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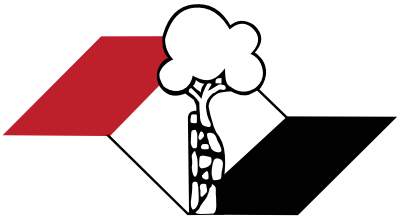

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(Reviewed January 2016)

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ACKNOWLEDGEMENTS
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Levels of Evidence for Primary Research Question[a]

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

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

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

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

[c] Studies provided consistent results.

[d] Study was started before the first patient enrolled.

[e] Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.

[f] The study was started after the first patient enrolled.

[g] Patients identified for the study based on their outcome, called "cases" eg, failed total arthroplasty, are compared with patients who did not have outcome, called ''controls'' eg, successful total hip arthroplasty.

[h] Patients treated one way with no comparison group of patients treated in another way.

SUMMARY

VOLUME 27–Nº 1–2019

Original Articles

FOOT

KNEE

OSTEOMETABOLIC

SPINE

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ARE SCORING SYSTEMS USEFUL FOR PREDICTING RESULTS OF TREATMENT FOR CLUBFOOT USING THE PONSETI METHOD?

OS SISTEMAS DE PONTUAÇÃO SÃO ÚTEIS PARA PREVER OS RESULTADOS DO TRATAMENTO DE PÉ TORTO EQUINOVARO PELO MÉTODO DE PONSETI?

Jiři Jochymek[1], Tereza Peterková[1]

1. Masaryk University, Medical Faculty, Faculty Hospital, Children´s Medical Centre (CMC), Department of Pediatric Surgery, Orthopedics and Traumatology (DPSOT), Brno, Czech Republic.

ABSTRACT

Objective: The aim of this study was to verify whether the Pirani and Dimeglio clinical scoring systems could predict results of Ponseti therapy. Methods: Forty-seven patients with clubfoot deformities treated with the Ponseti method were enrolled in the study. Clinical evaluation with the Pirani and Dimeglio scoring systems was performed before the treatment and after the second cast fixation. The number of fixations, necessity for achillotomy, and recurrence of the deformity were determined as parameters of the therapy results. The patients were divided into three groups according to the severity of their deformities, and the groups were compared with one another. Results: Clubfoot correction required an average of 6.8 casts. Five patients developed a recurrence. Comparing the therapy outcomes among the groups, we found statistically significant differences in the Pirani classification after the second fixation (the number of casts [p = .003] and necessity to perform an achillotomy [p = .014]) and in the Dimeglio scores before therapy (number of casts [p = .034]) and after the second fixation (number of relapses [p = .032]). Conclusion: Although clinical scoring systems showed some dependence on the parameters of treatment outcomes, their predictive function can be used in only a limited way. ***Level of evidence II, Prospective comparative study.***

Keywords: Club foot. Foot deformities, congenital, Foot.

RESUMO

Objetivo: O objetivo deste estudo foi verificar se os sistemas de pontuação clínica de Pirani e Dimeglio poderiam servir para prever os resultados do tratamento com o método de Ponseti. Métodos: Quarenta e sete pacientes com diagnóstico de pé torto equinovaro tratados pelo método de Ponseti foram incluídos no estudo. A avaliação clínica com os sistemas de pontuação de Pirani e Dimeglio foi realizada antes do tratamento e depois da segunda fixação de gesso. O número de fixações com gesso, a necessidade de realização de aquilotomia e a recorrência da deformidade foram determinadas como parâmetros dos resultados do tratamento. Os pacientes foram divididos em três grupos, de acordo com a gravidade das deformidades, e esses grupos foram comparados entre si. Resultados: A correção do pé torto exigiu uma média de 6,8 gessos e cinco pacientes apresentaram recidiva. Ao comparar os resultados do tratamento entre os grupos, verificou-se diferença estatisticamente significante na classificação de Pirani após a segunda fixação (número de gessos [p = 0,003], necessidade de realizar aquilotomia [p = 0,014]) e pontuação de Dimeglio antes do tratamento (número de gessos [p = 0,034]) e depois da segunda fixação (número de recidivas [p = 0,032]). Conclusão: Embora os sistemas de pontuação clínica tenham mostrado alguma dependência dos parâmetros dos resultados do tratamento, sua função preditiva pode ser usada de maneira limitada. ***Nível de evidência II, Estudo comparativo prospectivo.***

Descritores: *Pé torto equinovaro. Deformidades congênitas do pé. Pé.*

Citation: Jochymek J, Peterková T. Are scoring systems useful for predicting results of treatment for clubfoot using the ponseti method? Acta Ortop Bras. [online]. 2019;27(1):8-11. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Pes equinovarus congenitus (clubfoot) is the most common structural deformity of the foot with an incidence of 1– 2/1000 births.[1-3] Nowadays, the Ponseti method represents the gold standard treatment option for clubfoot deformity. It showed to be more effective and save method with less complications compared to the primarily surgical treatment.[4,5] The deformity is reduced by weekly manipulation and application of plaster casts gradually correcting all components of the deformity.

According to various authors, about 7%–10% are treatment-resistant feet and they recorded up to about 14% of recurrences.[6-8] Currently, it is difficult to determine the parameters that would reliably predict these cases at the beginning of treatment.

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

Study was conducted at the Medical Faculty, Faculty Hospital, Masaryk University, Brno, Czech Republic.
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The most commonly used method to evaluate clubfoot is by using clinical classification systems. The most preferred are Pirani[9] and Dimeglio scores[10]. Despite their sophistication, ratings are subject to the subjective view of the investigator in every scoring system.[6,11] Their limitations do not quite define the aspects of the whole deformity of the leg, which can be crucially involved in the rate of success of deformity therapy (for example ultrasound parameters)[12-14] which the scoring systems themselves do not have to take fully into account. Thus, a clear relationship between clinical classification and prognosis of treatment is still not clear. However, by using these scoring systems, it is possible at least partially to approximate an estimate of the further development of the deformity treated by the Ponseti method.

The aim of this prospective study was to determine the possible relationship between the Pirani and Dimeglio evaluation score systems at the start and during a treatment of clubfoot and the course and outcome of treatment on relatively large group of patients treated in our institution. The criteria for the success of the course and the treatment outcome were the number of necessary cast fixations for correction, the number of necessary percutaneous tenotomies of the Achilles tendon and the number of recurrences of clubfoot deformity.

MATERIAL AND METHODS

The set of patients

The analyzed group consisted of 47 patients, all treated by the first author of the study (JJ) between May 2013 and July 2016.

The group patients consisted of 30 boys (63.8%), 17 girls (36.2%), in 29 cases with right-side deformity (61.7%); in the remaining 18 (38.3%) cases, the left foot was involved. The mean age at the beginning of therapy was 20 days.

Inclusion criteria for inclusion to our study consisted of only patients with idiopathic and unilateral forms of deformity, who did not undergo previous or later treatment elsewhere and did not undergo any surgery on the affected limb prior to our initiation of Ponseti therapy. This work was approved by the Ethics Committee (03-12/ECUHB/2013) of our Hospital and with Informed Consent of parents of patients.

Clinical scoring systems

For incoming clinical evaluation and evaluation of the course of treatment, the controls were actually assessed by two clinical evaluation systems. One was a system developed by Professor Pirani (2002).[9] The Pirani classification uses for the deformity component of the clubfoot 0, ½, and 1 point to evaluate the degree and severity of the deformity. In particular, the hind and medial part of the foot are evaluated separately. In each of these parts, we evaluated three parameters: the hind foot contracture score (HCFS), dorsal crease, empty heel, and rigid equinus; and the mid-foot contracture score (MFCS), medial creasy, lateral edge convexity, and talus head position. The maximum number of points corresponding to the deformity is six.

The European Paediatric Orthopaedic Society (EPOS) prefers and recommends a scoring system used by French authors from Montpellier, led by Professor Alain Dimeglio (1995),[10] which uses for classification the degree of rigidity of the foot: I. st. soft-soft; II. st. soft-stiff; III. st. stiff-soft; and IV. st. stiff-stiff deformity. Dimeglio´s classification has 20 points and distinguishes four basic parameters (equinosity in the sagittal plane, varus deviation in the frontal plane, deformation of the block calcaneus and forefoot, and adduction of the forefoot in the horizontal plane), evaluated on a scale from 0 to 4 points, and another four adverse symptoms (dorsal crease, medial crease, cavus deformity, and calf hypotrophy), rated 1 point each.

The patients were carefully examined clinically in our department, and the severity of the deformity was scored according to the above-mentioned systems at the beginning of the therapy, prior to application the first cast, and subsequently repeated during the treatment. For statistical evaluation, the relationship between the severity of deformity according to both classification systems and the success-of-treatment criteria were used as the pre-treatment score and the score after a second cast fixation, respectively.

The number of required fixations was determined individually according to the condition of the foot, and the criteria for subsequent percutaneous achillotomy were also strictly defined. This was indicated when the dorsiflexion of the foot was impossible at least 10° after complete redress casting. We have consistently provided a classically adequate postoperative Ponseti regimen, with monitoring and other therapy (Figure 1).

Statistical analysis

Statistical analysis of our data was divided into two levels. Descriptive data for the continuous variables are presented as an average and a standard deviation; percentage distribution (%) was used for the category variables.

In the first phase, the statistical analysis was used to evaluate the dependencies between the classification systems and the parameters determining the effect of therapy by the Ponseti method. Depending on the nature of the variables, the Pearson, Spearman, or dot biserial correlation coefficient was used.

In the second phase, patients were divided into three groups according to the severity of the deformity. Patients were divided by using the Pirani scoring system into group 1 with 3–4 points, group 2 with 4.5–5 points, and group 3 with 5.5–6 points. When using the Dimeglio classification, group 1 had 6–10 points, group 2 had 11–15 points, and group 3 had 16–20 points. The results of treatment were subsequently compared between groups by using the Kruskal-Wallis test for continuous variables (number of cast fixations) or Chi-quadrate test for binary variables (achillotomy, recurrence).

IBM SPSS Statistics 20.0 software was used for statistical analysis, and all tests were performed at a statistical significance level of 0.05.

RESULTS

Of the 47 patients with unilateral equinovarus deformity, 36 of them (76.5%) underwent an achillotomy. Recurrence of deformity developed in five patients of the set (10.6%) during the follow-up period. To correct the deformity, it was necessary to use an average of 6.8 redress casts (4-10). The average preliminary score of 4.63 points by Pirani (3-6)

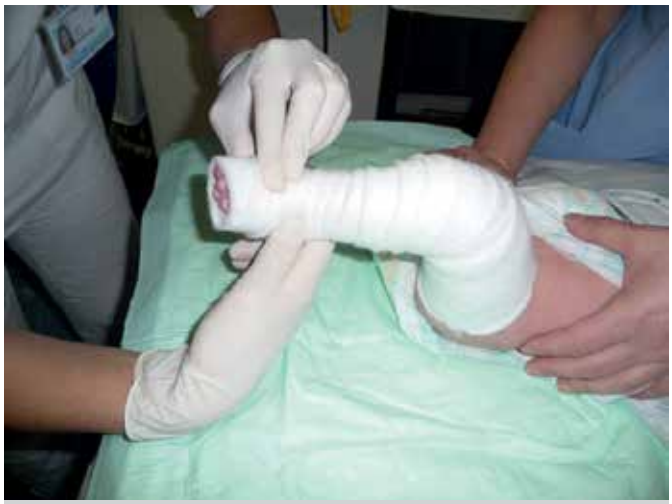

Figure 1. Ponseti casting.

and 15.4 points by Dimeglio (7-20) was assessed. Pirani´s average score after the second fixation was 3.58 points (2-4.5) and Dimeglio's score at this stage of treatment was 11.22 points (6-16). The general characteristics of the population parameters are shown in Table 1.
The relationship between the number of cast fixations and classification systems had a significant correlation in all cases, with the strongest dependence of correlation in the Pirani score after the second correction fixation (r = .572, p <.001).
Positive correlation was also found between the necessity of achillotomy and both classification systems. In this case, the correlation of the clinical score according to Pirani after the second cast fixation (r = .492, p = .003) showed the strongest.
Conversely, no significant correlation was found between recurrence and the classification system that was used, even in one case (p = >.05). The complete results of the relationship are shown in Table 2.
When dividing patients into groups according to the severity of deformity assessed according to classification systems, there was no difference between the groups in the treatment results, according to the Pirani score before treatment. On the other hand, a statistically significant difference was found in the number of cast fixations (p = .003) and the necessity to perform achillotomy (p = .014) between the groups when the scoring was performed after the second casting. A statistically significant difference was found in the Dimeglio scoring prior to therapy between groups in the number of cast fixations (p = .034) and in the same scoring system after the second cast fixation in the number of relapses (p = .032). Table 3.

Table 3. A detailed analysis of the clinical trials of clubfoot between groups of different deformity severities and their analysis within the parameters of treatment success. The groups were divided according to the gravity of the deformity, which was determined by the respective scoring systems: Pirani scoring: Group 1 with 3-4 points, Group 2 with 4.5–5 points, and Group 3 with 5.5–6 points. When using the Dimeglio classification, Group 1 has 6–10 points, Group 2 has 11–15 points, and Group 3 has 16–20 points.

		Number	Cast fixation	Achillotomy	Relapses
Pirani score before therapy	Group 1	17	6.06 ± 1,53	11 (64.7%)	0
	Group 2	17	7.85 ± 2.28	14(82.3%)	3 (17.6%)
	Group 3	13	7.67 ± 1.52	11 (84.6%)	2 (15.3%)
	p - value		**.091**	**.417**	**.347**
Pirani score after second fixation	Group 1	14	5.66 ± 1.61	8 (57.1%)	0
	Group 2	17	6.83 ± 1.82	14 (82.3%)	2 (11.7%)
	Group 3	16	8.80 ± 1,38	14 (87.5%)	3 (18.75%)
	p - value		**.003**	**.014**	**.332**
Dimeglio score before therapy	Group 1	9	5.45 ± 1,83	5 (55.5%)	0
	Group 2	17	6.47 ± 1,52	13 (76.4%)	2 (11.7%)
	Group 3	21	8.02 ± 194	18 (85,7%)	3 (14.2%)
	p - value		**.032**	**.050**	**.709**
Dimeglio score after second fixation	Group 1	18	6.34 ± 1.23	11 (61.1%)	2 (11.1%)
	Group 2	18	7.77 ± 1.75	15 (83.3%)	0 (0%)
	Group 3	11	8.40 ± 1.94	10 (90.9%)	3 (27.2%)
	p - value		**.077**	**.126**	**.037**

DISCUSSION

Although the prediction of the course and outcome of clubfoot treated by Ponseti method would be very useful and desirable, there is lack of evidence of reliable systems which could predict conditions such as the recurrence of the deformity, number of casts required or the need of percutaneous tenotomy of Achilles tendon. These conditions, already used by different authors, could be considered as the parameters of successfulness of the therapy.[12]
Although sophisticated scoring systems are widely used, especially Dimeglio[10] and Pirani,[9] it is a rating laden with a certain degree of subjectivity.[6,11] Differences in the clinical evaluation of one deformity by different investigators are described in the literature.[11] In addition, from the already published work, a clear, reliable, statistical correlation between the clinical examination and the outcome of treatment[12,13] has not been found.
Various parameters that could have an influence on the outcome of therapy for clubfoot deformity have been investigated in the literature, but there is no clear consensus among the authors.
Agarwal et al.,[15] in a retrospective analysis, examined the dependence among the number of fixations, the age of the patients, and the Pirani score evaluated before the onset of Ponseti therapy itself. They found that the number of cast fixations is variable, but significantly influenced by age and by the initial Pirani score. In our group of patients, we started, practically always, before reaching the second month of age, averaging in 20 days. From this reason, the analysis of age and its predictive effect on the outcome of treatment was not justified. Furthermore, the positive correlation of the initial Pirani score and the number of casts was observed in our analysis as well. Nevertheless, this trend is anticipated as the severe clubfoot deformity normally requires more casts compared to the mild or moderate deformities. Thus, we believe, that the correlation on its own, as the only statistical test, cannot lead to the certain statement about the prognosis of the therapy.
Dyer et al.[11] advocated Pirani scoring system as a quick, useful, and practical to use. They found significant correlation with the sense of necessity of Achilles tenotomy. Similarly, Scher et al.[16] found that higher scores by Pirani and Dimeglio indicated a high probability of the necessity to perform achillotomy. In our study, we can agree with this assertion in the first part of the statistical analysis, when

Table 1. General characteristics of population.

	Average
Age at the beginning of therapy (days)	20 ± 7.4 (7 – 42)
Pirani score before therapy	4.63 ± 0.8 (3 – 6)
Pirani score after second fixation	3.58 ± 0.7 (2 – 5)
Dimeglio score before therapy	15.4 ± 3.8 (7 - 20)
Dimeglio score after second fixation	11.22 ± 3.4 (6 – 16)
Number of cast fixations	6.8 ± 2.0 (4 – 10)
Follow-up (month)	13.3 ± 5.8 (8 – 34)
Sex (M/F)	30 (63.8%) / 17 (36.2%)
Side of deformity (R/L)	29 (61.7%) / 18 (38.3%)
Achillotomy (yes/no)	36 (76.6%) / 11 (33.4%)
Relapse (yes/no)	5/42

Table 2. Correlation of the clinical evaluation of equinovarus deformity before therapy and after a second cast fixation with parameters of the treatment outcomes.

	Number of casts		Relapses		Achillotomy	
	Correlation coef.	Significant correlation	Correlation coef.	Significant correlation	Correlation coef.	Significant correlation
Pirani score before therapy	.385	.014	.212	.125	.452	.005
Pirani score after second fixation	.584	.000	.231	.110	.488	.003
Dimeglio score before therapy	.451	.005	.277	.073	.336	.034
Dimeglio score after second fixation	.497	.002	.277	.070	.337	.035

both systems showed a positive degree of statistical significance in correlation with the necessity to perform achillotomy. However, in the second part of our analysis of this statement, we can agree only on the assumption that it is evaluation during the treatment up to the second cast fixation according to the Pirani test.

Gao et al.[17] found, that the Dimeglio and Pirani clinical scorings had a limited prognostic value, at least in the early stages of therapy. Our study results also support this statement, when the greatest significant differences between groups with different degrees of deformity were observed during the Pirani scoring after the second casting.

Goriainov et al.[18] focused their study on the occurrence of relapses after Ponseti therapy, and found a significant dependence between the Pirani score (total Pirani score and mid-foot score) evaluated before the therapy and the number of relapses. A similar trend in evaluation of relapses can be approximated in our analysis when we look at Dimeglio scoring after the second fixation between each group in the second part of the statistical analysis, when a statistically significant difference was found. However, the limitation factor is the small number of patients and recurrences in our analyzed group.

During statistical data processing, a certain degree of correlation between the clinical assessment of the deformity of the foot and some aspects of the treatment results was observed. The relationship was found in both the evaluation of the number of fixations necessary to correct deformity and the necessity of percutaneous achillotomy. On the other hand, we found no correlation between the important factor of the evaluation of the treatment outcome and the occurrence of relapse. The second part of our statistics was made to complement and extend the first part of the general correlations. In the second part, when evaluating groups with varying degrees of deformity, we found that it was best to provide a scoring according to Pirani after the second fixation. We found a significant difference in the number of casts and the necessity of achillotomy. Similarly, a statistically significant difference was found between these groups in the number of fixations by using Dimeglio scoring before treatment and in occurrence of relapses by using Dimeglio scoring prior to initiation of therapy.

The authors of the generally used classification systems emphasize the need not only to examine and score the deformity of the foot during treatment, but always before the next fixation.[6,11] This requirement is fully supported by some results of our prospective study. In the clinical evaluation of the foot by the Pirani score after the second casting was recorded, a statistically significant difference was found among the groups with different severities of deformity (in detailed analysis in the second part of the statistical analysis) in terms of the number of cast fixations required to correct the foot and the necessity for achillotomy. We did not reach the same or similar conclusion when we used Dimeglio´s scoring system. On the other hand, it only confirmed our personal affinity for the Pirani system of assessment, which we considered simpler and more accurate and reproducible. From the results of a detailed statistical analysis, the results showed that the prediction based on the established parameters of the treatment results can only be applied in a limited way.

The advantage of the study is certainly a relatively large number of patients. On the other hand, the analysis was performed by one pediatric orthopedic surgeon and no interobserver variability was calculated. Furthermore, the evaluation of severity of the deformity was made at the beginning of the therapy and after the second fixation can be a question for discussion. We want to consider this point in our next work, with the aim to determine when clinical scoring will show significant dependence on all parameters when evaluating treatment outcomes.

CONCLUSION

Clinical evaluation before Ponseti´s concept of casting shows some significant correlation with predictive factors in treatment outcome. A detailed analysis has shown that clinical scoring can be used in a very limited way to predict the outcome of the treatment. Better results in the prediction of the course and outcome of treatment were achieved in the evaluation and clinical scoring after the second cast fixation, but not in all the evaluated parameters. Thus, in the complexities of clubfoot deformity of the foot, Dimeglio and Pirani clinical scoring by itself before and during the treatment appears to be insufficient to predict the course and results of treatment by Ponseti concept.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. JJ (0000-0003-2504-087X)*: CPV - performed the surgeries and data analysis, and wrote the manuscript. TP: (0000-0001-5684-1886)*: MASP - drafted and reviewed the manuscript and contributed to the intellectual conceptualization of the study. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

MAGNETIC RESONANCE IMAGING PERFUSION TECHNIQUE IN THE EVALUATION OF ACHILLES TENDON INJURY IN RABBITS

TÉCNICA DE PERFUSÃO À RM NA AVALIAÇÃO DA LESÃO DO TENDÃO DE AQUILES EM COELHOS

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ABSTRACT

Objective: This study aimed to evaluate the dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) in the experimental model of Achilles tendon injury. Methods: Twelve white male adults New Zealand rabbits were divided into two groups, a group with resection of the central portion of the Achilles tendon (n = 8) and a control group (n = 4). Dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) was performed 4 weeks after the surgical procedure, followed by histological analysis of the tendons. Results: The main finding of this study was the difference ($p < 0.001$) in peak contrast enhancement on DCE-MRI, which demonstrated that the operated group had greater contrast uptake. The operated tendons showed histological disruption of their architecture, and cluttered appearance of tendinous fibers, with vascular and fibroblast proliferations. Conclusion: DCE-MRI is a technique with a potential to demonstrate changes in the vascularity pattern of the Achilles tendon before and after operation. DCE-MRI has a potential to be used in studies of tendinosis diagnosis and surgical follow-up. ***Level of evidence II, Experimental Study.***

Keywords: Magnetic Resonance Imaging. Perfusion. Tendon. Wound Healing.

RESUMO

Objetivos: Avaliar a captação do gadolínio (Gd) à ressonância magnética (DCRM) em modelo experimental de lesão do tendão de Aquiles. Métodos: Foram utilizados 12 coelhos machos, adultos e brancos da raça Nova Zelândia, distribuídos em dois grupos: operados (n = 8), com ressecção da porção central do tendão de Aquiles; e o grupo controle (n=4). Após quatro semanas, realizou-se ressonância magnética com técnica de avaliação dinâmica do meio de contraste, seguido de analise histológica dos tendões. Resultados: Houve diferença (p <0,001) do pico máximo de realce de contraste, na DCRM dinâmica do tendão de Aquiles entre os grupos operado e controle, sendo evidenciada maior captação de contraste no grupo operado. À histologia, os tendões operados apresentaram desorganização de sua arquitetura, fibras tendíneas de aspecto desordenado, com neoformação vascular e proliferação de fibroblastos. Conclusão: A DCRM apresentou potencial de demonstrar alterações do padrão de vascularização do tendão de Aquiles no pré e pós-operatório. A DCRM apresenta potencial para ser usada em estudos para controle de tratamento e diagnóstico da tendinose. ***Nível de evidência II, Estudo Experimental.***

Descritores: *Imagem por Ressonância Magnética. Perfusão. Tendão. Cicatrização.*

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INTRODUCTION

Magnetic resonance imaging (MRI) is one of the diagnostic methods of choice for evaluation of Achilles tendon (AT) injury. MRI has excellent contrast with soft tissues, high spatial resolution and multiplanar imaging, making it superior to other diagnostic imaging methods to study the anatomy and pathological alterations of AT. The signal changes to the standard MRI without the perfusion technique show little information suggesting the need for additional studies.[1,2]
Dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) is a physiological imaging method that evaluates contrast enhancement kinetics. Images obtained by this method are performed at the stage where the contrast agent is in equilibrium between blood vessels and interstitial spaces.[3] This technique provides information on tissue vascularization, perfusion, and capillary permeability. DCE-MRI has been used to evaluate various diseases of the musculoskeletal system, tumors [3] and arthropathies,[4,5] and it is rare to apply it in the tendon study.[6]
In this context, the objective of this study was to evaluate the feasibility of enhancement in DCE-MRI after experimental injury of the Achilles tendon in rabbits.

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

Study was conducted at the Program of Applied Sciences to Surgery and Ophthalmology of the Faculty of Medicine of UFMG.
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MATERIALS AND METHODS

This research was approved by the Animal Experimentation Ethics Committee of the Federal University of Minas Gerais (183/2012), adhering to the guidelines established from animal care. Twelve white male New Zealand rabbits (mean weight 2450 grams) were housed individually in stainless steel cages.

Surgical Procedure

The eight rabbits of the operated group were anesthetized with an intramuscular injection of Xylazine (Calminum, Agener União, Brazil) at the dose of 5-7 mg / kg. After 10-15 min, ketamine (Ketamine Agener 10%, Agener Union, Brazil) at a dose of 12-15 mg / kg was injected intramuscularly. During surgery, supplemental sedation was administered when necessary.

The central portion of the Achilles tendon of the right limb was resected measuring 10 mm in length and 3 mm in width (Figure 1), which corresponds to approximately one-third the width of the tendon. Four sutures with 5-0 nylon strand were used to identify the parched portion. Then, the tendinous sheath was sutured with PDS 6.0 and, the skin with 3-0 nylon. After the procedure the rabbits were kept inside the cage without immobilization.

Magnetic Ressonance

After four weeks of surgery, MRI was performed on rabbits using the HDxt Signa GE 1.5 Tesla device (GE Healthcare, Milwaukee, WI, USA). In right lateral decubitus, the right hind limb of the rabbit was positioned in a 9-channel knee coil (1 emitter and 8 receivers). The protocol consisted of a T2-weighted axial and sagittal sequence with fat suppression [RT (repetition time) / TE (echo time): 5000/75 ms; cutting thickness of 2.5 mm; 320 x 256 matrix; field of view (FOV), 100 mm; number of excitations (Nex), 2], a T1-weighted sequence, axial plane with FS (TR / TE: 700/15 ms, shear thickness, 2 mm, 320 x 256 matrix, FOV, 120 mm, Nex, 2).

The dynamic series used was 3D SPGR in the axial plane, with 1.2 mm cutting depth, TR / TE 4/9 ms, flip angle 8, an acquisition, FOV of 200, 128 of the matrix 128 and TA of acquisition) 20 s. These sequences were composed of 30 cuts, associated with 0.3 mmol/kg body weight gadopentetate dimeglumine (Magnevist, Schering, Berlin Germany 469mg / ml), injected through a 24 gauge catheter, previously inserted into the ear vein . The contrast agent bolus was injected by injection pump at the rate of 1.5 ml / sec with the animal into the apparatus. Contrast infusion was initiated immediately after the first sequence of the dynamic series, responding to the non-contrast phase. At the time of contrast infusion, the five dynamic sequences without intervals were started. In all animals, dynamic enhancement images were subtracted from the first SPGR sequence, pre-contrast.

Figure 1. Surgical procedure of the rabbit Aquilles tendon, showing the central segment of the resected Achilles tendon.

Magnetic resonance imaging

The study was conducted in dedicated General Eletric workstation, ADW 4.6, using specific software for dynamic study Functool.

Contrast enhancement measurements were performed using the region-of-interest (ROI) technique. The 5 mm diameter ROI was placed in the Achilles tendon at the same distance from its insertion in the calcaneus, in the region where greater contrast enhancement was observed in the various phases of the DCE-MRI. This evaluation was aided by the contrast capture color map provided by the workstation, with the intention of demonstrating the presence of the contrast and its dynamics of capture, as well as the correlation between the groups, obtaining contrast pick-up curves. The intensity of the enhancement is measured by magnetic resonance unit values, which are given by the workstation. The ROI was also placed in the tibial artery for simple demonstration of the presence of intravenous contrast. All the measurements of the operated and control groups were performed on the axial images and the time-intensity curve, based on the dynamic studies obtained in ROI. In the non-perfusion phase, the middle third of the Achilles tendon was evaluated for intrasubstantial signal intensity, presence of hyperintense foci, and signal heterogeneity. The evaluation was performed by the same experienced radiologist in the musculoskeletal evaluation, without knowledge of the histopathological result (WCTJ).

Histology

After four weeks of the surgical procedure, the animals were euthanized. The Achilles tendon was completely removed and dissected. Samples were fixed in 10% buffered formalin solution and embedded in paraffin. The cuts were performed transversally to the longitudinal axis of the tendon. From each tendon, six sections of paraffin were made, stained with hematoxylin-eosin (HE) and submitted to microscopic examination. All sections were analyzed by a single experienced pathologist.

Statistical analysis

Analysis of variance (ANOVA) was performed and then Fisher's test was used for post-hoc multiple comparisons, when ANOVA revealed a significant difference. The level of significance was set at $p < 0.05$.

Results

In the nonperfusion phase, in the control group (Figure 2), the Achilles tendon was homogeneous and hypointense, with regular and well defined contours in the T1 and T2 sequences without contrast. In the operated rabbits, all tendons showed changes in signal intensity in the weighted T1 and T2 sequences (Figure 3), represented by intrasubstantial hypersignal of irregular and ill-defined contours.

In the control group, in the perfusion phase (Figure 4), there was no significant contrast uptake in the direct observation of the images. The tendon sheath was thin, with no contrast enhancement. The study of the contrast uptake curve showed a slight tendon uptake. In the operated rabbits (Figure 5), in the perfusional sequence, there was tendon enhancement by the contrast medium, which was easily observed in the dynamic sequences or by the color map. The tendon sheath was thickened, with intense contrast enhancement. The contrast uptake curve showed intense enhancement.

Comparison of the MRI values obtained by means of the contrast uptake curves showed a significant difference between the values in the control and operated groups ($p < 0.0001$).

Figure 6 shows the histological appearance of the Achilles tendon in the control (a) and operated (b) groups. In the operated group, we also observed a reduction in the volume of the tendinous portion, diffuse thickening of the sheath, with reduction of adipose tissue and connective-vascular neoformation.

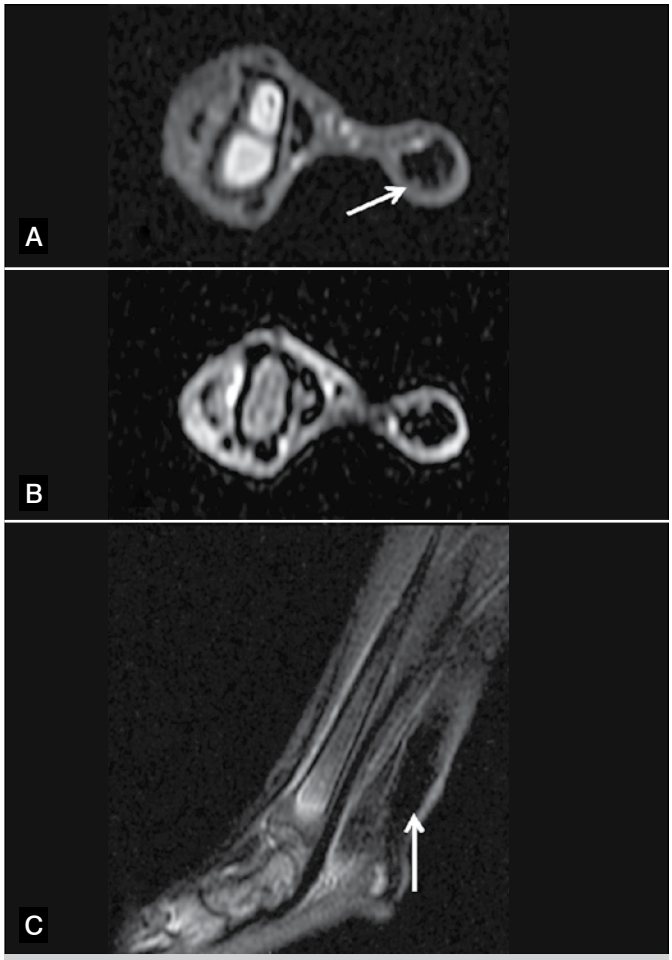

Figure 2. MRI images of Achilles tendon in rabbit of the control group: A) axial cut T1 (white arrow); B) T2 axial cut with fat saturation (corresponding area in a); C) Sagittal cut T2 with fat saturation (white arrow). Observe the homogeneity of the tendon that is diffusely hypointense.

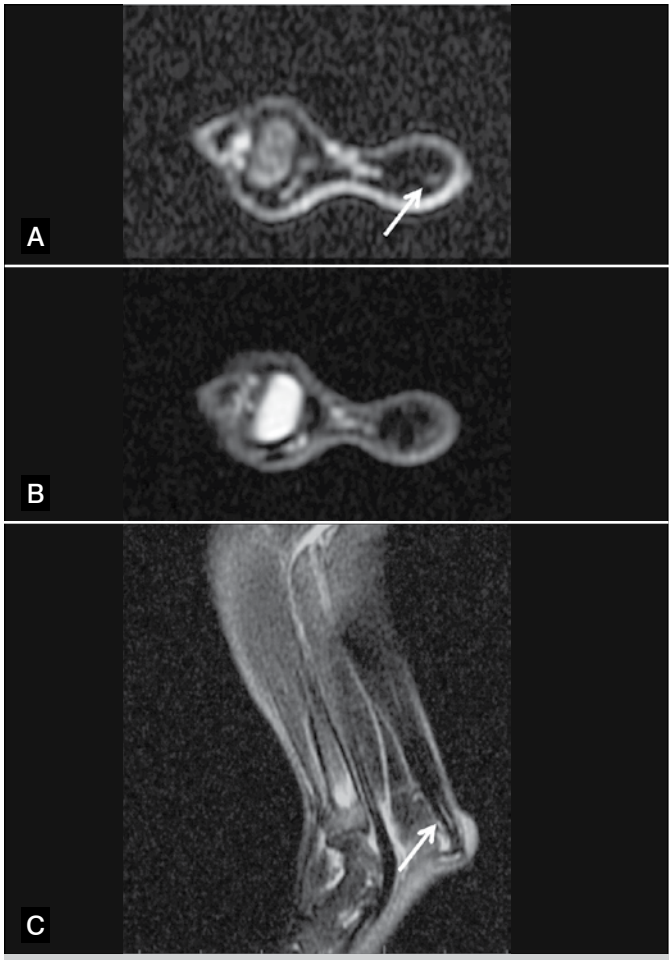

Figure 3. MRI images of the Achilles tendon in rabbit of the operated group: A) axial cut T1; B) T2 axial cut with fat saturation; C) sagittal cut T2. Observe the heterogeneity of the tendon that presents foci of signal hyperintensity in T1 and T2 (arrows).

DISCUSSION

Rabbits have been widely used in research related to the Achilles tendon, however, few studies have evaluated tendon using MRI in rabbits.[7,8] In the present study, healing was evaluated in the remodeling phase, which usually begins between the second and third week of the cicatricial process. In this way, it would be compatible with the minimum time for beginning the follow-up practiced in the clinical studies that use MRI in the control of treatment of tendinous and ligament injuries.[9] MRI of the rabbit Achilles tendon in the axial plane of 2 mm thickness allowed detailed vision that corresponded to the relationships found in sectional anatomy. Sagittal images of 2 mm thickness were less useful, which can be explained by the reduced size of tendons and their rotation in relation to the anteroposterior plane.

In this study, we observed a statistically significant difference between the curves resulting from the control and operated groups. This result is probably due to the fact that the normal tendon of the control group does not present significant contrast enhancement because it presents lower vascularization, including in histological studies, which demonstrate that its vascularization is mainly provided by the tendinous sheath.[10]

The main finding of this study was the difference of the maximum peak of contrast enhancement in the dynamic MRI of the Achilles MRD, between the group that underwent the surgical intervention and the control. The mechanism by which contrast enhancement is observed in

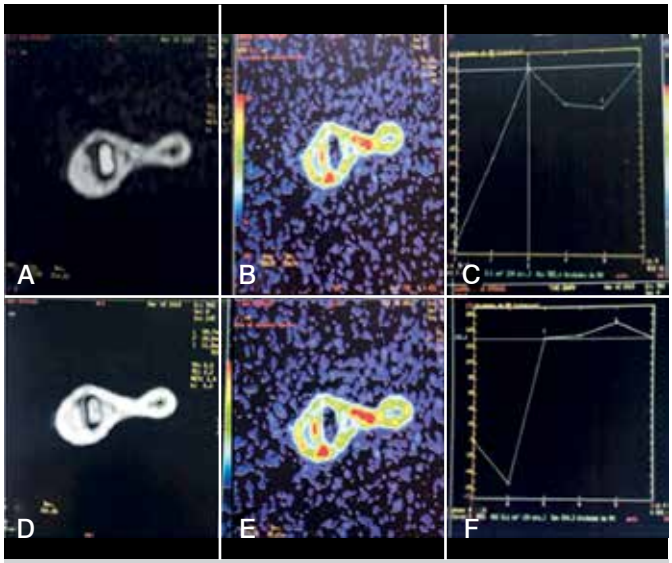

Figure 4. RM in rabbit of the control group: A) ROI within the tibial artery; B) color map showing red areas with maximum contrast gradients; C) curve of contrast uptake in the tibial artery; D) ROI inside the tendon; and. E) color map showing red areas with maximum contrast gradients; F) Contrast capture curve in the tendon.

