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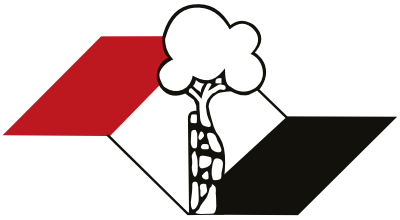

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LEVELS OF EVIDENCE FOR PRIMARY RESEARCH QUESTION: Access the following link.

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Levels of Evidence for Primary Research Question[a]

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

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

[a] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
[b] A combination of results from two or more prior studies.
[c] Studies provided consistent results.
[d] Study was started before the first patient enrolled.
[e] Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.
[f] The study was started after the first patient enrolled.
[g] Patients identified for the study based on their outcome, called "cases" eg, failed total arthroplasty, are compared with patients who did not have outcome, called ''controls'' eg, successful total hip arthroplasty.
[h] Patients treated one way with no comparison group of patients treated in another way.

SUMMARY

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FOOT AND ANKLE

LEARNING CURVE IN PONSETI METHOD – EVOLUTION IN 5 YEAR-INTERVALS

CURVA DE APRENDIZADO NO MÉTODO PONSETI – EVOLUÇÃO EM INTERVALOS DE 5 ANOS

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ABSTRACT

Objective: Evaluate whether the experience of the surgeon could reduce Ponseti treatment time, and a number of cast changes, and the evolution of the Pirani Score. Methods: 2 reference centers were evaluated. At Institution 1, 254 patients with idiopathic clubfoot (403 feet) were included, and at Institution 2, 32 patients (51 feet). At institution 1 (mentor), 3 intervals of 5 years each were analyzed. At the Institution 2 (trainee), 1 interval of 5 years was analyzed. Results: Patients treated by the mentor had fewer casts compared with the trainee ($p < 0.001$). At Institution 1, the three mentor intervals showed differences in the number of casts ($p < 0.05$). A statistically significant difference was observed only in the first mentor interval (2000 to 2005, average of 3.47 casts) compared with the 2 other intervals (2005 to 2010; average of 2.6 casts and 2011 to 2015; average of 2.79 casts; $p < 0.0001$). Pirani score decreases the most until the third clinic visit. Conclusion: The mentor's greater expertise was associated with fewer casts and shorter time to obtain correction in isolated clubfoot, especially right after the first 5 years of practice. Progression of the Pirani score in both institutions occurs between the first and the third casts. ***Level of Evidence III; Therapeutic Study, Retrospective Comparative Study.***

Keywords: Learning Curve. Clubfoot. Education, Medical. Inservice Training.

RESUMO

Objetivo: Avaliar se a experiência no Método Ponseti pode reduzir o tempo de tratamento e o número de gessos. Métodos: Na instituição 1 foram incluídos 254 pacientes com pé torto idiopático (403 pés) e na instituição 2, 32 pacientes (51 pés). Na instituição 1 (mentora) foram analisados 3 intervalos de 5 anos. Na instituição 2 (estagiária), foi analisado 1 intervalo de 5 anos. Resultados: Os pacientes tratados pelo mentor tiveram menos gessos em comparação aos tratados pelo estagiário ($p < 0,001$). Na Instituição 1, os três intervalos de mentores apresentaram diferenças no número de gessos até a correção dos pés ($p < 0,05$). Diferença estatisticamente significativa foi observada no primeiro intervalo do mentor (2000 a 2005, média 3,47 gessos) em comparação com os outros 2 intervalos (2005 a 2010; média 2,6 gessos e 2011 a 2015; média 2,79 gessos; $p < 0,0001$). O escore de Pirani diminui mais até a terceira consulta clínica. Conclusão: A maior expertise do mentor no Método Ponseti esteve associada ao menor número de gessos e ao menor tempo para correção do pé torto, principalmente logo após os primeiros 5 anos. A maior progressão do score de Pirani ocorre entre o primeiro e o terceiro gesso. ***Nível de Evidência III; Estudo Terapêutico, Estudo Comparativo Retrospectivo.***

Descritores: *Curva de Aprendizado. Pé Torto Equinovaro. Educação Médica. Capacitação em Serviço.*

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INTRODUCTION

Idiopathic clubfoot is one of the most common birth defects occurring in one in 1000 live births.[1,2] Natural evolution of the deformity has a major impact on family's social and emotional issues.[3-5] Until the beginning of the XXI century, treatment of clubfoot was essentially surgical, but results were poor and complications, including stiffness of the ankle and subtalar joint, pain, arthritis, residual deformity, and muscle weakness, were high.[1]

Ponseti Method revolutionized the history of clubfoot. Difusion of Ponseti Method was increased by the publication of Dr Ponseti 30 year results in JBJS, in 1995, and his book in 1996[2,3]. Orthopaedic services globally started to learn and apply Ponseti Method around 2000's and international publications reflect this tendency.[2] Compared with the traditional 2 day course/symposium format, the mentorship educational model can reduce complications and

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The study was conducted at the Hospital do Servidor Público Estadual de São Paulo (HSPE), São Paulo, Brazil.
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increase the effectiveness. However, transition to this new technology was not simple.[6] The usual structure for orthopedic surgeon's training needed to be revised. In 1999, Shafique Pirani introduced a fast and reproducible score.[7,8]
With diffusion of Ponseti Method, without adequate training, the number of complications increased. Medical training through mentorship educational model was able to reduce complications and improve effectiveness and efficiency of the Ponseti Method.[4,9]
In medical literature there are no specific studies on the learning curve in the Ponseti Method. The purpose of this retrospective cohort study was to demonstrate the orthopedic surgeon's learning curve in the Ponseti Method to treat idiopathic clubfoot considering the number of casts, treatment time and the correction progression according to the Pirani Score. Primary questions were: (1) Does greater experience in the Ponseti Method reduce the number of casts and treatment time? (2) Is the evolution of clubfoot correction through the Pirani Score modulated by the expertise in the Ponseti Method?

METHODS

This is a retrospective comparative cohort study. Data from 2 reference services with orthopaedic surgeons trained in Ponseti method were evaluated. At institution 1, patients undergone treatment by a senior orthopedic surgeon with more years in practice. In this center, 254 patients diagnosed with idiopathic clubfoot (403 feet) met the eligibility criteria. In institution 2, where patients were treated by an orthopedic surgeon with less years of practice, 32 patients with idiopathic clubfoot were included (51 feet).
In institution 1, data obtained from medical records were analyzed at 3 intervals of 5 years each, considering the total time of Ponseti Method practice (2000 to 2005, 2005 to 2010 and 2011 to 2015) totaling a period of 15 years. In the Institution 2, data were analyzed in 1 interval of 5 years (2011 to 2015). In both institutions, treatment was carried out with strict adherence to Ponseti Method.
Just after residency, the orthopaedic surgeon from institution 2 (TMG - *trainee*) and the orthopaedic surgeon from institution 1 (MPN - *mentor*) developed an academic relationship also based in mentorship to refine the practice in the Ponseti Method.
The learning curve in the Ponseti method was characterized by the average number of casts in each period of the mentor and the trainee.
Patients started treatment at 14 to 180 days of age. The minimum follow up was 15 weeks after Achilles tenotomy (last event to be included in data analysis). Cases without tenotomy were not included in the study. Neurological and or syndromic clubfoot, and with any previous surgery were excluded.
Two hundred and eight-six patients were evaluated, in a total of 454 feet. At Institution 1, the mentor treated 403 feet (88,76%) and data were analyzed at 3 intervals: from 2000 to 2005, from 2005 to 2010 and from 2011 to 2015. At Institution 2, the trainee treated 51 feet (11.24%) and data were analyzed in one interval from 2011 to 2015. Patients were consecutive, and not randomized in this study.
Institution 1 is a large tertiary hospital, with residency in orthopedics and fellowship in Pediatric Orthopedic Surgery, serving a metropolitan area with an estimated city population of 12 million people in 2020. Care at institution 1 was managed only by the orthopedic surgeon (mentor) who has been practicing there for 15 years and is the head of the Pediatric Orthopedic Department.
Institution 2 consisted of a small secondary pediatric hospital, with an estimated city population of 162,000 people in 2020. At institution 2 care was managed only by the orthopedic surgeon (trainee), who had 2 years of practice after residency in Pediatric Orthopedics.
Quantitative variables were: age (in months), time until tenotomy (in days) and number of casts. Qualitative variables were: gender, side, and professional responsible for the patient (mentor or trainee).
We compared the quantitative variables.Time until tenotomy was shorter in patients treated by the mentor ($p < 0.001$), the mentor needed fewer casts to obtain correction ($p < 0.001$), the age of patients treated by the mentor and the trainee did not have statistical relevance ($p = 0.0973$).
The analysis of the quantitative variables age (in months), time until tenotomy (in days) and number of casts were done with the t-Student Test. For all tests the significance level was 5%. Another quantitative variable was the correction evolution trough the Pirani Score. Comparison of the number of casts in the different time intervals was done by the ANOVA variable analysis.[10] Averages of the Pirani Score, number of casts and time until tenotomy were compared between the sides right and left. In this analysis, only patients with bilateral clubfoot were compared. As the different sides were from the same patient, the statistical analyses used was the Generalized estimating equation (GEE).[11-13] Model was adjusted considering normal distribution and unstructured correlation structure (significance level was 5%).
Correlation between the severity of the foot according to the Pirani Score and time to tenotomy was evaluated according to the Spearman coefficient (closer to +1 and -1, stronger the correlation). Evolution of the Pirani score through the appointments was analyzed, as well as this correlation and its comparison between genders and laterality through the approach of mixed models with repeated measures. For all comparisons was considered 5% as significance level.

Code availability

The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials. The data sets used and/or analysed during the current study are available from the corresponding author on reasonable request. The data are not publicly available due to information that could compromise the privacy of research participants.

Ethics approval

This study was approved by Institutional Ethics Committee under opinion number 1.365.728.

Consent to participate

Written informed consent according to the Declaration of Helsinki was obtained from all study participants and in applicable cases their parents or legal guardians.

Consent for publication

Written informed consent was obtained from all patient/parents/legal guardians for publication of this study and any accompanying images and videos. A copy of the written consent is available for review by the Editor of this journal.

RESULTS

Patients treated by the mentor needed fewer casts to obtain correction (average of 2.8 cats) than patients treated by the trainee (average of 5.5 cast; $p < 0.01$). Time until tenotomy was shorter in patients treated by the mentor, average of 15.9 days for patients treated by the mentor and 42.7 days, patients treated by the trainee ($p < 0.01$). (Table 1)
Regardless the professional, the Pirani score decreases the most until the third clinic visit, without differing in the subsequent appointments. (Figure 1)
There was no correlation between severity of the Pirani score and time until tenotomy (Spearman correlation 0.318).
There was a significant difference in the number of casts until correction between the 3 analyzed mentor intervals ($p < 0.05$).

Table 1. Comparison of professionals.

		Professional		
		1	2	p-value
Time until tenotomy	n	371	43	< 0.001
	Average	15.9	42.7	
	Median	14.0	32.0	
	Stardard deviation	10.0	34.2	
	Minimum value	2.0	7.0	
	Maximum value	70.0	158.0	
Number of casts	n	403	51	< 0.001
	Average	2.8	5.5	
	Median	3.0	4.0	
	Stardard deviation	1.3	3.3	
	Minimum value	1.0	1.0	
	Maximum value	7.0	14.0	

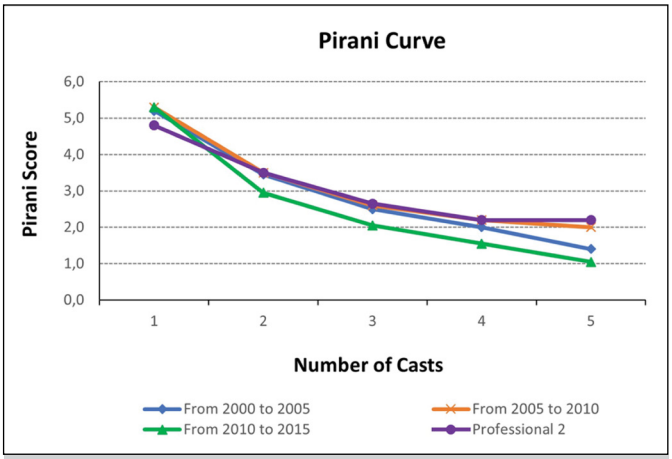

Figure 1. Pirani curve at all intervals (consecutive scores for every visit).

Only the first interval (2000 to 2005) compared to the others had statistical difference ($p < 0.05$), evidencing that after 5 years of experience the mentor needed fewer casts to obtain correction. In the first mentor interval (2000 to 2005) the average number of casts per patient until correction of the deformities was 3.47. In the second interval (2005 to 2010) was 2.6 and in the third interval the mentor needed an average of 2.79 casts to obtain correction, featuring a plateau. The mentor evolution shows that the number of casts per patient decreased as the experience increased over time. (Table 2, Figure 2)

DISCUSSION

Clubfoot is a public health matter, affecting 200,000 children every year in the world. The consequences when clubfoot is not treated can be devastating and can cause a high social and financial impact on patients, families and in the health care system.[4] Ponseti method provides good results, is low cost and highly reproducible when not modified.[14] However, close attention should be paid to details. Incorrect casting can lead to complication as complex clubfoot with requires even more specific and delicate treatment. Learning curve for medical procedures involving surgeries was designed for the United Kingdom's Health Ministry by Hoper and it has 4 main phases. First phase represents the beginning of training; in the second phase the curve ascends, and the gradient of this ascent indicates how quicky individuals' performance improves and may be a stepwise ascent as individuals learn and master stages of complex procedure. Improvements in performance tend to be most rapid at first and then tail off, as the degree of improvement attained with each case reduces as techique is refined. In the third phase, assuming an adequate aptitude, a point is reached when the procedure can be performed both independently and competently. Additional experience improves outcomes by very small amounts, until a plateau is reached. In the fourth phase, with advancing age, manual dexterity, eyesight, memory and cognition may deteriorate, outweighing any advantage from long experience, leading to a fall in the level of performance. An alternative curve has been also described, which exhibits temporary performance deterioration after technical competence has been achieved and the probable reasons are technical adaptations or over confidence resulting in lapses in technique or judgement.[15] (Figure 3)

Table 2. Comparison between different periods of professional 1

		Professional 1			
		From 2000 to 2005	From 2005 to 2010	From 2011 to 2015	Professional 2
Number of patients		39	96	118	33
Number of Casts	Number of feet	53	149	201	51
	Average	3.47	2.6	2.79	5.51
	Median	3	2	3	4
	Standard Deviation	1.3	1.3	1.33	3.26
	Minimum Value	1	1	1	1
	Maximum Value	6	7	7	14

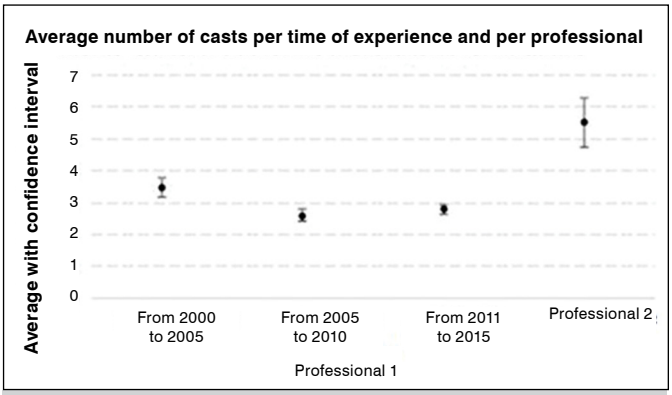

Figure 2. Average number of casts per length of experience and per professional.

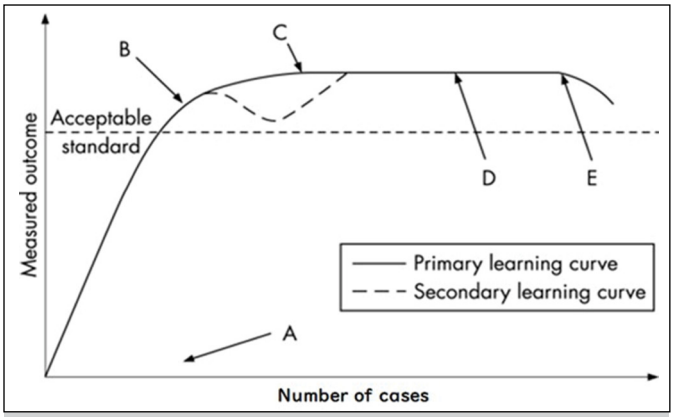

Figure 3. Hopper learning curve. A: Training start, B: Ability to perform the procedure competently and independently, C: Gain of professional experience doesn´t change the final result, D: Plateau, E: Drop in performance with advancing age.

Many orthopedic procedures such as resurfacing hip arthroplasties[16, 17] and the treatment of hip dysplasia[18] had described their learning curve. The learning curves show that practitioners improve their results and decrease complications as the experience increases. The purpose of our study was to demonstrate the orthopedic surgeon learning curve in the Ponseti method to treat idiopathic clubfoot considering the number of casts, treatment time and the correction progression according to the Pirani Score. We found that in the beginning of practice both practitioners obtained correction of the deformities in a similar way regarding number of casts, but as the mentor became more experienced over time the number of casts needed to obtain correction of the deformities decreased.

The mentor's learning curve demonstrated that the number of casts to correct the feet in the second interval (2005 to 2010) was fewer than in the first interval (2000 to 2005), but was similar to the third interval (2010 to 2015). It is possible to compare this curve to the drawing of Hoper learning curve.[19] The first interval as the coordinate A, in the beginning of training the curve raises demonstrating the gradually performance improvement as the practitioner learns and masters treatment techniques. The second interval as coordinate B in Hoper's learning curve drawing, when the practitioner is adequately qualified and can perform the procedure independently and competently. In the learning of the Ponseti Method, the alternative curve between coordinates B and C that exhibits temporary deterioration in performance after technical competence has been achieved may represent the period in which the practitioner has already reached technical competence and starts to make adaptations to the Ponseti method, in addition to mixed and more complex cases. Mentors third and last interval is represented by coordinate C, where additional experience improves results in very small amounts, suggesting a plateau on the learning curve (Figures 1 and 3). We can also infer that the learning curve in the Ponseti method is a tool that helps the training orthopedic surgeon self-evaluation.

