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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed January 2016)

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Type of Article	Abstract	Number of words	References	Figures	Tables	Maximum number of authors allowed
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Link the conclusions with the goals of the study, but avoid statements and conclusions that are not supported by the data, in particular the distinction between clinical and statistical relevance. Avoid making statements on economic benefits and costs, unless the manuscript includes data and appropriate economic analysis. Avoid priority claim ("this is the first study of ...") or refer to work that has not yet been completed.

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

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Levels of Evidence for Primary Research Question^a

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

		Types of study		
Level	Therapeutic Studies Investigating the Results of Treatment	Prognostic Studies – Investigating the Effect of a Patient Characteristic on the Outcome of Disease	Diagnostic Studies – Investigating a Diagnostic Test	Economic and Decision Analyses – Developing an Economic or Decision Mode
I	High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	High quality prospective study ^d (all patients were enrolled at the same point in their disease with ≥80% of enrolled patients)	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Sensible costs and alternatives values obtained from many studies; with multiway sensitivit 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 ^r 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 sensitivit analyses
	Prospective ^d comparative study ^e	Untreated controls from an RCT	Systematic review ^b of Level II studies	Systematic review ^b of Level II studies
	Systematic review ^b of Level II studies or Level I studies with inconsis tent results	Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% followup)		
		Systematic review ^b of Level II studies		
	Case control study ^g	Case control study ⁹	Study of non consecutive patients; without consistently applied reference "gold" standard	Analyses based on limited alternatives and costs; and poc estimates
ш	Retrospective ^t comparative study ^e		Systematic review ^b of Level III studies	Systematic review ^b of Level III studies
	Systematic review ^b of Level III studies		Case-control study	
			Poor reference standard	
IV	Case series ^h	Case series		Analyses with no sensitivity analyses
V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

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

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

^c Studies provided consistent results.

^d Study was started before the first patient enrolled.

^e Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip

arthroplasty) at the same institution.

^f The study was started after the first patient enrolled.

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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ORIGINAL ARTICLES

FOOT

EVALUATION OF KITE AND PONSETI METHODS IN THE TREATMENT OF IDIOPATHIC CONGENITAL CLUBFOOT
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HAND

KNEE

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ONCOLOGY

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TRAUMA

EVALUATION OF KITE AND PONSETI METHODS IN THE TREATMENT OF IDIOPATHIC CONGENITAL CLUBFOOT

AVALIAÇÃO DOS MÉTODOS DE KITE E DE PONSETI NO TRATAMENTO DO PÉ TORTO CONGÊNITO IDIOPÁTICO

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ABSTRACT

Objective: Clubfoot is one of the most common congenital deformities affecting the musculoskeletal system. The main conservative treatment for clubfoot includes the Ponseti's and Kite's methods. This study aimed to perform a comparative evaluation of the effectiveness of the Ponseti and Kite approaches for the conservative treatment of clubfoot. Methods: One hundred children with clubfoot abnormality, visiting the Martagão Gesteira Hospital, were divided in two groups. The first group received conservative treatment using the Kite method and the second group received conservative treatment using the Ponseti method. At the end of the treatment, both groups were evaluated based on the Pirani classification to verify whether there had been an adequate correction of the deformity. The variables studied included correction of deformity, age, sex, and laterality. Results: The effectiveness of the Kite and Ponseti methods of conservative treatment showed significant statistical differences. Conclusion: The present study shows that the efficacy of conservative treatment using the Ponseti method was 18% higher than that of the Kite method. Level of evidence II. randomized clinical trial.

Keywords: Clubfoot. Conservative Treatment. Orthopedics.

RESUMO

Objetivo: O Pé Torto Congênito Idiopático (PTC I) é um dos defeitos congênitos mais comuns, que envolvem o sistema músculo-esquelético, cujos principais tratamentos conservadores são através do método de Kite e de Ponseti. A presente pesquisa busca uma avaliação comparativa da eficácia dos métodos de Ponseti e de Kite, no tratamento conservador do PTC I. Metodologia: Foram tratadas 100 crianças portadoras da deformidade do PTC I, no Hospital Infantil Martagão Gesteira, sendo divididas em dois grupos. No primeiro grupo foi instituído o tratamento conservador pelo método de Kite e no segundo grupo foi instituído o tratamento conservador pelo método de Ponseti. Ao final do tratamento, ambos os grupos foram avaliados com base na classificação de Pirani para verificar se houve correção adeguada da deformidade. Foram estudadas as variáveis de correção da deformidade, idade, sexo e lateralidade. Resultados: Houve diferenca estatisticamente significante entre os métodos de tratamento conservador de Kite e de Ponseti. Conclusão: O presente estudo demonstrou que a eficácia do tratamento conservador pelo método de Ponseti foi superior em 18% em relação ao método do Kite. Nível de evidência II. ensaio clínico randomizado.

Descritores: Pé torto Equinovaro. Tratamento Conservador. Ortopedia.

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INTRODUCTION

Idiopathic congenital talipes equinovarus (ICTEV) may be defined as an inversion deformity characterized by three-dimensional structural deformities such as hindfoot equinus and varus, midfoot cavus, and forefoot adductus. It is present at birth and is one of the most common congenital defects involving the musculoskeletal system. ICTEV is also known as "clubfoot" and "talipes equinovarus" and has a global incidence of one case per 1000 live births, with some influence of genetic and ethnic factors. It is predominant in male patients, with a male:female ratio of 2.5:1. ICTEV is more commonly unilateral, on the right side, but may be present bilaterally in 50% of cases. When not treated or treated inappropriately, it may cause functional and psychological harm to the child.^{1,2}

The first written reports of ICTEV were by Hippocrates, around 400 BC, who described treatment with repeated manual manipulations, without the use of force, followed by immobilization with bandages to maintain the foot in the correct position. Guerin was the first to report the use of a plaster cast in 1836. In the twentieth century, forced corrections were reported with the use of devices such as the Thomas splint. Kite, in 1932, described his method of conservative

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

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management of ICTEV, using smooth and repeated manipulations, followed by cast immobilization. Later, in 1950, Ponseti developed his own technique that also uses manipulations and serial cast immobilizations.^{2,3}

The success of both methods mainly depends on the regularity of the cast changes, since the principles of reduction of the dislocated and sub-dislocated articulations of the foot are distinct. Thus, the objective of the present study was to provide criteria to help choose the most effective method of correction for ICTEV.

MATERIALS AND METHODS

A randomized controlled clinical trial was performed to compare two methods of conservative treatment with serial plaster casting for the correction of ICTEV of level of evidence II. The study was approved by the Ethics Committee of the Instituto Mantenedor do Ensino Superior da Bahia (IMES) under protocol number 56832316400005032. All patients had an informed consent form signed by their legal guardian. Data collection was performed from the follow-up of ICTEV treatment by two conservative methods at the Department of Orthopedics and Traumatology of the Hospital Martagão Gesteira, from January 2012 to May 2013. The patients were divided into two groups according to the different treatment methods (Kite and Ponseti), in which plaster casts were applied weekly for six to ten weeks. At the end of each treatment, the results for each participant were evaluated using the Pirani scoring system that is based on the physical appearance of the deformity during the clinical evaluation of the hindfoot and midfoot.

Procedures for plaster casting and corrective evaluation were performed at the outpatient department of Pediatric Orthopedics Unit of the Martagão Gesteira Hospital, where only a single clinician was responsible for performing such procedures from 2012 to May 2013. The study included infants of both sexes, aged 10 days to 12 months, diagnosed with ICTEV. The choice of treatment method for each patient was based on convenience and on an individual patient basis as either unilateral or bilateral.

The following inclusion and exclusion criteria were considered. Inclusion criteria consisted of patients diagnosed with ICTEV, aged between 10 days and 12 months, exhibiting unilateral or bilateral foot deformities. Exclusion criteria consisted of children without an ICTEV diagnosis, patients with associated underlying pathologies (myelodysplastic, neurological, or arthrogrypotic disorders), patients who were not able to change plaster casts for the Ponseti treatment weekly for socioeconomic reasons, patients whose legal guardian did not sign the informed consent form, and those who had been treated previously for the same pathology using therapeutic techniques other than the Kite and Ponseti methods.

The variables studied were sex, age, laterality of the deformity, and efficacy (correction of deformity) of the treatments.

RESULTS

A total of 100 children participated in the study; 50 underwent treatment with the Kite method and 50 received treatment with the Ponseti method. The study sample consisted of 58 (58%) boys and 42 (42%) girls, of which 40 (40%) children presented deformity in the left lower limb, 33 (33%) in the right lower limb, and 27 (27%) children presented bilateral deformity (Table 1).

In the Kite group, 38 (76%) children achieved satisfactory correction following treatment, and for 12 (24%) children, treatment was unsatisfactory. In the Ponseti group, 47 (94%) children achieved satisfactory correction, while treatment outcome was not satisfactory in 3 (6%) children (Table 2). Significance was calculated using Fisher's Exact Test, where p = 0.023.

Regarding the laterality of the deformity, in the group submitted to the Kite method that achieved a satisfactory correction, 16 children (42.1%) presented with deformity in the left foot, 17 (44.7%) in the right foot, and 5 children (13.2%) presented with the deformity in both feet (Table 3).

In the group submitted to treatment by the Ponseti method that achieved satisfactory correction, 14 children (29.8%) presented with the deformity in the left foot, 12 children (25.5%) in the right foot, and 21 children (44.7%) presented with bilateral deformities (Table 4). Of the patients who achieved correction after treatment with the Kite method, 27 (71%) were male and 11 (29%) were female, while of the patients who achieved correction after treatment with the Ponseti method, 24 (51%) were male and 23 (49%) were female (Table 5). Of the patients who achieved correction after treatment with the Kite method, 24 (63.2%) were aged between 10 to 15 days and 6 months and 14 (36.8%) were aged between 10 to 15 days and 6 months, and 10 (21.27%) were aged between 6 months and 1 year (Table 6).

DISCUSSION

The initial treatment for ICTEV is generally conservative; however, reports in the literature are controversial with regard to its indication as there are many different techniques described for manipulation, with treatment success rates ranging from 11% to 89%.²

In 1932, Kite, published a treatment method using manipulation that aimed at the correction of each component of ICTEV separately. First, the adductus was corrected with the abduction of the foot

Table 1. Characteristics of the laterality of the deformity of subjects of	
the study sample.	

Left	Right	Bilateral
40 (40%)	33 (33%)	27 (27%)
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Table 2. Correction after treatments by the Kite and Ponseti methods.			
Method	Corrected Not corrected Total		
Kite	38 (76%)	12 (24%)	50
Ponseti	47 (94%)	3 (6%)	50
Total	85	15	100

Table 3. Laterality of the correction through Kite's conservative method.			
Left Right Bilateral			
16 (42.1%)	17 (44.7%)	5 (13.2%)	

Table 4. Laterality of the correction through Ponseti's conservative method.			
Left Right Bilateral			
14 (29.8%)	12 (25.5%)	21 (44.7%)	

Table 5. Number of subjects who obtained correction by the Kite andPonseti methods, separated by sex.

Sex	Kite	Ponseti
Male	27 (71%)	24 (51%)
Female	11 (29%)	23 (49%)

 Table 6. Age of patients who obtained satisfactory correction in Kite and

 Ponseti methods.

Age	Kite	Ponseti
10–15 days to 6 months	24 (63.2%)	37 (78.7%)
6 months to 1 year	14 (36.8%)	10 (21.27%)

with a fulcrum on the midfoot and support in the tarsometatarsal joint (Lisfranc joint). To correct the varus, hindfoot eversion was performed using wedges and/or cast changes. Forefoot abduction and pronation were forced successively by the manipulations. Correction of the forefoot and hindfoot equinus through progressive dorsiflexion was attempted only after the adductus and inversion deformities had been corrected. However, the Kite method presented several complications such as the "rocker-bottom" deformity, residual cavus feet, navicular subluxation, ligament and capsular stiffness, among other alterations.⁴

According to Ponseti¹, his method of conservative treatment should be initiated in the first days of life. First, the cavus is corrected, maintaining forefoot supination with the plantar support on the head of the first metatarsus. In the subsequent three or four plaster casts, the adduction and varus deformity are corrected simultaneously, with counter-support on the lateral face of the head of the talus and forefoot abduction. When the abduction is performed, the varus is corrected and only then, the correction of the equinus with a plaster cast in the posterior part of the foot, with a slight dorsiflexion, is initiated. The plaster casts are applied weekly to maintain the degree of correction obtained and to soften the ligaments. Tenotomy is performed when necessary and a Dennis-Brown bar is used.

The Ponseti method¹, therefore, is still considered a surgical treatment, albeit minimally invasive and was regarded an outpatient procedure by Ponseti¹ for most patients, regardless of the severity of the deformity. The Kite method⁴, in turn, uses only conservative treatment in mild cases, and the surgical treatment is indicated for more severe deformities.¹

The Ponseti¹ and Kite⁴ methods are the most popular techniques for the correction of ICTEV deformities. Laaveg and Ponseti first described the technique in 1950 and obtained good results, avoiding the need for surgery in 89% of ICTEV cases. Kite⁴ described his technique in 1932 and obtained a success rate of 90% in patients who underwent treatment when younger than one year of age. However, other authors have failed to reproduce the same rate of good results; thus, these data have led to doubts about the effective success rate of these conservative methods.⁵⁻⁷

The collected sample consisted of 100 children, where 50 children were treated by Kite's conservative method and 50 children were treated by Ponseti's conservative method. Altogether, 127 feet with the ICTEV deformity were treated by Kite and Ponseti's methods. According to Ponseti¹ and Heber², there is a predominance of ICTEV deformity in males, and in the sample from the present study, 58% of the children were males, which is consistent with the literature. However, there was predominance of left laterality among patients in the present study, which is in agreement with the literature, while other authors reported the predominance of right deformity and up to 50% of bilaterality.^{1,2}

According to Ponseti¹, most cases of ICTEV achieve correction after five or six cast changes and often following an achillotenotomy. This technique has shown good results, including for plantigrade and flexible feet, with maintenance of function and absence of pain. The results of this study were in agreement with the literature, whereby most patients (94% of the children of the group treated by the Ponseti method) achieved a satisfactory correction based on Pirani scoring. Thus, a smaller number of cases of ICTEV required an open surgical method to achieve complete correction initiated by the cast changes following the Ponseti method than after the Kite method. Thus, there was a significant difference in efficacy between these two methods in the present study, as only 76% of patients in the group treated by the Kite method achieved a satisfactory correction p = 0.023 (P < 0.05).

In the Kite group, of the children who achieved successful treatment outcomes according to the Pirani score, 71% were boys and 29%

were girls. In this same group, 44.7% of the children achieved a satisfactory correction of the right foot deformity, 42.1% of the children achieved a satisfactory correction of the left foot deformity, and 13.2% of the children presented with correction of both feet. In the Ponseti group, of the children who achieved a successful treatment outcome according to the Pirani score, 51% were boys and 49% were girls. In this same group, 25.5% of the children achieved a satisfactory correction of the left foot deformity, 29.8% achieved a satisfactory correction of the left foot deformity, and 44.7% of the children presented correction of both feet.

According to Brandão⁸, the earlier conservative treatment is initiated, the more likely it is to be successful. The same was observed in this study, where 63.2% of the children who achieved correction with the Kite method and 78.7% of the children with correction by the Ponseti method were within the lowest age range of the study, between 10-15 days and 6 months of age.

The current literature is controversial in providing indications for the choice between Kite⁴ and Ponseti¹ conservative treatment methods for ICTEV. However, currently, most orthopedic services prioritize treatment using the Ponseti method due to its superior outcomes. Yet, there are advantages and disadvantages of both treatments that should be taken into consideration when selecting treatment. The advantages of applying Kite's (1932) plaster casting method are the shorter cast reaching the knee, fewer complications involved with its use, and a better manipulation of the patient is permitted. As we are dealing with very poor populations, cast changes can be performed biweekly considering the socio-economic reality of the population, without compromising the effectiveness of the treatment. However, as a disadvantage, the time required for the use of the cast is longer, ranging from 4 to 8 months.^{1,4,8}

As for the Kite method, the Ponseti method has advantages such reduced time of cast use and, during the selection of surgery, a minimally invasive technique is considered. Disadvantages of this method are the longer cast applied to the leg, which leads to more complications from its use; its difficult placement, which requires a longer learning curve; and more frequent cast changes, which must be performed weekly.^{6,7}

Studies comparing conservative treatment without the need for surgical intervention distinguish the two methods in favor of Ponseti. However, it would be more appropriate to compare conservative methods that are followed by a surgical procedure, given that the Ponseti technique is not an exclusively conservative method, and often requires achillotenotomy, although it is considered a minimally invasive outpatient procedure. When this comparison is made using complete treatment, i.e. conservative and surgical intervention, the success rate of the Ponseti method is only 1.27 times higher.^{7,9,10}

Sanghvi and Mittal⁶ suggest that the better results obtained in patients treated using the Ponseti Method¹ may be associated with the minimally invasive procedure in the Achilles tendon. Conversely, these results may also be associated with the failure of the Kite technique in correcting the heel deformity, validating Ponseti's¹ statement regarding "Kite's error"^{1,6,11}

Some limitations to this study must be considered. Although some patients met the inclusion criteria, they had to be excluded from the study due to an allergy to the plaster and the difficulty for some parents to return to the Orthopedics Clinic of the Hospital Infantii Martagão Gesteira for frequent visits, as they resided in remote areas and did not possess the financial resources to cover the costs of transportation.

Although the Kite method⁴ precedes the Ponseti method¹, the literature reports better outcomes with the latter, which presents a greater degree of correction and avoids open surgery. The achillotenotomy

procedure considered a minimally invasive procedure according to Ponseti¹. In this study, the results of the Kite method were not as satisfactory, as a significantly higher number of patients achieved correction of the foot deformity through conservative treatment using the Ponseti method.^{1,4}

CONCLUSION

Based on Pirani scoring, the present study demonstrated that the efficacy of the conservative treatment by the Ponseti method was statistically superior to that of the Kite method for conservative treatment of clubfoot.

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EPIDEMIOLOGY OF TRAUMATIC INJURIES OF THE UPPER LIMBS IN A UNIVERSITY HOSPITAL

EPIDEMIOLOGIA DAS LESÕES TRAUMÁTICAS DO MEMBRO SUPERIOR EM HOSPITAL UNIVERSITÁRIO

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ABSTRACT

Objective: To evaluate the epidemiology of traumatic injuries of the upper limbs treated at a university hospital and identify the causes, types of injuries, and risk factors. Methods: A prospective study was performed with accidents resulting in trauma categorized into three groups: domestic, occupational, or transportation-related. A questionnaire containing information about the patient and the accident was administered. Lesion characteristics were evaluated according to the injured area, the type of injury, and the management strategy adopted for each case. Results: A total of 613 patients were evaluated. The most frequent accidents were domestic (66.6%), predominantly involving men (67.9%) with a mean age of 31 years. Wrist lesions prevailed in transportation-related (31.1%) and domestic (29.6%) accidents, and in accidents involving fingers at work (54.2%). Closed fractures were more frequent and conservative treatment was indicated most often. Serious injuries were associated with finger accidents (39.4%). There was a correlation between the level of education and the type of accident. Conclusion: Traumatic injuries of the upper limbs were more frequent in domestic accidents and in male patients. Closed fractures were the most common type of fracture and were usually treated conservatively. Serious injuries were more often related to finger trauma. Education level influenced domestic, transportation-related, and occupational accidents. Level of Evidence IV, Case Series.

Keywords: Accidents, Occupational; Trauma; Epidemiology; Upper extremity; Hand; Risk factors; Incidence.

RESUMO

Objetivo: Realizar a epidemiologia das lesões traumáticas dos membros superiores, atendidas em Hospital Universitário, identificando sua origem e tipos de lesões, determinando fatores de riscos. Métodos: É um estudo prospectivo onde os acidentes foram caracterizados em três grupos: doméstico, trabalho ou transporte. Um questionário contendo informações pessoais e do acidente foi aplicado. Avaliaram-se as características da lesão referente ao seguimento afetado, tipo de lesão e conduta adotada para cada caso. Resultados: Avaliou-se 613 pacientes; os acidentes mais frequentes foram domésticos (66,6%), predominando o sexo masculino (67,9%), com média de idade 31 anos. As lesões em punhos prevaleceram nos acidentes de transporte (31,1%) e domésticos (29,6%). Nos acidentes de trabalho, lesões de dedos (54,2%). A fratura fechada foi mais recorrente e o tratamento conservador o mais indicado. As lesões graves relacionaram-se à acidentes em dedos (39.4%). Houve correlação entre nível de escolaridade e tipos de acidentes. Conclusão: Lesões traumáticas dos membros superiores são mais incidentes em acidentes domésticos e em pacientes do sexo masculino. A fratura fechada é a mais freguente e o tratamento conservador o mais indicado. As lesões graves são relacionadas a acidentes em dedos. A escolaridade apresenta diferenca em relação a acidentes doméstico, de transporte ou de trabalho. Nível de evidência IV, série de casos.

Descritores: Acidentes de trabalho. Trauma. Epidemiologia. Membro superior. Mão. Fatores de risco. Incidência.

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INTRODUCTION

Traumatic injuries of the upper limbs are responsible for a large number of patients who require care by emergency services. In addition to the impact of these lesions on patient health and daily life, they impose a significant economic burden on the community.¹ Studies related to occupational accidents show that hand injuries lead to permanent disability in about 50% of cases, with a high percentage of patients unable to return to work, for example, in cases with ulnar and median nerve injury (24%) and in patients with finger amputations (36%).²

In 2011, among the 50 International Classification of Diseases (ICD) codes with a higher incidence of work-related injuries, wrist and hand injuries (S61) were the most frequent, representing 10.1% of the total.³

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Performing unusual tasks, distraction, fatigue, performing activities with haste, use of malfunctioning equipment or tools, new work activities, and not using personal protective equipment (PPE) are associated with the occurrence of acute lesions in the upper limbs.⁴ The need for prevention has been emphasized especially in relation to the identification and control of risk factors.⁵

Accordingly, an update of the epidemiology of traumatic upper limb injuries would reinforce the need for ongoing development of preventive methods in order to avoid or minimize damage caused by accidents, since these have great physical, functional, and emotional impacts on the individual and the community.

The objective of this study was to perform an epidemiological assessment of patients with traumatic injuries of the upper limbs presenting to a University Hospital, to identify the cause and type of injuries, and to determine the risk factors.

MATERIALS AND METHODS

This prospective study was performed at a teaching hospital in a large urban center. The project was approved by the Ethics Committee of the Plataforma Brasil (CAAE 54547716.2.0000.5435, registered under number 1.473.589) and all patients signed an informed consent form. All patients in primary care with traumatic injuries of the upper limbs (fingers, hand, wrist, forearm, elbow, arm, and shoulder) treated in the emergency room by the Orthopedic Service between April and September 2016 were included in the study. Patients with injuries treated by other services, those with chronic injuries, and patients who refused to participate in the study were excluded.

The accidents were characterized into three groups based on origin: domestic, occupational (or work-related), or transportation-related (only related to a means of transportation).

A questionnaire was administered in a standardized manner by resident physicians of the service, collecting the information provided by the patient or by the responsible parent/caregiver.

The questionnaire contained personal information, including sex, age, occupational activity, education; information about the accident, including place of occurrence, day of the week, time of the day, alcohol consumption, use of PPE; employment status (self-employed, contract worker, temporary, service provider); and time of the day (beginning, middle, end).

The characteristics of the lesions were assessed with reference to specific follow-up; the type of lesion was described, with details about the affected structures and the management strategy adopted for each case. Severe lesions were characterized as having one of the following characteristics: exposed fracture, amputation, neurotendinous lesions, or surgical treatment.

The statistical methodology⁶ used was analysis of variance, which compares the means using the variance. The Equality Test of two proportions was used to compare whether the proportion of responses of two given variables and/or their levels were statistically significant. The chi-square test assessed whether two variables and their levels exhibited statistical dependence (association). The confidence interval (CI) for the mean determined the probability of confidence. The tests were performed with a significance level of 5% and 95% CI.

RESULTS

Data were obtained from 613 patients. The most frequent accidents were domestic (66.6%), followed by transportation-related (20.6%), and occupational (12.8%) accidents (Figure 1); there was a statistically significant difference in the frequency of domestic accidents in comparison to the others (p < 0.001).

Overall, 67.9% of patients were male and there was a statistically significant difference between the three groups (p < 0.001) (Figure 2). The mean age was 31 years for cases involving domestic accidents (range: 1–97), 39.6 years (range: 16–64) for those involving occupational accidents, and 28.9 years (range 3–84) for those involving transportation-related accidents (Figure 3).

When assessing the occurrence of accidents in terms of the time and day, 30% occurred in the afternoon, at the beginning of the week (Monday and Tuesday); on other days, there was a higher prevalence of accidents at night. There was also an increase in the percentage of accidents occurring on weekends (Friday, Saturday, and Sunday) (Table 1). There was no statistically significant correlation between the accidents occurring between different periods of the day or on specific days of the week.

With regard to the distribution of the injured upper limb segment by each group, there was a prevalence of wrist injuries in the transportation-related group (31.1%) and the domestic accidents group (29.6%); however, in cases involving occupational accidents, finger injuries were the most prevalent (54.2%) (Table 2).

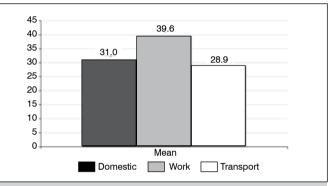


Figure 1. Distribution of patients according to the type of accident.

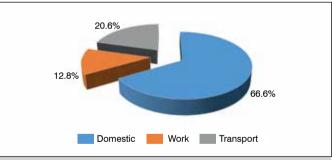
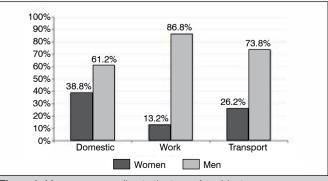


Figure 2. Sex distribution according to the type of accident.





A closed fracture was the most frequently recurring lesion type across all three groups, while finger-related injuries were significantly more frequent (86.7%) in transportation–related accidents compared to the other groups (p < 0.001) (Table 3).

Regarding the management strategy adopted, conservative treatment was the most frequently used (Table 4), and was significantly more common compared to other forms of treatment (p < 0.001). Severe lesions associated with finger accidents (39.4%) (i.e., fracture, amputation, neurotendinous lesions, or surgical treatment), showed the highest statistical significance in terms of incidence (p < 0.001) (Table 5).

There was no correlation between any accident group and alcohol consumption, which makes this variable neutral. With regard to education, there was a significant difference in the number of domestic accidents among illiterate patients (20%, p < 0.001), in the number of occupational accidents among patients with primary school education (51%, p < 0.001), and in the number of transportation-related accidents among patients with secondary school education (42%, p < 0.001). In patients with higher education, there was no significant difference between the groups (Table 6). By examining the group of occupational accidents in detail, there was no statistical correlation between the use of PPE and the labor market conditions; the same was observed with regard to the severity of lesions.

Table 1. Occurrence of accidents according to time period and weekday

	Morning		After	Afternoon N		ght	Total	
	N	%	N	%	N	%	N	%
Beginning of the week	44	27%	78	30%	39	22%	161	27%
Middle of the week	47	28%	72	28%	53	30%	172	29%
Weekend	74	45%	111	43%	84	48%	269	45%
Total	165	27%	261	43%	176	29%	602	100%

 Table 2. Distribution of affected region according to accident group.

		0		5	5 1		
Affected	Dom	Domestic		ork	Transport		
segment	N	%	N	%	N	%	
Shoulder	43	10.4%	5	6.0%	27	20.0%	
Arm	18	4.4%	1	1.2%	11	8.1%	
Elbow	49	11.9%	2	2.4%	9	6.7%	
Forearm	47	11.4%	2	2.4%	13	9.6%	
Wrist	122	29.6%	14	16.9%	42	31.1%	
Hand	61	14.8%	15	18.1%	16	11.9%	
Fingers	67	16.3%	45	54.2%	20	14.8%	
Multiple injuries	5	1,2%	1	1.2%	3	2.2%	
Total	412		83		135		

Table 3. Distribution of lesions according to accident group.								
Tipo de	Dom	estic	W	ork	Transport			
Ferimento	Ν	%	N	%	N	%		
Closed fracture	300	72.8%	41	49.4%	117	86.7%		
Open fracture	27	6.6%	17	20.5%	10	7.4%		
Laceration/ Perforation/Cut	17	4.1%	10	12.0%	3	2.2%		
Tendon lesion	21	5.1%	8	9.6%	1	0.7%		
Neurologic lesion	4	1.0%	0	0.0%	1	0.7%		
Vascular lesion	1	0.2%	0	0.0%	0	0.0%		
Dislocation	43	10.4%	5	6.0%	10	7.4%		
Amputation	3	0.7%	4	4.8%	0	0.0%		
Complex injury	0	0.0%	2	2.4%	0	0.0%		
Total	412		83		135			

Table 4. Distribution of management according to accident group.

Management	Dom	Domestic		ork	Transport		
wanagement	Ν	%	Ν	%	Ν	%	
Treatment conservative	329	79.9%	49	59.0%	104	77.0%	
Surgical treatment	77	18.7%	32	38.6%	29	21.5%	
Inpatient	0	0,0%	0	0.0%	1	0.7%	
Avoidance	1	0.2%	0	0.0%	0	0.0%	
No response	1	0.2%	0	0.0%	0	0.0%	
Total	412		83		135		

	a aa . a	
Table 5 Distribution c	of affected seamen	t according to severity.

	5		,
Follow-up	N	%	P value
Fingers	67	39.4%	<0.0001
Wrist	34	20.0%	<0.0001
Hand	20	11.8%	<0.0001
Elbow	13	7.6%	<0.0001
Forearm	13	7.6%	<0.0001
Arm	12	7.1%	<0.0001
Shoulder	6	3.5%	<0.0001
Multiple injuries	5	2.9%	<0.0001
Total	170		

 Table 6. Correlation of accident groups with alcohol consumption and level of education.