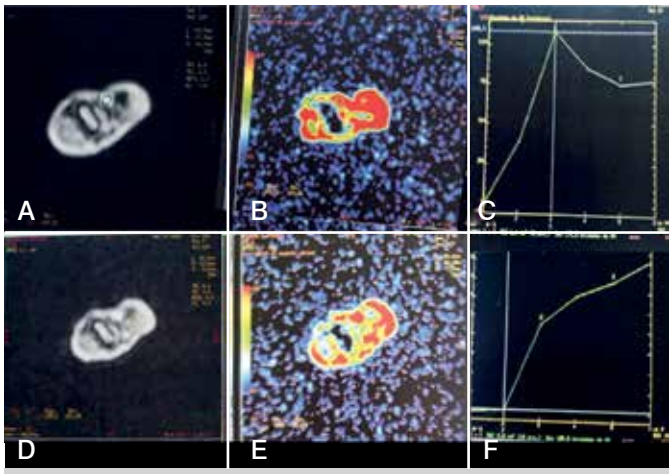

Figure 5. RM in rabbit of the operated group: A) ROI within the tibial artery; B) color map showing red areas with maximum contrast gradients; C) curve of contrast uptake in the tibial artery; D) ROI inside the tendon; and. E) color map showing red areas with maximum contrast gradients; F) Contrast capture curve in the tendon.

tendinopathies and in the postoperative period is not fully understood. It is known that the contrast agent initially distributes into the vascular compartment and then diffuses into the extracellular interstice. Increased vascularization and/or vascular permeability may explain the elevation of enhancement in pathological areas, as has been demonstrated in comparative cases of MR imaging with histological analysis.[11,12]

The increase of the extracellular matrix is a frequent finding in the histological evaluation of Achilles tendinopathies.[13] It is observed a derangement of the collagen fibers, an increase of vascularization and cellularity.[14] These findings are similar to those found in our experimental study, suggesting that it may help and corroborate the application of DCE-MRI in patients. Studies demonstrate the correlation between areas of maximum pain and maximal hypervascularity in tendons, allowing the use of methods that evaluate tissue vascularization.[15,16] DCE-MRI is a technique with the potential to demonstrate alterations in the Achilles tendon healing process, evidencing a greater contrast enhancement. Our results suggest that this technique could be used in clinical studies to control tendon lesions.

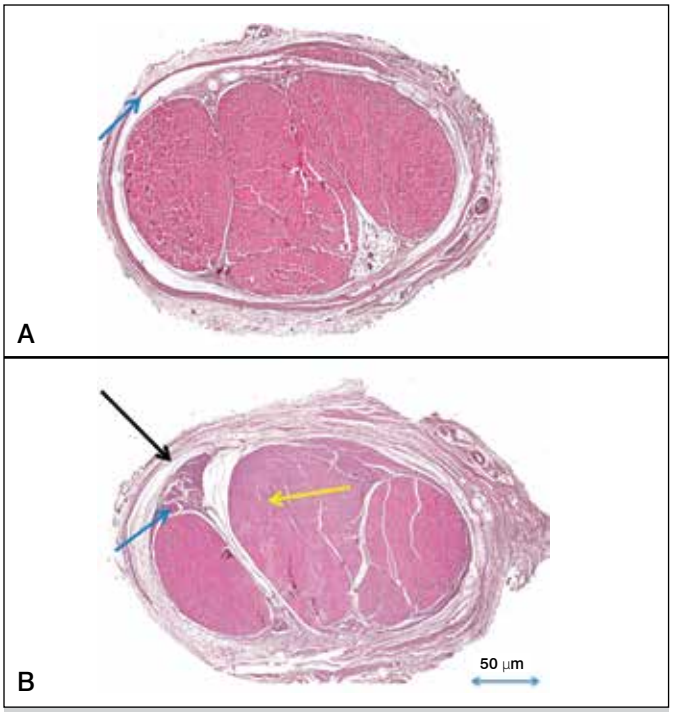

Figure 6. Histological cross section of Achilles tendon in rabbit of the control group (A) and the operated group (B). In (A), preserved architecture is observed, with organized tendon fibers, eosinophilic, sparse vessels and tendinous sheath with thin thickness, homogeneous and organized (arrow); (B), there is a resection area of the tendon with wedge fibrosis (blue arrow) and adjacent tendon with loss of eosinophilia, architectural disorganization (yellow arrow) and thickening of the tendon sheath (black arrow). Haematoxylin-Eosin stain.

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ORIGINAL ARTICLE

PREOPERATIVE ANALYSIS OF RADIOGRAPHIC FINDINGS IN 516 PATIENTS WITH HALLUX VALGUS DEFORMITY

ANÁLISE PRÉ-OPERATÓRIA DE ACHADOS RADIOGRÁFICOS EM 516 PACIENTES COM DEFORMIDADE DE HALLUX VALGUS

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ABSTRACT

Objective: This is a descriptive study to report our method of operative correction for patients with hallux valgus deformities. Methods: From 2006 to 2012, 516 consecutive patients (601 feet) with hallux valgus deformities were treated surgically in our department after conservative treatments were exhausted. The hallux valgus angle, intermetatarsal angle, distal metatarsal articular angle, and degree of osteoarthritis in the first metatarsophalangeal joint were measured on preoperative plain radiographs of the weight-bearing forefoot. Results: Young patients with severe intermetatarsal deviation received a combined proximal and distal osteotomy of the first metatarsal (n = 21). Patients with low intermetatarsal deviation received a distal metatarsal chevron osteotomy (n = 196), whereas patients with severe intermetatarsal deviation and less flexible deformities without osteoarthritis received a basal metatarsal osteotomy with a distal soft tissue procedure (n = 173). Elderly active patients with osteoarthritis in the first metatarsophalangeal joint received an arthrodesis (n = 100) or resection arthroplasty (n = 58). Conclusion: Determining a few simple angles on plain radiographs of the weight-bearing forefoot in combination with the age and level of activity of patients can help simplify the operative correction method by using the schema we developed. ***Level of evidence IV, case series.***

Keywords: *Hallux valgus. Radiography. Reoperation.*

RESUMO

Objetivo: Este é um estudo descritivo para relatar nosso método de correção cirúrgica para pacientes com deformidades de hálux valgo. Métodos: De 2006 a 2012, 516 pacientes consecutivos (601 pés) com deformidade de hálux valgo foram tratados cirurgicamente em nosso departamento, depois que os tratamentos conservadores foram esgotados. O ângulo do hálux valgo, o ângulo intermetatarsal, o ângulo articular metatarsal distal e o grau de osteoartrite da primeira articulação metatarsofalângica foram medidos em radiografias pré-operatórias simples do antepé com apoio de peso. Resultados: Os pacientes jovens com desvio intermetatarsal grave foram submetidos à combinação de osteotomia distal e proximal do primeiro metatarso (n = 21). Os pacientes com desvio intermetatarsal menor foram submetidos a osteotomia de Chevron no metatarso distal (n = 196), enquanto que os pacientes com desvio intermetatarsal grave e deformidades menos flexíveis e sem osteoartrite foram submetidos a osteotomia da base do metatarso com um procedimento distal no tecido mole (n = 173). Nos pacientes idosos ativos com osteoartrite na primeira articulação metatarsofalângica realizou-se artrodese (n = 100) ou artroplastia de ressecção (n = 58). Conclusão: Determinar alguns ângulos com radiografias simples do antepé com apoio de peso em combinação com idade e nível de atividade dos pacientes pode ajudar e simplificar o método de correção cirúrgica, usando o esquema que desenvolvemos. ***Nível de Evidência IV, Série de casos.***

Descritores: *Hallux Valgus. Radiografia. Reoperação.*

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INTRODUCTION

Hallux valgus is the most common forefoot deformity presenting to foot and ankle surgeons, often accompanied by foot pain and severe functional constraint. The global prevalence, as described in the international literature, is 23 % in 18 to 65 year old patients and up to 35 % in elderly over 65 years of age.[1] It has been widely reported, that women are more often affected than men - there are female / male ratios reported up to a level of 15:1.[2] The valgus deformity can be caused by multiple exogenous and endogenous factors such as wearing of tight and high-heeled shoes or genetic predisposition.[3-6] Diagnosis of hallux valgus is achieved by clinical examination. A plain radiograph of the weight bearing foot is required additionally. There still is no consensus about which clinical and

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radiographic findings lead to the indication of which method of operative correction of hallux valgus.[7-10]
We report our experience with special regard to the correlation of radiographic findings and resulting method of operative correction of the valgus deformity by developing a schema that helps to determine the correct indication.

MATERIALS AND METHODS

From 2006 to 2015, five hundred sixteen consecutive patients (601 feet) with a hallux valgus deformity were treated surgically in our university hospital orthopaedic department after exhausted conservative treatment. None of the patients had undergone prior surgery to the forefoot or suffered from concomitant diseases. The same board of surgeons in all presented cases chose indication for the method of operative correction.
Retrospectively, preoperative plain radiographs of the weight bearing foot were analysed. We measured the hallux valgus angle (HVA), the intermetatarsal angle (IMA), and the distal metatarsal articular angle (DMAA). Further we evaluated the radiographic signs of osteoarthritis in the first metatarsophalangeal (MTP) joint using the standard radiographic classification with stages from 0 to 3, stage 0 showing no signs of degeneration, stage 3 being a severe osteoarthritis with a loss of joint space.[11] The radiographs were read by the same board of surgeons indicating surgery. The length of the first and second metatarsal was measured to determine a protrusion of the first metatarsal and to calculate the MT-index, as described by Hardy and Clapham with a positive value meaning a longer first metatarsal (index plus type) and a negative value with a longer second metatarsal (index minus type).[12] The MT-index did not affect the decision on the operative method to correct the hallux valgus deformity, but often lead to additional procedures like distal metatarsal shortening in patients with severe metatarsalgia and an index minus type. However, in special cases with severe metatarsalgia and an index minus type, we performed an arthrodesis of the first metatarsophalangeal joint to functionally lengthen the first ray.
As shown in Figure 1, the methods of operative correction used in our department were either the distal chevron first metatarsal osteotomy, the proximal open-wedge reverse chevron metatarsal osteotomy with medial bone impaction and single screw stabilization combined with a distal soft-tissue procedure to release the lateral MTP-I joint capsule and the adductor hallucis tendon, the combined proximal and distal osteotomy of the first metatarsal, the arthrodesis of the first metatarsophalangeal joint using a dorsal plate and a plantar neutralization screw, the Keller-Brandes resection arthroplasty of the distal part of the first metatarsophalangeal joint with interposition of a capsular flap and temporary wire fixation, or the combined proximal osteotomy of the first metatarsal and Keller-Brandes resection arthroplasty of the distal part of the first metatarsophalangeal joint with interposition of a capsular flap with temporary wire fixation.
All patients undergoing hallux valgus correction surgery were postoperatively treated with full weight bearing in a special forefoot relief shoe for 6 weeks.
In the statistical analysis data are presented with the mean and standard deviation or with frequency in percentage. P-values were assessed using Analysis of Variance (ANOVA) or Pearson's Test. Differences between the groups were assessed by post-hoc Student´s t-Test. The level of significance was set at alpha = 0,05. Bonferroni correction was used in multiple comparisons, with alpha then set at 0,008 (0,05/6).
The research presented in this work conforms to the Helsinki Declaration and to local legislation. It has been approved by the ethical committee.

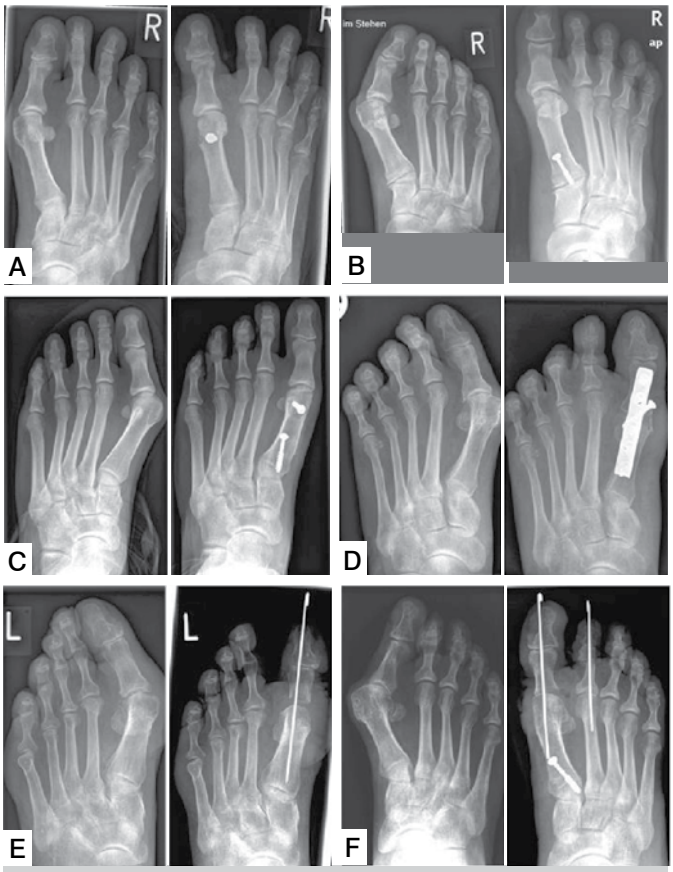

Figure 1. Pre- and postoperative radiographs 6 weeks after hallux valgus correction surgery. a) chevron osteotomy metatarsal-I; b) basal osteotomy of metatarsal-I with distal soft tissue procedure; c) distal and proximal double osteotomy of metatarsal-I; d) arthrodesis of metatarsophalangeal-I joint; e) resection arthroplasty of metatarsophalangeal -I joint; f) combined resection arthroplasty and basal osteotomy of metatarsal-I

RESULTS

The results are illustrated in Table 1. Five hundred sixteen consecutive patients underwent operative correction of their Hallux valgus deformity in our department between 2006 and 2015. 453 of the patients were female (87,8 %) with 531 feet, 63 were male (12,2 %) with 70 feet, which is a significant female / male ratio of approximately 7:1 (p=0,0105, Pearson). The median age of a male patient at the time of surgery was 54,5 years (range 16 to 77 years), while the median age of a female patient was 58 years (range 11 to 90 years). 310 times we performed surgery on the left foot, 291 times on the right foot.
The preoperative mean hallux valgus angle measured in plain radiographs was 34,5 degrees (SD 9,61; range 12-74). Overall the patients had a mean preoperative intermetatarsal angle of 15,5 degrees (SD 3,78; range 3-33). The mean distal metatarsal articular angle measured preoperatively was 17,5 degrees (SD 10,67; range 0-77). The mean radiographic stage of osteoarthritis was 1,3 (SD 0,80). In men, 16 feet showed no sign of degeneration at all, 25 feet were rated a mild stage 1 osteoarthritis with preservation of joint space, another 25 feet were a stage 2 osteoarthritis with joint space narrowing and 4 feet showed a severe radiographic osteoarthritis with loss of joint space. In 453 female patients, 90 feet showed no joint degeneration, 230 feet were rated a stage 1 mild osteoarthritis, 186 feet showed a stage 2 osteoarthritis with joint space narrowing and 25 feet showed a significant osteoarthritis with loss of joint space.

Table 1. Demographics and corresponding radiographic findings by methods of surgical correction.

	DOT (*)	COT (#)	BOT (§)	ART (+)	RAP (&)	BOT+RAP	p-value
N feet (percentage)	21 (4%)	196 (33%)	173 (29%)	100 (17%)	58 (10%)	53 (9%)	
Age [years]	29,90 (14,95)	44,15 (15,25) *	54,17 (10,76) *#	61,77 (10,52) *#§	72,60 (5,7) *#§+	72,91 (5,41) *#§+	<0,001
Sex [female]	20 (95%)	172 (88%)	154 (89%)	80 (80%)	52 (90%)	53 (100%)	<0,0105
OA [degree 0 to 3]	0,57 (0,15)	0,82 (0,05)	1,31 (0,05) *#	1,83 (0,07) *#§	1,62 (0,09) *#§	1,72 (0,10) *#§	<0,0001
HVA [angle]	40,57 (1,78)	27,59 (0,59) *	36,13 (0,26) #	39,77 (0,82) #§	35,21 (1,07) #+	41,45 (1,12) #§&	<0,0001
IMA [angle]	18,03 (0,74)	13,51 (0,24) *	16,78 (0,26) #	16,01 (0,34) #	13,57 (0,44) *§+	18,13 (0,46) #§+&	<0,0001
DMAA [angle]	29,86 (10,57)	15,98 (10,77) *	15,67 (7,08) *	18,23 (12,85) *	16,77 (9,31) *	21,75 (12,67) *#§	<0,0001

Data are presented with number (percentage) or mean (standard deviation). P-values were assessed with Analysis of Variance (ANOVA) or Pearson´s Test. Significance level was set at alpha = 0,008 (after Bonferroni correction by number of groups: 0,05 / 6). Differences between the groups were assessed by post-hoc Student´s t-Test. Significant differences between particular groups are shown by the special characters: *, #, §, + and &. N: number; DOT: Double osteotomy of proximal and distal MT-I; COT: Chevron osteotomy of MT-I; BOT: Basal osteotomy of MT-I with distal soft tissue procedure; ART: Arthrodesis; RAP: Resection arthroplasty (Keller-Brandes); BOT + RAP: Combined BOT and RAP procedure. OA: degree of osteoarthritis; HVA: Hallux valgus angle; IMA: Intermetatarsal angle; DMAA: Distal metatarsal articular angle

The mean preoperative length of the first metatarsal in our patients was 5,7 cm (SD 0,49; range 3,2-7,3), calculating the MT-index resulted in a mean of 0,45 cm (SD 0,31) index plus type. Only 2 male feet showed a negative MT-index value (2,9 %), meaning an index minus type with a longer second metatarsal and only 6 male feet showed an index plus minus type with an equal length of the first and second metatarsal (8,6 %). Only 13 female feet presented a preoperative index minus type with a negative MT-index value (2,4 %), 40 female feet showed an index plus minus type (11,4 %).

A combined proximal and distal osteotomy of the first metatarsal was only performed in young patients with an age of 29,9 years (SD 14,95). These patients had very mild signs of osteoarthritis with 0,6 (SD 0,15). The HVA on the other hand was very high in this group with 40,6 (SD 1,78), as well as high values of the IMA with 18,1 (SD 0,74). The DMAA was by far the highest in this group of patients with 29,9 degrees (SD 10,57).

The distal chevron metatarsal osteotomy was mainly performed in younger patients with a mean age of 44,2 years (SD 15,25). These patients presented only mild radiographic signs of osteoarthritis with 0,8 (SD 0,06). The HVA and the IMA were the lowest in this group with 27,6 degrees (SD 0,59) and 13,5 (SD 0,24), as well as close to the lowest values for the DMAA with 16,0 degrees (SD 10,77).

The proximal open-wedge reverse chevron metatarsal osteotomy with medial bone impaction and single screw stabilization combined with a distal soft-tissue procedure was performed in middle aged patients with moderate signs of osteoarthritis, which was 1,3 (SD 0,05). The HVA was 36,1 degrees (SD 0,62) and the IMA 16,8 degrees (SD 0,26). The DMAA was the lowest in this group of patients with a mean of 15,7 degrees (SD 7,08). The age of the patients at the time of surgery was 54,2 years (SD 10,76).

In patients having received an arthrodesis of the metatarsophalangeal joint, the radiographic signs of osteoarthritis were high with a mean of 1.8 (SD 0,07). The HVA values were high with 39,8 degrees (SD 0,82). The IMA was average with 16,0 degrees (SD 0,34), as well as the DMAA with 18,2 degrees (SD 12,85). At the time of surgery patients in this group were 61,8 years old (SD 10,52).

Keller-Brandes resection arthroplasty of the first metatarsophalangeal joint was only performed in elderly patients. The patients in this group were 72,6 years old (SD 5,70). They showed higher signs of osteoarthritis, which were 1,6 (SD 0,09). The HVA was 35,2 (SD 1,07), whereas the overall IMA and DMAA were close to the lowest in this group with means of 13,7 degrees (SD 0,44) and 16,8 degrees (SD 9,31).

The combined proximal osteotomy of the first metatarsal and Keller-Brandes resection arthroplasty of the first metatarsophalangeal joint was performed only in elderly female patients with a mean age of 72,9 years (SD 5,41). They showed higher signs of osteoarthritis with 1,7 (SD 0,10) and had the highest values for the HVA with 41,5 degrees (SD 1,12) and the IMA with 18,1 degrees (SD 0,46). The DMAA values also were quite high with 21,8 degrees (SD 12,67).

Under consideration of these demographic, radiologic and clinical findings the indication for a particular method of operative correction was set.

The first decision to make was whether to preserve the first metatarsaophalangeal joint in patients with sigs of osteoarthritis. If this is not possible and it had to be sacrificed, it is important to consider the individual patients level of activity. In younger active patients we perform an arthrodesis of the first MTP joint to achieve good function regarding the heel-to-toe movement. In elderly non-active patients we recommend a Keller-Brandes resection arthroplasty of the distal part of the MTP-I joint. Advantages are the faster recovery and fewer possible complications like non-unions. It is important to consider the intermetatarsal angle in these patients as we suggest combining this procedure with a basal osteotomy of the first metatarsal to narrow the fore foot if it shows values of 15 degrees or higher.

If there are no signs of osteoarthritis we preserve the first MTP joint. It then is important to evaluate the congruence of the joint. If the radiograph shows a congruent joint, we suggest performing a distal chevron osteotomy of the first metatarsal and single screw fixation. In patients with a congruent but more deviated joint surface presenting with a distal metatarsal articular angle of higher than 10 degrees, we recommend to excide a medial wedge. In younger patients with severe deviation, this often is not sufficiently leading to a satisfying correction, so we suggest combining it with a second basal osteotomy of the first metatarsal in presence of intermetatarsal angles of 15 degrees or higher to narrow the fore foot.

If on the other hand the radiographs show an incongruence of the first MTP joint, we need to perform a distal soft tissue procedure to release the lateral MTP-I joint capsule and the adductor hallucis tendon and correct the position of the first ray. Yet again we suggest to consider the intermetatarsal angle and to perform a basal osteotomy of the first metatarsal on addition in patients with values of 15 degrees and higher.

These results are summed up in Figure 2, a schema we developed in our department. It represents a simple algorithm to work out the correct method of operative correction using above-named radiographic signs and angles.

DISCUSSION

No other forefoot deformity is as common as the hallux valgus. Our data supports the international literature with a higher incidence in women with a ratio of 7:1 in our collective. There have been described over 150 methods of operative correction. The choice of which operative method to use is made individually in due consideration of the

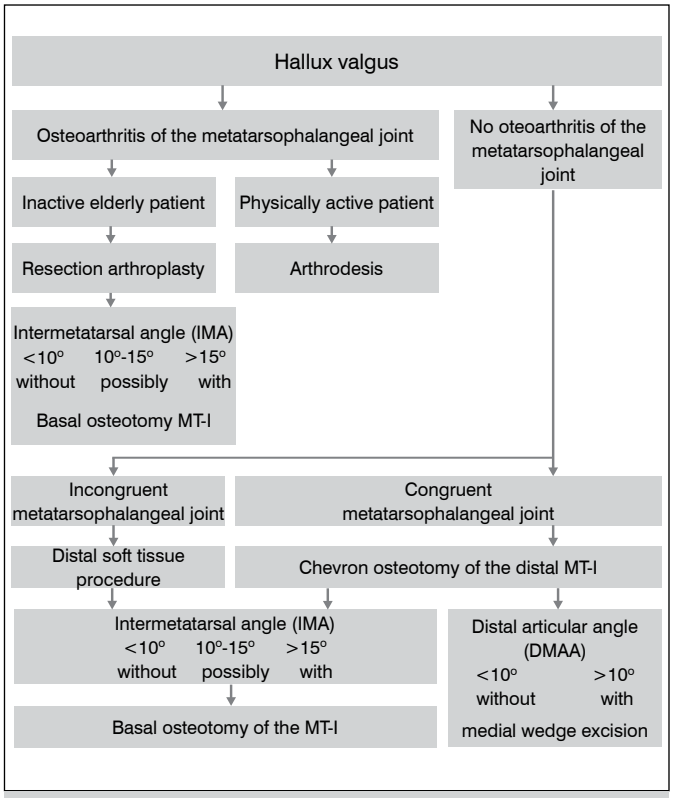

Figure 2. Treatment algorithm for operative correction of the Hallux valgus, modified Wulker schema[13].

particular deformity and the patient's clinical and social presentation. Therefore it is particularly difficult to conduct randomized clinical trials comparing different operative techniques.[7-10] Reviewing the literature, most authors compared operative techniques being very similar to another or comparing specific details of operative methods. Considering the huge variety of operative techniques and the low level of evidence in the existing literature it is challenging to give the precise indication for the individual patient. In general we indicate operative correction in patients with pain within the first ray, metatarsalgia or the development of symptomatic lesser toe deformities caused through hallux deviation. Conservative treatment has to be exhausted. The purpose of surgery mainly in younger patients is to restore the physiological anatomy of the foot. In elderly patients the main purpose is to improve function and minimize pain, often by sacrificing the first metatarsophalangeal joint through resection or arthrodesis.[13]

CONCLUSION

The present study does not value postoperative results of the mentioned methods of operative treatment. This is a descriptive study to report our experience and show the difficulty and our way of indicating the method of operative correction for patients with hallux valgus deformities in its variety. Determining a few simple angles in a plain radiograph of the weight bearing fore foot in synopsis with the age and level of activity of a certain patient can help and simplify indicating the correct method of operative correction using the schema we developed. There is a variety of operative methods to treat the diversity of hallux valgus deformities. Each surgeon needs to command several of these methods to be able to treat each individual patient sufficiently. It is essential to consider every facet of the patient, clinical and radiographic findings as well as the social life and activity.

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DIFFERENCES IN KNEE SENSORIMOTOR CONTROL BY PHYSICAL ACTIVITY LEVEL AND SEX

DIFERENÇAS NO CONTROLE SENSORIMOTOR DO JOELHO POR NÍVEL ATIVIDADE FÍSICA E SEXO

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ABSTRACT

Objective: The aim of this study was to compare the differences in knee sensorimotor control between healthy men and women by measuring the joint position sense (JPS), sensation of muscle tension (steadiness), and onset of muscle activation (OMA). Methods: Twenty-four healthy women and 27 healthy men were tested. Knee sensorimotor control was assessed using the JPS test with electrogoniometers in 3 different ranges of motion, sensation of muscle tension using the isometric steadiness technique, and OMA against a mechanical perturbation. Each assessment was compared by sex, physical activity level, and right or left lower limb. Results: The men obtained better values in the JPS test between 90º and 60º and between 30º and 0º than the women. The subjects with higher levels of physical activity also showed better values, between 90º and 60º and between 30º and 0º. The best results for steadiness were found in the women and the subjects with higher levels of physical activity. In the OMA test, no significant differences were found in the studied variables. Conclusion: The results suggest that higher levels of physical activity may determine better sensorimotor control. Men have better articular sensation, and women have better muscle strength control. ***Level of evidence III, Cross sectional study.***

Keywords: Knee. Physical Activity. Proprioception.

RESUMO

Objetivo: O objetivo desse estudo foi comparar as diferenças no controle sensório-motor de joelho entre mulheres e homens saudáveis medindo o sensação da posição articular (SPA), Coeficiente de variações da força (Steadiness) e inicio ou ativação muscular (IAM) Métodos: Foi avaliado 24 mulheres saudáveis e 27 homens saudáveis, realizando avaliações de SPA, o Sensação de tensão muscular (Steadiness) e o IAM, comparadas segundo sexo, nível de atividade física e extremidades inferiores direita ou esquerda. Resultados: SPA: Os homens obtiveram melhores valores nessa prova entre 90-60° (p=0,0127) e em 30-0° (p=0,0017) ao comparado com as mulheres. as pessoas com maior nível de atividade física também se encontram melhores resultados entre 90-60° (p=0,0328) e 30-0° (p=0,0173). STEADINESS: Os melhores resultados foram para as mulheres em ambas extremidades (direita p=0,0002 e esquerda p=0,0009) e pessoas com maior nível de atividade física (direita p=0,0065 e esquerda p=0,0173). Para IAM não foi encontrado diferenças significativas nas variáveis estudadas. Conclusão: Os resultados sugerem que tanto maior nível de atividade física puderam determinar maior resultado no controle sensório-motor. Os homens tiveram maior sensação articular e as mulheres maior controle steadiness. ***Nível de evidência III, Estudo transversal.***

Descritores: *Joelho. Atividade física. Propriocepção.*

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INTRODUCTION

The sensorimotor system (SSM) is responsible for transporting and integrating the sensory and motor information, central integration and processing of all components involved in maintaining articular homeostasis during body movements.[1] This means that the SSM provides functional joint stability throughout human movements and an inadequate functioning of this system can predispose to articular injuries.[2] Recent studies have shown that there are difference when evaluating the SSM between sex.[3] Moreover, SSM differences have been found between at different levels of activity.[4] Therefore, studies assessing the difference between gender and activity level are needed.

The main purpose of this study was to compare the differences in knee sensorimotor control combining measures of joint position

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sense (JPS), steadiness and onset of muscle activation, relating them to level of physical activity, gender and differences between the two extremities.

MATERIALS AND METHOD

Subjects

The sample is composed of 51 voluntary healthy subjects; 27 men (24,27 ± 3,28 years; 1,76 ± 0,06 m; 75,91 ± 8,54 Kg) and 24 women (24,67 ± 3,53 years; 1,64 ± 0,06 m; 58,71 ± 8,73 Kg), with a level of physical activity with a score of 2 to 8 on the Tegner´s scale.[5] Each one of the participants signed an informed consent previous to the assessments that were performed. This study was approved by the bioethics committee of the Pontificia Universidad Católica de Chile (Protocol number 14-146).

Outcomes Measurement

JPS Test

The aim of this test was to evaluate JPS, the ability of subjects to actively replicate a previously determined joint position. A uniaxial electrogoniometer (Kinectecnic Ltda, Santiago, Chile) for the measurement of the knee articular angle in 3 ranges of motion was used: 90º – 60º, 60º – 30º y 30º – 0º (Figure 1A). The subject was in sitting position with their knees initially in 90° of flexion. In each repetition the difference between the angle reached by the subject and the target angle is calculated by averaging the difference of 10 repetitions for each angle and extremity. For signal processing, the Igor Pro 6.0 (WaveMetrics Inc, Lake Oswego, USA) program was used.

Steadiness. Sensation of muscle tension

The purpose of this assessment was to evaluate the ability of subjects to maintain a constant force at 15% of maximum voluntary isometric contraction, which reflects fine muscle control.[6] First, the maximum voluntary isometric contraction (MVIC) was assessed. The patient was sitting with a knee flexion angle of approximately 90º anchoring to the distal end of the leg a load cell where the subjects were asked to perform a maximum isometric voluntary contraction of the extensor muscles of the knee. This was measured using an S beam load cell (Interface, Arizona, USA). The signal was captured using a Trigno Wireless System (Delsys, Boston, USA) with a sampling frequency of 2000 Hz.

Knee isometric steadiness was evaluated with the same setup as the MVIC assessment. Each subject was asked to exert knee extensor force to reach a specific target, a trapezoidal figure which represented the 15% of their MVIC (Figure 1B). Subjects were asked to reproduce this paradigm that lasted 20 seconds. To quantify fine muscular control, the coefficient of variation was calculated between the paradigm displayed on the screen and the exerted force of the the subject

Onset of Muscle Activation

The onset of muscle activation in the knee muscles was estimated utilizing surface electromyography, a method that was previously used in other studies.[7] EMG bipolar sensors (Delsys, Boston, USA) were positioned on the vastus medialis, vastus lateralis, semitendinosus, and biceps femoris muscles of each subject according to SENIAM recommendations.[8] The subjects were ask to stand over two destabilizing platforms (Figure 1C). A sudden fall of the platforms causes 20° of inversion at the ankle in a weight-bearing condition. The drop of the platforms was captured with a triaxial accelerometer, which was synchronized with sEMG signals. Both signals were sampled at 2000 hz. Activation latency for each muscle was calculated as delta time between the onset of acceleration during perturbation and onset of muscle activation.

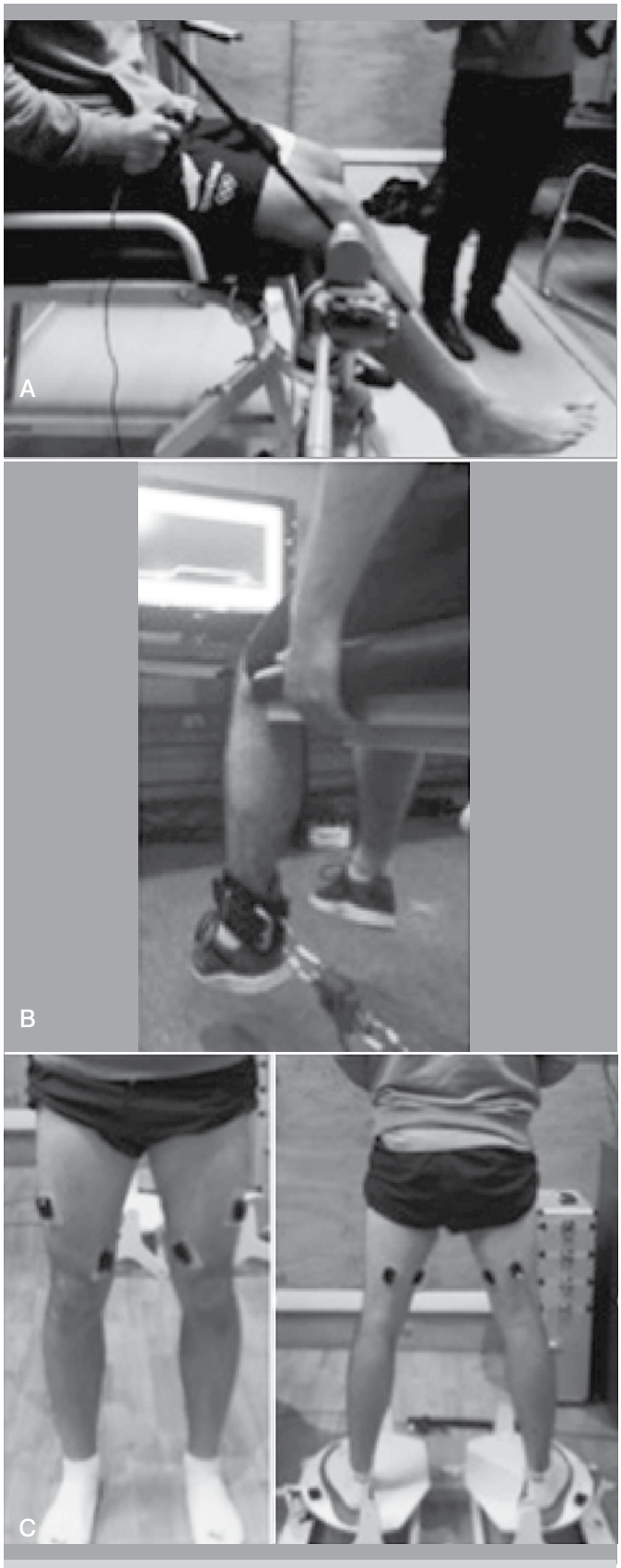

Figure 1. (A) Shows the joint position sense test with the uniaxial electrogoniometer. (B) Shows the steadiness test with the load cell and the paradigm to 15% of the MVIC. (C) Shows the knee muscle onset test with the position of the sEMG sensors and the platform.

Each one of the assessments was performed on both extremities in all subjects.
In order to make comparisons, subjects were divided into different groups depending on their individual characteristics (Table 1). In all assessments, each of the data obtained between the different groups was compared.

Statistical analysis

To evaluate the normal distribution of the data the Shapiro-Wilk test was used. The difference mean test was used in the case of data with normal distribution and the signed rank Wilcoxon test otherwise. A statistically significant result was considered when the p value was less than or equal to 0.05. STATA 9.1 software was used for the statistical analysis. For the different measured tests (JPS, Steadiness and onset of muscle activation) gender differences, differences between groups with different levels of physical activity, differences between the dominant and non-dominant limb, and differences between right versus left limb of the same subject were compared.