The mentor's evolution showed that the number of casts necessary to obtain correction decreased as the gain of experience increased, especially in the second interval five years after the beginning of practice. This evolution characterizes the learning curve in the Ponseti method to treat idiopathic clubfoot.

Both centers treated more than 50 clubfeet. The Ponseti International Association (PIA) guidelines recommend as able to treat clubfoot patients the professional who has treated at least 50 feet.[20]

Consequences when not treating a congenital clubfoot can be devastating. In ambulatory children, the deformity causes the child to walk on the lateral border of their foot. The social, emotional and financial consequences of non treated clubfoot are felt for a lifetime.[20,21]

The practice of many orthopedic procedures has already shown that there is an improvement of results and reduction of complications with the gain of experience.[16-18] Considering the number of casts per patient to obtain correction of deformities, both the mentor (average of 3 casts per patient) and the trainee (average of 5 casts per patient) managed to correct the deformities of clubfoot within the number of casts changes suggested by Dr Ponseti.[3,22]

The Pirani Score measure clubfoot severity visually, dynamic and tactile and assists the orthopedic surgeon in the learning curve of the Ponseti method.[7]

Indication for tenotomy is a corrected foot concerning forefoot alignment and an abduction of 70º degrees. The equinus correction through the subtalar joint is maximal, lacking only final degrees of ankle dorsiflexion. The authors had performed tenotomy in 98% of cases. No foot needed extensive surgery such as posterior or posteromedial release.

The most important decrease of the Pirani Score for all patients occurs from the first to the second cast and it's associated with the forefoot. Hindfoot deformities are the last to be corrected, and the equinus usually is obtained only with the tenotomy of the Achilles tendon.

There was no correlation between the severity of the Pirani score and time until tenotomy, meaning that the greater severity of the foot is not an indication that patient will need more casts until correction.[23,24] This is a relevant fact as the progression of correction depends more on how the foot will answer to treatment than to practitioner's expertise.

Patient's age, which often drives families away from less invasive treatment and may be a demotivating factor for the orthopedic surgeon to start the treatment, was not related to the number of casts (patients age from 14 to 180 days old). This finding was also observed by an European study comparing the success of the Ponseti method in patients younger and older than 6 months old.[25] An American study demonstrated that there is no urgency in start treatment in clubfoot newborn patients.[15]

Since 2016, PIA Brasil (Ponseti International Association affiliated), team formed by a group of pediatric orthopedic surgeons concerned with the correct diffusion and application of the Ponseti method, joined a partnership with Rotary International and with a global grant started a national training program. This was an educational program that has already trained 50 orthopedic practitioners of the Ponseti method in the mentorship model with the aim of improving the technique and creating a net of reference centers throughout the country. Differentials of the mentoring model include the close mentor/ trainee relationship, hands-on practice, contact with patients at various stages of treatment and case discussion with experienced mentors. This may collaborate for acceleration of young practitioners learning curves. This training program has already been replicated in other countries in Latin America.

We suggest that administration support, parent's groups support, and mentoring model training are relevant in the learning curve of the Ponseti method.

CONCLUSION

The experience of the orthopedic surgeon results in a shorter treatment time and fewer cast changes, when three 5-year interval times are analyzed, regardless foot's side or severity and patient's age or gender. The Pirani Score also followed the same pattern, characterizing Ponseti method learning curve.

AUTHORS' CONTRIBUTION: TGM: Conceptualization, Formal analysis, Investigation, Writing - Original Draft. MPN: Methodology, Validation, Writing - Review & Editing, Supervision.

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WRIST AND HAND

CLINICAL AND FUNCTIONAL EVALUATION OF WRISTS AND HANDS OF SPINAL CORD INJURED PATIENTS

AVALIAÇÃO CLÍNICA E FUNCIONAL DE MÃOS E PUNHOS DE PACIENTES LESADOS MEDULARES

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ABSTRACT

Introduction: The inability of the spinal cord to propagate sensory and motor stimuli as a result of the disruption of the nerve tracts is called spinal cord injury. Objective: This study analyzes clinically and radiologically the hands and wrists of spinal cord injured patients, evaluating their motor and sensitive functionality, in order to determine if these patients are more likely to develop degenerative alterations. Methods: 14 patients (8 paraplegics and 6 tetraplegics) were evaluated, undergoing anamnesis and clinical examination - a scale of muscular strength (MRC - Medical Research Council) and the amplitude measurement of the movement with a manual goniometer (ROM), were used for objective evaluation - and x-ray exams. The results were compared with pre-existing data from other studies. Results: When asked, only one of the 14 observed patients complained about constant wrist pain, described as level 3 (weak to moderate), based on the visual analog scale (VAS). The motor evaluation, MRC and ROM divided the group of patients into two subgroups: paraplegic and tetraplegic patients. The x-ray analysis showed, based on Kellgren and Lawrence classification, that all exam images fit grades 1 or 2 of osteoarthritis and osteoarthrosis. Conclusion: In conclusion, spinal cord injured patients showed none or minimal clinical and radiological signs of osteoarthritis on hands or wrists. Overall, the hands and wrists of spinal cord-injured patients behave similarly to noninjured patients. ***Level of Evidence III; Retrospective Comparative Study.***

Keywords: Osteoarthritis. Pain. Muscle Strength.

RESUMO

*Introdução: A incapacidade da medula espinhal de propagar estímulos sensoriais e motores como resultado do rompimento das vias nervosas é chamada de lesão da medula espinhal. Objetivo: Este estudo analisa clínica e radiograficamente mão e punhos de pacientes lesados medulares, avaliando função motora e sensitiva, a fim de determinar se estes pacientes estariam mais propensos a alterações degenerativas. Métodos: 14 pacientes (8 paraplégicos e 6 tetraplégicos) foram avaliados, passando por anamnese e exame clínico - sendo escala de força muscular (MRC - Medical Research Council) e a medição da amplitude de movimento com um goniômetro manual (ROM) foram utilizados para análise objetiva - e radiografias. Os dados obtidos foram comparados com literatura preexistente. Resultados: Quando questionados, apenas um dos 14 pacientes observados referiu dor crônica nos punhos, descrita como nível 3 (fraca a moderada), baseada na escala visual analógica. A avaliação motora, MRC e ROM dividiram os pacientes em 2 subgrupos: pacientes paraplégicos e tetraplégicos. A análise radiográfica mostrou, baseada na classificação de Kellgren e Lawrence, que todas as imagens se encaixam nos graus 1 ou 2 de osteoartrite e osteoartrose. Conclusão: Conclui-se, então, que pacientes lesados medulares apresentam nenhuma ou mínimas alterações clínicas e radiológicas para osteoartrite ou osteoartrose de punhos ou mãos. Ou seja, no geral, mãos e punhos de pacientes lesados medulares comportam-se como os pacientes sem lesão medular. **Nível de Evidência III; Estudo Retrospectivo Comparativo.***

Descritores: *Osteoartrite. Dor. Força Muscular.*

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INTRODUCTION

The inability of the spinal cord to propagate sensory and motor stimuli as a result of the disruption of the nerve tracts is called spinal cord injury. Motor and sensory dysfunctions are observed in the body segment below the level of the injury, affecting the locomotor system, viscera and homeostasis of the body, by deregulating the sympathetic nervous system.[1,2]

They can be complete or incomplete, which implies the clinical picture of the spinal cord injury, because in partial injury, muscle groups and sensory areas may be preserved, while in total injury there is total loss of these functions, and the entire body segment below the injury is affected.[1]

Spinal cord injury can be: tetraplegia, which consists of the loss of motor and/or sensory function affecting both the lower and upper limbs, trunk and pelvic organs, and paraplegia, which is the loss of function of the thoracic, lumbar and sacral segments, including the lower limbs.[2]

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

The study was conducted at the Ambulatório de Reabilitação Raquimedular, Hospital de Clínicas, Campinas, SP, Brazil.
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The most frequent traumatic causes are gunshot wounds, automobile accidents, falls from heights, and diving in shallow water. Non-traumatic lesions are tumors, infections, vascular changes, congenital malformations, or degenerative or compressive processes. In Brazil, traumatic spinal cord injuries are unknown, as they are not reported, and it is estimated that the annual incidence is approximately 40 cases/million in inhabitants. Isaiah 1:3-5
Spinal cord injury represents an important disabling syndrome since the sequelae become highly limiting in the physical and socioeconomic spheres. Therefore, rehabilitation aims to reintegrate him into the activities of society.[6-8] years
Orthopedic comorbidities are common and mainly affect the joints of the upper limbs, especially paraplegic ones. They are considered secondary to the increase in stress caused using these upper limbs, as they are recruited to try to compensate for the lack of lower limbs; Paraplegics use the strength of the upper limbs to move, either for body transfer and accommodation or for propulsion in a wheelchair and walker. The upper limbs of patients with spinal cord injury are recruited with greater frequency and strength when compared to patients without spinal cord injury, which results in greater stress and overload on these limbs. Studies indicate that the most important pain complaints are from the shoulder, elbow, wrist and hand.[9-12]
This study highlights these comorbidities related to the wrist and hand joints in paraplegic and quadriplegic patients and compares clinical and radiological criteria with normality parameters in the literature.

METHODS

The study was conducted at the spinal cord injury outpatient clinic of the University Hospital, SP, Brazil, in 2020/2021 and approved by the CAE ethics committee: 23257613.4.0000.5404.
A total of 14 patients were evaluated, eight paraplegic and six quadriplegics, aged between 28 and 68 years (mean 45 years). Of the patients, 12 were male and two were female. The ASIA test was performed to classify spinal cord injuries. The ASIA of each patient was related to the respective mechanism that led to the spinal cord injury. First, a subjective evaluation was performed, which consisted of a detailed anamnesis to evaluate complaints associated with pain, and an inspection of the patients' hands, looking for deformities, calluses, and retractions.[13,14]
Then, the sensory and motor evaluation of the patients' hands and wrists was performed bilaterally to determine the preservation of certain functions of the median, radial and ulnar nerves. The patients were separated into two subgroups, differentiating paraplegics (8 individuals) and quadriplegics (6 individuals).
The physical-motor examination seeks to identify lesions in the median nerve, which result in paralysis or paresis of the muscles responsible for hand abduction and the ability of the thumb to oppose or makes it impossible or difficult to grasp between the thumb and the other fingers of the hand. Injuries to the radial nerve, which cause difficulty grasping objects as they affect the extension of wrists and fingers. On the other hand, ulnar nerve injuries result in claw deformity in the little and ring fingers (hyperextension of the metacarpophalangeal joints and flexion of the interphalangeal joints).[15th]
To analyze the preservation of the sensory functionality of the superior peripheral nerves, we took into account the area of cutaneous innervation of these nerves, where the radial nerve is responsible for the cutaneous innervation of the lateral region of the dorsum of the hand, dorsum of the thumb, proximal phalanges of the index and middle fingers, and a large part of the posterior region of the arm and forearm; cutaneous innervation of the lateral half of the palm, palmar surface of fingers I-III and half of the IV finger, and dorsal surface of the middle and distal phalanges of the II and III fingers and lateral half of the IV finger; and, finally, the ulnar nerve, responsible for the cutaneous innervation of the hypothenar eminence and the medial region of the dorsum of the hand.[15th]
The superficial flexor, deep flexor, superficial extensor and deep extensor muscles of the hand were analyzed using the MRC-Medical Research Council as a parameter.[16]
During the physical examination, the range of motion (ROM) was measured using a goniometer to assess the angles of supination/radioulnar pronation and flexion/extension and abduction/adduction of the wrist. The values considered normal for joint range of motion are:[17]
Supination and radioulnar pronation: 0°-90°
- Wrist flexion: 0°-90°
- Pulse extension: 0°-70
- Pulse abduction: 0°-20°
- Wrist adduction: 0°-45

Angular and mobility measurements were performed by manual methods by three examiners. Each examiner performed three measurements and the mean was. (Figures 1 and 2)
considered in relation to the 9 measurements performed, this one was repeated for each angulation given by the manual goniometer. This method was performed due to the lack of a digital goniometer.
The study used radiographic examinations of the wrist in the anteroposterior and lateral positions for analysis and classification of the stages of osteoarthritis to compose the radiographic analysis of the patients. As exemplified below (both images are of the same patient):
The Kellgren and Lawrence system was used for the classification, which, according to the appearance of osteophytes in the marginal joints, periarticular ossicles or pseudocysts and joint reduction associated with subchondral bone sclerosis and marginal bone alteration, categorizes the radiological image and, consequently, the osteoarthritis of the patients. According to Kellgren and Lawrence's classification, OA can be divided into the following categories:[18]
0: no change, no osteoarthritis
1: some alteration may be found, indicating the onset of osteoarthritis, but without clinical repercussions
2: minimal and confirmed diagnosis of osteoarthritis, but minimal severity
3: Moderate
4: Record

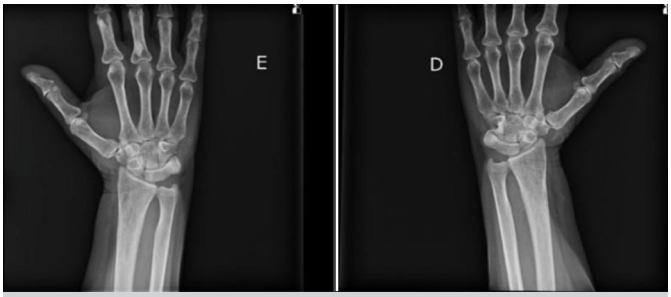

Figure 1. Anteroposterior view: radiographic image of the left and right hand and wrist, respectively.

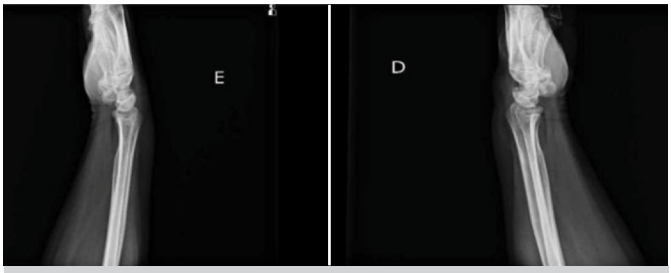

Figure 2. Lateral view: radiographic image of the left and right hand and wrist, respectively.

All analyses were performed bilaterally.
For the statistics, the data obtained according to these methods, their maximum values, minimum values, standard deviation and mean were considered.

RESULTS

Fourteen patients with a average age of 45 years (ranging from 28 to 68 years) participated in the study; 2 were female and 12 were male. Level and characteristic, according to the ASIA standard categorization, as well as the mechanism of this lesion, are described in the table below. (Tabela 1)[14]
ASIA "A") Complete Injury: Without preservation of motor and sensory functions in the sacral segment S4-S5.
ASIA "B") Incomplete Injury: Loss of motor function, but preserved sensory function below the neurological level and includes sensitivity of sacral segment S4-S5.
ASIA "D") Incomplete Injury: Preserved motor function below neurological level, and more than half of the key muscles below neurological level have a strength grade of 3 or more.[14]
During the anamnesis, one patient interviewed reported constant wrist pain, which he described as a level 3 pain (weak to moderate) according to the Visual Analog Pain Scale. The other 13 study participants reported no complaints of significant severity and constancy regarding pain. Also, no relevant deformities such as calluses and retractions were observed.[13]
Then, the physical examination was performed to evaluate the preservation of peripheral nerves of the upper limbs, following the distinction made between paraplegic and paraplegic patients. Among the paraplegic patients, only one of the eight patients observed presented some functional limitation, and a functional dysfunction was described only in the median nerve. For the group of quadriplegic patients, it was not possible to identify any level of functionality and preservation of these nerves, not having any type of movement or sensibility.
About the Muscle Strength Evaluation Scale (MRC-Medical Research Council), it is important to separate the patients into groups. For the paraplegic patients, the following averages were found. (Tabela 2)
In contrast, as already observed in the previous analysis, those quadriplegic patients presented mean, and standard deviation, 0 (zero) in the muscle strength evaluation, showing no evidence of muscle contraction - an expected characteristic due to the high spinal cord injury.

Table 1. The spinal cord injury is classified according to the international standardization determined by the American Spinal Injury Association-ASIA.

ASIA	injury mechanism
C3A	fall from height
C4A	car accident
C4B	car accident
C5A	shallow water diving
C6B	gunshot wound
C6B	shallow water diving
T4A	car accident
T4B	gunshot wound
T7A	fall from height
T7A	fall from height
T7A	car accident
T8A	car accident
T8D	spinal cord infarction
T12A	car accident

Then, the measurement of range of motion (ROM) was analyzed, with the goniometer as an instrument. Again, since this is an analysis of the active hand positioning ability, the data obtained for the quadriplegic patients were 0 (zero), mean and standard deviation. For the paraplegic patients, the results of the averages obtained were as follows. (Tabela 3)
Finally, radiographic examination was performed to investigate OA in these patients, which indicated the following results described below. (Tabela 4)
Among the patients analyzed, radiographs showed that from the total of 16 wrists and hands belonging to the paraplegic group, 81.25% fit OA stage 1 and 18.75% stage 2. For the quadriplegic group, the analysis showed a sample of 50% with OA stage 1, and the rest of them were classified as OA stage 2. A total of 12 wrists and hands of quadriplegic patients were counted.

DISCUSSION

The objective of this study was to carry out, through the methodologies presented, a functional and motor evaluation of patients with spinal cord injury and to try to compare whether their daily activities, with the use of wheelchairs and repetitive movements, favored the development of osteoarthritis; To evaluate the relevance of the data obtained to confirm whether, in fact, the use of wheelchairs in patients with spinal cord injury favored the development of joint problems in the wrists and hands.