		Dom	estic	W	Work Transport		sport	t Total		Durley	
		N	N %		%	N	%	Ν	%	P value	
Alashal	Yes	350	89%	73	96%	106	87%	529	90%		
Alcohol	No	42	11%	3	4%	16	13%	61	10%	0.110	
	Illiterate	77	20%	3	4%	7	6%	87	15%		
Education	Primary	182	48%	37	51%	54	46%	273	48%		
Education	Secondary	106	28%	29	40%	50	42%	185	32%	<0.001	
	Higher	14	4%	4	5%	7	6%	25	4%		

DISCUSSION

The upper limbs are indispensable for interaction with the external environment and are essential for the expression of individuality; thus, upper limb lesions can cause significant psychosocial and economic damage.

Three groups were considered to investigate the epidemiological aspects of accidents involving the upper limbs: domestic, transportation-related, and occupation-related causes. This was because the critical analysis of each group was necessary to evaluate the characteristics regarding the mechanisms of injury, place of occurrence, and severity of trauma.

In our series, domestic accidents were responsible for the majority of lesions encountered (66.6%). This incidence is similar to data reported by Frazier et al.⁷ and by Chung et al.⁸, in which 50% of injuries and 30% of trauma injuries occurred in a domestic environment, respectively. In the literature, between 62.9% and 66%^{7,9} of injuries were reported to occur in men, which is similar to the 67.9% reported in this study. This finding would indicate the occurrence of a higher number of hospital visits due to occupational accidents and domestic accidents, in both men and women.

The stratification of samples by average age confirms the greater concentration of accidents in economically-active patients, i.e., those aged between 28.9 and 39.6 years, in the three groups studied; this reflects a social and economic burden.^{7,9,10,11}

Our sample revealed a higher percentage of accidents occurring at night and in the evening, unlike the data reported by Lombardi et al.⁹, who reported a predominance of accidents in the morning. When considering the days of the week, there were a higher number of accidents on weekends; however, the current literature cites a uniform occurrence of accidents across all days of the week.^{9,12} It is assumed that factors, such as doubling of working hours, fatigue, and distraction may be responsible for such occurrences.

Lesions of the wrist were the most prevalent in this study, when taking into account transportation-related (31.1%) and domestic accidents (29.6%), which is in concordance with Chung et al.⁸ and Fonseca et al.¹¹. However, Larsen et al.¹³ describe a higher incidence of hand involvement among accidents. In cases of work-related accidents, there is a higher incidence of finger injuries reported in the literature, which is similar to that determined in our study (54.2%).^{79,11,13}

With respect to the type of lesion, closed fractures unexpectedly displayed the highest incidence in all groups. In contrast, published data indicates lacerations to the hands as the main injury.^{7,9,14,15} In our study, lacerations were among the least frequently observed type of lesions. When we take into account the severity of the lesions, the fingers were the most affected (39.4%) and mainly occurred in cases involving occupational accidents,^{10,14} which can be attributed to the proximity of the anatomical structures in the hand, which are more likely to undergo complex injuries.

With respect to the clinical management adopted for the three groups of accidents, conservative treatment was the most frequently used, suggesting that many of the accidents were related to low-energy impact, causing less severe lesions; nevertheless, these generate high costs to the health system and social welfare.⁸ Few studies have assessed the relationship between alcohol consumption and domestic and occupational accidents. In the present study, only 10% of the accidents reported alcohol use. These statistics demonstrate the difficulty of conducting research in this area using questionnaires, as we must take into consideration eventual biases in the individual's responses, which are influenced by fear, insecurity, and the potential legal implications involved in the use of alcohol. Therefore, it is possible that information regarding alcohol use may have been intentionally omitted by patients. In general, studies that assessed the relationship between education and types of accidents were not available in the literature. It is interesting to note the significant differences associated with illiterate patients in domestic accidents, patients with primary education in work-related accidents, and patients with secondary education in transportation accidents. Notably, in patients with higher education, there were no such differences, suggesting that improvement in education levels may lead to a reduction of the incidence of accidents in the different groups.

In this study, there was no correlation between the use of PPE and the severity of the lesions. Jin et al.⁴ correlated the use of gloves with severe injuries. This indicates that some equipment does not protect the worker from high-energy accidents; thus, we believe that it is important to prioritize awareness regarding precautionary measures during work activities in order to minimize accident risks. As a whole, this study stresses that the prevention of upper limb injuries requires multiple approaches, such as greater caution during everyday activities, especially at home. Attention should be given to activities in the evenings, at night, and on weekends. Proper maintenance of work equipment with suitable instructions with regard to handling, the adequacy of domestic environments (i.e., safety bars, nonslip floors), and caution in handling of sharp objects, require investments for the creation of projects and intervention strategies involving multidisciplinary teams to foster an increased awareness regarding the functional consequences that may arise from lesions of the upper limbs, as well as their socioeconomic impact.

CONCLUSIONS

The incidence of traumatic injuries of the upper limbs was found to be higher in domestic accidents and in male patients, regardless of the type of accident (domestic, transportation-relatred, or occupational). Closed fractures were the most frequent in cases of transportation accidents, and conservative treatment was the most suitable management strategy for any type of accident. The injuries with greater severity were associated with accidents involving fingers. The incidence of domestic, transportation-related, or occupational accidents were different according to education levels.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the drafting of the manuscript. SR (0000-0003-0345-3921)*, EJNO (0000-0002-1530-976X)* and AT (0000-0002-1952-2277)* were the main contributors in the drafting of the manuscript. GPR (0000-0002-2013-1417)* and PO (0000-0001-7693-3606)* performed data collection and completion of questionnaires, followed the patients, and gathered clinical data. EJNO, PO, and SR evaluated the statistical analysis. SR, EJNO, AT, and GPR performed bibliographic search and revision of the manuscript and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

LIFE QUALITY EVALUATION USING "TIME TRADE OFF" **MFTHOD FOR RHEUMATOID HANDS**

AVALIANDO OUALIDADE DE VIDA DO PACIENTE COM ARTRITE NAS MÃOS PELO MÉTODO "TIME TRADE OFF"

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ABSTRACT

Objective: Rheumatoid arthritis is a prevalent disease in the population (range 0.5% to 1%) and involves both orthopedic and rheumatologic treatment. The Time Trade-Off (TTO) technique, which determines the number of years the patient or the professional would be allowed before a successful procedure in terms of life expectancy and value of the procedure, has been gaining ground in clinical protocols. From this standpoint, we sought to compare evaluations provided by the patients, orthopedists, and rheumatologists in determining the TTO and to correlate their responses with the clinical repercussions using previously established scores such as the Brief Michigan Hand Questionnaire and the Disease Activity Score-28 (DAS-28). Methods: A prospective study was conducted that involved 37 patients with rheumatoid arthritis, orthopedists, and rheumatologists. The TTO guestionnaire was administered by an independent evaluator for evaluation using the DAS-28 and the Brief Michigan Hand Questionnaire. Results: The descriptive analysis revealed similar medians between the orthopedists, rheumatologists, and patients for single assessments. However, there was a weak correlation between the results from the patient and rheumatologist, the patient and Brief Michigan Questionnaire, and those of the orthopedic surgeon and the DAS-28. Conclusion: Similar median values demonstrated equivalent TTO among the orthopedist, rheumatologist, and patient. However, given the weak correlations between the scores, it was not possible to substitute results using a single evaluation scale. Level of Evidence II, Prognostic Studies.

Keywords: Arthritis, Rheumatoid/surgery. Hand/surgery. Quality of life. Surveys and Questionnaire.

RESUMO

Objetivo: Artrite reumatoide é uma doenca prevalente na população (0,5% a 1%), envolvendo tratamento tanto ortopédico, quanto reumatológico. A técnica do "Time Trade Off", que determina a quantidade de anos que o paciente ou o profissional daria para ter sucesso absoluto em determinado procedimento, vem ganhando espaço nos protocolos modernos. Diante disto, comparamos a avaliação dada pelo paciente, pelo ortopedista e pelo reumatologista usando "Time Trade Off" e correlacionamos com repercussão clínica e escores já estabelecidos: Brief Michigan Questionnaire (Anexo I) e Disease Activity Score-28 (DAS-28) (Anexo II). Métodos: Estudo prospectivo com 37 pacientes diagnosticados com artrite reumatoide, que foram submetidos ao questionário "Time Trade Off" pelo ortopedista, pelo reumatologista e por um avaliador independente, e avaliação através do DAS-28 e do Brief Michigan. Resultados: Através da análise descritiva, notou-se medianas semelhantes entre ortopedista, reumatologista e paciente. Entretanto, evidenciou-se correlação fraca entre paciente e reumatologista, paciente e o Brief Michigan; e ortopedista e o DAS-28. Conclusão: Valores de mediana semelhantes demonstram "Time Trade Off" equivalentes entre ortopedista, reumatologista e paciente. Mas, diante das correlações fracas entre os escores, não foi possível substituí--los por uma escala única de avaliação. Nível de Evidência II, Estudo Prognóstico.

Descritores: Artrite Reumatoide/cirurgia. Mão/cirurgia. Qualidade de Vida. Inquéritos e Questionários.

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INTRODUCTION

Rheumatoid arthritis is a systemic disease with a prevalence of 0.5% to 1% in the Brazilian,¹ European, and North American populations,² and affects up to 2.1 million Americans.³ Treatment involves medications, guidelines for joint protection

and energy conservation, as well as reconstructive and prophylactic surgery.4

In approximately 20% of patients with rheumatoid arthritis, the hands are affected at disease onset, while over 70% of these patients will also be affected through the course of their lives.⁴

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

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Regarding the socioeconomic implications, Yelin et al.⁵ report that one third of patients will be dismissed from work after five years of illness and after ten years, the remaining 50% will be unable to work. Surgery is indicated when there is no response to drug treatment and in the presence of deformities that compromise function, when other anatomical structures may be placed at risk, or when surgery may represent a functional advantage to the patient.⁶

However, the indication for surgery depends on a referral by the clinician, confirmation of the need for the procedure, and on the patient's understanding of the risks and benefits involved and the decision of whether to opt for surgical treatment.⁷ This entire process is subject to interference.³

Alderman et al.³ show that the perception of the benefits of surgery differ for the surgeon and for the rheumatologist, and it follows that the patient's perception may differ from both professionals.

Other studies have also reported a lack of consensus among orthopedic surgeons and rheumatologists and general practitioners as to the optimal timing of indication for a surgical procedure and the benefits that this procedure can deliver.³ An evaluation of the patient's expectations has not been described in the literature.

To address this issue within the context of a sensible use of health resources, the patient's opinion on the value of the treatment balanced with its benefits and risks has been highlighted in studies that determine clinical care protocols. The tools used for this assessment were method ranking, "Standard Gamble," the "Time Trade-Off" (TTO) technique, and the visual analog scale (VAS), among others.8 The TTO approach was introduced by Torrance et al.,⁹ and proposes a method of evaluating the value that the patient or professional would give to a certain procedure. This value is measured in years of life. Initially it was used to assess procedures that improve the patient's quality of life, but shorten their life expectancy. Subsequently, this technique has been used to evaluate the value that the patient gives to a certain procedure, thus offering an opportunity for a population to give their opinion on the value of different therapeutic resources. The primary objective of this study was to measure the differences in the value given by the patient, the rheumatologist, and the orthopedist to a hypothetical procedure that would provide the patient with the best possible outcome for the rheumatoid hand using the TTO technique, and thus, assess the degree of disability that the current condition generates in the patient. The secondary objective was to correlate the value obtained through the TTO technique with specific scales used in clinical decision making between orthopedists (Brief Michigan Hand Questionnaire) and rheumatologists (Disease Activity Score [DAS]-28).

MATERIALS AND METHODS

The study began after formal authorization was granted by the Research Ethics Committee of the Institution under number CAAE 69425917.1.0000.068. All patients enrolled in the study signed an Informed Consent Form.

A prospective study was performed with 37 patients diagnosed with rheumatoid arthritis who were submitted to the "TTO" questionnaire and independently assessed by the orthopedist and rheumatologist. An independent evaluator assessed the results obtained from the patient's Disease Activity Score (DAS)-28 Index and the Brief Michigan Hand Questionnaire.

Inclusion criteria:

- Adult patients from the hand surgery outpatient clinic of our institution diagnosed with rheumatoid arthritis
- Patients with hand deformities
- Patients who were followed-up by a rheumatologist from our institution.

Exclusion criteria:

- · Patients who did not complete the evaluations
- · Patients who did not agree to sign the consent form

EVALUATION

For each patient, the following information was collected:

- · Patient's identification
- Diagnosis of hand deformity
- Documentation of comorbidities and medications in use
- Assessment of the degree of hand function through the Brief Michigan Hand Questionnaire adapted for Brazilian Portuguese patients.¹⁰
- Assessment of disease activity (in patients with rheumatoid arthritis) using the DAS-28 index
- Questioning of the patient using the TTO technique
- Questioning of the orthopedist using the TTO technique
- Questioning of the rheumatologist using the TTO technique

Description of the Time Trade-Off technique:

An independent evaluator, not the orthopedist or the rheumatologist, interviewed the patient.

Based on a life expectancy table adjusted for age and sex for the year 2011,¹¹ the evaluator asked the patient the following questions: "Mr./Mrs. [PATIENT NAME], you are currently [X] years old. Based on IBGE's studies, you should live on average up to [Y] years. Thus, you have [Y-X] more years to live.

If you could change a few years of life for your hands to be healed, to a perfect condition, of these [Y-X] years, would you give five years of life to make your hands perfect?"

If the answer was positive, the evaluator repeated the question by increasing the number of years given by the procedure by five.

If the answer was negative, the evaluator repeated the question by decreasing the number of years given to the integer between the two numbers questioned.

The questions were repeated until the maximum number of years the patient would give for the procedure was obtained.

The difference between this age and life expectancy adjusted for the age of IBGE was the value in years that the procedure represented for the patient. This value was defined as TTO-Patient (Z).

To confirm the responses, the interviewer asked the patient: "You've opted for [Z] years. That means you would be willing, instead of living up to [Y] years with your hands in this condition, living up to [Y-Z] years with perfect hands.

If the response was POSITIVE, the value was accepted.

If the answer was NEGATIVE, the questionnaire procedure was repeated.

An orthopedist and a rheumatologist, independently, without consultation with the other, examined the patient's hands and in consideration of their life expectancy and comorbidities, also assessed the value of the procedure in terms of number of years of life. These values were defined TTO-Orthopedist and TTO-Rheumatologist, respectively.

The difference between the values obtained between the three values of the respondents (patient, orthopedist, rheumatologist) was calculated, considering the TTO as a numerical and continuous variable.

The alpha error value was set at 5% and the beta error value at 20%.

RESULTS

Among the 37 patients enrolled, 22 passed all the evaluations and 11 had the laboratory tests results necessary to calculate the DAS-28.

Of the 22 patients, who completed all the evaluations, 21 were women (95%) and one was a man (5%). The mean age of the sample was 58.0 ± 8.0 years and the mean life expectancy, according to IBGE data, was 82.2 ± 1.8 years.

A descriptive population analysis was performed (Table 1). The Kolmogorov-Smirnov normality test was applied, which showed a non-normal distribution of the population; therefore, it was necessary to use non-parametric tests. Thus, we used the non-parametric statistical tests, Spearman's rho, to obtain the correlation between indices demonstrated in Table 2, interpreting values as follows:

 ± 0.9 indicated a very strong correlation.

 ± 0.7 to 0.9 indicated a strong correlation.

 ± 0.5 to 0.7 indicated a moderate correlation.

 ± 0.3 to 0.5 indicated a weak correlation.

 ± 0 to 0.3 \pm indicated a negligible correlation.

The correlations found, based on this analysis, were:

- Weak positive between orthopedist and rheumatologist
 Weak positive between patient and the Brief Michigan I
- Weak positive between patient and the Brief Michigan Hand Questionnaire
- Weak negative between orthopedist and the DAS-28 score.

	Brief michigan	TTO. Patient	TTO. Orthopedist	TTO. Rheumatologist	DAS-28
Mean	45.37 (14 To 97)	7.34 (0 To 30)	2.36 (1 To 4)	2.38 (0 To 7)	2.89 (1.55 to 4.44)
Standard deviation	17.17	9.60	1.01	2.02	0.93
Median	43.75	2	2	2	2.63

Table 1. Descriptive statistics of the Time to Trade-off results

TTO: Time to Trade-off.

Table 2. Correlation coefficient (Spearman's rho).								
	Brief michigan hand questionnaire	DAS-28	TTO Patient	TTO. Orthopedist	TTO. Rheumatologist			
Brief michigan hand questionnaire	1.000	-0.202	0.302	-0.185	-0.281			
DAS 28	-0.202	1.000	0.011	-0.308	0.133			
TTO. Patient	0.302	0.011	1.000	-0.105	-0.055			
TTO. Orthopedist	-0.185	-0.308	-0.105	1.000	0.318			
TTO. Rheumatologist	-0.281	0.133	-0.055	0.318	1.000			

DISCUSSION

At first glance, the mean TTO values between the orthopedist (2.36) and the rheumatologist (2.38) were similar, unlike the patient's TTO (7.34), which was much higher. A more concordant analysis could be inferred between the orthopedist and the rheumatologist than either in relation to the patient. However, as the population showed a non-normal distribution, the median analysis between the patient, orthopedist and rheumatologist, which was similar (mean 2.0), was also determined. The explanation for the higher mean obtained in the patients is that there were few cases of patients reporting a high TTO, which skewed the results toward a higher mean.

Through the Spearman's rho test, we attempted to correlate the scales to find one scale that could replace the triple assessment (TTO, Michigan, DAS28). The results did not allow unification by any of the scores, with most correlations being negligible and with only three weak correlations.

Although the correlation between the orthopedist and the rheumatologist was low, it presented a positive value, inferring some degree of concordance between the two professionals. This was also true for the analysis between the patient and his Brief Michigan Questionnaire that also presented a positive value, which was to be expected, as the patient completed his own personal Brief Michigan Questionnaire, analyzing functional status.

The weak but negative correlation between the orthopedist and the DAS-28 suggested a non-concordance of values between the two variables, in addition to their statistically low significance.

Considering the results of this analysis, it is recommended that the scales continue to be used, each for the specialty to which it is most familiar – the orthopedist using the Brief Michigan Questionnaire and the rheumatologist using the DAS 28, for example. The same scale is recommended to be used by the patients at different periods in time in order to compare the functional evolution.

The study presented some limitations, such as a small sample size (22 patients) completing all the evaluations, and the seven cases of rheumatologic evaluation performed by different evaluators. Another weakness involved the evaluation by a single orthopedist or rheumatologist for each case. An assessment by more than one professional could be determined to define inter-observer agreement or disagreement.

A strong point of this study was the unprecedented attempt to compare these the scales by the three professional figures typically involved in the treatment of the rheumatoid patient: the patient, the orthopedist, and the rheumatologist.

The TTO technique has the advantage that it can be used for different diseases.¹²⁻¹⁴ Thus, it is possible to estimate which disease or injury may impair the quality of life of the patient. This characteristic leads to the use of the technique in public health policies to determine priorities for inclusion of different diseases or injuries in the coverage list of national health systems.¹² Pathologies that affect a patients' quality of life in a complex manner, however diverse they may be, can have each individual effect compared using this technique.^{13,14} Another strong point of this study was the use of an easy-to-interpret quality of life scale, which has been used in studies for setting priorities in public health.

A potential outcome of this study would be to open the results of TTO evaluations to orthopedists and rheumatologists and to compare the criteria used by each in order to increase the degree of interaction during patient evaluations between the two professionals. After this comparison, it would be possible to evaluate a different group of patients and repeat the study to verify whether there is an increase in the correlation of grades given by the health care professionals.

CONCLUSIONS

The TTO of the patient, orthopedist, and rheumatologist, when analyzed together, have an equivalent value. None of the assessment scales, neither the DAS-28 nor the Brief Michigan Hand Questionnaire, could be replaced by a single scale alone.

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Appendix 1. Brief Michigan Hand Questionnaire.

Patient:	
Date: / /	
Evaluator:	
VAS	
0	100

Instructions: This survey asks you for your views about your hands and your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer EVERY question by marking only one answer. If you are unsure about how to answer a question, please give the best answer you can. Please answer every question, even if you do not experience problems with your hands or wrists. Some questions may ask you about your ability to complete certain tasks. If you do not do a certain task, please estimate the difficulty with which you would have in performing it. Questions pertaining to work include occupational work, housework, and schoolwork. Please circle one answer for each question.

		Very good	Good	Fair	Poor	Very poor
11	Overall, how well did your hand(s) work during the past week?	1	2	3	4	5
2	Here was the consistion (faciling) in your hand(a) during the past weak?	Very good	Good	Fair	Poor	Very poor
2	How was the sensation (feeling) in your hand(s) during the past week?	1	2	3	4	5
	Na	Not at all difficult	A little difficult	Somewhat	Moderately	Very
3	How difficult was it for you to hold a frying pan during the last week?			difficult	difficult	difficult
		1	2	3	4	5
		Not at all difficult	A little difficult	Somewhat	Moderately	Very
4	How difficult was it for you to button a shirt or blouse during the past week?	1	2	difficult	difficult	difficult
		1	2	3	4	5
5	In the past 4 weeks, how often were you unable to do your	Always	Often	Sometimes	Rarely	Never
5	work because of problems with your hand(s)/wrist(s)?	1	2	3	4	5
6	In the past 4 weeks, how often did you take longer to do tasks in	Always	Often	Sometimes	Rarely	Never
0	your work because of problems with your hand(s)/wrist(s)?	1	2	3	4	5
7	How often did the pain in your hand(s)/wrist(s) interfere with your	Always	Often	Sometimes	Rarely	Never
<u> </u>	daily activities (such as eating or bathing) in the past week?	1	2	3	4	5
8	Describe the pain in your hand(s)/wrist(s) in the past week.	Very mild	Mild	Moderate	Severe	Very severe
Ľ	Describe the pair in your hand(s)/whist(s) in the past week.	1	2	3	4	5
		Strongly agree	Agree	Neither agree	Disagree	Strongly disagree
9	I am satisfied with the look of my hand(s).	1	2	nor disagree	4	5
		'	2	3		J
	In the past week, the appearance of my hand(s)	Strongly agree	Agree	Neither agree	Disagree	Strongly disagree
10	interfered with my normal daily activities.	1	2	nor disagree	4	5
	interfered with my normal daily adavites.	'	<u>د</u>	3		J
		Very satisfied	Somewhat	Neither satisfied	Dissatisfied	Very dissatisfied
11	In the past week, how satisfied were you with the motion of your fingers?	1	satisfied	nor dissatisfied	4	5
		'	2	3	т	Ŭ Ŭ
		Very satisfied	Somewhat	Neither satisfied	Dissatisfied	Very dissatisfied
12	In the past week, how satisfied were you with the motion of your wrist?	1	satisfied	nor dissatisfied	4	5
			2	3	7	, , , , , , , , , , , , , , , , , , ,

Appendix 2. Disea	ase Activity So	core-28 (DAS	6-28)		
DAS28 form Patient name:					Date of Birth: /
Observer name:					Date: / /
	Left		Right		How active was your arthritis during the past week? – Visual
	Swollen	Tender	Swollen	Tender	Activity Scale (VAS)
Shoulder					(Please mark the degree of activity on the scale below by placing a vertical line)
Elbow					

Extremely active Not active at all

DAS28 = 0.56*(t28) + 0.28*(sw28) + 0.70*Ln(ESR) + 0.014*VAS

For free online calculator visit www.das28.nl

Swollen Joint Count (0-28)
Tender Joint Count (0-28)
ESR
Visual Activity Scale (VAS) (0-100mm)
DAS28 - 0 56*/+28) + 0 28*/ow28) +

Wrist

Knee Subtotal

Total

Swollen

Tender

1 2 3

4 5

MCP

PIP

ASSESSMENT OF THE REGENERATION CAPACITY OF SEMITENDINOSUS AND GRACILIS TENDONS

REGENERAÇÃO DOS TENDÕES DOS MÚSCULOS SEMITENDÍNIO E GRÁCIL APOS RETIRADA

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ABSTRACT

Objectives: To evaluate the regenerative capacity of gracilis (G) and semitendinosus (ST) tendons, to examine the sensitivity and specificity of signs and symptoms in the assessment of hamstring tendons, and to assess the thickness and insertion site of regenerated tendons. Methods: Thirty sequential knees were subjected to anterior cruciate ligament reconstruction with semitendinosus and gracilis tendons. After surgery, the patients were followed up clinically with physical examination and magnetic resonance imaging (MRI). Results: Overall, 36.66% of the tendons were visible on MRI, whereas 83.33% were palpable. On MRI, the distal insertion site of the regenerated semitendinosus tendon was visible proximal to the landmark of the medial femoral condule in 28%, at the same level in 16%, and distally in 56% of the cases. Gracilis tendon insertion was visible proximally in 36.66% of cases, at the same level in 10%, and distally in 53.33%. Eleven knees exhibited complete regeneration. Conclusion: Partial or total regeneration of the ST and G tendons was apparent on MRI. Palpation is effective for evaluating regeneration of the ST and G tendons; however, MRI is still the gold standard. ST and G tendons regenerated completely in only a small percentage of patients, limiting reuse as a graft in cases with new ligament injuries of the knee. Level of Evidence II, Prospective comparative study.

Keywords: Knee, Tendons, Magnetic Resonance Imaging, Physical Examination.

RESUMO

Obietivo: Avaliar a capacidade de regeneração dos tendões Grácil e Semitendíneo; Identificar a sensibilidade e especificidade da manobra semiológica para detecção da presença dos tendões isquiotibiais; verificar espessura e região de inserção dos tendões regenerados. Métodos: 30 pacientes foram submetidos à cirurgia para reconstrução do LCA, com retirada dos tendões do semitendíneo e grácil. Após a cirurgia, os pacientes foram acompanhados clinicamente por exame físico e por RM. Resultados: Observou-se que em 36,66% eles se apresentavam visíveis, enquanto 83,33% os tendões estavam palpáveis. Observou-se à RM, guanto a região da inserção distal dos tendões regenerados: Semitendíneos, 28% proximal ao ponto padronizado do MFC, 16% se apresentaram ao nível e 56% distal. Já guanto aos tendões do Grácil, 36,66% apresentavam-se proximais, 10% ao nível e 53,33% distal. Onze tendões do ST e do G tiveram regeneração completa. Conclusões: Ficaram caracterizadas, por RM, as regenerações parciais ou totais dos tendões ST e G;a palpação, é eficaz para avaliar a regeneração dos tendões, porém RM mantem-se como padrão ouro; apenas parte dos pacientes os tendões ST e G se regeneraram de maneira completa, limitando a sua reutilização como enxerto nos casos de nova lesão ligamentar. Nível de Evidência II, Estudo prospectivo comparativo.

Descritores: Joelho. Tendões. Ressonância Magnética. Exame Físico.

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INTRODUCTION

Knee ligament reconstruction is a common procedure.¹ In general, a graft is placed in the position of the original ligament and assumes its function. Among the potential grafts available, there has been an exponential increase in the use of semitendinosus (ST) and gracilis (G) tendons in recent decades because of lower morbidity at the donor site, greater technical ease in removal, and the potential for

accelerated recovery with decreased pain compared to that with other grafts. These features enable earlier rehabilitation without substantial loss of resistance, as these tendons produce similar or better results, with stretching characteristics comparable to those of other grafts.²⁻⁴

The versatility of this type of graft has also allowed the development of reconstruction techniques for practically all ligaments of the

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knee using these tendons, in addition to ligament and tendon reconstructions extrinsic to the joint.

This scenario underlines the importance of evaluating the regenerative capacity of the hamstring tendons, as these are associated with the return of knee flexion strength.^{1,5} In 1992, Cross et al.,⁶ using magnetic resonance imaging (MRI) in 4 patients, demonstrated that these tendons present substantial regenerative potential. Since then, several authors have studied this potential from a macroscopic⁷⁻¹⁰ as well as histological standpoint.^{11,12} However, the literature on the regenerative capacity of the tendon, as well as its consistency and thickness, is unclear. Moreover, the new insertion site shows some variability.^{1,3,4,8} In this context, there is ample evidence in the literature indicating that tendons and ligaments are generally able to heal intrinsically.^{9,10} The mechanisms involved in regeneration, according to Eriksson et al., can be both intrinsic and extrinsic in origin.⁸ Extrinsic healing involves regeneration from the peritendinous tissue, with gradual invasion of capillaries and formation of granulation tissue. Intrinsic healing involves regeneration originating from the two ends of a cut tendon, without formation of granulation tissue or vascular invasion of peritendinous tissue.8

As the capacity for regeneration and the location of neotendinous insertion of the hamstrings remain controversial, the objectives of the present study were: (1) to assess the regenerative capacity of tendons at the graft donor site in patients undergoing anterior cruciate ligament (ACL) reconstruction with ST and G tendons, (2) to determine the sensitivity and specificity of signs and symptoms in the assessment of these tendons, and (3) to assess the thickness and insertion site of regenerated tendons.

MATERIALS AND METHODS

After approval by the ethics committee, 29 sequential patients (30 knees) were selected based on the following inclusion criteria: isolated lesions with a surgical indication, absence of ligament injuries or previous knee surgery, absence of metallic materials in the knee or thigh (incompatible with MRI), no history of lower limb muscle injury, no limitation in range of motion, consent to participation in the rehabilitation protocol, commitment to outpatient follow-up, and signing of an informed consent form. The exclusion criteria were: ligament injuries or previous knee surgery, presence of metallic materials in the knee or thigh, history of muscle injury in the lower limb, or inability to participate in the rehabilitation protocol or outpatient follow-up. Each patient underwent surgery for ACL reconstruction using the same technique (isometric reconstruction) and fixation (bioabsorbable screws), and ST and G tendons were completely removed from the muscles up to the myotendinous junction in all cases. After surgery, patients were clinically followed-up with physical examination and MRI.