RESULTS

JPS Test

A significant difference was found between men and women in the knee JPS test at 90º-60° (p=0,0127) and at 30º-0° (p=0,0034) when comparing the right extremities of both genders (Figure 2 A). When comparing left extremities a significant difference was found in the range of 60º-90° (p=0,0034) (Figure 2 B). In both comparisons men had better results.
The group with higher level of physical activity had significantly better values in at 90º-60° (p=0,0328) in the right limb and 30º-0° (p=0,0173) in the left limb compared with the group that performed a lower level of physical activity (Figure 2 C and 2 D). No significant differences were found when comparing the dominant limb with the non dominant limb, however the results showed that the left limb showed better results in JPS at 60º-30° (p = 0.0048) (Figure 2 E). (Table 2 A, B)

Steadiness

Women had significant better values compared to men in the right (p=0,0002) and left limb (p=0,0009), (Figure 3 A). The group with higher level of physical activity had significant better values in right steadiness (p=0,0065) and left (p=0,0173) compared to the group that performed a lower level of physical activity (Figure 3 B). (Table 3 A, B)

Onset of Muscle Activation

The left limb showed better results in the timing of muscle onset for vastus medialis (p = 0.0466) when compared with the right leg. (Figure 4 E). (Table 4 A, B)

Table 1. Mean +/- (standard deviation) of demographic data for subjects who complete the 3 evaluations.

Variable	Groups	
Gender	**Men (n=27)**	**Women (n=24)**
Level of physical activity Tegner´s scale	More than 5 (n=28)	Less or equal to 5 (n=23)
Age	Older than 25 years (n=18)	Younger or equal to 25 years (n=33)
Dominance	Dominant limb (n=51)	Non dominant limb (n=51)
Extremity	Right (n = 51)	Left (n=51)

Information of each group in which subjects were divided to make comparisons of each evaluation. n = number of subjects per category.

DISCUSSION

JPS Test

Previous studies have demonstrated significant differences between men and women when comparing knee proprioception.[3,9] In these studies women present reduce proprioception ability, which is consistent with the data obtained in our study where worse values in joint repositioning are shown in the female population in the most extreme measurement ranges (90º-60º y 30º-0º). A possible explanation for this is that women have greater articular laxity, so capsuloligamentous receptors would need a greater stimulus to trigger a response equal to that of men.[1] Men also have a higher proportion of muscle mass, which could provide them with more quantity of musculotendinous proprioceptive receptors.
Subjects with a lower level of physical activity also presented worse values in knee JPS. Some studies in professional footballers[4] and in elite tennis players[10] agree with our data and confirm that physical activity level is also a factor that can influence the proprioceptive assessment performance. Moreover, higher proprioception ability have been found in competitive athletes .[11] Therefore, it is possible to hypothesized that training enhance the proprioception ability.
In this study no significant differences were found between the dominant and non-dominant limb. However, when comparing the left and right limb (i.e.: without considering dominance) we found better values in the joint repositioning test in the left side. This is consistent with the results published by Daniel J. Goble[12] , which indicates a close relationship between the left side of the body and the right hemisphere of the brain. Moreover, Natio et al. used a regional map with neuroimaging of the brain's response while applying vibrations to tendons and found that the proprioceptive signals from the proprioceptive receptors generated more information to the right hemisphere of the brain, so the left side of the body should have better proprioceptive values.[13,14] Therefore, it seems that the left lower limb have better proprioceptive performance.

Steadiness

The results of the present study also show better steadiness values in the group of women as compared to men, as the study of Brown et al.[15] According to this study, the main difference in steadiness is attributable to the absolute muscle strength, which is higher in men compare to women. Regarding to the physical activity level, results show that subjects with a higher level of physical activity present better isometric steadiness than sedentary subjects. Different studies have shown that strength training improves isometric steadiness due to sensorimotor control improvements, which would explain the better result in trained subjects.[16,17] Moreover, this assessment has be related to a greater risk of injury, as seen in various publications that patients with anterior cruciate ligament reconstruction.[18] Therefore, this assessment provides an insight in muscle function and may be use in other clinical settings.

Onset of Muscle Activation

No significant differences were found in most of the onset of muscle activation. Nevertheless, other studies have found that healthy people that have greater anterior knee laxity present an increase in timing of muscle onset of biceps femoris.[19] If there is an increased time of muscle onset, it can compromise joint stability, being similar to what happens when there is a ligament injury and damage to receptors that send the afferent signal, and the signal initiating this reflex may be compromised.

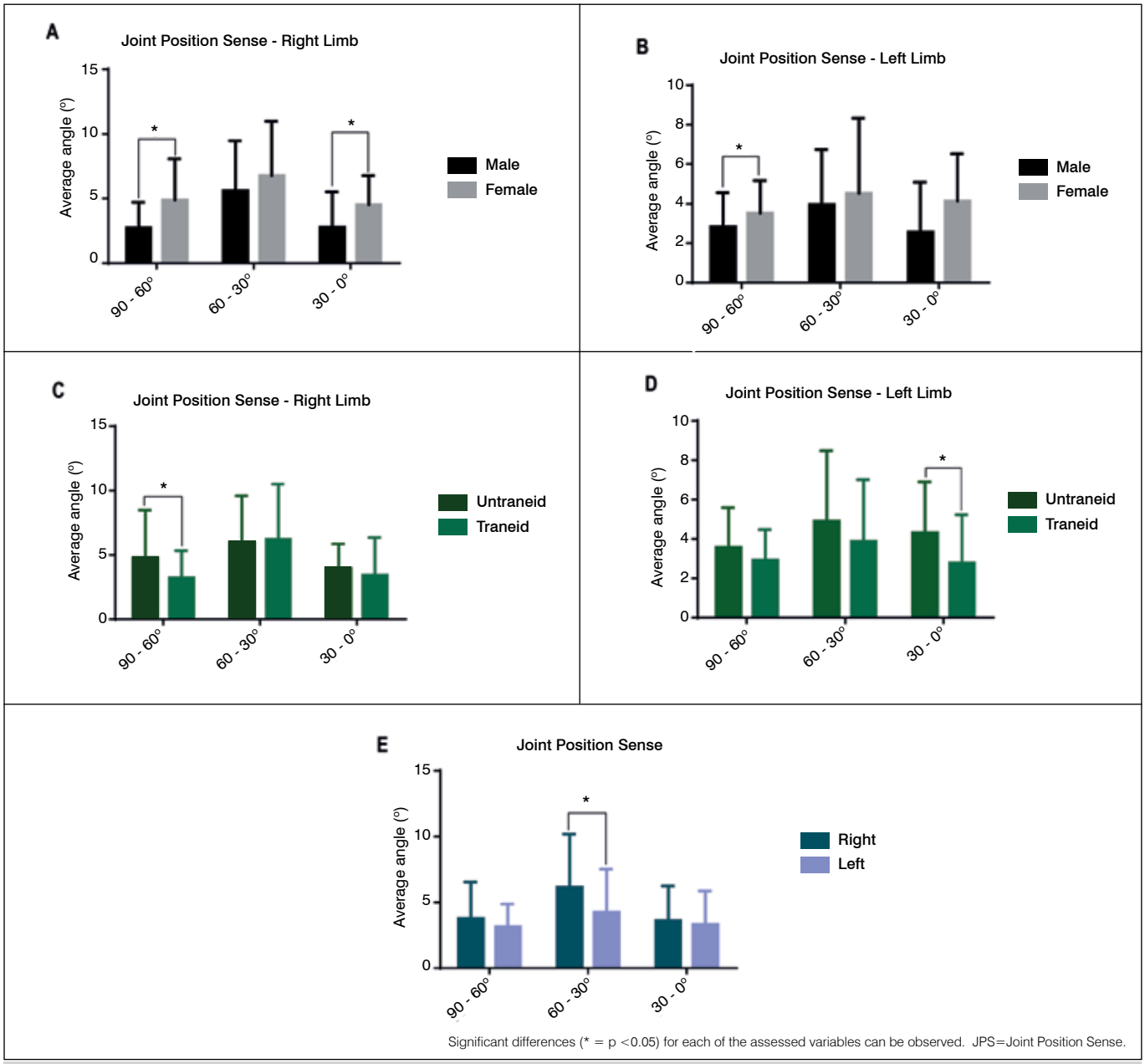

Figure 2. Results for joint position senses (JPS) for the comparisons between male - female, trained - untrained and right limb -left limb. All data shown as median and standard deviation. (A) It shows JPS in degrees for the right limb for males and females. (B) It shows JPS in degrees for the left limb for males and females. (C) It shows JPS in degrees for the right limb for trained and untrained. (D) It shows JPS in degrees for the left limb for trained and untrained. (E) It shows JPS in degrees for the left and right limb.

Table 2 A. Means Angles Values for Joint Position Sense by gender, physical activity or both limbs.

Variable	Indicator	Limb	Mean 90º -60º	SD	Mean 60º - 30º	SD	Mean 30º - 0º	SD
Gender	Male	Right	2,75	1,95	5,59	3,87	2,79	2,71
		Left	2,82	1,73	3,96	2,79	2,56	2,53
	Female	Right	4,88	3,18	6,78	4,20	4,52	2,25
		Left	3,51	1,65	4,52	3,80	4,13	2,40
Level of physical activity	Tegner > 5	Right	3,24	2,07	6,24	4,27	3,42	2,94
		Left	2,93	1,53	3,88	3,13	4,92	3,55
	Tegner ≤ 5	Right	4,77	3,71	5,97	3,62	3,97	1,89
		Left	3,57	2,01	4,92	3,55	4,31	2,59
Limb	Right		3,75	2,79	6,15	4,03	3,60	2,63
	Left		3,14	1,71	4,22	3,28	3,30	2,57

Values expressed in degrees. Abbreviations: SD: Standard Deviation.

Table 2 B. Comparison of Means Angles Values for Joint Position Sense between gender, physical activity or both limbs.

Evaluation	Limb	Range	MD	ES	P. Value
Differences between gender (Female – Male)	Right	90º - 60º	2,12	1,95	0,0127 *
		60º - 30º	1,18	1,13	0,3358
		30º - 0º	1,73	0,70	0,0017 *
	Left	90º - 60º	0,68	0,47	0,1311
		60º -30º	0,56	0,92	0,8949
		30º - 0º	1,57	0,69	0,0034 *
Differences between Level of physical activity (Lower– Higher)	Right	90º - 60º	1,52	0,80	0,0328 *
		60º - 30º	- 0.27	1,20	0,4109
		30º - 0º	0,54	0,78	0,2450
	Left	90º - 60º	0,64	0,50	0,1062
		60º -30º	1,03	0,97	1,0374
		30º - 0º	1,51	0,74	0,0229 *
Differences between Both Limbs (right – left)		90º - 60º	0,60	0,45	0,0941
		60º -30º	1,92	0,72	0,0048 *
		30º - 0º	0,30	0,51	0,2531

* P < 0,05. Abbreviations: MD= Mean Difference. ES= Error Standard.

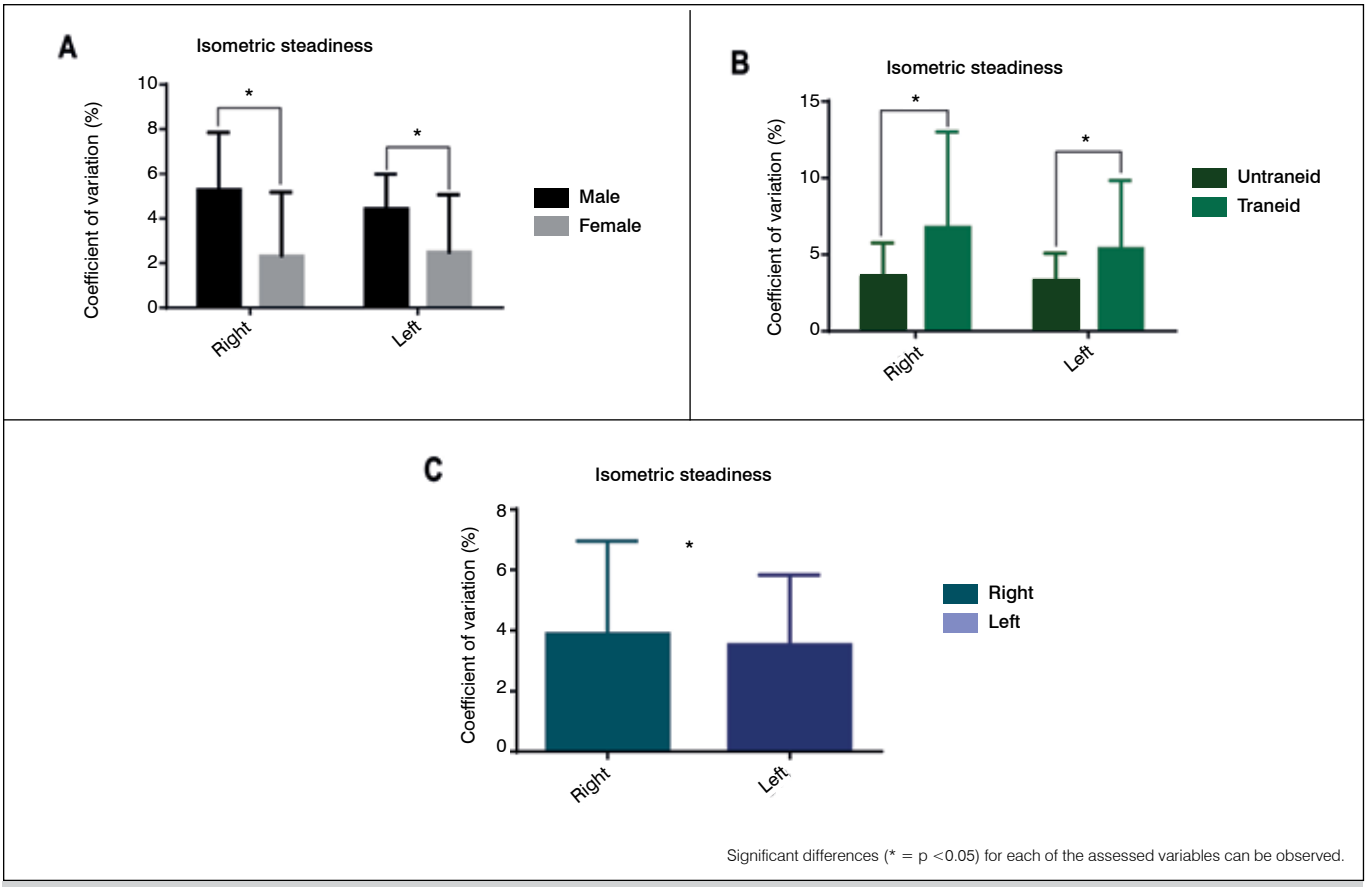

Figure 3. Results for isometric steadiness for the comparisons between male - female, trained - untrained and right limb -left limb. All data shown as median and standard deviation. (A) It shows the coefficient of variation for the isometric steadiness for males and females. (B) It shows the coefficient of variation for the isometric steadiness for trained and untrained. (C) It shows the coefficient of variation for the isometric steadiness for right limb and left limb.

Table 3 A. Mean Percentages for Values Steadiness by gender, physical activity or limb evaluated.

Variable	Indicator	Right Limb Mean	SD	Left Limb Mean	SD
Gender	Male	5,28	2,57	4,44	1,55
	Female	2,32	2,86	2,49	2,58
Level of physical activity	Tegner > 5	3,50	2,24	3,28	1,79
	Tegner ≤ 5	6,71	6,23	5,38	4,45
Limb		3,88	3,07	3,52	2,30

Values expressed in percentage. Abbreviations: SD: Standard Deviation.

Table 3 B. Comparison of Mean Percentage for Values Steadiness by differences between gender, physical activity or both limbs.

Evaluation	Limb	MD	ES	P. Value
Gender (Female – Male)	Right	- 2,90	0,70	0,0002*
	Left	- 1,90	0,50	0,0009*
Level of physical activity (Lower – Higher)	Right	3,20	1,20	0,0065*
	Left	2,00	0,90	0,0173*
Limb (right – left)		0,30	0,50	0,2531

* P < 0,05. Abbreviations: MD= Mean Difference. ES= Error Standard.

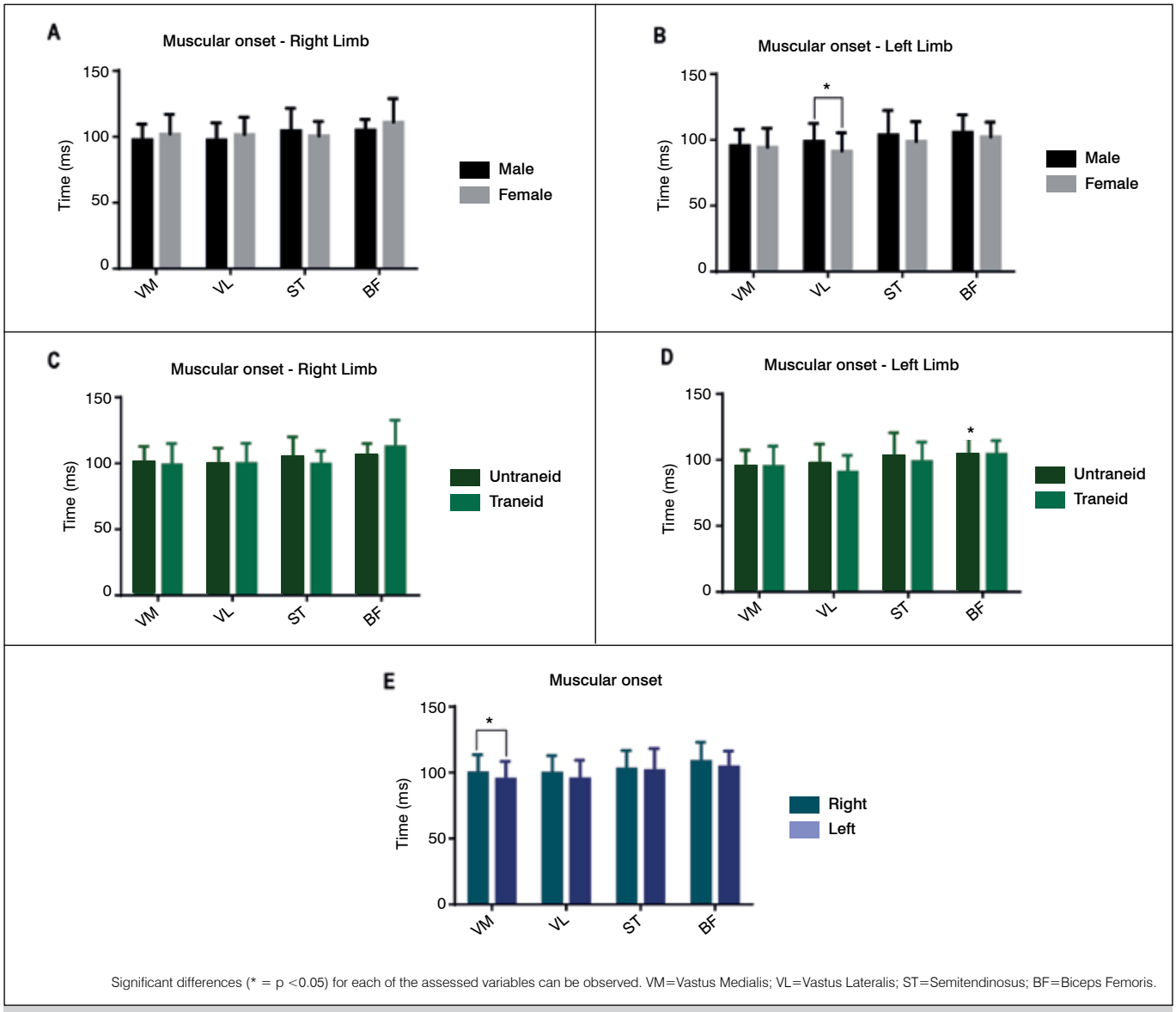

Figure 4. Results for muscular onset for the comparisons between male - female, trained - untrained and right limb -left limb. All data shown as median and standard deviation. (A) It shows time of muscular onset for the right limb, for males and female. (B) It shows time of muscular onset for the left limb, for males and females. (C) It shows time of muscular onset for the right limb, for trained and untrained. (D) It shows time of muscular onset for the left limb, for trained and untrained. (E) It shows time of muscular onset for the right limb and left limb.

Table 4 A. Mean Values for time of Muscle Onset by gender, physical activity and both limbs.

Variable	Indicator	Limb	MV Mean	SD	LV Mean	SD	ST Mean	SD	FB Mean	SD
Sex	Male	Right	97,57	12,01	97,42	13,19	104,74	16,83	105,07	8,12
		Left	95,61	12,31	98,94	13,57	103,87	18,49	105,85	13,25
	Female	Right	102,0	15,07	101,72	13,12	100,64	10,89	111,12	17,81
		Left	94,38	14,61	91,42	14,00	98,98	14,95	102,25	11,31
Level of physical activity	Tegner > 5	Right	100,45	12,32	99,43	12,20	104,32	15,85	105,83	9,29
		Left	94,91	12,51	97,45	14,64	102,87	17,78	103,87	13,44
	Tegner ≤ 5	Right	98,76	16,26	99,95	15,23	99,53	9,87	112,73	20,07
		Left	95,06	15,32	90,83	12,54	98,63	14,90	104,23	10,46
Limb		Right	99,85	13,69	99,62	13,18	102,69	14,16	108,48	14,57
Left			94,97	13,42	95,09	14,15	101,42	16,80	104,00	12,28

Values expressed in milliseconds. Abbreviations: SD: Standard Deviation. MV= Medial Vastus. LV= Lateral Vastus. ST= Semitendinosus. FB= Femoral Biceps.

Table 4 B. Comparison between Mean for time of Muscle Onset by differences between gender, physical activity and both limbs.

Evaluation	Limb	Muscle	MD	ES	P. Value
Gender (Female – Male)	Right	MV	4,46	4,07	0,2858
		LV	4,29	3,92	0,2287
		ST	- 4,10	4,27	0,6555
		BF	6,04	4,66	0,3012
	Left	MV	- 1,23	4,09	0,7421
		LV	- 7,51	4,11	0,0357 *
		ST	- 4,89	5,07	0,4595
		BF	- 3,60	3,75	0,6269
Level of physical activity (Lower - higher)	Right	MV	- 1,68	4,30	0,3487
		LV	0,52	4,15	0,4504
		ST	- 4,79	4,49	0,1464
		BF	6,90	4,72	0,0763
	Left	MV	0,15	4,25	0,4860
		LV	- 6,62	4,34	0,0675
		ST	- 4,23	5,36	0,2175
		BF	0,36	3,92	0,4631
Limb (right – left)		MV	4,88	2,87	0,0466 *
		LV	4,52	2,88	0,0602
		ST	1,26	3,31	0,3516
		BF	4,47	2,96	0,0677

* P < 0,05. Abbreviations: MD= Mean Difference. ES= Error Standard. MV= Medial Vastus. LV= Lateral Vastus. ST= Semitendinosus. FB= Femoral Biceps.

CONCLUSION

Men presented better JPS and steadiness that women, which may be attributable to a higher laxity of women and higher muscle strength of men, respectively. Subjects with higher training showed better JPS and steadiness values. This is consistent with the literature, where training results in sensorimotor adaptation.

AUTHORS' CONTRIBUTIONS: All authors contributed individually and significantly to the development of this article. CSM (0000-0001-9913-3310)*: wrote and reviewed the manuscript, contributed to the intellectual conceptualization of the study and the entire research project. AV: wrote and reviewed the manuscript. IC (0000-0003-3831-6513)*: performed measurements for the assessments and outcome assessment analysis. FJB (0000-0003-3552-8262)*: contributed to the intellectual conceptualization of the study and reviewed the manuscript. CO (0000-0001-7240-1928)*: performed the statistical analysis and reviewed the manuscript. FL (0000-0001-9255-2555)*: performed measurements for the assessments and wrote the manuscript. *ORCID (Open Researcher and Contributor ID).

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PROTOCOL FOR TREATING ACUTE INFECTIONS IN CASES OF TOTAL KNEE ARTHROPLASTY

PROTOCOLO DE TRATAMENTO DAS INFECÇÕES AGUDAS NAS ARTROPLASTIAS TOTAIS DO JOELHO

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ABSTRACT

Objective: To retrospectively evaluate the results after applying a protocol for treating acute infections in cases of total knee arthroplasty and to establish factors predictive of success or failure. Methods: Thirty-two patients who were diagnosed with acute infection of the knee following total arthroplasty between 2004 and 2009 were retrospectively evaluated. Infections following arthroplasty were treated in accordance with the protocol for acute infections following arthroscopy recommended at our institution. Results: With application of a treatment protocol for acute infections following total knee arthroplasty, 26 patients (81.2%) had good results and 6 (18.8%) had unsatisfactory results. Statistical analysis showed that the variables correlated with a worse prognosis were age (p = 0.038) and number of surgical debridement procedures performed (p = 0.038). Conclusion: Our treatment routine was effective for infection. Prosthesis revision was performed in 2 cases when the initial surgical debridement failed to control the infection. ***Nível de Evidência IV, Série de casos.***

Keywords: Arthroplasty, replacement, knee/methods. Arthroplasty, replacement, knee/adverse effects. Infection.

RESUMO

Objetivos: Avaliar retrospectivamente os resultados da aplicação do protocolo de tratamento das infecções agudas após artroplastia total do joelho e estabelecer fatores preditivos de bons resultados ou falhas. Métodos: Trinta-e-dois pacientes diagnosticados com infecção aguda após artroplastia total do joelho entre 2004 e 2009 foram avaliados. Os casos caracterizados como infecção foram tratados de acordo com o protocolo de tratamento recomendado em nossa instituição. Resultados: Através da aplicação de nosso protocolo para infecções agudas após artroplastia total do joelho, 26 (81,2%) pacientes tiveram bons resultados e seis (18,8%) apresentaram resultados insatisfatórios. Após a análise estatística, as variáveis que se correlacionaram com um pior prognostico foram idade (p=0,038) e número de procedimentos cirúrgicos para limpeza realizados (p=0,038). Conclusão: Nosso protocolo de tratamento foi efetivo no controle de infecção após as artroplastias. Revisão da prótese em dois tempos deve ser realizada quando o primeiro desbridamento cirúrgica não for eficaz no controle do quadro infeccioso. ***Level of evidence IV, case series.***

Descritores: *Artroplastia do joelho/métodos. Artroplastia do joelho/efeitos adversos. Infecção.*

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INTRODUCTION

Locomotor system disorders are increasingly prevalent worldwide.[1,2] Chronic joint pain lasting more than 3 months affects about one-fourth of the population over 18 years, and the knee is the most commonly affected joint.[2]

Total knee arthroplasty is very popular, but success is not guaranteed.[3] Mechanical or biological failure can occur, including failure due to infection.[4,5]

Infection after total knee arthroplasty occurs in 1-3% of cases worldwide, and invariably requires lengthy and costly treatment.[6-8] The estimated annual expenditure for treatment in the USA is USD 300 million; on our service alone, the annual expenditure exceeded USD 90,000 between 2005 and 2006.[1,8]

The diagnosis of infection after knee arthroplasty must comply with predetermined clinical and laboratory criteria, as pathologic characterization is not always easy, and treatment should follow protocols that consider the type and time of antibiotic use, indications for surgical joint debridement, removal of instrumentation, placement of antibiotic-loaded cement spacers, and prosthesis replacement.[9]

This prospective study evaluated outcomes after application of a treatment protocol for acute infection in total knee arthroplasty and identified factors predictive of success or failure in treatment of infected arthroplasty.

MATERIALS AND METHODS

The study was approved by the Research Ethics Committee of our institution (CAAE: 05424312.1.0000.0068). We prospectively

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

Study was conducted at the Knee Division, Instituto de Ortopedia e Traumatologia, HC/FMUSP, São Paulo, SP, Brazil.
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evaluated 32 patients with a diagnosis of acute knee infection after total arthroplasty between 2004 and 2009. Diagnostic criteria for infection included local clinical parameters, such as inflammation around the wound and secretion from the surgical incision, systemic parameters, such as a decline in general condition and fever, and laboratory parameters, such as elevation of leukocyte count, erythrocyte sedimentation rate, and C-reactive protein.

Cases diagnosed as infection following arthroplasty were treated according to the protocol used for acute infections after knee arthroplasty recommended by the institution.[9]

Initial evaluation characterized the infection as superficial or deep. Superficial infections were initially treated only with broad-spectrum antibiotics, and deep infections were treated with surgical debridement in combination with antibiotics.

Infections that did not resolve after surgical debridement underwent prosthesis removal and placement of antibiotic-loaded cement spacers, with subsequent revision 6 weeks after satisfactory control of the infectious process (Figure 1).

Based on the protocol, 8 patients were treated with antibiotics alone, 19 with antibiotics combined with surgical debridement, and 5 with antibiotics, surgical debridement, prosthesis removal, and spacer placement.

Patients who had remission of the infectious process with preservation of knee function were considered to have good results, and those without control of the infection or with impairment of function (requiring arthrodesis, resection arthroplasty, or amputation) were considered to have poor results.[10]

We evaluated patient data including age at arthroplasty, presence of clinical comorbidities, body mass index, and number of previous orthopedic surgeries; microbiological data, including results of intraoperative cultures and microbial load; and data related to application of the protocol including the time between arthroplasty and diagnosis of infection and the number of surgical debridements performed.

The data were analyzed and correlated with treatment outcomes. Fisher's exact test was used in statistical analysis for the association between independent variables and outcomes, the Kolmogorov-Smirnov and Mann-Whitney tests were used for the association between quantitative variables and outcomes, and Spearman's correlation was used for the associations between variables.

RESULTS

Use of the protocol for treatment of acute infections after total knee arthroplasty resulted in 26 (81.2%) cases with good results and 6 (18.8%) with poor results. Among those with poor results, 1 died, 2 required amputation, 1 had aseptic loosening, 1 required knee arthrodesis, and 1 received long-term antibiotic therapy.

Twenty-two patients were male and 10 were female. Age ranged from 35 to 83 years, with a mean of 67.4. Twenty-three patients were older than 65 years, and 9 were younger than 65 years.

Ten (31.2%) patients had no comorbidities. The most prevalent comorbidity was systemic arterial hypertension, in 20 (62.5%) cases. Three (9.3%) patients had diabetes mellitus and 3 (9.3%) had rheumatoid arthritis.

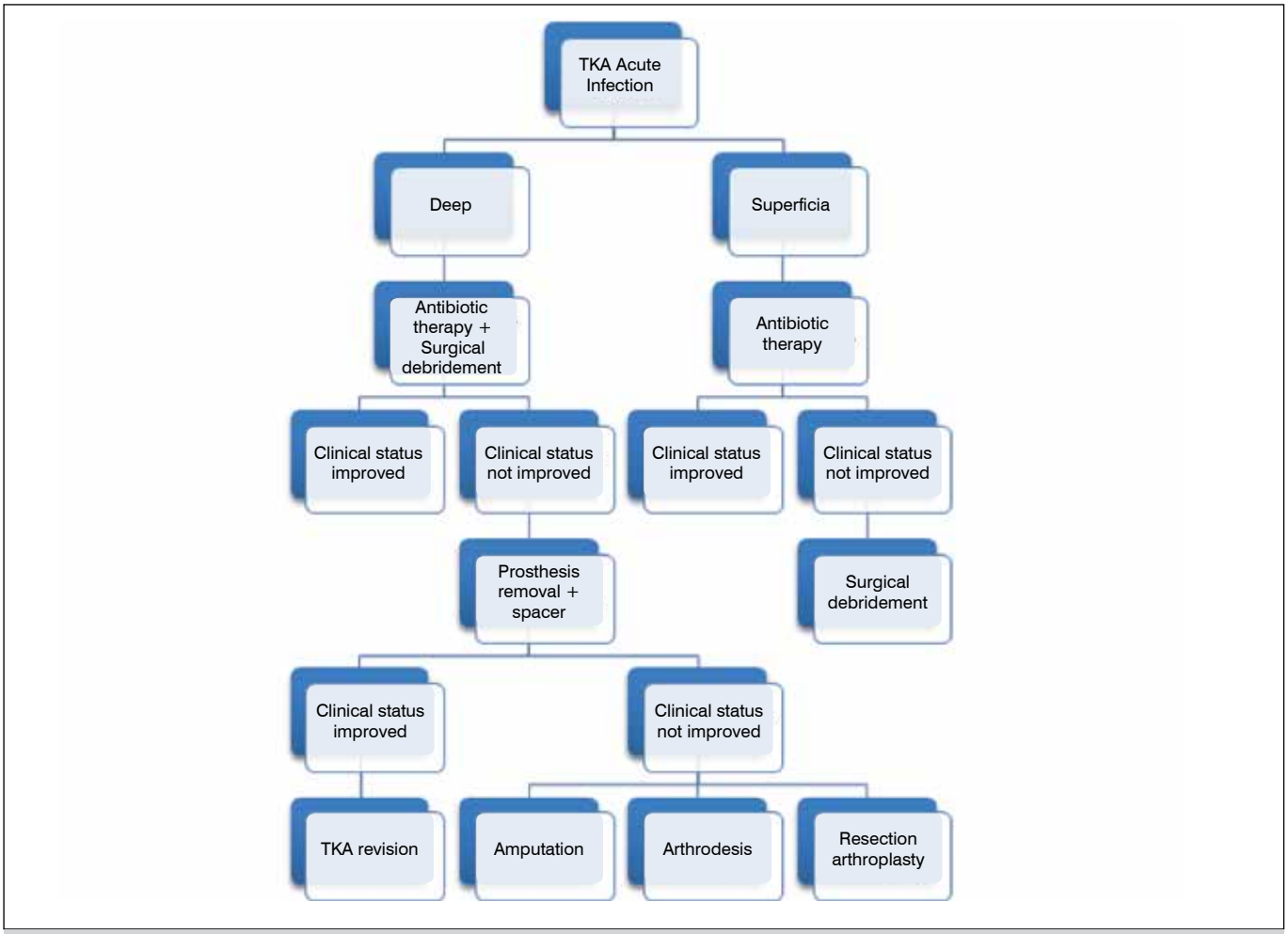

Figure 1. Treatment algorithm in the IOT-HC/FMUSP protocol for acute infection after total knee arthroplasty.

Body mass index (BMI) was determined in only 23 patients, of whom 14 (60.8%) had a BMI greater than 30, which is considered the cutoff for obesity. Nine patients (39.1%) had normal weight or were overweight. None of the patients were underweight (BMI less than 18.5).

The number of previous orthopedic surgeries was evaluated in 29 patients. Fourteen (48.3%) had previously undergone surgery, and arthroplasty was the index procedure in 15 (51.7%).

In 14 cases (43.7%), no microorganism was isolated. *Staphylococcus aureus* was the most prevalent agent, and was isolated in 8 cases (25%). Other bacteria were isolated in 10 cases (31.3%). Of the 18 cases (56.2%) with positive cultures, eleven (34.4%) had only 1 organism isolated, and 7 (21.9%) had more than 1 isolated.

Fourteen (43.8%) patients were diagnosed with infection less than 10 days after arthroplasty and 18 (56.2%) were diagnosed more than 10 days after surgery.

Sixteen (50%) underwent only 1 surgical debridement, 7 (21.9%) did not require a surgical procedure to treat the infection, and 9 (28.1%) underwent more than 1 procedure (Table 1).

In statistical analysis, the only patient-related variable that was associated with worse prognosis was age. Patients younger than 65 years undergoing arthroplasty had a poor prognosis for remission of the infectious process and preservation of function ($p=0.038$). Variables such as sex, BMI, diabetes mellitus, rheumatoid arthritis, and the number of previous orthopedic surgeries showed no significant association with outcomes ($p>0.05$). There was no statistically significant association between the microbial load and the outcome ($p>0.05$). The time elapsed between arthroplasty and diagnosis of infection showed no statistical correlation with a poor outcome ($p=0.365$). However, patients who underwent more than one surgical debridement were more likely to have a poor outcome ($p=0.038$).

Table 1. Summary of treatment results using the protocol.

	Number	Percentage
Outcome		
Good	26	81.2%
Poor	6	18.8%
Mean age (range)	67.4 (35-83)	
Sex		
Male	10	31.2%
Female	22	68.8%
Comorbidity		
None	10	31.2%
Systemic arterial hypertension	20	62.5%
Rheumatoid arthritis	3	9.3%
Diabetes mellitus	3	9.3%
BMI (23 patients analyzed)		
Greater than 30	14	60.9%
Less than 30	9	39.1%
Previous orthopedic surgery (29 patients analyzed)		
Yes	14	48.3%
No	15	51.7%
Infectious agent isolated		
No	14	43.7%
S. aureus	8	25%
Others	10	31.3%
Number of agents isolated		
None	14	43.7%
One agent	11	34.4%
More than 1 agent	7	21.9%
Time between surgery and diagnosis of infection		
More than 10 days	18	56.2%
Less than 10 days	14	43.8%
Number of surgical debridements		
None	7	21.9%
One	16	50%
More than 1	9	28.1%

DISCUSSION

Most cases of total knee arthroplasty show good results. However, complications can still occur. Infection is one of the most serious complications because of the difficulty of early diagnosis, the lengthy and costly treatment, and the severe sequelae.[8,11]

Infection after arthroplasty can occur due to noncompliance with surgical protocols, surgery itself, or patient-related factors. Some examples are systemic diseases, clinical conditions, and patient living conditions.