Table 2. MRC-Medical Research Council (0) Absence of contraction; 1) Outline of muscle contraction; 2) Active movement, but not overcoming gravity; 3) Active movement against gravity; 4) Active movement against gravity and with resistance; 5) Complete mobility, overcoming additional resistance.[16]

Muscles	Averages MRC	Maximum value MRC	Minumum value MRC	Standard deviation
Left flexor superficialis	4,8	5	4	0,44
Right flexor superficialis	5	5	5	0
Left flexor profundus	4,8	5	4	0,44
Right flexor profundus	5	5	5	0
Left extensor superficialis	4,8	5	4	0,44
Right extensor superficialis	5	5	5	0
Left extensor profundus	4,4	5	3	0,89
Right extensor profundus	4,4	5	3	0,89

Table 3. The normal values for joint range of motion are: radio-ulnar supination and pronation: 0°-90°; wrist flexion: 0°-90°; wrist extension: 0°-70°; wrist abduction: 0°-20°; wrist adduction: 0°-45°.[17]

Measure	Angulation Average	Standard Deviation
Left radioulnar supination	88,4°	1,81
Right radioulnar supination	87,2°	4,08
Left radioulnar pronation	86,8°	4,43
Right radioulnar pronation	86°	4,18
Left wrist flexion	75,2°	11.54
Right wrist flexion	77°	13.85
Left wrist extension	62,6°	11,58
Right wrist extension	56,8°	5,89
Left wrist abduction	33,8°	15,56
Right wrist abduction	34,6°	12,05
Left wrist adduction	56,2°	10,75
Right wrist adduction	55,2°	9,80

Table 4. Kellgren-Lawrence Arthrosis Rating Scale - 0) None; 1) Questionable 2)Minimal; 3)Moderate; 4)Severe.[18]

Patient asia	Years of age	Osteoartrite XR left	Osteoartrite XR right
T8A	36	1	1
T7A	68	1	1
T12A	28	1	1
T8D	61	1	1
T4B	29	1	1
C4B	58	2	1
C4A	50	2	2
C3A	42	2	2
T7A	42	2	2
C5A	35	2	1
C6B	35	1	1
T7A	43	1	1
T4A	55	1	2
C6B	52	1	1

Most of the patients were male, young adults, with equal distribution in relation to the height of the lesions and different mechanisms for these lesions.

With the results obtained, it was possible to perceive that patients with spinal cord injury have mild or absent clinical and radiographic alterations in the wrists and hands. Among the patients analyzed, only 32.14% had signs of osteoarthritis (category 2), and the remainder were classified as category O or 1 osteoarthritis, which presented mild alterations, without a definitive diagnosis and without clinical repercussions worthy of note.

In the functional and motor evaluations carried out during the development of the research, the following will be discussed:

In the anamnesis, only one of the patients reported complaints associated with pain, such as inflammatory pain, or worsening at rest and with some morning stiffness, which improved after 30 minutes of movement. The remaining patients did not complain of significant pain.

In the motor physical examination, the objective was to identify lesions of the median, radial and ulnar nerves, the results found corroborated findings in the literature. The clinical findings were consistent with those expected for the ASIA examination, which is the characteristic and height of the spinal cord injury, as described by Mazurek, Michael T.MD et al (2001) and Maynard FM Jr et al (1997).[14.15]

According to the authors, during the physical examination, the preservation of the sensory function of the superior peripheral nerves was analyzed, as well as in the motor evaluation, the sensory results obtained did not diverge from those expected, as described by Mazurek, Michael T.MD et al (2001) and Maynard FM Jr et al (1997). The clinical findings were consistent with those expected for the disease, as indicated by the existing literature, i.e., the characteristic and height of the spinal cord injury.[14.15]

James, M. A. (2007) postulated in relation to the "Muscle Strength Rating Scale (MRC-Medical Research Council)", important for the diagnosis of weakness the study showed that the highest scale observed was 5, corresponding to the normal parameters of force against the gravitational force and the applied resistance, and the smallest scale was 3, which demonstrates active movement against the force of gravity, but not overcoming the added resistance. In patients with a scale below 5, the results were consistent with the ASIA, i.e., the characteristic and height of the spinal cord injury, and there was no correlation between the change in the behavior of the functional status and muscle strength with the objective of the research. In the quadriplegics, the mean and standard deviation were 0 (zero) in the evaluation of muscle strength, with no evidence of muscle contraction - a characteristic expected due to the high spinal cord injury.[16th]

Wrist goniometry, an evaluation technique used to determine the range of motion restrictions of these patients. As previously noted, the analysis of all patients is within normal range of motion values. We did not observe any representative alteration in the reduction of joint mobility in the patients studied, with the exception of the quadriplegic group, which, as it was an analysis of the ability to actively position the active hand, the data obtained for the quadriplegic were 0 (zero), mean and standard deviation. Therefore, during the evaluation, the results on range of motion also did not diverge from the expected results, according to data found by Marques, Amélia Pasqual (2003) and Maynard FM Jr et al (1997). The clinical findings were consistent with those expected for ASIA, i.e., the characteristic and height of the spinal cord injury.[14.17]

Radiographic analysis of these patients was performed in order to look for any sign indicative of osteoarthritis and to use it as a comparison with the clinical data previously obtained. The classification of wrist osteoarthritis, therefore, indicated that, of the 28 radiographs analyzed, 67.86% of the cases fell into categories 0 and 1, i.e., no radiographic alterations or, at most, minimal alterations, without a closed diagnosis of osteoarthritis or any clinical repercussion. The remaining 32.14% fall into stage 2, i.e., with evidence of osteoarthritis, but of low grade.[18th]

It is noteworthy that most of these patients are extremely debilitated, one of the possible causes of osteoarthritis can facilitate the development of preventive strategies, seeking to improve the quality of life of these individuals. Delaying or preventing the onset of osteoarthritis requires lifestyle changes that can minimize more serious clinical problems, especially in patients with spinal cord injury, in whom the approach is more complex, since therapeutic resources are scarcer and not always accessible.[19.20 am]

The importance of this study lies in the use of this material as an object of analysis for other research related to the theme, thus serving as a comparative support for the composition of other research in the area.

Some limitations were: angular and mobility measurements were performed by the manual method, which was used due to the lack of a digital goniometer. No study on the hand and wrist pattern in spinal cord injury was found in the literature. This paucity of publications suggests that more studies are needed to define standards and compare different treatments for this group of patients.

CONCLUSION

We conclude that the use of wheelchairs and repetitive movements in patients with spinal cord injury does not favor the development of high degrees of osteoarthritis. The evaluations and tests applied to 14 patients with spinal cord injury show that the results followed the normal standard, with the exception of the quadriplegic group, in which the evaluations could not be performed due to the inability to perform and measure range of motion, muscle strength and nerve preservation.

The rest of the patients did not present significant alterations that express a relationship between the use of wheelchairs and the development of osteoarthritis. Therefore, the wrists and hands of these patients behave similarly to uninjured individuals.

AUTHORS' CONTRIBUTION: IFP, DNS: Participação ativamente da redação e da discussão dos resultados do manuscrito. MBM: Revisão da gramatical da língua inglesa. OFS: revisão crítica do seu conteúdo intelectual do manuscrito CKB, ACjr: Contribuição substancial na concepção do artigo, análise dos dados para o trabalho, participação ativa da discussão dos resultados e Revisão e aprovação final da versão do manuscrito.

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RANDOMIZED CLINICAL TRIAL OF ASPIRIN AS PROPHYLAXIS FOR THROMBOEMBOLISM IN HIP ARTHROPLASTY

ENSAIO RANDOMIZADO DA ASPIRINA NA PROFILAXIA DO TROMBOEMBOLISMO EM ARTROPLASTIA DO QUADRIL

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ABSTRACT

Objective: This study aims to evaluate aspirin as a chemical prophylaxis (200 mg) in total hip arthroplasty. Methods: the study compared two groups and used ultrasonography (USG) to screen for low-deep venous thrombosis. Group 1 received 600 mg (control), and Group 2 received 200 mg of (intervention), associated with the use of elastic compression stockings and early walking Results: fourteen patients were allocated to Group A (200mg), and 16 to Group B (600mg); in group A (200mg), 3 cases with thrombus below the popliteal vein were detected at the first USG examination. All of them are in the left lower limb (21.4%). In group B (600 mg), 5 cases were identified after the first exam (31.2%). All cases were asymptomatic and followed the protocol with prophylaxis only with Aspirin. Conclusion: In the statistical data, there were no differences in the presence of thrombus between the 200- and 600 mg groups, which is credited to using low-dose aspirin in low doses (200mg). Hematimetric levels returned to baseline levels and suggested there was no chronic or acute bleeding related to the use of aspirin. The manuscript was prepared according to the CONSORT guideline 2010. ***Level of Evidence I; Longitudinal Randomized Comparative Clinical Study.***

Keywords: Disease Prevention. Thromboembolism. Total Hip Replacement. Aspirin.

RESUMO

Objetivo: Este estudo pretende avaliar a aspirina como profilaxia química (200 mg) na artroplastia total do quadril. Métodos: estudo comparando dois grupos com diferentes doses de aspirina e utilizando a ultrassonografia (USG) para rastreamento da trombose venosa profunda baixa. O grupo 1, 650 mg ao dia de aspirina (controle) e o grupo 2, 200 mg de aspirina ao dia na mesma posologia (intervenção) e associados ao uso de meias elásticas de compressão e deambulação precoce. Resultados: quatorze pacientes foram alocados no grupo A (200 mg) e 16 no grupo B (650 mg). No grupo A foram detectados 3 casos com trombos abaixo da veia poplítea ao USG sendo 21,4% . Já no grupo B, 5 casos foram identificados após o primeiro exame (31,2%). Todos assintomáticos e sem sinais de sangramento ativo ou queda da hematimetria no momento da detecção dos trombos. Conclusão: os dados sugerem não haver diferença na incidência de trombo em ambos os grupos, não sendo a profilaxia com a aspirina dose-dependente. Os níveis hematimétricos retornaram aos níveis iniciais o que sugere não ter havido sangramento crônico ou agudo relacionado ao uso. ***Nível de Evidência I; Estudo Clínico Randomizado Longitudinal Comparativo.***

Descritores: *Prevenção de Doenças. Tromboembolia. Artroplastia Total do Quadril. Aspirina.*

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INTRODUCTION

Knee and hip joint reconstruction increase exponentially each year. Joint replacement gives a great improvement in life quality. The level of activity for elderly patients and the improvement in the quality of implants are factors that explain the high demand.[1,2] In the United States, more than 600,000 arthroplasties are performed per year.[3] Among the complications of joint replacements, infections and thromboembolic events are the most feared. The presence of assimptomatic thrombus in vessels distal to the popliteal vein is estimated between 20 and 30%; however, there´s no need treatment and prophylaxis must be maintained.[1,3,4-5] Simptomatic deep venous thrombosis may reach an incidence close to 5% and pulmonary thromboembolism, up to 2% in such patients.[7-9] he ideal drug for the prophylaxis of thromboembolic diseases needs to be highly effective, accessible in dosage and low cost with low risk of postoperative bleeding. There is still no consensus regarding the

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The study was conducted at the Orthopedics and Traumatology Department of the Hospital das Clinicas de Pernambuco, attached to the Surgery Department of the Federal University of Pernambuco, Recife, PE, Brazil.
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drug or their ideal dose, and protocols vary between services. Until 2001, when routine prophylactic chemical measures were instituted for arthroplasties, the incidence of deep venous thrombosis and thromboembolic diseases could reach up to 30%.[1,3,7] Currently, the use of prophylactic measures alone or in association has reduced the incidence close to 2%.

Prophylaxis methods can be divided into chemical or mechanical. Chemical prophylaxis such as warfarin, aspirin, low molecular weight heparin, factor Xa inhibitors and can be used alone or in association with mechanical prophylaxis through the use of pneumatic compression systems in the immediate postoperative period, as well as the early walking in the first 24 hours.[2,6,9] On the other hand, the use of such substances can cause bleeding of variable magnitude in the postoperative period, requiring a new surgical approach and, therefore, the dose to be administered also becomes a concern for surgeons.[4,6]

Another issue with no consensus is the period of use of chemical prophylaxis which, according to the protocols, can be from 3 to 35 days or even just for the period of hospitalization. In a meta-analysis published in 2020, Gulraj et al. evaluated 13 randomized clinical studies on the use of aspirin associated or not with other drugs, all with different protocols of drugs and doses.[9] The time of appearance of signs and symptoms of deep venous thrombosis or pulmonary thromboembolism ranges from 21 to 34 days postoperatively.[4,5] The ideal prophylaxis method should have a low incidence of thromboembolism, as well as postoperative bleeding, and be used for a short period of time.

METHODS

The study was carried out with 30 patients, all operated on at the orthopedics service of Hospital das Clínicas from May 2019 to May 2021. Goldman grade I or II, without contraindications to the use of aspirin. Patients classified as medium or high risk for thromboembolic disease were excluded, as well as patients with recent episodes of gastrointestinal bleeding, acute myocardial infarction, use of anti-platelet aggregation agents, hip revision surgeries, previous hematological diseases, chronic use of corticosteroids.

Patients who met the inclusion criteria were operated on by the main researcher, using the same surgical approach. The implant used was a complete metal prosthesis with transoperative use of tranexamic acid. After the procedure, the patients were sent to the post-anesthesia recovery room with guidance on the immediate use of elastic compression stockings and with Aspirin scheduled to start 12 hours after the end of the surgery. Patients were divided into two groups by the assistant researcher and blinded to the main examiner. For group A, dose of 300 mg was given twice a day. The period of use was 30 days. Group B received only 200mg twice a day in two doses for 30 days. The patients were randomly distributed by the assistant researcher in a 1:1 ratio, with identification of the dosage used only at the end of the second USG doppler exam, after the sixth week in the end of the postoperative follow-up.

The patients were discharged from the hospital with orientation to use the medication at a dose of 200 or 600mg per day and, in the first postoperative week, were referred to the radiology outpatient clinic of the same hospital for the first ultrasound examination with Doppler flowmetry of the lower limbs for research purposes: thrombus below the popliteal vein. This examination was carried out by two radiologists participating in the research and in case of asymptomatic thrombus, prophylaxis was maintained for the same period. In the cases of patients identified as having a thrombus and symptomatics or signs suggestive of thromboembolic disease, the therapeutic would be adopted instead of the prophylactic one . The patients were instructed to return for the second USG examination with Doppler flowmetry and a new medical review in the sixth week, under the same criteria previously adopted for the diagnosis and treatment of thromboembolic diseases.

The presence of the thrombus below the popliteal vein confirmed by the 2 radiologists present in the study was analyzed as a dichotomous variable as the primary objective of the study. Hematocrit and hemoglobin data before, immediate and late postoperative, in addition to the symptomatological questioning were considered for the evaluation of bleeding due to aspirin use as a secondary objective of the study.

Data were stored using a Microsoft Excel 2010 spreadsheet and analyzed using STATA/SE 12.0 software. The tests were used with 95% confidence and the results presented in tables with their respective frequencies. Numerical variables are presented with measures of central tendency and dispersion. For quantitative variables, the Kolmogorov-Smirnov test was used. The chi-square test and Fisher's exact test and Student's t test were applied to categorical variables for variables with normal distribution. As for the variables that did not comply with the normality tests, they were submitted to the Mann-Whitney test for comparison with groups with normal distribution.

The study was approved by the Research Ethics Committee of the Health Sciences Center (CCS) of the Hospital das Clínicas at UFPE and the National Research Ethics Committee (CONEP) and the Ministry of Health under CAAE number: 66155517.2.0000.5208. Obtaining the term of free and informed consent was carried out by the main researcher, consisting of the steps of resolution 466/12 of the Ministry of Health – Brasil

RESULTS

From May 2019 to May 2021, a total of 30 patients underwent the total hip arthroplasty procedure, according to the inclusion criteria, 14 in group A (200mg) and 16 in group B (600mg) randomized in a 1:1 ratio and blinded to the main examiner. Nineteen (63.3%) were female and 11 (36.7%) were male (p= 0.389). Table 1 Age ranged between 18 and 71 years old with a mean of 49.2 +_ 12.8. Nineteen (63.3%) surgeries were performed on the right hip and 11 on the left hip (36.7%) with no simultaneous bilateral surgery (p= 0.919). Moore access was performed in all cases and two patients in group B required blood transfusion in the immediate postoperative period (12.5%) due to a drop in blood count below 10g/dl of hemoglobin or 30% of hematocrit. However, there was no statistically significant difference. (p=0.485).

The etiological diagnosis was distributed among mechanical causes with 19 cases (63.3%), six from autoimmune diseases (20%) and 5 cases, idiopathic Aseptic Necrosis of the Femoral Head (16.7%).

For the presence of a thrombus detectable on ultrasound examination with Doppler flowmetry, the patients were divided in groups A and B, with the first examination being performed with a mean time of 7.1 days +_ 1.4 for the first group and 5+_ 1.3 days for group B respectively (p = 0.001), with no statistical difference between the mean time for both. (Table 2)

In group A (200mg) 3 assynptomatic cases with thrombus below the popliteal vein were detected at the first USG examination with Dopplerflowmetry, all in the left lower limb (21.4%). In group B (600 mg), 5 aassymptomatic cases were identified after the first exam, 2 in the right lower limb and 3 in the left lower limb (31.2%).

Table 1. Gender distribution between groups A (intervention) and B (control).

Variable	Group A	Group B	p -value
Genre	a(%)	a(%)	
Female	10 (71.4)	9 (56.2	0.389*
Male	4 (28.6)	7 (43.8)	

All cases were asymptomatic and without signs of active bleeding or drop in blood count at the time of thrombus detection and therefore followed the protocol with prophylaxis only with Aspirin in the same dosages already in use. The presence of a thrombus identified by one examiner was confirmed at the same time in a consecutive examination by the second radiologist.

After the sixth postoperative week, the patients came back for the second USG examination with Doppler, after the 30-day period of medication use had ended. In group A, 3 assymptomatic patients (21.4%) with thrombus below the popliteal vein were identified, 1 in the right lower limb and 2 in the left lower limb. (Table 3) In group B, two assymptomatic patients (12.6%) had a thrombus diagnosis confirmed by two radiologists. No patient had clinical signs or symptoms of thromboembolic disease.

For the hematimetric quantitative variables (hematocrit and hemoglobin), the results were submitted to the Kolmogorov-Smirnov Normality test and Student's t tests were applied when the normality pattern was observed. Values are shown in graphs 1 and 2 and no significant differences were observed between groups ($p > 0.05$). (Figures 1 and 2) There were no gastrointestinal complaints of patient-detectable bleeding or surgical wounds in either group.

The relative incidence of thrombi detectable at the first test in both groups (30 patients) was 7 patients and one of them had a positive bilateral test (23.3%). After performing the second imaging exam to detect a thrombus below the popliteal vein, only one new case was diagnosed in group A (3.3%). Two positive exams in the first evaluation were not identified again in the second exam, suggesting thrombus reabsorption. There was no record of bleeding from the surgical wound, gastrointestinal complaint or report of change in stool color suggesting gastrointestinal injury.