Physical examination

Physical examination to evaluate regeneration of the ST and G tendons was performed in accordance with the technique described by Cross et al.⁶ In the ventral decubitus position, the patient performed knee flexion against resistance, in order to demonstrate the presence or absence of the regenerated tendon in the posterior medial aspect of the knee.⁶ The examiner proceeded with inspection, followed by palpation of the region (Figure 1). Following physical examination, the patient was referred for MRI directly, so that both could be performed on the same day.

Magnetic Resonance Imaging

The results of these examinations were evaluated by two experienced radiologists who were specialists in musculoskeletal imaging. Discrepancies between the radiologists were resolved by consensus,



Figure 1. Visualization of the semitendinosus and/or gracilis tendons on physical examination, with knee flexion against resistance. Arrow: Regenerated tendons in the posterior medial aspect of the knee.

without the requirement for a third evaluator. The radiologists were informed that the tendons had been removed but were unaware of the interval between removal of the graft and the MRI examination. The MRI was performed on the segment of the lower limb between the middle third of the thigh and the proximal third of the leg. A Philips model NT 10 instrument, operating at a high magnetic field was used. A quadrature surface coil array was used to image the L-spine, which allowed simultaneous acquisitions with a 400-mm field of view. The T1-weighted turbo spin echo technique was used with a repetition time of 550 ms and echo time of 12 ms. The images were obtained in coronal (Figures 2 and 3) and transverse planes (Figure 4), with a slice thickness of 5 mm and no gaps. We

used the following to classify tendon regeneration based on location: P, proximal to the most distal point of the medial femoral condyle (MFC) surface; N, at the most distal point of the surface of the MFC; D, distal to the most distal point of the joint surface of the MFC; C, complete regeneration (up to the insertion point of the pes anserinus).

Statistics

The confidence interval (CI) and sampling error were calculated using the MRI values obtained from evidence of regeneration of the ST and G tendons. The sensitivity (S), specificity (E), positive predictive value (PPV), and negative predictive value (NPV), with their respective 95% CIs, were calculated for statistical comparison of the ability of physical examination and MRI evaluation to demonstrate ST and G tendon regeneration. There is no consensus on the gold standard for the evaluation of ST and G tendon regeneration. In this study, MRI examination was considered the gold standard.

RESULTS

Thirty knees (18 right, 12 left) of 29 adult patients (26 men) submitted to ACL reconstruction with quadruple autografts of ST and/or G tendons were evaluated in this study. One patient underwent surgery on both knees, but at different time points. Patient ages ranged from 19 to 49 years (mean, 32 years). The average interval between surgery and the date of MRI and physical examination (performed on the same day) was 17 months (range: 9 to 34 months).

Magnetic Resonance Imaging

MRI examination of the knee was performed to assess the regenerative capacity of the ST and G tendons, but the current status of the tendon grafts in the knees of these patients was also analyzed.

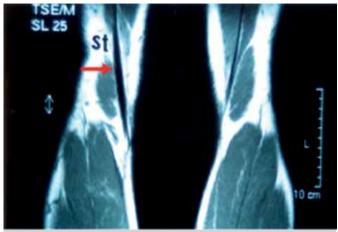


Figure 2. Magnetic resonance image of the knee: coronal section. Turbo spin-echo sequence: T1-weighted. Arrow: Regenerated semitendinosus tendon.

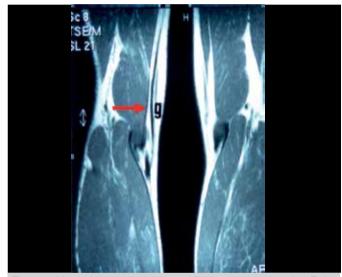


Figure 3. Magnetic resonance image of the knee: coronal section. Turbo spin-echo sequence: T1-weighted. Arrow: Regenerated gracilis tendon (g).

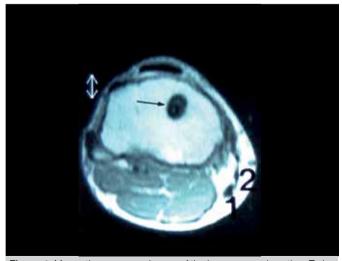


Figure 4. Magnetic resonance image of the knee: coronal section. Turbo spin-echo sequence: T1-weighted. Arrow: Regenerated gracilis tendon (g).

Transverse MRI images enabled location of the distal ends of the regenerated tendons with greater precision and were used to define their position with respect to the most distal point on the articular surface of the MFC.

Table 1 shows that 25 (83.33%) of the ST tendons and 30 (100%) of the G tendons were visualized with MRI, demonstrating regeneration. With regard to the region distal to the insertion of the regenerated tendons, it was found that among 25 ST tendons, 7 (28%) had their most distal portion proximal (P) to the standard point of the MFC, 4 16%) were at the same level (N), and 14 (56%) were distal (D) to the standard point. Regarding the G tendons, of the 30 (100%) that showed regeneration, 11 (36.66%) were proximal (P) to the standard MFC point, 3 (10%) were at the same level (N), and 16 (53.33%) were distal (D). Eleven ST and G (36.66%) tendons had their distal extent identified in the pes anserinus region, thus indicating complete regeneration.

Therefore, it can be inferred that significant regeneration occurred in both tendons. For ST tendons, the regeneration rate was 83.33%. Considering sample variability, the estimated proportion showing tendon regeneration in the population was 0.833 ± 0.134 (95% Cl 0.699-0.967, with sampling error = 0.134). For G tendons, the regeneration rate was 100% and Cls could not be calculated.

Physical examination

Regarding the visibility of tendons following the Cross maneuver⁸, 11 cases (36.66%) were visible, whereas 19 (63.33%) could not be visualized (Table 2). In contrast, on palpation, among the 30 knees evaluated, the ST and/or G tendons were palpable in 25 (83.33%), while in 5 cases (16.66%), palpation was not possible.

Inspection and palpation were more reliable than MRI. Thus, on palpation (Table 3) we observed the following: S = 0.96 (95% CI 0.805–0.993), E = 0.80 (95% CI 0.376–0.964), PPV = 0.960 (95% CI 0.805–0.993), NPV = 0.80 (95% CI 0.376–0.964). On inspection, the values were (Table 4) S = 0.44 (95% CI 0.267–0.629), E = 1 (CI 0.566–1.000), PPV = 1 (95% CI 0.741–1.000), NPV=0.263 (95% CI 0.118–0.488).

DISCUSSION

The first study on regeneration of the ST and G tendons was carried out by Cross et al.,⁶ who used MRI in 4 patients to show that tendons showed increased regenerative potential. In 1997, Simonian et al. described the same phenomenon using MRI in 9 patients; on the basis of their results, they suggested tendon reuse in new ACL lesions.² In the present study, the regeneration of the ST tendon was demonstrated by MRI examination in 83.33% of cases and that of

 Table 1. Characterization of the semitendinosus and/or gracilis muscle tendons on physical examination stratified according to whether they were palpable and/or visible.

Tendons	Yes	No	Total
Palpable	25	5	30
Visible	11	19	30

Table 2. Characterization of the semitendinosus (ST) and gracilis (G) tendons using MRI, and the anatomical relationship between the most distal point of the joint and the medial femoral condyle.

Tendons	Р	N	D	С	Total	NI	
ST	7	4	3	11	25	5	
G	11	3	5	11	30	-	
Total	18	7	8	22	55	5	

P: proximal, N: at the same level, D: distal, C: complete regeneration (up to the *pes anserinus*), NI: not identified.

Table 3. Comparison of data obtained using clinical evaluation and MRI.							
N⁰	Age (years)	ISE (months)	Р	v	ST	G	
1	25	34	Y	Y	С	С	
2	40	31	N	N	NI	Р	
3	23	24	Y	Y	С	С	
4	34	24	Y	N	N	N	
5	32	23	Y	Y	С	С	
6	42	23	Y	Y	С	С	
7	39	23	Y	N	С	С	
8	33	22	Y	Y	С	С	
9	42	21	Y	N	NI	D	
10	29	20	N	N	NI	Р	
11	30	17	Y	N	N	N	
12	42	16	Y	Y	С	С	
13	31	16	Y	Y	С	С	
14	35	15	Y	Y	D	Р	
15	31	15	N	N	NI	Р	
16	37	15	Y	N	N	D	
17	28	14	Y	Y	С	С	
18	36	14	N	N	NI	Р	
19	19	13	Y	N	Р	Р	
20	23	13	Y	N	N	N	
21	25	13	Y	N	D	Р	
22	36	13	Y	Y	D	D	
23	31	12	Y	N	С	С	
24	31	12	Y	N	Р	Р	
25	27	11	Y	N	Р	D	
26	39	11	Y	N	Р	D	
27	25	10	Y	N	Р	Р	
28	49	10	Y	N	Р	Р	
29	33	10	N	N	Р	Р	
30	29	9	Y	Y	С	С	

Patient Number (N°), age, and interval between the date of surgery and the date of physical and MRI exams (ISE). Columns 3 and 4 characterize semitendinosus (ST) and/or gracilis (G) tendons based on physical examination, i.e., presence of palpable (P) and/or visible (V) tendons. Y: yes, N: = no. Columns 5 and 6 characterize the ST and G tendons using MRI and their anatomical relationships with the most distal point of the joint end of the medial femoral condyle. P: proximal; N = at the same level; D: distal; C: complete regeneration (up to the *pes anserinus*); NI = not identified.

 Table 4. Comparison of palpation and magnetic resonance imaging (MRI) findings in determining regeneration of semitendinosus and/or gracilis tendons.

Va	Yes		MRI	
Tes	5	No	Total	
	Yes	24	1	25
Palpation	No	1	4	5
	Total	25	5	30

the G tendon in 100% of cases. Only 36.66% of patients, however, displayed complete regeneration of the tendons. Comparing our results with published data, we observed that Zaccherotti et al. found regeneration of ST tendons in 70% of patients at 7 months post-operatively.¹² Suijkerbuijk *et al.* analyzed 18 studies in a systematic review and concluded that there was, in fact, tendon regeneration, but that the strength and mechanisms facilitating this regeneration remain uncertain.¹³ These results were supported by Papalia et al., in a meta-analysis of 19 studies including approximately 400 individuals.¹⁴ Thus, the results of the above studies regarding the prevalence of regeneration supports the results of the present study, independent of the methods and protocols used for imaging tests

and follow-up time, which makes our conclusions more precise than those of previous studies.

Papandrea et al. identified complete regeneration only if present at 18 months postoperatively,⁹ whereas Eriksson et al. identified complete regeneration in patients evaluated between 6 and 12 months postoperatively.⁸ In the present study, the complete regeneration of these tendons was more frequently found after a 1-year interval after surgery and the date of MRI evaluation. We analyzed 6 patients with an interval of less than 1 year (ranging from 9 to 11 months). Of these, only 1 patient (16.66%) presented complete regeneration of the tendons (Table 5). The remaining 24 had a postoperative period of greater than 1 year (ranging from 12 to 34 months) and 10 of these (41.66%) presented complete tendon regeneration (Table 5).

The results obtained in this study, however, lead us to assume that we cannot rely on the reuse of these tendons for a new ACL lesion within this time interval, given that only a small portion of cases showed complete regeneration (only 36.66% reached the region of the hamstring anatomical insertion).

In terms of physical examination, firm structures similar to tendinous fibers were observed in the region that previously contained the tendons used as grafts. These structures were sometimes clearly visible; however, most times, they were only palpable due to the presence of abundant adipose tissue in the region. However, we observed during our study that when these tendons were clearly palpable and visible, they appeared regenerated on MRI examination. This was clearly demonstrated when comparing the physical examination results with those obtained by MRI examination using statistical analysis (Tables 4 and 5). When comparing palpation to MRI, we found high values for sensitivity, specificity, PPV, and NPV, which are signs that palpation is quite efficient in evaluating the regeneration of ST and G tendons (misinterpretation occurred in only 2 cases). When comparing inspection (visualization) to MRI, there was low sensitivity (sensitivity = 0.440, with a 95% CI 0.267-0.629), which means that inspection is not a reliable test to evaluate the regeneration of the ST and G tendons. The low NPV also indicates that inspection can provide us with a large number of false-negative results.

Despite the alleged regenerative capacity of the hamstring tendons, the clinical significance of this finding as well as the biomechanical characteristics of the new tendons remain unclear.¹⁴⁻¹⁶ Studies evaluating the correlation between the regeneration of ST and G tendons and the recovery of knee flexor muscle strength have been published recently. In 2012, Choi et al., evaluated 45 patients using isokinetic tests and found a direct relationship between knee flexor strength and the degree of regeneration of the flexor tendons.¹⁷ Furthermore, the number of regenerated tendons (both or only one) had a direct correlation with the knee flexor force measured by isokinetic testing. These authors considered that the technique used for graft removal might display a significant correlation with the rate of regeneration. In our clinical setting, the data described herein are relevant as harvesting of homologous grafts necessary for the treatment of multi-ligament knee injuries and revision surgeries, where contralateral hamstrings are not available and other tendons are not of sufficient length for satisfactory reconstruction, is difficult. Nevertheless,

Table 5. Comparison of visual inspection and magnetic resonance imaging (MRI) findings for the evaluation of semitendinosus and/or gracilis tendon regeneration.

Yes				
TE	5	No	Total	
	Yes	11	0	11
Visualization	No	14	5	19
	Total	25	5	30

this study has limitations, with the number of participants (n = 30) examined being the most important. Obviously, an extension of the follow-up period would eventually allow the aggregation of cases in the group that obtained tendon regeneration, without interfering with the outcome results. Clinical parameters (strength, range of motion, flexibility, and functional scores) were not taken into consideration in this study, as the aim was to observe tendon regeneration and not surgical outcome.

CONCLUSION

Partial or total regeneration of ST and G tendons was evaluated with MRI in patients who underwent ACL reconstruction using

autografts of these tendons. Palpation on physical examination was effective to evaluate the regeneration of ST and G tendons. Our study showed that MRI was the most reliable method to evaluate ST and G tendon regeneration. Over the time interval studied, only a fraction of patients presented complete regeneration of the ST and G tendons.

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ORIGINAL ARTICLE

ARE TRAUMATOLOGISTS TREATING OSTEOPOROSIS TO PREVENT NEW FRACTURES IN BRAZIL?

OS TRAUMATOLOGISTAS TRATAM OSTEOPOROSE, PARA PREVENIR UMA NOVA FRATURA, NO BRASIL?

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ABSTRACT

Objectives: To determine the proportion of traumatologists who investigate osteoporosis in elderly patients with fractures and recommend secondary prevention of osteoporotic fractures. Methods: We distributed guestionnaires to 244 physicians attending the 2015 Brazilian Congress of Orthopedic Trauma. We determined the respondents' profiles and assessed how they investigated and treated osteoporosis in elderly patients with fractures. Results: Overall, 32% of the respondents reported that their knowledge level regarding osteoporosis ranged from 0-5 (out of 0-10). In total, 42% of the participants reported that they usually requested DXA for elderly patients with fractures and less than 30% reported prescribing supplemental calcium and/or vitamin D. We considered physicians conducting a complete treatment for the patient as those who in addition to requesting DXA prescribed supplemental calcium, vitamin D, and specific medications for their elderly patients, and recommended non-pharmacological measures. Only 0.8% of the participants fulfilled all these criteria. In addition, 47% of the traumatologists reported that they did not treat osteoporosis directly but instead, referred osteoporotic patients to a qualified physician. Conclusion: Less than 50% of the surveyed traumatologists investigated and performed secondary prevention against osteoporotic fractures after treating an elderly patient with a fracture. Level of evidence III, Economic and Decision Analyses - Developing an Economic or **Decisions Model.**

Keywords: Osteoporosis. Osteoporotic Fracture. Secondary Prevention. Surveys and Questionnaires.

RESUMO

Obietivo: Avaliar a proporcão de traumatologistas que investigam a osteoporose nos pacientes idosos com fraturas e recomendam a prevenção secundária das fraturas osteoporóticas. Métodos: Distribuímos questionários para 244 médicos participantes do Congresso Brasileiro de Traumatologia Ortopédica em 2015. Determinamos o perfil dos mesmos e avaliamos como os entrevistados investigam e tratam a osteoporose nos pacientes idosos com fraturas. Resultados: Entre os entrevistados, 32% relataram que seu nível de conhecimento sobre osteoporose seria algo entre 0 e 5 (de 0 a 10). No total, 42% dos participantes relataram que frequentemente solicitam DXA para pacientes idosos com fraturas, mas menos de 30% relataram prescrever suplementação com cálcio e/ou vitamina D. Consideramos como prescritores do tratamento completo para o paciente aqueles médicos que, além de solicitar DXA, prescrevem suplementação de cálcio, vitamina D e medicamentos específicos para seus pacientes idosos, além de recomendar medidas não farmacológicas. Apenas 0,8% dos participantes preencheram todos esses critérios. Além disso, 47% dos traumatologistas relataram que não tratam a osteoporose, mas encaminham seus pacientes com osteoporose para um médico que o faz. Conclusão: Menos de 50% dos traumatologistas pesquisados investigam e realizam prevenção secundária contra fraturas osteoporóticas após tratamento de paciente idoso com fratura. Nível de evidência III, Análises econômicas e de decisão - Desenvolvimento de modelo econômico ou de decisão.

Descritores: Osteoporose. Fraturas por Osteoporose. Prevenção Secundária. Inquéritos e questionários.

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INTRODUCTION

Osteoporosis is characterized by decreased bone mineral density and disruption of the bone microarchitecture leading to increased bone fragility.¹ It is defined by the World Health Organization as a bone mineral density T-score below -2.5 standard deviations determined by dual-energy x-ray absorptiometry (DXA).² According to current estimates, osteopenia and osteoporosis affect millions of individuals worldwide.^{2–5} Osteoporosis, which often affects elderly

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patients, may be a silent disease until complicated by a fracture, which may occur with minimal trauma or even in its absence. Fractures of the vertebra, proximal femur, and distal radius are considered sentinel events.⁵ Up to 50% of women and 20% of men older than 50 years are estimated to have an osteoporotic fracture throughout life.³

In this context, it is important to consider the costs associated with hospital admissions, outpatient care, and medical procedures to treat these fractures, which are potentially preventable in a large proportion of patients.⁵⁻⁸

We must understand the importance of properly treating osteoporosis to prevent serious complications such as new fractures and secondary deformities, chronic pain, and loss of independence. These measures may also reduce mortality in the elderly population. Still, we observe that the diagnosis and treatment of this disease are flawed in many countries worldwide.^{14,9}

The aim of this study was to assess the percentage of orthopedic traumatologists in Brazil who investigate and treat osteoporosis with the objective of preventing new fractures in elderly patients.

MATERIALS AND METHODS

We invited participants of the 21st Brazilian Congress of Orthopedic Trauma (*Congresso Brasileiro de Trauma Ortopédico*, CBTO), held in May 2015 in Belém (Pará, Brazil), to fill out an anonymous questionnaire. The questionnaire consisted of multiple-choice questions and was answered by 244 physicians, of whom 184 were orthopedic traumatologists and 60 were residents in orthopedics and traumatology. The data obtained were analyzed and correlated using the programs Excel 2011 and Epilnfo, version 3.5.2.

The research project of this study was approved by the Ethics Committee in Research (CAAE 39276614.5.0000.5479). The physicians who filled out the questionnaires signed a Free and Informed Consent Form. We determined the profile of the participating physicians by including two questions in the survey: (1) For how long (in years) have you been practicing orthopedics? and (2) In which region of Brazil do you practice? The answers to these questions were compared with deidentified data from the Brazilian Society of Orthopedic Trauma (Sociedade Brasileira de Trauma Ortopédico, SBTO) in order to evaluate how the participants would compare with the actual profile of the overall sample of orthopedic traumatologists in Brazil.

We assessed the degree of knowledge of the participants regarding osteoporosis, and whether they investigate and treat the disease, and if they do so, how they conduct the investigation and treatment. We also questioned the degree of knowledge that the surveyed traumatologists consider to have regarding the disease, and how much they wish they knew about it. In order to assess the knowledge about the disease, we asked the participants to select among six options the correct T-score cutoff value that establishes the diagnosis of osteoporosis, as defined by the World Health Organization.² To evaluate if the participants performed any investigation or treated osteoporosis, we asked them if after diagnosing and treating a fracture in an elderly patient, whether they request any additional tests to identify or confirm the occurrence of osteoporosis. We also asked if they recommend non-pharmacological measures and prescribe supplemental calcium, vitamin D, or any specific medication (antiresorptive agents or bone forming agents) to at least 50% of their patients.

For the purpose of this research, we considered as managing osteoporosis adequately those physicians who:

- Requested DXA to investigate or confirm a diagnosis of osteoporosis;
- Answered the correct T-score value that establishes the diagnosis of osteoporosis (-2.5 standard deviations);

- Prescribed supplemental calcium and vitamin D to at least 50% of their elderly patients diagnosed with a fracture;
- Prescribed any medication specifically to treat osteoporosis to at least 50% of their elderly patients diagnosed with the disease;
- Recommended some type of non-pharmacological treatment/ prevention (such as fall prevention, smoking cessation, decrease in alcohol consumption, or regular physical activity);
- Referred the patient to a specialist qualified to treat osteoporosis (for those participants who did not treat osteoporosis).

RESULTS

Table 1 shows the distribution of the participants according to the region in Brazil where they practice orthopedics. Excluding the residents who answered the questionnaire, 40% of the participants reported to have been practicing orthopedics for less than 10 years, whereas the remaining 60% reported more than 10 years of practice. Data obtained from the SBTO showed that 27% of the members of the society had concluded training less than 10 years before the data were collected, whereas 73% had done so more than 10 years before.

When questioned about their degree of knowledge about osteoporosis on a scale between 0 (zero) and 10 (ten), 32% of the participants responded knowing between 0–5, and 68% reported knowing between 6–10. A total of 97.5% of those who reported knowing between 0–5 answered that they would like their degree of knowledge about osteoporosis to increase to 6–10.

When we asked if the physicians would be interested in participating in a workshop/seminar if promoted by the SBTO, Brazilian Society of Orthopedics and Traumatology (Sociedade Brasileira de Ortopedia e Traumatologia, SBOT), or some other medical society or recognized educational institution, 91% responded that they would. When we assessed the degree of knowledge of the participants about osteoporosis, 76.5% of the residents and 66% of the traumatologists answered the correct T-score cutoff value. A total of 42% of the participants responded that they request DXA to investigate or diagnose osteoporosis in an elderly patient with a fracture, but when we analyzed only the responses given by residents, the corresponding rate was much lower (16%). Among the physicians who reported requesting DXA, 35% answered incorrectly the T-score cutoff value that determines the diagnosis of osteoporosis.

When we excluded the responses by residents, we found that 18% of the respondents prescribe vitamin D, 24% prescribe calcium, and 27% prescribe antiresorptive/bone forming agents during follow-up of elderly patients diagnosed with a fracture. Among medical residents, the corresponding percentages are 3.4% for supplemental calcium and vitamin D and 1.6% for specific medications. The corresponding values are 3.4% for supplemental calcium and vitamin D, and 1.6% for specific medications.

Table 1. Distribution of the participants according to the region in the country where they practice and compared with data provided by the Brazilian Society of Orthopedics and Traumatology (SBTO).

Region	Total n	%	ER n	%	SBTO
North	27	11.06%	22	11.95%	4.22%
Northeast	34	13.93%	28	15.21%	11.22%
Midwest	14	5.73%	14	7.60%	6.55%
Southeast	157	64.34%	113	61.41%	60.49%
South	12	4.91%	7	3.80%	17.49%
Total	244	100%	184	100%	100%

Total n - Total number of participants; % - Percentage; ER n - All participants, excluding residents. SBTO - Percentage of members of the Brazilian Society of Orthopedic Trauma (Sociedade Brasileira de Trauma Ortopédico) distributed by geographical region of practice. As for non-pharmacological treatment, 41% of the participants reported as offering this recommendation, with similar rates between traumatologists and residents (45.7% and 38.9% respectively).

Overall, 47% (n=103 out of 244) of the respondents reported requesting DXA, of whom 65% (n=67 out of 103) knew the correct T-score value. A total of 34 respondents (52% of 67 or 14% of 244) also prescribe supplemental calcium and vitamin D, and nine of these (26% of 34 or 3.6% of 244) prescribe a medication specifically to treat osteoporosis. Only two respondents (22% of 9 or 0.8% of 244) reported that they conduct a complete treatment in which they request and interpret the tests, prescribe supplemental calcium, vitamin D and appropriate medications, and recommend non-pharmacological treatment (Figure 1).

Overall, 47% of the traumatologists and 43% of the residents reported not treating osteoporosis but instead, referring their patients to a medical professional who is qualified to do so.

DISCUSSION

When we compared the profile of the participants, we observed that they share similar characteristics with members of the SBTO in terms of the region of the country where they practice. The values remained within 95% confidence intervals for the Midwest, Southeast, and Northeast regions, but were above the interval for the Northern region and below it for the Southern region. This may be explained by the fact that the meeting was located in the Northern region of Brazil (Belém, PA) and also by the continental dimensions of our country. Still, the similarities between the groups confirm that our cohort was representative of the overall members of SBTO.

There was a greater participation of physicians who had finished training less than 10 years before the survey when compared with data provided by SBTO. In our understanding, this is due to the fact that individuals who have been practicing for less time tend to participate more frequently in workshops and meetings, seeking to improve knowledge to make up for a shorter experience, and possibly a greater academic commitment, availability, and disposition to participate in the study and fill out the questionnaire. Regarding secondary prevention, traumatologists in practice for more than 10 years have a greater commitment to research, knowledge, and treatment of osteoporosis, and are more prone to recommend secondary prevention, whereas those with a shorter practice experience refer their patients to specialized care (Figure 2).

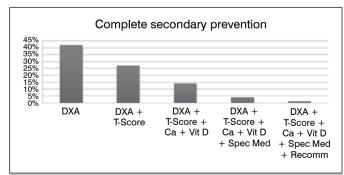


Figure 1. Percentages of physicians who conduct a complete treatment of osteoporosis. Among all participants, the percentages of those who request DXA (DXA), also knows the correct T-score cutoff value (DXA + T-score), also prescribes supplemental calcium and vitamin D (DXA + T-score + Ca + Vit D), also prescribes specific medications (DXA + T-score + Ca + Vit D + Sp Med [antiresorptive or bone forming agents]), and also recommends non-pharmacological measures to their patients (DXA + T-score + Ca + Vit D + Sp Med + Recomm).

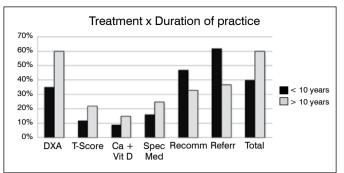


Figure 2. Distribution of follow-up scenarios according to the duration of orthopedics practice. The bars show the percentages of participants who reported requesting DXA (DXA), knowing the correct T-score to establish a diagnosis of osteoporosis (T-score); recommending supplemental calcium and vitamin D (Ca + Vit D), prescribing specific medications for osteoporosis (Spec Med), recommending non-pharmacological measures (Recomm), and referring the patient when not performing treatment (Referr).

The large difference observed between the numerical values obtained with the questions "How much do you think you know?" (average = 6) and "How much would you like to know?" (average = 9.3) suggests that the participants are interested in osteoporosis and are willing to learn about it, a fact that was confirmed when 90% answered that they would have an interest in participating in a workshop/meeting organized on this subject by a recognized medical society or institution.

When we assessed specifically the participants' technical knowledge about osteoporosis treatment, most traumatologists and residents knew the correct T-score value; however, less than half of them reported requesting additional tests to investigate the diagnosis or support the treatment, with only 16% of the residents having reported doing so. This finding is concerning because it demonstrates an inconsistency in the process of specialized medical training that needs to be corrected. The National Osteoporosis Foundation and the World Health Organization recommend that all adults older than 50 years who are diagnosed with a fracture should be investigated with DXA.^{2,10}

The treatment of osteoporosis involves both pharmacological and non-pharmacological measures. Medical entities such as the Brazilian Society of Endocrinology and Metabolism (Sociedade Brasileira de Endocrinologia e Metabologia) and the World Health Organization have demonstrated that the amount of calcium and vitamin D consumed by the population usually falls short of the actual requirement, and their supplementation is often necessary.^{2,5,11,12} Regarding specific medications to treat osteoporosis, such as antiresorptive and bone forming agents, several studies and systematic reviews have demonstrated their efficacy in secondary prevention.¹³⁻¹⁶

We considered as appropriately recommending secondary prevention those traumatologists who reported that they investigated the occurrence of osteoporosis, knew the definition of the disease according to current and established criteria, prescribed pharmacological treatment and supplementation, and recommended non-pharmacological measures.¹⁷ Only 0.8% of the traumatologists and none of the residents fulfilled all these criteria.

We also considered as appropriately managing the patients those surgeons who after treating an osteoporotic fracture, referred the patient to a specialist qualified to treat the osteoporosis. Less than half of the traumatologists (47%) and residents (43%) reported doing that. This fact is concerning, considering that many fractures could be avoided if the underlying disease were treated correctly.^{5,7,13,18,19} Although this is a global problem,

it has some particularities in Brazil, as reflected by a study among physicians members of the Brazilian Society of Internal Medicine (Sociedade Brasileira de Clínica Médica) that has shown that only 35% of the general practitioners believe that osteoporosis treatment is effective.²⁰

CONCLUSION

Our results show that less than half of the traumatologists in Brazil diagnose and recommend secondary prevention for osteoporotic fractures, only 0.8% of them treat these patients correctly, and 47% refer the patients to specialized care.