Infection following total knee arthroplasty can be direct or hematogenous. Direct infection can occur due to the absence of laminar flow in the surgical environment, inadequate sterilization, incorrect manipulation of surgical material, and excessive number of assistants and others in the surgical environment; variables directly associated with surgical technique, such as prolonged operative time, inadequate hemostasis, and excessive manipulation of soft tissue are also contributory factors. Hematogenous infection can be due to spread from patient foci, such as airway or urinary tract infections, skin ulcers, dental abscesses, or even quiescent bacteria from previous orthopedic surgeries.[5]

Following diagnosis, classification is necessary to determine the appropriate treatment protocol. Superficial infection involves only skin and subcutaneous tissue, and deep infection involves the joint itself; nosocomial infection occurs less than 1 year after arthroplasty and community-acquired infection occurs more than 1 year after surgery; acute infection occurs less than 4 weeks after arthroplasty, before formation of a biofilm, and is otherwise considered chronic.[5,9]

Treatment of infection following arthroplasty aims to preserve the prosthesis, with use of a broad-spectrum systemic antibiotic based on hospital microbial profiles; surgical debridement is used to identify the agent through cultures that guide specific antibiotic therapy.[12]

Many different treatment protocols have been recommended. In the 1970s, the prosthesis was removed, and arthrodesis was attempted. In the 1980s, Freeman recommended one-stage revision.[13]

Two-stage revision was first reported in 1979 and was popularized by Insall in 1983.[14,15] The use of a spacer to decrease soft tissue retraction and place antibiotics at the site of infection was introduced by Borden and Gearen[16] in 1987. Use of a functional spacer, which we believe is the best solution, was introduced in 1995.[17] Two-stage revision is still limited by the cost of treatment and the limited options for local antibiotic use.[18]

Some treatment recommendations lack consensus in the literature. In acute deep infections, antibiotic therapy alone shows satisfactory results in 23-68% of cases. Much of this can be explained by the fact that surgical debridement prevents biofilm formation, in contrast to the results from clinical treatment alone.[9,19,20] The number of surgical debridements before prosthesis removal is needed varies. Wasielewski et al.[21] consider multiple procedures to be beneficial, whereas Sherrell et al.[22], similar to our conclusions, consider multiple procedures to be undesirable. It is also unclear whether revision after resolution of infection should be performed in 1 or 2 stages. Immediate replacement is undoubtedly less time-consuming and costly, but 2-stage revision has a higher success rate and is more commonly performed.[13,23-26]

We intended to evaluate our findings and correlate the results with patient conditions, microbial load, and application of the protocol. The success rate was significantly higher than that in previous reports.[27-29]

The only patient-related variable associated with a poor outcome was age younger than 65 years; this can be explained by the fact that younger patients usually have more severe joint damage, leading to earlier need for surgery, and resulting in greater surgical trauma. Moreover, younger patients are more active. Earlier surgical indications may be related to comorbidities, such as inflammatory diseases,

which would also result in a worse prognosis.[30] Our study examined the correlation between age and other factors that could lead to worse prognosis, such as BMI, diabetes, and rheumatoid arthritis, but no statistical association was found, indicating that younger patients have worse prognosis independent of other variables.

There was no statistical correlation between the microbial load or virulence and worse prognosis. This indicated that correct application of our protocol led to a successful outcome, regardless of the infectious agent.

Another factor predictive of worse prognosis was the number of surgical debridements. The more delayed the surgical debridement after infection, the greater the chance of biofilm formation. Thus, a greater number of surgical debridements favored biofilm formation and delayed a 2-stage prosthesis revision.

Early diagnosis of infection is not always easy, and specific tests are lacking.[5,31-33] Genetic analysis using messenger RNA is not yet clinically available.[34] Better characterization of the biofilm and a method to overcome this barrier to remove bacteria adherent to implants are essential to success using different types of treatments.[35]

CONCLUSION

Analysis of the results following application of our treatment protocol led to highly successful infection control and preservation of knee function. Our outcomes were even better than those in recent prior studies. Younger patients who underwent serial surgical debridements in an effort to maintain the prosthesis had worse outcomes. Two-stage prosthesis revision should be performed when the infection is not successfully controlled after initial debridement.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of the article. JRP (0000-0003-1621-5252)* and CPH (0000-0003-1139-2524)* were the main contributors to the writing of the article. JRP, RGG (0000-0002-1715-4343)*, MKD (0000-0003-1999-9478)*, and ALML (0000-0002-2396-9880)* performed the surgery, followed the patients, and gathered clinical data. CPH and JRP evaluated the data obtained from the statistical analysis. CPH, GLC (0000-0001-8656-5552)*, and JRP conducted bibliographic research and article review and contributed to the intellectual concept for the study. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

DIAGNOSIS AND MANAGEMENT OF PAGET'S DISEASE OF BONE - SERIES OF 8 CASES

DIAGNÓSTICO E MANEJO DA DOENÇA DE PAGET ÓSSEA - SÉRIE DE 8 CASOS

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ABSTRACT

Paget's disease of bone is a chronic condition characterized by focal abnormalities of absorption and formation of bone, and it may lead to anatomical deformities, pain, fractures, and malignant transformation. It is common in the UK, Australia, New Zealand, and North America and has a strong hereditary component, affecting first- to third-degree relatives. The etiology remains unclear and treatment is based on control of the disease with bisphosphonates, with the aim of relieving symptoms and correcting laboratory abnormalities. Surgical treatment may also be necessary to correct deformities or treat pathological fractures. This study evaluated the management and course of 8 patients with Paget's disease of bone, followed in the Orthopedic Clinic of this hospital. Among these patients, 1 had concomitant advanced prostate carcinoma, highlighting the association between Paget's disease and secondary bone diseases that can affect the differential diagnosis. ***Level of evidence IV, Study type: Case Series.***

Keywords: Paget´s Disease. Osteitis Deformans. Neoplasm Metastasis.

RESUMO

A doença de Paget Óssea é uma afecção crônica, caracterizada por distúrbio focal da absorção e formação ósseas, podendo levar a deformidades anatômicas, dor, fraturas e malignização das lesões. É frequente no Reino Unido, Austrália, Nova Zelândia e América do Norte. Mantém forte relação de incidência com parentes de primeiro a terceiro graus. Sua etiologia ainda permanece incerta e o tratamento se baseia no controle da doença, com uso de bisfosfonados, visando melhora dos sintomas e das alterações laboratoriais. O tratamento cirúrgico também pode ser necessário, para correção de deformidades ou para tratamento de fraturas. Este estudo compilou oito pacientes em acompanhamento pela doença de Paget Óssea, no Ambulatório de Ortopedia deste hospital, acerca do tratamento realizado e como evoluíram. Dentre os pacientes acompanhados, houve um caso de carcinoma de próstata concomitante ao Paget, chamando atenção para outras patologias ósseas que são diagnósticos diferenciais ou coexistem com a doença. ***Nível de evidência IV, Tipo de Estudo: Série de Casos.***

Descritores: *Doença de Paget. Osteíte Deformante. Metástase Neoplásica.*

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INTRODUCTION

As described by Sir James Paget in 1877, Paget's disease of bone is a chronic condition characterized by focal areas of excessive bone reabsorption accompanied by increased bone formation, resulting in anatomical and structural changes that can lead to pain, deformities, fractures, and progression to osteosarcoma or chondrosarcoma, among other complications.[1,2] Paget's disease predominantly occurs in males, with a male:female ratio of 1.8:1. It is rarely found in individuals under 50 years of age and is prevalent in approximately 2-4% of people over age 50.[1] It is more common in the UK, followed by Australia, New Zealand, and North America, reflecting the prevalence of British migrants in these areas. Conversely, it is rarely found in Scandinavian countries, Africa, and Asia.[3] The etiology of Paget's disease is uncertain, and there is a strong relation in its incidence among first-degree relatives.[1,3] Among those affected, mutations are found in sequestosome 1/p62, which plays an important role in the differentiation and response of osteoclasts to RANK-L and interleukin-1 cytokines.[1] Some theories claim that environmental factors and viral infections may influence the onset of Paget's disease. There has been a gradual decline in disease incidence without the identification of contributory factors.[1]

DIAGNOSIS

Paget's disease diagnosis is based on clinical features, such as bone pain, arthropathy, deformities, fractures, deafness, and neurological complications. Circumscribed osteoporosis, mosaic lesions, and bone deformities can be found on radiography and scintigraphy through hyperscanning of the affected areas. Laboratory tests may show changes in alkaline phosphatase and liver function tests, especially gamma-glutamyl transferase and vitamin D levels.[1,3,4,5]

TREATMENT

Paget's disease is treatable, but not all patients require treatment. The main factor indicating drug treatment is bone pain at the affected site.

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

Study was conducted at the Hospital das Clínicas of the Faculdade de Medicina de Botucatu, UNESP, Botucatu, SP, Brazil.
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Asymptomatic cases should be individually managed, and treatment is recommended when there is a risk of fracture, especially in the femur, tibia, humerus, and spine, or, in the case of the skull base, to prevent deafness. Once there is a fracture, it will be difficult for the patient to respond to treatment. For young patients with the disease, treatment involving the joint areas in an attempt to prevent secondary arthrosis is also possible. However, evidence that these treatments prevent complications is limited, given the difficulty in conducting randomized studies of relatively rare diseases. The drugs most commonly used to treat Paget's disease are second- and third-generation bisphosphonates, such as alendronate, pamidronate, and risedronate, which have replaced the use of calcitonin and etidronate. Vitamin D deficiency should be corrected, and calcium supplementation should be prescribed to prevent hypocalcemia induced by bisphosphonates or secondary hypocalcemia due to hyperparathyroidism. Drug treatment aims to relieve bone pain, normalize alkaline phosphatase levels, and induce remission of osteolytic lesions. Surgery may be indicated for fractures, correction of deformities, spinal stenosis with neurological complications, and joint replacements due to arthrosis.[1,4,5]

PATIENTS AND METHODS

This study describes the management, diagnostic approach, treatment, and recent clinical status of 8 patients with Paget's disease of bone who were examined at the Orthopedic Clinic of this hospital. The study was approved by Plataforma Brasil, with CAAE protocol number 53081416.2.0000.5411.

Case 1

E.M., male, 62 years old. A monostotic lesion in the left humerus was discovered by chance after a radiographic study of the arm 19 years prior. He was administered alendronate at the time, but is currently asymptomatic and rarely has pain. He has impingement syndrome in the left shoulder secondary to bone deformities from Paget's disease. He is only followed up at the orthopedics department.

Case 2

E.G.C., male, 78 years old, with a monostotic lesion in the right hemipelvis. He has been treated with alendronate for periods of 3-6 months, with 6-month intervals between treatment courses. He remains asymptomatic. He is monitored by urology for prostate adenocarcinoma and underwent radiation therapy in 2008 and orchiectomy in 2010. The prostate-specific antigen level remains <0.2. He had a stroke and has residual left hemiparesis. He is currently followed up at the orthopedics and urology departments.

Case 3

J.A.P., 75 years old, male. While under treatment at the urology department for a urethral stricture, pelvic radiography identified local bone changes. Staging revealed polyostotic disease, with lesions in the skull, pelvis, and spine. With few symptoms, he did not undergo drug treatment for Paget's disease. He is followed up at the orthopedics and urology departments.

Case 4

G.O.S., male, 46 years old. He had fallen from a height of <2 m in November 2014 and fractured the right femoral diaphysis. Changes on radiography were compatible with Paget's disease and a pathological fracture was diagnosed. Indirect reduction and internal intramedullary nail fixation led to good recovery. Although asymptomatic, alendronate was started in March 2015, to be discontinued in November 2015. He is only followed up at the orthopedics department.

Case 5

R. N. F., male, 89 years old. He had fallen from a height of <2 m in October 2014 and had a pathological fracture of the right elbow. Staging was compatible with a monostotic lesion in the right distal humerus. The fracture was treated with direct reduction and internal fixation, with good callus formation during recovery. The patient was asymptomatic before treatment and remains so. He took alendronate for 6 months after the fracture, and is only followed up at the orthopedics department.

Case 6

Z.M.G.S., female, 50 years old. Bone lesions were found in the spine on imaging for low back pain. Staging revealed polyostotic disease in the right humerus, spine, left hemipelvis, skull, and left femur. She is otherwise symptomatic but has elevated alkaline phosphatase levels. Her condition is monitored by the orthopedics department, and she was referred to the endocrinology department in June 2015.

Case 7

A.D.D., male, 49 years old. He sustained a pathological right intertrochanteric fracture in August 2015 after falling from a height of <2 m. Intraoperative pathologic diagnosis was compatible with Paget's disease of bone. He remains asymptomatic at the fracture site. Complete laboratory and imaging staging are pending to determine whether he has monostotic or polyostotic disease. He is only followed up at the orthopedics department.

Case 8

L.B.C., female, 76 years old. Paget's disease was diagnosed because of a bone deformity in the left tibia, and complete staging is pending to determine whether the disease is monostotic or polyostotic. She has pain in the left leg unrelated to physical activity. Endocrinology recently initiated risedronate. She is followed up at the orthopedics and endocrinology departments.

DISCUSSION

Paget's disease is routinely managed by the specialties of orthopedics and endocrinology. We believe that multidisciplinary follow-up is useful for diagnosis and staging as well as treatment. Because Paget's disease mainly affects people over the age of 50, it is important to evaluate the possibility of other primary and secondary bone diseases, such as malignant metastases and multiple myeloma, which are included in the differential diagnoses or may even coexist with Paget's disease. New drugs that modulate calcium metabolism, such as denosumab, may prove to be valuable in patients who cannot take bisphosphonates.[6] Paget's disease requires follow-up care and assessment for possible development of malignancy.[2]

CONCLUSION

Paget's disease of bone is often diagnosed by chance on imaging studies for other diseases. Bisphosphonate treatment is effective in controlling pain and alkaline phosphatase levels in most patients. Because of the greater prevalence in older populations, it is important to consider Paget's disease in the differential diagnosis, in addition to the possibility of coexisting bone malignancies.

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COMPARISON OF IMPLANT DENSITY IN THE MANAGEMENT OF LENKE 1B AND 1C ADOLESCENT IDIOPATHIC SCOLIOSIS

COMPARAÇÃO DA DENSIDADE DO IMPLANTE NO TRATAMENTO DA ESCOLIOSE IDIOPÁTICA DO ADOLESCENTE LENKE 1B E 1C

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ABSTRACT

Objective: To compare radiographic and surgical outcomes of Lenke 1B and 1C patterns. Methods: One hundred twenty patients with Lenke 1B and 1C scoliosis were grouped according to implant density as follows: low density (LD) of ≤1.4 and high density (HD) of >1.4. Matched subgroups (30 patients each) based on age, curve magnitude, and body mass index (BMI) were analyzed. Radiographic parameters were evaluated before operation, immediately after operation (ipo), and at 2 years' follow-up. SRS-30 was administered before operation and at 2 years' follow-up. Results: The major curves of the LD (n = 82) and HD groups (n=38) were respectively 59.1° and 65.6° before operation ($p < .001$), 26.3° and 22.9° ipo ($p = .05$), and 29.9° and 19.8° at 2 years' follow-up ($p < .001$). No significant differences in postoperative trunk shift and coronal balance were found ($p = .69$ and $p = .74$, respectively). The HD group had higher blood loss ($p = .02$), number of implants ($p < .001$), levels fused ($p = .002$), and surgical time ($p < .001$). The HD group had a higher prevalence of hypokyphosis from before operation to follow-up ($p < .001$). No significant differences were observed in the SRS-30 scores before operation and at 2 years' follow-up. The matched groups had similar preoperative major curves ($p = .56$), ages ($p = .75$), and BMIs ($p = .61$). Significantly longer surgical time ($p = .009$), higher density ($p < .001$), and better correction ($p = .0001$) were found in the HD group at 2 years' follow-up. No significant differences were found in the SRS-30 scores before operation and at 2 years' follow-up. Conclusion: LD constructs included fewer segments fused, lower intraoperative estimated surgical blood loss, and shorter operation time, and potentially decreasing complication risks due to fewer implants. ***Level of evidence III, Retrospective Cohort Study.***

Keywords: Scoliosis. Lenke 1B. Lenke 1C. Adolescent idiopathic scoliosis. Screw instrumentation.

RESUMO

Objetivo: Comparar os desfechos radiográficos e cirúrgicos da escoliose Lenke 1B e 1C. Métodos: Cento e vinte pacientes com escoliose Lenke 1B e 1C foram agrupados de acordo com a densidade do implante, como segue: baixa densidade (BD) de ≤ 1,4 e alta densidade (AD) de > 1,4. Foram analisados os grupos pareados (30 pacientes cada) com base na idade, magnitude da curva e índice de massa corporal (IMC). Os parâmetros radiográficos foram avaliados antes da cirurgia, no pós-operatório imediato (POI) e no acompanhamento de dois anos. O questionário SRS-30 foi administrado antes da cirurgia e no acompanhamento de dois anos. Resultados: As principais curvas dos grupos BD (n = 82) e AD (n = 38) foram respectivamente 59,1° e 65,6° antes da operação ($p < 0,001$), 26,3° e 22,9° no POI ($p = 0,05$) e 29,9° e 19,8° aos 2 anos de acompanhamento ($p < 0,001$). Não foram encontradas diferenças significantes no desvio do tronco e no balanço coronal no pós-operatório ($p = 0,69$ e $p = 0,74$, respectivamente). O grupo AD teve mais perda sanguínea ($p = 0,02$), número de implantes ($p < 0,001$), níveis de fusão ($p = 0,002$) e tempo de cirurgia ($p < 0,001$). O grupo AD teve maior prevalência de hipocifose do período anterior à cirurgia até o acompanhamento ($p < 0,001$). Não houve diferenças significantes nas pontuações do SRS-30 antes da operação e aos 2 anos de acompanhamento. No pré-operatório, os grupos pareados tinham curvas principais ($p = 0,56$), idade ($p = 0,75$) e IMC ($p = 0,61$) semelhantes. Constatou-se tempo cirúrgico expressivamente maior ($p = 0,009$), maior densidade ($p < 0,001$) e melhor correção ($p = 0,0001$) no grupo AD aos 2 anos de acompanhamento. Não foram encontradas diferenças significantes nas pontuações do SRS-30 antes da cirurgia e no acompanhamento de 2 anos. Conclusão: As estruturas de BD incluíram menos segmentos fundidos, menor perda de sangue intraoperatória estimada, menor tempo de cirurgia e menos risco de complicações, com possibilidade de redução, por causa do menor número de implantes. ***Nível de evidência III, Estudo retrospectivo de coorte.***

Descritores: *Escoliose. Parafusos ósseos.*

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INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is a 3-dimensional deformity with a coronal, sagittal, and rotational deformity of the spine that arises in otherwise healthy children. Curves greater than 50° at skeletal maturity may progress over time, resulting in worsening deformity and, in the case of thoracic curves, subtle pulmonary.[1,2] Due to the possibility of curve progression, surgical treatment is typically recommended for deformity greater than 50°, particularly in the skeletally immature patient.[3,4] Pedicle screw instrumentation is currently the preferred method to achieve optimal correction of deformity in AIS.[5] However, preferred instrumentation montage remains controversial because the optimum number and configuration of implants has not been determined.[6-8]

Implant density is defined as the number of implants per level fused. A study group report showed that implant densities varied from 1.04 to 2.0 screws per level, yet the mean percentage of major curve correction was only changed from 64% to 70% .[9]

For the most common type of AIS, the Lenke 1 thoracic deformity, high density (HD) constructs are often utilized for gaining significant correction.[8, 10, 11] For 1A AIS curves, maximum correction has essentially no risk of coronal decompensation postoperatively. However, for 1B and especially 1C patterns, maximum correction enhances the risk of coronal imbalance, and therefore more modest correction to maintain overall trunk balance is usually recommended. Using a lower density (LD) construct with fewer anchor points is one possible technique to counter the tendency for maximum correction with a HD construct.

The purpose of this study was to compare outcomes in Lenke 1B and 1C AIS patients treated by either HD or LD constructs. Our hypothesis was that LD constructs would show no difference in radiographic or surgical outcomes compared to HD constructs, and by virtue of using fewer implants, would decrease operative time and blood loss, potentially reducing risk of complications and costs.

MATERIALS AND METHODS

We reviewed a single institution retrospective database of surgically treated AIS patients with Lenke 1B and 1C curve patterns between 2002 and 2013. Full approval University of Texas Southwestern IRB.

Inclusion criteria were complete radiographic and clinical data preoperatively, immediately after surgery, and at 2-year follow-up, and perioperative surgical data. Outcome measures include radiographic parameters, surgical data, and patient-reported SRS-30 data at follow up.

The study cohort was divided into two groups based on implant density. The low density (LD) group was defined as implants per level less than or equal to 1.4 (Figure 1, 2) and higher density (HD) was defined as greater than 1.4 per level fused (Figure 3, 4). At least 75% of the implants had to be pedicle screws for both cohorts. The relationship between implant density and clinical, radiographic, and surgical variables were investigated. We also analyzed Risser grade data based on the two density groups to determine if Risser grade has an effect on density. Separately, we compared matched subgroups based on preoperative age, curve magnitude, and BMI, created with 30 patients from LD group and 30 from HD group to analyze the relationship between implant density and surgical outcomes.

Statistical analysis using the Mann-Whitney test based on non-parametric measures was performed on the entire study group and the matched subgroups.

RESULTS

One hundred and twenty AIS patients met the inclusion criteria, with 58 Lenke 1C and 62 Lenke 1B curves. There were 107 female and 13 male patients. The mean age at the surgery was 14.3 years (range 9.8-19.1 years). The preoperative mean main thoracic Cobb angle measured 61.2°, corrected to 25.3° postoperatively, and was 28.5° at 2-year follow-up. Overall mean implant density was 1.3 with an average of 9.6 levels fused.

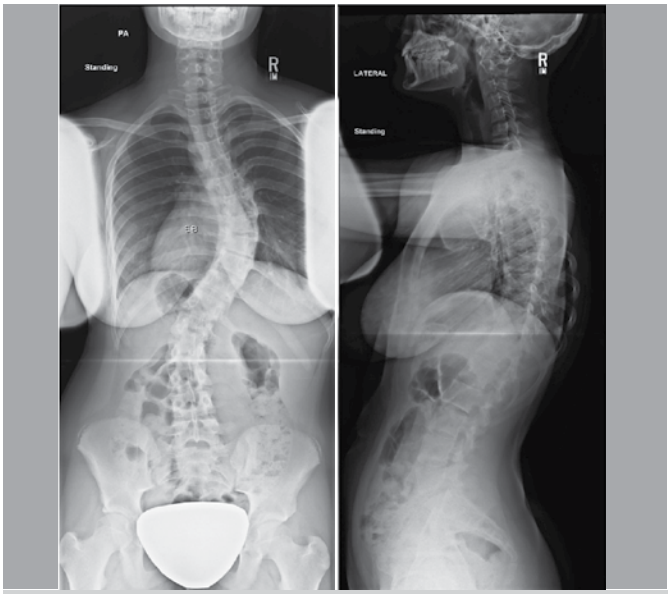

Figure 1. Coronal and sagittal radiographs of a 14 year-old female with 58° preoperatively.

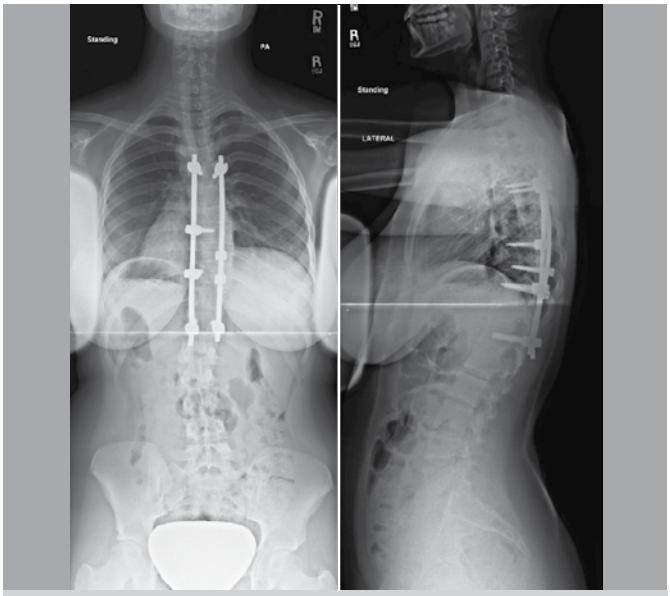

Figure 2. Two-year postoperative radiographs of patient treated with PSF with low implant density, 1.0.

There were 82 patients in the LD group and 38 in the HD group. The mean preoperative major curves of LD and HD groups were 59.1° and 65.6° ($p<0.001$); 26.3° vs. 22.9° ($p=0.05$) at immediately postoperative, and 29.9° vs. 19.8° ($p<0.001$) at 2-year follow up. The HD group had significantly higher major coronal Cobb angle and more correction in major coronal Cobb angle ($p<0.001$). The HD group had a larger preoperative trunk shift ($p=0.02$) than the LD group, but by 2-year follow up, the trunk imbalance difference had resolved (Table 1). There were a larger number of implants per level in the HD group (1.6±0.1 vs 1.1±0.2; $p<0.0001$), and the HD group required one additional level fused (10.2 ± 1.6 vs. 9.3 ± 1.3, $p=0.002$) (Table 2).

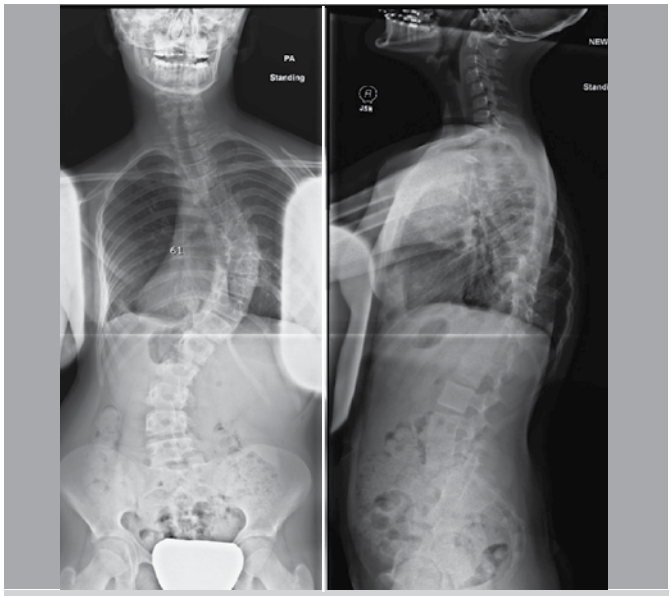

Figure 3. Coronal and sagittal radiographs of a 14 year-old female with 61° preoperatively.

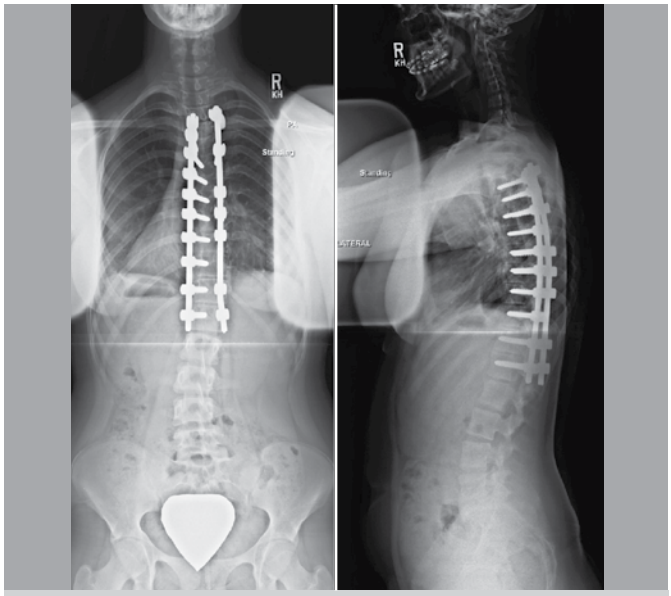

Figure 4. Two-year postoperative radiographs of patient treated with PSF with higher implant density, 1.7.

In the sagittal plane, the HD group had a larger preoperative mean T2-T12 kyphosis ($p<0.01$) and realized greater decrease in kyphosis ($p<0.001$) than the LD group. Consequently there was no difference at follow up in sagittal plane alignment between the groups. There was no difference between LD and HD groups in correction and maintenance of correction of trunk shift and coronal balance ($p=0.69$, $p=0.74$ and $p=0.83$, $p=0.57$) (Table 1).

There was no difference in any of the 5 categories of SRS-30 scores at preop and 2 year follow up (Table 3). There was no correlation between implant density and BMI ($p=0.72$) (Table 4). However, the HD group required significantly longer operative time than the LD group (294 vs 251 minutes, $p<0.001$) and had greater intraoperative blood loss (641 vs. 496 cm^3, $p=0.02$) (Table 2).

The matched subgroups had similar preoperative curve magnitude ($p=0.55$), age ($p=0.75$), BMI ($p=0.61$) and level fused ($p=0.09$)

Table 1. Study Cohort Radiographic Outcomes

	LD	HD	p
Preop Major Curve	59.1 ± 6 (49, 77)	65.6 ± 10.5 (48, 92)	<0.001
2 Year Major Curve	29.9 ± 11.5 (-20, 53)	19.8 ± 16.1 (-44, 44)	<0.001
Δ Major curve: preop &immediate	-32.8 ± 9.5 (-60, -9)	-42.6 ± 12.3 (-68, -15)	<0.001
Preop Coronal Balance	10.7 ± 9.5 (0, 41)	12.5 ± 10.5 (0, 40)	0.42
2-Year Coronal Balance	13.3 ± 11 (0, 50)	12.2 ± 10.1 (0, 38)	0.72
Preop Trunk Shift	15.5 ± 10.2 (0, 39)	20.7 ± 12.1 (1, 47)	0.02
2-Year Trunk Shift	8.9 ± 7.8 (0, 30)	9.6 ± 8.3 (0, 28)	0.84
Preop Kyphosis	27.2 ± 13.9 (1, 65)	34.7 ± 13.6 (7, 61)	0.007
2-Year Kyphosis	34 ± 11.5 (7, 60)	33.3 ± 12.5 (5, 53)	0.93
Δ Kyphosis: preop & immediate	3.3 ± 11 (-24, 24)	-5.6 ± 10.5 (-27, 11)	<0.001

Table 2. Study Cohort Surgical Outcomes

	LD	HD	p
Level fused	9.3 ± 1.3	10.2 ± 1.6	0.002
Total Implants	10.1 ± 2.2	16.4 ± 2.4	<0.001
Implant Density	1.1 ± 0.2	1.6 ± 0.1	<0.001
EBL	496.4 ± 309.1	640.9 ± 381.1	0.02
Operative Time	251 ± 68.1	293.6 ± 73.1	<0.001

(Table 4). The HD group had significantly higher overall number of implants per level (1.6±0.1 vs 1.1±0.2; $p<0.0001$) (Table 5), and achieved greater correction at 2 years (20.7° vs. 31°, $p<0.001$) compared to the matched LD group. HD group were more hypokyphosis from preop to immediate follow-up ($p=0.02$). There was no statistically significant difference between 2 groups' preoperative or 2 year coronal balance or trunk shift (Table 6). However there was a significant difference between operative time (HD 292 minutes vs. LD 252 minutes, $p= 0.008$). HD group had higher mean blood loss than LD group, although this difference was not significant ($p=0.22$) (Table 5). There was no difference in SRS-30 total scores at preop and 2 year follow-up and again Risser grade had no effect on density.

DISCUSSION

Lenke Type 1 thoracic scoliosis is the most common type of AIS deformity. To correct the deformity and to recover the trunk balance is the main goal in the surgical management of AIS patients.[12] Additionally, significant correction has been a desired goal since the introduction of higher density constructs in the 1980's. Several studies confirm that increased implant density of pedicle screw instrumentation is correlated with increased coronal correction.[8,10,11] On the other hand studies of lower-density fixation, such as skipped pedicle screw placement constructs, report this to be an efficient and safe method in management of AIS.[13-17]

Radiologic parameters after AIS surgical treatment do not correlate with clinical outcomes as evaluated by SRS 30 questionnaire scores, confirming that the need for greatest deformity correction is perhaps unfounded. In this study, patients treated with HD instrumentation had larger preoperative

Table 3. SRS scores: Preop vs 2 year follow-up in study cohort and matched groups.

	Study cohort						Matched group					
	Preop			2 Year follow-up			Preop			2 Year follow-up		
	LD	HD	P	LD	HD	P	LD	HD	P	LD	HD	P
Pain	4 ± 0.6	4.1 ± 0.6	0.38	4.2 ± 0.7	4.3 ± 0.5	0.41	3.9 ± 0.6	4.1 ± 0.5	0.25	4.1 ± 0.8	4.4 ± 0.4	0.46
Appearance	3.3 ± 0.6	3.2 ± 0.5	0.44	4 ± 0.7	4.3 ± 0.5	0.16	3.2 ± 0.7	3.3 ± 0.5	0.83	4 ± 0.7	4.3 ± 0.5	0.31
Activity	4.2 ± 0.5	4.1 ± 0.6	0.83	4.2 ± 0.5	4.3 ± 0.5	0.16	4.2 ± 0.6	4.2 ± 0.5	0.98	4.1 ± 0.6	4.4 ± 0.4	0.06
Mental	4.1 ± 0.6	3.9 ± 0.7	0.57	4.2 ± 0.6	4.2 ± 0.6	0.65	3.9 ± 0.6	4.1 ± 0.5	0.37	4.2 ± 0.6	4.2 ± 0.6	0.73
Satisfaction	3.6 ± 0.9	3.6 ± 0.9	0.8	4.4 ± 0.7	4.6 ± 0.5	0.1	4.1 ± 0.8	3.6 ± 0.8	0.44	4.5 ± 0.7	4.6 ± 0.5	0.65
Total Score	3.9 ± 0.4	3.8 ± 0.4	0.73	4.1 ± 0.3	4.3 ± 0.3	0.16	3.8 ± 0.5	3.9 ± 0.3	0.75	4.1 ± 0.3	4.3 ± 0.2	0.1

Table 4. Preop clinical: Study cohort and matched group.

	Study cohort			Matched group		
	LD	HD	p value	LD	HD	p value
Age at surgery	14.4 ± 2	14.1 ± 2	0.47	14.2 ± 2.2	14.3 ± 2.1	0.75
Height	156.8 ± 8.4	157.3 ± 8.6	0.70	154.4 ± 8.7	157.6 ± 8.7	0.17
Weight	54.6 ± 52.5	54.6 ± 16.7	0.82	54.1 ± 14.8	55.6 ± 18.1	0.73
BMI	22.1 ± 20.7	21.9 ± 5.2	0.48	22.5 ± 4.9	22.1 ± 5.7	0.61
Preop, major curve	59.1 ± 6	65.6 ± 10.5	0.00	62.7 ± 7	61.7 ± 7.6	0.55
Total Score	3.9 ± 0.4	3.8 ± 0.4	0.73	4.1 ± 0.3	4.3 ± 0.3	0.16

Table 5. Matched Groups Surgical Outcomes.

	LD	HD	P
Level fused	9.4 ± 1.3	10 ± 1.5	0.09
Total Implants	10.3 ± 2.3	16.1 ± 2.5	<0.001
Implant Density	1.1 ± 0.2	1.6 ± 0.1	<0.001
EBL	486.7 ± 216.2	642.3 ± 420.8	0.23
Operative time	251.7 ± 82.5	292.5 ± 73.6	0.008

Table 6. Matched Group Radiographic Outcomes.

