added to the Grade 2; In Grade 4, narrowing of the glenohumeral joint was added to the Grade 3 characteristics. Grade 5 comprised instances of humeral-head collapse with evident signs of avascular collapse and necrosis of the humeral head, representing the maximum degree of RCA evolution.

We used one of the two commonly approach in RSA, the Mackenzie approach (anterior–superior) or deltopectoral approach.^{1,11} The minimum follow-up time was two years and the maximum was 10 years, mean of 5.25 years. There was no loss of follow-up due to

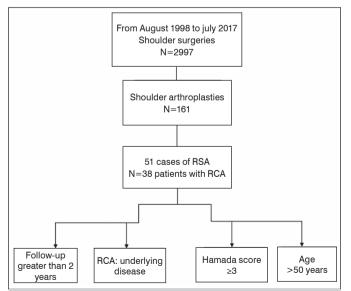


Figure 1. Flow chart of the selection of 35 patients with rotator cuff arthropathy, submitted to reverse shoulder arthroplasty from August 2007 to July 2015, Salvador, Bahia 2018.

natural death in this sample. We did not have any cases of patients undergoing reverse arthroplasty as a follow-up of another previous arthroplasty, and cases of patients undergoing reverse arthroplasty associated with muscle transfer.¹²

HRQoL instrument

We applied the SF-36 questionnaire to all included patients. The 36-Item Short Form Health Survey (SF-36) is a generic HRQoL instrument composed of eight domains: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and mental health functional capacity (MH). The SF-36 scores were normalized by QualityMetric Health Outcomes ™ Scoring Software 4.5, transforming scores to a mean of 50 and standard deviation of 10. The eight domains were aggregated into Physical Component Summary and the Mental Component Summary scores. The normalization process enables comparisons among the scales of the respective domain or summaries component scale.^{5,8} The license was obtained by the Optum's PRO Core and Executing License Agreement: @ QM043387. Cronbach's Alpha coefficient was used to evaluate the internal consistency. We considered values under 0.60 to 0.70 as satisfactory¹³ and higher than 0.70 as ideal.

Statistical analysis

We described mean, standard deviation, and range for the continuous variables, whereas categorical variables were described by frequencies and proportions. We used Mann-Whitney non-parametric tests to compare the SF-36 means differences among different groups. The chi-square test was used to evaluate the association of two categorical variables. Data were analyzed by using the Statistical Package for the Social Sciences 22 (SPSS).

Ethical procedures

The study was approved by the Ethics Review Board of São Paulo Hospital, Federal University of São Paulo under the Certificate of Presentation of Ethical Appreciation (number 2.795.825) in accordance with the Declaration of Helsinki 2013 and the National Council Resolution 466/12 and. All participants were informed and signed a consent form approved by the Ethics Board.

RESULTS

Our study enrolled 35 patients; 29 (82.9%) females and 6 (17.1%) males, and mean age 75.7 years, ranging from 50 to 89 years. The dominant side was frequently affected (68.6%), most of the cases were Hamada 3 (57.1%) followed by Hamada type 4 (42.9%). Mackenzie approach was used in 30 (85.7%) patients, while the deltopectoral approach, in 5 (14.3%) patients. The minimum follow-up time was two years and the maximum was 10 years, mean of 5.25 years. There was no loss of follow-up due to natural death in this sample. Of the 35 surgeries, five intra-operative RSA complications were observed: one acromial fracture, two glenoid fractures, one fracture on the humeral side, and a compressive injury of the axillary nerve. The cases were treated with immobilization, fixation and associated corticosteroid therapy. All cases presented resolution after 60 days. The means of HRQoL domains of these patients did not differ from those without any intra-operative complications (P>0.05%).

Table 2 shows the eight normalized SF-36 domains, physical and mental components summaries, and Cronbach's Alpha coefficient. Physical Functioning, Role Physical and Role Emotional were below average, but within the standard deviation. All SF-36 domains had reliability above the desirable Cronbach's Alpha (≥ 0.6).

HRQoL was also evaluated in both physical and mental aspects, considering severity of RCA. According to Hamada classification (3 or 4), there were no statistical differences in means of SF-36

 Table 1. Characteristics of 35 patients submitted to reverse shoulder arthroplasty between August 2007 and July 2015, Salvador, Bahia, Brazil, 2018.

29 (82.9)
75.7 (50 - 89)
24 (68.6)
11 (31.4)
20 (57.1)
15 (42.9)
5 (14.3)
30 (85.7)
5.25 (2 a 10)

Table 2. Mean, Standard deviation, and internal reliability of the eight SF-36v2 domains of the 35 patients submitted to ARS, Salvador, Bahia, Brazil, 2018.

SF-36 Domains	Mean ± SD	Cronbach's Alpha
Physical Functioning (PF)	47.55 ± 10.26	0.91
Role Physical (RP)	46.28 ± 12.36	0.92
Bodily Pain (BP)	52.26 ± 8.36	0.74
General Health (GH)	55.40 ± 7.09	0.68
Vitality (VT)	61.67 ± 8.41	0.78
Social Functioning (SF)	52.14 ± 6.86	0.61
Role Emotional (RE)	45.75 ± 12.64	0.88
Mental Health (MH)	53.83 ± 10.99	0.77
Physical Component Summary (PCS)	50.01 ± 7.66	-
Mental Component Summary (MCS)	54.05 ± 9.03	-

domains and its physical (P=0.227) and mental (P=0.400) components summaries between the two groups. We stratified the sample in two groups according to the age: less than 75 years of age and equal to or greater than 75 years, and no statistical significance was also observed in both physical (PCS, P=0.805) and mental (MCS, P=0.730) component summaries. No statistical differences in PCS (P=0.268) and MCS (P=0.831) mean scores were observed between patients followed up for less than five years and patients followed up for five years or more.

We analyzed the SF-36 physical domains and the Physical Component Summary according to the presence or absence of other orthopedic comorbidities, which were not related to RSA surgery. PF (P = 0.007), RP (P = 0.001), BP (p = 0.008), and PCS (P=0.001) were significantly higher in patients without other orthopedic impairment (Table 3).

We also evaluated SF-36 mental health domains and the Mental Component Summary according to the occurrence of new cases of depression during the follow-up period. VT (P = 0.025), RE (P = 0.029), MH (0.003), and MCS (p = 0.003) were significantly higher in patients without depression (Table 4).