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PATHOLOGICAL FRACTURES DUE TO BONE METASTASES FROM IUNG CANCER: RISK FACTORS AND SURVIVAL

FRATURA PATOLÓGICA DEVIDO À METÁSTASE ÓSSEA DO CÂNCER **DE PULMÃO: FATORES DE RISCO E SOBREVIDA**

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ABSTRACT

Introduction: Pathological fractures are frequent skeletal-related events among lung cancer patients, which result in high morbidity and decreased overall survival and make operative treatment decisions challenging. Objectives: To identify risk factors associated with the occurrence of pathological fractures in patients with lung cancer and to determine survival. Methods: We conducted a retrospective cohort study with 407 lung carcinoma patients diagnosed between 2006 and 2015. The prevalence of bone metastases and pathological fractures was calculated. Statistical analysis was conducted using a chi-squared test, and the odds ratio and 95% confidence interval were calculated. Overall survival was determined using the Kaplan-Meier method and differences were compared using the log-rank test. Results: The prevalence of bone metastases and pathological fractures was 28.2% (n = 115) and 19.1% (n = 22), respectively. Pathological fractures were more frequent among patients with bone metastases at the time of diagnosis of lung cancer (24.7% [n = 20] vs. 5.9% [n= 2]; p < 0.05). The median overall survival following the diagnosis of lung cancer, bone metastases, and pathological fracture was 6, 4, and 2 months, respectively. Conclusions: Pathological fracture was associated with synchronous bone metastases and overall survival times were considerably reduced. Level of Evidence IV, Case Series.

Keywords: Lung neoplasms, Bone, Fractures.

RESUMO

Introdução: Fratura patológica é um evento esquelético frequente em pacientes com câncer de pulmão, resultando em alta morbidade e sobrevida global reduzida que torna a decisão de tratamento cirúrgico desafiadora. Objetivos: Identificar fatores de risco associados à ocorrência de fraturas patológicas em pacientes com câncer de pulmão e determinar a sobrevida. Métodos: Conduzimos um estudo retrospectivo de coorte com 407 pacientes diagnosticados com carcinoma pulmonar entre 2006 e 2015. A prevalência de metástase óssea e fratura patológica foi calculada. Análise estatística foi conduzida usando o teste X2, e razão de chances e o intervalo de confianca de 95% foi calculado. A sobrevida global foi determinada usando o método de Kaplan-Meier e as diferenças foram comparadas usando o teste do log-rank. Resultados: A prevalência de metástases ósseas e fraturas patológicas foi de 28,2% (n = 115) e 19,1% (n = 22), respectivamente. Fraturas patológicas foram mais frequentes em pacientes com metástases ósseas ao diagnóstico do câncer de pulmão (24,7 % [n = 20] vs. 5,9% [n = 2]; p < 0.05). A sobrevida global média após o diagnóstico do câncer de pulmão, da metástase óssea e da fratura patológica foram 6, 4 e 2 meses, respectivamente. Conclusão: Fratura patológica foi associada à metástase óssea sincrônica e a sobrevida global consideravelmente reduzida. Nível de Evidência IV. Série de Casos.

Descritores: Neoplasias pulmonares. Osso. Fraturas.

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INTRODUCTION

The bone represents one of the most frequent sites of metastases from lung cancer, occurring in approximately 15-40% of patients.¹ Skeletal-related events (SREs) are prevalent among these patients, resulting in high morbidity and a reduced quality of life.^{2,3} Despite the negative impact of bone metastases (BMs) on lung cancer prognosis, the unpredictability of survival makes an indication of palliative surgery challenging. Therefore, the elucidation of factors that can determine which patients will survive for a longer or shorter time is fundamental in guiding optimal treatment decisions. In previous studies conducted by Oliveira et al., adenocarcinoma was associated with the higher risk of developing BMs.^{3,4} Therefore, we postulated that lung cancer histological subtype could also be correlated with the occurrence of PFs. In this study, we aimed to identify risk factors associated with the occurrence of PFs in patients with BMs from lung cancer and to assess the impact of this SRE

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on survival. This analysis can support the decision to surgically treat these patients, or not, and identify in which patient palliative surgery would be better indicated.

MATERIALS AND METHODS

The medical records of 413 patients who had been diagnosed with malignant primary lung tumors at our institution between 2006 and 2015 were retrospectively evaluated. Inclusion criteria included a pathological confirmation of lung carcinoma and complete tumor staging data. Lung carcinomas were stratified based on the World Health Organization's classification system: adenocarcinoma (ADC), squamous cell carcinoma (SCC), large-cell carcinoma (LCC), NSCLC not otherwise specified (NOS), and SCLC.⁵

Events of interest included BMs and PF occurrence, and death. BMs were diagnosed by histopathological examination or using Technetium-99m bone scintigraphy with two additional imaging modalities (plain films and computed tomography or magnetic resonance imaging). BMs and PFs were classified, according to the time of diagnosis of the primary tumor, as either synchronous or metachronous. Collected variables included age, sex, smoking status, histological subtype, metastatic sites, a PF, the time of diagnosis of BMs and PFs in relation to the time of diagnosis of the primary tumor, and survival. Patients diagnosed with a second malignant primary tumor who had an unknown date of death were excluded from survival analysis. The minimum follow-up period following a diagnosis of BMs was 24 months, excluding patients with a survival of < 24 months. The proportions of the variables among patients who developed or did not develop a PF were compared using a chi-squared test. The relationship between the variables and the occurrence of a PF was also evaluated using odds ratios (ORs) and 95% confidence intervals (CIs). Overall survival (OS) and associations with the variables were analyzed using the Kaplan-Meier method. Differences between patients who developed or did not develop a PF, in addition to a synchronous or metachronous PF, were evaluated using the log-rank test. All statistical analyses were performed using Statistical Package for the Social Sciences for Windows, software version 10.0 (SPSS Inc., Chicago, IL, USA). A p < 0.05 was considered statistically significant.

The study protocol was approved by the appropriate Institutional Review Board committee (protocol number 113/11). All study participants provided written informed consent and research was conducted in accordance with the Declaration of Helsinki.

RESULTS

Among 413 lung cancer patients, 407 (98.5 %) who met the inclusion criteria for histological subtype were analyzed. The patients' clinicopathological characteristics are summarized in Table 1, and a cohort diagram is presented in Figure 1.

ADC was the most prevalent histological subtype (46.7 %; n = 190), followed by SCC (25.1 %; n = 102).

The prevalence of BMs was 28.3 % (n = 115). Synchronous BMs occurred significantly more frequently than metachronous BMs (19.9 % [n = 81] vs. 8.4 % [n = 34]; p < 0.01). In total, 79 patients experienced 122 SREs, with an overall prevalence of 68.7 % among patients with BMs. Radiotherapy was the most frequent SRE (60.7 %; n = 74), followed by PF (19.1 %; n = 22), spinal cord compression (9.0 %; n = 11), surgical treatment for BMs (6.6 %; n = 8), and hypercalcemia (5.7 %; n = 7) (Figure 1).

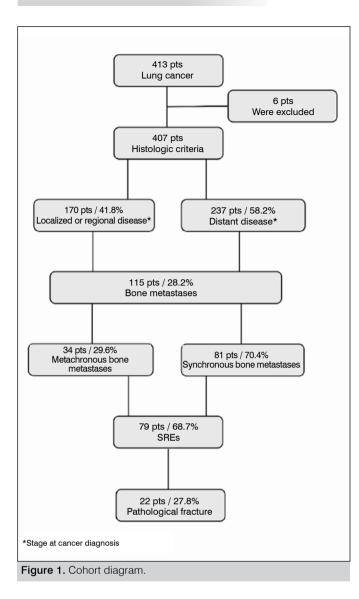
PF fracture was more common among ADC patients (23.9 %; n = 16). The Figure 2 shows the prevalence of PFs according to lung cancer histology. Among 115 patients with BMs, 305 BMs and 22 PFs occurred. The most frequent site of BMs and PFs included the spine (32.1 %; n = 98) and humerus (36.4 %, n = 8), (Figure 3).

To evaluate the relationship between the patients' clinicopathological characteristics and the occurrence of PFs, we compared the prevalence of histological subtype, smoking, synchronous or metachronous BMs, and the location of BMs in patient groups with or without PFs (Table 3). Among patients who developed a PF, the prevalence of ADC, SCC, LCC, NSCLC, and SCLC was 72.8 % (n = 16), 4.5 % (n = 1), 4.5 % (n = 1), 9.1 % (n = 2), and 9.1 % (n = 2), respectively. The ORs and 95 % Cls are displayed in Table 3. Smoking was significantly associated with the occurrence of a PF. The prevalence of smoking in patients with a PF was substantially higher than the prevalence of smoking in patients without a PF (95.5 % [n = 21] vs. 74.2 % [n = 69]; p < 0.05).

 Table 1. Clinicopathological characteristics of different histological subtypes of lung cancer in patients with or without bone metastases and pathological fractures.

	Lung canc	er patients	Lung canc	er patients	Lung canc	er patients		cancer patients Lung cancer patients one metastasis with bone metastasis		
Characteristic	cohort	overall	without bon	e metastasis	with bone	metastasis		athological ture	with patholo	gical fracture
	N =	407	N =	292	N =	115	N =	93	N	= 22
	N	%	N	%	N	%	N	%	N	%
Mean age (range)	63.4 year	rs (32-87)	65.7 yea	rs (42-84)	62.6 year	rs (32-87)		years -83)		years 9-87)
Gender										
Male	250	61.4	175	59.3	75	65.2	61	65.6	14	63.6
Female	157	38.6	117	40.7	40	34.8	32	34.4	8	36.4
Smoking										
Never smoked	55	13.5	30	10.3	25	21.7	24	25.8	1	4.5
< 40 packs/year	96	23.6	63	21.6	33	28.7	24	25.8	9	41.0
\geq 40 packs/year	256	62.9	199	68.1	57	49.6	45	48.4	12	54.5
Histology										
ADC	190	46.7	123	42.1	67	58.3	51	54.8	16	72.8
SCC	102	25.1	87	29.8	15	13.0	14	15.1	1	4.5
LCC	11	2.7	9	3.1	2	1.8	1	1.1	1	4.5
NOS/NSCLC	56	13.7	40	13.7	16	13.9	14	15	2	9.1
SCLC	48	11.8	33	11.3	15	13.0	13	14	2	9.1

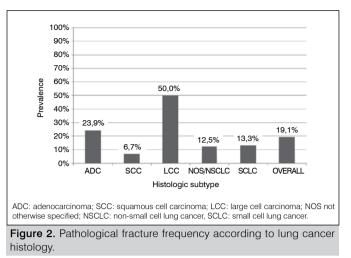
ADC: adenocarcinoma; LCC: large cell carcinoma; NOS: not otherwise specified; NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer.



The prevalence of a diaphyseal PF (36.0 %) was significantly higher than that of a metaphyseal PF (9.5 %), demonstrating an increased risk of a PF in the diaphyseal region (OR: 5.34, 95 % Cl: 1.65–17.2; $\rho < 0.01$). PFs were more frequently observed in patients with synchronous BMs (24.7 %) compared to patients with metachronous BMs (5.9 %) (OR: 5.24, 95 % Cl: 1.15–23.8; $\rho < 0.05$).

The primary treatment method for PFs was non-operative, based on immobilization and radiation. Surgical treatment was performed in 8 patients (36.3 %) through internal fixation with an intramedullary nail (22.7 %; n = 5) or megaprosthesis replacement (13.6 %; n = 3). The sample size for analysis of OS was 95. Twenty patients (17.4 %) were excluded due to the diagnosis of a second malignant primary tumor (10.4 %; n = 12) or as a result of an unknown date of death (7.0 %; n = 8). The median OS times following a diagnosis of lung cancer, BMs, and PF were 6 months, 4 months, and 2 months, respectively (Table 4). Kaplan-Meier curves with 95 % CIs are presented in Figure 4.

Median OS times following a diagnosis of BMs were compared between patient groups who developed or did not develop a PF. The median OS times were 7.4 months and 6.4 months, respectively, with no statistical significance (p>0.05). The median OS times of patients with synchronous or metachronous PFs were 3.6 months and 10.7 months, respectively, with no statistical significance (p>0.05).



DISCUSSION

The skeleton is one of the most frequent sites of metastatic carcinoma dissemination.⁶ In the present cohort of lung cancer patients treated at a single academic general hospital, 28.3 % of lung cancer patients (n = 115) had secondary bone involvement. Studies comparing the frequencies of metastatic sites in NSCLC patients demonstrated a bone dissemination frequency of 20-40 %.^{2,3,7-10} Although bone involvement usually means the cancer is incurable, a proportion of patients do survive for prolonged periods. Consequently, these patients are more likely to develop SREs.¹¹ Recent advances in the treatment of cancer have prolonged survival.¹² As survival increases, SREs, including PFs, are gaining increasing importance, since a prolonged survival increases the risk of such complications over a long period. In the present study, the PF rate reached 19.1 % in patients with secondary bone involvement from lung cancer. This finding was comparable to that of Saad et al. (16.6 %: n = 127), who evaluated the significance of PFs in the survival of patients with different primary tumors.¹¹

The patients included in the present study had independent risk factors for the occurrence of PFs: the presence of BMs and a lung cancer diagnosis.¹³ In the evaluation of variables associated with the occurrence of PFs, statistical significance was reached for the time of diagnosis or location of BMs and smoking. PFs occurred more frequently in patients with synchronous BMs (24.7 %) compared to patients with metachronous BMs (5.9 %). The frequency of this event was probably higher in the synchronous group, owing to the longer period that these patients are exposed to BMs without specific treatment.

We postulate that the predisposition of cancer patients to developing a PF is multifactorial in origin. In addition to being most obviously and directly related to reduced bone strength, compromised by the presence of metastatic lesions, the risk of developing a PF may also be enhanced by other factors (e.g., immobility, malnutrition, and chemotherapy). Moreover, a major bias is associated with PF risk in lung cancer patients, because of the direct relationship between smoking and lung cancer. However, smoking was independently associated with an increased risk of developing a PF. A previous study reported that smoking increases the PF risk in lung cancer patients, as observed in the present study.¹⁴ Other possible factors related to the occurrence of a PF include the association between lung cancer and chronic obstructive pulmonary disease and, consequently, the use of corticosteroids that result in bone demineralization.¹⁵

BMs are associated with a poor prognosis in patients with cancer.¹⁶ In a study conducted by Sathiakumar *et al.*, the risk of death was 2.4 times higher in patients who developed BMs compared to those who

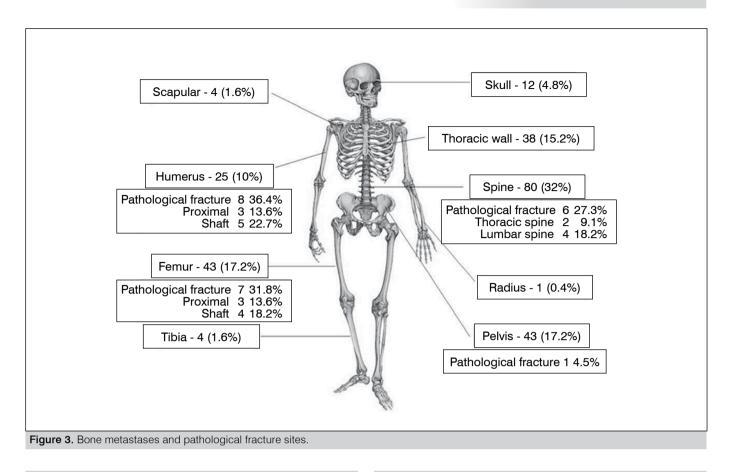


Table 2. Analysis of histological subtype, synchronous bone metastases,
smoking, and bone location as factors associated with pathological
fractures in lung cancer patients.

	Pa	Pathological Fracture					
	· ·	Yes		No	OR	IC (95%)	p-value
	N	%	Ν	%			
Histology							
ADC	16	72.8%	51	54.7%	2.19	(0.79-6.11)	0.125
SCC	1	4.5%	14	15.1%	0.26	(0.03-2.16)	0.188
LCC	1	4.5%	1	1.1%	4.38	(0.26-72.9)	0.262
NOS/NSCLC	2	9.1%	14	15.1%	0.56	(0.11-2.68)	0.467
SCLC	2	9.1%	13	14.0%	0.61	(0.12-2.95)	0.540
Bone Metastasis							
Synchronous	20	90.1%	61	65.6%	E 00		0.005
Metachronous	2	9.9%	32	34.4%	5.08	(1.11-23.1)	0.035
Smoking							
Yes	21	95.5%	69	74.2%		(1 01 07 1)	0.000
No	1	4.5%	24	25.8%	7.7	(1.01-67.1)	0.029
Location							
Dyaphyseal	9	60.0%	16	22.5%	E 04	(1.05.17.0)	0.005
Metaphyseal	6	40.0%	55	77.5%	5.34	(1.65-17.2)	0.005

ADC: adenocarcinoma; SCC: squamous cell carcinoma; LCC: large cell carcinoma; NOS: not otherwise specified; NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer.

Table 3. Analysis of overall survival following a diagnosis of lung cancer,
bone metastases, and pathological fracture.

	Survival in months after							
	Lung cancer	Bone metastases	Pathological fracture					
Ν	95	95	15					
Minimum	0.2	0.2	0.5					
Maximum	46	38.5	24					
Median	6	4	2					
Mean	9.4	6.6	4.7					

did not.¹⁷ The OS time of patients with BMs from lung cancer was low in the present study. The median OS times following a diagnosis of lung cancer (6 months) and BMs (4 months) were shorter than the previous study. The median OS time observed following a diagnosis of lung cancer (6 months) in the present study was similar to the OS time predicted (7.2 months) in a study conducted by Wao *et al*.¹⁸ The present study also demonstrates similar findings to those reported in a French retrospective study in which the median survival time was estimated to be 5.8 months following a diagnosis of BMs.¹⁹ The median survival times following a diagnosis of lung cancer (6 months) and BMs (4 months) were very similar. The high proportion of patients who had BMs at time of diagnosis of lung cancer (70.4 %; n = 81) explains this small difference.

The impact of PFs on the outcome of lung cancer patients may be even greater than predicted because the prevalence of PFs in lung cancer patients may be limited by reduced OS times. Therefore, with increasing survival times due to advances in treatment methods, this problem may become even more relevant.

PFs usually occur 5 months after a diagnosis of BMs and the median OS time after the first event in lung cancer is 5 months.²⁰ The median

	N	Survival time*		Surv				
	N	Mean Median		6 months 12 months		24 months	p-valor	
Pathological frac	cture							
Yes	15	7.4	3.0	40.0 (15.2-64.8)	13,3 (0-30.5)	13,3 (0-30.5)	0,790	
No	80	6.4	4.0	31.2 (21.1-41.4)	13,7 (6.2-21.3)	2,5 (0-5.9)		
Sychronous	7	3.6	1.5	28.6 (0-62.0)	0	0	0,093	
Methachronous	8	10.7	6.2	50.0 (15.3-84.6)	25,0 (0-55.0)	25,0 (0-55.0)		
* months								

Table 4. A comparison of overall survival following a diagnosis of bone metastases in lung cancer patients who developed or did not develop metachronous and synchronous pathological fractures.

* months.

OS time following a diagnosis of a PF in the present study was even smaller (2 months), as expected, due to the high proportion patients with advanced stage disease. This finding suggests that a PF was a terminal event in our cohort. In the present study, there was no statistically significant difference in the OS times following a diagnosis of BMs in lung cancer patients who developed or did not develop a PF, probably owing to the small number of patients (n = 15) who experienced this SRE. Conversely, we exhibited an opposing trend with a longer OS time in patients who experienced a PF. This result may be absolutely justified by the paradoxical effect of the influence of OS on the patient's PF risk. The presence of a PF effectively reduces the OS estimated after its occurrence. However, for comparison between the patient groups, the OS time following a diagnosis of BMs was used. Thus, the higher the OS time the longer the patient had to develop a PF and, therefore, the greater the risk of experiencing this SRE. The patient's OS time before experiencing a PF is correlated with the risk of developing a SRE and is taken into consideration when estimating OS times. According to this method of comparison, when a patient survives with BMs for a longer period before the occurrence of a PF, the effect in reducing the OS time is even more underestimated. In contrast, patients who survive for a short time following a diagnosis of BMs may not have sufficient time to experience a PF. Therefore, the short OS time (2 months) following a diagnosis of a PF should be noted. One interesting observation that eliminates the effect of the OS time prior to the development of BMs and supports the above is the analysis of patients who experienced a synchronous PF. The shortest OS time in the univariate analysis was recorded in this group. The median OS time in this group was 1.5 months, compared to 6.2 months in the patient group who experienced a metachronous PF. Synchronous PFs determine a similar OS time following a diagnosis of lung cancer, BMs, and a PF. The present study did not have sufficient power to detect the statistical significance of differences in OS time in relation to the occurrence of a PF due the small number of patients in each group. However, the observation of this trend is relevant. In addition, the progressively shorter OS times following a diagnosis of lung cancer (6 months), BMs (4 months), and a PF (2 months) reflects the general developmental stages of compatible disease with its natural history. This allows us to infer that the occurrence of a PF is a terminal event in the course of the disease and the OS time after this SRE is considerably shorter.

The precise correlation between PFs and decreased OS rates in patients with BMs from lung cancer has yet to be fully elucidated. Several factors may be involved, including increased mortality from PF surgery, loss

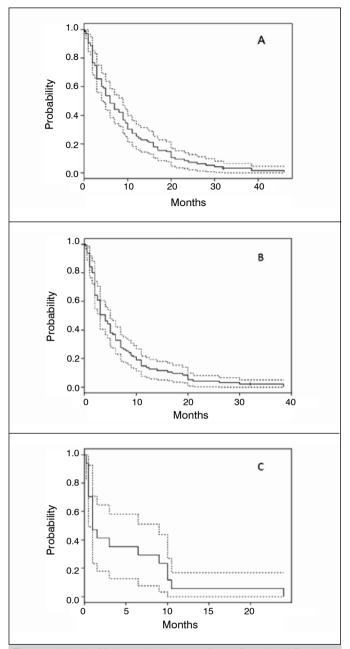


Figure 4. Kaplan-Meier survival curves of overall survival following a diagnosis of (A) lung cancer, (B) bone metastases, and (C) pathological fracture.

of functional independence, increased risk of deep vein thrombosis, and other complications (e.g., clinical changes and disease biology).²⁰ BMs are associated with a poor prognosis in lung cancer patients. Moreover, lung cancer patients with BMs are more likely to experience SREs, including PFs that correlate with increased mortality, the use of financial resources, and a reduced quality of life. With the advancement of other therapies, especially chemotherapy, increased survival and the prevention of bone-related complications through pharmacological and surgical interventions will become even more important in the management of this disease.

In conclusion, the occurrence of PFs in lung cancer patients was associated with synchronous BMs, diaphyseal location, and smoking. OS times following a diagnosis of PF were considerably reduced, suggesting a terminal stage of disease. AUTHORS' CONTRIBUTIONS: Each individual author contributed individually and significantly to the development of this work. MBRO (0000-0003-1986-7002)*: wrote, reviewed, performed the procedures, analyzed the data, evaluated the medical records; BCM (0000-0002-0479-0244)*: wrote the article; evaluated the medical records RAM (0000-0002-1502-8394)*: analyzed the data; and reviewed the article; CRCF (0000-0003-1802-0037)* evaluated the plain films and reviewed the article; FCQM (0000-0003-3250-6738)*: drafted and reviewed the article and contributed to the intellectual concept of the study; MEMP (0000-0002-8699-3933)*: wrote the article, performed statistical analysis and contributed to the intellectual concept of the study and the entire research project. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

DOES COGNITIVE CAPACITY INTERFERE WITH THE OUTCOME OF OBERLIN TRANSFER?

A CAPACIDADE COGNITIVA INTERFERE NO RESULTADO DA CIRURGIA DE OBERLIN?

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ABSTRACT

Objective: To determine the relationship between the functional outcome achieved following Oberlin transfer, the cognitive level of the patient, and the time elapsed between the trauma event and surgery. Methods: Eighteen patients with a traumatic injury to the brachial plexus (C5-C6 and C5-C7) were evaluated. Seventeen (94.4%) patients were males and one (5.6%) was female, with a mean age of 29.5 years (range 17-46 years). We evaluated the active range of motion, elbow flexion strength, and Disabilities of the Arm, Shoulder and Hand (DASH) and determined the correlation between the procedural outcome and the patient's cognitive level, as assessed by the Mini-Mental State Exam (MMSE). Results: We found statistically significant correlations between the MMSE scale and strength recovery (84.4%, p<0.001), which was classified as excellent, and between the MMSE and British Medical Research Council (BMRC) scales (78.4%, p>0.001), which classified cognitive level as good. Conclusions: We found a positive correlation between cognitive capacity and functional outcome of patients submitted to Oberlin surgery. The time elapsed between trauma and the surgical procedure showed an inversely proportional correlation with the strength of recovery. Level of Evidence II, Retrospective Study.

Keywords: Brachial Plexus. Nerve Transfer. Cognition. Ulnar nerve. Musculocutaneous nerve

RESUMO

Objetivo: Determinar a relação entre o resultado funcional obtido com a cirurgia de Oberlin, o nível cognitivo do paciente e com o tempo decorrido entre o trauma e a cirurgia. Métodos: Foram analisados dezoito pacientes, sendo 17 homens (94,4%) e uma mulher (5,6%), com idade média de 29,5 anos (17 a 46 anos), com lesão traumática alta do plexo braguial (C5-C6 e C5-C7). Avaliamos a amplitude de movimento ativa, a forca muscular de flexão do cotovelo e o questionário DASH (Disabilities of the Arm, Shoulder and Hand) e determinamos a correlação entre o resultado obtido e o nível cognitivo do paciente, avaliado pelo Mini Exame do Estado Mental (MEEM). Resultados: Observamos correlações de significância estatística entre MEEM e recuperação de força (84,4%, p<0,001), classificada como ótima; MEEM e BMRC - British Medical Research Council (78,4%, p> 0,001), classificada como boa. Conclusões: Verificamos correlação positiva entre a capacidade cognitiva e os resultados funcionais dos pacientes submetidos à cirurgia de Oberlin. O tempo decorrido entre o trauma e o procedimento cirúrgico apresenta uma relação inversamente proporcional com a recuperação da força. Nível de Evidencia II, Estudo retrospectivo.

Descritores: Plexo Braquial. Transferência de Nervo. Cognição. Nervo Ulnar. Nervo Musculocutâneo.

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INTRODUCTION

The incidence and severity of the brachial plexus injury have both been increasing worldwide. Upper trunk impairment results in significant disability, with loss of shoulder function (abduction of the shoulder and external rotation), elbow flexion, and supination of the forearm. For these patients the priority is to restore elbow function, followed by abduction and external rotation of the shoulder.¹⁻¹⁰ Neurotization techniques have significantly improved the outcome of surgical treatment of upper brachial plexus injuries.¹¹ Recent studies have shown superior results with regard to elbow flexion when ulnar nerve fascicles are used as a donor,^{1,5} in a technique described by Oberlin,⁶ which uses a predominantly motor fascicle of the ulnar nerve that is transferred to the motor branch of the biceps. The satisfactory results obtained with this technique are related to the fact that nerve suturing is done to a healthy area, is single-threaded and at a short distance from the target muscle, and relies on the use of a well-vascularized nerve for the transfer.^{1,5,11} It is a procedure that causes minimal morbidity to the donor site.³

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

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Brachial plexus injury leads to central functional remodeling, with attention being focused on the sensorimotor areas of the brain.¹² Not only age but also surgical repair techniques are of the utmost importance for sensitivity recovery following the repair of peripheral nerve injury. If regenerating axons are misdirected, a reorganization or other adaptive processes at the level of the somatosensory cerebral cortex becomes necessary. Such processes are believed to depend on the patient's cognitive capacity.¹³ There is likely to be a positive correlation between cognitive ability and the outcome of functional sensitivity after peripheral nerves have been repaired, which suggests that variations in such factors may help to explain result variability.^{13,14} The main goal of this study is to determine the relationship between the functional outcome obtained with Oberlin transfer and the patient's cognitive level, and the time elapsed between trauma and surgery.

MATERIALS AND METHODS

We conducted a cross-sectional study with patients from the Hand Surgery and Microsurgery Outpatient Clinic at Universitary Hospital, São Paulo, Brazil. The study was approved by the local institutional ethics review board (approval number: 2.550.903) and all patients signed an informed consent form before inclusion in the study.

We included patients with traumatic injuries to the brachial plexus at C5-C6 and C5-C6-C7 levels, above 15 years of age, undergoing Oberlin transfer, either associated or not with concomitant procedures to the brachial plexus (reconstructions with grafting, intraplexal or extraplexal neurotizations such as: transfer of the accessory nerve to the suprascapular nerve, from the motor branch of the triceps muscle to the axillary nerve) and followed them up postoperatively for a period of at least six months. Patients diagnosed with obstetric paralysis, pediatric patients, and patients with lower or total brachial plexus injuries were excluded from the study.

Eighteen patients were therefore evaluated, of whom 17 (94.4%) were males and one was female (5.6%), with a mean age of 29.5 years (17-46 years). With regard to the level of the injury, 13 patients presented C5-C6 injuries (72.2%) whereas five of them had C5-C7 injuries (27.8%). The time elapsed between trauma and the surgical procedure ranged from three to 17 months, with an average of 9.2 months.

We evaluated the active range of motion, elbow flexion strength, and DASH (Disabilities of the Arm, Shoulder and Hand)¹⁵ questionnaire and then determined the correlation between the outcome obtained and the patient's cognitive level, as assessed by the Mini-Mental State Examination (MMSE).¹⁶ We also correlated the time between injury and surgery with the functional outcome.

Goniometry was used to define the range of free active motion. With the patient standing, the goniometer was placed in the sagittal plane with its center on the elbow joint; then, starting from the maximum extension position, the patient was instructed to perform maximum flexion, with the obtained value being expressed in degrees.

Muscle strength was measured during elbow flexion in two ways: by using the British Medical Research Council (BMRC) scale or a dynamometer.