	LD	HD	p
Preop Major Curve	62.7 ± 7 (51, 77)	61.7 ± 7.6 (48, 75)	0.56
2 Year Major Curve	31 ± 15.7 (-20, 53)	20.7 ± 11.8 (-19, 39)	<0.001
Δ Major curve: preop &immediate	-32.8 ± 11.1 (-60, -9)	-39.2 ± 10.9 (-64, -15)	0.02
Preop Coronal Balance	9.9 ± 7.4 (0, 24)	12.7 ± 11.3 (0, 40)	0.52
2-Year Coronal Balance	11.9 ± 9.6 (0, 38)	13.5 ± 11 (0, 38)	0.65
Preop Trunk Shift	16.2 ± 9.6 (2, 37)	18.8 ± 11.4 (1, 47)	0.37
2-Year Trunk Shift	9.9 ± 7.3 (0, 30)	10.7 ± 8.6 (0, 28)	0.87
Preop Kyphosis	26.5 ± 13.9 (1, 57)	32.7 ± 13.3 (7, 56)	0.07
2-Year Kyphosis	33.6 ± 13.1 (8, 60)	32.7 ± 12.9 (5, 53)	0.89
Δ Kyphosis: preop & immediate	2.3 ± 10.2 (-24, 24)	-4.3 ± 10.3 (-27, 11)	0.02

curve magnitudes and achieved more coronal correction and sagittal plane change, consistent with current HD practice, but two year postoperative SRS-30 scores not surprisingly did not demonstrate any differences between LD and HD groups. Increasing implant density in our study had no effect on the SRS-30 outcomes, including appearance and trunk balance parameters.[18]

Thoracic hypokyphosis (THK) is a main feature of the 3-dimensional deformity typical of Lenke 1 AIS patients.[19,20] THK can be exacerbated with further flattening of thoracic contour with pedicle screw instrumentation,[21,22] although the effect of implant density on sagittal contour correction is inconsistent.[11,13] In our study, correcting coronal deformity with HD implant instrumentation generated a lordotic change in sagittal contour at immediate and 2 year follow-up measured from T2-T12, although the absolute thoracic kyphosis at 2-year follow up was within normal limits in the entire cohort as well as the subgroups. This sagittal plane alteration illustrates a commonly-noted effect of greater implant density, an inverse relationship between thoracic curve correction in the coronal and the flattening of the sagittal plane. The effect of marked THK on the respiratory function in AIS has been previously documented.[1,2]

It is generally accepted that increased blood loss and allogeneic transfusion are associated with increased surgical complications. There is also conflicting literature regarding the contributing factors toward increased intraoperative blood loss in the management of pediatric spinal deformity.[23-25] Increased blood loss is frequently associated with larger preoperative Cobb angles, longer fusion constructs, and the addition of osteotomies.[23,25-27] Chang et al. suggested that the use of fewer screws can reduce bleeding and shorten the operative time.[21] We have shown that LD implant instrumentation achieved similar outcomes, as judged by SRS-30 scores (Table 4), as HD constructs, with significantly reduced blood loss and shorter operative time. An additional theoretical advantage of an LD construct is related to the fewer number of pedicle screws to be inserted. Malpositioned screws have been implicated in vascular and neurologic injuries, with up to 1.8-5.1% of screws being malpositioned in pediatric deformity cases.[28] Assuming 10 spinal levels are fused with two screws placed per level, this potentially represents one malpositioned screw per patient.29 While the clinical significance of asymptomatic malpositioned implants remains unknown, reducing the number of implants used decreases the amount of intraoperative radiation for screw placement, and theoretically decreases the potential for malpositioned implants, and thus the potential for revision surgery to correct malpositioning as well as decreasing the risk of vascular or neurologic injury. Finally, although not specifically evaluated in this study, the use of fewer implants can also save cost of surgical management.

In conclusion, we have demonstrated in this single-institution comparison of Lenke 1B and 1C curve patterns treated by either LD or HD constructs that, while the correction achieved in the HD group is greater than that for the LD group, the patient-derived outcomes at 2 year follow up as judged by the SRS-30 scores are no different. Advantages of the LD constructs included fewer segments fused, lower intraoperative blood loss and less operative time, and potentially decreasing complication risks due to fewer implants. Given the equivalent clinical outcomes, a reduction in the number of pedicle screws used for spinal fusion would increase patient safety and surgical efficiency. LD instrumentation was successful in the treatment of AIS with Lenke 1B and 1C patients with satisfactory correction of coronal and sagittal deformity while reducing blood loss and operative time.

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ORIGINAL ARTICLE

POSTEROLATERAL ARTHRODESIS AND INTERBODY ARTHRODESIS FOR LUMBAR CANAL STENOSIS

ARTRODESE POSTEROLATERAL E ARTRODESE INTERSOMÁTICA PARA ESTENOSE DE CANAL LOMBAR

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ABSTRACT

Objectives: To compare the clinical outcomes and quality of life of patients surgically treated for lumbar spinal stenosis with decompression and posterolateral fusion, and decompression with interbody fusion. Methods: The study included 88 patients with lumbar canal stenosis who underwent surgery treatment (decompression and interbody fusion in 36 patients and decompression and posterolateral fusion [PL] in 52 patients). The clinical outcomes were assessed using the Oswestry Disability Index (ODI), Roland-Morris (RM) functional disability scale, and visual analog scale (VAS) for pain. These questionnaires were administered preoperatively and 1 month, 6 months, 1 year, and 2 years postoperatively. Results: Eighty-eight patients had surgery 2 years prior. The ODI and RM scale scores showed significant differences in the posterolateral group. In the interbody group, the ODI score showed a significant change only from before to 1 and 2 years after surgery. The VAS score significantly changed only from before to after surgery in the posterolateral group, but in the interbody group, the change was also observed at 1 month and 1 year after surgery. Conclusions: The two techniques are effective surgical treatment options for lumbar canal stenosis as long as they are well indicated. ***Level of evidence III, Comparative prospective case-control study.***

Keywords: Spinal stenosis. Spinal fusion. Quality of life.

RESUMO

Objetivos: Comparar os desfechos clínicos e a qualidade de vida dos pacientes tratados cirurgicamente de estenose de coluna lombar por descompressão e fusão posterolateral e por descompressão e fusão intersomática. Métodos: O estudo incluiu 88 pacientes com estenose de canal lombar submetidos a tratamento cirúrgico (descompressão e fusão intersomática em 36 pacientes e descompressão e fusão posterolateral [PL] em 52 pacientes). Os desfechos clínicos foram avaliados pelo Índice de Incapacidade de Oswestry (ODI), Questionário de Incapacidade Roland-Morris (RM) e pela escala visual analógica (VAS) para dor. Esses questionários foram administrados no pré-operatório e 1 mês, 6 meses, 1 ano e 2 anos depois da cirurgia. Resultados: Oitenta e oito pacientes foram operados dois anos antes. Os escores do ODI e do questionário RM mostraram diferenças significantes no grupo posterolateral. No grupo intersomático, o escore do ODI mostrou alteração significante somente antes da cirurgia e 1 e 2 anos depois dela. O escore da VAS mudou significativamente só de antes da cirurgia para depois dela no grupo posterolateral, porém, no grupo intersomático, a alteração foi verificada também 1 mês e 1 ano depois da cirurgia. Conclusões: As duas técnicas são opções eficazes de tratamento cirúrgico da estenose de canal lombar, desde que sua indicação seja correta. ***Nível de evidência III, Estudo prospectivo comparativo de caso-controle.***

Descritores: *Estenose espinal. Fusão vertebral. Qualidade de vida.*

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INTRODUCTION

Degenerative joint disease is the leading cause of chronic disability all over the world and usually presents with joint pain, tenderness, stiffness, locking, and effusion.[1] Lumbar degenerative disease is the most frequent and fast growing reason of spinal surgeries on patients over 65 years old, and fusion is often necessary.[2,3] The rate of lumbar fusion increases ten times faster than other orthopaedics procedures like total hip or knee replacement.[2] One consequence of the degeneration is the stenosis. The narrowing of the spinal canal which causes spinal cord compression, or stenosis of the lumbar canal, was first described by Verbiest in 1954.[4] According to the author, the symptoms of the nerve roots compression due to hypertrophy of the articular processes occurred when the patient was in the upright position and mainly walking. Further studies described compression of nervous structures due

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

Study was conducted at the Faculdade de medicina do ABC, Santo André, SP, Brazil.
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to other components such as hypertrophy of the yellow ligament, synovial cyst facet, and loss of height of the intervertebral disc.[5]
Patients with spinal canal compression will complaint of neurogenic claudication with or without radicular pain. When symptomatic patients with stenosis confirmed by imaging, tomography and lumbar MRI, should initially be treated conservatively with physical therapy, pain medication and foraminal injection.[6] Surgical decompression is indicated when conservative treatment fails, when the patient developed cauda equina or progressive motor deficit.[7]
Lumbar arthrodesis is needed when there is instability and can be accomplished through posterolateral fusion (PL), when bone graft is placed between transverse processes, and interbody fusion (IB) technique if the bone graft is put between vertebral bodies. The use of IB fusion is indicated when the origin of pain is the intervertebral disc.[8] The advantages are better support for the anterior column, indirect foraminal decompression, restoration of lordosis and better removal of an important factor pain that is the intervertebral disc. However this technically is more demanding.[9-11] When the source of pain is the facet joint, PL fusion is indicated.[3] This technique is easier to be accomplished and has less complication rate, but generates more pain due to the need for greater exposure and damage to paravertebral muscles.[12] Despite the tendency nowadays to be the use of IB fusion, there are little support in scientific publications for its superiority.[8] Numerous studies comparing the different techniques have very broad satisfactory results ranging from 36 to 95% success rate which leaves the surgeons with no conclusion of the best technique.[13] This study analises the outcome of these two technique for lumbar stenosis and their impact on the quality of life.

OBJECTIVE

To compare the clinical and the quality of life of patients surgically treated for lumbar spinal stenosis with two different techniques: decompression with postero-lateral fusion, and decompression with interbody fusion.

MATERIALS AND METHODS

We was approved by the Medical Ethical Committee of Faculdade de Medicina do ABC (CAAE: 13842913.5.0000.0082). From May 2011 to November 2012, we compared 36 patients who underwent the decompression and interbody fusion (IB) with 52 patients who underwent decompression and postero-lateral fusion (PL). All participants signed the Free and Informed Consent Form.
The inclusion and exclusion criteria and outcome measurements were identical in the 2 groups. All patients had the diagnosis of one-level lumbar canal stenosis in by imaging (plain radiography, dynamic radiography and magnetic resonance of the lumbar spine). They presented neurogenic claudication complaint, functional impairment for more than 6 months and failure of conservative treatment. Exclusion criteria were previous surgery, psychiatric disorders (use of medications for psychiatric disorders or psychiatric monitoring), tumor, infection, myelopathy signs of spinal cord compression.
In both groups the surgeries were performed by two seniors surgeons. All patients were in prone position with general anaesthesia. The incision was longitudinal over the segment affected, confirmed with the aid of fluoroscopy. Posterior decompression, including laminectomy, medial facetectomy, and foraminotomy and pedicle screw fixation were performed in all patients. In the first group, the PL, the graft used was obtained from the lamina removed during surgical decompression. In the IB group, a cage was placed via transforaminal (TLIF), and we used the lamina graft.
During follow-up of patients we used the postoperative generic questionnaires specific for spine surgery, Oswestry Disability Index[14] (ODI) and Roland Morris[15] (RM). To quantify pain we used the visual analogue pain scale (VAS). These questionnaires were performed preoperatively, after one month, 6 months, 1 year and 2 years postoperative.
Analyses were performed using the SPSS - Statistical Package for Social Sciences (v18.0). For comparisons between categories and points in time, we used Bonferroni post hoc tests due to performing multiple tests. The level of significance was set at 0.05 or 5%.

RESULTS

We followed a total of 88 patients for 2 years after surgery. The patients characteristics are showed in Table 1. There were 39 females (44.3%) and 49 males (55.7%). Fifty two (59.1%) patients underwent the PL technique, 27 females and 25 males, and 36 (40,9%) the IB, 12 females and 24 males. The mean age was 60.2 years, 62.4 for PL and 58 for IB technique.
The ODI and RM (Table 2) showed diference in PL group when comparing pre-operative with 6 months, 1 year and 2 years, and 1 month with 6 months, 1 year and 2 years. On the IB group (Table 3) the change was seen only on the comparison of ODI score in pre-operative with 1 year and 2 years, but RM only changed comparing per and post-operative moments.
When compared ODI e RM on the both techniques two year after surgery, there was no statistically significant difference. The graphical representation of the relationship between ODI, RM and their respective time points is shown in the Figure 1 e 2.
The analogue visual scale (Table 2) changed in the PL group comparing pre and postoperative results only, but for the IB group (Table 3) the change was also comparing 1 month and 1 year. In the prospective analysis, there was a progressive decline in average values. Significant differences were observed between the analyzes statistics between different time points of pain. However, the comparative analysis showed in both groups no statistically significant difference between moments when paired observation after six months.

DISCUSSION

The lumbar canal stenosis is the most common cause of low back pain and radicular pain in patients after the fifth decade of life.[2,3] In advanced cases, muscle atrophy, joint instability, or deformity may develop.[1] The arthritic changes in the spinal column (spondylosis) with involvement of the facet joints and intervertebral discs, in

Table 1. Sample Features.

Age (years)		
Mean	60.2	
PL		62.4
IB	58.0	
Total of patients		88
Gender - n (%)		
Masculine	49	(55,7%)
Feminine	39	(44,3%)
Total of patients		88
Gender - n (%) PL technique		
Masculine	25	(48,0%)
Feminine	27	(52,0%)
Total of patients	52	(59.1%)
Gender - n (%) IB technique		
Masculine	24	(66,7%)
Feminine	12	(33,3%)
Total of patients	36	(40,9%)

PL: Posterolateral fusion group. IB: Interbody fusion group.

Table 2. Oswentry, Roland Morris and Visual Analogue Scale questionnaires (posterolateral fusion group).

Set of Variables ODI		Significance (p)		
		RM	VAS	
Pre	1 M	0,022	0,003	< 0,001
	6 M	< 0,001	< 0,001	< 0,001
	1 Y	< 0,001	< 0,001	< 0,001
	2 Y	< 0,001	< 0,001	< 0,001
1 M	Pre	0,022	0,003	< 0,001
	6 M	< 0,001	< 0,001	1,000
	1 Y	< 0,001	< 0,001	1,000
	2 Y	< 0,001	< 0,001	1,000
6 M	Pre	< 0,001	< 0,001	< 0,001
	1 M	< 0,001	< 0,001	1,000
	1 Y	1,000	1,000	1,000
	2 Y	1,000	1,000	1,000
1 Y	Pre	< 0,001	< 0,001	< 0,001
	1 M	< 0,001	< 0,001	1,000
	6 M	1,000	1,000	1,000
	2 Y	1,000	1,000	1,000
2 Y	Pre	< 0,001	< 0,001	< 0,001
	1 M	< 0,001	< 0,001	1,000
	6 M	1,000	1,000	1,000
	1 Y	1,000	1,000	1,000

Pre: Preoperative period; M: Month; Y: Year; ODI: Oswentry Disability Index; RM: Roland Morris; VAS: Visual Analogue Scale.

Table 3. Oswentry, Roland Morris and Visual Analogue Scale questionnaires (interbody fusion group)

Set of Variables ODI		Significance (p)		
		RM	VAS	
Pre	1 M	0,060	< 0,001	< 0,001
	6 M	0,001	< 0,001	< 0,001
	1 Y	< 0,001	< 0,001	< 0,001
	2 Y	< 0,001	< 0,001	< 0,001
1 M	Pre	0,060	< 0,001	< 0,001
	6 M	0,354	0,109	0,160
	1 Y	0,006	0,006	< 0,001
	2 Y	0,008	0,001	0,001
6 M	Pre	0,001	< 0,001	< 0,001
	1 M	0,354	0,109	0,160
	1 Y	0,373	0,483	0,050
	2 Y	1,000	0,131	0,098
1 Y	Pre	< 0,001	< 0,001	< 0,001
	1 M	0,006	0,006	< 0,001
	6 M	0,373	0,483	0,050
	2 Y	1,000	1,000	1,000
2 Y	Pre	< 0,001	< 0,001	< 0,001
	1 M	0,008	0,001	0,001
	6 M	0,198	0,131	0,098
	1 Y	1,000	1,000	1,000

Pre: Preoperative period; M: Month; Y: Year; ODI: Oswentry Disability Index; RM: Roland Morris; VAS: Visual Analogue Scale.

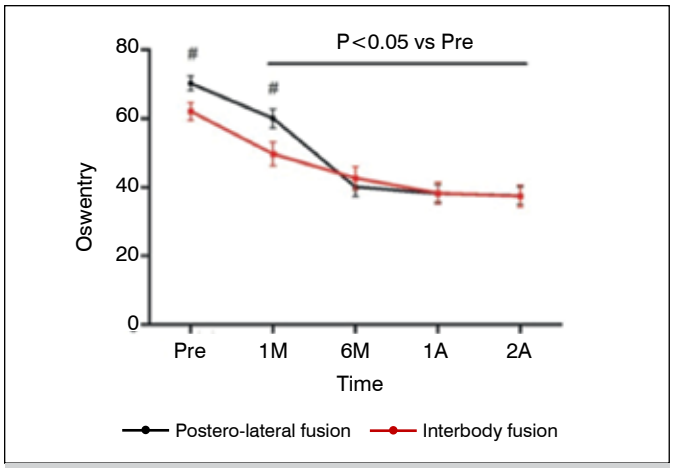

Figure 1.

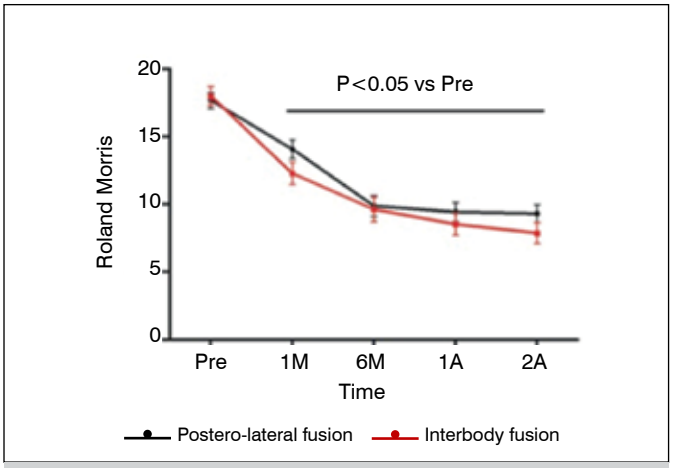

Figure 1.

addition to these common signs and symptoms, may also cause neurologic impingement.[16] When surgical treatment is well indicated there are good clinical outcomes.[17] PL that fuses the transverse processes and facet joint after decompression has been widely applied, and has had good clinical results and union rates.[12] PLIF was introduced to address some disadvantages of PL by replacing the disc with an autogenous bone graft or a cage.[12]

Posterolateral lumbar arthrodesis includes fusion of bilateral transverse processes with fusion rate of 81-100% and clinical success rate of 60-98%. Circumferential fusion has fusion rate varying from 74 to 98% in adult with spondylolisthesis.[18] A multicenter randomized study compared surgical procedures in 211 patients aged 25-65 and showed no significant difference in clinical outcome after two years.[19] Despite the fact that the current study was not randomised, the inclusion and exclusion criteria were the same in both groups. We showed that, regardless of the technique performed, good results were obtained.

The study showed that there was no improvement immediately after the surgery in the PL and IB groups, but after 6 months in the first group and only after 1 year in the second group the difference was seen. The RM results showed improvement at all periods postoperative when compared to the pre op period in the both groups. The ODI and RM are specific questionnaires for postoperative spine surgery. At high levels of disability, the ODI may still show change

when RM scores are maximal, at the other end of the scale, RM scores may still discriminate when ODI scores are at a minimum. Therefore it is recommended to use the ODI in patients who are likely to have persistent severe disability and the RM in patients who are likely to have relatively little disability.[20] Our patients have, in general, very advanced disease due to long waiting list for surgery, witch can explain the more sensitive results in the ODI questionnaire. The VAS scale has shown the patients have less pain after surgery, fulfilling its purpose. In the IB group there is another improvement after 1 year when comparing to 1 month. This observation can be explained by an indirect decompression of the intervertebral foramen to introduce the cage. This theoretical advantage of interbody fusion can be the cause of the pain improvement in the IB group.

CONCLUSION

With this study, we can conclude that the two techniques are effectives options for surgical treatment for stenosis of the lumbar canal, as long as it is well indicated. In both procedures, there was a gradual and statistically significant improvement in questionnaires studied for up to 1 year, with maintenance of the índices at two year followw-up.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of the manuscript. ORN (0000-0002-9873-8876)* and ANM (0000-0001-8679-1859) monitored patients and collected clinical data. AEMC (0000-0002-0148-4372)* and LYJA (0000-0002-8489-5256)* were the main contributors in writing the manuscript and evaluated the data from the statistical analysis. LMRR (0000-0001-6891-5395)* conducted the bibliographic research and revised the manuscript, and contributed to the intellectual conceptualization of the study. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

ROTATION ASSESSMENT IN ADOLESCENT IDIOPATHIC SCOLIOSIS WITH ROD DEROTATION

AVALIAÇÃO DA ROTAÇÃO NA ESCOLIOSE IDIOPÁTICA DO ADOLESCENTE COM DERROTAÇÃO DA HASTE

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ABSTRACT

Objective: Adolescent idiopathic scoliosis (AIS) is characterized by rotational and lateral deformity of the spine. The measurement of vertebral rotation is important for prognosis and treatment. Our objective was to evaluate whether the Nash-Moe method can be used to measure axial deformity correction with surgical treatment using the rod derotation maneuver at both the apex and extremities of the deformity in patients with AIS. Methods: Rotation was assessed using the Nash and Moe criteria, on preoperative and postoperative radiographs. We also evaluated the severity on the coronal plane using the Cobb method, ratio of correction achieved, screw density, and number of vertebrae involved in the instrumentation. Results: The Cobb method correction average was 54.8%. When we disregarded vertebrae that presented preoperative Nash-Moe grade 0, the average measurable correction was 54.5% in the first non-instrumented vertebra above, 69.2% in the first instrumented vertebra, 32.2% in the apical vertebra, 36.8% in the last instrumented vertebra, and 30% in the first non-instrumented vertebra below. In our study, 32.14% of the patients presented a measurable correction in the apical vertebra. Conclusion: On the axial plane, correction can be satisfactorily evaluated using the Nash-Moe method. ***Level of Evidence VI. Case Series.***

Keywords: Scoliosis. Deformity. Spine.

RESUMO

Objetivo: A escoliose idiopática do adolescente é caracterizada por deformidade rotacional e lateral da coluna vertebral. A medição da rotação vertebral é importante para o prognóstico e tratamento. Nosso objetivo foi avaliar se o método de Nash-Moe pode ser usado para medir a correção da deformidade axial com o tratamento cirúrgico usando a manobra de derotação em ambos os ápices e extremidades da deformidade em pacientes com EIA. Métodos: A rotação foi avaliada usando os critérios de Nash e Moe em radiografias pré e pós-operatórias. Também avaliamos a severidade no plano coronal pelo método de Cobb, a razão de correção alcançada, a densidade do parafuso e o número de vértebras envolvidas na instrumentação. Resultados: A correção do método de Cobb foi de 54,8%. Quando desconsideramos vértebras que apresentavam grau 0 no pré-operatório de Nash-Moe, encontramos, em média, 54,5% de correção mensurável na primeira vértebra não instrumentada acima, 69,2% na primeira vértebra instrumentada, 32,2% na vértebra apical, 36,8% na última vértebra instrumentada e 30% na primeira vértebra não instrumentada abaixo. Em nosso estudo, 32,14% dos pacientes apresentaram uma correção mensurável na vértebra apical. Conclusão: No plano axial, a correção pode ser avaliada satisfatoriamente pelo método de Nash-Moe. ***Nível de Evidência VI. Série de casos.***

Descritores: *Escoliose. Deformidade. Coluna.*

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INTRODUCTION

Adolescent idiopathic scoliosis is characterized by rotational and lateral deformity of the spine and no defined pathological cause or process.[1-3] The Cobb angle measurement has been used to quantify the severity of AIS; however, this method is limited to sagittal and coronal plane evaluation. The measurement of vertebral rotation is important for defining the prognosis and treatment.[4] To measure the vertebral rotation, the method of Nash and Moe[5] is commonly used. One of the first forms developed for instrumentation in the surgical treatment of scoliosis was the Harrington system[6]. However, this technique can cause loss of the sagittal curvature.[7] Subsequently, Cotrel et al.[8] developed a system of segmental instrumentation with better correction of the scoliotic curve on both the coronal and sagittal planes. The disadvantages are the increased surgical time and the risk of spinal cord injury.[9] Currently, fixation of the spine using pedicular screws is emphasized because they offers safety, rigidity in assembly and better three-dimensional correction. This procedure is considered a reliable and safe method of instrumentation and preserves mobility with the smallest number of segments submitted to arthrodesis.[10-12]

In 1988, Cotrel et al.[8] described a maneuver that consists of derotating a pre-shaped rod similar to the physiological sagittal curvature,

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Study was conducted at the Orthopedics and Traumatology Institute of HC/FMUSP-São Paulo, Brazil.

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resulting in conversion of the coronal curve into sagittal curvature without additional compression or distraction.[8,13] Suk[12] and Lee et al.[14] described the application of Direct Vertebral Rotation (DVR) to the apical vertebra for correction of the vertebral rotation. This maneuver cannot be performed without pedicular screws and specialized instruments. We use the derotation maneuver to correct scoliotic curves,[8] and do not routinely perform DVR[12] because literature shows that rod derotation affects the deformity on the axial plane, because of the translation of the rotated vertebra.[11,15-18] The objective of the study was to evaluate whether the Nash-Moe method can be used to measure axial deformity correction with surgical treatment using the rod derotation at both the apex and extremities of the deformity in patients with AIS.

MATERIALS AND METHODS

The study was a transversal, retrospective case series, and the sample was selected by convenience by analyzing medical records with imaging exams of patients diagnosed with AIS submitted to surgical treatment at our service from June 2013 to August 2014 with a minimum follow-up of 2 years. The study was approved by the institutional research ethics committee: Comitê de Ética e Pesquisa do Instituto de Ortopedia e Traumatologia do Hospital das Clínicas de São Paulo - CEP/IOT-HCFMUSP - number 1482.353; CAAE: 5472.5216.8.0000.0068. All the participants signed the Free and Informed Consent Form.

The parameters were evaluated based on panoramic orthostatic radiographs as recommended by the Scoliosis Research Society (SRS).[19] Rotation was assessed using the Nash and Moe criteria[5] on pre- and postoperative radiographs.

The following parameters were evaluated with the Nash and Moe method:[5] the last non-instrumented vertebra above the first vertebra of the instrumentation, the first instrumented vertebra, the apical vertebra, the last instrumented vertebra, and the first non-instrumented vertebra below the last vertebra of the instrumentation.

We also evaluated the severity of the scoliotic curve using the Cobb method both pre- and postoperatively, and the ratio of correction achieved. Another parameter included in the evaluation was the screw density across the curve and at the apex of the main curve (considering the 3 vertebrae at the apex of the main curve), in addition to the number of vertebrae involved in the instrumentation and whether there was a correlation between the screw density across the curve and at the apex with greater angular correction.

The inclusion criteria were: patients with AIS diagnoses followed at the outpatient clinic of the Spine Surgery Division; between 10 and 17 years old when submitted to surgical treatment with pedicle screw instrumentation; surgical correction performed using the rod derotation maneuver[8]; and image examinations of good technical quality that included full spine radiographs (front + lateral) before and after surgery. The following exclusion criteria were used: patients with other diagnoses; surgical treatment with other correction techniques; incomplete medical records or imaging tests; patients without 2 years of follow-up. The results of the measurement of vertebral rotation between the radiographs by the Nash-Moe method were compared between the pre- and postoperative periods. To determine whether statistical relationships existed between the data from the pre- and postoperative periods, we used Pearson's chi-square test.

RESULTS

We included 28 patients who met the inclusion criteria, with a predominance of female patients (96.4%) over male patients (3.6%); the mean age at the time of surgical treatment was 14.5 years old. In the preoperative period, the mean value was 78.3° whereas in the postoperative period, the mean value was 36.3°, corresponding to a mean correction of 54.8%. On average, the implant density was 74.6% with a peak density of 62%, and the mean number of vertebrae involved in the instrumentation was 11.9 (Table 1). No correlation existed between the implant density of the scoliotic curve and the degree of correction or between the implant density at the apex of the main curve and the degree of correction.

Regarding the preoperative Nash-Moe grades, grade 0 was found for the non-instrumented vertebra above in 60.7%, grade 1 in 32.1% and grade 2 in 7.1%. The first instrumented vertebra presented grade 0 in 53.6%, grade 1 in 39.3% and grade 2 in 7.2%. The apical vertebra presented grade 1 in 14.3%, grade 2 in 32.1%, grade 3 in 42.9% and grade 4 in 10.7%; no cases with grade 0 were found. The last instrumented vertebra presented grade 0 in 32.1% , grade 1 in 42.9% and grade 2 in 25%, whereas the first non-instrumented vertebra below had grade 0 in 64.3%, grade 1 in 32.1% and grade 2 in 3.6% (Table 2).

Regarding the postoperative Nash-Moe grades, the non-instrumented vertebra above presented degree 0 in 75% and degree 1 in 25%. The first instrumented vertebra presented grade 0 in 67.9% and grade 1 in 32.1%. The apical vertebra showed grade 0 in 3.6%, grade 1 in 25%, grade 2 in 32.1%, grade 3 in 32.1% and grade 4 in 7.1%. The last instrumented vertebra presented grade 0 in 50%, grade 1 in 32.1% and grade 2 in 17.9%, whereas the non-instrumented vertebra below presented grade 0 in 75%, grade 1 in 21.4% and grade 2 in 3.6% (Table 3).

Comparing the Nash-Moe value between the preoperative and postoperative periods relative to the non-instrumented vertebra, when the preoperative grade was 1, 55.6% maintained grade 1, and 44.4% changed to grade 0. In contrast, when the preoperative grade was 2, 100% changed to grade 1 ($p < 0.05$).

Table 1. Characteristics of 27 Female Patients and 1 Male Patient.

	average	Variation	IC 95%
Age	14.5 years	11-17	13.7-15.3
Preoperative Cobb	78.3º	46-121	71.9-84.7
Postoperative Cobb	36.3º	15-73	30.1-42.4
Curve correction	54.8%	29-71	49.7-59.9
Screw Density	74.6%	58-100	70.5-78.6
Screw density at apex	62%	16-100	54.4-69.5
Number of vertebrae involved in arthrodesis	11.9	7-15	11.1-12.7

Table 2. Preoperative Nash-Moe Frequency.

	Nash-Moe				
	0	1	2	3	4
Vertebra not instrumented above	60.7%	32.1%	7.2%	0	0
First instrumented vertebra	53.6%	39.3%	7.1%	0	0
Apical vertebra	0	14.3%	32.1%	42.9%	10.7%
Last instrumented vertebra	32.1%	42.9%	25%	0	0
Vertebra not instrumented below	64.3%	32.1%	3.6%	0	0

Table 3. Postoperative Nash-Moe Frequency.

	Nash-Moe				
	0	1	2	3	4
Vertebra not instrumented above	75%	25%	0	0	0
First instrumented vertebra	67.9%	32.1%	0	0	0
Apical vertebra	3.6%	25%	32.1%	32.1%	7.1%
Last instrumented vertebra	50%	32.1%	17.9%	0	0
Vertebra not instrumented below	75%	21.4%	3.6%	0	0

Regarding the first instrumented vertebra, when the preoperative grade was 1, 63.6% maintained the same degree, and 36.4% changed to grade 0. In contrast, when the preoperative grade was 2, 100% changed to grade 1 ($p < 0.05$).
Regarding the apical vertebra, when the preoperative degree was 1, 75% maintained the same degree, and 25% regressed to grade 0. In contrast, when the preoperative grade was 2, 66.7% maintained the same grade, and 33.3% regressed to grade 1; none regressed to grade 0. When the preoperative grade was 3, 66.7% maintained the same grade, 25% regressed to grade 2, and 8.3% regressed to grade 1. When the preoperative grade was 4, 66.7% maintained the same grade, and 33.3% regressed to grade 3 ($p < 0.05$) (Table 4).
Regarding the last instrumented vertebra, when the preoperative grade was 1, 58.3% maintained the same degree, and 44.7% regressed to grade 0. In contrast, when the initial degree was 2, 71.4% maintained the same grade, 28.6% regressed to grade 1, and none were reduced to grade 0.
Considering the non-instrumented vertebra below, when the preoperative grade was 1, 66.7% maintained the same degree, and 33.3% regressed to grade 0. In contrast, when the preoperative grade was 2, 100% maintained the same grade ($p < 0.05$). In all of the vertebrae evaluated, when the preoperative grade was 0, no change was observed in the postoperative period .
On average, 21.4% of the patients had a measurable correction in the above non-instrumented vertebra, 21.4% of the patients in the first instrumented vertebra, 32.2% in the apical vertebra, 25% in the last instrumented vertebra, and 10.7% in the first non-instrumented below. However, vertebrae with neutral rotation (i.e., Nash-Moe grade 0) were not expected to undergo postoperative correction (Table 5). When we disregarded the vertebrae that presented preoperative Nash-Moe grade 0, we found, on average, 54.5% exhibited a measurable correction in the above non-instrumented vertebra, 69.2% in the first instrumented vertebra, 32.2% in the apical vertebra, 36.8% in the last instrumented vertebra and 30% in the first non-instrumented vertebra below. In all of the vertebrae evaluated, when the preoperative grade was 0, no change was observed in the postoperative period (Table 6). This absence of unexpected response to neutral rotation also contributed to the validation of the method. The correlations were statistically significant, demonstrating that the axial correction promoted by the Nash-Moe method of indirect derotation can be measured.

Table 4. Nash-Moe Correction: Apical Vertebra.

	Post					
Pre	0	1	2	3	4	
0	0	0	0	0	0	
1	1 (25%)	3 (75%)	0	0	0	$p < 0.05$
2	0	3 (33.3%)	6 (66.7%)	0	0	$p < 0.05$
3	0	1 (8.3%)	3 (25%)	8 (66.7)	0	$p < 0.05$
4	0	0	0	1 (33.3%)	2 (66.7%)	$p < 0.05$
Total	1	7	9	9	2	28

Table 5. Number of Vertebrae with a Measurable Correction.

	Relative Correction by Nash-Moe Grade					Total Correction per Vertebra Measured
Preoperative Nash-Moe grade	0	1	2	3	4	
Vertebra not instrumented above	0	44.4%	100%	0	0	21.4%
First instrumented vertebra	0	36.4%	100%	0	0	21.4%
Apical vertebra	0	0	33.3%	33.3%	33.3%	32.2%
Last instrumented vertebra	0	41.7%	28.6%	0	0	25%
Vertebra not instrumented below	0	33.3%	0	0	0	10.7%

Table 6. Number of Vertebrae with a Measurable Correction Excluding Grade 0.

	Relative Correction by Nash-Moe Grade				Total Correction per Vertebra Measured
Preoperative Nash-Moe grade	1	2	3	4	
Vertebra not instrumented above	44.4%	100%	0	0	54.5%
First instrumented vertebra	36.4%	100%	0	0	69.2%
Apical vertebra	0	33.3%	33.3%	33.3%	32.2%
Last instrumented vertebra	41.7%	28.6%	0	0	36.8%
Vertebra not instrumented below	33.3%	0	0	0	30%

DISCUSSION

Kadoury et al.[15] evaluated the degree of scoliosis correction on the three planes of the deformity with a three-dimensional reconstruction model using paired X-rays in AP and profile. Harrington-Luque instrumentation,[6,7] CD indirect derotation[8] and the direct vertebral derotation of Suk were compared, and the results indicated that spinal correction on the coronal plane exhibited the same tendency for the three types of instrumentation. Regarding spinal correction on the sagittal plane, both the CD indirect derotation[8] and third-generation pedicle screws restore the physiological values of thoracic kyphosis and lumbar lordosis. Regarding the axial plane, the technique of indirect derotation with pedicle screws presented 64% correction of the apical vertebra, far superior to the old CD system with hooks: 33% correction. The correction obtained with indirect derotation and pedicular screws was comparable to that obtained with Suk DVR—approximately 74%.[15] Rodrigues et al.[20] used the Nash-Moe method to evaluate the rotational correction of the apical vertebra between the pre- and postoperative periods, and obtained a measurable axial correction in 52.38%. In our study, 32.14% of the patients presented a measurable correction in the apical vertebra. This divergence can be justified by the greater severity of the cases evaluated. While Rodrigues et al. [20] found 62.38° for the thoracic curves and 40.52° for the lumbar curves on average in the preoperative period, our mean value was 78.3°. The significant difference found in the axial correction of the ends of the scoliotic curve might suggest that isolated derotation of the stems is sufficient for the global derotation of the curve. However, if the surgical goal is to achieve more aggressive derotation at the apex of the curve, the aggregate use of DVR maneuvers in the apex region might be important.
Tang et al.[21] prospectively assessed patients undergoing DVR versus indirect derotation using a computed tomography (CT) protocol. They also evaluated clinical criteria using the Spinal Appearance Questionnaire (SAQ) and SRS-22 Questionnaire (SRS-22). Although there was more correction with DVR compared to rod derotation, the difference was not statistically significant and did not result in better clinical results or correction of the hump.[21] Seki et al.[22] evaluated the correction of axial rotation with the stem derotation and DVR techniques using intraoperative tomography. DVR resulted in a slight but significant additional rotational effect in reducing the axial deformity after the initial indirect derotation, but the greater axial correction did not generate better results in the clinical evaluation.[22]

We acknowledge the absence of correlations between the correction obtained and evaluation of quality of life, pain and satisfaction using questionnaires as a limitation of our study.

The Cobb correction was 54.8%, which is comparable to the values obtained by Rodrigues et al.[20]: 61.36% for thoracic curves and 53.66% for lumbar curves. However, these values were lower than those obtained by Hempfing et al.[23] and Gotfryd,[24] which were 71.9% and 74%, respectively. Comparing the preoperative angular value and the absolute angular value correction, we found mean values of 78.3° of preoperative Cobb and 42° of absolute correction, which were higher than those found by Rodrigues et al.,[20] Hempfing et al.[23] and Gotfryd.[24] The greater severity of the cases in our study could justify the lower relative correction.