Among the 8 patients who presented positive exams, five had rheumatic diseases as etiological diagnosis (62.5%), which suggests, as a post-horc observation, an association between venous thromboembolism and diseases of the autoimmune system.

Table 2. Incidence of thrombus identified on usg 1 (4-7 days post op).

USG 1 MID		
	Group A	**Group B**
Yes	0 (0.0)	2 (12.5) 0.485**
No	14 (100)	14 (87.5)
USG 1 MIE		
	Group A	**Group B**
Yes	3 (21.4)	3 (18.8) 1,000**
No	11 (78.6)	13 (81.2)

Table 3. Incidence of thrombus by groups after USG 2 (6 weeks).

USG 2 MID		
	Group A	**Group B**
Yes	1 (7.1)	1 (6.3) 1,000**
No	13 (92.9)	15 (93.7)
USG 2 MIE		
	Group A	**Group B**
Yes	2 (14.3)	1 (6.3) 0.586**
No	12 (85.7)	15 (93.7)

(*) Chi-Square Test (**) Fisher's Exact Test.

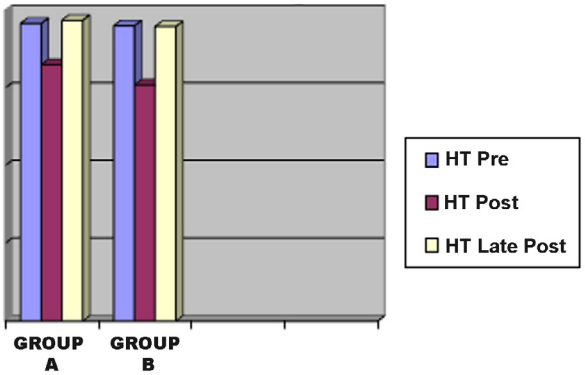

Figure 1. Measured hemoglobin value curve.

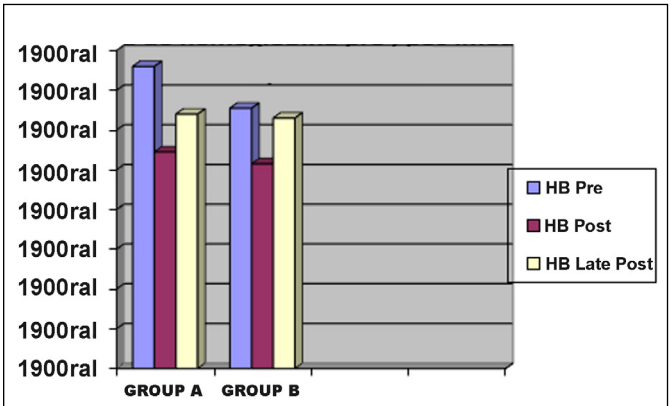

Figure 2. Pre, immediate post and late post hemoglobin curve.

DISCUSSION

In 1977 Harris et al. published a prospective study comparing aspirin with placebo in 95 patients undergoing total hip arthroplasty and found an incidence almost 3 times higher in the second group ($p < 0.03$).[10] The diagnosis, at the time, was made through contrast radiography of the lower limbs (phlebography). Two years before Zekert et al. identified a significant reduction in necropsy studies of patients who underwent orthopedic surgery and used some drug as prophylaxis of thromboembolic diseases.[11] Historical studies have already suggested a high incidence of thromboembolic events and the need for chemoprophylaxis in patients undergoing major orthopedic procedures involving the hip joint. However, ther´s no a gold standart fot this solution.

The present study corroborates protocols adopted in some countries such as the United States of America, where the American Association of Orthopedic Surgery (AAOS) (lit), suggests the use of aspirin with level of evidence 1b according to GRADE. In this same guideline developed and published together with the American Academy of Hematology in 2019, the AAOS suggests the association of chemoprophylaxis with mechanical methods such as elastic compression stockings or pneumatic compression pumps for the lower limbs.

In a Chinese study, Zhou et al studied the incidence of venous thromboembolism using Doppler ultrasonography prospectively in a total of 120 randomized patients. There was no statistically significant difference between the aspirin and low molecular weight heparin groups. Both associated with mechanical prophylaxis ($p = 0.05$).[12]

On the other hand, British works, as well as the National Institute for Health and Care Excellence (NICE), in the last update in 2018, do not recommend aspirin as the drug of first choice for patients undergoing major orthopedic procedures, despite being this recommended conduct with a low level of evidence, with a persistent lack of consensus regarding the ideal drug and duration of use.[13]

In addition ,a uniform protocol in centers around the world, the dose of aspirin to be used also becomes a variable without conclusive

studies. Parvizi et al demonstrated in a 2021 study the effectiveness of aspirin in major orthopedic surgeries in more than 5000 patients studied at a dose of 325mg twice a day.[14] On the other hand, when reducing the dose, the same author published a randomized clinical trial showing the efficacy of aspirin at a dose of 81mg a day in 2009.[15] For the results presented in this study, there was no statistically significant difference between the groups that received doses of 600mg or 200 mg daily for 30 days. None of the patients identified through the USG examination with Doppler developed symptoms due to the presence of the thrombus in veins below the popliteal. As for the variable presence of clinical signs of gastrointestinal tract bleeding, there was no record of a significant drop in hemocrit or hemoglobin with recovery of preoperative levels after 6 weeks of study, even with the use of aspirin. Some studies show an increased incidence of gastrointestinal bleeding, such as that by Arboy et al. Published in 2020 showing a slightly higher relative risk in patients using aspirin.[16]

Obviously there is a bias in the number of cases with 30 patients, requiring larger and multicenter studies to establish a standard protocol. The COVID-19 pandemic greatly slowed the progression of the study by suspending surgical procedures. The post horc observation of the high incidence of thrombus detectable by USG in patients with rheumatological diseases draws attention to the association between this variable and the non-use of aspirin for these patients. However, studies need to be directed in this direction in order to raise evidence on the subject.

AUTHORS' CONTRIBUTION: RCL: Acted as the primary surgeon for all cases in the study, collected post-operative data, surveyed the literature, and produced the text. ERF: Assisted in the surgeries of the cases in the study, collected literature and calculated statistics, and helped to revise the text.YAL: Participated in the surgeries of the cases in the study as a second assistant, collected the patients' post-operative data, monitored the patients being followed up, collaborated in the literature survey, and textual development. RRSM: Carried out all the USG control examinations on the patients studied, also took part in data collection, and contributed to the writing of the text.

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BENEFITS OF A CLINICAL PATHWAY IN TOTAL KNEE ARTHROPLASTY

BENEFICIOS DE UM PROGRAMA DE CUIDADOS CLÍNICOS EM ARTROPLASTIA TOTAL DE JOELHO

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ABSTRACT

Objective: Demonstrate whether a multiprofessional Clinical Pathway Program in Total Knee Arthroplasty (CPPA) contributes to optimizing hospital care. Method: Retrospective study of medical data of care indicators in 310 patients divided into two groups: A- who underwent arthroplasty in the last biennium before the introduction of the CPPA (n=144) and group B- who underwent TKA in the biennium after the introduction of the CPPA (n=166). Results: Postoperative showed a significant difference in favor of group B over group A for hospitalization time in days 4.33 ± 2.79 and 5.4 ± 1.67 (p<0.001), time of prophylactic antibiotic in hours 28.13 ± 33.77 and 81.49 ± 40.91 (p<0.001), referral to the intensive care unit 40.9% and 73.4% (p<0.001), initiation of thromboprophylaxis within 24 hours 97.9% and 82.5% (p<0.001), use of elastic stockings and/or intermittent compression prescribed for thromboprophylaxis 89.5% and 31.2% (p<0.001), initiation of rehabilitation within 24 hours 90.1% and 66.1% (p<0.001), readmissions within 30 days 4 .1% and 3% (p = 0.76), readmissions 90 days 2.7% and 6.6% (p = 0.183), transfusions 5.5% and 15.2% (p = 0.033). Conclusion: The implementation of a multiprofessional CPPA contributed to the implementation of care protocols, favoring greater patient safety. ***Level of Evidence III; Retrospective Comparative Study.***

Keywords: Arthroplasty, Replacement, Knee. Managed Care Programs. Quality of Health Care.

RESUMO

Objetivo: Demonstrar se um Programa de Cuidados Clínicos multiprofissional em Artroplastia Total de Joelho (PCCA) contribui para a otimização assistencial hospitalar. Método: Estudo retrospectivo em prontuários de indicadores assistenciais em 310 pacientes divididos em dois grupos: A- submetidos a artroplastia no último biênio antecessor a introdução do PCCA (n=144) e grupo B- submetidos a ATJ no biênio após a introdução do PCCA (n=166). Resultados: Indicadores pós-operatórios mostraram diferença significativa a favor do grupo B sobre o grupo A para tempo de hospitalização em dias 4,33 ± 2,79 e 5,4 ± 1,67 (p<0,001), tempo de antibiótico profilático em horas 28,13 ± 33,77 e 81,49 ± 40,91 (p<0,001), encaminhamento para unidade de terapia intensiva 40,9% e 73,4% (p<0,001), início da tromboprofilaxia dentro de 24h 97,9% e 82,5% (p<0,001), uso de meias elásticas e/ou compressão intermitente prescritos para tromboprofilaxia 89,5% e 31,2% (p<0,001), tempo para iniciação da reabilitação em 24h 90,1% e 66,1% (p<0,001), readmissões em 30 dias 4,1% e 3% (p = 0,76), readmissões 90 dias 2,7% e 6,6% (p = 0,183), transfusões 5,5% e 15,2% (p = 0,033). Conclusão: A implementação de um PCCA multiprofissional contribuiu para o cumprimento dos protocolos assistenciais favorecendo maior segurança para os pacientes. ***Nível de Evidência III; Estudo Retrospectivo Comparativo.***

Descritores: *Artroplastia do Joelho. Programas de Assistência Gerenciada. Qualidade da Assistência à Saúde.*

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INTRODUCTION

Total knee arthroplasty (TKA) is the gold standard therapeutic procedure and widely performed for the treatment of gonarthrosis.[1-3] It is noteworthy the exponent growth of this surgery, which is accompanied by an increase in clinical complications associated with large additions of financial resources, a fact that adds relevance to the care issue in order to mitigate the risks involved in these surgeries.[2-7]

In this context, in order to amplify the therapeutic standardization and optimization of the best medical practices, the Clinical Pathway Programs in Arthroplasties (CPPA) in which multiprofessional teams are trained and monitored to execute institutional care protocols are presented as an alternative for hospital management.[1,8,9]

A CPPA aims to guide, monitor and generate action plans for health care based on scientific evidence within the culture of a health institution.

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

The study was conducted at the HCor, São Paulo, SP, Brazil.
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The objective of this study is to assess whether the implementation of a CPPA under the guidance of the Joint Commission International (JCI) can increase the safety of care for patients undergoing total knee arthroplasty.

MATERIALS AND METHOD

The retrospective study of patients records analysis was carried out at our Hospital after approval by the Research Ethics Committee (number CAAE 61212716.0.0000.0060). The patients were divided into two groups: Group A (GA) patients who underwent TKA in the last biennium prior to the introduction of CPPA (2013-2014), and Group B (GB) patients who underwent TKA in the last biennium after the start of the CPPA without the impact of the Covid-19 pandemic (2018-2019).

The care indicators identified in the medical records were established and required by the JCI for the CPPA, as follows:

- length of hospital stay (LOS);
- administration of antibiotic prophylaxis (ATBp) – interval 60min to 05min before the start of surgery;
- suspension of ATBp within 24 hours;
- average ATBp administration time;
- initiation of prophylaxis for deep vein thrombosis (DVT) within 24 hours postoperatively;
- use of adjuvant methods for prophylaxis DVT– intermittent pneumatic compression device (IPCD) and/or compression stockings (CS);
- immediate postoperative care location: Intensive Care Unit (ICU) or Inpatient Unit Care (IUC);
- time to start postoperative physical therapy rehabilitation;
- time to start the postoperative gait;
- readmissions 30 days after surgery;
- readmissions at 90 postoperative days;
- blood transfusion;

All indicators were identified by a single researcher with absolute anonymity of the samples, thus excluding the need to apply the written informed consent form of the participants.

In addition to the care indicators presented, the population profile was also compared between the groups through: age, sex, laterality, body mass index (BMI) and Physical State Classification of the American Society of Anesthesiologists (ASA).

All patients who underwent primary unilateral TKA were included in the study. Patients in both groups whose medical records did not contain all the information for the indicators defined for the study were excluded.

Statistical analysis

The indicators referring to the patients as well as the care performances of the CPPA were presented through categorical variables described in absolute and relative frequencies, and through numerical variables, described by the mean, standard deviation, median and quartiles. For the comparative statistical analysis between the data obtained from the studied groups, the Fisher's Exact test and the Mann-Whitney test were used.

The tests used a significance level of 5% and the analyzes were carried out with the help of the statistical software R (R Core Team-2021).

RESULTS

A total of 168 patients were identified in group A (GA), two of which were excluded, resulting in a final sample of 166 patients. In group B (GB), 146 patients were identified, two of which were excluded, resulting in 144 patients, totaling 310 patients evaluated.

The comparative population analysis between the groups showed no statistically significant difference for age ($p = 0.896$), sex ($p = 0.529$), laterality ($p = 0.374$), BMI ($p = 0.881$) and ASA ($p = 0.076$). Female patients were more prevalent in both groups (74% in GA and 69% in GB). The mean age, BMI and ASA were 69 years old, 29.8 Kg/m2 and 2 in AG, and 70 years old, 29.8 Kg/m2 and 2 in GB, as shown in Table 1.

Regarding the management of preoperative ATBp induction, it was not statistically different ($p = 0.259$) since 97.5% of the GA patients and 97.7% of the GB patients received the medication within the time interval between 60 and 5 minutes prior to the surgical incision, with cefuroxime being the most widely administered medication. Regarding the extension period of ATBp, approximately 2% of the patients in the GA and 91% of the patients in the GB discontinued the use of antibiotics within 24 hours after the end of the surgery ($p < 0.001$). The mean post-surgical ATBp extension time was 81.4h in GA and 28h in GB, with statistical significance of $p < 0.001$, as shown in Table 2.

For the pharmacological thromboprophylaxis indicator started within 24 hours of the end of surgery, a significant improvement was observed in GB ($p = <0.001$), with enoxaparin being the most used drug in both groups. It was observed that in GB the association of adjuvant mechanical methods in the lower limbs was present in 31.2% of the GA and in 89.5% of the GB ($p < 0.001$). (Table 2)

The beginning of physical therapy rehabilitation showed results with a wide care difference in relation to the groups, since in the GA 66.1% of the patients started rehabilitation activities on the first postoperative day while in the GB 90.1% received assistance in the same period ($p. < 0.01$). The beginning of gait also showed positive results, as in the GA only 7% of the patients walked on the first postoperative day, while in the GB 63.8% performed gait training in the same period ($p < 0.01$). (Table 3)

The percentages of readmissions at 30 and 90 days did not show significant statistical differences ($p = 0.76$ and $p = 0.183$), however, it was observed in the GA that 9.6% of patients (01 cellulitis, 01 wound debridement, 01 debridement surgery, 01 extensor mechanism rupture, 03 suspected DVT, 07 arthrofibrosis, 01 urinary infection, 01 patellar dislocation) and in GB 6.9% of patients (01 transient ischemic, 01 dehydration, 01 urinary infection, 02 arthrofibrosis, 01 drainage hematoma, 02 incision debridement, 01 surgical debridement, 01 erysipelas) required hospital care after surgical discharge. (Table 3)

The number of blood transfusions was significantly different between the groups ($p = 0.033$). In GA 15.2% of patients and in GB and 5.5% in GB required this therapy. (Table 3)

Table 1. Indicators and comparative statistical analysis of population epidemiological data from groups A (GA) and B (GB). Body Mass Index (BMI), American Society of Anesthesiologists Physical Status Classification (ASA), Total Knee Arthroplasty (TKA).

	Before CPPA (n=166)	After CPPA (n=144)	Total (n=310)	P
Age average	69.65 ± 8.67	70.28 ± 7.59	69.94 ± 8.18	0,896
Age median	70.5	70	70	
Sex				**0,529**
Male	45/166 (27.11%)	45/144 (30.77%)	90/310 (28.8%)	
Female	121/166 (72.89%)	99/144 (69.23%)	220/310 (71.2%)	
Laterality				**0,374**
TKA right	94/166 (56.63%)	75/144 (52%)	169/310 (54,5%)	
TKA left	72/166 (43.37%)	69/144 (48%)	141/310 (45,5%)	
ASA				**0,076**
1	12/166 (7.23%)	3/144 (2.08%)	15/310 (4.84%)	
2	139/166 (83.73%)	131/144 (90.97%)	270/310 (87.1%)	
3	15/166 (9.04%)	10/144 (6.94%)	25/310 (8.06%)	
BMI average	29.86 ± 4.75	30.02 ± 4.27	29.93 ± 4.53	0,881
BMI median	29.5	29.18	29.36	

Table 2. Indicators and comparative statistical analysis of data associated with prophylactic antibiotic therapy and thromboprophylaxis (ATBp) in groups A (GA) and B (GB). Antibiotic (BMI), deep vein thrombosis (DVT), postoperative (PO), intermittent pneumatic compression device (IPCD).

	Before CPPA (n=166)	After CPPA (n=144)	Total (n=310)	P
management ATB 60 - 5 min before surgery				**0,259**
No	4/166 (2,4%)	3/144 (2.1%)	7/310 (2,3%)	
Yes	162/166 (97,5%)	141/144 (97.9%)	303/310 (97,7%)	
ATBp (hours); average	81.49 40.91	28.13 33.77	56.79 46.18	<0,001
ATBp suspension within 24h				**<0,001**
No	163/166 (98.19%)	15/144 (10.42%)	178/310 (57.42%)	
Yes	3/166 (1.81%)	129/144 (89.58%)	132/310 (42.58%)	
Prophylaxis DVT within 24h				**<0,001**
No	29/166 (17.47%)	3/144 (2.08%)	32/310 (10.32%)	
Yes	137/166 (82.53%)	141/144 (97.92%)	278/310 (89.68%)	
Mechanical prophylaxis				**<0,001**
compression stockings	28/166 (16.87%)	72/144 (50%)	100/310 (32.26%)	
compression stockings + IPCD	24/166 (14.46%)	57/144 (39.58%)	81/310 (26.13%)	

Table 3. Indicators and comparative statistical analysis of data associated with physical therapy rehabilitation postoperative period (PO) and blood transfusion in groups A (GA) and B (GB).