For the first evaluation, the patient was instructed to remain in the seated position, with an upright trunk to avoid compensatory movements during the test. The examiner stabilized the patient's shoulder, providing the necessary support. The strength was graded as M0 when no sign of muscle contraction was observed; M1, muscle fasciculation; M2, when strength did not overcome the force of gravity; M3, when it overcame gravity, but did not overcome a resistance; M4, when it overcame the resistance, but was not normal; M5, normal strength. A lower than M3 result was considered poor and the patient did not undergo the dynamometry test.

The evaluation using the dynamometer followed the guidelines of the American Society of Exercise Physiologists (ASEP), as described by Brown.¹⁷ Elbow flexion strength was measured in kilograms (kgf) by using a Lafayette® Manual Muscle Test (MMT) model 01163

comprised of two rigid adjustable straps, with one end fixed to the ground by a suction cup and the other end in the patient's hand. The patient remained seated and kept the elbow at a 90° angle close to the body while keeping the forearm in a supinated position. The device has been set to adapt to the patient's height. We took three consecutive measurements, with an average interval of 30 seconds between them, with each contraction lasting five seconds. The mean of the three measurements was then considered for analysis. With the lack of knowledge of the degree of muscular strength of the limb involved before the injury, the value obtained was compared with the contralateral side, muscle strength M5, which is closest to what is considered normal and then the percentage of force recovery was determined. The strength of the contralateral side was assessed in the same way as was the strength of the affected limb. The collected data were stored with the aid of Windows Excel, and then compared and analyzed by using statistical software (SPSS V20 for Windows). We used a significance level of 0.05 (5%) in our study, and constructed all the confidence intervals with a 95% statistical confidence level. Pearson's correlation was used to measure the degree of relationship between all the quantitative variables and to validate the correlations, the Correlation Test was used.

The correlation ranged from -1 to 1, but in order to facilitate reading and/or understanding, the values were transformed into percentages: values between 0% and 20% were considered as very poor; between 20% and 40% as poor; between 40% and 60% as fair; between 60% and 80% as good; and between 80% and 100% as excellent.

RESULTS

When comparing the time interval between trauma and surgery with the BMRC scores and strength recovery, we found negative and inversely proportional correlations (-90.4%, p<0.001, excellent correlation; -69.9, p=0.001, good correlation), respectively. We also found a negative correlation between DASH and BMRC (-67.0%, p=0.002) and between DASH and strength recovery (-64.4%, p=0.004). (Table 1)

We also found statistically significant correlations between the MMSE scale and strength recovery (84.4%, p < 0.001), which was classified as excellent; between the MMSE and BMRC scales (78.4%, p > 0.001), classified as good, and a fair correlation between the MMSE and active range of motion (AROM) scales (47.8%, p < 0.045). In comparing MMSE and DASH, a fair relationship, albeit with no statistical significance, was observed (-43.0%, p 0.075). (Table 1)

DISCUSSION

Brachial plexus injury is a severe trauma to the peripheral nervous system, which can cause central remodeling, as revealed by functional MRI (magnetic resonance imaging). However, this remodeling is

Table 1. Correlation of	Quantitative Variables
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		Age	Time since Trauma	AROM	BMRC	Strength Recovery	DASH
Time Interval	Corr (r)	47.1%	ITaulila				
between Trauma x Surgery	P-value	0.049					
AROM	Corr (r)	-27.2%	-61.8%				
	P-value	0.274	0.006				
BMRC	Corr (r)	-37.1%	-90.4%	69.3%			
	P-value	0.129	<0.001	0.001			
Strength Recovery	Corr (r)	-27.0%	-69.9%	72.1%	89.3%		
	P-value	0.278	0.001	0.001	<0.001		
DASH	Corr (r)	16.1%	57.4%	-41.0%	-67.0%	-64.4%	
	P-value	0.524	0.013	0.091	0.002	0.004	
MMSE	Corr (r)	-33.7%	-56.3%	47.8%	78.4%	84.4%	-43.0%
	P-value	0.171	0.015	0.045	<0.001	<0.001	0.075

Corr (r)- Correlation

mainly restricted to the somatosensory cortex. The exact mechanism remains unknown. Several authors^{13,14,18} have related the results from peripheral nerve injury repair with the patients' cognitive capacity. Rozén et al.¹⁵ described the correlation between restoring functional sensitivity with the cognitive capacity of patients undergoing nerve repair in the forearm. This result is related to the brain's capacity for remodeling and adapting to new functional demands. Boender et al.,¹⁶ in undertaking a prospective multicenter study, found no association between cognitive capacity and sensory recovery, or that it was probably not as strong as suggested in previous retrospective studies. The cognitive function reflects a set of processes and activities that are used in perceiving, thinking and employing these processes not only in sentence comprehension, for instance, but also in object recognition, touch perception and spatial orientation.¹³ There is reason to believe that the brain's ability to understand, use and adapt to cortical reorganization after nerve repair may reflect the individual's cognitive capacity.¹⁴

The positive correlations found in the study may be related to a better understanding, by the patient, of the treatment used. Communication and an excellent physician-patient relationship are of the utmost importance for a good adherence to the proposed treatment. Such adherence can be understood as the degree of agreement between the guidance received (relative to postoperative care, attendance at follow-up, and rehabilitation) and the patient's behavior. Numerous factors can interfere with the adherence process and consequently the desired outcome. Patient-related factors that can interfere with the adherence process may be related to biosocial traits, such as schooling, socioeconomic level, occupation, marital status, religion, health beliefs, life habits, and cultural aspects.

The patient must be an active agent throughout the process, and have a wish to seek to improve and rehabilitate those functions that have been lost or impaired by the trauma. A variety of combinations of therapeutic procedures aimed at helping the individual to learn or relearn their normal response pattern can be used. Patients with high cognitive levels are expected to more easily understand the guidelines being given to them, which therefore results in greater functional requirement, a factor that may explain the regular relationship we observed between DASH and MMSE in our study.

Another factor related to the recovery of muscle function is the time variable. A sufficient number of motor fibers should reach the target organ within a given period of time to achieve the desired function.⁴ Teboul et al.⁹ observed that patients operated on six months after injury had a 64.7% chance of a useful recovery of biceps function. On the other hand, patients operated on before that 6-month period following injury had an 86.7% chance of gaining useful elbow flexion.⁵ In a study conducted by Leechavengvongs et al.,⁴ in which 32 patients were analyzed, the only patient who did not attain functional strength underwent the procedure 12 months following injury.³ Our study corroborates the results described in the literature: we found that patients undergoing the surgical procedure with periods of time greater than 12 months following injury did not attain elbow strength. This highlights the significant inverse correlation between time since trauma and recovery of muscle strength. It is worth mentioning one case of a patient operated on 15 months after injury who managed to recover functional strength grade 3 (BMRC).

The literature defines a 6- to 12-month time interval as the appropriate time window for offering surgery to patients with upper trunk traction, avulsion injury. Although this may be considered ideal, Oberlin transfer can be attempted even in patients 12 to 24 months after injury, since the risk-benefit ratio in these patients can still be favorable.⁸

Taking into consideration this time interval and the patient's cognitive level, treatment planning can be better defined while respecting their individual characteristics and requirements to achieve the best functional outcome.

CONCLUSION

We found a positive correlation between the cognitive capacity and functional outcome of patients submitted to Oberlin surgery. The time elapsed between trauma and the surgical procedure has an inversely proportional correlation.

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ACCURACY OF PEDICLE SCREW INSERTION: A COMPARISON BETWEEN FLUOROSCOPIC GUIDANCE AND NAVIGATION TECHNIQUES

ACURÁCIA DA INSERÇÃO DE PARAFUSOS PEDICULARES COMPARANDO FLUOROSCOPIA E NAVEGAÇÃO

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ABSTRACT

Objectives: To compare the accuracy of insertion of pedicle screws into the thoracic spine using fluoroscopic guidance or computer-assisted navigation techniques. Methods: Eight cadaveric thoracic spines were divided into two groups: the fluoroscopy group, in which pedicle screws were inserted with the guidance of a C-arm device, and the navigation group, in which insertion of the screws was monitored using computer-assisted navigation equipment. All procedures were performed by the same spinal surgeon. The rate of pedicle breach was compared between the two groups. Results: There was one intra-canal perforation in each group. Both perforations were medial in direction, and the breaches were 2 to 4 mm deep. There were no statistically significant differences in breach rate between the two groups. Conclusions: The accuracy of insertion of pedicle screws in the thoracic spine using computer-assisted navigation is equivalent to that achieved using fluoroscopic guidance. Computer-assisted navigation improves the safety of the surgical team during the procedure due to the absence of exposure to radiation. Therefore, there is a need for future randomized controlled trials to be conducted in the clinical setting to evaluate other outcomes, including duration of surgery and blood loss during the procedure. Level of evidence IV.

Keywords: Pedicle screw. Spine. Spinal fusion. Neuronavigation. Fluoroscopy.

RESUMO

Objetivos: Comparar a acurácia da inserção de parafusos pediculares na coluna torácica, utilizando fluoroscopia ou técnicas de navegação assistidas por computador. Métodos: Estudo experimental com cadáveres. Oito colunas torácicas proveniente de cadáveres foram divididas em dois grupos: no grupo Fluoroscopia os parafusos pediculares foram inseridos com orientação de um aparelho tipo C-arm, e no grupo Navegação o monitoramento foi feito com um equipamento de assistência por computador. Todos os procedimentos foram feitos pelo mesmo cirurgião de coluna. A taxa de violação do canal foi comparada entre os grupos. Resultados: Houve uma perfuração de canal em cada grupo, ambas mediais, com 2-4 mm de profundidade. Não houve diferenças significativas entre os dois grupos em termos de taxa de perfuração do canal. Conclusão: A acurácia na inserção de parafusos pediculares na coluna torácica é igual comparando-se a navegação assistida por computador e o método de monitoramento por fluoroscopia. Como a segurança do procedimento para a equipe cirúrgica é maior com o método da navegação, devido à ausência de exposição à radiação, há necessidade de se realizarem estudos clínicos controlados no ambiente clínico, que avaliem outros desfechos. como o tempo de cirurgia e de sangramento. Nível de evidência IV.

Descritores: Parafusos Pediculares. Coluna Vertebral. Fusão Vertebral. Neuronavegação. Fluoroscopia.

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INTRODUCTION

Pedicle screw fixation plays an important role in many spinal surgeries, providing superior post-operative spinal stability. Stabilization methods for better consolidation of arthrodesis evolved through the decades.¹⁻³ Pedicle screw instrumentation was used by Roy-Camille in the 1960s and 1970s however, it was with the work by Cotrel-Dubousset, in the 1980s, that pedicle screw fixation gained popularity as the third generation of spine instrumentation.² In 1998, pedicle screw instrumentation was downclassified from an FDA Class III to Class II,

and has been since then gaining popularity. This technology is now the standard care in arthrodesis of the thoracolumbar spine, due to the improved fusion rates and rigidity provided by these constructs.^{1,2} Studies have found that pedicle screws are biomechanically advantageous when compared to the previously used rod and hook systems.³ As the morphology of the pedicle is complex and due to its proximity to a number of significant tissues (e.g., the spinal cord and nerve roots), screw misplacement might lead not only to a decreased stability but also to neurological, vascular, and visceral injuries.⁴ Many surgeons

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consider the majority of cortical violations to be clinically silent depending on the location and the length of penetration⁵ — that can be categorized according to the length of perforation (up to 2 mm. 2-4 mm or greater than 4 mm).⁶ However, even those initially silent perforations may be responsible for instability of the biomechanical construct, reduced fusion rates, or accelerated adjacent-level degeneration.⁷ The normal anatomy is naturally complex, and pedicles can be difficult to instrument due to pathological abnormalities. Scoliosis, rotation and asymmetric compression of vertebrae can significantly alter pedicle anatomy and complicate pedicle screw placement.8 The freehand technique for the placement of the pedicle screw is essentially a blind technique that depends on the correct identification of anatomical landmarks and experience of the surgeon to ensure proper insertion. Misplacement rates have been reported to range from 5% to 41% in the lumbar spine and from 3% to 55% in the thoracic spine when using conventional techniques.^{1,9} A recent review on the subject brings us the result of nine studies based on the freehand technique insertion of pedicle screws in the thoracolumbar spine, revealing an accuracy rate of 71.9% to 98.3%.¹⁰ Due to the difficulties and risks inherent to the implant insertion, new techniques have been developed to decrease the rate of misplaced screws and to increase the accuracy of positioning.¹⁰ The technology more widely used is the intraoperative fluoroscopic C-arm.¹¹ Studies have generally shown that accuracy rates of screws placed with this technique have ranged from as low as 27.6% to above 90%.¹² Fluoroscopy-assisted instrumentation has a much smaller learning curve when compared with the freehand technique. In theory, the error rate should be lower, since fluoroscopy can give surgeons a chance to correct the mistakes before inserting the screw.¹⁰ However, this additional safety mechanism is associated with potential safety disadvantages, as the increased exposure of the surgeon and his staff to radiation.^{13,14}

Alternatively, a monitoring method that came up with the aim of increasing the accuracy of screws insertion and reducing exposure to radiation was computer-assisted navigation.^{15,16} Following the introduction of CT–guided spinal navigation (O-arm), numerous reports in the literature have been published demonstrating its utility in increasing the accuracy of pedicle screw placement and, at the same time, decreasing the incidence of neurological injury from misplaced pedicle screws.^{15,16} There have been many studies about pedicle screw placement accuracy with this technique, but due to differing definitions of breach and the lack of control groups, many of these studies are difficult to compare.¹⁰ Therefore, there is a shortage of direct comparison studies with standardized methodology.

OBJECTIVE

The objective of this experimental study was to compare the accuracy of insertion of pedicle screws in the thoracic spine using fluoroscopy or computer-assisted navigation techniques.

MATERIALS AND METHODS

Ethical Committee

This study was submitted to the Ethical Committee through the Plataforma Brasil by the CAAE 37515014.3.0000.5054 and approved with the protocol 1.000.463 on 03/24/2015.

Study design and setting

This is an experimental study with unclaimed fresh cadavers, obtained from the local Forensic Institute. Only the thoracic vertebrae of the cadavers were used. Cadavers presenting spinal trauma or important spinal deformities were excluded. The project was approved by the Research Ethics Committee of the Walter Cantídio University Hospital, where the experiments took place, and all institutional and governmental regulations concerning the ethical use of human cadavers were followed.

MATERIALS

Eight fresh cadavers were obtained, male and female. They were dissected in the prone position for median longitudinal posterior access. A section of the thoracic spine, with five vertebrae in each sample, was removed. They were divided into two groups of four pieces each (the Fluoroscopy versus the Navigation group), totaling 20 vertebrae or 40 pedicles per group.

In both groups, polyaxial pedicle screws, with a diameter of 4.0 mm and lengths of 30 and 35 mm, were used.

For imaging, the fluoroscopy equipment used was Fluorostar 7900 (GE, Salt Lake City, UT, USA). The navigation device was the Aimnav (Micromar, Diadema, SP, Brazil).

METHODS

All vertebrae samples in the Navigation group were submitted to computed tomography (CT) scans before the surgical experiment. All the pieces were then positioned on the surgical table and fixed by positioners used for hip replacement surgery (Figure 1) for operations. The same surgeon performed all procedures.

In the Fluoroscopy group, the screws were inserted with the guidance of a combination of anterior-posterior and lateral view images (Figure 2). In the Navigation group, the screws were inserted using a computer assisted navigation system. CT scans from the Navigation group were inserted into the navigation software and selected points were marked for navigator calibration (Figures 3 and 4).

After the screws have been inserted, the pieces were dissected and examined in search of pedicle breaches. Violations were registered as medial (intracanal), inferior (foraminal), lateral, superior or anterior cortical.

Statistical analysis

The violation cases were recorded as frequencies. The rates of pedicle breach were compared in both groups using the exact Fisher test (as the number of expected events was below 5). A significant value of p < 0.05 was adopted.

RESULTS

No cadaver presented morphological abnormalities that would justify exclusion from the experiment. A total of 80 pedicle screws were inserted, 40 in each group. A total of 350 fluoroscopic images were necessary in the Fluoroscopy group, 8.75 per screw or pedicle in average. No fluoroscopy image was produced in the navigation group. In the Fluoroscopy group, 1 out of 40 screws was misplaced (2,5%). This was a medial cortical breach, between 2-4 mm. In the Navigation group, there was also 1 case of pedicle violation (2,5%), of equal position and size of perforation (Figure 5).

No statistically significant differences between the two methods were found (p > 0.05).



Figure 1. Spine section (1) prepared to be dissected and instrumented, fixed by retractors (2).

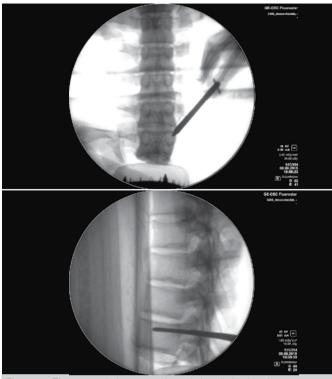


Figure 2. Fluoroscopic image on frontal view (left) showing an appropriate entry point in the upper-side corner of the pedicle projection, and on lateral view (right) showing good positioning of drilling.

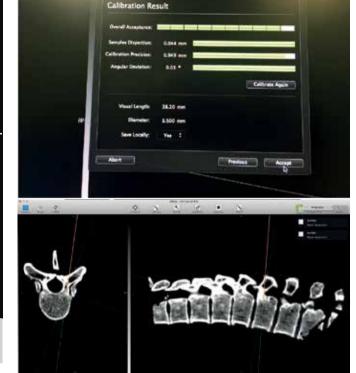


Figure 3. Marking of selected points for navigator calibration.

DISCUSSION

Fluoroscopy is currently the most widely used method of pedicle screws insertion.¹¹ However, as mentioned above, it has some intrinsic disadvantages, such as the amount of radiation to which the surgical team is exposed.^{13,17} Numerous studies show good accuracy rates in the insertion of pedicle screws with computer-assisted navigation when compared to the conventional method of fluoroscopy, but the superiority of navigation in terms of insertion accuracy is still doubtful, with variable breach rates between studies.¹⁸

Laine et al.¹⁹ demonstrated a greater misplacement rate in fluoroscopy group (13.4%) when compared to the navigation (4.6%). However, in that study, rates were not significantly different when only the breaches greater than 4 mm were considered (1.4% in fluoroscopy group versus 0% in the navigation group). Another study also found superior accuracy in the screws insertion with computer-assisted navigation



A

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New Tool

Figure 4. Computer screen showing a satisfactory result of calibration (A) and axial (B) and lateral view (C) representing, in orange color, the already drilled path and, in green, the projection path.

(2% of breach rate versus 23% with use of fluoroscopy).²⁰ Tabaraee et al.¹³ conducted an experimental study in cadaver, similar to the present study, performing a direct comparison of the two methods, and also found no statistically significant differences between the groups.

In a meta-analysis of 130 studies involving clinical and cadaveric, prospective and retrospective studies, there were no statistically significant differences between the insertion of screws by two methods in the thoracic spine.¹⁵ Another systematic review of 30 studies, more recently published, found greater accuracy in the insertion of pedicle screws with navigation (84.3%) compared to fluoroscopy (68.1%). However, only 1 of the 30 studies was a randomized controlled trial. All others were only level 3 (observational studies with control groups) and 4 (observational studies).²¹ The comparison between studies, is difficult, due to lack of standardization of the imaging methods and the lack of uniform criteria for classifying the violations as events.¹⁹ Different screw misplacement grading systems are used to assess the screw placement accuracy, but usually including the following categories: Grade 0, no pedicle perforation; Grade 1, perforation of 0-2 mm; Grade 2, 2-4 mm; Grade 3, perforation greater than 4 mm.⁶

Another cause of the difficulty in comparing and interpreting studies is that the accuracy depends on the assessed levels. A preponderance of lumbar levels tends to increase the overall rate of success since the pedicles of these vertebrae are larger and easier to be instrumented when compared to the thoracic levels.¹⁰ For this reason, even the published systematic reviews can not be taken in consideration as the real accuracy for all levels.²²

We chose to use thoracic vertebrae due to the smaller diameter of the pedicles and a smaller available space for spinal cord at this



Figure 5. Dissection of the vertebrae that had a misplaced screw: fluoroscopy group in the left, navigation group in the right.

level as compared with the lumbar levels. In the thoracic spine, the clinical consequences of a pedicle breach are more severe, with greater neurologic déficits.¹⁰ In fact, studies show that in the thoracic spine, lower accuracy rates are evidenced with the freehand technique, with fluoroscopy or navigation.⁸

Because computed-assisted navigation surgery is not a reality in our setting yet, we did not record or evaluate the time necessary for completing each procedure, and this could be considered a limitation of the present study. However, the literature is also controversial about surgical time comparisons between fluoroscopy or navigation-assisted surgeries of the spine. Some studies show increased surgical time of the computer-assisted navigation method when compared to the fluoroscopy¹³ but others conclude that, in trained hands, navigated surgery can present a shorter surgical time, ^{20,23} Therefore, studies are needed to investigate the surgical time, bleeding and other potentially serious complications related to surgical time in the instrumentation of the thoracic spine using fluoroscopy or navigator-assisted methods.

CONCLUSION

The accuracy in the insertion of pedicle screws in the thoracic spine is equal comparing the computer-assisted navigation and fluoroscopy-assisted methods. As the safety of the procedure is greater for the surgical team with the navigation method, due to the absence of exposure to radiation, there is a need for randomized controlled trials in the clinical setting that evaluate other outcomes, such as the safety for the patient too, considering the surgical time and bleeding.

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COMPLICATED LUMBAR TUBERCULOUS SPONDYLODISCITIS IN DISSEMINATED TUBERCULOSIS, TREATED USING A NON-CONVENTIONAL ANTERIOR SUPPORT SYSTEM FOR HYDROSTATIC DISTRACTION: A CASE REPORT

TRATAMENTO DE ESPONDILODISCITE LOMBAR COMPLICADA EM TUBERCULOSE DISSEMINADA COM SISTEMA HIDROSTÁTICO DE DISTRAÇÃO LOMBAR: RELATO DE CASO

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ABSTRACT

Objective: To describe a case of disseminated tuberculosis affecting the lumbar spine that was treated using a non-conventional anterior support system. Background: Tuberculous spondylodiscitis is the most common and most severe form of extrapulmonary tuberculosis. Although antibiotic therapy is the most frequently used treatment, surgery is necessary in cases of neurological deficit, spinal instability, significant deformity, severe sepsis, paravertebral and epidural abscesses or in cases wherein clinical treatment has failed. A surgical procedure is also indicated when a biopsy is required. With the development of new methods for reconstruction and fixation of the spine, complete debridement of the tuberculous foci has become an increasingly common approach, but there is a lack consensus on the best technique. Methods and results: The patient suffered from disseminated tuberculosis affecting the lumbar region of the spine, with an abscess in the psoas muscle. He underwent extensive debridement via both anterior and posterior approaches, using a non-conventional anterior support system that promotes hydrostatic distraction. Conclusions: Treatment using the hydrostatic distraction system was able to reestablish both the stability and anatomy of the lumbar curve. Level of evidence IV, Case report.

Keywords: Spinal tuberculosis, Osteoarticular tuberculosis, Debridement, Surgical procedures.

RESUMO

Objetivo: Descrever um caso de tuberculose disseminada afetando a coluna lombar, tratada com um sistema de suporte anterior não convencional. Contexto: Espondilodiscite tuberculosa é a forma mais comum e mais grave de tuberculose extrapulmonar. Embora o principal tratamento seja a antibioticoterapia, o tratamento cirúrgico é importante em casos de déficit neurológico, instabilidade da coluna e deformidade significativa, sepse grave, abscessos paravertebrais ou peridurais ou em casos de falha do tratamento clínico. Cirurgia também é necessária quando há necessidade de biópsia. Com o desenvolvimento de novos métodos para a reconstrução e fixação da coluna, cada vez mais se faz o debridamento completo do foco da tuberculose vertebral, mas há falta de consenso sobre a melhor técnica. Métodos e Resultados: O paciente sofria de tuberculose disseminada afetando a coluna, na região lombar, com abscesso do músculo psoas. Foi tratado com extenso debridamento pelas vias anterior e posterior. usando um sistema não convencional de suporte anterior que promove distração hidrostática. Conclusões: O tratamento com o distrator hidrostático foi capaz de restabelecer a estabilidade e a anatomia da curva lombar. Nível de evidência IV, Relato de caso.

Descritores: Tuberculose da coluna Vertebral. Tuberculose osteoarticular. Desbridamento. Procedimentos cirúrgicos operatórios.

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INTRODUCTION

Extrapulmonary tuberculosis is the result of a combination of factors, such as the type of pathogen, the host genetics, and environmental factors. Factors related to the pathogen relate to its virulence and its biological properties of dissemination. Factors related to the host are focused on the patient's immune status; the vast majority of patients who develop extrapulmonary dissemination having some type of immunodeficiency, with infection by the HIV virus and systemic lupus erythematosus being the most common.¹

The incidence of extrapulmonary tuberculosis varies in different parts of the world, according to race, age, sex and comorbidities. Incidence of around 37% is reported in Cambodia, while in China the incidence is close to 7%.¹

In their meta-analysis, Webster and Shandera proposed a prototype of patients at higher risk of developing extrapulmonary tuberculosis; young women, infected by the HIV virus, without diabetes, non-smokers and who do not use alcohol in excess. On the other hand, the typical profile of patients with pulmonary tuberculosis is more elderly males, who smoke and drink alcohol in excess, and who are generally not infected by the HIV virus.¹

Among the various forms of extrapulmonary tuberculosis, tuberculous spondylodiscitis is the most serious and common form, representing around 40% to 50% of all cases of tuberculosis that affect the osteoarticular system. Its overall incidence has increased due to the increase in the phenomena of migration, malnutrition, and the rate of infection by the HIV virus.²⁻⁵

The most common treatment of vertebral complication is still antibacterial chemotherapy. However, surgical treatment plays an important role in some situations, such as in the presence of neurological deficit, significant spinal instability and deformity, severe sepsis, paravertebral and epidural abscesses, and in cases of clinical treatment failure. A surgical procedure is also needed when there is a need for biopsy.^{2,3}

For many years, "Hong Kong" surgery (focal debridement) was the main choice for the treatment of lumbar tuberculosis. Recent studies show that incomplete debridement is the main cause of recurrence after surgery in cases of vertebral tuberculosis. The recurrence rate is around 13% to 26% in the first surgery, and can reach 6% to 23% in the second surgery.^{6,7}

In view of this, and with the development of new methods of reconstruction and fixation of the spine, surgeons are beginning to understand the importance of complete debridement of foci of vertebral tuberculosis. As a result, the current trend, in cases of lumbar tuberculosis complicated with abscess formation, is a broad surgical approach, with the aim of reducing this reoperation rate.^{6,8} The aim of this article is to report a case of disseminated tuberculosis with lumbar involvement complicated with psoas muscle abscess, which was treated by surgery with extensive debridement, by the anterior and posterior approaches, using a non-conventional anterior support system that promotes distraction through hydrostatic means, reestablishing the stability and anatomy of the lumbar curve.

Case report

Written informed consent was obtained from the patient for publication of the study.

A male patient, 35 years of age, from Bolivia, living in Brazil for five years, previously healthy, came to the basic health unit reporting a history of pneumonia for the preceding 12 months, treated for one month with oral antibiotics. Following these symptoms, he began to develop lumbar pain, with progressive worsening, associated with pain and difficulty moving the left leg, and difficulty walking. He was advised to take painkillers and perform physiotherapy exercises. He presented partial improvement of symptoms with physiotherapy; however, after two months, he developed hematuria associated with fever and vomiting, with worsening lumbar pain.

He was then evaluated at a health care unit, this time with a suspected urolithiasis. During clinical investigation through laboratory tests and imaging exams, lung alteration was observed, associated with an abscess of the left psoas muscle. The patient reported weight loss of around 20 kg during this period. His clinical condition significantly worsened, and he was admitted for treatment and complementary examinations.

In the physical examination at hospital admission, the patient was conscious and oriented, with decreased muscle strength in the muscle groups innervated by the nerve roots of the lumbar spine L2 and L3 on the left (grade 3) and L4, L5 and S1 on the left (grade 5), according to the American Spinal Injury Association Impairment Scale motor impairment scale adopted by the (ASIA), without motor or sensory deficits identified in the right leg. He had severe pain on moving the left leg. Although motor strength was partially preserved, he was unable to walk, and could not tolerate standing due to lower back pain and irradiation to the left leg.

Serologies were performed for HIV, hepatitis B and hepatitis C, all with negative results. Exams for autoimmune, immunosuppression and immunodeficiency disorders not related to HIV were also negative. Imaging exams performed on admission and during hospitalization showed:

- Complete CT of the abdomen: free liquid in the cavity, diffuse infiltration of mesenteric fat. Lesion of lithic appearance in the vertebral body of the fifth lumbar vertebra (L5), with the formation of a heterogeneous mass that has invaded the adjacent left psoas muscle and spinal canal.
- Esophagogastroduodenoscopy: esophageal-mediastinal fistula.
- CT scan of the chest with contrast: bilateral nodular pleural thickening, more voluminous on the right. Enlarged lymph nodes in the right internal mammary chain, and pleural effusion in the right lung.
- Computed tomography of the thoracic and lumbosacral spine (Figure 1): lytic lesion of the vertebral body of the fifth lumbar vertebra, affecting the left pedicle, with enlargement of the left psoas muscle, suggestive of fluid build-up.
- MRI of the skull: imaging findings consistent with meningeal inflammatory or infectious process, predominantly frontal. Cortical change in the adjacent subcortical white matter is also highlighted, which may be related to the area of cerebritis in the left frontal lobe. It is known that these findings can be found in association with neurotuberculosis. Foci of restriction to the dissemination of water molecules adjacent to the above-mentioned inflammatory or infectious process, compatible with acute ischemia associated with the meningeal process described, were also found.
- MRI of the lumbar spine (Figure 2): presence of fluid build-up with peripheral enhancement shown by the contrast, centered on the upper terminal of the vertebral body of L5, extending to the paravertebral musculature in the left iliopsoas. Presence of three small foci of liquefaction (2.5 x 1.3 cm; 3 x 1.8 cm; 3.1 x 1.9 cm). A reduction in height of the vertebral body of L5 of more than 50% is observed. There is a highlighted area in the anterior epidural space, extending from the fourth lumbar vertebra (L4) to the first sacral vertebra (S1), compressing the dural sac and nerve roots of the cauda equina in the fifth lumbar vertebra.