Regarding the density of implants, we obtained a value of 74.6%, which is superior to that achieved by applying the CD strategic vertebrae concept[8,13,24] (59.9%) and comparable to that of Suk's segmental instrumentation concept[11,12,14,18,24] (80.3%). Currently, the real value of constructions with high implant density is being questioned. Le Naveaux et al.[25] demonstrated that low-density instrumentation with strategically placed screws mainly in the concavity of the curve resulted in correction similar to that of high-density instrumentation. Increasing the number of implants led to limited improvement of the three-dimensional correction and excessive stiffness, increasing the forces on them.[25]

On average, more fused levels were identified in our series (11.9) than those identified in the literature (8.4).[24]

Although CT is becoming a popular method to evaluate the axial deformity of scoliosis, the higher radiation load to which the patient is exposed and the greater added cost must be considered.[4,26] Despite the many advantages of these new technologies, radiographic methods remain the least expensive, safest and most commonly used, serving as baselines for the accuracy of future developments.[4,26] Radiographs are routinely obtained orthostatically, whereas CT is obtained in the supine position, which causes the deformity to appear less severe in terms of both curvature and rotation.[4,26] The Nash-Moe method uses two-dimensional radiography to measure three-dimensional changes. However, it can be performed quickly by both experienced and training surgeons for a safe and inexpensive evaluation of the surgical maneuvers performed.[4,26] Other methods, such as intraoperative tomography, are not available in the majority of spine surgery centers worldwide. Although the Nash-Moe method is less accurate than the Perdriolle method, we chose the former because of its greater applicability and reproducibility.[4,26]

We identified no studies that evaluated the use of the Nash-Moe method for the correction of the curve in the extremities or the apex in patients treated by derotating the rod with segmental instrumentation using pedicular screws. We believe in the effectiveness of this method for spinal axial rotation analysis. Future comparative studies with larger populations may prove the efficacy of this method for the evaluation of pre- and postoperative results on the axial plane.

CONCLUSION

Rod derotation with screw instrumentation and without the use of DVR, as recommended by Cotrel-Dubousset, can correct all three planes of deformity. On the axial plane, the deformity correction can be satisfactorily evaluated using the Nash-Moe method.

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ORIGINAL ARTICLE

RADIATION EXPOSURE DURING SPINE SURGERY USING C-ARM FLUOROSCOPY

EXPOSIÇAO A RADIAÇÃO DURANTE CIRURGIAS DE COLUNA COM RADISOCOPIA

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ABSTRACT

Objective: To evaluate the radiation dose received by staff in spine surgeries, including those who are not considered occupationally exposed workers. Methods: All spinal surgeries performed in the same department during a period of 12 months were evaluated with regard to the exposure of surgeons, scrub nurses, and auxiliary personnel working in the operating room to radiation from C-arm fluoroscopy. Radiation was measured by 15 film badge dosimeters placed on the professionals' lapels, gloves, and room standardized sites. The films were analyzed in the dosimetry laboratory by collections per period. Results: During the 12 months, 81 spinal surgeries were performed by the same team, with surgical times ranging from 1 to 6 hours. The total radiation dose ranged from 0.16 mSv to 2.29 mSv depending on the dosimetry site. The most exposed site was the wrist of the main surgeon. Conclusion: The results showed that in the spinal surgeries in our setting, the radiation doses are low and within legal limits. Nevertheless, constant training of professionals is essential for radiation protection of medical staff and patients. ***Level of evidence I/b, exploratory cohort study.***

Keywords: Radiation. Absorption, Radiation. Radiation, Ionizing. Radiation Exposure. Radiation Dosage. Radiography.

RESUMO

Objetivo: Avaliar a dose de radiação recebida pela equipe cirúrgica em cirurgias de coluna, incluindo entre aqueles que não são considerados trabalhadores com exposição ocupacional. Método: Todas as cirurgias de coluna realizadas num mesmo departamento num período de 12 meses foram avaliadas quanto à exposição dos cirurgiões, enfermeiros/instrumentadores e auxiliares trabalhando na sala cirúrgica à radiação do fluoroscópio tipo "C-arm". A radiação foi medida por 15 dosímetros de filme posicionados nas lapelas, luvas dos profissionais e também em pontos padronizados da sala. Os filmes foram analisados no laboratório de dosimetria em coleções por período. Resultados: Durante 12 meses, 81 cirurgias de coluna foram realizadas pela mesma equipe, e cada cirurgia durou entre 1 e 6 horas. A dose total de radiação variou de 0,16 mSv a 2,29 mSv dependendo do local de mensuração. O local com maior exposição foi o punho do cirurgião principal. Conclusão: Os resultados mostraram que nas cirurgias de coluna no nosso serviço, as doses de radiação foram baixas e dentro dos limites legais. Porém, o treinamento dos profissionais é essencial para a proteção contra a radiação dos profissionais de saúde e seus pacientes. ***Nível de evidência I/b, estudo de coorte exploratório.***

Descritores: *Radiação. Absorção de radiação. Radiação ionizante. Exposição à radiação. Dose de radiação. Raios X.*

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INTRODUCTION

Since Wilhelm Röntgen discovered x-rays in 1895, medicine has been using its benefits for diagnoses and therapy. In recent decades, ionizing radiation has been used more frequently, with the development of new diagnostic and therapeutic techniques.[1] High quality images that allow quick and accurate diagnoses are considered indispensable nowadays in the clinical setting. The use of fluoroscopically-guided techniques in surgery has been increasing, and images in real time are now a vital tool for minimally invasive procedures. The International Commission on Radiological Protection states:

"*Interventional radiology offers to medicine in all countries, no matter the stage of development, the opportunity to treat a greater range of pathologies, in more patients and at lesser cost. Interventional techniques reduce the need for expensive operating suites and extended hospital in-patient admissions. They also reduce most of the risks to the patient by the use of minimally invasive techniques*

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

Study was Spine Surgery Division, Instituto de Ortopedia e Traumatologia, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (IOT-HCFMUSP), São Paulo, Brazil.
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and through lesser requirements for general anesthesia".[2] As a consequence of the increasing use of imaging in the surgical setting, exposure times, and the radiation doses involved with the use of fluoroscopy, have been increasing too.[3]

It is known that frequent exposure to ionizing radiation can cause serious health effects. Therefore, the risk to which individuals are exposed during tasks involving ionizing radiation must be carefully considered by professionals who work with radiology, radiotherapy and nuclear medicine services.[3-5] In relation to the maximum amount of ionizing radiation to be used, there are principles that must be adhered to, in order to protect the patient. However, this dosage limitation does not apply to the exposure of medical staff to radiation. As a result, this exposure can be high in medical diagnosis, when compared with other medical procedures that use ionizing radiation. In fact, imaging exams are now the procedure that most contributes to radiation exposure.[3] But there is a dose-response relationship between exposure to low doses of radiation and mortality, with significant increases in risk observed with doses of 100 to 200 mGy or higher.[6]

Ionizing radiation is used in a large number of procedures carried out in surgery centers. One such procedure is orthopedic surgery using the C-arm fluoroscope. The C-arm is essential in spinal surgeries, to guide the correct execution of the procedure. Despite the use of modern equipment with automatic control systems to limit exposure to radiation, which automatically adjust the voltage (kV), electrical current and exposure time (mAs) to compensate for variations in thickness and density of the tissues being observed, the resulting radiation dose is significant for the patient, and also for the staff involved in the surgical procedures.[3,4]

Some studies have evaluated radiation doses in medical diagnoses and surgical centers, whether for patient, for occupationally exposed individuals (OIEs), or for the whole staff involved in the procedure. The majority of these studies either simulate surgical procedures or carry out the measurements during orthopedic or other procedures, in real time.[7-9] However, there are no studies in Brazil focused on surgeons' exposure to ionizing radiation during surgical operations to the spine.

MATERIALS AND METHODS

This experimental study was conducted in the Spine Surgery Department of a large, public, university hospital in Brazil. The protocol was approved by the local ethics committee and all the participants (surgeons, technicians, nurses and auxiliary staff) involved signed informed consent forms for the radiation dose evaluations and inclusion in the study.

All the spinal surgeries performed in the department over a twelve-month period were evaluated. The same fluoroscopy equipment was used in all the procedures. Radiation film badge dosimeters were attached to fifteen standard sites, and kept in operation throughout the surgery:

1. Standard
2. Surgical center 1 – operating room wall
3. Surgical center 2 – opposite wall of the operating room
4. Below the operating room table
5. Surgeon 1 - attached to the lapel, over the lead apron
6. Surgeon 1 - attached to the lapel, under the lead apron
7. Surgeon 1 - wrist
8. Surgeon 2 - attached to the lapel, over the lead apron
9. Surgeon 2 - attached to the lapel, under the lead apron
10. Surgeon 2 - wrist
11. Instrumentator (scrub nurse) - attached to the lapel
12. Resident - attached to the lapel
13. C-arm operator - attached to the lapel, over the lead apron
14. C-arm operator - attached to the lapel, under the lead apron
15. Auxiliary - in the c arm

The C-arm operator and the surgeons 1 (main surgeon) and 2 (auxiliary surgeon) used two badges attached to the lapel, one over the lead cover and another underneath it, and one attached to the wrist, under the surgical glove. Care was taken to leave the movements of the hands and arms free. Figure 1 shows how the film badge dosimeters were attached to the staff members, and Figure 2 shows the operating room table and the attachment of the dosimeter to the wall.

After each study period, the film badges were developed and analyzed in a radiology laboratory, and the following variables were recorded: date, procedure type and duration, voltage and electrical current of the C-arm, and the distances between the main beam of the C-arm and the professionals. These data were recorded on a filing card, as shown in Figure 3.

RESULTS

During the twelve-month period, 81 spinal surgeries were performed. The mean distances from the professionals to the radiation emission site during the procedures were almost the same in all procedures (Table 1). Table 2 shows data relating to the duration of surgery, and the voltage and electric current registered in the C-arm, which varied according to the type of surgery performed.

The radiation doses recorded in the dosimeter devices over periods ranging from one to three months were grouped and analyzed in the laboratory. The results of each period are presented in Table 3. The total radiation doses varied from 0.16 mSv (under the lead apron) to 2.29 mSv (on the wrist of the main surgeon).

The last column of Table 3 shows the cumulative dose for the entire study period of about a year. The highest estimated dose was indicated for the badge dosimeters placed over the lead cover of surgeons 1 and 2, the professionals who are positioned closest to the primary beam and the patients. In such cases the dose to the professional is lower due to the protection offered by the lead apron, as indicated by the dosimeters positioned below this protective covering.

Figure 1. Attachment of film badge dosimeters to staff member body: A: lapel; B: lapel under lead apron; C: lapel over lead apron; D: inside the surgical glove; E; under sterile surgical glove; F: position on the wrist.

DISCUSSION AND CONCLUSIONS

Exposure to radiation can be a cause of concern in spinal surgeries, which is a complex procedure usually involving six professionals in our service and lasting from one to six hours. Handling the fluoroscope potentially exposes surgeons to a radiation dose higher than the annual recommendation in orthopaedic procedures.[10] A study on different types of surgery using fluoroscopy[11] has shown that the total dose in orthopaedic procedures can reach 2.92 mGy/m^2, with an effective dose of 58.4 mSv. As pointed out by Anupam Mahajan et al., orthopaedic surgeons are not considered as to be workers exposed to radiation, and radiation is usually seen as an additional secondary occupational hazard for them.[12] Still, there are non-surgeon personnel in the operating room, and these should receive monitoring and protection. An experimental study using phantom anthropometric figures and simulating the spinal surgery setting showed that scatter radiation

Figure 2. Operating room bed, under which a film badge dosimeter was placed and the operating room wall with a dosimeter badge attached.

Date	Procedure type	Duration (h: min)	Voltage (kV)	El. Curr. (mA)	Distance (cm)					
					C1	C2	Instr.	Resid.	Oper.	Aux.

C1 = Surgeon 1; C2 = Surgeon 2; INSTR. = Instrumentator (scrub nurse); RESID. = Resident; OPER. = C-arm operator; AUX. = Auxiliary.

Figure 3. Filling card used to record the data.

Table 1. Medium distance from the professionals to the radiation emission site during the procedures.

Professional	Surgeon 1	Surgeon 2	Instrumentist	Resident	C-arm operator	Auxiliary
Distance (cm)	40	40	60	100	100	120

Table 2. Data collected during the procedures. Periods refer to the time taken for each batch of film badges to be taken to laboratory analysis.

Procedure	Duration (h, min)	Electric tension (kV)	Electric current (mA)
Period A: two months			
Scoliosis	1h10'	75	0,9
Scoliosis	0h50'	62	0,7
Lumbar arthrodesis	2h00'	85	0,9
Scoliosis	0h50'	80	0,4
Lumbar arthrodesis	1h10'	90	0,8
Lumbar arthrodesis	1h30'	86	1,4
Lumbar arthrodesis	2h10'	88	1,3
Period B: November, one month			
Lumbar arthrodesis	1h20'	82	1,1
Lumbar arthrodesis	1h35'	86	1,3
Cervical arthrodesis	2h20'	80	2,3
Scoliosis	1h10'	80	1,1
Lumbar arthrodesis	2h10'	92	0,9
Period C: one month			
Infiltration	2h05'	65	1,2
Scoliosis	3h00'	74	1,6
Lumbar arthrodesis	1h30'	104	1,0
Lumbar arthrodesis	3h00'	80	0,9
Infiltration	1h55'	71	1,4
Lumbar scoliosis	1h45'	77	2,1
Period D: one month			
Lumbar arthrodesis	2h40'	86	1,4
Lumbar arthrodesis	1h50'	90	2,4
Cervical arthrodesis	1h20'	75	1,6
Lumbar arthrodesis	2h510'	88	1,8
Period E: one month			
Scoliosis	3h10'		
Lumbar arthrodesis	2h10'	70	2,0
Lumbar arthrodesis	1h55'	78	1,8
Period F: two months			
Lumbar arthrodesis	1h30'	104	1,0
Lumbar arthrodesis	3h00'	80	0,9
Scoliosis	3h30'	90	1,2
Lumbar arthrodesis	3h00'	72	2,0
Scoliosis	3h30'	-	-
Scoliosis	2h00'	-	-
Scoliosis	1h30'	-	-
Period G: three months			
Cervical arthrodesis	5h00'	80	4,0
Scoliosis	6h40'	50	1,3
Cervical arthrodesis	1h00'	80	4,0
Lumbar arthrodesis	0h50'	104	0,7
Arthrodesis I	1h05'	101	0,7
Arthrodesis I	3h00'	70	2,0
Scoliosis	4h00'	104	0,8
Cervical arthrodesis	4h00'	80	1,6
Scoliosis	4h00'	88	3,6
Lumbar arthrodesis	3h30'	82	3,2
Lumbar arthrodesis	5h00'	95	3,2
Lumbar arthrodesis	2h00'	90	3,6
Cervical arthrodesis	3h00'	68	2,0
Scoliosis	4h00'	88	3,6
Cervical arthrodesis	2h40'	60	2,8
Cervical arthrodesis	1h40'	60	2,0
Scoliosis	2h00'	60	2,6
Lumbar arthrodesis	2h00'	65	3,0
Lumbar arthrodesis	3h30'	101	1,6
Cervical arthrodesis	5h00'	71	3,0
Scoliosis	3h00'	70	1,4
Scoliosis	4h00'	105	2,4
Scoliosis	4h00'	76	2,7
Lumbar arthrodesis	3h30'	109	7,1
Cervical arthrodesis	3h30'	60	1,4
Lumbar arthrodesis	3h00'	70	3,2
Scoliosis	4h00'	70	2,0
Period H: two months			
Lumbar arthrodesis	3h30'	48	2,4
Lumbar arthrodesis	1h10'	90	2,4
Lumbar arthrodesis	2h30'	62	3,4
Cervical arthrodesis	4h00'	65	2,4
Cervical arthrodesis	2h00'	70	1,6
Scoliosis	2h30'	84	5,6
Lumbar arthrodesis	2h20'	76	2,1
Cervical arthrodesis	4h00'	64	1,8
Scoliosis	3h00'	74	1,6
Lumbar arthrodesis	1h30'	70	1,6
Lumbar arthrodesis	3h30'	76	4,0
Lumbar arthrodesis	4h00'	70	1,6
Decompression	5h30'	76	2,4
Scoliosis	5h00'	74	1,6
Lumbar arthrodesis	3h30'	76	2,4
Lumbar arthrodesis	3h30'	82	3,0
Lumbar arthrodesis	4h00'	80	2,6
Scoliosis	4h30'	80	2,0
Lumbar arthrodesis	4h30'	80	2,6
Scoliosis	6h00'	70	4,5
Cervical arthrodesis	3h30'	81	4,0
Lumbar arthrodesis	3h30'	70	4,0
Lumbar arthrodesis	3h30'	82	3,0

Table 3. Results from radiation doses measurements per period (as indicated in Table 2); periods refer to the time taken for each batch of film badges to be taken to laboratory analysis.

Professional	Dose (mSv) per period								
	A	B	C	D	E	F	G	H	Total
Standard	-	-	-	-	-	-	-	-	-
Surgical center 1 – operating room wall	0.06	0.03	-	-	-	-	0.08	-	0.17
Surgical center 2 – operating room wall	-	-	0.05	0.03	-	-	0.09	0.11	0.28
Below patient bed	-	-	-	0.8	0.44	-	0.19	-	1.43
Surgeon 1 - attached to the lapel, over the lead apron	0.15	0.13	0.05	0.08	0.03	0.05	0.41	0.29	1.19
Surgeon 1 - attached to the lapel, under the lead apron	0.02	-	0.02	-	-	-	0.03	0.09	0.16
Surgeon 2 - attached to the lapel, over the lead apron	0.02	0.07	0.05	0.21	0.06	-	0.29	0.12	0.82
Surgeon 2 - attached to the lapel, under the lead apron	0.02	-	0.02	0.04	-	-	0.06	0.60	0.74
Instrumentator (scrub nurse)	-	-	-	-	0.02	-	0.09	0.12	0.23
Resident	0.06	-	0.02	-	-	-	0.09	0.10	0.27
C-arm operator - attached to the lapel, over the lead apron	0.06	-	0.02	0.09	-	-	0.04	0.08	0.29
C-arm operator - attached to the lapel, under the lead apron	-	-	-	-	-	0.03	0.04	0.09	0.16
Auxiliary	-	-	-	-	0.07	-	0.13	0.04	0.24
Surgeon 1 - wrist	1.43	-	-	0.81	-	-	-	0.05	2.29
Surgeon 2 - wrist	0.10	-	-	0.35	0.07	0.02	0.02	0.03	0.59

Doses not mentioned are below the minimum detectable level (0.02 mSv).

doses decreased as distance from the patient increased during the use of C-arm fluoroscopy. The study showed that the distance between the patient and the C-arm configuration, among other factors, could reduce radiation exposure during intraoperative use of the C-arm.[13] The position of the professional can also significantly alter the radiation exposure,[14] and the radiation dose may differ between the first assistant, the theatre nurse and the anesthesiologist, who might be exposed to higher radiation doses than the surgeon.[15] In our study, we measured exposure to radiation in a real setting: the operating room during spinal surgeries, with real professionals at work, and we carefully evaluated the distances and the different measurement sites. It seems that in our setting, the exposure to radiation is below the legal requirements. The wrist badge dosimeters evidenced that the radiation dose in our surgeons' hands is also well below the maximum limit of 500 mSv per year.[3,4,16,17]

Analysis of the radiation dose registered by the film badge dosimeters, giving the estimated radiation to which staff are exposed, showed that there were no cases in which the values were above the level stipulated as total tolerated levels for an individual (1,5 mSv).[3,4] The doses to which all professionals were exposed in this study were slightly above the natural radiation levels in the environment, but far below the maximum dose allowed by local law (20 mSv as a five-year average).[3,4,16,17]

The results show that in this type of medical procedure, and under these study conditions, the resulting doses are low and the recommended limits were respected. Nevertheless, continual training of professionals is essential to ensure that medical staff and patients are protected against radiation.

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ORIGINAL ARTICLE

VALIDITY AND RELIABILITY OF THE MANCHESTER SCALE USED IN THE ORTHOPEDIC EMERGENCY DEPARTMENT

VALIDADE E CONFIABILIDADE DA ESCALA DE MANCHESTER APLICADA NO PRONTO-SOCORRO ORTOPÉDICO

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ABSTRACT

Objectives: To describe the clinical utility of the Manchester triage scale adapted for orthopedic emergency departments and to evaluate its validity in identifying patients with the need for hospital care and its reliability when reproduced by different professionals. Methods: Five triage flowcharts were developed based on the Manchester scale for the following orthopedic disorders: traumatic injuries, joint pain, vertebral pain, postoperative disorders, and musculoskeletal infections. A series of patients triaged by two orthopedists was analyzed to assess the concordance between the evaluators (reliability) and the validity of the Manchester scale as predictive of severity. Results: The reliability analysis included 231 patients, with an inter-observer agreement of 84% (Kappa = 0.77, p <0.001). The validity analysis included 138 patients. The risk category had a strong association with the need for hospital care in patients with trauma (OR = 6.57, p = 0.001) and was not significant for non-traumatic disorders (OR = 2.42; p = 0.208). The overall sensitivity and specificity were 64% and 76%, respectively. Conclusion: The evaluated system presented high reliability. Its validity was adequate, with good sensitivity for identifying patients requiring hospital care among those with traumatic lesions. However, the sensitivity was low for patients with non-traumatic lesions. ***Level of Evidence III, Retrospective Study.***

Keywords: Triage. Classification. Risk. Orthopedics.

RESUMO

Objetivos: Descrever a utilização clínica da escala de triagem de Manchester adaptada ao pronto-socorro ortopédico e avaliar sua validade para detectar pacientes com necessidade de cuidados hospitalares e sua confiabilidade quando reproduzida por diferentes profissionais. Métodos: Cinco fluxogramas de triagem foram desenvolvidos com base na escala de Manchester: lesões traumáticas, dor articular, dor vertebral, transtorno pós-operatório e infecção musculoesquelética. Uma série de pacientes triados por dois ortopedistas foi analisada para avaliação da concordância entre os avaliadores (confiabilidade) e sua validade como preditivo de gravidade. Resultados: A avaliação da confiabilidade incluiu 231 pacientes, com concordância inter-observadores de 84% (Kappa = 0,77; p <0,001). A análise da validade incluiu 138 pacientes. A classificação de risco apresentou forte associação com a necessidade de cuidados hospitalares em pacientes com trauma (OR = 6,57; p = 0,001), não sendo significativa nos transtornos não-traumáticos (OR = 2,42; p = 0,208). A sensibilidade geral foi de 64% e a especificidade de 76%. Conclusão: O sistema avaliado apresentou alta confiabilidade. Sua validade foi adequada, com boa sensibilidade para detectar pacientes com necessidade de procedimentos hospitalares em lesões traumáticas, enquanto a sensibilidade foi baixa em pacientes com lesões não-traumáticas. ***Nível de Evidência III, Estudo Retrospectivo.***

Descritores: *Triagem. Classificação. Risco. Ortopedia.*

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INTRODUCTION

Triage systems aim to identify patients with severe conditions who need urgent management, prioritizing their care in emergency departments. Hospital accreditation bodies have required the implementation of clinically validated triage systems in emergency departments. Long waiting times have been associated with greater morbidity in patients who need urgent attention.[1]

Most triage systems used in practice are based on a five-level risk model whose application ideally takes place within a short interval from the arrival of the patient at the emergency department.[2] The Australasian Triage Scale, Canadian Triage and Acuity Scale, Emergency Severity Index, and Manchester Triage System (MTS) are the most commonly cited in the literature, with studies reporting adequate overall validity and reliability.[2-7] The Manchester system is one of the most widely used in practice[8] and includes 52 flow charts for various clinical conditions, including some orthopedic disorders, such as back pain, local infections, and trauma.[9] Some studies have reported specific

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Study was conducted at the Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo (IOT-HCFMUSP), São Paulo, SP, Brazil.
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systems for orthopedic triage in outpatient services,[10,11] but not in emergency departments.

This study aimed to develop a triage scale based on the Manchester system adapted to orthopedic management and to evaluate the scale for inter-examiner agreement (reliability) and validity in detection of higher severity clinical conditions.

MATERIALS AND METHODS

The Manchester system divides orthopedic disorders into five groups: traumatic injuries, joint pain, vertebral pain, postoperative disorder, and musculoskeletal infection. A flow chart was developed for each group based on severity criteria, including pain level assessed with the visual analog scale (VAS), infectious signs, presence of deformity or bleeding, and time of appearance of symptoms, among others (Attachments 1 to 5). The flow charts were adapted from corresponding charts in the Manchester scale.[9] The urgency categories (assigned risk) and the maximum waiting time were standardized according to the MTS (immediate: 0 minutes; very urgent: 10 minutes; urgent: 60 minutes; routine: 120 minutes; non-urgent: 240 minutes). This study was approved by the institutional ethics committee (protocol number 1,127; registration number: 13,611).

Reliability was evaluated prospectively for this study. For seven days, all patients treated in our emergency department were triaged by two physicians: initially by an orthopedic physician of the emergency room staff (attending physician), and later by a third-year resident physician. The evaluations were carried out in separate rooms to avoid evaluation bias. The evaluation of the attending physician was used to define the patient flow after triage. Examiner agreement was calculated using the kappa coefficient. This analysis included all patients aged ≥18 years who were evaluated by both physicians, regardless of follow-up after triage.

Validity was evaluated retrospectively by analyzing the data from the medical records of patients triaged in the period described. A list of clinical outcomes considered relevant within each group was defined, and medical records were evaluated to detect patients who had one or more outcomes after triage. The association between the risk assigned to the patient and the presence of a clinical outcome was analyzed using logistic regression to evaluate the validity of the scale. Patients with incomplete medical records whose clinical course could not be identified were excluded from this analysis. Among the clinical outcomes evaluated, the need for hospitalization and the need for surgical treatment were included in all groups of injuries. The outcomes specific to each group included:

Traumatic injuries: radiographic diagnosis of fracture or dislocation, with the need for reduction or immobilization;

Joint pain: definitive diagnosis of septic or aseptic arthritis, with the need for joint puncture or intravenous analgesia;

Vertebral pain: clinical or radiological diagnosis of fracture, tumor, infection, or radiculopathy, with the need for intravenous analgesia or hospitalization;

Postoperative disorder: clinical or laboratory diagnosis of postoperative infection, implant failure, or release, requiring intravenous analgesia or hospitalization

Musculoskeletal infection: laboratory and/or radiological diagnosis of septic arthritis or osteomyelitis, with the need for intravenous antibiotic therapy.

In the statistical analysis, the triage categories were evaluated separately and grouped as follows: "high priority" (very urgent and urgent categories) and "low priority" (routine and non-urgent categories). The association between the category and the presence of a clinical outcome was calculated using univariate logistic regression analysis and the chi-square test or Fisher's test according to the number of observations in each group. The sensitivity and specificity of the scale were calculated, in addition to the undertriage rate (number of patients with negative outcomes who were classified as "high priority" divided by the total number of patients classified as "high priority") and overtriage rate (number of patients with positive outcomes classified as "low priority" divided by the total number of patients). The sample size was determined according to the number of patients observed during the study period. Stata Software 13.0 (Stata Corp, College Station, TX, USA) was used for statistical analysis.

RESULTS

The reliability analysis included 231 patients with the following distribution: traumatic injuries: 106 patients (46%); joint pain: 58 (25%); vertebral pain: 49 (21%); postoperative disorder: 14 (6%); and musculoskeletal infection: 4 (2%). The validity analysis included 138 patients. The mean age was 42.2 years, with the same number of male and female patients.

The analysis of risk distribution showed that patients with traumatic injuries were almost equally classified as "high priority" (very urgent = 25%, urgent = 27%) and "low priority" (routine = 43%; non-urgent = 5%). In contrast, patients with joint pain and vertebral pain were mostly classified as "low priority" (93% and 84%, respectively). Patients with postoperative disorders and musculoskeletal infections were almost equally distributed, based on a limited number of cases (Table 1). The inter-examiner agreement varied among the groups: traumatic injuries: 84%; joint pain: 88%; vertebral pain: 76%; postoperative disorder: 93%; and infection: 75%. The overall reliability was 84%, with a kappa coefficient of 0.77 ($p < 0.001$).

The validity analysis of the overall sample showed a statistically significant association between the assigned risk and the presence of a clinical outcome, both in the individual and grouped categories (odds ratio [OR] = 5.71; confidence interval [CI] 95% = 2.60 to 12.54, $p < 0.001$). Similarly, the analysis of traumatic injuries showed a statistically significant association between the assigned risk and the presence of a clinical outcome, both in the individual (OR = 0.29; 95% CI = 0.15 to 0.59; $p = 0.001$) and grouped categories (OR = 6.57; 95% CI = 2.16 to 20.03, $p = 0$, 001). The analysis of non-traumatic injuries did not show a statistically significant association between the assigned risk and the presence of an outcome, both in individual and grouped categories (OR = 2.42; 95% CI = 0.61 to 9.58; $p = 0.208$) (Table 2).

Table 1. Urgency levels assigned by the attending and resident physicians to patients evaluated in the study according to the pathology group.

	Very Urgent	Urgent	Routine	Non-urgent
Trauma (n = 106)				
Attending	26 (25%)	29 (27%)	46 (43%)	5 (5%)
Resident	28 (26%)	29 (27%)	42 (40%)	7 (7%)
Joint pain (n = 58)				
Attending	1 (2%)	3 (5%)	24 (41%)	30 (52%)
Resident	0	5 (9%)	23 (40%)	30 (52%)
Vertebral pain (n = 49)				
Attending	0	8 (16%)	21 (43%)	20 (41%)
Resident	0	8 (8%)	29 (60%)	16 (33%)
Postoperative period (n = 14)				
Attending	2 (14%)	4 (29%)	7 (50%)	1 (7%)
Resident	2 (14%)	4 (29%)	6 (43%)	2 (14%)
Infection (n = 4)				
Attending	0	2 (50%)	1 (25%)	1 (25%)
Resident	1 (25%)	2 (50%)	1 (25%)	0
TOTAL (n = 231)				
Attending	29 (13%)	46 (20%)	99 (43%)	57 (25%)
Resident	31 (13%)	44 (19%)	101 (44%)	55 (24%)

Table 2. Patients with clinical outcomes divided according to the pathology group and the risk assigned.

	Very Urgent	Urgent	Routine	Non-urgent	P-value
Trauma (n = 29)	11 (38%)	12 (41%)	6 (21%)	0	0.002
Non-traumatic (n = 13)					
Joint pain (n = 6)	0	0	4 (67%)	2 (33%)	0.779
Vertebral pain (n = 5)	0	2 (40%)	1 (20%)	2 (40%)	0.185
Postoperative (n = 0)	0	0	0	0	-
Infection (n = 2)	0	2 (100%)	0	0	-
TOTAL (n = 42)	11 (26%)	16 (38%)	11 (26%)	4 (10%)	< 0.001

The sensitivity of the scale in the overall sample was 64% (95% CI = 48% to 78%) and specificity was 76% (95% CI = 66% to 84%). For traumatic injuries, sensitivity was 79% (95% CI = 60% to 92%) and specificity was 63% (95% CI = 46% to 78%), while in non-traumatic injuries, sensitivity was 31% (95% CI = 9% to 61%) and specificity was 85% (95% CI = 73% to 93%). The overtriage rate was 38% in patients with traumatic injuries and 69% in patients with non-traumatic injuries, while the undertriage rate was 9% in patients with traumatic injuries and 13% in patients with non-traumatic disorders.

DISCUSSION

The scale presented in this study is an alternative to orthopedic emergency services that evaluate pre-care risk. With the data from this study, we confirmed the high reliability of the adapted Manchester scale, demonstrating good reproducibility when used by different professionals. We also demonstrated adequate validity for identification of patients with severe traumatic injuries. The scale had low sensitivity for non-traumatic injuries, and its validity could not be demonstrated in this group of pathologies, which can be partially explained by the method chosen for validation. Despite this shortcoming, the scale proved to be easy to use in clinical practice, based on objective criteria for the classification of patients and guiding of flow in the emergency room.

The reliability, or reproducibility, of a classification scale and any diagnostic test represents its ability to produce consistent results when used independently.[12] A risk scale with good average validity but low reliability produces dispersed results, with little clinical use.[12] The scale described in this study showed a good agreement rate (84%; kappa = 0.77) according to previously established criteria.[13] Van der Wulp et al. reported consistent reliability (kappa = 0.62) using the MTS in a general population, but did not find an association between the experience of nurses and system reliability.[5] Van Veen et al. observed high reliability (kappa = 0.83) when using the Manchester system for the triage of children using written case scenarios.[14]

The validity of a diagnostic test should be ideally evaluated by comparing it to a gold standard. However, in the absence of this test, substitute markers are used as references.[12] In our study, we used markers indicating two types of outcomes: the definitive diagnosis of orthopedic pathology and the need for hospital care or procedures. Although they are clinically relevant outcomes, their severity was not considered, which may have influenced the validity analysis of the scale. In the groups of non-traumatic disorders, patients who developed a clinical outcome (N = 13) were mostly underdiagnosed (N = 9) and classified as "low priority," which is related to the low sensitivity of the scale in these groups of pathologies. The presence of mild clinical signs in patients requiring procedures may explain this incongruence (e.g., patients with joint effusion and low pain level who underwent joint puncture). Parenti et al. conducted a systematic review on the validity and reliability of the MTS scale, showing low safety of the method due to a high undertriage rate and low sensitivity to identify higher levels of urgency.[7] Our findings on non-traumatic injuries corroborate these data.

The undertriage rate of a risk scale evaluates its ability to detect patients with greater urgency correctly and is inversely proportional to their sensitivity.[15] A high undertriage rate means that patients who need urgent care are not detected, and is related to low sensitivity of the method. Ideally, undertriage rates should be less than 5%.[15] However, most studies validating risk scales show values 5%.[7] In the present study, the undertriage rate in traumatic injuries was 9% and sensitivity was 79%, which are considered adequate for clinical use. Roukema et al. reported an undertriage rate of 15% and a sensitivity of 63% when using the Manchester scale. In the assessment of emergency conditions in pediatric patients[16] with non-traumatic injuries, our data showed low sensitivity (31%) for the identification of patients with clinical outcomes and an undertriage rate of 13%. As already mentioned, this shortcoming may be related to the method used in validation, but we cannot rule out failure of the scale to identify patients with greater severity, as shown in previous studies that evaluated the Manchester system in different scenarios.[7]

The overtriage rate of a diagnostic test represents the percentage of patients who do not have emergency conditions but are mistakenly classified as priority. A high overtriage rate overloads the emergency department, and may impair the care of patients with a true emergency. Ideally, overtriage rates should vary between 25 and 50%.[15] In our study, the overtriage rate for traumatic injuries was 38% and specificity was 63%; these are within the appropriate range for clinical use. In non-traumatic injuries, the overtriage rate was 69% and the specificity was 85%. Storm-Versloot et al. reported a 29% overtriage rate and great variability in the specificity of MTS, showing lower values at lower levels of urgency (level 1 = 100%; 2 = 95%; 3 = 66%; and 4 = 2%).[17] Other studies showed significant variability in sensitivity and specificity when the MTS scale was used in different scenarios according to the assigned urgency levels.[5,18-20]

This study had some limitations. Retrospective validity evaluation involved a significant loss of patient follow-up and incomplete medical records data, resulting in a limited number of cases. This may have influenced the outcome of scale validation. Specifically, the "postoperative disorder" and "musculoskeletal infection" groups had few cases, preventing adequate data analysis. As noted, comparison with a gold standard would be more appropriate for validation, and the use of clinical markers may have generated inconsistencies. In most studies, triage was performed by nurses. In our study, triage was performed by orthopedic physicians, which may limit the generalization of the data.

In conclusion, this study presented a triage system based on the Manchester system adapted to orthopedic scenarios. The system showed high reliability when used by different professionals and was efficient in detecting patients with traumatic injuries who needed hospital care. The system had low sensitivity for detecting patients with non-traumatic injuries who required hospital care. These findings do not preclude the use of the Manchester system in the orthopedic emergency department, but greater attention should be given to avoid undervaluing the clinical presentation of patients with non-traumatic injuries.