	Before CPPA (n=166)	After CPPA (n=144)	Total (n=310)	P
Physiotherapy				
Immediate PO	63/166 (37.95%)	75/144 (51.75%)	138/310 (44.5%)	<0,001
1º PO	47/166 (28.31%)	55/144 (38.46%)	102/310 (32,9%)	
2º PO	46/166 (27.71%)	14/144 (9.79%)	60/310 (19.3%)	
3º PO	8/166 (4.82%)	0/144 (0%)	8/310 (2.5%)	
4º PO	2/166 (1.2%)	0/144 (0%)	2/310 (0.6%)	
Walk				
Immediate PO	0/166 (0%)	13/144 (9.03%)	13/310 (4.19%)	<0,001
1º PO	12/166 (7.23%)	79/144 (54.86%)	91/310 (29.35%)	
2º PO	95/166 (57.23%)	51/144 (35.42%)	146/310 (47.1%)	
3º PO	49/166 (29.52%)	1/144 (0.69%)	50/310 (16.13%)	
4º PO	7/166 (4.22%)	0/144 (0%)	7/310 (2.26%)	
6º PO	3/166 (1.81%)	0/144 (0%)	3/310 (0.97%)	
Readmission within 30 days				
No	161/166 (96.99%)	138/144 (95.83%)	299/310 (96.45%)	0,76
Yes	5/166 (3.01%)	6/144 (4.17%)	11/310 (3.55%)	
Readmission within 90 days				
No	155/166 (93.37%)	140/144 (97.22%)	295/310 (95.16%)	0,183
Yes	11/166 (6.63%)	4/144 (2.78%)	15/310 (4.84%)	
Blood transfusion				**0,033**
No	144/166 (86.75%)	136/144 (94.44%)	280/310 (90.32%)	
Yes	22/166 (13.25%)	8/144 (5.56%)	30/310 (9.68%)	

Regarding the place of hospital stay in the immediate postoperative period, it was observed that in the GA only 26.5% of the patients were referred to the UI, while in the GB the percentage of this assistance was 59%, exposing a significant behavioral change in care for not using the ICU for postoperative support ($p < 0.001$). The mean length of hospital stay (LOS) for GA patients was 5.4 days and 4.3 days for GB patients, showing that CPPA significantly contributed to the decrease in LOS ($p < 0.001$). (Table 4)

DISCUSSION

The results found in the study showed that a Clinical Care Program in Arthroplasty can contribute to the gain of hospital care performance, positively impacting the response of protocols and institutional guidelines.

The essence of a CPPA is to act in the control and compliance of the best therapeutic practices, intervening with medical professionals, physiotherapists, pharmacists, psychologists and nursing staff in constructive tasks that generate controls and feedback on the performance of their actions in the therapeutic management of patients and, thus, engaging professionals in a process of continuous improvement, reducing the risk of complications and waste of resources.[3,10-15]

Regarding the prescription of pATB during TKA, although drug induction did not present a significant difference between the groups, a disruptive change was observed associated with the extension of postoperative administration with the introduction of CPPA ($p < 0.001$) with the suspension in 24h. This behavioral change is very relevant for the sustainability of public health since Mobarki et al[16] and Chokshi et al[17] expressed the worrying global crisis that we are experiencing due to antibiotic resistance due to the misuse of these drugs.[18] Although there is scientific discussion regarding the extent of pTAB management in arthroplasties, it is currently defined by consensus and international guidelines that the 24-hour period would be ideal if there is no clinical peculiarity that requires another care profile.[19]

The prescription of thromboprophylaxis was also largely optimized with the implementation of CPPA not only in the pharmacological form, but also with the association of adjuvant therapy such as intermittent compression devices and/or elastic compression stockings, which showed a significant increase in use ($p < 0.001$) without impairing the beginning of patients' physical mobilization and rehabilitation activities.[20-22]

Mosaad et al[23] and Weng et al[24] described that the pharmacological routine for thromboprophylaxis is relevant and a priority, however the time of drug administration is essential to add prophylactic efficiency and, in this context, a significant improvement in the drug administration within 24 hours of surgery, indicating that patients

Table 4. Indicators and comparative statistical analysis of data associated with the patient's place of stay in the postoperative period (PO) whether in the inpatient unit care (ICU) or intensive care unit (ICU) and the length of hospital stay in the groups A (GA) and B (GB).

	Before CPPA (n=166)	After CPPA (n=144)	Total (n=310)	P
Immediate postoperative care				**<0,001**
IUC	44/166 (26.51%)	85/144 (59.03%)	129/310 (41.61%)	
ICU	122/166 (73.49%)	59/144 (40.97%)	181/310 (58.39%)	
Lenght of stay; average	5.4 ± 1.67	4.33 ± 2.79	4.9 ± 2.32	<0,001
Lenght of stay; median	5	3	5	

were in better compliance with the institutional protocol to reduce the risk of thromboembolism.

A relevant point is the management of general care associated with the immediate postoperative follow-up. In the case of elderly patients and often linked to comorbidities under the care responsibility of an orthopedic surgeon, it is understandable that the medical team is insecure in the face of potential clinical instabilities that may occur in patients resulting from organic responses to surgical trauma. This context enhances the referral of patients to the ICU after surgery, a place that empirically increases the risks in agreement with Barnett et al[25] Despotovic et al.[26]

One of the contributions of the CPPA to mitigate the use of the ICU in the immediate postoperative period was the establishment of a standardization of preoperative surgical risk screening performed by a team of cardiologists who monitored the daily evolution of patients during the perioperative care journey together with the surgical team providing the patient with a double medical guardianship during the hospital stay.

It would be opportune to amplify, in Brazilian private hospitals, intermediary care support in the immediate postoperative period in order to reduce the need to refer some patients to intensive care units that require more attention. Our institution, at the moment, does not have an intermediate level between the ordinary inpatient unit and intensive care.

In relation to blood transfusions Slover et al[27] demonstrated that this need can reach 8% in arthroplasties. This study showed a positive response related to this indicator in the post-CPPA group with a decrease of 7.7%. A relevant factor for this finding is due to the better control and clinical stabilization of anemias during the preoperative evaluation, in addition to the establishment of criteria for the indications of transfusions that are shared with the clinical team and not only the judgment of the orthopedic surgeon.

Physiotherapy rehabilitation protocols focusing on the "fast track" concept were created by physical therapists and agreed with orthopedic surgeons in order to optimize recovery during hospital stay. This action significantly reflected in the improvement in the beginning of physical mobility and gait in the immediate postoperative period and on the first postoperative day, with a percentage of 90.1% of patients in gait activity within 24 hours of the postoperative period. This condition certainly had an impact on reducing the length of hospital stay, corroborating the results demonstrated by Foni et al,[3] Tayrose et al[28] Ayalon et al.[29]

It was observed that readmissions for arthrofibrosis decreased in patients operated after CPPA and we postulate that this condition may be linked to rehabilitation started earlier, as well as the sharing of a booklet with exercises that patients should perform daily at home for the functional optimization of the operated knee.

All these care optimizations allowed patients undergoing surgery after CPPA to reach the clinical and orthopedic criteria for hospital discharge established by the presence of walking with the aid of walkers, controlled and tolerable pain with oral medications, and range of motion of the operated knee at 90º in length of stay 20% shorter than pre-PCCA patients, without increasing readmission rates.

Limitations of the study

As in any retrospective study of data analysis in medical records, the number of patients evaluated and the quality of the data identified in the records can always carry empirical bias for the results found.

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ORTHOPEDIC ONCOLOGY

GIANT CELL TUMOR OF BONE: A MULTICENTER EPIDEMIOLOGICAL STUDY IN BRAZIL

TUMOR DE CÉLULAS GIGANTES ÓSSEAS: ESTUDO EPIDEMIOLÓGICO MULTICÊNTRICO NO BRASIL

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ABSTRACT

Introduction: Giant cell tumor of bone (GCTB) mainly affects young adults' long bone epiphyses, threatening bone strength and joint function. Surgery is the primary treatment, although post-surgery recurrence is significant. This study analyzes patient profiles, treatments, and outcomes for GCTB in Brazil. Methods: We retrospectively assessed local recurrence, metastasis, and treatment approaches in 643 GCTB patients across 16 Brazilian centers (1989-2021), considering regional differences. Results: 5.1% (n=33) developed pulmonary metastases, 14.3% (n=92) had pathological fractures, and the local recurrence rate was 18.2% (n=114). Higher rates of pulmonary metastases (12.1%) and advanced tumors (Campanacci III, 88.9%) were noted in lower-income North and Northeast regions. The North also had more pathological fractures (33.3%), extensive resections (61.1%), and amputations (27.8%). These regions faced longer surgical delays (36-39 days) than the South and Southeast (27-33 days). Conclusions: Our findings corroborate international data, underscoring regional disparities in Brazil that may lead to worse outcomes in disadvantaged areas. This highlights the need for improved orthopedic oncology care in Brazil's economically and structurally challenged regions. ***Level of Evidence III; Retrospective Cohort.***

Keywords: Bone Neoplasms. Giant Cell Tumor of Bone. Curettage. Recurrence.

RESUMO

Introdução: O tumor de células gigantes do osso (TCG) atinge principalmente epífises de ossos longos em adultos jovens, impactando a resistência óssea e a funcionalidade articular. O tratamento principal é cirúrgico, mas há significativa recorrência pós-operatória. Este estudo analisa o perfil de pacientes e tumores de TCG no Brasil, abordagens de tratamento e resultados. Métodos: Avaliamos retrospectivamente taxas de recorrência, metástase e tratamentos em 643 pacientes tratados em 16 centros brasileiros de 1989 a 2021, considerando a distribuição geopolítica. Resultados: 5,1% desenvolveram metástases pulmonares e 14,3% tiveram fraturas patológicas. A recorrência local foi de 18,2%. Regiões economicamente menos favorecidas, como Norte e Nordeste, mostraram maiores incidências de metástases pulmonares (12,1%) e tumores avançados (Campanacci III, 88,9%). O Norte teve alta ocorrência de fraturas patológicas (33,3%), cirurgias extensas (61,1%) e amputações (27,8%). Nessas regiões, o tempo pré-cirúrgico foi mais longo (médias de 36 e 39 dias) comparado ao Sul e Sudeste (27 e 33 dias, respectivamente). Conclusões: Os resultados refletem disparidades regionais no Brasil, sugerindo que condições socioeconômicas influenciam os desfechos clínicos. Estes achados são importantes para melhorar o cuidado oncológico ortopédico em regiões desfavorecidas do país. ***Nível de Evidência III; Coorte Retrospectiva.***

Descritores: *Neoplasias Ósseas. Tumor de Células Gigantes do Osso. Curetagem. Recidiva.*

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BACKGROUND

Giant cell tumor of bone (GCTB) is a benign primary bone tumor that is known to be locally aggressive. Histologically, GCTB is characterized by the presence of numerous multinucleated giant cells surrounded by a monotonous population of mononuclear stromal cells. This tumor predominantly affects adults between the ages of 20 and 40, with a predilection for the epiphyses of long bones. There is no significant gender disparity, although it appears to be more common in females. The incidence of GCTB is not accurately known, although registries from Japan, Australia, and Sweden have estimated it at 1.03 to 1.33 cases per million per year.[1-3]

The standard treatment for any primary bone tumor is complete surgical resection; however, in selected cases, treatment with the receptor activator of nuclear factor kappa-B ligand (RANK-L)

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The study was conducted at the Hospital de Clínicas de Porto Alegre (HCPA), Department of Orthopedics and Trauma, Porto Alegre, RS, Brazil.
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inhibitor denosumab, bisphosphonate therapy, or even radiation therapy may be employed. Delayed treatment and local recurrence are issues of great importance, as they may lead to impairment of joint function, bone loss, and a theoretical high risk of metastasis. Despite its local aggressiveness and considerable risk of local recurrence (10–75%), GCTB has a favorable prognosis in terms of overall survival (approximately 98% at 5 years). Due to their rarity, primary bone tumors should be managed at referral centers, as diagnosis and treatment are challenging and expensive.[4,5]

In Brazil, 70% of the population is served by the public Unified Health System (SUS), established in 1988. The system has long been overburdened, leading to lengthy waiting times for specialized treatment. Furthermore, there are substantial variations in care quality among the country's geopolitical regions due to the variation in investments made by each state of the federation. Patients with bone tumors rely on the availability of appointments with specialists in their respective city or state. In many cases, delaying treatment can result in clinical deterioration and poor outcomes.[6]

Despite the large number of patients with GCTB treated at referral centers in Brazil, few studies on this topic have been published to date, and a gap in information regarding the epidemiological profile of this tumor persists. This study aims to elucidate patient and tumor characteristics, management practices, and outcomes in the unique context of Brazil – a middle-income country with a publicly funded, universal health system serving a very large population across different geopolitical regions. Our findings could help redirect financial and human resources to optimize outcomes.[3,7,8]

METHODS

This research project (number 94280918.0.0000.5327) was approved by the ethics committee of the coordinating center (Hospital de Clínicas de Porto Alegre, state of Rio Grande do Sul) and, subsequently, by the 18 participating centers. Orthopedic follow-up was performed according to the routine protocol of each center. Case report forms were completed and sent to the coordinating center. The inclusion criteria for this study were: histopathological diagnosis of GCTB; treatment of the primary tumor at the same health care facility in which it was diagnosed; and availability of complete medical records. Patients of all ages with tumors in the appendicular and axial skeleton were included. The lead researcher at each participating center reviewed the data from medical records and then sent them via e-mail to the coordinating center. All lead researchers were active members of the Brazilian Association of Orthopedic Oncology (ABOO) while the study was ongoing.

General variables such as age, sex, and region of the country where the patient was treated were extracted from medical records, as were specific characteristics related to the tumor, such as anatomical location, presence of metastases, type of surgery, use of cavity filling material, adjuvant treatment, Campanacci radiological classification, presence of pathological fracture, local recurrence, death, and use of denosumab. For analysis, all variables were stratified by the geopolitical region of Brazil (North, Northeast, South, and Southeast) in which the patient was treated. Cases from 1989 to 2021 were included. The sample consisted of 653 patients. Of these, we excluded 10 due to lack of data on initial treatment and one confirmed diagnosis of tenosynovial giant cell tumor. Therefore, we retrospectively analyzed the records of 643 patients with a histologically confirmed diagnosis of GCTB treated at 16 health care facilities across 8 Brazilian states. Two centers which approved the study protocol ultimately did not include patients. The North, Northeast, South, and Southeast regions included 18, 87, 170, and 368 patients, respectively.

Quantitative variables were expressed as mean (SD), while categorical variables were expressed as absolute and relative frequencies. Data were analyzed in SPSS version 21.0.

RESULTS

The general characteristics of the sample are shown in Table 1. The cohort comprised 351 (54.6%) women and 292 (45.4%) men, with a mean age of 32 (SD, 13) years, ranging from 8 to 77 years. The median follow-up was 7.1 years. Campanacci stage I and II tumors accounted for 38.6% (n=248) of cases, and Campanacci stage III tumors, for 61.4% (n=395). Data were missing in 3 cases. Appendicular tumors accounted for 92.1% of cases (n=597), the knee being the most frequently affected level (52.2%; 175 distal femur, 133 proximal tibia, and 27 proximal fibula), followed by hand and wrist (18.7%; 74 distal radius, 26 hand, and 20 distal ulna), foot and ankle (9.6%; 29 distal tibia, 18 in metatarsus, talus, and calcaneus, and 1 distal fibula) and scapular girdle (6.0%; 30 proximal humerus, 6 scapula, and 2 clavicle). Tumors located in the axial skeleton accounted for 7.1% of cases (n=46), with the most common sites being the pelvic girdle (n=20), sacrum (n=12), and spine (n=12).

Surgery was performed in 626 patients, with curettage in 50.2% (n=323), marginal or wide resection in 43.4% (n=279), and amputation in 3.7% (n=24). Patients treated without surgery accounted for 2.6% (n=17) of cases. The reasons for not operating were unresectable tumors, major surgical morbidity, personal and family decisions, and poor clinical condition. Of the 323 patients who underwent curettage, 15.4% (n=50) were treated without adjuvant therapy, 40.5% (n=131) received only one adjuvant (ethanol or fulguration or drilling), and 44.0% (n=142) received two or more combined adjuvants. The bone defect was filled in 95.7% (n=309) of cases, and the remaining 4.3% (n=14) received no filling. Bone cement

Table 1. General characteristics.

Variables	n (%)
Campanacci grade	
I/II	248 (38.6)
III	395 (61.4)
Pulmonary metastasis	
No	616 (94.9)
Yes	33 (5.1)
Pathological fracture	
No	551 (85.7)
Yes	92 (14.3)
Type of surgery	
Curettage	323 (50.2)
Marginal/wide	278 (43.2)
Amputation	24 (3.7)
Not performed	17 (2.6)
Type of filling (n=323)	
Cement	271 (84)
Cement and bone graft	11 (3.4)
Bone graft alone	23 (7.1)
No filing	14 (4.3)
Missing	4 (1.2)
Adjuvant (n=323)	
None	50 (15.4)
One	131 (40.5)
Combined (two or more)	142 (44.0)
Local recurrence*	114 (18.2)
Denosumab*	
No	542 (86.6)
Yes	84 (13.4)

*Only surgically treated patients (n=626).

<< SUMÁRIO

(PMMA) was used in 271 cases (Figure 1), cement combined with bone graft in 10 cases, and bone graft alone in 23 cases. (Figure 2) There were no data on the specific type of reconstruction after wide and marginal resections.

A total of 97 patients were treated with denosumab. Indications for use were preoperative cytoreduction (57 cases), local recurrence (14 cases), tumors associated with major surgical morbidity (5 cases), pulmonary metastases (4 cases), and other reasons (4 cases). Patients treated with preoperative denosumab showed a local recurrence rate of 14% (8/57). Denosumab was used in only 15% (97/643) of the patients due to the scarcity of resources at public health facilities.