The acid-fast bacilli (AFB) smear was positive in the analysis of sputum samples, and the diagnosis was defined as disseminated tuberculosis (pleural, pulmonary, lymph node, peritoneal, lumbar with psoas abscess and neurotuberculosis). The patient was then started on rifampicin 150 mg (4 pills once a day), isoniazid 75 mg

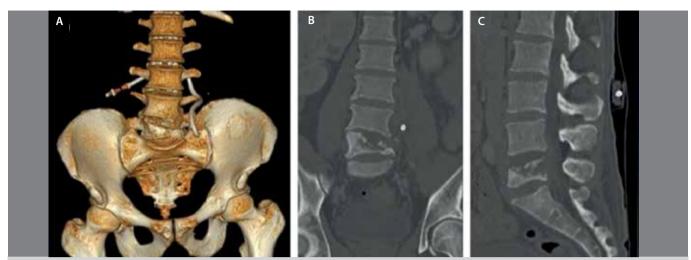


Figure 1. Computed tomography scan of the lumbar spine A) 3D reconstruction with evidence of percutaneous drain; B) coronal cut; C) sagittal cut.

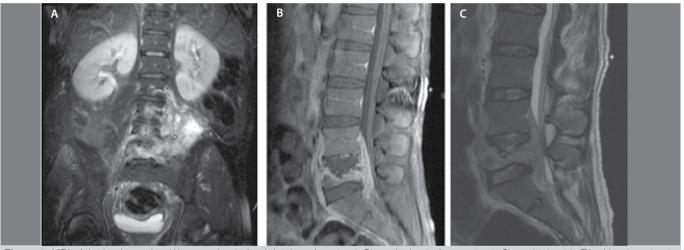


Figure 2. MRI of the lumbar spine (A) coronal cut after injection of contrast; B) sagittal cut after contrast; C) sagittal cut in T2 without contrast.

(4 pills once a day), pyrazinamide 400 mg (4 pills once a day), and ethambutol 275 mg (4 pills once a day).

During hospitalization, the patient was treated by the interventional radiology team, and percutaneous drainage of the left psoas muscle abscess was attempted, through the installation of a 12 F pigtail Skater catheter. The emergence of a purulent secretion was observed, in which the DNA of Mycobacterium tuberculosis was detected by polymerase chain reaction (PCR), and the acid-fast bacillus was isolated. The patient's symptoms worsened, and a new percutaneous approach was attempted, without success, with worsening of the laboratory and clinical parameters. At that time, it was suggested that the sepsis may be associated with infection of the orifice used for the drainage catheter. Antibiotic therapy was therefore started: vancomycin (2 g attack dose, then 500 mg every 6 h) and piperacillin/tazobactam (4 g/500 mg every 6 h) for one week. Two weeks after the start of treatment, the patient presented new clinical worsening, with high levels of respiratory discomfort. In light of these new symptoms, chest CT scan was performed, which revealed voluminous pleural effusion in the right lung. Levofloxacin 750 mg 1x/day was empirically introduced, with good evolution for the first 11 days. After that, the patient's general health and mental confusion deteriorated. Meropenem 1 g 8/8 h and vancomycin 1 g 8/8 h were introduced. The patient showed good response to treatment, and after four days on the latter antimicrobial regimen,

it was decided to change vancomycin for linezolid 600 mg 12/12 h. Meropenem + linezolid was maintained for six days, after which the patient underwent surgery to the lumbar spine.

It was decided to perform surgery for the psoas muscle abscess and osteomyelitis of L5. A double route was used, with the anterior extraperitoneal approach, performed by the general surgery team, giving access to the body of L5, which was submitted to subtotal resection along with the discs of L4-L5 and L5-S1 (Figure 3). At this time, new samples of materials were collected for laboratory analysis, decompression of the neural elements was performed, with drainage of the anterior epidural abscess, followed by intense debridement and copious irrigation with saline; a device with hydrostatic distraction was introduced (Aesculap Hydrolift Vertebral Body Replacement, Tuttlingen, Germany), replacing the body of L5 and the discs of L4-L5 and L5-S1. Due to the local infectious process, no type of bone grafting was used. The distraction was applied gradually, with reestablishment of the lumbar lordosis, visualized during the surgery through serial radioscopic imaging (Figure 4). After performing the anterior approach, all the surgical drapes and instruments were changed; the patient was repositioned in the prone position, and posterolateral arthrodesis of L4 to S1 was performed via the posterior route, using a bone graft from the iliac crest + instrumentation with pedicle screws that extend from vertebra L4 and S1 bilaterally.

The material collected during surgery (bone fragment of the body of L5, disc L5, soft tissue, and secretion) was sent for culture. Mycobacterium tuberculosis was detected in the fragment of the disc of L5 and in a fragment of soft tissue. The AFB test was positive for a fragment of soft tissue.

Immediately after surgery, the patient was sent to the intensive care unit, and was discharged to the ward on the following day. Back on the ward, he was encouraged to walk right away, using a walking frame, gradually progressing to walking unaided. On the second postoperative day, control x-ray was performed (Figure 5). On the fourth postoperative day, control CT was performed, showing adequate positioning of the pedicle screws and interbody device (Figure 6). Control MRI was performed on the fifth postoperative day, showing a decrease in the paravertebral fluid collection, and the presence of the interboby device and pedicle screws (Figure 7). The patient presented a satisfactory improvement curve and was discharged after 11 postoperative days, prescribed with rifampicin, isoniazid, pyrazinamide and ethambutol, in the doses mentioned above. Now, four months after surgery, the patient presents very favorable evolution, with full recovery of motor strength in the left leg, and no complaints of pain at rest or walking. He continues to use rifampicin 150 mg (4 tablets once a day) and isoniazid 75 mg (4 tablets once a day), the intention being to complete nine months from the introduction of the medication. Pyrazinamide and ethambutol were suspended after two months from the start of the tuberculosis treatment.

DISCUSSION

The case presented here is not usual; this is a young patient, without significant comorbidities and without documented immunosuppression, who developed a serious condition of extrapulmonary

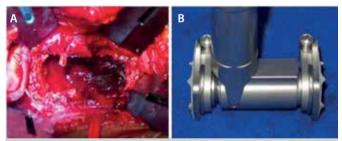


Figure 3. (A) Debridement of the body of L5; B) device with hydrostatic distraction system (Aesculap Hydrolift Vertebral Body Replacement).

tuberculosis, refractory to initial treatment with antimicrobial chemotherapy. The patient developed disseminated tuberculosis (pleural, pulmonary, lymph node, peritoneal, lumbar, neurotuberculosis) with complication of lumbar tuberculosis, developing an abscess of the psoas muscle. Despite the attempts at percutaneous drainage through interventional radiology, the patient presented disease progression, with worsening of clinical status. The surgical treatment of cases of lumbar tuberculosis complicated by abscess of the psoas muscle is well supported in the medical literature.^{2,3} But there is a great deal of discussion as to which surgery can be used in these cases, from minimally invasive surgery to larger-scale surgery, with double access and extensive debridement. The anterior approach allows the debridement of paravertebral abscesses and reconstruction of the anterior spine, with restoration of sagittal alignment.³ Zhang et al. reported a series of 23 patients treated with anterior debridement with structured graft associated with posterior instrumentation, obtaining a good therapeutic response.⁸ The posterior approach alone has some technical advantages that have been discussed by some authors, the main ones being: less surgical time. less bleeding, faster postoperative recovery, and the

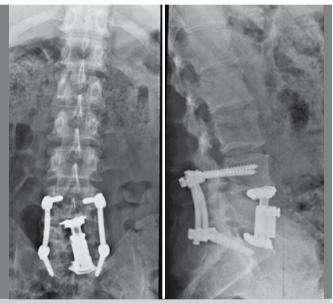


Figure 5. Postoperative control x-rays (anterior-posterior and profile positions).

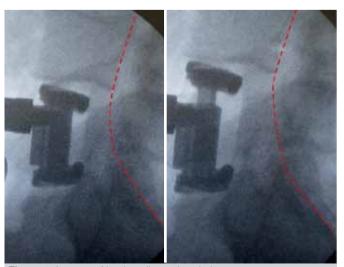


Figure 4. Images of lumbar distraction during surgery.

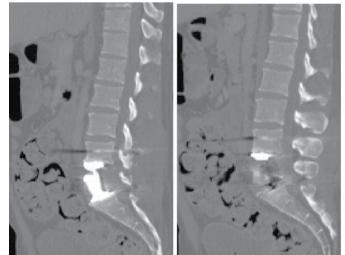


Figure 6. Postoperative control CT scan of the lumbar spine.

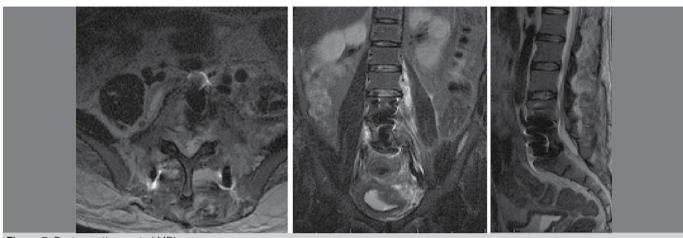


Figure 7. Postoperative control MRI.

fact that a general surgeon is not required.⁵ Tang et al. report a case using the posterior approach alone, in a patient with thoracic involvement who underwent unilateral costotransversectomy. In that case, it was possible to perform anterior decompression, associated with anterior reconstruction with cage, and posterior fixation using pedicle screws.⁵

Posterior access to the vertebral bodies of the lumbar spine is a little more difficult to achieve than in the thoracic spine. Moreover, in cases where lumbar spondylodiscitis is associated with abscess of the paravertebral musculature, the anterior approach allows access to and debridement of the abscess. In the case described, we achieved satisfactory debridement by the anterior route, and reconstruction with a device that enables distraction by a hydrostatic mechanism, enabling control of sagittal alignment, with serial radioscopic imaging during surgery. Posterior fixation, with stimulus to consolidation of the posterolateral arthrodesis with iliac graft, helped to increase the stability of the assembly, allowing early weight-bearing on the first postoperative day, followed by rapid and encouraging recovery on the subsequent days. The patient was discharged 11 days after surgery.

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ORIGINAL ARTICLE

FOUR-LEVEL EN BLOC VERTEBRECTOMY: A NOVEL TECHNIQUE AND LITERATURE REVIEW

VERTEBRECTOMIA EM BLOCO EM QUATRO NÍVEIS: NOVA TÉCNICA E REVISÃO DA LITERATURA

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ABSTRACT

Objective: To demonstrate a novel technique for multilevel en bloc post-vertebrectomy reconstruction. Methods: A novel technique for en bloc multiple post-vertebrectomy reconstruction was used in a patient presenting for curative resection of Ewing's Sarcoma at the oncology center of a public university hospital. Results: The procedure described was feasible for en bloc resection of the four vertebrae. The reconstruction was acceptable and satisfactory in terms of mechanical stability and was without any neurological sequelae in the patient. Conclusion: The use of an allograft with a locked intramedullary nail was an adequate solution for reconstructing the anterior and medial spines after multilevel vertebrectomy. In addition, the association of four intramedullary nails provided stability to the reconstruction. Immediate benefits of the technique compared to other commonly used techniques were shorter hospitalization times and reduced surgical morbidity. Level of Evidence V, Clinical study of a new surgical technique and a literature review.

Keywords: Reconstructive Surgical Procedures. Spinal Neoplasms. Spine. Thoracic Surgery. Orthopedics

RESUMO

Objetivo: Demonstrar uma nova técnica de reconstrução por vertebrectomia em bloco multinível. Métodos: Descrição de uma reconstrução pós-vertebrectomia em bloco multinível, em paciente tratado num hospital oncológico público universitário. com indicacão de resseccão curativa de sarcoma de Ewing. Resultados: O procedimento proposto foi viável para a ressecção em bloco de quatro vértebras e a reconstrução foi aceitável e satisfatória em termos de estabilidade mecânica, sem causar dano neurológico ao paciente. Conclusão: O uso de aloenxerto com parafuso intramedular bloqueado é uma solução adequada para a reconstrução da coluna anterior e medial após vertebrectomias multiníveis. Além disso, a associação de guatro parafusos intramedulares dá estabilidade à reconstrução. Benefícios imediatos da técnica são o tempo de hospitalização mais curto e a redução da morbidade cirúrgica, em comparação com outras técnicas, comumente utilizadas. Nível de Evidência V. Estudo clínico de nova técnica cirúrgica e revisão da literatura.

Descritores: Procedimentos Cirúrgicos Reconstrutivos. Neoplasias da Coluna Vertebral. Coluna Vertebral. Cirurgia Torácica. Ortopedia.

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INTRODUCTION

Around 5% to 10% of all primary malignant bone tumors occur in the vertebral spine. According to the literature, the mean survival is between six and eight months when the vertebral spine is affected by primary or metastatic tumors.¹

In the past, malignant tumors of the vertebral spine were considered incurable, because achieving wide surgical margins appeared to be surgically impossible. For a long time, intralesional resection was the option for surgical treatment of tumors of the spine, but the results were oncologically poor.²

Ewing's Sarcoma is one of the most common forms of primary malignant bone tumors in children and adolescents. The most common primary sites of involvement are the pelvis, femur and tibia. Primary involvement of the spine is rare, with an incidence of only 5%.^{3,4}

En bloc resection of primary malignant tumors of the vertebral spine with oncological surgical margins has attracted great interest, as it increases the survival rate and improves local control of the tumor. As a result, various total vertebrectomy techniques have been developed for tumors of the vertebral spine.

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

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Greater development of this technique, called "total en bloc vertebrectomy",⁵ has revealed the possibility of achieving oncologically secure resection margins. Thus, the surgical option to improve both local control of the tumor and overall survival has become technically viable.^{5,6,7}

En bloc resection is associated with a high rate of complications. On the other hand, it decreases the risk of local recurrence and mortality related to the tumor. En bloc resection is, therefore, a very demanding process, but it can be performed with an acceptable degree of safety.⁸

It is indicated in cases of aggressive malignant tumors and primary benign tumors of the vertebral spine, single metastatic tumors of primary tumor with favorable prognosis (good prognostic scores), and extracompartmental, multisegmental vertebral tumor manifestations, according to Tomita type 6.⁷ Contraindications include disseminated vertebral metastatic disease and detection of distant metastases in the staging investigation, and biologically unfavorable tumors or diffuse malignant tumors with primary systemic dissemination (Tomita score < 4-5 points, Tokuhashi score < 12 points).^{9,10}

The main complication of multilevel en bloc resection associated with reconstruction is posterior instrument failure. Although these patients with instrument failure present back pain, the neurological complications are not catastrophic.¹¹

In regard to irrigation, we have two main concerns in these cases of en bloc vertebral resection: spinal cord ischemia after ligation of the segmental arteries, and excessive perioperative bleeding. Interruption of the artery of Adamkiewicz, the most important artery, does not adversely affect neurological function. We strongly advocate that our surgeons sacrifice up to three pairs of segmental arteries, even including the artery of Adamkiewicz, if necessary. The recent development of new preoperative embolization techniques ensures a more aggressive, more extensive, and safer embolization for this type of procedure.^{12,13}

Total en bloc vertebrectomy can be performed through the anterior and posterior approaches, isolated or combined, or through a single posterior approach. For most one- or two-level tumors, the posterior approach is sufficient. In patients with three or more levels of involvement, the neovascular structures are initially approached via the anterior route, then en bloc resection is performed via the posterior route, with instrumentation of the pedicle screws and anterior reconstruction.¹⁴

There are some options for post-vertebrectomy reconstruction; some studies demonstrate that a system of replacement of the vertebral body through a carbon fiber interbody cage has low complications, but is limited to just a few levels involved in the en bloc resection.¹⁵

Nowadays, artificial bone grafts are more commonly used, without a significant decrease in the rate of incorporation when compared with the previously used techniques, i.e. autologous grafts. However, the reconstructions involving fewer resected levels are also limited. Distributing the load across a greater number of screws ensures stability and decreases the danger of failure and loosening of the main implant.¹⁶ The aims of this work are to present a new technique for four-level en bloc post-vertebrectomy reconstruction, and to carry out a literature review on multilevel en bloc vertebrectomies.

CASE REPORT

In December 2014, a 32-year-old patient presenting progressive low back pain associated with paresthesia of the lower limbs for four years, who had undergone surgical treatment three times, was selected for treatment with en bloc multilevel post-vertebrectomy reconstruction. In the first surgery, performed three years previously, a partial resection of the tumor was performed, and histopathological study of the surgical pieces, with diagnosis of Ewing's An MRI scan was taken of the thoracic-lumbar spine, eight months after the last surgery, revealing a suspected tumor mass due to local recurrence or residual progressive at the corresponding vertebral levels (Figure 1). The MRI showed a voluminous expansive lobulated lesion in the left-side foraminal regions of T10-T11 and T11-T12 and in the left pedicles and posterior portion of vertebral bodies T10, T11 and T12, with epidural lesional component of T9-L2, particularly in T11. The patient was then referred to our service.

The patient received neoadjuvant chemotherapy with ifosfamide and etoposide. The physical examination showed back pain in the thoracic-lumbar areas and decreased mobility of the thoracic-lumbar spine, without neurological defect, classified as Frankel D. In terms of prognosis, we used the Tomita score (< 4-5 points) and the Tokuhashi index (< 12 points).^{9,10} There was no evidence of distance metastases in the staging. Our team decided to perform complete en bloc resection of the injured vertebrae (T10 to L1).

The new surgical technique was performed with the consent of the local ethics committee (Protocol IOT 1346) and the patient signed the Free and Informed Consent Form.

A total of three surgical interventions were performed at our service, over a period of 18 days (Figure 2). The first was via the posterior route, involving release of the fibrosis and dural sac, the second was a thoracoscopy for ligation of the segmental arteries, and the third, multilevel en bloc resection of four vertebrae and reconstruction via the posterior route.

Surgical technique

In the first intervention, via the posterior route, we made an incision with a spindle from T5 to L5, separating the erector spinae muscles from the bone structures. A previous laminectomy was observed at levels T10 to T12. Next, we inserted the pedicle screws in T5-T8 and L2-L5 bilaterally, extending the laminectomy and arthrectomies from T9 to L1. There was also a previous pediculectomy from T10 to L1. Finally, we performed circumferential release of the dural sac, and ligated the roots from T9 to L1, bilaterally.

In the second intervention, 11 days after the first, we performed an anterior and thoracoscopic approach, with ligation of the segmental arteries of T10 to T12, bilaterally, by the thoracic surgery team. The patient was put under general anesthesia with selective intubation, and positioned lying on the right side. We performed mini-thoracotomies of 2.0 cm, one on the midde-axilary line in the sixth left intercostal space, another on the axillary-posterior line in the seventh left intercostal space, and a final one on the axillary-posterior line in the ninth intercostal space. We used a 10.5 millimeter tube needle for optics of 10 and 30 millimeters.

We identified vertebral bodies T10, T11 and T12. We opened the parietal pleura of these bodies, and dissected the arterial and venous segmental branches. We ligated the proximal and distal segmental vessels with a metal clamp (LT300) and transected them by electrocauterization. We drained the pleural cavity with a thoracic drain, through the portal in the ninth intercostal space. The patient was then repositioned lying on the left side, and we performed the same technique to access the thoracic cavity, ligating the contralateral vessels.

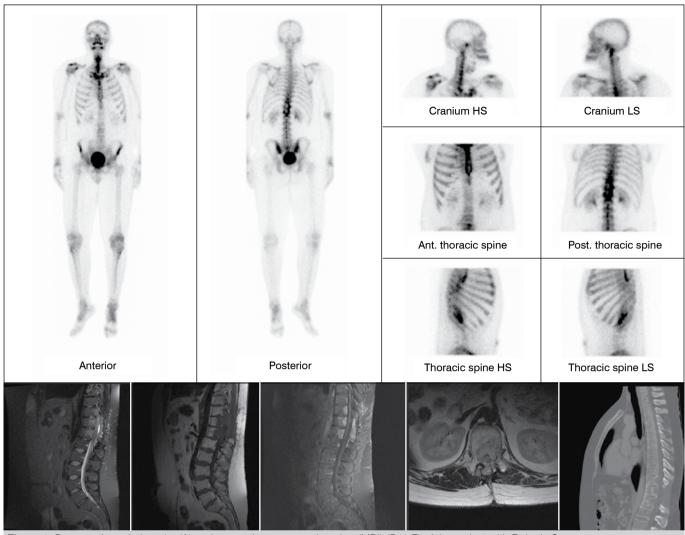


Figure 1. Preoperative scintigraphy (A) and magnetic resonance imaging (MRI) (B to F) of the patient with Ewing's Sarcoma.

In the third and final surgical intervention, we performed total en bloc resection of the tenth thoracic vertebra at the first lumbar vertebral level, via the posterior approach.

Resection

The important surrounding structures were released manually, from the anterior surface of the vertebral spine, without violating the tumor. We moved the parietal pleura to the side of the vertebrae, and observed the bilateral ligature of segmental arteries T10, T11 and T12 that had been done in the second intervention. We ligated segmental arteries from L1, bilaterally, under direct vision. Next, we released the diaphragm and the aortic artery from the spine by manual blunt dissection. We placed spatulas ("shoes") between the aorta and the spine. We then dissected from T9-T10 and L1-L2, using disc tweezers, chisels and scalpel, and removed the longitudinal posterior and anterior ligaments. Finally, we resected the four vertebrae (T10 to L1) en bloc, working clockwise.

Reconstruction

1. Preparation of the allograft with 0.9% saline solution, nail fixation (Interlocking Orthofix Inc.) and blocking of the intramedullary system, performed on a sterile auxiliary surgical table.

2. Placement of the graft system + nail, through fixation from vertebrae T9 and L2 with an awl, inserting the allograft with an

humeral interlocking nail without locking it, sliding the nail initially distally and then sliding it proximally after placing between vertebrae T9 and L1, locking the locking screw in the allograft, and rotating the nail for lordosis in conjunction with the graft.

B.3. Compression of the systems of four nails on the allograft + interlocking. It is important to emphasize that the fact that the interlocking of the humerus is slightly curved helped maintain the sagittal alignment of the spine.

After inserting two JP drains, we closed the wound.

The total surgery time was 22 hours, with replacement of 4 RBC (red blood cell) concentrates and 1 FFP (fresh frozen plasma), to replace the loss of approximately 4000 ml of blood. The histopathological exam showed a piece measuring $12.2 \times 5.2 \times 5.2$ centimeters, including the tumor lesion, measuring 9.2×2.2 centimeters, occupying the region of vertebral bodies T10 to L1. Ewing's Sarcoma was confirmed, with caudal and cranial resection margins free of tumor, and the presence of angiolymphatic invasion.

Postoperative management

In the postoperative period (Figure 3), the patient remained in the intensive care unit (ICU) for three weeks, presenting the main complication of infection of the surgical site, which was resolved by two surgical cleanings, ten days apart, the first one week after the primary surgery and the second nine days after the reconstruction,

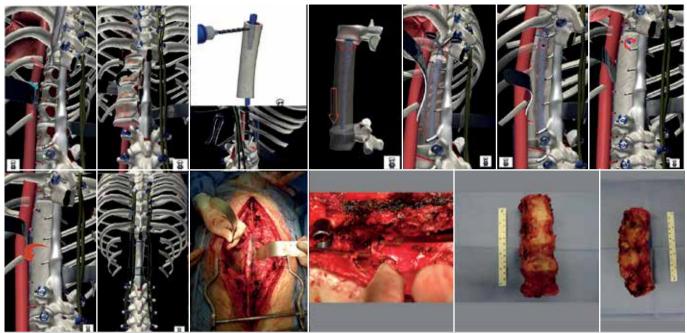


Figure 2. Operative imaging of the patient with Ewing's Sarcoma: operative planning (A-J), photographs of the surgery (K-Q) and photographs of the excised pieces (R, S).



Figure 3. Postoperative radiographs (A-D) and magnetic resonance imaging (MRI) (5-6) of the patient with Ewing's Sarcoma.

together with the use of antibiotics (piperacillin/tazobactan and linezolid for three months).

We opted for early mobilization on postoperative day one, with the assistance of a trained physiotherapist. The patient was encouraged to perform walking training on day 10 after the final surgical procedure. On postoperative day 20, we encouraged the patient to walk unaided, and indicated discharge from hospital.

We performed follow-up at one, two, three and six months postoperative. In the postoperative period, no adjuvant therapy was given, due to maximum toxicity having been reached by the neoadjuvant chemotherapy. At the six-month follow-up, there was no evidence of local recurrence or distant metastatic lesions, and the patient presented good neurological function.

DISCUSSION

Different authors have reported surgical approaches by the combined access route, presenting low rates of complications.^{17,18} The reconstruction techniques differ in various aspects; there is the option to use a double nail system, as opposed to the four nail system, although the latter offers more stability. In terms of

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the number of levels used in the fixation, there is controversy over longer fixations, with three or four levels above and below generally being indicated for more pathological bones, and shorter fixations when two levels are involved.

In relation to the reconstruction, the most common alternatives are mesh cage, expandable cage, vascularized fibula, and allograft, selected based on the size of the en bloc vertebrectomy. In the case described, owing to the fact that it was an extensive resection, our choice was for the allograft. We also opted to use an interlocking nail to fix the graft, seeking to block a nail within the allograft to avoid migration or pistoning of same, and movement of the allograft. Our preference is for a combined posterior approach for multilevel en bloc resections. To achieve tumor-free margins, en bloc excision of the tumor in the thoracic-lumbar vertebral spine requires extension of the resection margins, including all the structures that could be affected and are potentially resectable, such as the intervertebral discs above the affected vertebrae, in the cranial-caudal direction. The incidence of complications is significantly higher in revision surgeries, compared with patients who have not undergone previous surgery. The rate of local recurrence in these revision surgeries is even more significant¹⁹ because it is very difficult to recognize and obtain tumor free margins.

The most extensive resection described in the literature was of five vertebrae, with a marginal resection achieved. A case was reported involving a patient with a large chordoma of the thoracic spine, who underwent a successful spondylectomy of 5 levels with bilateral chest wall resection for en bloc resection without neurologic compromise.²⁰

The reconstruction through the system of four bars and posterior pedicle screws associated with allograft of the femur fixed with locked humeral nail offers good conditions for bone fusion, despite the fact that we have not yet obtained postoperative follow-up data during these six months.

Patients who have undergone previous surgeries tend to present higher rates of complications. Local recurrence worsens the prognosis and quality of life. This fact shows that the prognosis is related mainly to how the first treatment is done.

Thus, a realistic assessment of the oncological usefulness of surgical interventions, and an assessment of the surgical viability, must precede any consideration in the indications for en bloc multilevel

resection, in order to justify the risk to the patient. Usually, this decision is taken as part of an interdisciplinary approach, involving the experience and therapeutic options of all the teams involved in the oncological treatment of these patients.

Our technique enables both resection and stabilization via the combined posterior approach. The advantage of this procedure is the ability to control the posterior and anterior vascular nerve structures and the mediastinal and visceral structures, during the resection. It is important to highlight that the use of the nail (Interlocking Orthofix Inc) improves the reliability of mechanical stability of multilevel en bloc resections, adequately accommodating the transition anatomy of the thoracic-lumbar spine and decreasing the risk of migration when associated with the posterior four-nail system.

The case report highlights the feasibility and safety of resection multilevel block, although our short follow-up is an aspect to be improved for the further development of the technique. Therefore, experience in surgery and techniques for the reconstruction of the vertebral column as well as a multidisciplinary approach of the tumor, are prerequisites for a good result.

AUTHORS' CONTRIBUTIONS: DKN (0000-0001-7895-4830)*, WGJT (0000-0001-9036-629X)*, and AFC (0000-0002-7797-5274)* conducted the bibliographic search and evaluated the statistical analysis. LPH (0000-0003-4008-3667)* and IDR (0000-0001-6533-4528)* performed data collection and were involved in patient follow-up. TEPBF (0000-0002-0819-7712)* was the main contributor in the drafting of the manuscript, being responsible for the revision of the manuscript and contributing to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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RELIABILITY OF THE MICHIGAN STATE UNIVERSITY (MSU) CLASSIFICATION OF LUMBAR DISC HERNIATION

CONFIABILIDADE DA UNIVERSIDADE DO ESTADO DE MICHIGAN (MSU) CLASSIFICAÇÃO DA HERNIAÇÃO DE DISCO LOMBAR

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ABSTRACT

Objective: The Michigan State University (MSU) classification of lumbar disc herniation (LDH) is periodically used by various authors to classify disc herniation. We assessed the reliability of this classification system among orthopedic residents at our institute. Methods: Fifty T2 axial-cut magnetic resonance images (MRI) corresponding to the level of maximal disc herniation from patients diagnosed with a single LDH were selected and distributed to six orthopedic residents. All six residents gave a specific rating for each image based on the MSU classification; in addition, three residents gave ratings on two different occasions. The degree of agreement among residents was analyzed by calculating inter-observer and intra-observer reliability using the Kappa statistic. Results: The inter-observer reliability among the six residents calculated as the Fleiss' Kappa was 0.422, which indicates moderate reliability. The intra-observer reliability of three selected residents calculated by Cohen's Kappa was 0.750. 0.772, and 0.859, which indicates substantial to almost perfect reliability. Variations in ratings were frequent in images portraying a broad-based disc herniation with spinal canal stenosis. Conclusion: Our findings demonstrate moderate homogeneity of ratings given by residents; however, test-retest results proved the ratings to be consistent. Level of Evidence II, Diagnostic studies - investigating a diagnostic examination.