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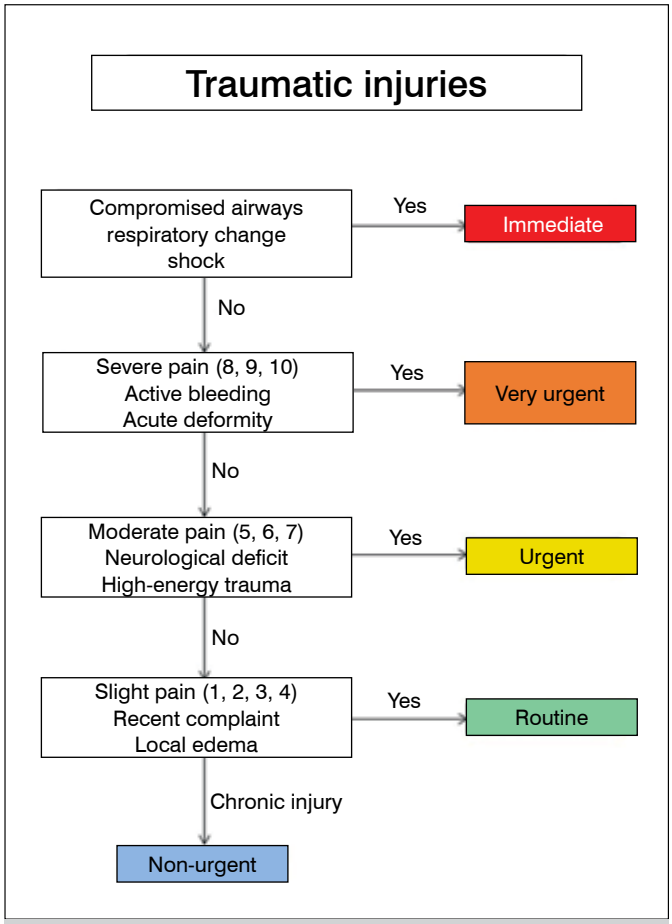
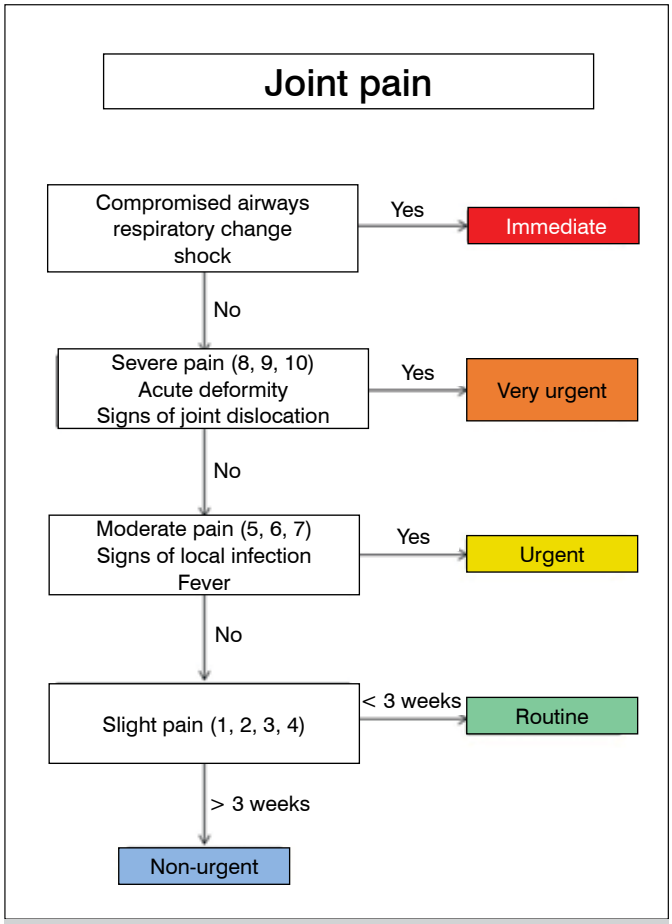
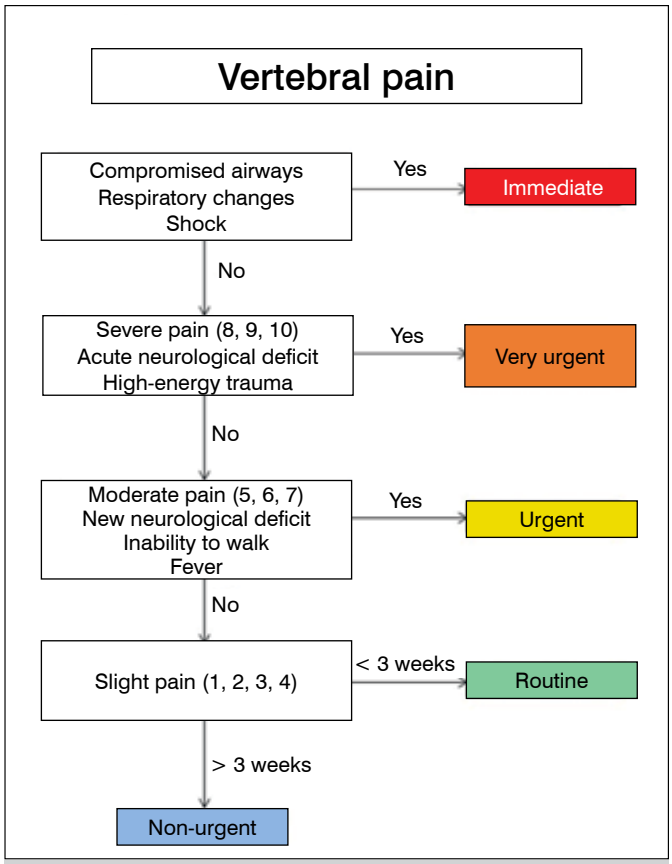


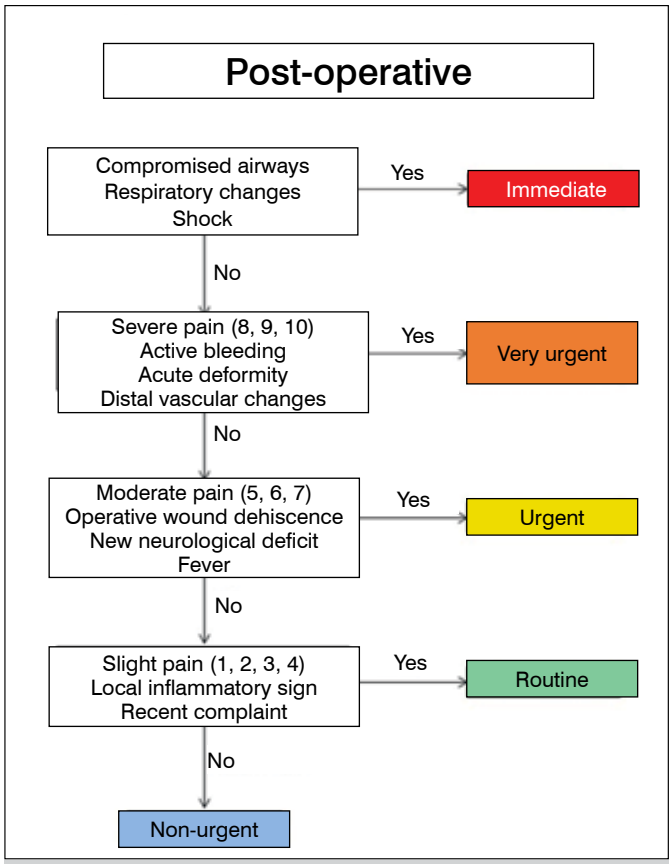
Annex 1. Triage flow chart - Traumatic injuries.



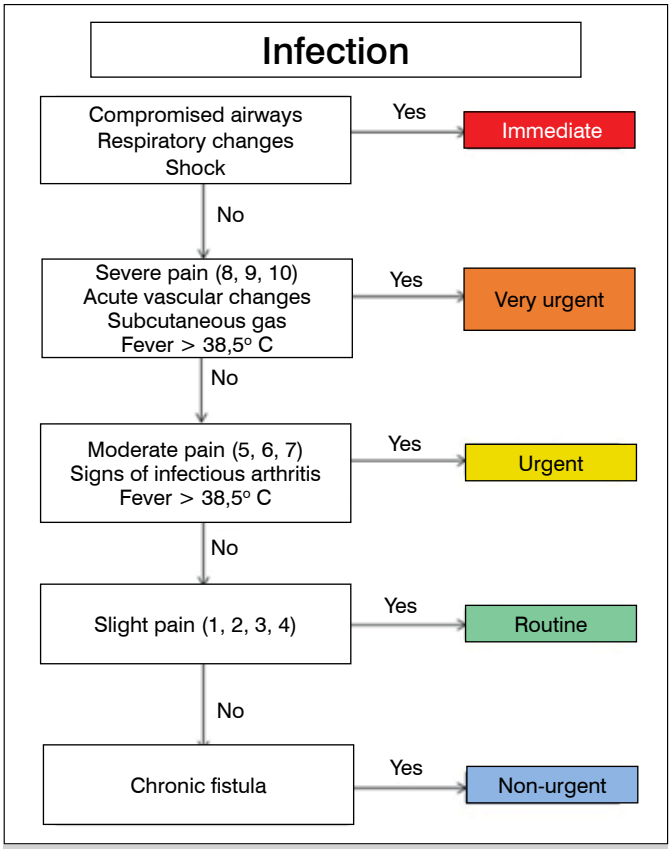
Annex 2. Triage flow chart - Joint pain.



Annex 3. Triage flow chart - Vertebral pain.



Annex 4. Triage flow chart - Postoperative disorder.



Annex 5. Triage flow chart - Musculoskeletal infection.

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CLINICAL EVALUATION OF PATIENTS WITH VANCOMYCIN SPACER RETAINED FOR MORE THAN 12 MONTHS

AVALIAÇÃO CLÍNICA DE PACIENTES COM ESPAÇADOR DE VANCOMICINA RETIDO POR MAIS DE 12 MESES

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ABSTRACT

Objective: There is no consensus in the literature regarding the time taken to remove antibiotic spacers in the treatment of bone infections. The aim of this study is to evaluate the clinical results of patients with prolonged retention of the same. Methods: Patients selected were diagnosed with post-osteosynthesis infection and/or osteomyelitis and were submitted to treatment using an orthopedic cement spacer (polymethylmethacrylate) with vancomycin, retaining it for a period of more than 12 months. They were clinically evaluated to determine the presence of local or systemic infectious signs via hemogram, investigations of inflammatory markers, liver, renal and, with radiographic control. Results: Eighteen patients were included in the study. The mean retention time of the spacer was 30.4 months (15 - 61 months). No patient had clinical signs of local or systemic infectious relapse at the time of evaluation. Seven patients (39%) presented non-disabling pain in the operated limb. Seventeen patients (94%) presented a reduction in C-reactive protein values compared to the preoperative period. Radiographically, no migration, no spacer failure, or bone sequestration occurred. Conclusion: In this retrospective case series, cement spacer retention with vancomycin for more than 12 months was associated with good clinical results, without relapse of the infectious condition. ***Nível de Evidência IV. Estudos Terapêuticos - Investigação dos Resultados do Tratamento.***

Keywords: *Osteomyelitis, Polymethyl Methacrylate, Anti-Bacterial Agents.*

RESUMO

Objetivos: Na literatura não há consenso em relação ao tempo para a retirada dos espaçadores com antibiótico no tratamento das infecções ósseas. O objetivo deste estudo é avaliar os resultados clínicos de pacientes com retenção prolongada dos mesmos. Métodos: Foram selecionados pacientes com infecção pós-osteossíntese e/ou osteomielite submetidos a colocação de espaçador de cimento ortopédico (polimetilmetacrilato) com vancomicina que retiveram o mesmo por período superior a 12 meses. Os pacientes foram avaliados clinicamente quanto à presença de sinais infecciosos locais ou sistêmicos, laboratorialmente com hemograma, marcadores inflamatórios, função hepática, renal e radiograficamente. Resultados: Dezoito pacientes foram incluídos no estudo. O tempo médio de retenção do espaçador foi de 30,4 meses (15 a 61 meses). Nenhum paciente apresentou sinais clínicos de recidiva infecciosa local ou sistêmica no momento da avaliação. Sete pacientes (39%) apresentaram dor não incapacitante no membro operado. Dezessete pacientes (94%) apresentaram redução nos valores da proteína C reativa comparativamente ao período pré-operatório. Radiograficamente, não houve migração, falha do espaçador ou identificação de sequestro ósseo em nenhum caso. Conclusão: Nessa série de casos retrospectiva, a retenção do espaçador de cimento com vancomicina por mais de 12 meses foi associada a bons resultados clínicos, sem recidiva do quadro infeccioso. ***Level of Evidence IV. Therapeutic Studies Investigating the Results of Treatment.***

Descritores: Osteomielite. Polimetil Metacrilato. Antibacteriano.

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INTRODUCTION

In orthopedic surgery, the use of polymethylmethacrylate (PMMA) bone cement has proven effective in stabilizing implants and filling dead space created in the treatment of infection after osteosynthesis[1]. In 1970, Buchholz and Engelbrecht were the first to describe their use associated with antibiotics[2,3] followed by publications showing the efficacy of this association in the treatment of orthopedic infections[1,4,5]. Its advantages compared to oral or intravenous antibiotic therapy include the release of local antibiotics in higher concentrations, relative lower serum level, and consequent reduction in toxicity associated with the use of systemic antibiotics[6].

There is no consensus in the literature regarding the time for the removal of the spacer, and few studies describe the effects of its retention in the long term. The main disadvantage of the use of cement is the need for a second surgery for its removal since the reduction in antibiotic concentration over time could favor local bacterial proliferation and biofilm formation[1-3,7]. However, some authors have described patients with spacer retention for up to

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Study was conducted at the Universidade de São Paulo, Faculdade de Medicina, Instituto de Ortopedia e Traumatologia, São Paulo, São Paulo, Brazil.
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76 months without significant clinical repercussions[8]. At present, there is no consensus on the safety and effectiveness of retention of cement spacers for prolonged periods.

The objectives of this study included the evaluation of the clinical results of patients with spacer for more than 12 months, the laboratory evaluation of inflammatory and infectious tests, and their radiographic evaluation.

MATERIALS AND METHODS

This study consists of a series of retrospective cases and was conducted at a tertiary health service with the approval of the Research Ethics Committee (78931417.3.0000.0068). Patients with an infectious condition after a fracture fixation and/or acute or chronic osteomyelitis were selected and subjected to the placement of a cement spacer with vancomycin.

Patients were selected for this study on a voluntary basis and signed an informed consent form. Selected participants, all aged between 18 and 65 years, had a history of osteomyelitis or a diaphyseal fracture of the femur, tibia or humerus, and were operated between January 2012 and December 2016. Those patients had undergone surgical treatment with the use of a spacer (PMMA) and antibiotic (vancomycin), within a minimum postoperative time of 12 months. They were invited to undergo clinical, laboratory and radiographic evaluation. We excluded patients who showed signs of clinical or neurological sequels, as those prevented an accurate evaluation, as well as those who had lost their outpatient follow-up documents. Demographic data, fracture time and location, confirmation of osteomyelitis diagnosis, comorbidities, presence of persistent surgical wound drainage, secondary infections, refractures, seroma formation, possible nephrotoxic and hepatotoxic effects of antibiotic therapy, gastrointestinal effects, thromboembolism, and the presence of surgical wound dehiscence were all analyzed.

The selected patients were invited for clinical, laboratory, and radiographic evaluation. During the consultation, blood samples were collected for laboratory analysis, we then compared the results with those of the exams performed prior to the PMMA placement. Complete blood count, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, gamma-GT, total bilirubin and fractions, albumin, coagulogram, creatinine, urea, and C-reactive protein were analyzed. New radiographs of the anteroposterior and lateral views of the operated limb were requested to evaluate bone changes related to the bone cement spacer (PMMA) and to investigate possible signs of osteomyelitis.

Two types of spacers were evaluated in this study: diaphyseal spacers (used in infections of intramedullary rods) and spacers in pearl necklaces (used in commonly-occurring cavitary infections in metaphyseal regions). Intramedullary diaphyseal spacers are made of an internal structure made using Kirschner wire with 2.0 mm diameter that is manually molded according to the length of the affected bone. The proximal portion of the wire is bent in a loop shape, allowing for the introduction and removal of the spacer. The pearl necklaces are manually molded and connected using a Nylon 0 wire. The mixing time of polymethyl methacrylate powder with the liquid polymer was standardized to 30 s before the addition of the antibiotic (2 g of vancomycin for every 40 g of cement).

Patients were subjected to follow-up exams 1 week, 2 weeks, 4 weeks, 3 months, and 6 months after the procedure, and annually after that. The criteria for defining the last surgery included the absence of secretion or inflammatory signs around the surgical wound and a clinical improvement of pain and laboratory parameters (reduction of CRP and blood count without changes). All patients were discharged with antibiotic therapy guided by the cultures, with a minimum time of 6 weeks of treatment. There was no need for funding for the execution of this project.

RESULTS

In total, 18 patients met the selection criteria. The mean age was 39.9 (range: 18 - 61) years; 13 patients (72.2%) were male and five patients (27.8%) were female (Table 1). Half of the patients evaluated had undergone surgery due to Chronic Hematogenous Osteomyelitis, and the other half were operated due to a postoperative infection (Table 2). Five patients (27.8%) contracted an infection after an automobile accident, three (16.7%) after falls and one (5.6%) after a firearm injury. The mean retention time of the spacers was 30.4 months, ranging from 15 to 61 months, with 12 patients (66.7%) with diaphyseal spacers and six with pearl necklaces (33.3%). Eleven patients underwent surgery on the femur (61.1%), six on the tibia (33.3%), and one on the humerus (5.6%). Three patients were diagnosed with systemic arterial hypertension (16.7%) and two with diabetes mellitus (11.1%). Of the 18 patients, 11 (61.1%) declared to be social drinkers and three (16.7%) were smokers.

Table 1. Demographic and clinical characteristics of selected patients.

	n = 18
Age	39.9 (SD 13.75)
Gender	
Male	13 (72.2%)
Female	9 (27.8%)
Type of spacer	
Diaphyseal	12 (66.7%)
Pearl necklace	6 (33.3%)
Region (diaphysis)	
Femur	11 (61.1%)
Tibia	6 (33.3%)
Humerus	1 (5.6%)
Retention time	30.4 months (SD 13.36)
Comorbidities	
HAS	3 (16.7%)
DM	2 (11.1%)
Other	4 (22.2%)
Habits and addictions	
Social Drinking	11 (61.1%)
Smoking	3 (16.7%)

Abbreviation: SD, Standard Deviation.

Table 2. Clinical results.

Case	Age	Diagnostic	VAS	Bacteria	PCR (mg/L) *
1	41	COM	6/10	Streptococcus anginosus	155.0 - 10.7
2	52	COM	2/10	S. aureus/S. epidermidis	329.1 - 1.6
3	25	COM	0/10	Serratia marcescens	53.3 - 0.7
4	59	COM	0/10	P. aeruginosa/K. pneumoniae	7.6 - 20.9
5	18	COM	0/10	S. epidermidis	21.0 - 1.4
6	39	COM	0/10	S. aureus/S. epidermidis	410.6 - 2.0
7	31	COM	0/10	S. epidermidis	108.4 - 14.2
8	61	COM	0/10	S. aureus	17.8 - 7.5
9	18	COM	0/10	S. aureus	94.0 - 1.5
10	32	POI	6/10	Staphylococcus lugdunensis	29.6 - 1.5
11	53	POI	6/10	S. aureus	45.0 - 1.3
12	50	POI	3/10	S. aureus	40.7 – 3.5
13	51	POI	3/10	S. aureus	110.0 - 21.8
14	47	POI	1/10	S. aureus	79.9 - 11.0
15	38	POI	0/10	Proteus mirabilis	8.3 - 2.1
16	35	POI	0/10	Peptostreptococcus anaerobius	95.1 - 9.3
17	48	POI	0/10	S. aureus	13.9 - 3.0
18	20	POI	0/10	S. aureus	271.4 - 6.3

Abbreviation: VAS, Visual Analogue Scale of Pain; COM, Chronic Osteomyelitis; POI, Postoperative Infection. * Values in the presence of infection and during outpatient return after 12 months of spacer retention. Reference value: <5.0 mg/L.

In cases of chronic hematogenous osteomyelitis, *Staphylococcus aureus* was the most prevalent bacteria isolated, affecting four patients (44.4%). Only one patient in this group showed an increase in the C-reactive protein when comparing the results in the presence of infection and during the outpatient return after 12 months of retention. *S. aureus* was also responsible for six postoperative infections (66.7%), with all cases showing a decrease in the C-reactive protein (Table 2). No change was observed when comparing the results of the other laboratory tests requested (complete blood count, AST, ALT, alkaline phosphatase, gamma-GT, total bilirubin and fractions, albumin, coagulogram). All of the above exam results were within the reference values.

No signs of new fractures of infectious recurrence, such as thickening of the periosteum or bone sequestration, were observed in any of the patients. In fracture cases, Lane and Sandhu's criteria were used, and a maximum score was assigned for each fracture, with total bone formation, absence of fracture line and cortical remodeling.

DISCUSSION

The primary objective of this study was to clinically evaluate and identify possible late complications (clinical, laboratory or radiographic) of patients with retention of the PMMA spacer with vancomycin after a minimum period of 12 months. The initial hypothesis of the study was that retaining the PMMA spacer with vancomycin for more than 12 months in patients with good clinical evolution and control of local infectious signs can be tolerated by a significant number of patients, without negative clinical repercussions in the long term.

The main disadvantage in the use of PMMA is the need to remove the spacer, as it can act as a growth medium for resistant organisms[9]. One of the pioneering studies on this subject was conducted by Kendall et al.[10], who analyzed an *in vitro* model associating acrylic cement with antibiotics. Viable organisms were found in cement after 96 hours and, for this reason, the authors began to recommend the cautious use of cement in clinical practice. However, the combination of antibiotics with PMMA in the treatment of infected or at-risk orthopedic lesions has been shown to reduce infection rates, both in animals and clinical studies[5]. In a retrospective study, Selhi et al.[11] described the retention of intramedullary implants with bone cement and antibiotics for a period ranging from 6 weeks to 22 months (mean, 10.6 months) with satisfactory results in the treatment of infected non-union fractures. The authors mention studies that retained implants for up to 753 days without any complications other than implant breakage in a single patient. Similarly, Paley et al.[12] followed-up on patients with intramedullary bone cement and antibiotic implants for a period ranging from 32 to 48 months (mean 40.9 months), without recurrent infections in this interval.

Following the selection criteria, 18 patients with spacer retention with an interval ranging from 15 to 61 months, with a mean of 30.4 months (SD = 13.36) were selected. In all cases, the patients chose to remain with the spacers and not to be subjected to a new surgical procedure for their removal. It was found that none of the patients had persistent drainage of the surgical wound, dehiscence of the surgical wound, formation of seroma near the site of bone cement insertion, fever, or thromboembolic episodes. Pain assessment using the Visual Analogue Pain Scale showed that 11 patients (61.1%) reported no pain in the operated limb. Of the seven patients who complained of continued pain, five (71.4%) were in the group of patients with postoperative infection secondary to fracture fixation. Trauma and its sequels are possible factors of interference in this evaluation. In the group of patients whose initial infectious condition was caused by hematogenous osteomyelitis (n = 9), only two (22.2%) reported pain in the clinical evaluation. The complications described by Lou et al.[2], such as persistent drainage of content through the surgical wound, infection of the external fixator fixation pin, thromboembolism and recurrent infection, was not observed in any patient.

According to Hake et al.[9], the preparation of cement with antibiotics can be divided into high- and low-doses categories. High doses correspond to > 3.6 g of antibiotic for every 40 g of cement, and low doses correspond to < 2 g for every 40 g of cement. Zalavras et al.[5] also recommend the association of 4 g of vancomycin for every 40 g of cement in the treatment of exposed fractures and osteomyelitis. In this study, we used 2 g of vancomycin for every 40 g of cement, with the addition of antibiotics being standardized to 30 s after mixing cement with a liquid monomer, resulting in higher concentrations after six weeks when compared to the method of simultaneous mixing of cement and antibiotics before the addition of liquid monomer[13].

Despite the description of renal failure secondary to the use of antibiotic spacers in patients undergoing total knee arthroplasty[14], none of our patients showed an increase in serum creatinine levels between pre- and postoperative levels. Furthermore, liver function was maintained in every patient. As for the levels of C-reactive protein, the values were significantly lower upon outpatient return, except in one patient.

This study has some limitations, mainly linked to the fact that we only examined a retrospective series of cases that did not involve a comparison with the control group. Only patients who retained the spacers for a prolonged period with good clinical evolution were analyzed, and no clinical, radiographic and laboratory comparisons were made with those who required new surgical intervention in less than 12 months. Since the cases of treatment failure were not evaluated, it was impossible to evaluate risk factors for unfavorable clinical outcome. Late removal of the spacers to evaluate biofilm formation or bone tissue culture in search of latent infection would add relevant clinical information to this study. Similarly, serum vancomycin levels were not measured, which could show the levels of residual concentration of the antibiotic associated with spacer retention.

Despite the limitations of this study, it was possible to demonstrate that patients with antibiotic cement spacers who had favorable clinical signs, with infectious control, remained clinically well with the retention of the spacer for 12 months or longer. No adverse clinical signs, such as pain and local infectious recurrence, or laboratory and radiographic signs of poor prognosis related to the retainment of the spacer were observed. With the findings of this study, we cannot and do not intend to establish a definitive treatment for patients with spacers, nor do we recommend the prolonged retention of spacers as a routine treatment. Comparative observational studies, including patients with negative and positive clinical outcomes, are necessary for the establishment of definitive recommendations. However, the data from this study demonstrate that in patients in whom spacer retention is necessary, the infectious condition can be kept under control, and no complications directly associated with spacer retainment for more than 12 months were identified.

CONCLUSION

This study showed that patients with vancomycin cement spacers with good clinical evolution throughout more than 12 months could maintain a controlled infectious condition with spacer retention, and no complications or adverse events directly associated with spacer retention were identified.

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ACETABULAR RECONSTRUCTION IN PAPROSKY TYPE III DEFECTS

RECONSTRUÇÃO ACETABULAR EM DEFEITOS POR PAPROSKY TIPO III

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ABSTRACT

Objectives: Severe pelvic deficiency presents a difficult problem in hip arthroplasty. Specifically, the goals are to restore the pelvic bone stock, place the acetabular component in the correct anatomical position, and optimize joint stability. Currently, many surgical techniques have been developed for prosthetic revision surgery for acetabular complex defects, but no consensus has been reached on the best treatment. The objective of this study was to review mid-term cases of severe bone defect (Paprosky type III) treated with a bone allograft and ring Bursch-Schneider anti-protrusion cage (BSAC). Methods: A retrospective consecutive series review of the first 23 complex acetabular reconstructions performed between 2006 and 2011 was conducted. The series included the learning curve of the procedure and a minimum 5-year follow-up. Conclusion: Our study confirmed the efficacy of using a frozen morselized allograft combined with a metal ring-type BSAC for acetabular reconstruction. The anatomical location of the center of rotation of the hip must be recovered for long-term success. In massive loosening cases, the anatomical center of rotation can only be restored by bone density reconstruction using a graft protected by a ring to improve the centering of the head. ***Level of Evidence IV, Case Series.***

Keywords: Joint revision, hip arthroplasty, bone graft, reconstructive surgical procedure

RESUMO

Objetivos: A deficiência pélvica severa apresenta um problema difícil na artroplastia do quadril. Especificamente, os objetivos são restaurar o estoque ósseo pélvico, colocar o componente acetabular na posição anatômica correta e otimizar a estabilidade da articulação. Atualmente, existem muitas técnicas cirúrgicas para a cirurgia de revisão protética em defeitos do complexo acetabular, mas não há consenso sobre o melhor tratamento. Os objetivos deste trabalho são revisar casos de médio prazo operados por apresentar defeito ósseo grave (Paprosky tipo III) tratado com aloenxerto ósseo e gaiola anelar Bursch - Schneider anti protusio (BSAC). Métodos: Foi realizada uma revisão retrospectiva consecutiva das primeiras 23 reconstruções acetabulares complexas realizadas entre 2006 e 2011. Esta série inclui a curva de aprendizado do procedimento e tem um acompanhamento mínimo de 5 anos. Conclusão: Em conclusão, nosso estudo confirma a eficácia do uso de aloenxerto morselado congelado combinado com um anel de metal tipo BSAC durante a reconstrução acetabular. É necessário recuperar o centro de rotação do quadril em sua localização anatômica para o sucesso a longo prazo. Em casos de soltura maciça, o centro anatômico de rotação só pode ser restaurado pela reconstrução da densidade óssea usando um enxerto protegido por um anel que melhora a centralização da cabeça. ***Nível de Evidência tipo IV, Série de Casos.***

Descritores: *Revisão articular, artroplastia do quadril, enxertos ósseos, procedimentos cirúrgicos reconstrutivos.*

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INTRODUCTION

In recent years it has been producing an increase the number of surgeries revision total hip arthroplasty (THA). This is because the indications for THAs are expanding include younger patients with more planned activity and demands.[1] Charnley in 1979 suggested that revision prosthetic surgery would be the main cause of concern in the THA. Nowadays, THA loosening rates have been increasing so that doubled revision surgery each 10 years.[2]

In prosthetic revision surgery, where a significant acetabular loss is there, must perform an acetabular reconstruction. The purpose of the acetabular reconstruction is to obtain a stable, permanent fixation of a new acetabular component to restore the center of rotation and, if possible restoring bone stock. During revision surgery simple acetabular defects, either cavitary or segmental, can be solved with conventional cementless THA (hemisferic acetabular components). However, combined segmental and cavitary defects are more difficult, especially those with no upper acetabular coverage.[3,4]

Currently there are many surgical techniques for prosthetic revision surgery in acetabular complex defects, but there is no consensus on the best treatment. The impacted bone graft is an attractive treatment option for restoring severe acetabular bone defects (Paprosky type III) in total revision of the THA;[5] however, it requires the placement of a metal frame for attaching a primary stabilization.[6,7]

The objectives of this paper is to review medium term cases operated by presenting a severe bone defect (Paprosky type III) treated with bone allograft and ring Bursch - Schneider ant protusio cage

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

Study was conducted at the Department of Orthopaedic Surgery, Hospital Universitario de Vic, Barcelona, Spain.
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(BSAC). This review technique is attractive because it addresses the three objectives of the acetabular reconstruction: providing a stable and lasting fixation for a new acetabulum, restore the center of rotation; and achieve the restoration of bone stock.

METHODS AND MATERIALS

A retrospective consecutive series review was undertaken of the first 23 complex acetabular reconstructions performed between 2006 and 2011 (Table 1). This series includes the learning curve of the procedure and has a minimum 5-year follow-up. All cases were performed by the senior author (JM), a consultant orthopaedic surgeon with an interest in revision hip arthroplasty surgery. All patients were operated using cancellous allograft bone crushed with BSAC and a cemented cup.

The average time between the initial total hip replacement (THA) and the revision acetabular surgery was 111 months (range, 12-228 months). Acetabular bone status was classified during the operation according to the criteria of Paprosky et al.[3] as Grade 3A (15 hips) and Grade 3B (8 hips). Different cemented (3 hips) and cementless (20 hips) THAs were revised in this series. Each revised cup was individually assessed; 16 (69,56%) only underwent acetabular revision, whereas 7 (30,44%) underwent revision of both components. In all cases where a revision was done, an uncemented stem was used (Conelock-Biomet).

The cohort included 10 men (43.47%) and 13 women (56,52%) with an average age at the time of revision surgery of 77.04 years (range, 68–88 years). The average number of procedures performed before the present acetabular revision was 1.78 (range, 1–3). Diagnosis at the time of cemented cage reconstruction was as follows: aseptic loosening/mechanical failure (n = 19), instability (n = 1), reimplant for infection (n = 3). Preoperative evaluation according to the scale of MD Score average was 6.6 (range 5-9). The surgical planning, in cases where a intrapelvic penetration of the acetabular loosened component existed, included performing a digital subtraction angiography (DSA) arteriogram, to locate the femoral artery (Figure 1). The primary objective was to restore the center of rotation of the hip.

All procedures were performed by the same surgeon, in supine position and using an anterolateral Watson-Jones aproach. The acetabular component was removed with the required extractional instrumentrs, preserving as much bone as possible. Cystic areas were aggressively debrided. Then, the acetabulum was inspected to identify osteolysis areas, determine the type of bone defects, and evaluate the presence of pelvic discontinuity. The acetabular bone bed was reamed with hemispherical reamers. Acetabular margins were defined, and the cup was always placed at the nearest of the center of rotation of the hip. In revision surgery with large bone defects, the obturator foramen is always a good reference for positioning the cup down and out. In all cases we use fresh frozen allograft femoral head, got in the bone bank. Bone was morselized with a bone mill, or manually using a rongeur. Then placed the BSAC ring, pinning the inner pin on the ischium and the other flange bolted to the ileum with 5 screws, checking its stability (Figure 2). Then put a cemented polyethylene cup size to the size of the corresponding ring.

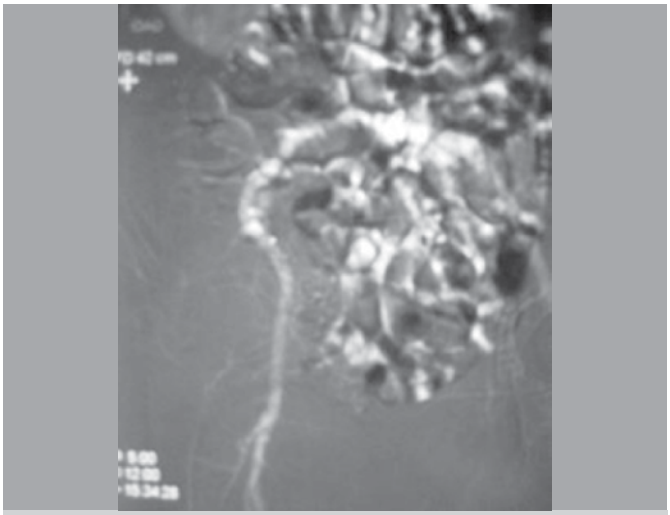

Figure 1. Digital subtraction angiography (DSA).

Table 1. Summary of the 23 consecutive acetabular impaction graftings performed by using impaction grafting of a defect that has been contained with a metallic Bursch-Schneider antiprotusio cage, followed by implantation of a cemented polyethylene cup.

Case	Gender	Age	Merle 'Aubigne score	Prior surgeries	Type acetabular defect	Side	Intervencio	Graft type	Type of cage	Concomitant femoral revision	Merle D'Aubigne score	Follow-up (months)
			Preop.								Postop.	
1	F	74	6	2	3.A	R	SEPTIC	Fresh frozen	BSAG	Yes	14	48
2	F	76	5	1	3.A	R	Mechanical failure	Fresh frozen	BSAG	Yes	16	51
3	F	79	7	1	3.B	R	Mechanical failure	Fresh frozen	BSAG	Yes	17	60
4	F	82	6	3	3.B	R	Mechanical failure	Fresh frozen	BSAG	Yes	16	59
5	F	73	7	3	3.A	R	Mechanical failure	Fresh frozen	BSAG	Yes	16	56
6	M	71	6	1	3.A	R	Mechanical failure	Fresh frozen	BSAG	No	16	49
7	M	78	5	1	3.B	R	Mechanical failure	Fresh frozen	BSAG	Yes	17	53
8	M	83	7	1	3.A	R	Mechanical failure	Fresh frozen	BSAG	No	15	54
9	M	85	8	2	3.A	R	Instability	Fresh frozen	BSAG	No	16	51
10	M	88	7	1	3.B	R	Mechanical failure	Fresh frozen	BSAG	No	15	49
11	M	77	6	2	3.B	R	Mechanical failure	Fresh frozen	BSAG	Yes	17	48
12	F	68	6	2	3.A	L	RECANVI PTM ESQ.	Fresh frozen	BSAG	Yes	16	58
13	F	69	8	1	3.A	L	Mechanical failure	Fresh frozen	BSAG	Yes	17	54
14	F	75	7	1	3.A	L	Mechanical failure	Fresh frozen	BSAG	No	15	52
15	F	76	6	3	3.B	L	Mechanical failure	Fresh frozen	BSAG	Yes	16	49
16	F	77	7	1	3.A	L	Mechanical failure	Fresh frozen	BSAG	Yes	17	48
17	F	77	7	2	3.A	L	Mechanical failure	Fresh frozen	BSAG	No	16	55
18	F	82	6	2	3.B	L	SEPTIC	Fresh frozen	BSAG	Yes	16	49
19	F	83	6	3	3.A	L	Mechanical failure	Fresh frozen	BSAG	Yes	16	48
20	M	72	6	3	3.A	L	Mechanical failure	Fresh frozen	BSAG	No	17	54
21	M	73	7	2	3.B	L	Mechanical failure	Fresh frozen	BSAG	Yes	15	55
22	M	75	8	1	3.A	L	Mechanical failure	Fresh frozen	BSAG	Yes	16	52
23	M	79	9	2	3.A	L	SEPTIC	Fresh frozen	BSAG	Yes	16	50

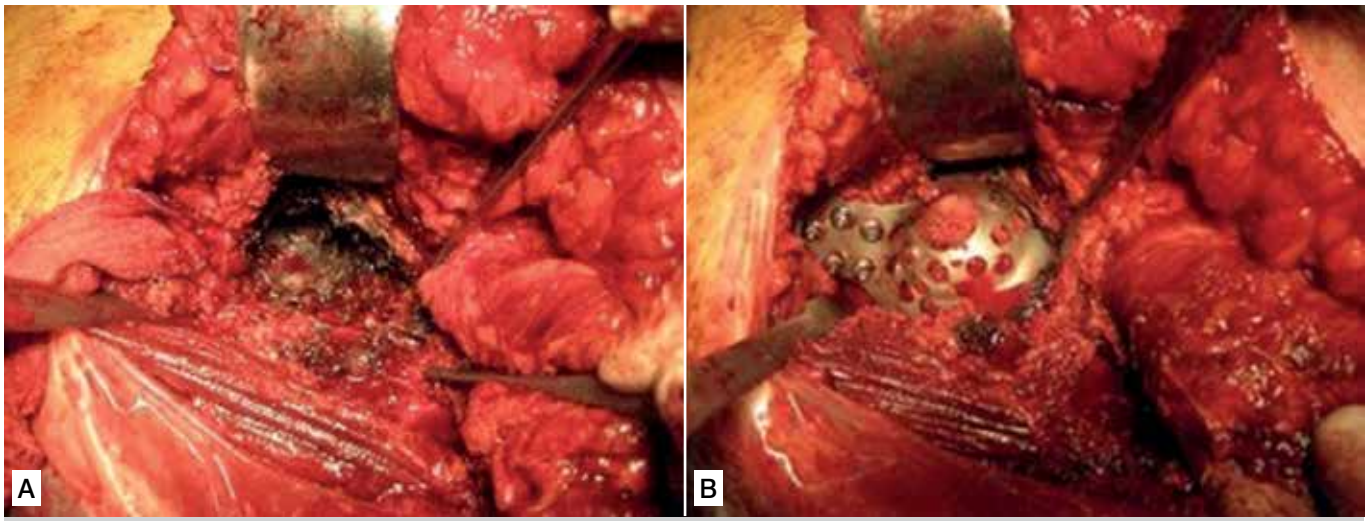

Figure 2. A) Extensive posterolateral acetabular exposure with massive bone loss. B) Reconstruction acetabular with a allograft and Bursch-Schneider antiprotusio cage.