Patients diagnosed with GCTB had pulmonary metastases present at initial staging in 5.1% of cases (n=33), and pathological fractures in 14.3% (n=92). Among those with metastatic GCTB, the mortality rate was 15.1% (5/33). The rate of local recurrence among those who underwent surgery was 18.2% (n=114). As expected, curettage had a higher rate of local recurrence (24.4%) compared to wide and marginal resections (12.5%). (Table 2) The local recurrence rate according to affected bone was 30% (4/12) in the sacrum, 26.6% (8/30) in the proximal humerus, 25.6% (19/74) in the distal radius, 17.1% (30/175) in the distal femur, 14.2% (19/133) in the proximal tibia (Figure 3), and 10% (2/20) in the pelvis.

The analysis stratified by geopolitical region demonstrated higher rates of lung metastases (12.6%) and Campanacci stage III tumors

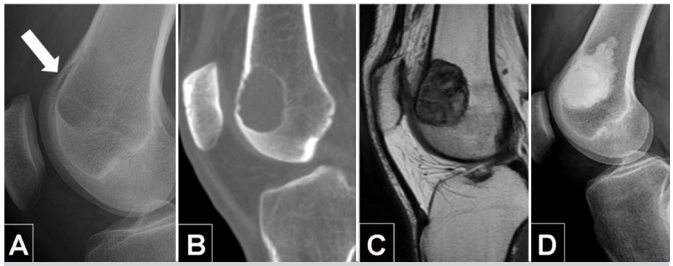

Figure 1. A) Preoperative radiograph and B) computed tomography scans displaying a meta-epiphyseal lesion causing endosteal erosion (Campanacci II) and expanding the anterior cortex of the distal femur (arrow). C) Contrast-enhanced MRI of the knee revealing the medullary and cortical boundaries of a giant cell tumor of bone (GCTB). D) Postoperative radiograph depicting the cavity filled with cement after curettage. Despite endosteal involvement and medullary osteolysis, joint structure and function were successfully restored.

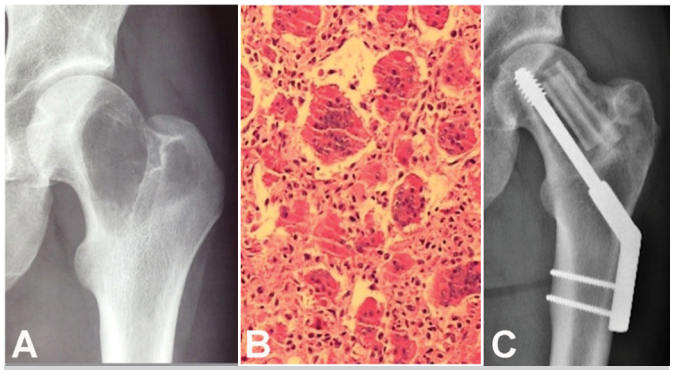

Figure 2. A) Preoperative radiograph showing an osteolytic lesion partially confined to the left proximal femoral epiphysis (Campanacci II). B) Microscopic view of the bone lesion after a core needle biopsy, revealing multiple multinucleated giant cells within a stroma of mononuclear cells. C) 12-month postoperative follow-up radiograph after curettage, fulguration, and alcoholization of the tumor bed, plate fixation, and filling with xenograft and autologous fibula. There was complete incorporation of the graft.

Table 2. Local recurrence rate and cohort characteristics.*

Variables	Local recurrence n=114 (%)
Sex – n(%)	
Female	71 (11%)
Male	43 (7%)
Campanacci grade – n(%)	
I/II	40 (6%)
III	74 (12%)
Anatomical site – n(%)	
Sacrum and spine	6/22 (27%)
Humerus and scapula	10/37 (27%)
Wrist and hand	25/120 (21%)
Foot and ankle	13/61 (21%)
Pelvis and hip	4/31 (13%)
Knee	53/333 (16%)
Elbow	2/12 (16%)
Other sites	1/10 (10%)
Skeletal distribution – n(%)	
Axial	10/53 (19%)
Appendicular	104/573 (18%)
Type of surgery – n(%)	
Curettage	79/323 (24%)
Marginal/wide	35/279 (12%)
Amputation	0 (0%)
Type of filling – n(%)	
Cement (PMMA)	60/271 (22%)
Cement and bone graft	1/10 (10%)
Bone graft alone	10/23 (43%)
No filling	6/14 (42%)
Adjuvant – n(%)	
None	18/50 (36%)
One	33/131 (25%)
Combined (two or more)	28/142 (20%)
Preoperative denosumab	8/57 (14%)

*Only surgically treated patients (n=626).

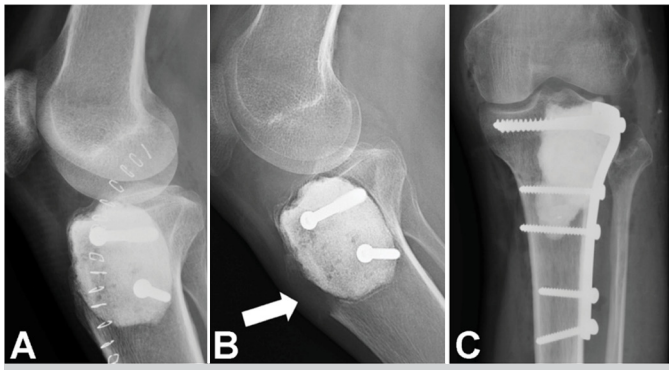

Figure 3. A) Immediate postoperative radiograph of the knee after curettage of a proximal tibial GCTB; cement is visible filling the defect. B) After 18 months, there was local recurrence with severe osteolysis adjacent to the cement and rupture of the cortical bone. C) Anteroposterior radiograph showing surgical treatment of the recurrence (curettage, drilling, fulguration, and alcoholization with 99% ethanol) with successful joint preservation. Bone cement and reinforcement with a proximal tibia plate were used.

(88.9%) in the Northeast and North, respectively. Likewise, the North region had higher rates of pathological fractures (33.3%), wide resection (61.1%), and amputations (27.8%). Finally, there was a longer interval between tumor diagnosis and primary surgery in the Northeast and North regions (36 and 39 days) compared to the South and Southeast regions (27 and 33 days). (Table 3)

DISCUSSION

In Brazil, several referral centers for the treatment of bone tumors have been accumulating cases of GCTB in their records for decades. Despite this large number of patients, only a few case series have been published. To address this issue, we developed a research project which would collate patients from the country's main referral centers and create a multicenter database. This first Brazilian epidemiological study on GCTB included 643 patients and gave further support to some findings already described in the international literature. We consider that the local recurrence rate was high (18.2%), although previous cases series have reported recurrence rates ranging from 10% to 75%.[5,9,10] The high recurrence rate observed in the curettage cohort (24.4%) can be partially attributed to the inclusion of patients treated since the late 1980s, when the range of adjuvant therapies, diagnostic imaging techniques, and treatment modalities available was limited. Even though curettage entailed a twofold local recurrence rate relative to resection, many authors still prefer this technique in order to protect the bone structure and ensure joint function.[9-11] Moreover, due to the large proportion of patients with Campanacci stage III tumors (61.4%), we hypothesize that diagnostic and treatment delays may have occurred in some of the cases. This may also reflect the difficulty of accessing specialized care through the public health system.

Tumors located in the axial skeleton have been observed to have higher rates of local recurrence compared to those in the appendicular skeleton. Balke et al.[12] examined nineteen patients with GCTB of the spine and sacrum and reported an overall local recurrence rate of 66.7%, and 15.4%, respectively. Likewise, Junming et al.[13] evaluated 22 patients with cervical spine GCTBs treated consecutively; the local recurrence rate was 71.4% for subtotal resection, and 7.7% for total spondylectomy.[12-14] Generally, this outcome has been linked to the difficulty of surgical approaches to the spine and pelvis, incomplete resections, larger tumors, and the biological characteristics of the neoplasm.[14-16] In our cohort, we observed a higher rate of local recurrence for lesions located in the sacrum (33%, 4/12) and spine (20%, 2/10) than for most appendicular lesions. Additionally, we observed a high rate of local recurrence in our patients with tumors of the proximal humerus and distal radius.[17,18] In the proximal humerus, a local recurrence rate of 26.6% was observed, while curettage and resection of distal radius lesions was associated with local recurrence rates of 35% and 16%, respectively. Theoretically, this higher risk of local recurrence may be related to the high percentage of stage III tumors at diagnosis, proximity to blood vessels, incomplete curettage, and the biological behavior of the tumors.[5,10,18] The prevalence of lung metastasis is increased in patients with local recurrence, and considerably worsens survival rates.[14,19] In our study, the metastasis rate was indeed higher (13%) in patients with local recurrence, and the rate of death in metastatic patients was 15%. These data corroborate the findings of previous studies.

Denosumab has become a leading pharmacological option for the treatment of GCTB. Indications for use include locally extensive disease, unresectable tumors, major surgical morbidity, pulmonary metastases, local recurrence, preoperative or postoperative treatment, and even pain control.[20] In general, tumors with poor prognosis are treated with denosumab. Examples include tumors located in the pelvis, spine, or even in the long bones when overly aggressive. As a result, poorer outcomes in terms of local recurrence, metastases, and death seemingly associated with the use of denosumab may be explained by patient selection bias. Moreover, treatment with curettage after denosumab may be surgically challenging due to extensive bone formation inside the lesion. Theoretically, neoplastic cells confined to the trabecular bone that has not been removed would be the reason for local recurrence. In our series, preoperative denosumab followed by curettage did not increase the rate of local recurrence.

GCTB is a highly curable neoplasm; however, several factors can interfere with the success of treatment. Studies have demonstrated that delayed diagnosis and treatment of GCTB correlate with larger tumors, higher recurrence rates, and higher rates of local complications. Furthermore, patients in whom diagnosis or treatment of GCTB are delayed are more likely to require more aggressive treatments, such as amputation or chemotherapy. Additionally, we identified that the disparities in development and health investments among Brazilian geopolitical regions were reflected in the characteristics and outcomes of our patients with GCTB.[6] Despite the limited scope of our cohort, regions with a lower human development index and annual per capita income, such as the North and Northeast, showed higher rates of pulmonary metastases, stage III tumors, pathological fractures, wide resections, and amputations, as well as a longer time between diagnosis and primary treatment, as compared to states in the more highly developed South and Southeast regions. Measures to promote and protect health should be taken in order to reduce these inequalities between regions in Brazil. It should be borne in mind that treatment of GCTB is the responsibility of high-complexity referral centers, and investments must be made as needed in order for individuals to have access to these institutions as quickly as possible. The findings in this cohort are certainly replicable for other musculoskeletal tumors, particularly regarding a similar situation of delayed diagnosis, but with even worse prognosis. The main limitation of this study which may have had an effect on our findings is that the sample comprised patients who were treated in different decades, by surgeons with varying levels of experience in the treatment of GCTB, and with great variation in the availability of imaging modalities, surgical materials, and histopathological

Table 3. Sample characteristics stratified by Brazilian geopolitical region.

Variables	South (n=170; 26.4%)	Northeast (n=87; 13.5%)	Southeast (n=368; 57.2%)	North (n=18; 2.8%)
Campanacci grade – n(%)				
I/II	62 (36.5)	27 (31.0)	157 (42.7)	2 (11.1)
III	108 (63.5)	60 (69.0)	211 (57.3)	16 (88.9)
Pulmonary metastasis – n(%)	5 (3.0)	11 (12.6)	16 (4.6)	1 (5.6)
Pathological fracture – n(%)	27 (15.9)	9 (10.3)	50 (16.6)	6 (33.3)
Type of surgery – n(%)				
Curettage	99 (59.3)	51 (58.6)	171 (48.3)	2 (11.1)
Marginal/wide	65 (38.9)	30 (34.5)	173 (48.9)	11 (61.1)
Amputation	3 (1.8)	6 (6.9)	10 (2.8)	5 (27.8)
Local recurrence – n(%)	35 (21.0)	16 (18.4)	62 (17.5)	1 (5.6)
Time between diagnosis and surgery (days)**	27 (6-69)	36 (18-78)	33 (6-80)	39 (20-91)

**Median (interquartile range).

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analysis. Nonetheless, to the best of our knowledge, the 640 patients included in this study comprise the largest case series with epidemiological data on GCTB in Latin America.

CONCLUSIONS

Among patients with GCTB in Brazil, characteristics such as sex, age, tumor aggressiveness, anatomical location, type of surgery performed, local recurrence rate, and metastases were similar to those described in the international literature. Patients treated in geopolitical regions with a lower HDI and per capita income presented higher rates of pathological fractures, metastases, larger tumors, and amputations, as well as longer delays between diagnosis and treatment. Despite the large cohort size, limitations and possible biases of this study should be considered.

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PHYSIOTHERAPY

CORRELATION OF THE SAGITTAL BALANCE WITH POSTURAL ANALYSIS OF THE PELVIS AND LUMBAR SPINE

CORRELAÇÃO DO EQUILÍBRIO SAGITAL E ANÁLISE POSTURAL DE PELVE E COLUNA LOMBAR

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ABSTRACT

Objective: Evaluate and correlate the sagittal balance parameters with the postural of the pelvis and lumbar spine. Methods: 80 individuals of both sexes, aged between 20 and 35 years, were evaluated. Biophotogrammetry was done with the SAPO software program. Measurements of the sagittal balance parameters were obtained by analyzing a lateral view panoramic radiography of the vertebral column, in which the anatomical points of reference were digitally marked. The calculation of the angles was done automatically by the Keops program. Results: In Keops assessment, 17.5% of the sample had high pelvic incidence angles (> 60°), 31.5% had low pelvic incidence angles (< 45°), and 51.2% had medium pelvic incidence angles (between 46° and 59°). SAPO showed 12,5% lordosis, 40% retroversion, and 47,5% normal curvature. In the right lateral view, pelvic incidence angle had a moderate and positive correlation with vertical alignment of the trunk and with vertical alignment of the body, and a negative and moderate correlation with horizontal alignment of the pelvis. Conclusion: Differences were found between vertical alignment measurements from the postural evaluation system (SAPO). A positive correlation was found between PI from Keops and pelvic anteversion from SAPO. ***Level of Evidence II; Prospective Study.***

Keywords: Spine. Software. Rehabilitation. Posture.

RESUMO

Objetivo: Avaliar e correlacionar o equilíbrio sagital com parâmetros posturais da pelve e coluna lombar Métodos: Foram avaliados 80 indivíduos de ambos os sexos, com idade entre 20 e 35 anos. A biofotogrametria foi realizada com o software SAPO. As medidas dos parâmetros do equilíbrio sagital foram obtidas pela análise de uma radiografia panorâmica em perfil da coluna vertebral, na qual os pontos anatômicos de referência foram marcados digitalmente. O cálculo dos ângulos foi feito automaticamente pelo programa Keops. Resultados: Na avaliação Keops, 17,5% da amostra apresentavam ângulos de incidência pélvicos altos (> 60°), 31,5% tinham ângulos de incidência pélvicos baixos (< 45°) e 51,2% apresentavam ângulos de incidência pélvicos médios (entre 46° e 59°). O SAPO apresentou 12,5% de lordose, 40% de retroversão e 47,5% de curvatura normal. Na vista lateral direita, o ângulo de incidência da pelve apresentou correlação moderada e positiva com o alinhamento vertical do tronco e com o alinhamento vertical do corpo e negativa e moderada com o alinhamento horizontal da pelve. Conclusão: Foram encontradas diferenças entre as medidas de alinhamento vertical do sistema de avaliação postural (SAPO). Uma correlação positiva foi encontrada entre IP de Keops e anteversão pélvica de SAPO. ***Nível de Evidência II; Estudo Prospectivo.***

Descritores: *Coluna Vertebral. Software. Reabilitação. Postura.*

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INTRODUCTION

Posture acquisition occurs throughout life and is affected by constitutional, environmental, and lifestyle factors. Postural deviations can affect the musculoskeletal structures and cause an abnormal displacement of the center of mass over the support base, generating pain, joint instability, muscular weakness and functional deficiencies,[1] in addition to altering the load and pressure distribution on the joint surfaces, leading to joint degeneration and inadequate muscular tensions.[2]

Making a good assessment is the first step in treating alterations of body alignment and posture. One of the most used forms of assessment is biophotogrammetry, which can be done with the Postural Evaluation System (SAPO), a software program that measures horizontal and vertical angles and distances between body segments using photographs with luminescent markers placed in predetermined regions of the body.[3]

Assessment of the sagittal plane of balance with a three-dimensional view is a recent development that has been used to evaluate and plan

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The study was conducted at the Laboratory for the Study of Movement (LEM) at the Institute of Orthopedics and Traumatology at Hospital das Clínicas, Medical School, University of São Paulo (HC FMUSP), São Paulo, SP, Brazil.
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surgical procedures for stabilization of the spine. Sagittal balance depends on the morphological and spatial parameters of the pelvis, hip and spine, measured with a panoramic radiography of the spine. The main parameters used are the pelvic incidence angle (PI),[4] defined as the angle between a line perpendicular to the midpoint of the sacral plateau and another line connecting this point to the central axis of the femoral head. It is an anatomical parameter, constant, immutable and exclusive of each individual, which does not depend on age and orientation of the pelvis and which is consolidated after bone growth ends.[5,6] In addition to PI, the sacral slope angle (SS) and the pelvic version angle or pelvic balance angle (PV) are also used in the diagnosis, evolutionary prognosis and treatment of spinal disorders. Sagittal balance parameters are objective measures that open a new perspective in the evaluation and treatment of postural alterations, improving rehabilitation and training programs by making them more specific and individualized.

The goal of this study was to evaluate the sagittal balance parameters measured by the software program *Keops* and the postural parameters in the right and left side views measured by the SAPO program, and to look for correlations among the parameters measured by *Keops* and between those and results from biophotogrammetry of the pelvis and lumbar spine.

METHODS

Design, local and ethics

This is a cross-sectional study performed at the Laboratory for the Study of Movement (LEM) of the Institute of Orthopedics and Traumatology of Hospital das Clínicas from the Medical School of the University of São Paulo (HC FMUSP) approved by the Ethics Research Committee (protocol number: 0466/12).