The association of predictor variables with the SF-36 physical and mental components was explored using multivariate linear regression analysis. (Table 5) Having other orthopedic comorbidity (P = 0.0001), depression (P = 0.001), and longer follow-up time (P = 0.041) were predictors of the Physical Component Summary Score. The variable depression (P = 0.002) was a good predictor of the Mental Component Summary (P = 0.002).

Table 3. Mean, Standard deviation of the SF-36 physical domains and physical component summary according to presence or absence of other orthopedic comorbidity in 35 patients submitted to ARS, Salvador, Bahia, Brazil, 2018.

SF-36 domains	With other orthopedic comorbidity N=11	Without other orthopedic comorbidity N=24	P*
Physical Functioning (PF)	41.12 ± 8.95	50.50 ± 9.59	0.007
Role Physical (RP)	34.38 ± 8.63	51.74 ± 9.73	0.001
Bodily Pain (BP)	46.98 ± 6.35	54.68 ± 8.15	0.008
General Health (GH)	54.33 ± 5.83	55.89 ± 7.66	0.451
Vitality (VT)	60.88 ± 7.84	62.03 ± 8.80	0.684
Physical Component Summary (PCS)	42.31 ± 4.67	53.54 ± 6.00	0.001

*Mann-Whitney test.

Table 4. Mean, Standard deviation of the SF-36 mental health domains and mental component summary according to the depression in 35 patients submitted to ARS, Salvador, Bahia, Brazil, 2018.

Depression N=5	No depression N=30	P*				
53.31 ± 6.12	63.03 ± 7.99	0.025				
53.88 ± 4.85	51.85 ± 7.16	0.664				
32.16 ± 13.73	48.01 ± 11.15	0.029				
39.08 ± 9.32	56.29 ± 9.32	0.003				
43.08 ± 4.03	52.77 ± 8.32	0.003				
	$\begin{array}{c} \textbf{N=5} \\ \hline 53.31 \pm 6.12 \\ \hline 53.88 \pm 4.85 \\ \hline 32.16 \pm 13.73 \\ \hline 39.08 \pm 9.32 \end{array}$	N=5 N=30 53.31 ± 6.12 63.03 ± 7.99 53.88 ± 4.85 51.85 ± 7.16 32.16 ± 13.73 48.01 ± 11.15 39.08 ± 9.32 56.29 ± 9.32				

*Mann-Whitney test.

Table 5. Results of a multiple linear regression equation having PCS and MCS as the dependent variables in 35 patients submitted to reverse shoulder arthroplasty between August 2007 and July 2015, Salvador, Bahia, Brazil, 2018.

	PCS* (R ² = 48%)		
Variables	В	EPB	P*
Constant	52.14	1.852	.0001
Other orthopedic comorbidity	-14.08	1.773	.0001
Depression	284	2.315	.001
Surgical time	-8.07	.307	.041
	MCS** (R ² = 25%)		
Variables	В	EPB	P*
Constant	55.88	1.447	0.0001
Depression	-12.80	3.830	0.002

The numbers in columns are regression coefficients (B), standard errors (SE_B) and P values. *PCS- Physical Component Summary; ** Mental Component Summary.

DISCUSSION

Reverse shoulder arthroplasty has been widely used in the last decade, however, there are few reports of quality of life after this surgery. In our study, physical and mental HRQoL was not associated with severity of RCA before RSA, nor either with age. Decreases in Physical Functioning, Role Physical, Bodily Pain and Physical Component Summary were associated with other orthopedic comorbidities, not related to RSA. Vitality, Role Emotional, Mental Health, and Mental Component Summary were significantly higher in patients without depression. Multivariate linear regression showed that having other orthopedic comorbidities and depression were predictors of lower Physical Component Summary (PCS) scores and longer follow-up time was a good predictor of PCS scores. Depression was also a predictor of the Mental Component Summary scores. Solved intra-operative RSA complications did not interfere in HRQoL during follow-up evaluation.

HRQoL comprises patients' subjective assessments of physical and mental health related to or affected by diseases and treatments.⁵ Considering patients' integrality, we opted for the use of the 36-Item Short Form Health Survey questionnaire (SF-36), which is widely used for health-related quality of life outcomes and allowed us to evaluate not only physical aspects of HRQoL but also the mental ones.⁸ Furthermore, all SF-36 domains presented good reliability, being above the desirable Cronbach's Alpha (≥ 0.6).¹³

There are some concerns about the use of the reverse prostheses in elderly patients related to the decreases in prosthesis duration, functionality and health-related quality of life outcomes.¹⁴⁻¹⁷ Our data showed no statistically significant differences between patients with less than 75 years of age and equal to or greater than 75 years in both PCS (P=0.805) and MCS (P=0.730) SF-36 component summaries. These data corroborate with a previous report,¹⁴ showing good outcomes in terms of function, satisfaction and quality of life recovery in elderly submitted to RSA. Age above 70 years has been reported as a predictor of decreased return to sports activities.¹⁸

The scientific literature reports the association of advanced age and comorbidities with RSA complications and low functional outcome.¹⁴ Satisfaction with treatment was associated with decreasing in pain and improvements in shoulder range of motion, and strength⁷ in 320 total shoulder surgeries (TSS). We found associations of other orthopedic comorbidities with lower HRQoL Physical Functioning (P = 0.007), Role Physical (P = 0.001), Bodily Pain (p = 0.008) and PCS (P=0.001), but not with age as we reported before. HRQoL improvement after RSA⁶ has been reported in studies with shorter follow-up time and no predictors of HRQoL were described. In our study, multivariate linear regression analysis evidenced that having other orthopedic comorbidities (P = 0.0001) and depression (P = 0.001) were predictors of lower PCS, while higher follow-up

time (P = 0.041) was predictors for higher PCS. Depression (P = 0.002) was a predictor of MCS (P = 0.002).

Health-related quality of life indicators did not differ significantly PCS (P=0.268) and MCS (P=0.831) - according to the time (<5; \geq 5 years) elapsed after surgery. HRQoL scores were similar to the general population even in those with higher time of RSA follow-up. However, multivariate linear regression identified longer follow-up time as a predictor of higher Physical Component Summary score (P=0.041). These findings are in accordance with a previous report⁶ that in a five-year follow-up period found similar functionality and health-related quality of life between patients who had undergone RSA and healthy controls that were followed up for less than five years. Physical (PCS, P=0.227) and Mental (MCS, P=0.400) Momponent Summaries did not differ significantly according to RSA severity (Hamada 3 and Hamada 4).