Keywords: Inter-observer variability. Intervertebral disc. Intervertebral Disc Displacement. Reliability. Spondylosis.

RESUMO

Objetivo: A classificação da hérnia de disco lombar (LDH) da Michigan State University (MSU) é usada periodicamente por vários autores para classificar as hérnias discais. Pretendemos avaliar a confiabilidade deste sistema de classificação entre os residentes de ortopedia em nosso instituto. Métodos: Cingüenta imagens de RM axial do corte T2 correspondendo ao nível de hérnia discal máxima de pacientes que foram diagnosticados com uma única LDH foram selecionadas e distribuídas para seis residentes ortopédicos. Todos os seis residentes deram uma classificação específica para cada imagem com base na classificação MSU; Além disso, três residentes deram notas em duas ocasiões diferentes. O grau de concordância entre os residentes foi analisado calculando-se a confiabilidade interobservador e intraobservador pela estatística Kappa. Resultados: Descobrimos que a confiabilidade interobservador entre seis residentes, calculando o Kappa de Fleiss, foi de 0,422; isso indica confiabilidade moderada. No entanto, a confiabilidade intra-observador de três residentes selecionados mostrou-se substancial (Kappa de Cohen = 0.750, 0.772 e 0.859 em três residentes. respectivamente). Variações na observação foram freqüentes se houvesse hérnia discal ampla com estenose do canal vertebral. Conclusão: Nossos achados demonstram homogeneidade moderada das avaliações dadas pelos residentes; no entanto, teste-reteste provou que as classificações eram consistentes. Nível de Evidencia II, Estudos diagnósticos investigação de um exame para diagnóstico.

Descritores: Variações dependentes do observador. Disco Intervertebral. Deslocamento do Disco Intervertebral. Reprodutividade dos testes. Espondilose.

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INTRODUCTION

Displacement of disc material beyond the limits of the intervertebral disc space is termed as a disc herniation.¹ Such lumbar disc herniations (LDHs) are supposedly classified according to the long-established anatomical classification system.¹ This system incorporates all varieties of herniations and classifies them into protrusion, extrusion and sequestration. The generality of this classification makes it difficult to imagine or picturise the exact shape of the disc herniation by knowing just the type, without looking at the magnetic resonance (MR) image. This disadvantage can be overcome by using more precise systems as that of Wiltse et al or the Michigan State University (MSU) classification system.^{2,3} We believe that the MSU classification is simple and clearly defines the shape, location and extent of the disc herniation particularly in

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the lumbar spine. It only requires a single T2 axial cut MRI image that corresponds to the level of maximal herniation, considering the upward or downward migration in case of a sequestrated disc.² Based on this classification, the size of the disc herniation is described as Grade 1, 2 and 3; the location of the disc herniation is described as Zone 1, 2 and 3 (Figure 1). On combining the size of the disc herniation with its location, ten distinct types can be obtained. Our residents were comfortable with this classification; hence, we decided to quantify the reliability of this objective system, among orthopaedic residents at our institute.

MATERIALS AND METHODS

Retrospectively, we selected 50 T2 axial cut MR images at the level of maximal herniation that belonged to patients who were diagnosed with a single LDH that required intervention. This selection included patients with varied severities of disc induced lumbar radiculopathy, who underwent conservative management, selective nerve root block and/or mini open discectomy as a definite management. Our selection included patients with degenerative spondylosis or ligamentum flavum thickening at the chosen level; however, none of the patients had a concomitant inflammation, infection or neoplasia affecting the disc level.

A single appropriate T2 axial cut MR image corresponding to the level of maximal herniation in each patient was chosen by a single experienced surgeon. These images were given to six orthopaedic residents for categorising the disc herniation based on the MSU classification system. The residents were previously aware of this classification system; however, they did not use it as a routine. They were initially briefed about the system in a calibrating teaching session using the original work published by Mysliwiec LW et al.² All queries were addressed, following which a copy of the original work and the 50 selected MR images were provided to the residents. Residents were advised to take adequate time to analyse each image before giving a response. They were not put under an obligation to time, as to when their responses need to be submitted. This was not a part of their routine work, but to be carried out at their will, during their free time without any stress. By this way, instances of fatigue affecting the judgement of the residents were avoided; also, the precision and consistency of their judgment were maintained. All residents returned their response with a classification for each MR image within a week.

As the classification system includes 10 types, each type was given a number from 1 to 10. Therefore, six sets of nominal variables were

obtained from the responses received from the residents. This data was used to determine the inter-observer reliability by calculating the Fleiss' Kappa (statistical measure for assessing the reliability of agreement between multiple raters). The same MRI images were shuffled and provided to three of the residents (Resident 1, 2 and 6) for reassessment after a month. Their response was collected and was compared with their previous ratings. This data was used to determine the intra-observer (test-retest) reliability by calculating the Cohen's Kappa (statistical measure for assessing the reliability of agreement between two raters) for each resident. The inferred results were tabulated. Statistical analyses were done using IBM SPSS Statistics for Windows, Version 20.0, Armonk, NY: IBM Corp. Implied consent was obtained from the study participants when they agreed to participate in this research. This study was approved by the institutional review board of Chang Gung Memorial Hospital (IRB No - 201700227B0) and was performed in compliance with the 1964 declaration of Helsinki, its later amendments or comparable ethical standards.

RESULTS

The selected MRI images (n = 50) included all types of LDHs described in the MSU classification taken from 50 different patients (Age = 46.9 ± 8.7 ; Male = 31; Female = 29). The residents who rated the MRI images were in their third year of residency training and they took approximately a week to classify all 50 axial cut MRI images. Data received from the residents were in the form of classification types described in the MSU system. The most appropriate classification type for an MRI image was considered as the one which majority of the residents had an agreement. Accordingly, the total number of images belonging to each classification type was tabulated; this represents the range and severity of disc herniations among the selected images (Table 1). The classifications provided by the Residents were later numerically rated from 1 to 10 for computation purposes.

There was agreement among three or more raters for 48 (96%) of the selected MRI images which reduced to 37 (74%) when calculated

Table 1. Cases in each classification type and their agreement percentages.										
Туре	1 A	1B	1C	2A	2B	2AB	2C	3A	3B	3AB
No. of Cases	5	5	1	6	10	8	3	5	5	2
Percentage of agreement	70.02	73.34	100	80.57	65	60.44	55.57	70	63.34	75

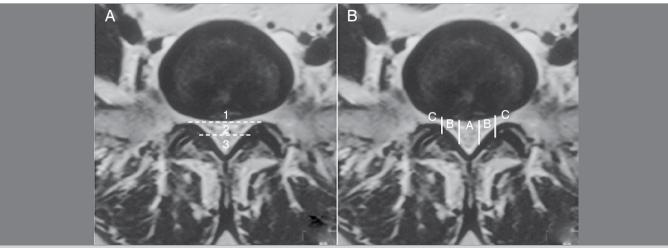


Figure 1. Grading and Zoning as per the MSU classification system. A) Lines representing grading of disc prolapse are drawn in the horizontal axis. B) Lines representing zoning of disc prolapse are drawn in the vertical axis.

for agreement among four or more raters. Only six (12%) of the MRI images had 100% agreement among raters; these images were of types 1A, 1B, 1C, 3B and two of 2A. However, this data does not depict the reliability of the classification system.

The agreement percentage for each MRI image was calculated, based on which the mean agreement percentage for each classification type was calculated to check if there was a relation between herniation severity and resident agreement (Table 1). We noticed the types 1A, 1B, 1C, 2A, 3A and 3AB to have a mean agreement percentage of 70 or above. However, 2B, 2AB, 2C and 3B had mean agreement percentages ranging between 55 and 65, with 2C having the least mean agreement percentages among Residents could be due to the herniations being broad based in an already stenosed canal (Figure 2).

The tabulated ratings of all residents were used to calculate the pair wise Cohen's Kappa and a matrix was generated (Table 2). The inter-rater or inter-observer reliability was determined by calculating the Fleiss' Kappa which was found to be 0.422 (Table 3). According to Cohen, our measure of Kappa falls under moderate agreement (0.41-0.60).⁴ This can be accepted considering that reliability is expected to be low when multiple data collectors are required to make finer discriminations as in MSU classification; however, a measure above 0.60 could have been adequate.⁴

After a month's interval, the MRI images were shuffled and provided to three Residents for reassessment, independent of their previous measures. Their previous and latest rating for each MRI image was tabulated. We found that 39 (78 %), 40 (80 %) and 44 (88%) of the recent ratings by Resident 1, 2 and 6 respectively, were consistent with their previous measures. This data was used to determine the Intra-rater or intra-observer (test-retest) reliability by calculating the Cohen's Kappa for each resident. A Kappa measure of 0.750 (Substantial agreement), 0.772 (Substantial agreement) and 0.859 (almost perfect agreement) was obtained for resident 1, 2 and 6 respectively. Hence, the intra-observer reliability can be interpreted as substantial to almost perfect.

DISCUSSION

Classifying lumbar disc herniation can provide vital assistance for clinical management of the condition. MRI is considered the ideal tool for analysis of such lumbar disc herniations.⁵⁻⁹ Both sagittal and axial cut images can provide valuable information of the underlying pathology. However, axial cut image at the pathological level is given sole priority by the MSU classification system which is periodically

Table 2. Pair wise Kappa matrix.

	Resident 1	Resident 2	Resident 3	Resident 4	Resident 5	Resident 6
Resident 1	1.000	0.461	0.365	0.357	0.502	0.656
Resident 2	0.461	1.000	0.394	0.330	0.546	0.508
Resident 3	0.365	0.394	1.000	0.292	0.363	0.451
Resident 4	0.357	0.330	0.292	1.000	0.235	0.458
Resident 5	0.502	0.546	0.363	0.235	1.000	0.456
Resident 6	0.656	0.508	0.451	0.458	0.456	1.000

 Table 3. Inter-observer and intra-observer reliability assessment using Kappa Statistic.

Reliability	Statistical Measure	Kappa	Interpretation
Inter-observer	Fleiss' Kappa	0.422	Moderate
Intra-observer (Resident 1)		0.750	Substantial
Intra-observer (Resident 2)	Cohen's Kappa	0.772	Substantial
Intra-observer (Resident 6)		0.859	Almost perfect

practiced by authors around the world to optimize management strategies for patients with lumbar disc herniations.^{2,10-12} The concept of considering a single axial cut image at the level of maximal herniation may be unlike the "Lumbar disc nomenclature: version 2.0" where sagittal images are taken into consideration;¹³ even so, the MSU classification clearly defines the shape, location and extent of the disc herniation.

Even though, our residents were comfortable with this classification system, a calibrating session was held to refine their understanding of this system. In this session, we discuss the MRI of several patients and ask residents to classify them according to the MSU classification system. They were then asked to justify why they chose a particular type for each discussed MRI. If there were disagreements, rules were framed to give the most appropriate rating for a specific MRI. By this way, we believe that the understanding of the classification system was refined.

We used the Kappa statistic to determine the reliability of the MSU classification system.⁴ This is because the ratings given by the six residents were considered as nominal variables. Hence we determined the inter-observer reliability by calculating the Fleiss' Kappa for more than two raters which is an extension of Cohen's Kappa that is used for calculating agreement among two raters. Besides that, the intra-observer (test-retest) reliability was determined using the measure of Cohen's Kappa as it involves one previous and one recent rating by each resident. Our results were finalized based on

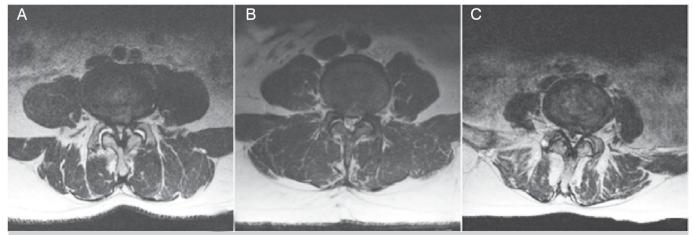


Figure 2. Examples of deceptive MRI that had least agreement among residents. A) Frequently rated as type 2a or 2ab. B) Frequently rated as type 2b or 2ab. C) Frequently rated as type 2ab or 2c

accepted interpretations of the Kappa statistic.^{4,14} We inferred a moderate inter-observer reliability and substantial to almost perfect intra-observer reliability.

The reason for obtaining a moderate inter-observer reliability needs to be discussed. Firstly, this could be because we chose multiple raters who had to rate multiple categories.¹⁴ It is an accepted fact that when multiple data collectors are required to make finer discriminations, reliability is difficult to be obtained.⁴ Besides that, this could be because the types 2B, 2AB, 2C and 3B had mean agreement percentages ranging between 55 and 65 only. On analysing the reason for less agreement among Residents for these types, we found that this was mainly due to the herniations being broad based in an already stenosed canal due to degeneration. Apart from these factors, the learning curve to get familiarized to this classification system may also be considered; however, if appropriate rules are framed to interpret such deceptive MRI, better inter-observer reliability can be achieved and findings can be correlated with clinical presentations to guide management.

It should be noted that this classification system does not take into account a bulging disc, either symmetrical or asymmetrical as described in the Lumbar Disc Nomenclature 2.0;^{1,13,15} however, the system holds good for herniated discs. Clinical presentation of patients does not depend on the anatomy of the disc prolapse alone but rather depends on many other factors that can cause symptoms.^{13,16} These include disc degeneration, reactive vertebral body marrow changes, ligamentum flavum hypertrophy, facet hypertrophy or associated segmental instabilities.^{17,18} In spite of a significant MRI finding of a disc herniation, asymptomatic clinical presentations are also a possibility.^{16,19-20} Hence, even though MSU classification can describe the exact anatomic appearance of a herniated disc, management protocols cannot be formulated with its sole guidance. Other concomitant parameters should be given equal importance along with MSU classification type to optimize management protocols; yet, it is vital to know the anatomic appearance of the disc by an objective system like MSU classification to plan the approach and procedure if intervention is considered.

Limitation

Our results and interpretation could be influenced by each resident's understanding and experience with this classification system. This could have biased our results of reliability.

CONCLUSION

The inter-observer and intra-observer reliability of the MSU classification for lumbar disc herniations was calculated among orthopaedic residents. Our findings demonstrate moderate homogeneity of the ratings given by the residents; however, test-retest proved the ratings to be consistent. This observation implies that the MSU classification could be of clinical importance; however, appropriate rules need to be framed to interpret deceptive MRI which is highly essential to delineate optimal management protocols.

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SURGICAL CORRECTION OF SEVERE AND FIXED CHIN-ON-CHEST DEFORMITY

CORREÇÃO CIRÚRGICA DE GRAVE DEFORMIDADE FIXA DO TIPO QUEIXO-NO-PEITO

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ABSTRACT

Objective: To describe a successful surgical treatment for the challenging severe and fixed chin-on-chest deformity due to isolated neck extensor myopathy (INEM). Background data: INEM is an idiopathic cause of dropped head syndrome (DHS) that results in severe cervicothoracic kyphosis, defined as chin-on-chest deformity. The existing literature on surgical management is limited, with outcomes ranging from poor to excellent. INEM may present to the spinal surgeon for consideration of surgical management. Methods: The authors present a technique that uses a staged posterior and anterior approach combined with osteotomies and corpectomy to correct the severe and fixed deformity. A state of the art anterior and posterior instrumentation system was used. Results: At the three-months follow-up, there was good deformity correction and the patient's satisfaction was high, with no neurological deterioration occurring. Conclusions: The technique illustrated in this study represents a successful option to treat this debilitating deformity. More evidence is needed to set up a definitive algorithm for the management of this condition. Level of evidence IV, Case Report.

Keywords: Surgical procedures operative. Spinal diseases. Cervical vertebrae. Osteotomy. Decompression, surgical.

RESUMO

Objetivo: Descrever o tratamento cirúrgico de deformidade desafiadora, grave, de queixo-no-peito devida a miopatia isolada do extensor do pescoco. Contexto: A miopatia isolada do extensor do pescoco é uma causa, idiopática, da síndrome da cabeça caída. Resulta em grave cifose cérvico-torácica, chamada de "deformidade gueixo-no-peito". A literatura sobre o tratamento cirúrgico da deformidade é limitada, com resultados de pobres a excelentes. A miopatia isolada do extensor do pescoço pode ser considerada para tratamento cirúrgico. Métodos: Os autores apresentam a técnica, que usa vias anterior e posterior em estágios, combinadas com osteotomias e corpectomia para corrigir a deformidade, grave e fixa. A melhor instrumentação e sistemas para abordagem anterior e posterior foram utilizadas. Resultados: Após três meses de follow-up, houve boa correção da deformidade e a satisfação da paciente foi alta, sem deterioração do status neurológico. Conclusões: A técnica se mostrou boa opção para tratamento de sucesso desta deformidade. Mais evidências são necessárias para estabelecer um algoritmo definitivo para a condução dessa deformidade. Nível de evidência IV, Relato de Caso.

Descritores: Procedimentos cirúrgicos operatórios. Doenças da coluna vertebral. Vértebras cervicais. Osteotomia. Descompressão cirúrgica.

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INTRODUCTION

Dropped head syndrome is a disease characterized by a severe neck extensor muscle weakness, resulting in a chin-on-chest deformity in the sitting or standing position, correctable by passive neck extension, isolated or associated to neuromuscular diseases.^{1,2} Extreme weakness in the paraspinal muscles, with absence of a neuromuscular disease or specific abnormalities in eletroneuromiography and muscle biopsy is termed isolated neck extensor myopathy (INEM).^{3,4} The resulting chin-on-chest deformity starts as a flexible deformity,

which becomes rigid as a consequence of prolonged flexion and calcification of the anterior longitudinal ligament.⁴

Treatment results with physical therapy, massage and acupuncture are inconsistent in cases series reports,^{2,5,6} and most studies show little improvement with non-surgical management.^{3,5,7} A collar can help the patient to maintain horizontal gaze and eye contact, and facilitate activities of daily living, although there are problems with compliance to the collar, skin pressure lesions and possible worsening of muscular weakness with prolonged use.^{2,6} The goal of the surgical

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management of dropped-head syndrome is to improve quality of life by correcting the deformity, decompressing of neural elements when necessary and promoting long-term stabilization,⁸ reating patients for whom conservative measures failed or for those who do not have treatable conditions as a cause for the dropped-head.^{9,10}

CASE REPORT

Our patient is a 56-years-old female referred to our hospital after 12 years of symptoms and conservative treatment in the northeast of the country. She complained of progressive drop of the head with incapability to extend neck or to look forward, and denied any serious trauma history or previous diseases. Previous medical records were not available.

She reported that symptoms initiated insidiously, with weakness of the hind neck muscles, with mild cervical pain. After three years, she was incapable to extend the head. In her home region, she was then treated with physiotherapy. By the time she was referred to our specialized center, she had had several falls from her own height without any major injuries or detected fractures. The deformity had become rigid, and she was considered inoperable.

The head was totally supported by her chest, causing face deformity of left cheek and ear. The clinical aspect of the patient is shown in Figure 1. Even with a passive maneuver in supine position, the head could not be extended, and the anterior left sternocleidomastoid seemed



Figure 1. Clinical photos of the patient showing the fixed chin-on-chest deformity with the head rotated to the right, before surgery.

contracted. Superior and lower limbs strength were grade V (normal); sensitivity was normal and symmetric in torso and limbs. No pathologic reflex or signs of myelopathy were found. The patient could barely walk leaning on the walls and furniture, and she refused to use a cane or crutches. Feeding was possible only in the supine position. Investigation was initiated with rheumatology, genetics and neurology specialists. Ankylosing spondylitis and rheumatoid arthritis were discarded by serum exams. Head MRI was normal, and the neurology team also discarded Parkinson's disease, lateral amyotrophic sclerosis and myasthenia gravis, as well as tumors and psychiatric diseases. The patient had no diabetes or hypertension. and she was not a smoker. She was then diagnosed with isolated neck extensor myopathy (INEM), and surgery was planned and patient signed Free and Informed Consent Form for surgery and publication of this case report. The approval of the Research Ethics Committee is waived for case reports in our institution.

Lateral mass screws were placed at C2, C3 and C4 and pedicle screws at T1, T2 and T3. The posterior elements of C5, C6 and C7 (lamina, facet joints and pedicles) were fully resected. After extensive release, the head started to move, which caused a decrease in the motor evoked potentials (MEP) of about 30%. In that moment, one of assistants, outside the sterile field, started reduction, by gently tractioning the head; this recovered the initial MEP results, and great correction was achieved. Two rods were molded and fixed and one autograft from the resected local bone was placed in the fusion area. Patient was admitted to the intensive care unit (ICU) (Figure 2). After one week, anterior corpectomy of C5 and C6 with autogenous iliac crest bone graft with anterior plating from C4 to C7, with placement of mesh cage, was performed (Figure 3). After three days, the patient was discharged from the ICU and started rehabilitation using a cervicothoracic brace. She was able to walk by the fourth postoperative day. The patient went home 20 days after the second procedure, in use of a Philadelphia brace. The brace had to be discontinued after four weeks due to occipital ulceration, and a soft collar was recommended by the second postoperative month. The patient was still happy with the procedure in the third month of follow-up, but she complains about head rotation, that was not fully corrected. Even so, she would undergo surgery again if necessary. Nowadays she walks independently without any support (Figure 4).

DISCUSSION

A challenge of the correction of chin-on-chest deformity is choosing the number of levels to be instrumented. Sharan et al.⁴ advocate a posterior instrumented fusion from C2 to T3, T4, or T5. This procedure has the advantage of retaining some rotation as well as flexion and extension

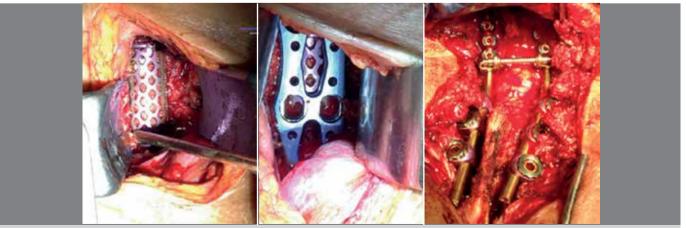


Figure 2. Surgical procedure.

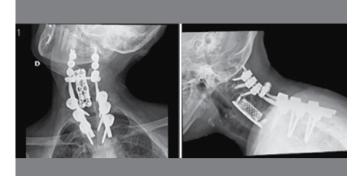


Figure 3. Radiographic images after surgery.



Figure 4. Clinical photos showing the patient after surgery.

at the upper cervical levels. Although the deformity usually starts at C4, the authors recommend starting the construct at C2 in an effort to avoid long-term failure. We performed a Grade 7 osteotomy,¹¹ i.e., resection of one or more entire vertebral bodies discs and uncovertebral joints, posterior lamina and facets. In our case, no correction was possible with positioning or tractioning the head; reduction was only possible after removal of all posterior elements of three vertebrae, C5, C6 and C7. Like in most cases reported, we fixed vertebrae from C2 to T3. The anterior approach did not improve correction but promoted stability and decompression of neural elements.

The literature on the surgical management on this uncommon condition is very limited, with the largest series describing only nine patients, being the only report on long-term results.⁷ The average follow up was 6 years, and only four cases were primary INEM, the others had undergone local radiation therapy. All cases were fixed from C2 to thoracic levels ranging from T1 to T5.7 Most patients experienced improved neck positioning and elimination of pain while standing and walking and reported marked improvement in quality of life and activity level. ^{2,7} Another study with 26 patients with chin-on-chest deformity secondary to ankylosing spondylitis also showed good results in the long term, with improvement in quality of life and achieving fusion, but with one death postoperatively and six neurologic complications (no quadriplegia).¹² The most reported complications in those series were pneumonia and skin ulcer caused by the prolonged use of orthosis; pseudoarthrosis and implant failure were also reported. Our patient also had skin ulcer, which caused orthosis discontinuation,

without loss of correction or implant failure.

CONCLUSION

We reported a case of dropped head syndrome with severe and fixed chin-on-chest deformity attributed to INEM, which poses a surgical challenge. Surgical issues to consider involves the optimal timing to intervention, the choice of approach (anterior X posterior X 360), and the levels for decompression and fusion. We consider that neurologic complications can be avoided in the moment of release of posterior elements by using a provisory rod or by an assistant holding the head. Although there is no formal standard care for this condition, appropriate surgical treatment of this patient was possible following the principles for surgical spine treatment: decompression of neural elements, if necessary; correction of deformity and stabilization.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of the manuscript. AHAO (0000-0003-2112-4654)* and FGBZ (0000-0002-7659-8315)* were the main contributors in writing the manuscript. RMM (0000-0001-59585646)* and AFC (0000-0002-7797-5274)* underwent surgery, monitored patient and collected clinical data. TEPBF (0000-0002-7969-7845)* contributed with the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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REDUCTION IN KNEE PAIN SYMPTOMS IN ATHLETES USING AN ACUPUNCTURE PROTOCOL

REDUÇÃO DA SINTOMATOLOGIA DOLOROSA DE JOELHO EM ATLETAS UTILIZANDO PROTOCOLO DE ACUPUNTURA

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ABSTRACT

Pain in the lower limbs is common in athletes and a limiting factor in performance. Acupuncture has shown positive effects as an analgesic treatment and may potentially be used for pain reduction in runners. This study aimed to analyze the parameters associated with knee pain by correlating strength parameters of the musculature assessed in runners treated with acupuncture. A descriptive longitudinal study was conducted on 34 runners of both sexes aged 20 to 52 years, who presented with knee-related pain from January to June, 2015. Two pain questionnaires and a maximal strength test with electromyographic evaluation of the rectus femoris, vastus lateralis, and medialis muscles were used, and patients were monitored during five follow-up visits after an acupuncture protocol. All participants reported experiencing a decrease in knee pain after treatment. The affected limbs showed an increase in average strength by 34% and 25% compared to the contralateral limb. An increase in the number of motor units recruited for the three muscles was observed in both limbs. In conclusion, the proposed acupuncture protocol was effective in reducing pain symptoms in the knee region of athletes, thus influencing their gain in strength and muscle balance. Level of Evidence IV, Case series.

RESUMO

A dor em membros inferiores é comum em atletas e representa um aspecto limitante ao rendimento. Buscando atenuação para a dor desta população, utiliza-se a acupuntura por apresentar bons efeitos na analgesia. Objetivo: analisar os parâmetros relacionados à dor de joelho correlacionando os parâmetros de força das musculaturas avaliadas em corredores submetidos a tratamento de acupuntura. Métodos: Foi realizado um estudo longitudinal, de janeiro a junho de 2015, com 34 corredores de 20 a 52 anos de ambos os sexos, que apresentassem dor de joelho. Foram aplicados dois questionários de dor e um teste de força máxima com avaliação eletromiográfica dos músculos reto femoral, vasto lateral e medial, com cinco atendimentos seguindo um protocolo de acupuntura. Resultados: Todos os voluntários relataram diminuição da dor de joelho após o tratamento. A média de força do membro afetado teve incremento de 34% e do membro contralateral de 25%. Verificou-se aumento no número de recrutamento de unidades motoras para os três músculos avaliados em ambos os membros. Conclusão: O protocolo proposto se mostrou eficaz na diminuição da sintomatologia dolorosa na região de joelhos de atletas corredores, interferindo no ganho de forca e no equilíbrio muscular. Nível de Evidência IV, Série de casos.

Keywords: Acupuncture. Analgesia. EMG. Knee joint. Athletes.

Descritores: Analgesia por Acupuntura. Eletromiografia. Articulação do joelho. Atletas.

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INTRODUCTION

According to epidemiological studies, 27% to 70% of runners incur some form of injury over a 1-year period, which can cause discomfort during training and lead to performance below expected levels in competitions.¹

Acupuncture therapy may be beneficial for attenuating and/or resolving pain in runners, as this technique is known for its analgesic effects when applied in patients with chronic knee pain.² This approach is widely used in Brazil and consists of the insertion of stainless steel needles at specific points in several areas of the body.³ Needles can be inserted either at or near the pain site and may also be inserted at points associated with the underlying symptoms.⁴

In order to provide a reliable level of scientific evidence for acupuncture techniques to guide clinical practice, this study sought to analyze the effects of a treatment protocol using acupuncture and to report the effects on pain parameters in the knee region of runners; the results presented here provide a clear methodological description favoring the application and reproducibility of this technique in clinical practice.

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

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MATERIALS AND METHODS

The study sample consisted of 34 street runners from the city of Curitiba, of both sexes, aged between 20 and 52 years, who presented pain in the knee region.

Runners with compromising lesions in the lower limbs that could prevent a proper evaluation, pregnant runners, and runners with cognitive impairments that could interfere with the understanding of any part of the study were excluded. The survey was conducted after participants signed an informed consent form. This research protocol was approved by the Committee on Ethics in Human Research at the Universidade Tecnológica do Paraná (under the number CAEE: 30166314.2.0000.5547).

The McGill Pain Questionnaire was used together with the visual analog scale (VAS) and the Faces Pain Scale to assess pain intensity; the assessments were conducted before and after treatment. In order to ensure the reliability of the protocols, the participants were not provided access to their answers before treatment.

Each individual's skin was prepared by trichotomy and cleansing with a 70% alcohol solution in the areas specified for the placement of the surface electrodes (10-mm diameter Ag/AgCl electrodes, Meditrace®), which were positioned in a bipolar configuration. The reference electrode was positioned on the left side of the acromion process.