Participants

A total of 80 individuals were evaluated, being 46 females and 34 males, with a mean age of 25 ± 4.1 years. The inclusion criteria were: Having a level of cognition sufficient to understand the procedures and follow given instructions, sedentary individuals, according to the International Physical Activity Questionnaire (IPAC), individuals with BMI < 30, absence of disease/traumas or *sequelae* that compromise the locomotor system (musculoskeletal and nervous system) and absence of diseases of the vestibular system or compromised balance. The exclusion criteria were not being able to perform the tests.

Procedures

All individuals agreed to participate in the study by reading and signing the informed consent form. After that they answered a questionnaire with personal information, socio-demographic.

Assessments

Assessment 1: Panoramic radiography of the vertebral column in orthostatic position with the arms flexing in front of the body. The panoramic images were submitted to the *Keops* program after identifying the anatomical points used to measure the sagittal balance parameters: PI, PV, and SS.

Assessment 2: Postural evaluation with the Postural Evaluation System (SAPO). Styrofoam markers were placed in the anatomical points of the trunk and limbs: acromion, anterior superior iliac spine, posterior superior iliac spine, greater trochanter, and lateral malleolus. Images from the right and left lateral views were used: vertical alignment of the trunk, vertical alignment of the body, and horizontal alignment of the pelvis.

Statistical Analysis

The normality and homogeneity of variance were confirmed by the Komorov-Smirnov test and levene test, respectively. The data were presented by means of means, standard deviation (SD). Pearson's correlation was used to relate the dependent variables: lumbar lordosis angles, thoracic cifosis, pelvic angle of incidence, pelvic inclination and sacral inclination with independent variables (SAPO angles): vertical alignment of the trunk, vertical alignment of the body and horizontal alignment of the pelvis. For the entire analysis, the statistical software SPSS (Statistical Package for Social Science) version 22.0 for Windows was used and a significance index of $p \leq 0.05$ was adopted.

RESULTS

Table 1 shows the angles measured by the Keops and SAPO software programs. In the SAPO program, the right and left lateral views were analyzed and in the Keops program, the pelvic incidence angle was measured in 80 individuals of both sexes.

Fourteen (17.5%) had a high pelvic incidence angle, above 60° (63.8 ± 4.0°); 41 (51.2%) had a moderate pelvic incidence angle between 45-59° (52.0 ± 3.4°) and 25 (31.2%) had a low pelvic incidence angle, under 45° (42.8 ± 1.9°). The SAPO program measurements resulted in 10 (12.5%) individuals with pelvic anteversion, 32 (40%) with pelvic retroversion, and 38 (47.5%) with neutral pelvis, assessed by the horizontal alignment of the pelvis in the right and left lateral views. (Table 2)

We looked for correlations among the angles measured by the *Keops* software program (Table 3). The sacral inclination and lumbar lordosis angles showed a positive and moderate correlation; the pelvic incidence angle showed a positive and weak correlation with the lumbar lordosis angle, and the thoracic kyphosis angle showed a positive and weak correlation with the lumbar lordosis angle.

Tables 4 and 5 show the correlations between measurements of the Keops and SAPO software programs: Pelvic incidence angle showed a moderate and positive correlation with vertical alignment of the trunk,

Table 1. Angles (degrees) measured by the Keops and SAPO programs for postural evaluation (n = 80).

Angle	Average (SE)
KEOPS	
Pelvic Incidence (°)	51.2 (8.1)
Sacral Slope (°)	41.1 (6.2)
Pelvic Tilt (°)	10.3 (6.0)
Lumbar lordosis angle (°)	60.3 (11.3)
Thoracic kyphosis angle (°)	37.2 (12.3)
SAPO: right side view	
Vertical alignment of the trunk (°)	-2.5 (3.2)
Hip-trunk and thigh angle (°)	-5.3 (6.9)
Vertical alignment of the body (°)	1.4 (2.0)
Horizontal alignment of the pelvis (°)	-7.1 (12.4)
SAPO: left side view	
Vertical alignment of the trunk (°)	-1.5 (2.8)
Hip-trunk and thigh angle (°)	-4.5 (6.4)
Vertical alignment of the body (°)	2.7 (1.4)
Horizontal alignment of the pelvis (°)	-6.3 (1.9)

Table 2. Distribution of the subjects according to the pelvic incidence angles (PI) measured by the Keops program and pelvis position assessed by SAPO (n = 80).

PI	High (> 60°)	Medium (45-59°)	Low (< 45°)
	14	41	25
Pelvis	**Anteversion**	**Neutral**	**Retroversion**
	10	38	32

PI: Pelvic incidence angle.

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Table 3. Correlation values (r) between the pelvic incidence angle, pelvic tilt angle, and sacral slope angle with the thoracic kyphosis angle, and lumbar lordosis angle measured by the Keops program (n = 80).

Angles	Lumbar lordosis angle	Thoracic kyphosis angle
	r(p)	r(p)
Pelvic incidence	0.546 (p ≤ 0.001)*	0.057 (0.615)
Sacral slope	0.541 (p ≤ 0.001)*	0.010 (0.926)
Pelvic tilt	0.122 (0.283)	0.028 (0.804)
Lumbar lordosis angle	–	0.334 (0.002)*
Thoracic kyphosis angle	0.334 (0.002)*	-

Pearson's coefficient * p ≤ 0.05.

Table 4. Correlation values (r) between the Keops sagittal balance variables and the SAPO postural variables in the right lateral view for the group of subjects (N = 80).

Variables	VAT	HTTA	VAB	HAP
	r(p)	r(p)	r(p)	r(p)
Pelvic incidence	0.638 (0.053)*	0.166 (0.141)	0.078 (0.491)	-0.496 (p ≤ 0.001)*
Sacral slope	-0.031 (0.786)	- 0.042 (0.714)	0.049 (0.668)	-0.288 (0.010)
Pelvic tilt	0.000 (0.999)	-0.181 (0.108)	0.044 (0.696)	-0.250 (0.025)
Lumbar lordosis angle	-0.067 (0.557)	-0.136 (0.228)	-0.043 (0.707)	-0.376 (p ≤ 0.001)*
Thoracic kyphosis angle	0.064 (0.574)	-0.047 (0.678)	0.032 (0.267)	0.031 (0.787)

Pearson's coefficient (R) * p ≤ 0.05. Legend: VAT - vertical alignment of the trunk; HTTA: hip-trunk and thigh angle; VAB: vertical alignment of the body; HAP: horizontal alignment of the pelvis.

Table 5. Correlation values (r) between the Keops sagittal balance variables and the SAPO postural variables in the right lateral view for the group of subjects (N = 80).

Variables	VAT	HTTA	VAB	HAP
	r(p)	r(p)	r(p)	r(p)
Pelvic incidence	0.638 (0.053)*	0.166 (0.141)	0.078 (0.491)	-0.496 (p ≤ 0.001)*
Sacral slope	- 0.031 (0.786)	- 0.042 (0.714)	0.049 (0.668)	-0.288 (0.010)
Pelvic tilt	0.000 (0.999)	-0.181 (0.108)	0.044 (0.696)	-0.250 (0.025)
Lumbar lordosis angle	-0.067 (0.557)	-0.136 (0.228)	-0.043 (0.707)	-0.376 (p ≤ 0.001)*
Thoracic kyphosis angle	0.064 (0.574)	-0.047 (0.678)	0.032 (0.267)	0.031 (0.787)

Pearson's coefficient (R) * p ≤ 0.05. Legend: VAT - vertical alignment of the trunk; HTTA: hip-trunk and thigh angle; VAB: vertical alignment of the body; HAP: horizontal alignment of the pelvis.

and a negative and moderate correlation with horizontal alignment of the pelvis. Horizontal alignment of the pelvis showed a moderate and negative correlation with lumbar lordosis angle in the right lateral view. In the left lateral view, horizontal alignment of the pelvis showed a weak and negative correlation with pelvic incidence angle, and a moderate and negative correlation with lumbar lordosis angle.

DISCUSSION

High pelvic incidence angles are correlated with increased pelvic anteversion or increased lordosis. The sagittal balance measurements allow us to quantify the degree of lumbar lordosis and pelvic version, thus providing objective measurements which can be used to evaluate the results of treatment programs for disorders of the spine. Postural assessment can be done by physical examination and by specific quantitative tests, both of which are subjective and poorly reproducible. A panoramic radiography of the spine, aided by anatomical reference points, improves the assessment of normal and pathological postures.

Sagittal balance variables, measured by digital evaluation of the panoramic radiography of the spine, are not often used in physiotherapy, and we could not find in the literature studies that used or compared this method of evaluation with biophotogrammetry and/or other commonly used evaluation methods. Sagittal balance variables have been valued[5-9] in the evaluation and treatment of disorders of the spine, especially in surgical treatments.

Weinberg et al.[8] found a higher PI among black people. In the present study, although the influence of race was not evaluated, there was a predominance of low pelvic incidence angle, a result that would not be expected for the Brazilian population, which has a high degree of racial miscegenation between whites and blacks. This is something to be elucidated in future studies with larger samples.

Some authors report no significant differences between men and women regarding the pelvic incidence, sacral slope and pelvic tilt angles,[9-12] but according to Sudhir et al.[11] the pelvic incidence angle is larger in women. In this study, no difference was found between the sexes: 46 women had a PI of 50.1 ± 7.8°, and 34 men had a PI of 52.7 ± 8.4°, in agreement with some authors.[9-12]

The pelvic tilt and sacral slope angles were 10.3 ± 6.0° and 41.1 ± 6.2°, respectively, within the normal range (10°-25° for pelvic tilt, and 30°-50° for sacral slope)[13,14] as expected for the study population.

Rogala et al.[15] reported that high pelvic tilt angles are associated with pelvic retroversion, constituting a compensatory measure for maintaining sagittal balance. The lumbar lordosis and thoracic kyphosis angles were 60.3 ± 11.3° and 37.2 ± 12.3°, respectively, In the right and left lateral view assessment done by SAPO, 47.5% of the sample had pelvic anteversion (-12.7 ± 3.7° in the right side view, and -10.9 ± 7.4, in the left side view) within the physiological values of a pelvis in neutral position. Lumbar lordosis with anteversion (-15.7 ± 1.3° in the right side view, and -15.2 ± 1.6°, in the left side view) was found in 12.5% of the sample. Retroversion (7.2 ± 1.6° in the right side view, and 7.3 ± 1.6° in the left side view) was found in 40% of the sample.

Souza et al.[16] assessed the reliability of the horizontal alignment of the pelvis and found values that are in agreement with the present study, with a large variation but good reliability, however, he also acknowledged the difficulties involved in adequately collecting the SAPO parameters.

Results from the *Keops* software program are in agreement with those from SAPO for the current sample. There is a predominance of moderate pelvic incidence angles (*Keops*), and physiological anteversion (SAPO), followed by low incidence angles (*Keops*) and retroversion (SAPO), and finally by individuals with high incidence angles (*Keops*) and anteversion of the pelvis (SAPO). The two methods converged on the results, a fact that corroborates the reliability of both.

Nery[17] reported that the SAPO program is a good tool for postural evaluation, but had reservations regarding the lateral views. Souza et al.[16] reported that horizontal alignment of the pelvis and vertical alignment of the body, as measured by SAPO, are highly reliable, but emphasized that vertical alignment of the trunk and hip angle are not reliable, mainly due to the difficulties involved in properly positioning the markers.

Ferreira et al,[7] in a study aimed at validating the SAPO software program, reported that horizontal alignment of the pelvis, vertical trunk and body alignment, and hip angle are reliable measurements. The four measurements are within the normal range reported in the literature, according to which, pelvic anteversion can range from -10 to -15°, however, the large variation in horizontal pelvic alignment makes it difficult to establish physiological parameters. The software program *Keops*, is based on an objective measurement, i.e., a panoramic radiography of the vertebral column, and it also associates large negative anteversion angles

with high pelvic incidence angles and lumbar lordosis. Pelvic incidence angle has a moderate and positive correlation with vertical alignment of the trunk and the body, showing that the larger the anterior tilt of the body, the larger the angle of pelvic incidence, due to the need of maintaining postural balance in orthostatism. In the right lateral view, a moderate and positive correlation between PI and horizontal alignment of the pelvis was found, showing that the higher the PI and lumbar lordosis, the greater the anteversion of the pelvis, with the angles of horizontal alignment of the pelvis becoming more negative. These data were not completely confirmed, since in the left lateral view the correlation was positive but weak. The imprecision of the lateral measurements in SAPO may justify the difference between the right and left lateral views. The best correlation found was between PI and horizontal alignment of the pelvis, a fact which should be expected according to the literature.[5,6,10,7,12]

There is a tendency of associating PI with the position of the pelvis and curves of the lumbar and thoracic spine, however, there is a range of small variations in the posture acquisition process which may justify the moderate and weak correlation found between the variables from Keops and SAPO.

PI is the determining parameter of sagittal balance, because it is individual, constant, and remains with the individual during their lifetime,[9,10,14] thus directly interfering in the spinopelvic relation. However, acquisition of the postural pattern, which takes place throughout the life of an individual, can be influenced by other factors besides the PI angle, which leads to variations in pelvis positioning and spinal curvature.

PI alone cannot be used as an indicator of pelvis positioning and spinal curvature, since an individual may create different strategies to maintain sagittal balance. PI is a good guiding parameter, but other variables need to be considered to better understand an individual's posture.

Sagittal balance variables are useful for surgeons and rehabilitation teams to better evaluate and treat spinal disorders, mainly due to its three-dimensional character.

The SAPO program variables used in this study were those that measure the same regions composed by *Keops*: position of the pelvis and curvatures of the spine. SAPO is a two-dimensional evaluation and therefore may be insufficient to evaluate the spinopelvic relation.[7] SAPO is a useful tool which complements clinical evaluation, due to standardization of the measurements,[17] however, an objective tool like the software program *Keops*, which is based on radiography, improves the objective evaluation and has a lower likelihood for errors. The photographic technique, which uses markers placed at specific points on the body, can lead to positioning errors and measurement errors, especially in lateral views.[17]

The association of three-dimensional measurements, such as the evaluation performed by the *Keops* program, can improve postural assessment and physiotherapeutic interventions.

CONCLUSIONS

The majority of the study population was within the normal range, having a moderate pelvic incidence angle (PI) and neutral pelvic anteversion.

Differences were found between the right and left vertical alignment measurements from the postural evaluation system (SAPO).

No correlations were found among the three-dimensional variables of sagittal balance from the Keops program.

A positive correlation was found between PI from Keops and pelvic anteversion from SAPO.

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PHYSIOTHERAPY

ORTHOSTATIC SUPPORT IN PARAPLEGIC AND AMPUTEE PATIENTS: A CONTROLLED TRIAL

SUPORTE ORTOSTÁTICO EM PARAPLÉGICOS E AMPUTADOS: UM ENSAIO CONTROLADO

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ABSTRACT

Introduction: Functional incapacity caused by physical alterations leads to significant limitations in daily activities and has a major impact on the return of people with disabilities to the social space and the workplace. This calls for an evaluation of the long-term influence of the use of a device specially developed for orthostatic posture on the physiological, biomechanical and functional parameters of amputees and spinal cord patients. Objective: The objective was evaluate the effect of postural support device use on function, pain, and biomechanical and cardiologic parameters in spinal cord injury and amputees patients compared to a control group. Methods: The orthostatic device was used by the participants for a period of ten consecutive days, for three cycles of 50 minutes each day, and a 15-day follow-up. Participants were positioned and stabilized using adjustable straps on the shoulders, trunk, and hips. The primary outcome was brief pain inventory. Fifteen participants were included the control group, 15 in the amputee group, and 15 in the spinal cord group. Results: Our results demonstrate that the use of the device allows the orthostatic position of amputees and spinal cord patients evaluated for ten days, leading to improved functionality and pain in the spinal cord and amputee groups compared to the control group. In addition, no changes were observed for secondary outcomes, indicating that the use of the device did not cause harm interference to patients. Conclusion: The long-term use of the orthostatic device is beneficial for improving functionality, reduce pain in amputees and spinal cord injury patients. ***Level of evidence II; Therapeutic Studies - Investigating the results of treatment.***

Keywords: Spinal Cord Injuries. Amputees. Posture.

RESUMO

Introdução: A incapacidade funcional causada por alterações físicas leva a limitações significativas nas atividades diárias e gera um grande impacto no retorno das pessoas com deficiência ao espaço social e ao local de trabalho, demandando a avaliação da influência em longo prazo do uso de um dispositivo especialmente desenvolvido para a postura ortostática nos parâmetros fisiológicos, biomecânicos e funcionais de pacientes amputados e com medula espinhal. Objetivo: O objetivo foi avaliar o efeito do uso do dispositivo de suporte postural na função, dor e parâmetros biomecânicos e cardiológicos em pacientes com lesão medular e amputados em comparação com um grupo controle. Métodos: O aparelho ortostático foi utilizado pelos participantes por um período de dez dias consecutivos, em três ciclos de 50 minutos diários, com acompanhamento de 15 dias. Os participantes foram posicionados e estabilizados por meio de alças ajustáveis nos ombros, tronco e quadris. O desfecho primário foi o questionário Breve Inventário de Dor. Quinze participantes foram incluídos no grupo controle, 15 no grupo amputado e 15 no grupo medular. Resultados: Nossos resultados demonstram que o uso do dispositivo permite a posição ortostática de amputados e pacientes com lesão medular avaliados por dez dias, levando a melhora da funcionalidade e dor nos grupos de amputados e medula espinhal em relação ao grupo controle. Além disso, não foram observadas alterações nos resultados secundários, indicando que o uso do dispositivo não causou interferência prejudicial aos pacientes. Conclusão: O uso prolongado do dispositivo ortostático é benéfico para melhorar a funcionalidade, reduzir a dor em amputados e pacientes com lesão medular. ***Nível de Evidência II; Estudos Terapêuticos - Investigação dos resultados de tratamento.***

Descritores: *Traumatismos da Medula Espinal. Amputados. Postura.*

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INTRODUCTION

Functional disability caused by physical alterations leads to significant limitations in daily activities and generates a great impact on the return of people with disabilities into the social space and workplace. Limited mobility has been associated with important psychosocial factors that lead a high risk of developing severe symptoms of depression and consequent worsening health-related quality of life.[1-3]

About 250.000 to 500.00 people worldwide suffer from spinal cord injury, which results in paralysis, sensorimotor deficit, and consequently sedentary behavior, generating direct effects on health, functioning, and functional independence.[2] In the United States, about 1.7 million people reported the loss of a limb in 2007,[4] with the number of lower limb amputations increasing annually due to the high incidence of diabetes and cardiovascular disease.[5] The impact of lower limb amputation resulting from traumatic illness or injury is great for walking skills and community engagement.[6] Considering that the number of people affected by both conditions is high and predispose to relevant factors such as limited mobility and social reintegration, inclusion strategies should be prioritized to reduce the psychosocial and physical risks associated with the dysfunction.[7] Changes in the spinal cord lead to peripheral and central cardiovascular adaptations such as increased peripheral vascular resistance, reduced capillarization, and decreased artery diameters, which cause static hypotension resulting from a decline in blood pressure, limiting the stand position.[8] On the other hand, amputees also show changes in heart rate due to loss of aerobic capacity related to reduced walking ability and show changes in muscle strength and balance due to deconditioning and disuse.[9] To re-establishment of the locomotion and mobility functions of patients with physical disabilities related to the lower limb, assistive devices have been developed to allow the standing position and gait.[10,11] Thus, the function of the orthoses is to generate stability of the affected limb and, in some cases, assist in the gait pattern with the lowest possible energy consumption.[10,11]

Ergonomic position is necessary and has been developed regarding the need for changes in work to accommodate workers' characteristics.[12] Considering that when returning to the work and social environment, the individual with disability needs follow to a specific workplace rules, like a specific workload and specific positions adopted in a laboral environment. That is why limitations in the use of positioning orthosis occur since they generate a very large amount of physical energy expenditure and generated limited mobility. In addition, in most cases, prior training is required to restore the patient's aerobic capacity and strength to do the task.[8,9]

To the best of our knowledge, this is the first study that aims to assess the influence of the use of a device specially developed for the orthostatic posture on the physiological, biomechanical, and functional parameters of spinal cord and amputee patients in long term. The objective was to evaluate the effect of postural support device use on function, pain, and biomechanical and cardiologic parameters in spinal cord injury and amputees patients compared to a control group.