Retrospective design, case series, and small sample size are some limitations of this study. Further, it was not possible to evaluate the SF-36 questionnaire and degree of physical activity preoperatively. However, our study was carried out with the casuistic of only one surgeon, we used the same prostheses brand in all patients and all patients had the same underline disease. Our sample is relevant for the homogeneity of included cases and time of follow-up.

Patients submitted to RSA for RCA presented good health-related quality of life, considering both mental and physical SF-36 scores. Lower Physical Functioning, Role Physical, Bodily Pain and Physical Component Summary scores were associated with other orthopedic comorbidities. Lower Vitality, Role Emotional, Mental Health and Mental Component Summary scores were associated with depression. Having other orthopedic comorbidity and depression were predictors of lower Physical Component Summary and longer follow-up time was a predictor of PCS scores. Depression was also a predictor of the Mental Component Summary.

AUTHORS' CONTRIBUTIONS: This manuscript, which describes a multi-institutional study, has five authors. Each author made significant individual contributions to this manuscript. LMBL (0000-0001-6324-7797)* contributed to the project design, surgeries, data collection, data interpretation analysis, writing of the article, and approval for publication. L L-K (0000-0003-3736-0002)* contributed to the data analysis, statistical analysis, critical review of the text, and approval for publication, PSB (0000-0003-4441-4742)* contributed to the data analysis, critical review of the text, and approval for publication, GP (0000-0002-0488-0944)* contributed to the data analysis, critical review of the text, and approval for publication, BE (0000-0002-3301-1457)* contributed to the data analysis, research supervision, critical review of the text, and approval for publication. *ORCID (Open Researcher and Contributor ID).

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A RETROSPECTIVE CASE-SERIES ON THE USE OF S53P4 BIOACTIVE GLASS FOR THE ADJUNCTIVE TREATMENT OF SEPTIC DIAPHYSEAL NON-UNION

SÉRIE DE CASOS RETROSPECTIVO SOBRE O USO DO VIDRO BIOATIVO S53P4 COMO ADJUVANTE NO TRATAMENTO DE PSEUDOARTROSES INFECTADAS DA DIÁFISE DOS OSSOS LONGOS

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ABSTRACT

Objective: Non-union and persistence of infection at a fracture site for long periods are always described as a challenge to orthopedists, especially in cases of severe compound fractures with comminution and segmental bone loss. This is a case series of septic non-unions, using S53P4 bioactive glass for adjunctive treatment, using internal syntheses or external fixators. The objective is to retrospectively evaluate the results of the use of S53P4 bioglass for the adjunctive treatment of septic non-unions. Methods: We reviewed 18 patients with septic non-unions. The patients were preoperatively classified using the Non-union Scoring System (NUSS) and union outcomes were assessed by the modified radiographic union scale in tibial (RUST) fractures. Of the 18 patients treated, six underwent internal osteosynthesis and 12 were treated with external fixators in combination with bioactive glass grafting. Results: The patients had a mean NUSS score of 56.6 (standard deviation of 7.6) and fracture union was achieved according to the RUST score in 17 of 18 cases (94.4%), with a mean value of 10.2 (standard deviation of 1.0). One patient was lost to follow-up. Reevaluation using the modified RUST score was 12.3 (SD = 1.0), maintaining union of 17/18. Conclusion: The fracture union rate was high, according to the literature, as was control of infection. Level of Evidence IV, Case series.

Keywords: Bone Diseases, Infectious. Fracture Healing. Bone Substitutes. Fractures, Ununited. Fracture Fixation. Osteomyelitis.

RESUMO

Objetivo: A não união e a persistência de infecção no local de uma fratura por períodos prolongados são sempre descritas como desafios para os ortopedistas, especialmente em casos de fraturas expostas graves, com cominuição e perdas de segmentos ósseos. Esta é uma série de casos de não consolidações infectadas, utilizando o vidro bioativo S53P4 como adjuvante no tratamento, utilizando-se sínteses internas ou fixadores externos. O objetivo é avaliar retrospectivamente os resultados do uso do biovidro S53P4 como adjuvante no tratamento de não uniões infectadas. Métodos: Foram revistos 18 pacientes com não consolidações infectadas. Os pacientes foram classificados antes da cirurgia pelo Non-Union Severity Score (NUSS), e os resultados quanto à consolidação foram avaliados pelo escore de RUST modificado (escala radiográfica de consolidação da tíbia). Dos 18 pacientes tratados, seis foram submetidos à osteossíntese interna e 12 foram tratados com fixadores externos, associados à enxertia com vidro bioativo. Resultados: Os pacientes tinham resultado NUSS médio de 56,6 (desvio padrão de 7,6) e a consolidação foi obtida segundo o escore de RUST em 17 de 18 casos (94,4%), com valor médio de 10,2 (desvio padrão de 1.0). Um paciente abandonou o seguimento. A reavaliação pelo escore de RUST modificado foi de 12,3 (PF=1,0), mantendo a consolidação de 17/18. Conclusão: O índice de consolidação foi elevado, segundo a literatura, bem como controle infeccioso. Nível de evidência IV, série de casos.

Descritores: Doenças Ósseas Infecciosas. Consolidação da Fratura. Substitutos Ósseos. Fraturas não Consolidadas. Fixação de Fratura. Osteomielite.

Citation: Gaiarsa GP, Reis PR, Kojima KE, Silva JS, Lima ALLM. A retrospective case-series on the use of s53p4 bioactive glass for the adjunctive treatment of septic diaphyseal non-union. Acta Ortop Bras. [online]. 2019;27(5):273-5. Available from URL: http://www.scielo.br/aob.

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

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Article received in 02/28/2019, approved in 05/23/2019.