The quadriceps muscles were assessed during knee extension movements with maximal isometric contraction, performed using a leg-extension chair device (Figure 1) with the participant sitting, the trunk sustained by the dorsal support of the chair, and the upper limbs crossed over the chest. The contraction was performed with the lower limb flexed at 60°. A maximum contraction of 3 seconds was requested and was repeated three times, with a rest interval of 2 minutes between contractions. The electromyographic data of the rectus femoris, vastus lateralis, and vastus medialis muscles were analyzed. Both the affected limb and the contralateral limb of the participants were assessed; the latter was used as a control in the data analysis.

The extensor chair was fitted with a load cell that registered the signal strength of the knee extension movement (Figure 1). An electromyography (EMG) device (EMG Systems® Brazil) was used



Figure 1. Extensor chair fitted with the load cell

and set with an acquisition frequency of 1-kHz signals. The Ag/ AgCl electrodes were positioned on the distal third of the rectus femoris, vastus medialis, and vastus lateralis muscles.

The electromyograph was previously calibrated by the support staff of EMG Systems®, Brazil. The load cell was calibrated with a manual Crown® dynamometer with a capacity of 50-kilogram force (kgf) with 5-kgf divisions and a precision equal to 1% of the total capacity. The calibration was performed considering variations of 5 kgf (5 kgf, 10 kgf, 15 kgf, and so forth). Force correction was performed individually by

$$CCcalb = (CCn-CC_{baseline}).65 = (kgf)$$

where CCcalb is the corrected value, CCn the crude value, $CC_{baseline}$ the residual value of the load cell, and 65 the conversion factor of volts (V) to kgf.

The signals were processed using MATLAB® R2008a (MathWorks, Inc) with third-order Butterworth type pass-through 30–450 Hz filtering, as well as band-reject type filters on the harmonics of the electric grid (60, 120, 180, 240, 300, 360, and 420 Hz). For the spectral domain, the median frequency descriptor (MDF) was extracted using the fast Fourier transform, algorithm, according to the following equation:

$$MF = \int_{0}^{MF} P(f)df = \frac{1}{2} \int_{0}^{fs/2} P(f)df$$

where *MF* is the median frequency and the power spectrum. Time-domain EMG signal processing was performed using the median absolute amplitude equation, shown as the energy median (ME), as defined in the equation

$$ME_{axis} = \frac{1}{2} \left(|EMG_{axis}|_{\frac{n}{2}} + |EMG_{axis}|_{\frac{n}{2}+1} \right)$$

where *ME* is the median energy (median absolute amplitude) and is the EMG signal.

The acupuncture protocol used was developed for this study, based on pressure points of systemic acupuncture with evidence supporting a decrease in pain symptomatology in the knee region. DongBang® needles (DongBang Acupuncture Inc., Seoul, South Korea) of 0.25×30 mm were used. The first acupuncture application was performed immediately after EMG data were collected. The volunteer was placed in a supine position on a stretcher for all applications of this protocol.

After the first application, four additional weekly acupuncture sessions were performed, each with a duration of 60 minutes. The time of needle permanence at each point was 40 minutes. Needle insertion was performed in the following order: E35 (*Dubi*), EX-LE-4 (*Neixiyan*), and the cranial point (sensory and motor areas in the cranial region contralateral to the affected limb). The needles were withdrawn in the same sequence.

Statistical analysis

Statistical procedures were performed using the Statistical Package for Social Sciences (SPSS) version 21.0 and Microsoft Office Excel 2010. The Shapiro-Wilk test was used to verify the normality of distributions. Normally distributed variables were described by means and standard deviations (SD), and the values before and after acupuncture application were compared using dependent t-tests.

Variables with non-normal distributions were assessed with nonparametric procedures; descriptive data were presented as the median and interquartile range, and comparisons were performed using the Wilcoxon test. Pain scores were assessed with the same nonparametric procedures, due to the subjective nature of the evaluation and the ordinal characteristics of the variables. Maximum and minimum values were used for the description of these scores.

Comparisons between variables before and after the acupuncture sessions were reported as absolute differences (delta, Δ) and relative (%) changes with respect to the respective central tendency measure. The significance level was set at p < 0.05 for all analyses.

RESULTS

The sample comprised 34 volunteers of both sexes (25 males [73.53%] and nine females) with a mean age of 34 years, a mean weight of 75 kg, a mean height of 1.71 m, and a mean body mass index (BMI) of 25 kg/m².

Athletes reported, on average, a history of 7 years of practice and generally trained 7 hours per week. In addition, they reported 2 years and 9 months of injury on average, with 18 athletes reporting pain in the right knee and 16 reporting pain in the left knee.

Table 1 shows the values of force applied by the quadriceps muscles. Table 2 presents the amplitudes of the contraction signal of the affected and of the contralateral limb. Table 3 presents the median frequency (Fmed) of the affected and contralateral limbs. All tables show the values obtained before and after treatment, as well as the improvement achieved in each limb as a percentage, the delta value (difference between the first and second evaluation), and the p-value obtained from the statistical analyses.

Table 4 shows the data related to pain in the knee region before and after the implementation of the protocol, evaluated using the McGill Pain Questionnaire and VAS assessments.

Table 1. Analysis of the strength of the quadriceps muscles.	
Earoa (kaf)	

Force (kgt)							
	Before	After	%	Δ	P-value		
Affected limb ^a	17.14±17.14	25.12±18.65	47	7.98	0.001		
Contralateral limba	25.12±15.71	26.66±17.30	6	1.54	0.001		

^amean±standard deviation, dependent t-test.

Table 2. Signal amplitude of contraction.

Signal	amplitude (uV)

	Affected Limb					
Muscle	Before (median/AmpInt)	After (median/AmpInt)	%	Δ	P-value	
Rectus femoris ^a	233.81±241.41	333.47±263.70	43	99.66	0.001	
Vastus lateralis ^a	263.96±127.19	307.37±303.48	16	43.41	0.025	
Vastus medialis ^a	206.02±226.27	256.59±310.49	25	50.57	0.001	
		Contralateral Limb				
Rectus femoris ^a	300.29±247.57	352.70±268.51	17	52.41	0.023	
Vastus lateralis ^a	267.64±175.42	339.44±254.88	27	71.80	0.002	
Vastus medialis ^a	205.63±146.23	271.05±261.56	32	65.42	0.029	

amedian \pm interquartile range, Wilcoxon test.

Table 3. Median frequency.

Median frequency							
Muscle		Affected Limb					
Mean	Before	After	%	Δ	P-value		
Rectus femoris ^a	104.70±11.02	105.61±11.35	1%	0.91	0.476		
Vastus lateralis ^b	122.00±31.50	111.50±32.50	-9%	-10.5	0.019		
Vastus medialis ^a	102.67±11.12	106.64±12.97	4%	3.97	0.036		
		Contralateral Limb					
Rectus femoris ^a	105.73±12.00	104.73±13.03	-1%	-1.00	0.507		
Vastus lateralis ^b	128.00±33.75	113.00±36.25	-12%	-15.00	0.002		
Vastus medialis ^a	105.02±11.57	106.94±11.91	2%	1.92	0.294		

 $^{a}mean\pm standard\ deviation,\ dependent\ t-test;\ ^{b}median\pm interquartile\ range,\ Wilcoxon\ test.$

Table 4. Pain scores.

Table 4. Faill scores.								
	Pain	Min	Max	Median∖ Interquartile range	Improvement	Δ	P-value*	
VAS	Before	04	10	6.35±1.66	48.03%	-3.30	0.001	
VAS	After	00	06	3.05±1.66	40.03%	-3.30	0.001	
McGill	Before	07	56	19.17±10.05	58.89%	-11.29	0.001	
wicdill	After	01	20	7.88±5.17	50.09%	-11.29	0.001	

*Wilcoxon test.

DISCUSSION

The mean strength of the quadriceps muscle group of the affected limb was 17 kgf before treatment and increased to 25 kgf after acupuncture treatment. For the contralateral limb, the mean strength was 25 kgf at the first and 26 kgf at the second assessment.

The mean force of the quadriceps both in the affected limb and in the contralateral limb showed a significant gain (p < 0.001 for both). These results are supported by previously published data^{5,6} claiming that when a decrease in symptoms of pain in the treated region occurs, a gain in strength can be achieved. Since the volunteers perceived a reduction in previously experienced pain, they were able to train properly again, as pain is a limiting factor for muscle function.⁷

The affected limb showed a 47% gain in mean strength while in the contralateral limb, the mean strength increased by 6%; this was sufficient to produce a similar final mean strength in both limbs, indicating a balance of muscle strength between the limbs (25.12 kgf and 26.66 kgf). Muscle imbalance is one of the most common factors reported as a likely cause of sports injuries.^{8,9} Bilateral deficits greater than 10–15% are indicators of muscular imbalances and may also be associated with a high risk of injury (joint, muscular, and tendinous) and a reduction in sports performance.^{10,11} When subjected to the acupuncture protocol, the volunteers not only experienced a reduction in pain in the knee region, but also gained strength in the affected limb; they could thus balance muscle strength between the affected and the contralateral limb, which consequently promotes the prevention of future injuries.

Regarding the amplitude of the electromyographic signal, there was an increase in the recruitment number of motor units after

treatment for the three muscles evaluated, for both the affected and the contralateral limb.

The rectus femoris muscle of the affected limb showed a significant improvement, with a gain of 43% (p < 0.001). The vastus medialis muscle showed a gain of 25% (p < 0.001) and the vastus lateralis muscle a gain of 16% (p = 0.025). A different pattern was observed in the contralateral limb, where the biggest improvement occurred in the vastus medialis muscle, with a gain of 32% (p = 0.023), followed by the vastus lateralis muscle with a gain of 27% (p = 0.029), and the femoral rectus muscle with a gain of 17% (p = 0.002).

With regard to the amplitude of the electromyographic signal, there was a significant difference in the number of recruited motor units after treatment in both limbs in the three muscles evaluated. Muscular hypertrophy and changes in motor unit recruitment are important factors associated with strength development. An increase in signal amplitude has been reported to represent an increase in the recruitment capacity of motor units upon the application of various strength training schemes.¹²

Another phenomenon that generates an increase in the amplitude of the electromyographic signal is the increased synchronization of motor units, due to an increase in the number of action potentials firing from motor units of multiple synergistic muscle groups over the same unit of time.^{12,13} The function of synchronization is to increase the rate of force development during rapid contractions, as was observed in this study. Synchronization of motor units improves intra- and intermuscular coordination, thereby increasing the muscle's capacity to generate the greatest force.¹²

With regard to the Fmed, there was no difference in action potential speed in the muscles before and after treatment in both the affected and the contralateral limb. This similarity between the values obtained before and after acupuncture treatment was somewhat expected, as different authors have observed a reduction in Fmed in the muscles of the thigh with or without using fatigue protocols.¹⁴

When an increase in the firing frequency occurs, this represents an increase in the conduction velocity of the action potentials of the larger-diameter motor units.¹² The results of this study indicate that there was an increase in the temporal domain but not in frequency, since no specific muscular training was performed. There was no general modification in neural activation in this population of athletes, but with a reduction in pain and thus in physical limitations, more motor units could be activated for the exercises already performed by the athletes. A variety of adaptations is responsible for increasing strength, power, and rate of strength development. In sedentary individuals, neural adaptations predominately occur at the beginning of a training program; it is thus plausible that certain training methods and strategies effective for such a population do not induce the same magnitude of adaptations in trained individuals.¹²

All volunteers reported feeling an improvement of pain symptoms in the knee region at the end of the 5-week treatment period. Regarding the assessment of pain, classified by the VAS, the mean for the affected limb was 6.35. After implementation of the protocol, the mean VAS score decreased to 3.05, which represents a reduction of 48.03% (p = 0.001). Taking into account the values obtained with this scale, 28 volunteers showed a decrease in pain of at least 50%, five volunteers reported decreased pain but with the reduction not exceeding 50%, and only one volunteer reported feeling, numerically, the same initial and final degree of pain.

The initial value of the sum of the responses in the McGill Pain Questionnaire was 19.17, which subsequently decreased to 7.88, with an average pain reduction of 58.89%. The total number of descriptors chosen before the implementation of the acupuncture protocol was 255, and the mean was 7.50. In the assessment following the implementation of the acupuncture protocol, the number of descriptors fell to 153, with a mean of 4.50 (improvement of 40%, p = 0.001).

Both methods used to evaluate pain showed a statistically significant reduction in pain, corroborating the results of other studies regarding the effects of acupuncture.^{2,15–20} For this reason, acupuncture has been proposed for the treatment of several painful conditions.

Reis et al.¹⁸ evaluated the effects of traditional acupuncture on pain levels and on the performance of the autonomic nervous system through the variability of the heart rate (HR) of individuals with hypersensitive myofascial trigger points located in the trapezius and/or rhomboid muscles. A clinical study was carried out with 11 participants of both sexes, with ages ranging from 18 to 50 years. Treatment with acupuncture reduced pain and significantly reduced the HR. The study also showed that all participants displayed a decrease in symptomatology compared to the initial condition after acupuncture, presenting an initial mean score of 7.6 on the VAS and a final mean score of 3.6, a 47.36% improvement. The present study revealed a similar mean improvement (48.03%), with an initial mean of 6.35 and a final mean score of 3.05 on the VAS.

A reduction in pain symptoms as the one reported by the volunteers in the current study enables runners to perform running movements in a proper manner, because it eliminates the compensation behavior that commonly occurs when pain is present. Al Snih et al.,¹⁹ who conducted a study with 544 participants, and Neogi et al.,²⁰ who conducted another study with 2940 participants, both reported that the presence of pain was associated with a reduction in motor function in both men and women. Clinical experience shows that when a particular sport is poorly executed, it generates intense overload. Furthermore, asymmetry can lead to complications and some undesirable postural alterations, as the random repetition of specific movements in practice may lead to the accumulation of unilateral load.²¹

CONCLUSIONS

The acupuncture protocol proposed in this study led to a significant improvement in the treatment of knee pain symptoms of runners. It enabled participating athletes to execute movements characteristic of running in a more appropriate way, by promoting the balance in muscle strength between the limbs and thus preventing sports injuries and changes in sport performance.

The analysis of electromyographic signals is an appropriate methodology for monitoring alterations related to changes in the pre- and post-treatment recruitment of motor units and in the development of muscular strength.

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SPRING PLATES IN DISTAL RADIO FRACTURES: "IN VITRO" MECHANICAL PROPERTIES

PLACA MOLA NAS FRATURAS DISTAIS DO RADIO - PROPRIEDADES MECÂNICAS "IN VITRO"

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ABSTRACT

Background: Distal radius fractures are one of the most common orthopedic injuries and appear in various patterns. Volar plate fixation is not always considered the gold standard treatment. Objective: To measure the resistance of a fragment-specific fixation assembly model obtained by plate fixation associated with different K-wire sizes. Method: In this original experimental study, novel II, axial compression of bone materials was tested. Results: In both groups, the maximum force supported by the fixation method in our study was ten times greater than the physiological load to which the wrist was subjected under physiological conditions. Discussion: In this study, we obtained encouraging results when compared to results reported in the literature. Our study showed that our bone fixating system was mechanically adequate for articular fractures of the intermediate column of the radius (Melone classification). The results were similar or superior to the results of pressure resistance and stiffness when data from the literature was used as reference. Conclusion: The proposed fixation method demonstrated adequate resistance for fixation of the intermediate column of the distal radius. Increasing K wire size caused augmented resistance of the fixation. Level of Evidence II, Prospective comparative study.

RESUMO

Introdução: A fratura da extremidade distal do rádio é uma afecção frequente, com variedade de apresentações e nem sempre são passíveis de fixação volar única. Objetivo: Quantificar a resistência obtida no modelo experimental de fixação do fragmento específico, utilizando fio de Kirschner pré moldado, associado a fixação proximal com placa e parafuso. Métodos: Estudo experimental original, nível II, no qual foram realizados ensaios mecânicos com objetivo de avaliar a resistência a compressão axial. Resultados: Os valores de força máxima suportada pelo método de fixação foram pelo menos 10x maiores do que a carga fisiológica a qual o punho é submetido. Discussão: A fixação do tipo fragmento específico vem se mostrando útil e segura, permitindo uma mobilidade precoce segura. Os resultados analisados demonstraram que a montagem proposta em nosso estudo foi mecanicamente adequada para a fixação das fraturas articulares da borda volar ulnar (classificação de Melone) do rádio, tendo resultados semelhantes ou superiores quando comparados a literatura, avaliando a rigidez e a pressão o qual o sistema foi submetido. Conclusão: O método de fixação proposto demonstrou resistência adequada para fixação das fraturas da coluna intermediária do rádio. O aumento da espessura do fio provocou um aumento da força resistida da montagem. Nível de Evidência II, Estudo prospectivo comparativo.

Keywords: Fractures fixation. Frthopedics. Clinical trial.

Descritores: Fixação de fratura. Ortopedia. Ensaio clínico.

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INTRODUCTION

Distal radius fracture is the most common fracture in patients presenting to emergency units, and its incidence is approximately 640 thousand per year in the USA.¹ The incidence shows a bimodal distribution, affecting predominantly young males and elderly females.² Approximately 57% to 66% of distal radius fractures are extra-articular, followed by complete articular fractures that affect 25% to 35% of patients and partial articular fractures that affect 9% to 16% of patients.³

The most frequent mechanism of injuries reported are falls from the individual's height onto an outstretched hand or high-energy trauma.³ Fernandez and Jupiter² described a classification for distal radius fractures according to the mechanism of injury, subdivided into five types of injury. The AO classification considers the direction of the fracture line and the number of fragments. It is a complex and detailed classification but does not correlate with treatment options. Robert Medoff has developed a classification for intra-articular fractures based on recognition of five main fragments: the radial styloid, dorsal

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wall, impacted articular fragments, dorsal-ulnar corner (die-punch fragment), and volar rim fragments.² These fragments may occur in isolation or in combination. For a better understanding of the fracture and surgical planning, the orthopedist must also identify the direction of deviation and the mechanism of injury. This classification is used to guide treatment in that it facilitates the choice of modular components for treating the specific fragments.²

Numerous options have been described for the treatment of distal radius fractures, including conservative treatment and external and internal fixations. The choice of treatment depends on the clinical profile of the patients, their demand, and the type of fracture.³ Anatomic reduction, stable fixation, and early mobilization are the primary objectives of treatment of long-standing, complex intra-articular distal radius fractures^{4,5}. The main method of internal fixation used is the locked volar plate. This method is able to satisfactorily fix articular distal radius fracture to a large degree, providing stability and facilitating early mobility. However, the surgical approach is usually not specific and complications such as irritation and tendon rupture, implant release, and secondary loss of reduction may occur.⁶⁻⁹ In addition to the complications above, locked materials are costly and largely unavailable in orthopedic services in our country. The advent of computed tomography with 3D reconstruction has provided a better understanding of intra-articular distal radius fractures. This feature has allowed more efficient preoperative planning by the surgeons and more accurately define the best approach for each fracture.¹⁰ According to Wolfe¹¹ there are four situations in which the isolated use of the volar plate will lead to failure: (1) complex multifragmentary disruption of the articular surface caused by shear or compressive forces; (2) fracture-dislocations (shear fractures) of the wrist; (3) carpal, radiocarpal or radioulnar instability; and (4) complex fractures with substantial metaphyseal-diaphyseal extension. In these cases, a more thorough and individualized approach is necessary to achieve better results.

Medoff and Kopylov endorsed the concept of fragment-specific fixation in distal radius fractures by individually stabilizing each fragment using a hybrid technique with plates and Kirschner (K)-wires.¹² The concept of fragment-specific fixation evolved with the perception that a single implant was not sufficient to properly fix all fracture configurations.¹³ Mechanical tests demonstrated that rigid fixation of each fragment was necessary to achieve adequate stability to permit early mobilization.^{14,15} Each fragment was fixed individually with low profile implants or clips, which lessened contact with adjacent tendons and thus avoided complications described in other models; it also allowed a personalized approach for each fracture, permitted the use of mini-incisions, avoided unnecessary exposures, reduced surgical aggression, and ensured stability of each fragment, ultimately allowing early mobilization.^{5, 16-20}

Therefore, the objective of the present study was to evaluate the rigidity of assemblies obtained using 1.0-mm and 1.2-mm K-wires, fixed with 3.5 mm screws and 3-hole 1/3 plates, following the principles of specific fragment characteristics. A viable assembly is proposed using low cost materials widely available in orthopedics and traumatology services.

MATERIAL AND METHODS

As this was a purely biomechanical study, not involving living specimens, the study did not require ethics committee approval.

Specimens

Anatomic synthetic bones such as right radius (model 3011) produced by the National Bone Industry were used as test samples. The radius bones were cut transversely 12 cm from the distal articular surface inserted in an acrylic block (colorless self-polymerizing acrylic – JET) suitable for the test machine. A demarcation was created to simulate the volar rim fragment, as described by Melone². The fragment originating from the osteotomy had an area of approximately 1.5 cm². Two holes were made 7 mm from each center, with an orientation perpendicular to the proposed fracture line. Samples were divided into 2 groups: in Group 1 (1.0-mm assembly) the radius bones were drilled with a 1.2 mm drill bit. In Group 2 (1.2-mm assembly) the radius bones were drilled with a 1.5 mm drill bit. After the perforation, osteotomies were performed according to previously established protocol.

All cuts, osteotomies, and perforations were performed at the Precision Laboratory of the USP - Ribeirão Preto Campus.

Implants

The implants were prepared from pre-molding of 1.0-mm and 1.2-mm K-wires according to the conformations shown in Figure 1. The fractures were fixed using molded K-wires inserted into pre-established holes and fixed proximally with plate and screws, the final configuration thus forming a three-point fixation (Figures 2 and 3).

Experimental Groups

Destructive axial compression tests were performed for the two experimental groups comprising four specimens each. Group 1 consisted of assemblies using K-wires having a 1.0-mm diameter and Group 2 consisted assemblies using K-wires of 1.2 mm diameter.

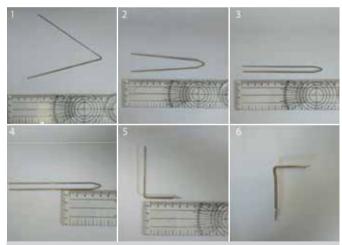


Figure 1. Molding of 1.0-mm and 1.2-mm Kirschner (K)-wires.



Figure 2. Examples of Kirschner (K)-wires inserted into pre-established holes.



Figure 3. Examples of final fixation with the 3-point configuration.

Mechanical tests

The tests were carried out using a universal test machine (UTM), EMIC DL10000 (INSTRON EMIC, São José dos Pinhais, PR, 83020, Brazil) available at the Bioengineering Laboratory of the Ribeirão Preto Medical School (USP), connected to a computer equipped with software controlling the applied loads and storage and interpretation of the obtained data. Both the control condition and the measurements of the applied loads and the deformations produced were carried out using the TESC v. 1.10 program.

Destructive tests (maximum load) were performed on the UTM, with axial compression. Initially three pilot runs were carried out for standardization; the results of these runs were not included in the analysis. Eight destructive tests were performed, four for each group. The obtained values were analyzed and submitted to statistical analysis. The maximum force at which the material could be subjected without rupture and the rigidity of the assembly were analyzed.

RESULTS

Statistical analysis was performed separately for the 4 samples from Group 1 (1.2-mm K-wires) and for the 4 samples from Group 2 (1.0-mm K-wires). Group 1 assembly presented a mean maximum force of 660.8 N (\pm 28.23) and mean rigidity of 210 N/mm (\pm 20.98). Group 2 (1-mm) assembly exhibited a mean maximum force of 512.1 N (\pm 59.03) and mean rigidity of 258.0 N/mm (\pm 44.58). Other descriptive variables such as minimum, median, maximum, mean, standard deviation and coefficient of variation of both maximum force and rigidity are reported in Tables 1 and 2 and also in Figures 4 and 5.

Comparison of Group 1 and 2 (1.2-mm \times 1-mm) assemblies Maximum Force

To compare force and rigidity variables between the groups, the student t-test was used. A statistically significant difference was observed in the maximum force variable, between the 1.2-mm and 1-mm groups (p = 0.003) (Figure 6).

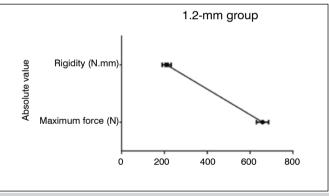
Increasing the diameter of the K-wires used in the assembly resulted in a higher load carrying capacity. The 1.2-mm group was able to withstand loads 29% higher than the 1.0-mm group, on average. The values of the maximum force supported by the assemblies in our tests in both groups were higher than the physiological load to which the wrist is subjected by muscle tension, which is 50 N.^{21,22} The assembly in which the 1.2-mm K-wires were used was able to withstand up to an average 12-fold higher load than

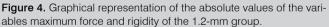
Table 1. Group 1.2-mm Assembly. D	escriptive variables of the test
samples.	

	Maximum force (N)	Rigidity (N.mm)
Number of samples	4	4
Minimum	621.9	179.8
Median	660.8	218.8
Maximum	690.2	224.1
Mean	658.4	210.4
Standard Deviation	28.23	20.98
Coefficient of variation	4.29%	9.97%

Table 2. Group 1-mm Assembly. Descriptive variables of the test samples.

	Maximum force (N)	Rigidity (N.mm)
Number of samples	4	4
Minimum	423.4	210.2
Median	512.1	258.0
Maximum	564.9	304.6
Mean	503.1	257.7
Standard Deviation	59.03	44.58
Coefficient of variation	11.73%	17.30%





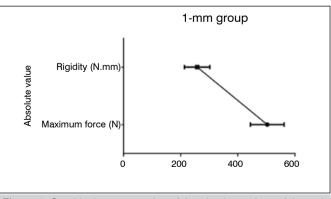


Figure 5. Graphical representation of the absolute values of the variables maximum force and rigidity of the 1-mm group.

that exposed to physiologically. The Group using the 1.0-mm K-wires supported on average about a 10-fold higher load than under physiological conditions.

Similar differences between the groups were not observed on evaluation of the rigidity variable, p = 0.103 (Figure 7). Increasing the thickness of the K-wire did not result in a significant increase in the assembly's rigidity.

DISCUSSION

The clinical usefulness and versatility of fragment-specific fixations lies in the ability to anatomically adjust the rigidity of the fractures that cannot be properly fixed using a single implant or with external fixation.^{5,23,24}

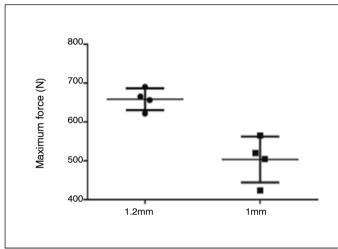
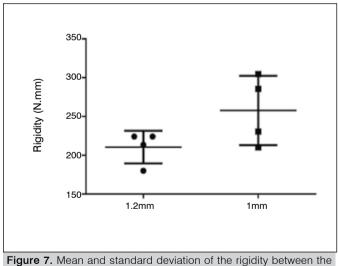
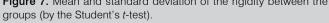


Figure 6. Mean and standard deviation of the comparison of the maximum force between the groups, after the application of the Student's *t*-test .





Positive results have been obtained in several studies, with good and excellent results in 85% of treated C2 and C3 fractures (AO classification).²⁵ Benson et al.²⁶ showed that the technique of fragment-specific fixation guaranteed sufficient stability to allow use of the hand after the third postoperative day without increasing the risk of soft tissue injury or secondary loss of reduction. When compared to the volar plate, the fragment-specific fixation technique provided a significant increase in early mobility, early return to work and activities of daily living, significantly reducing the risk of early joint rigidity, but the results of these two techniques (volar plate and fragment-specific fixation) occurred tardively, and were similar in the above-mentioned conditions.²¹

The versatility of the association of the K-wires with the plates and screws is based on their modest profile and their widespread availability, which makes them good candidates for fragment-specific fixation. In our study, we developed an assembly to fix fragments of the intermediate column and tested its safety as a fixation method through destructive biomechanical tests.

Our results were encouraging, both with in terms of the comparison of compressive forces exerted on a normal resting wrist caused by muscle tension,^{21,22} and in terms results from other mechanical studies.

Hara et al.²⁷ quantified the distribution of forces through the wrist in a mechanical test detailing the peak pressure in each region under a load of 10 kg. The value was higher in the scaphoid fossa, 2.4 MPa, followed by the lunate fossa with 1.5 MPa, and smaller in the triangular fibrocartilage, which supported 1.1 MPa. Considering the maximum force obtained in our tests and converting this to Pascal units, the maximum pressure supported by our assembly was 4.40 MPa in the 1.2-mm wire Group and 3.41 MPa in the 1.0-mm wire Group. These values indicate that our assemblies were capable of supporting loads up to 3-fold higher than those demonstrated in the study by Hara et al.²⁷

Our fixation method was able to withstand a pressure 10-fold higher than that supported by the percutaneous fixation with K-wire described by Naidu.¹⁵ We believe this was due to the configuration of our fixation assembly, composed of K-wires associated with plates and screws, which increased the rigidity of the assembly.

The present study demonstrated that the proposed assembly was mechanically adequate for fixation of articular fractures in the intermediate column of the radius and exerts sufficient resistance to counteract the physiological forces of the wrist at rest and even support small loads (up to 10 kg).

When compared to results of other studies in the literature, our results were satisfactory, and we encourage the use of such fixation method in clinical practice.

CONCLUSIONS

The proposed assemblies show adequate resistance for fixing fractures of the intermediate column of the radius and supported loads of up to 10 kg. Increasing the thickness of the K-wire of the assembly produced an increased resistance of the maximum force.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the preparation of the manuscript. ALCLAL (0000-0001-9676-8003)*, AMP (0000-0003-1971-9923)* and LT (0000-0003-1735-377X)* were the main contributors to the writing of the manuscript. ALCLAL, AECI (0000-0002-0756-6432)* and ACS (0000-0002-3119-2362)* conducted the biomechanical tests and gathered clinical data. AFC (0000-0002-8760-6235)*, AECI and AMP did the bibliographic research. NM (0000-0002-1239-7602)* and CHB (0000-0003-3858-602X)* reviewed the manuscript and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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