In all cases, low-molecular-weight heparin was used as an anticoagulant during the first month after surgery, and 2 g of Cefazoline was used in the initial anesthesia in no septic revision. Following our normal hospital procedure, surgical bleeding was controlled with tranexamic acid. During the postoperative period, ambulatory re-education was carried out. Patients were evaluated clinically using the Merle d'Aubigne score (MD). Radiological assessment was carried out by means of a standard AP X-ray of the pelvis and lateral hip, checking for migration, osteolysis and signs of radiolucency in the three DeLee acetabular zones.

RESULTS

We had no intraoperative complications. In all cases has gotten a good stability in the rings anclage and acetabular components have been chosen. We had no infections nor vascular injuries or nerve complications. Postoperative prosthetic dislocation has been done in 4 cases (17.39%), all were resolved with bloodless reduction. Mean blood of these patients was 650cc (300-800cc range), therefore we can say that they are bleeding interventions that have had to resort to transfusion in 14 cases (60.86%). From the clinical point of view, the mean MD at the end of the follow-up was 16 points (range 14-17). At the final of the follow-up has not been any reoperation in these patients. The radiographic assessment does not demonstrate mobilization components, although the assessment of the incorporation of the grafts is difficult to assess because of the multitude of metallic artefact (Figure 3). No new intervention has been made during the follow-up of our series.

DISCUSSION

Our study has important limitations. This is a retrospective study done without a control group. Rather, the study was performed with a single observer, limiting how bias in interpreting results. This study supports our surgical approach and highlights the benefit of correctly position the center of rotation, which led us to use the ring BSAC.
The restitution of the lost bone stock is one of the biggest challenges of acetabulum revision surgery. Classification systems for the acetabular defect allow unification in the defect and can give guidelines for treatment. The AAOS classification system described by D'Antonio et al.[9] grades the acetabular defect in five types: segmental, cavitary or combined deficiencies, pelvic discontinuity, and arthrodesis. The Paprosky classification system[3] stratifies the degree of bone loss based on radiographic parameters to guide the identification of reconstructive options.

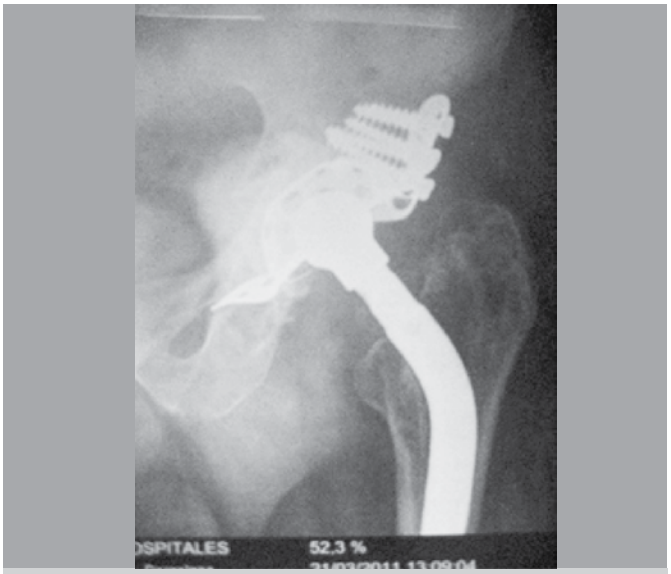

Figure 3. Stable fixation 4 years follow-up of a revision THA in defect Paprosky type 3 B.

In four patients of our series, we could see a dislocation of the prosthesis. This happened at the beginning of the cases. All were resolved without the need for new surgeries. These dislocations made us think that the use of a hip stabilizing orthosis in abduction would be appropriate. For this reason, we have used this type of orthosis for three months after the operation. This prevented new dislocations.
In grade III Paprosky acetabular defects the first major problem we face is the loss of bone stock that exists and therefore we have to get an acetabular regeneration. Some authors when faced with loosening and significant bone loss[10,11,12,13] have chosen to use a cemented cup of the next larger size and fill the defect with cement. This approach is still used despite Sofcot 1988 report[14] that highlighted a repeated rate of 33.3% of loosening with this technique and potential rate of 25% at 5 years detachment. These data support the need to rebuild and restore acetabular bone stock in revision arthroplasty by placing bone graft. Many surgeons have used the structural allograft in

combination with a cemented cup, without using a reinforcing ring or without cemented cup.[15,16,17,18,19,20] After promising initial results,[15] was reported failures after 5 years[21] (20% rate of loosening), 10 years[22] (loosening rate 47%) and then at 16[23] (66% rate of loosening). Nowadays, the morselized frozen allograft is giving excellent results. Graft incorporation occurs in two phases: initial phase with partial resorption of the graft and repopulation phase where new bone is formed in the graft host.[19,20,24,25] The incorporation of frozen morselized allografts has been verified in animals[26,27] and confirmed in vivo.[28,29] The use of isolated bone graft when faced with significant bone loss does not solve the associated problems such as mechanical stability and integration of the graft. Therefore, it seems appropriate to use a metal protective ring to stabilize these allografts and improve integration. There are two types of metal reinforcing rings: one type only provides a proximal fyxing (Müller ring type) and the other provides dual fixing through a hook (Ganz ring, cross Kerboull) or screw (BSAC). Some authors believe that the use of proximal fixation alone is not enough and that many of the failures can be attributed to the lack of primary stability.[1,30] Gerber et al.[31] adds that most failures occurred due to lack of primary stability of the ring, which led to graft lysis after loosening. For that reason in our series we have always resorted to using BSAC ring with good results.

There are many advantages with the combination of a reinforcement ring with a graft. First, the center of rotation of the hip is more likely to be restored[31,32,33,34] which avoids the "high" center of rotation of the hip advocated by some surgeons.

We have managed to restore the center of rotation of the hip in all cases with the technique used. However, the elevation of the center of rotation is an acceptable alternative if several conditions are met: limited bone defects, without combined effect of rotation center. Second, the graft is protected and stabilized, which is essential for the integration of the graft.[30,31] Few studies have compared the use of different reinforced rings. Bonnomet et al.[32] found the ring BSAC to be better than the Muller ring in loosening cases with severe bone loss. Our series with a minimum follow-up of 4 years confirmed the good long-term results described in other published studies.[1,3,35,36,37,38,39]

Patients who have Paprosky grade 3 acetabular defects are in a very unfavorable clinical situation with great functional limitations. The clinical results achieved at follow-up demonstrated a marked improvement (Figure 4). These patients would be, in case of don't realise this surgery, candidates to a Girdlestone resection arthroplasty. Radiological evaluation of bone graft resorption is difficult after using allograft bone impacted with cement and metal rings with an acetabular revision, but the stability of cemented cup gives us an important tranquillity. In most cases there is a uniformity of the graft. But be cautious, because the results may deteriorate beyond 10 years. Allografts have been known resorptions later (after 10 years), therefore we must continue to monitor the long term this type of reconstruction.[37]

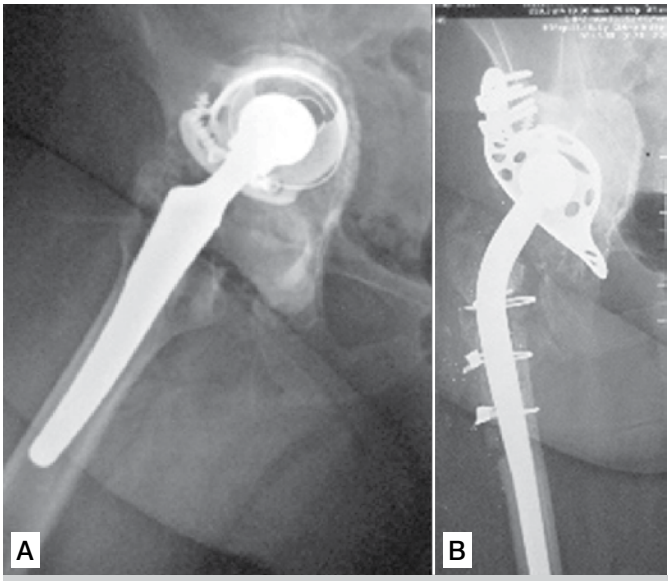

Figure 4. A) Preoperative acetabular defect paprosky type 3 B. B) Five years follow-up acetabular reconstruction.

Radiological evaluation of bone graft absorption is difficult after using allograft bone impacted with cement and metal rings in an acetabular revision, but the stability of cemented cup gives us an important tranquillity. In most cases there is a uniformity of the graft. But it's important to be cautious, because the results may deteriorate beyond 10 years. When allografts, it has been known absorptions later (after 10 years), therefore we must continue controlling long term this type of reconstruction.[37]

CONCLUSION

Our study confirms the efficacy of using a frozen morselized allograft combined with a metal ring type BSAC during acetabular reconstruction. It is necessary to recover the center of rotation of the hip on its anatomical location for long term success. In massive loosening cases, the anatomical center of rotation can only be restored by the reconstruction of bone density using a graft protected by a ring which improves the centring of the head.

AUTHORS' CONTRIBUTIONS: All authors contributed individually and significantly to the development of this work. JJMC (0000-0003-1790-3241)*: wrote and reviewed the manuscript, performed the surgeries, and contributed to the intellectual conceptualization of the study and the entire research project; LG: performed the surgeries and data analysis, and wrote the manuscript; and APP: participated in the surgeries; reviewed, drafted, and reviewed the manuscript.
*ORCID (Open Researcher and Contributor ID).

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Review Article

RADIOACTIVE CEMENT OF PMMA AND HAP-Sm-153, Ho-166, OR RE-188 FOR BONE METASTASIS TREATMENT

CIMENTO RADIOATIVO DE PMMA E HAP-Sm-153, Ho-166 OU RE-188 NO TRATAMENTO DE METÁSTASES ÓSSEAS

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ABSTRACT

Polymethylmetacrylte (PMMA) is used in the fields of dentistry and biomedicine as a constituent of bone cements. Hydroxyapatite (HAp) is a bioceramic produced naturally in the bones. PMMA and HAp are fundamental constituents in the preparation of bone cements. Bisphosphonates have also been used as radiopharmaceutical in dental implants and nuclear medicine, or as palliative systemic treatment for pain reduction in bone metastasis. Vertebroplasty and kyphoplasty are bone cement-based techniques used in orthopedics, being minimally invasive procedures with low risks of infections, applied in osteoporosis and high-impact fractures. Recently, Núcleo de Radiações Ionizantes da Universidade Federal de Minas Gerais proposed a synthetic composite of M-HAp with a metallic nuclide M. After irradiation, M-HAp was added to PMMA, compounding a radioactive bone cement that can recover bone body stabilization, pasting microfractures and recomposing the anatomy and functionality of the affected parts by the compression of bone metastases, with possible pain reduction through quick radiation-induced decompression. Computational dosimetric models, and the synthesis and characterization of bioceramics that incorporate Re-188, Ho-166, or Sm-153 have demonstrated the benefits of these biometrics as promising alternative therapies, mainly from their ability to maintain the ionization in the bone structure, thereby sparing the spinal cord. This article presents a review on this topic. ***Level of Evidence V, Expert Opinion.***

Keywords: Cement. PMMA. Hydroxyapatite. Vertebroplasty. Kyphoplasty. Radioisotopes.

RESUMO

Polymethylmetacrylte (PMMA) é um composto utilizado na indústria e desde os anos 80's também tem sido empregado nas áreas odontológica e biomédica como constituinte de cimentos ósseos. A hydroxyapatite (HAp) é uma biocerâmica produzida naturalmente nos ossos. Esses dois componentes são constituintes fundamentais no preparo de cimentos ósseos. A síntese artificial de HAp pode ser feita pelo método sol-gel. Bifosfanatos tem também sido utilizado na odontologia em implantes dentários e na medicina nuclear, como radiofármaco ou no tratamento paliativo sistêmico de redução de dor das metástasis ósseas com ^{153}Sm--EDTPM. A Vertebroplastia e Cifoplastia são técnicas empregadas na ortopedia utilizando o cimento ósseo, sendo procedimentos minimamente invasivos de baixo risco de infeções, aplicadas em osteoporose e fraturas de alto impacto. Recentemente, no Grupo de Pesquisa NRI – Nucleo de Radiações Ionizantes/UFMG, foi proposto um compósito de M-HAp com nuclideo metálico M incorporado na matriz, que após ativado é adicionado ao PMMA constituíndo um cimento ósseo radioativo que pode recuperar a estabilização o corpo ósseo, colando microfraturas, recompondo a anatômia e funcionalidade de peças afetadas pela compressão das metástases ósseas com possível redução de dor pela rápida descompressão induzida pela radiação. Modelos dosimétricos computacionais, sintese e caracterização destas biocerâmicas incorporando Re-188, Ho-166 ou Sm-153 tem indicado benefícios radioterapêuticos promissores, podendo se tornar uma alternativa para radioterapias convencionais, principalmente por conter a dose absorvida na estrutura óssea, por exemplo no corpo da vertebra poupando a medula espinhal. O presente artigo apresenta uma revisão sobre o tema. ***Nível de Evidência V, Opinião do Especialista***

Descritores: *Cimento ósseo radioativo. PMMA. HAp. Vertebroplastia. Cifoplastia. Radioisótopos.*

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INTRODUCTION

At the present time, there are few clinical procedures to meet the countless cases of cancer in advanced stages with confirmed and widespread metastases. These represent critical clinical situations where the disease spreads from in situ for loco-regional sites, toward the entire human body, becoming systemic and affecting organs and skeleton. At that stage, medical science does not bring hope to the patients, and death can happen weeks or months after

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Study was conducted at the Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, MG, Brazil.
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confirmed a diagnosis of disseminated metastasis, as a consequence of the morbidity of this disease. Bone involvement by micro tumors produces trauma that generate huge intensity of pain. In most cases the pain is severe due to several secondary metastatic processes produced by the micro-fractures in the bone structure, being recommended by clinical staff introducing palliative measures for pain reduction. In this clinical picture, it is understandable that the disease has already progressed to a stage of irreversibility and it is not likely a full recovery of the patient. Morphine is of the common use, among other medications; even if such drug doesn't act on recovering induced compression fractures produced by cancerous tumors metastatic.[1]

There are possible interventions by the radiation therapy (RT), chemotherapy or surgical procedures. Although there is a great limitation of beam portals and of bone target volume at RT. Teletherapy brings deleterious effects because it is inevitable the exposition of other vital organs or regions of the body to ionizing radiation; especially considering the clinical condition and the patient's weakened immune system.

In the 80ties, Harrington K.D. proposed the use of polymerized methyl methacrylate for stabilization of vertebral bodies with fractures or dislocations induced by bone metastases. Metastasis induces an increase in the internal pressure of the vertebral body and compromise the patient care.[2] A solution was presented for pain reduction but the exothermical effects provided by the polymerization of methyl methacrylate became a part of the side effects of the procedure.[2,3] In accordance to Harrington, on the post-surgery of 13 to 14 pacients, an improvement in pain was observed with the stabilization of the spine with the use of metyl-methaclylate. However, external radiation therapy was held in addition. The source of radiation was external to the body and the restorative cement was used only to improve stability of the vertebral body. The clinical benefits with the use of PMMA extended from 13 to 45 months the postoperative procedure.

In the 90th, this cement was used as a mechanism for the stabilization of the vertebral bodies. In cases of bone metastasis, the irradiation therapy provided by linear accelerators complements the treatment using Intensity Modulation Radiation Therapy (IMRT). IMRT proposes dose reduction in adjacent tissues;[4] however, it involves greater complexity including multiple fields to limit the prescribed dose at the target volume. In other procedures, the use of radioisotopes as rhenium-186 or stroncium-89, were considered with intravenous application providing an imparted absorbed dose in bone structure covering a broader systemic distribution, but with a clinical effect in favour of pain reduction. However, the restorative cement of the vertebral bodies was still the option held.[5]

In 1987, the vertebroplasty and kyphoplasty were introduced. Those techniques considered using the restore bone cement based on the volume of the affected vertebral bodies and the metastasis-type classification, well documented in the literature. It is worth mention that Harrington K.D introduced this classificaion in the early 80's.[6,7]

Similat to the palliative IMRT, the association of radiation therapy with vertebroplasty and kyploplasty procedures had the goal of reducing the symptoms of the bone metastases. In the early 90th, the Sm-153-EDTMP systemic therapy was investigated. The intraveneous use of Sr-89 and Re-186 produced a toxic effect holding high spinal cord neurological deficits due to an effect of demyelination.[8]

In 2006, a new material was introduced by the NRI research group - *Nucleo de Radiações Ionizantes* at UFMG, namely Radioactive Bone Composite including polymetylmetacrylate (PMMA) and an aggregate of hydroxyhepatite incorporating a radioactive metal in its structure.[9-12] Despite all the research and investiment in the radioactive cement in the NRI/UFMG, it is being a challenge the improvement of biocomposite affinity on the bone structure, the expantion of the absorbed dose distribution in situ, and the generation of knowledge in the properties of the radioactive cement and its interactions with the metastasis-bone interface.

The present review addresses these issues and describes this possible radiotherapic treatment represented by the interstitial insertion of an amount of radioactive cement within a bone structure, in particular in the thoracic vertebrae body. The cement contains a ceramic composite that maintains a radioisotope beta-emitter inserted into its amorphous structure. It can hold a spatial distribution such that ionizing radiation is spread and absorbed into the desired metastatic lesions, preserving the healthy adjacent tissues, avoiding possible invasive surgical procedures, and reducing indiscriminate radiation exposures.[13]

Some cancer epidemiological data in Brazil

Cancer data on a global scale, according to Globocan 2018, report that in the world about of 18 million people per year get sick because of cancer, holding the larger impact on women with breast cancer (24.2%), colon and rectum (9.5%), lung (8.4%), uteri cervix (6.6%); and, on men, with prostate (13.5%), colon and rectum (10.0%), liver (6.3%), lung (14.5%), stomach (7.2%); among others.[15] Our country is no stranger to this problem since the incidence of breast cancer has reached 29.5%, with 59,700 new cases in 2018-2019.[14]

Breast cancer has produced the greatest female cancer mortality in Brazil for several decades, with the incidence increasing significantly every year. Statistics have shown that, in 1986 when the Sistema Único de Saúde-SUS was stablished, 12.8% of women died due to cancer that year, and breast cancer was the leading cause of these deaths. In 1998, the total number of cases of breast cancer was about 32,000 whose 66% of women died. At 2014, the southeastern region of the country showed the highest number of registered cases followed by the Northeast and South of which 60% of deaths occurred due to breast cancer.[16] Studies showed that the common standard metastatic conditions are the visceral (liver, lung or pleura and breast) but in smaller proportion there is bone metastases, and consequently the possibility of application of percutaneous technique with bone cement.

Regarding the cancer incidence, it is urgent to develop protocols for addressing the problems that affect patients with dissiminated cancer in order to expand the action of the SUS in whole contry. Since breast cancer is the most likely to manifest metastasis both in thoracic region as in other parts of the body, new treatment methods need to expand, improve and be disseminated to increase the quality of life of patients and achieve a complete remission, even in clinical unfavorable situations. Even in regions with lower concentration of population, the numbers of cases are in smaller proportion, but they are still having a high impact and increasing incidence.[16] In addition, it is desirable the development and application of therapies that produce a lower operational cost, being minimal invasive, in order to reduce the risk of infections for patients whom in most cases are immune depleted.

The study of cements for treatments of bone metastases contains a number of clinical and technical knowledge that must be considered and detailed, at the time that new protocols are developed in the frame of the innovation of palliative treatments; in which the use of radioactive bone cement is promising.

Anatomic classification and structural mechanical functions of the bone tissue

When James Weinstein in 1989 established an anatomical classification of the regions of the vertebral body, it was possible to identify the most frequent metastases types in each of the regions and thus specify the most difficult to treat by their proximity to the spinal cord. This anatomical distribution basically presents four regions, in which regions III and IV, laid down in front of the spine,

are those that attend a percutaneous procedure by inserting a bone acrylic.[3,13,17] Those two regions due to your nature have the greatest tendency to collapse as a result of the metastases because those support a greater natural compression of the skeletal structure. In the long bones, abnormalities (tumors or metastases) are frequent in the metaphyseal region. Such tissue is a kind of intermediary tissue between the spongy tissue (epiphyses) and mature or osteolytic tissue (diaphyses).
The mechanical properties maintain an important role in the study of the skeletal system. Understanding your conformation and type of structures that are part of your composition are keys to propose possible substitute materials. Such material must have greater affinity for bone tissue, represented by the fibrils of collagen, which is the substance that composes most of the bone tissue, and the other substances as apatitas carbonate crystals and all proteins that are not collagens.

Bone diseases, types of metastasis

There are different bone neoplasms that degenerates the bone tissue being classified as benigns or malignants. Sarcomas are malignant neoplasms that manifestate in different regions of the bone tissue. However, the most relevant anomalies are especially those produced by the metastasis that represents the dissimination process of different cancer cells, via vascular or lymphatic systems, toward the bone bodies, where the clonogenic process is kept inside the bone. Bone metastasis is present in 80% of the loco-regional breast carcinoma.[20]

Bone cement, structure and composition

Several biomaterials have been proposed for the replacement of bone tissue or for the reconstituion of parts of them that are missing. Such material is able to add and paste parts of the structural bone. The fractures can be filled by acrylic PMMA cement, or even can be recomposed with biocompatible substances implanted as arrays as bioceramics of calcified phosphates.[21] Such bioceramics participate in the processes of adsorption and reabsorption of calcium, which manifest in biological phenomena such as the osteogeneses present in the regeneration of bone tissue in destroyed regions.[21] There are several studies in biophosphanates, among which we can highlight the hydroxyapatite (HAp). HAP presents itself in the natural bone with 69% of mass weight. Cristals of HAps are also distributed in the fiber matrix of collagen, which represents 20% of the bone tissue.[13] Since this substance is a natural bone constituent, HAp mixed with PMMA was proposed as biomaterial, reaching a great response of osteoblasts adhesion.[22.23]

Therapeutic treatment and percutaneous procedures

The vertebroplasty is a percutaneous minimally invasive procedure developed for surgery in spinal bone.[1] The procedure is performed by inserting acrylic in the fracture of the vertebral body. Such acrylic was developed and described for the first time in France in 1987.[6,13] This procedure makes use of a larger gauge needle to puncture the fractured vertebral body, where it is inserted the bone cement, stabilizing and reinforcing the bone structure to recover its original configuration. The technique was first used in the treatment of vertebral hemangiomas and subsequent in fractures of compression in osteolytic metastases and osteoporoses.[17] The technique has also been used for the treatment of osteoporosis and pathologic fractures by compression.In the United States, the most of the applications are related to osteoporosis. The literature reports a satisfactory rate of 90% pain reduction in metatatic sites. Besides, the percutaneous kyphoplasty procedure differentiates from the vertebroplasty technique. In Kiphoplasty, a balloon is inserted into the collapsed vertebral body, and the balloon is inflated prior to insertion of the bone cement. [3] in this case, the bone cement is contained internally by the surface of the balloon. Figure 1 illustrates some associated instruments to vertebroplasty.
Both techniques, using polymethylmethacrylate (PMMA), improve the stability of the vertebra and attempt to retrieve the original anatomical nature. The indications of vertebroplasty and kyphoplasty are to the treatment of tumors in the spine bone and the thoracic pain reduction from fractures of the lumbar vertebral bodies in patients with cancer. The contra indications are the epidural compression of the nervous system and the absence of recognition of symptomatic sites. Other contraindications are on coagulopathy and local infections.[24] One of the possible failures of these techniques that make use of restorative cements is the cement extravasation, although it is an unlikely phenomenon.
The treatments are completed with teletherapy in the metastatic lesions that can be prescribed by IMRT (Intensity Modulated Radiotherapy) or IGRT (Image-guided Radiotherapy). These procedures provide a single high dose application, assuming a no-split dose-protocol with absorbed doses limited. This procedure is scheduled after surgical removal of the tumor or metastic lesions. The IMRT is radiotherapy where there are a suitable modulation of beam-intensities and the full covering of the target region, accompanied by the reduction of dose in the surrounding healthy tissues. Some anatomical and physiological unique aspects of the vertebral

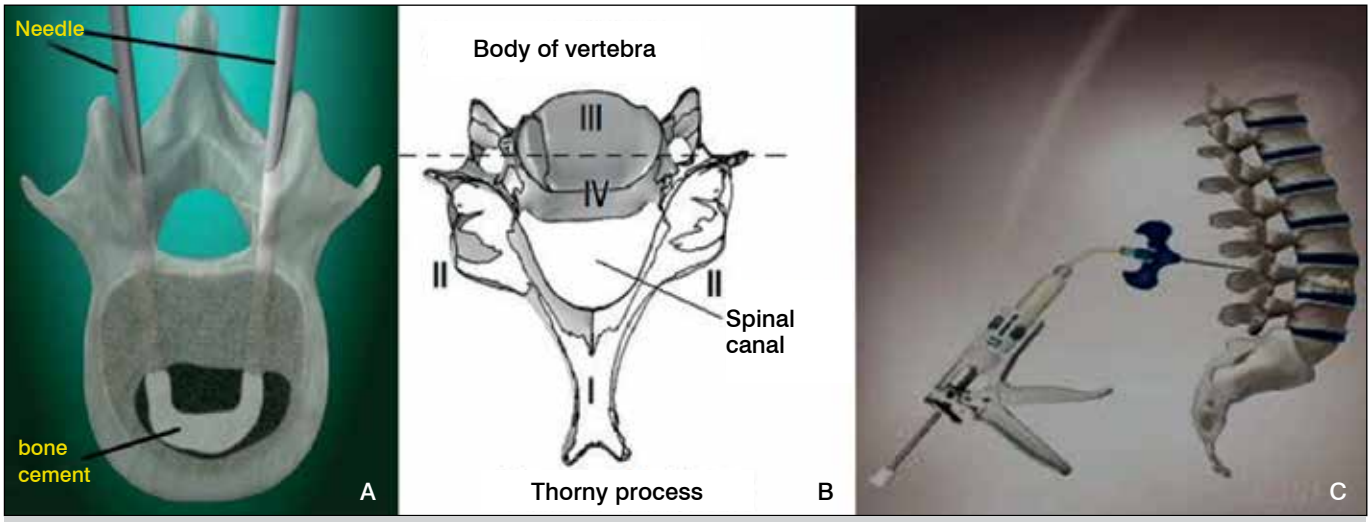

Figure 1. Minimal invasive procedures: anatomical position of vertebrae. (A) Vertebroplasty; (B) anatomical regions of the vertebrae according to Harrington; (C) Kit and Vertebroplasty simulation.[3]

body are of relevance.[4] The RT procedure´s restriction is on the low dose tolerance of the spinal cord to a no-fractionated regime. In fact, the recommended dose on the body of the vertebra must be greater than the tolerance dose of marrow, which produces a greater commitment for late neuro effects due to demyelination of the tissues of the nervous system, since its radiosensibility.

Systemic therapies are part of combined procedures for treatment of metastases. Chemotherapy, combined or mono, involves a set of drugs that depend on the histology of the tumor and of its quimio sensibility. In general, the drugs used in prostate or breast metastasis are cytotoxic agents with low specificity. The biophosphanates are used as pain reductions in cases of acute and moderate pain, contributing in the resorption of bone tissue removed by osteoclasts, and shrinking the tumors associated with osteolysis. [18] Studies in biophosphanates have shown a significant rate decrease of fractures of the skeletal system. The systemic drugs with intravenous administration containing strontium-89 and rhenium-186 may be used as systemic radiation therapy of the spine, being an alternative to treat pain.[25]

In 2008, Sm^{153}-EDTMP was incorporated into kyphoplasty;[7,26] however, limited into a balloon. Consequently, the applied dosimetry was neglegible.[27] At the kyphoplasty percutaneous procedure; the Sm^{153}-EDTMP was incorporated with the PMMA. The EDTMP is a biphosphanate that carries the Sm^{153} radioisotope by coordinating connection forming a complex.[7,26] The advantage of using a radioisotope is in optimizing the distribution of the effective dose, which may provide the prescribed dose predefined in other radiation therapies. The β-emitters P-32, Y-90, Ho-166 are included on the radioisotope group useful for these palliative treatment. In addition, those beta-particles emitters hold lower range in trabecular tissue; and, consequently, the spatial dose distribution is contained in the bone region, unlike with Tc-99, which is a gamma emissor.[27]

Radioactive material production, vertebral model and computational dosimetry

Studies conducted in our laboratory NRI-Nucleo de Radiações Ionizantes, by Drs. Rodrigo D'alessandro de Macedo, Márcia Flavia Silveira, Blanda Alves Donanzam, and Dr.Ilza Dálmazio, together with the present authors, provided the developed of the radioactive cement PMMA + M_HAp, being M a β^--emitter radioisotope ligand to the matrix of hydroxyapatite, and so providing a radioactive cement. [9-12] The synthesis of the bioceramic crystals of hydroxyapatite linked to the cold metal (cold = non-radioactive) was done using sol-gel technique.[9-12]

Initially, the cement was developed containing small amoung of mass of HAp in relation to the mass of the PMMA.[9] In these conditions, the material presented a very rapid polymerization. In addition, the biomechanical properties match with those of the compact bone. Such inorganic structure hinders the calcium trades by absorption and reabsorption present in the process of restoration of natural injured bone.

The M-HAp crystals exposed to thermal and epithermical neutron fluxes, about 2.6×10^{12} and 2.8×10^{11} neutron$\times cm^{-2} \times s^{-1}$, respectively, in an irradiation time of 8 h, provided specific mass activities more than enough to control bone metastasis. The ^{188}Re, ^{166}Ho and ^{153}Sm nuclides were chosen, mainly due to the easiness of the chemical synthesis, the low cost of the reagents, as well as the radiodosimetric advantages produced by β^--emitters. There were good spatial dose distributions in the vertebrae body and a rapid accumulation of dose, due to the short half-lives of nuclides; as well a negligible dose on spinal cord.[10,11]

The dosimetry of bone cements was demonstrated by studies in computational models.[10,11] In Figure 2, the employed computational model of the spinal cord is depicted. The model was developed with the aid

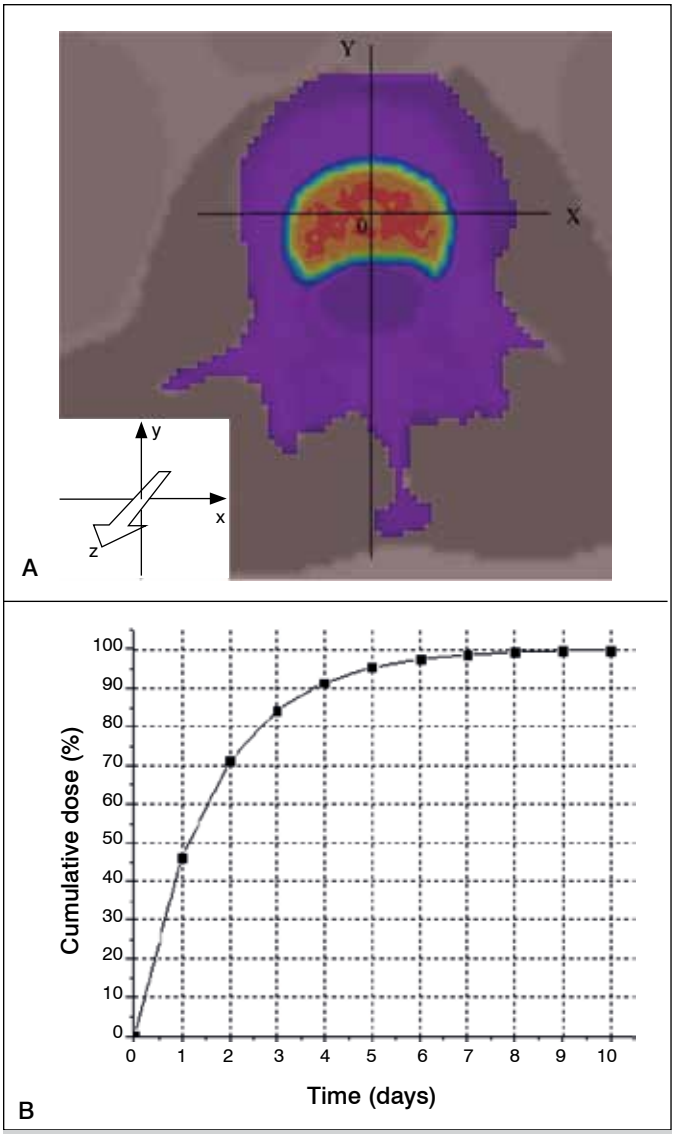

Figure 2. Computational model with MCNP5/Siscodes - BED. (A) vertebral model of the spine and isodose distribution. (B) accumulated dose curve for cement bound with Ho-166.[11]

of the SISCODES program and the transport of particles was made in code Monte Carlo N-Particle version 5 (MCNP5). The absorbed dose and the BED (Biological Effective Dose) in the body of the vertebrae and spinal cord have been assessed.[22,23] A HAp + Ho^{166}HAp + PMMA cement, containing one milligram of Ho^{166}HAp, provided a BED of 102 Gy_{10}, considering a activity of 32.5 MBq. In this procedure, there was a 10-folds reduction in spinal cord dose compared to an external beam radiotherapy procedure using IMRT or IGRT.

Figure 2b depicts a representation of the accumulated absorbed dose in function of time produced by the proposal radioactive concrete with Ho-166, whose total dose reaches 100% after a period of 10 days. On ongoing research, the bone cement is being synthesized with Sm-152 and activated in Sm-153. The half-lives of Ho-166 is 26.8 h and Sm-153 46.50 h, and both are beta emitters. The specific activity obtained for M-HAp, irradiated in the IPR1/CDTN reactor, was 32.5 MBq$\times mg^{-1}$ to Ho-166 is 14.5 MBq$\times mg^{-1}$ to Sm-153. The larger half-life of Sm-153 can encourage management of distribution of this radiopharmacal to the hospitals, improving the cost-benefit ratio.

FINAL REMARKS

Radioactive bone cement offers promising features for the treatment of bone metastasis in situ. However, finding the optimum conditions of application represents a challenge. Possible biomedical studies must be developed involving radio-toxicity, cytotoxicity, dosimetry, radiobiology, clinical response, among others. In an application, one can expect a good viscocity, a suitable curing time, high porosity after curing, and permeability to bone cells that progressively are able to regrow after the end of the radiation exposure. The cement must reach the regions of metastatic lesions that usually found in the trabecular bone, where the fractures are not of high impact. In these cases, the pain is associated with the compression of the existing micro tumors and presence of possible microfractures.[25]

The affected bone tissue has natural porous and have less resistant than compact one, showing constant regeneration. In these sites, other natural biological features are present, such as medular cell diffusions, angiogenesis and revascularization.[29-30] The future goal has been to transform the radioactive cement post-exposure more nature with characteristics of the porous bone tissue. The procedure should be optimizing avoiding unwanted effects such as thermal necrosis, produced by polymerization of PMMA where local temperatures can reach up to 110° C, and chemical necrosis, produced by excess of chemicals that induce polymerization. The ideal is to have a composite that deals with the metástasis in situ and produces a porous matrix that does not stop the natural bone regeneration processes.

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