INTRODUCTION

Although definitions vary, infected or septic nonunion is defined as a state of failure of union and persistence of infection at the fracture site for 6 to 8 months.¹ Infected non-unions of long bones are mostly due to a severe open fracture with extensive comminution and segmental bone loss or after internal fixation of a comminuted closed fracture.² Associated risk factors include exposed bone devoid of vascularized periosteal coverage, purulent discharge, positive bacterial cultures from the deep surrounding wound tissues, and necrotic bone containing empty lacunae. Septic non-unions of the long bones present a significant challenge to the orthopedic surgeon in providing optimal treatment for this condition. Soft-tissue loss with multiple sinuses, osteomvelitis, osteopenia, complex deformities with limb-length inequality. stiffness of adjacent joint, multidrug-resistant infections, and smoking all complicate treatment as well as recovery. Careful debridement of necrotic tissue, protection of the soft tissue and restoration of viable vascularity to the infected site have been the goals of the surgical procedure to adequately treat osteomyelitis and septic nonunion fractures. Unfortunately, appropriate tissue debridement can leave considerable bone defects, which might be filled by bone grafts, as adjuvant to surgical and antibiotic treatments.³ There are several limitations related to the application of autologous bone graft harvesting and its consequences to the donor site.^{4,5} Thus, researches on the use of bone graft substitutes has gained importance over the past. Bioactive glass [BAG] is a bone graft substitute for cavitary lesions with potential long-term inhibition on bacterial growth.6

This is a case series report on the application of bioactive glass [BAG] in the management of septic non-unions. To our knowledge, there is no previous report of BAG use for this indication in the literature. This may be an interesting area for future research on BAGs and Nonunion.

MATERIALS AND METHODS

This is a retrospective study on 18 patients clinically and radiologically diagnosed with septic nonunion of long bones and treated by surgical procedure associated with bioactive glass BAG-S53P4 BonAlive® Granules (BonAlive®, Finland) from July 2011 to July 2015. All patients were followed-up for at least one year after surgery and the Nonunion Score System (NUSS)^{1,7} was applied for pre-surgical severity evaluation and at 12 months follow-up for treatment guide. Patients underwent surgery with soft tissue coverage, infected bone resection, and application of BAG-S53P4 as a scaffold at the nonunion site, with internal synthesis or external frame fixation. All patients were also submitted to systemic antibiotic therapy administered for 3 to 6 months after surgery, as determined by the hospital's protocol. The outcomes were assessed by digital X-Rays and bone healing evaluation according to the Radiographic Union Scale In Tibial fractures (RUST) score^{8,9} and Modified RUST score^{10,11} at discharge visit after being followed up for up to two years, considering patients had either removed their external fixator or were healed with no deformities, pain, or new fractures at final visit. Results are descriptive and expressed in terms of mean and standard deviations (SDs). Approved By the Cientific committee under the number IOT1303. As a retrospective study no informed consent was signed.

RESULTS

Eighteen (18) patients, 6 females (33%) and 12 males (67%), were surgically treated for septic nonunion and underwent resection, BAG-S53P4 application with either internal (n = 6, 33%) or external frame fixation (n = 12, 67%). Mean age at surgery date was

33.6 ± 12.6 years-old, with an age range of 19 to 59 years-old. Patients had mean NUSS of 56.6 ± 7.6 points with a range of 44 to 74 points. The bones affected were tibia in 50% and femur in 50%. From the 12 patients who used external fixators, mean time to withdrawal in month was 7.2 ± 5.6 with a range of 3.2 to 22.6. After two years follow-up, radiological healing was achieved in 17/18 (94.4%) with mean RUST score of 10.2 ± 1.0 One patient was lost to follow-up.

DISCUSSION

Vital factors are involved in bone healing, including cellular environment, growth factors, bone matrix, mechanical stability and vascularization.^{7,12} Based on this, multiple concomitant therapies (or so called polytherapy) have been proposed for fracture healing particularly in nonunions,⁷ such as surgical implantation of mesenchymal stem cells (MSCs) at the nonunion sites, growth factors applications, and use of scaffolds (osteoconductive material), all aimed at stimulating the cascade of events for ultimate bone repair. Nevertheless, adequate treatment of osteomyelitis and septic non-unions is challenging and must include careful debridement of necrotic tissue, protection of the soft tissue and restoration of viable vascularity to the infected area. However, appropriate tissue debridement can leave considerable bone defects and the present case-series autologous bone graft harvesting was not an option. Thus, bioactive glass [BAG] was used as bone graft substitute for cavitary lesions for these septic nonunion and segmental lesions.

Traditional classification systems for bone non-unions are not validated for treatment follow-ups; thus Calori et al.^{1,13} proposed and validated the Nonunion Score System [NUSS], aiming at comparing results of similar severity nonunion cases in order to direct treatment strategies. This classification gives points to 8 bone quality and fracture/nonunion characteristics, 1 soft tissue status, and 6 patient blood tests/associated diseases status, and gives a severity score for non-unions. The first group should have usual treatment, bone graft, decortication, nail exchange or plate augmentation, the second group should receive specialized attention, the third group, over 50 points, should receive specialized attention with the Diamond concept. All patients in the present case-series were NUSS group 3 (44 to 74 points); (over 75 points should be submitted to amputation) with nonunion lesions classified as complex and characterized by impairment of both biological and mechanic conditions for bone healing. Their treatments involved resection of the nonunion and the remaining bone defect was approached by bone filling with BAG and with either internal or external fixation. Their treatments were partly in accordance with the treatment algorithm previously proposed as principles of polytherapy,¹³ with application of one of the biotechnological approaches, such as cells, scaffold and growth factors. In the present case-series, patients were treated with surgical resection, internal or external fixators and, instead of the proposed biotechnological approaches, BAG was applied at the nonunion site based on its potential to act as a scaffold and angiogenesis capacity and on its proven osteo-stimulation and antibacterial properties.¹⁴ On cavitary defects is was left as a standalone bone graft, on segmental bone defects it was compressed on the bone transport during the reabsorption period. Average time for radiological healing was 7.2 months (SD = 5.6 months), with a range of 3.2 to 22.6, with one patient lost to follow-up and another patient presenting a non-infectious late complication outside of the follow-up window. Our radiological healing was comparable with radiological healing found in NUSS group 3 patients previously described (9.5 \pm 1.4 months).¹³

The present higher SD and ranges in our study were probably due to sample size of the case-series (11 *versus* 84).¹³ This case series reports successfully treated septic nonunion of fractures with BAG associated to internal or external fixation and surgical debridement. The use of RUST and Modified RUST score to evaluate consolidation is an effort to have more reliable data. RUST score evaluates each cortex on AP and Lateral view and gives 3 points, Modified RUST 4 points, 1 to no callus, 2 to callus formation, 3 to bridging callus, and 4 remodelling callus, a result over 11 points is considered healed.

CONCLUSION

Patients submitted to treatment on external frames the removal of the frame with no deformation and no refracture in a one year period is a strong evidence of consolidation. The 17 patients considered healed had over 11 points on modified RUST score, considered healed by the score. Further clinical studies are required to validate BAG effectiveness for non-union treatment, as the growing evidence of BAGs effectiveness on infection control was found by our data too.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. GPG (0000-0003-1481-3048)*: Surgical treatment and review of medical records. PRR (0000-0001-9126-4359)*: Surgical treatment and clinical follow-up. KEK (0000-0002-3700-2718)*: Review of manuscripts and classification. JSS (0000-0001-8901-3120)*: Review of manuscripts. ALLML (0000-0002-2396-9880)*: Clinical follow-up of infection and pertinent literature review. *ORCID (Open Researcher and Contributor ID).

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Systematic Review Article

QUALITY OF LIFE OF PATIENTS WITH SARCOMA AFTER CONSERVATIVE SURGERY OR AMPUTATION OF LIMBS

QUALIDADE DE VIDA DE PACIENTES COM SARCOMA APÓS CIRURGIA CONSERVADORA OU AMPUTAÇÃO DE MEMBROS

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ABSTRACT

Objective: To conduct an integrative review on quality of life (QOL) of patients with sarcoma who underwent conservative surgery or limb amputation. Methods: We conducted a six-step integrative review by searching the databases LILACS, SciELO, PePSIC, Embase, and PubMed, using the descriptors: "Quality of life", "Bone cancer", "Sarcoma", "Limb Salvage," and "Amputation." Ten studies were selected according to: database, type of study, methods, researcher's profession, sex, histological type, title, country/region, and periodical/year of publication. Results: Nine quantitative and one qualitative studies were included. All were conducted by physicians and correlated to QOL with the impact of diagnosis, psychosocial aspects, cancer treatment, and survival. Other aspects included type of surgery, functionality, rehabilitation, and a multidisciplinary approach. The QOL results were similar for conservative surgery and amputation in eight studies. In two, it was concluded that patients undergoing conservative surgery had a better QOL. Conclusion: The number of studies on QOL in patients with sarcoma is small. In most, there was no difference between the study groups. In addition, the studies indicated the importance of evaluation of QOL, since it has a direct effect on patients' physical manifestations and impacts their coping abilities. Level of evidence III, System review.

RESUMO

Objetivo: Conduzir uma revisão integrativa sobre gualidade de vida de pacientes com sarcoma, submetidos à cirurgia conservadora ou à amputação de membros. Métodos: Revisão integrativa em seis etapas, com busca nas bases de dados LILACS, SciELO, PePSIC, Embase e PubMed, utilizando--se os descritores: "gualidade de vida", "câncer ósseo", "sarcoma", "salvamento de membro" e "amputação". Dez estudos foram selecionados de acordo com banco de dados, tipo de estudo, método, profissão do pesquisador, sexo, tipo histológico, título, país/região, periódico/ano de publicação. Resultados: Foram incluídos nove estudos quantitativos e um qualitativo. Todos foram conduzidos por médicos e correlacionaram a qualidade de vida com impacto do diagnóstico, aspectos psicossociais, tratamento do câncer e sobrevida. Outros aspectos incluídos foram tipo de cirurgia, funcionalidade, reabilitação e abordagem multidisciplinar. Os resultados da qualidade de vida foram semelhantes para cirurgia conservadora e amputação em oito estudos. Em dois, concluiu-se que os pacientes submetidos à cirurgia conservadora tiveram melhor qualidade de vida. Conclusões: O número de estudos sobre qualidade de vida em pacientes com sarcoma foi pequeno. Na maioria, não houve diferenca entre os grupos. Além disso, os estudos indicaram a necessidade de valorizar a avaliação da qualidade de vida, pois esta tem efeito direto nas manifestações físicas e impacto no enfrentamento da doença. Nível de evidência III, Revisão sistemática.

Keywords: Quality of life; Sarcoma; Limb Salvage; Amputation.

Descritores: Qualidade de vida. Sarcoma. Salvamento de membro. Amputação.

Citation: Silva RS, Guilhem DB, Batista KT, Tabet LP. Quality of life of patients with sarcoma after conservative surgery or amputation of limbs. Acta Ortop Bras. [online]. 2019;27(5):276-80. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Sarcomas are rare (<1% of malignant neoplasms) and highly aggressive solid tumors. They affect all age groups, but their incidence is higher during childhood and adolescence. Further, they are the fifth leading cause of death due to cancer in children, adolescents, and young adults. They may occur at any anatomical location, but are more frequent in the extremities (60%) and three times more frequent in the legs than in the arms. The most common histological types are osteosarcomas, Ewing's sarcomas, and chondrosarcomas, accounting for 95% of all bone cancers. Lung metastases is frequently observed in the patients, particularly in those with Ewing's sarcomas (50%) and osteosarcomas (90%).¹ The oncological treatment is multimodal, including surgery of the primary tumor with limb-sparing surgery or amputation of

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

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Article received in 01/28/2019, approved in 03/13/2019



the affected limb, chemotherapy before surgery (neoadjuvant), chemotherapy after surgery (adjuvant), and radiotherapy for some histological types.¹

Cancer is a complex chronic disease, and its treatment requires an adequate infrastructure with material and human resources (a multi-professional team) and presents challenges to specialists and the society. The search for more effective and less mutilating treatments is necessary to cause minimal damage to the patient's quality of life (QOL) and functional abilities and to minimize psychological and emotional distress. Depending on the complexity of the case, in addition to the deterioration of QOL and psychological and emotional consequences, the patient may experience major physical and functional limitations.²

The concept of QOL has been studied in recent years through the integration of different areas of knowledge, such as medicine. social sciences, and psychology, and has been applied in a scientific and systematic manner since the 1970s.³ This concept has been systematized by the World Health Organization (WHO) and defined as physical, mental, and social well-being. It relates to the individual's perception about his/her health, personal satisfaction, correct diagnosis, adequate treatment, and cultural values.⁴ As a consequence of the change in paradigm for the understanding of health-disease process, from essentially biomedical to neglected socioeconomic, psychological, and social aspects, an interest in QOL as a global concept for health assessment has emerged.⁵ However, in some studies, the term "QOL" is still a synonym for physical health improvement. In literature, some studies have used this term considering only one of its dimensions, usually the physical dimension, without taking into account the psychological, environmental, and social dimensions.⁴

Currently, QOL in healthcare is very important, and WHO has developed instruments to assess QOL, within the multidimensional perspective, for several countries and cultures. The World Health Organization QOL Questionnaire (WHOQOL)⁶ instrument was initially created, and WHOQOLBREF followed, both of which have been validated for use in Brazil.⁷ Other specific instruments to access QOL that have been developed, such as the European Organization for Research and Treatment of Cancer Core QOL Questionnaire⁸ and the Functional Assessment of Cancer Therapy-General,⁹ were validated for use in Brazil, and they have been used in studies of patients with cancer.

The topic of QOL of patients with cancer has been frequently studied in the Brazilian and international literature. Therefore, the objective of the present study was to conduct a integrative review of the Brazilian and international literature on the QOL of patients with sarcoma who underwent limb-sparing surgery or amputation of upper or lower limbs.

MATERIALS AND METHODS

We did a integrative review to provides synthesis of knowledge and applicability of results of significant studies to practic. We did the six stages of the integrative review process by Ursi's data collect instrument:¹⁰ 1st phase - preparing the guiding question, 2st phase - searching or sampling the literature, 3st phase - data collection, 4st phase - critical analysis, 5 and 6st phase - discussion of results and presentation. 1st phase: the guiding question was "Patients with sarcoma undergoing conservative limb surgery have better quality of life than those undergoing amputation?" 2st phase - searching or sampling the literature in this study, the following databases were searched to obtain the abstracts of interest: LILACS, SciELO, PePSIC, Embase, and PubMed. The following descriptors were used: "*QOL*," "Bone cancer," "Sarcoma," "Limb-sparing surgery," and "Amputation." 3st phase - data collection.

The criteria of inclusion of studies for the present review were the following: full-text studies that assessed the QOL of patients with sarcoma of the upper or lower limbs who underwent limb-sparing surgery or amputation to resect the primary tumor, written in Portuguese, English, or Spanish, with no publication date limit imposition. The data collection was performed between March and December of 2018. The search, assessment, and selection of studies and the extraction of results were conducted by two independent reviewers. The criteria for exclusion of studies were the following: studies that assessed the QOL of patients with different types of cancer or other diseases who underwent limb-sparing surgery or amputation, studies that compared the QOL of patients with bone cancer with that of the normal population, studies that assessed the QOL only in patients who underwent limb-sparing surgery or only in patients who underwent amputation, studies that focused only on functionality of the operated limb or survival of the patients, studies that emphasized on the type of endoprosthesis used in limb-sparing procedures, case studies of a single patient, studies that assessed the QOL of caregivers of patients with cancer, and studies of animals. Finally, the articles of thirty-two studies on the topic were obtained, and the five databases were examined to ensure there were no duplicates. Of these, ten studies were selected for this review. Figure 1 shows the flowchart of the data-search process. The analysis of the categories and subcategories of the abstracts was based on the study by Castro and Remor:¹¹ database in which the article was indexed, Virtual Health Library, LILACS, SciELO, PePSIC, Embase, and PubMed; type of study, randomized clinical trial or observational study (cohort, case-control, cross-sectional, series, and case report); method used in the study, quantitative or gualitative; profession of the researcher who published the article

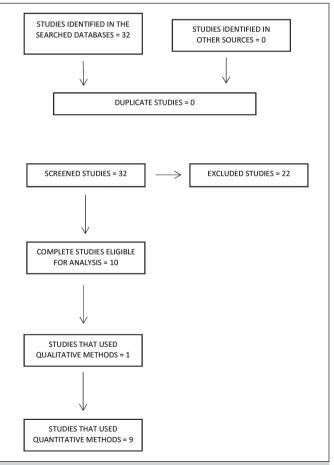


Figure 1. Flowchart of the data-search process.

(physician, psychologist, nurse, physiotherapist, multidisciplinary team, or others); sex of the participants; histological type of the participants' sarcoma; title of the article (QOL, functionality, impact of the disease, type of treatment, rehabilitation, survival, surgical technique, and instruments were the terms used to collect the data); country and region where the research was conducted; and journal in which the article was published and year of publication. Ethical approval: This article does not contain studies with human or animal participants by any of the authors.

RESULTS

It is important to note that the number of scientific studies on the QOL of patients with sarcoma is small. Moreover, when we focused on the studies on the QOL of patients who underwent different types of surgery (limb-sparing or amputation), the number of studies decreased considerably, from thirty-two to ten. There were no duplicated studies in the five analyzed databases. All studies on the QOL of patients with sarcoma who underwent limb-sparing surgery or amputation were indexed in a single database (PubMed). With regard to the method, there was a predominance of quantitative studies (90%) with one qualitative study (10%).

The researchers responsible for the ten selected studies were all physicians (100%) with the following specializations: oncology, hematology, and cancer surgery.

The majority of the studies (60%) did not have data on the sex of the participants, and the male sex predominated in those that did (60%). Further, 40% of the studies did not state the histological type of sarcoma, and in the remaining, there was a predominance of osteosarcoma (90%), followed by Ewing's sarcoma (6%) and chondrosarcoma (2%). Other histological types mentioned were spindle-cell sarcoma, myxoid sarcoma, and leiomyosarcoma. It is important to note that in studies with information regarding the affected limbs, the lower limbs were more often affected (93%) than the upper limbs (7%). With respect to the type of surgical procedure performed to resect the tumor, the percentages of amputation and limb-sparing surgery were similar (approximately 50% each). All studies correlated QOL with several aspects of the disease. A majority correlated QOL with the impact of the diagnosis, psychosocial aspects, treatment of the cancer, and survival. Other aspects were also associated with the QOL of these patients, namely the type of surgery and surgical technique, functionality of the operated limb, postoperative rehabilitation, and multidisciplinary approaches.

In the present review, the SF36¹² instrument was the most used (50%) to assess the QOL, followed by the EORTC QLQC30.8 Moreover, 30% of the studies used the Beck Depression Inventory¹³ to evaluate depressive symptoms and other psychological disorders that could interfere with these patients' QOL. In addition to the illness itself, mood disorders in individuals with cancer have been receiving increasing attention. An association between cancer and mood disorders, such as depression, is frequent and may be related to poor adherence to treatment, progress, and QOL of patients. Another important concern among the researchers was to correlate postoperative functionality of the operated limb with QOL of patients who underwent the two types of surgery (limb-sparing surgery or amputation). The instrument of the American Musculoskeletal Tumor Society¹⁴ was the most frequently used (70%) instrument among the studies, followed by other instruments, such as the Toronto Extremity Salvage Score¹⁵ and the Barthel Index for Activities of Daily Living¹⁶ to assess function. The country with the greatest number of publications was the United States, with 60% of the studies. These studies were conducted at the Sarcoma Center of the University of Texas MD Anderson Cancer Center in Houston, at the Ohio State University in Columbus, at the Mayo Clinic Schools of Medicine in Arizona and Florida, and at the Memorial Sloan-Kettering Cancer Center in New York City. The remaining studies were conducted in Japan, Germany, Sweden/ Norway, and Canada. It is important to note that we did not find any study conducted in Brazil on the researched topic that was eligible for inclusion in the present study.

There was a diversity of international journals that published on the topic. With regard to the year of publication, the articles for the ten studies were published between 1997 and 2013.

Finally, the results of QOL were similar among eight studies. However, in two studies, it was concluded that patients who underwent limb-sparing surgery had higher scores than those who underwent amputation. The conclusion of one qualitative study in our review was that the impact of surgical treatment on the QOL is based on the capacity to preserve anatomical structures necessary for function. With regard to functionality of the operated limb, three studies showed that patients who underwent limb-sparing surgery had higher scores than those who underwent amputation. Table 1 shows the studies included in the review according to author, journal, year, and country of publication, objective, methodology, and outcomes.

DISCUSSION

The critical analysis, discussion of results published on the QOL of patients with sarcoma who underwent limb-sparing surgery or amputation showed that the number of publications was small and that all considered QOL in its most encompassing context, including all domains as proposed and systematized by WHO. Although the concept of QOL used by WHO is encompassing, this view is not yet fully consolidated, which is demonstrated by the fact that most studies correlate QOL with treatment results, functionality of the operated limb, and survival of the patient.

The researchers investigated the physical, functional, and psychological aspects associated with the impact of the disease and with the surgical and oncological treatment. However, a large number of the excluded studies still used the concept of QOL, focusing only on physical well-being.⁴ There is a growing need to assess new procedures and medications for patients with bone cancers and at different stages of treatment. However, the attention of health professionals remains focused on the physical consequences of the disease and not on the QOL of the patient, taking into account the patient's subjective perception of his/her health.⁵

We emphasize on the fact that although the studies included in the present review address psychosocial aspects of QOL of patients with cancer, these studies were all conducted by physicians. The emotional challenges experienced by patients with cancer are many, including accepting the disease, dealing with visible body changes due to chemotherapy and surgery, dealing with changes to routines of daily life, and direct confrontation with death. For this reason, it is important that professionals from various areas of healthcare study this subject to provide integral care to patients and their families.²⁷ According to Aksnes et al.²² in their study with 118 patients with osteosarcoma and Ewing's sarcoma, chronic pain in patients with amputated lower limbs is associated with poor walking functionality and deterioration of QOL. In addition, it may hinder the fitting of prosthesis and return to work and school and may cause emotional and sexual changes. The authors state that leg amputation below the knee results in significantly better functionality than amputation above the knee. Griesser et al.²⁰ and Beck et al.²³ observed that patients who underwent limb-sparing surgery or hip disarticulation had significantly reduced functional and QOL outcomes associated with urinary tract changes. Conversely, Yonemoto et al.¹⁸ reported that better postoperative functionality of the operated limb does not necessarily guarantee a better QOL of the patient. This study showed that patients who underwent limb-sparing surgery had higher QOL scores.

Authors/ journals	Country/year	Objective	Methodology	Outcomes
Alan et al. ¹⁷	USA 1997	Assess the QOL of patients who underwent limb-sparing surgery or amputation of lower or upper limb.	Cross-sectional study N = 4 QOL = Instruments to measure psychosocial function, economic and overall well- being, and Beck Depression Inventory	The impact of treatment on QOL is based on the capacity to preserve structures necessary for function to meet the patient's expectations with appropriate oncologic treatments and on providing a rehabilitation program that can be followed in the long-term to improve functionality. The most used measures of QOL included measures of physical, psychosocial, economic and overall well-being.
Yonemoto et al. ¹⁸	JAPAN 2007	Assessment of the long-term QOL of osteosarcoma survivors who underwent amputation or limb-sparing surgery.	Prospective Cohort Study N =33 QOL = SF 36	The group of patients who underwent limb-sparing surgery had higher QOL scores than the group of amputation patients. There were no differences in function between patients who underwent amputation and those who did not. Side effects related to treatment, such as secondary neoplasms and infertility, were rare.
Ottaviani et al. ¹⁹	USA 2009	Assess the QOL of osteosarcoma survivors who underwent amputation or limb-sparing surgery.	Review study N = not reported QOL = SF36, Beck Depression Inventory	QOL in terms of functionality, psychological success, and effects on marriage and work did not differ significantly between patients with osteosarcoma who underwent amputation and those who did not. However, amputation patients appear to have made satisfactory adjustments to their deficits with or without a functional external prosthesis.
Griesser et al. ²⁰	USA 2012	Assess the QOL of patients who underwent hip amputation or conservative surgery.	Retrospective cohort study N = 15 QV = SF36	There was no statistical difference with regard to QOL and functionali between the groups. The patients' age had an impact on physical performance (the older the patient, the worse the physical performance Because of the small number of participants, it was not possible to observe statistically significant differences between the two groups.
Zahlten- Hinguranage et al. ²¹	GERMANY 2004	Assess the QOL and functionality of patients with lower-limb sarcoma who underwent amputation or limb-sparing surgery.	Retrospective cohort study N = 124 QOL = EORTC QLQC30	The results of the assessments of QOL were similar in both groups and the functionality scores were slightly higher among the patients who underwent limb-sparing surgery. The results showed that there is no advantage of limb-sparing surgery over amputation with regard to overall QOL.
Aksnes et al. ²²	SWEDEN and NORWAY 2008	Assessment of the long- term QOL and functionality of patients with sarcoma who underwent limb-sparing surgery or amputation.	Prospective cohort study N = 118 QOL = SF36	Patients who underwent amputation above the knee had lower functionality scores than patients who underwent limb-sparing surgery. There was no difference in QOL between patients who underwent amputation and to limb-sparing surgery. It was concluded that the majority of bone tumor survivors adapted to their physical limitations, were able to work, and had a good overall QOL.
Beck et al. ²³	USA 2008	Assess functional ability and QOL of patients with sarcoma who underwent hip amputation/disarticulation or conservative surgery.	Retrospective cohort study N = 97 QOL = EORTC QLQC30	There was no difference in functionality between the two groups; however, patients who underwent amputation/disarticulation had more phantom pain and greater intestinal/bladder involvement. There was no difference in QOL between the two groups. The majority of the participants of both groups were fully independent with regard to transportation, mobility, eating, and personal hygiene.
Rougraff et al ²⁴	USA 1994	Assessment of the long-term functional ability and QOL of patients with osteosarcoma of the distal femur who underwent limb-sparing surgery or amputation.	Prospective cohort study N = 127 QOL = Instruments to measure psychosocial function and Beck Depression Inventory	There were no significant differences in survival rates or in the duratic of disease-free periods after surgery between the two groups. Patien who underwent limb-sparing surgery had higher functionality scores th those who underwent amputation. No difference was observed betwee the groups with regard to the patient's acceptance of the postoperativ state, walking ability, or amount of pain. There was no apparent difference in psychosocial or QOL outcomes between the groups.
Gary et al ²⁵	USA 2013	Assess the overall QOL of lower-limb sarcoma survivors who underwent amputation or limb-sparing surgery.	Original article N = 82 QOL = QOL Questionnaire (QLQ), Minnesota Multiphasic Personality Inventory, and Visual Analog Scale	The overall QOL of the patients who underwent limb-sparing surgery was significantly better than that of patients who underwent amputation (p < 0.01). Significant differences were observed with regard to econor well-being, professional satisfaction, and occupational relationships
Ronald et al. ²⁶	CANADA 2009	Assess published studies on QOL and functionality of sarcoma survivors who underwent limb-sparing surgery or amputation.	Review study N = 2710 QOL = SF 36	Most studies showed that the functional outcomes were better among patients who underwent limb-sparing surgery than among those who underwent amputation. There were no differences in QOL between the groups.

QOL : Quality of life, SF-36: Medical Outcomes Short-Form Health Survey. EORTC QLQC30: European Organization for Research and Treatment of Cancer. QLQ: Quality of life Questionnaire.

Rougraff et al.,²⁴ in a prospective cohort study with 227 patients with osteosarcoma of the distal femur who underwent limb-sparing surgery or amputation observed that the best QOL was related to the capacity of preserving anatomical structures necessary for functioning and meeting the patient's expectations regardless of the type of surgery. They also concluded that increased hospitalization and postoperative recovery time have a negative impact on the patient's QOL. Moreover, Gary et al.,²⁵ stated the importance of ensuring that the surgical procedure preserves anatomical structures

required to sustain functioning and of undergoing a rehabilitation program with an interdisciplinary team. Zahlten-Hinguranage et al.,²¹ in a retrospective cohort study with 124 patients who underwent limb-sparing surgery or amputation of lower limbs, obtained similar results for QOL in both groups and observed that the best QOL was associated with the maintenance of physical, cognitive, and sexual functioning; phantom pain control; body image acceptance; and a perception of overall quality of health. The same result for QOL was reported in the study by Ronald et al.²⁶ Ottaviani et al.¹⁹ conducted a qualitative study of patients with osteosarcoma who underwent amputation and observed that the psychological and QOL outcomes were similar to those of patients who underwent limb-sparing surgery. The patients who underwent amputation had physical limitations related to the ability to walk, and most patients still experienced phantom pain. Some patients who underwent limb-sparing surgery required reoperation due to complications related to the endoprosthesis and infections, which are common in cancer patients. The QOL in terms of functionality of the operated limb, cognitive and psychosocial functioning, including marriage and work, did not differ significantly between patients with osteosarcoma who underwent amputation and those who did not. However, patients who underwent amputation appeared to have adapted to either using or not using prostheses.

In summary, it is important to conduct studies with teams of professionals from different areas, according to a trend of interdisciplinary follow-up of patients with cancer, arising from the fact that a single specialization cannot cover all the knowledge necessary to address a subject as complex as QOL of patients with cancer. We observed a global trend for a predominance in the quantitative approaches for the health of patients with chronic disease among studies on QOL in different types of cancer.²⁸ However, the use of qualitative methods is important because it allows exploring specific features that involve various domains of the individual's everyday life. Moreover, Flek published studies on QOL, wherein psychometric instruments were used for its assessment.¹⁹ It has been reported that religion and spirituality have a positive influence on the capacity to cope with the disease and on QOL,²⁸ but this was not observed in the studies selected for this review. Fleck at al²⁹ proposed the challenge of "the key is not just to add years to life but to add life to years," to contribute to achieving the sought-after "humanization of healthcare," which includes a greater investment in QOL of patients with cancer. In recent years there has been an increasing interest in the development of instruments capable of assessing an individual's QOL in different situations.

CONCLUSION

The results of this review show that the QOL was not different between patients with sarcoma who underwent limb-sparing surgery and those who underwent amputation. A similar outcome was observed with regard to the functionality of the operated limb. The studies indicated the need to value the assessment of QOL in all its domains, including psychosocial and cultural aspects, because these may have a direct effect on physical manifestations and a positive impact on coping with the disease. Hence, they emphasize on the importance of support from a multidisciplinary team, of strong family relationships, of the possibility of returning to work, of professional performance, and of the ability to make plans and envision life prospects.

AUTHORS' CONTRIBUTIONS: Each individual author contributed individually and significantly to the development of this work. RSS (0000-0003-0937-2647)*: Substantial contribution regarding conception and design of the study and acquisition, analysis, and interpretation of data; wrote and reviewed the article. DBG (0000-0003-4569-9081)*: reviewed the article and contributed to the intellectual concept of the study. KTB (0000-0003-1300-4281): analysis and interpretation of data; wrote and reviewed the article. LPT (0000-0001-9630-5738) analysis and interpretation of data; wrote and reviewed the article. *ORCID (Open Researcher and Contributor ID).

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