METHODS

Design

A non-randomized controlled trial. The study was approved by the Local Ethics Committee (CAAE 30603420.3.0000.5040) and prospectively registered at Registro Brasileiro de Ensaios Clínicos (REBEC) (identifier U1111-1257-5736). All participants were informed about the procedures and signed the written consent form. All methodological steps followed the recommendations of Consolidated Stands of Reporting Trials (CONSORT).

Participants

The participants were recruited between October and December 2020 in the Centro de Pesquisa, Desenvolvimento e Inovação Dell – DELL LEAD. The eligibility criteria were: adults, aged between 18-50 years, height 1.55-1.75 cm, maximum weight 100 kg, of both sexes, without associated vascular pathologies (clotting disorders, decompensated diabetes, etc.), with stabilized blood pressure. The control group was composed by healthy people and without motor changes in the lower limbs. In the amputee group was selected people with unilateral lower-limb amputee. The paraplegic group was selected people with diagnostic of a total or partial paraplegic, with a maximum of 10 years of the lesion and without musculoskeletal deformities in lower limbs. The exclusion criteria were: individuals with height and weight outside of the defined, established limits, unstable blood pressure, and severe vascular alterations. Furthermore, they exclude people with cognitive or psychological dysfunction that influence the performance of the tests, like panic syndrome, severe anxiety, or depression.

Intervention

The proposed intervention consisted of using the orthostatic device by the participants for a period of ten consecutive days, used for three cycles of 50 minutes each day, with a 10-minute rest between each cycle and a 15-day follow-up after the end of the experiment. Initially, demographic data were collected and applied to the questionnaires: Brief pain Inventory (BPI),[13] Functional Independence Measure (FIM),[14,15] and sleep quality by Epiworth Sleepiness Scale.[16] Then, measurements of vital signs [blood pressure (BP), oxygen saturation (SatO2), and heart rate (HR)] were performed. On a stretcher, the participants were positioned to collect measures of joint range of motion[17] and muscle strength using a handheld dynamometer.[18]

Participants were positioned in the orthostatic device and stabilized using adjustable straps on the shoulders, trunk, and hips. In addition, a wider velcro band was added in the region of the legs (above the knee) and the region of the tibialis anterior. These bands allowed greater stability of the lower limb in the standing posture, especially for the paraplegic group, due to limitations in motor control. Once positioned, the device was elevated, allowing the participant to remain in the standing position. At the base of the equipment, a mechanism was installed that allowed movement in ankle dorsiflexion to generate mobility in the joint during the orthostatic position.

After the volunteers were placed in orthostatism, evaluations of the autonomic nervous system (heart rate variability), body thermography of the trunk, hip, thigh, leg, and feet regions, and plantar pressure by baropodometry were performed. During the proposed period of daily intervention, consisting of three cycles of 50 minutes of standing position, the variables heart rate, oxygen saturation, and blood pressure were measured every 25 minutes to monitor the stability of vital signs. After completing the three cycles of 50 minutes with a 10-minute rest (totaling 3 hours of equipment use), the heart rate variability, body thermography of the trunk, hip, thigh, knee, leg, and feet regions, and plantar pressure were measured again. The volunteers were again positioned on the stretcher, and measurements of range of motion and muscle strength were taken. The study variables were collected at baseline, on the fifth day, at the end of the experiment (tenth day), and at follow-up.

Outcome measures

Trained therapists collected all outcome measurements. The measures were obtained before the intervention (baseline), five days, ten days (end of intervention), and 15 days after the end of intervention (follow up).

Functionality was considered the primary outcome. Secondary outcomes were: sleepiness level, pain, plantar pressure, muscle strength, ROM, oxygen saturation, heart rate variability, and thermography.

Function, Pain, and level of sleepiness was measured with Functional Independence Measure (FIM)[4,15] and Brief Pain Inventory (BPI) was used for pain assessment.[13] The sleepiness assessment was performed using the Epworth Sleepiness Scale[16]

The analysis of mean plantar pressure and stabilometry was performed by a baropodometer (T-Plateda Medicapteurs®, France).[19] A FLIR C2 6.4 infrared camera was used to collect thermographic data. Averages of the trunk, hip, thigh, knee, leg, and feet regions were performed. Data were analyzed and edited by FLIR Tools+. The images were captured at a fixed distance of one meter away from the participant, and the room temperature was regulated at 25 degrees.[20]

Heart rate variability: For data collection, EmWave® software (Quantum Intech, Inc. Boulder Creek, CA, USA)[21] was used.

Muscle strength and ROM: The assessment of muscle strength was performed using a manual dynamometer (SP Tech, Medeor MedTech, Santa Catarina, Brazil), with a maximum capacity of 90.72 kgf (200 lbf) and reliable for use in this population.[22] Three isometric contractions lasting 15 seconds were performed for trunk extension, knee flexion and extension, internal and external rotation of the hip and and plantar flexion and dorsiflexion of the ankle (Supplemental Material).

Statistical analysis

Statistical analysis followed the intention-to-treat concept and was carried out by a researcher not involved in the evaluation and treatment protocols. A significance level of 0.05 was set. The linear mixed-effect model was applied to the primary and secondary variables. "Time" and "group" were considered fixed effects, whereas the participants were considered the random effect. The time by group interaction was included in the analysis to assess the differential effect between the groups at each follow-up. The dependent variable baseline value was included as a covariate to correct possible differences. Statistical analyses were performed using the SPSS.

RESULTS

Forty five participants were included: 15 in the control group, 15 in the amputee group, and 15 in the paraplegic group. The participants' baseline characteristics are presented in Table 1. One individual in the amputee group dropped out for personal reasons and one in the paraplegic group dropped out for blood pressure decompensation. (Figure 1)

Differences between groups were shown for the total score and in motor subescale in the functional independence measure of the paraplegic group when compared to the control group at the end of the experiment ($p<0.05$). An increase in the FIM was also observed for the cognition subscale, indicating an improvement in the values compared to the control group in the follow-up period ($p<0.05$) (Table 2). For the measure of pain assessed by the BPI, the paraplegic group had evidence of differences with reduced values for the severity subscale at the end of the experiment and for the interference subscale on day five, ten, and follow up assessments (after baseline) when compared to the control group ($p<0.05$ (Table 3). There were no differences within and between groups over time in relation to excessive sleepiness (Supplemental Material).

The assessment of plantar pressure showed evidence of differences between the amputee group compared to the control group ($p<0.05$). The paraplegic group, on the other hand, had lower foot area values in the assessment after five days of device use and lower lateral velocity values when compared to the control group. (Table 4)

For the thermography variable, evidence of difference was observed between the control group and the amputee group for the temperature of the hip region, with an increase of 2 degrees at follow-up ($p<0.05$). The paraplegic group, showed a decrease of 1.87 degrees compared to the control group in the follow-up period and an intra-group reduction ($p=0.02$) when compared over the evaluation time (Table 5). The analysis of blood oxygen saturation remained within the limit accepted as adequate for patients.(Supplemental Material).

The heart rate variability data do not show evidence of difference within and between groups over the period evaluated. The stress index variable presented values between 7.9 (3.6) to 10.3 (4.7) in the control group, 7.5 (2.4) to 10 (6.8) in the amputee group, and 5.5 (2.6) to 6.7 (3.8) in the paraplegic group. The sympathetic nervous system showed values between 1.2 (1.1) to 1.9 (1) in the control group, 0.8 (1) to 1.8 (2.9) in the amputee group, and from 0.6 (0.8) to 0.7 (1.1) in the paraplegic group. For the evaluation of

Table 1. Sociodemographic characteristics of the study sample (n=45).

	Control (N=15)		Amputees (N=15)		Spinal Cord (N=15)	
Sex						
Male	4		9		12	
Female	11		6		3	
Marital status						
Not married	12		10		11	
Married	3		5		4	
Physical activity						
practitioners	8		14		11	
non-practitioners	7		1		4	
	Average	**SD**	**Average**	**SD**	**Average**	**SD**
Age (years)	22.73	2.54	35.00	8.66	31.4	7.80
height (m)	1.63	0.09	1.65	0.07	1.68	0.10
Weight (kg)	67.85	14.72	73.26	12.67	62.13	14.32
BMI (kg/m ^{2})	25.51	4.69	26.88	5.12	21.74	2.84

SD: Standard Deviation. BMI: Body Mass Index.

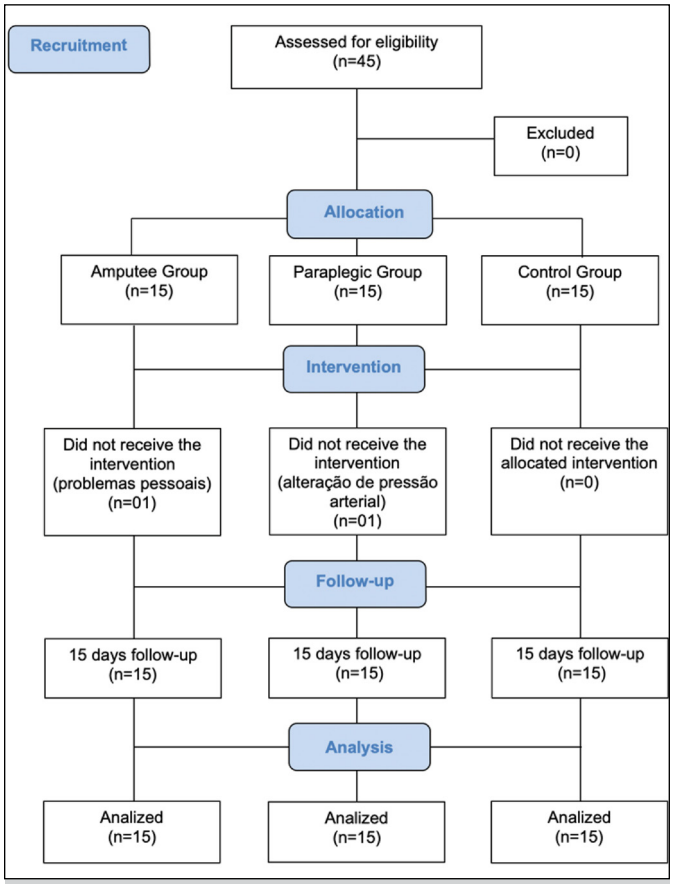

Figure 1. Flow chart of participant inclusion criteria.

Table 2. Measure of Functional Independence (MIF).

		Unadjusted Mean (SD)			Inter-group analysis	
		Control (N=15)	Amputees (N=15)	Spinal cord (N=15)	Diff Average (95%CI) Control - Amputees	Diff Average (95%CI) Control - Spinal Cord
MIF - Total	Baseline	126 (0.00)	122.53 (1.68)	116.67 (3.90)		
	Day 5	126 (0.00)	122.53 (1.68)	116.13 (3.60)	0.00 (-0.95 to 0.95)	0.53 (-0.42 to 1.5)
	10th day	126 (0.00)	122.60 (1.24)	115.60 (4.27)	0.06 (-0.88 to 1.02)	1.10 (0.11 to 2.00)*
	Day 15 (Follow-up)	126 (0.00)	122.33 (1.23)	116.13 (3.85)	0.20 (-1.15 to 0.75)	0.53 (-0.42 to 1.50)
	Intra-group analysis	p>0.9999	p=09633	p=0.9048		
MIF - Motor	Baseline	91 (0.00)	87.73 (1.33)	82 (4.03)		
	Day 5	91 (0.00)	87.73 (1.49)	81.40 (3.62)	0.00 (-0.97 to 0.97)	0.6 (-0.4 to 1.58)
	10th day	91 (0.00)	87.67 (1.17)	80.87 (4.10)	0.06 (-1.04 to 0.90)	1.13 (0.15 to 2.11)*
	Day 15 (Follow-up)	91 (0.00)	87.40 (1.30)	81.33 (3.83)	0.33 (-1.31 to 0.64)	0.66 (-0.31 to 1.64)
	Intra-group analysis	p>0.9999	p=0.8881	p=0.8874		
MIF - Cognition	Baseline	35 (0.00)	34.80 (0.56)	34.67 (0.72)		
	Day 5	35 (0.00)	34.80 (0.41)	34.73 (0.59)	0.06 (-0.14 to 0.28)	0.06 (-0.35 to 0.08)
	10th day	35 (0.00)	34.93 (0.26)	34.73 (0.59)	0.06 (-0.14 to 0.28)	0.06 (-0.28to0.15)
	Day 15 (Follow-up)	35 (0.00)	34.93 (0.26)	34.80 (0.56)	0.13 (-0.08 to 0.34)	0.13 (0.34 to 0.08)*
	Intra-group analysis	p>0.9999	p=0.6516	p=0.9879		

Table 3. Brief Pain Inventory (BPI).

Unadjusted Mean (SD)					Inter-group analysis	
		Control (N=15)	Amputees (N=15)	Spinal cord (N=15)	Diff Average (95%CI) Control - Amputees	Diff Average (95%CI) Control - Spinal cord
BPI - Severity	Baseline	1.39 (1.70)	1.35 (1.08)	4.18 (5.81)		
	Day 5	1.80 (1.50)	1.32 (1.82)	2.85 (5.72)	0.44 (-2.26 to 1.37)	1.74 (-0.07 to 3.57)
	10th day	1.02 (1.26)	0.95 (0.89)	1.65 (2.49)	0.03 (-1.85 to 1.79)	2.16 (0.34 to 4.00)*
	Day 15 (followup)	0.53 (0.77)	0.77 (1.26)	1.92 (2.43)	0.27 (-1.55 to 2.1)	1.41 (-0.41 to 3.23)
	Intra-group analysis	p=0.0779	p=0.5522	p=0.4014		
BPI - Interference	Baseline	0.58 (1.16)	1.20 (1.32)	2.60 (2.97)		
	Day 5	0.91 (1.38)	0.69 (1.30)	1.09 (1.78)	0.83 (-2.07 to 0.40)	1.80 (0.6 to 3.1)*
	10th day	1.02 (2.02)	0.49 (0.72)	0.99 (1.87)	1.14 (-2.40 to 0.09)	2.00 (0.81 to 3.3)*
	Day 15 (followup)	0.11 (0.25)	0.11 (0.37) [to]	0.85 (1.99)	0.62 (-1.85 to 0.61)	1.30 (0.04 to 2.51)*
	Intra-group analysis	P=0.2659	P=0.0370	P=0.1155		

the parasympathetic nervous system, values between -0.6 (1.3) to 0.16 (1.5) were observed for the control group, from 0.55 (2.3) to 0.36 (2) for the amputees' group and 1.3 (2.1) to 2 (2.7) for the paraplegic group (Supplemental Material).

The intra-group evaluation also did not show evidence of difference in muscle strength (Table 5) and range of motion values (Supplemental Material). Differences in knee flexion strength were observed in the control group compared with amputees at follow-up ($p<0.05$) and in the control group compared with the paraplegic group at final and follow-up evaluation ($p<0.05$). (Table 6)

DISCUSSION

The use of the device allows the orthostatic position of amputees and SCI patients evaluated for ten days, leading to improved functionality and pain in the spinal cord and amputee groups compared to the control group. In addition, no changes were observed for secondary outcomes, indicating that the use of the equipment did not cause harm or negative interference to the patients.

In this study, patients with spinal cord injury showed a reduction in the interference values of pain in daily activities with clinically relevant changes[23] on the fifth and tenth days of using the orthostatic device. Considering that the device allowed the individual to stand in an orthostatic posture, the change may have influenced the individual's perception of pain interference in activities. In addition, patients who presented pain in the spinal cord injury group had a clinically important improvement compared to the other groups, suggesting that changing posture and remaining in orthostatism had a great impact for this population.

The SCI group had lower values of hip range of motion after using the device. This finding is expected since amputees tend to have greater mobility, perform posture transfers more easily and need more of the hip joint for dislocations.[24] At the same time, patients with spinal cord injury spend most of the time sitting or lying down with limited change in posture.[25]

The circulatory support system allowed the patients' ankles to be mobilized during the stay in orthostatism, reducing the chances of edema appearing due to the position for a prolonged period and consequently helped in the local circulation avoiding overload in the foot region, which can be confirmed by stability in the measurement of foot area and plantar pressure over time. Trunk and hip stabilization bands helped in weight distribution without generating local temperature increase and discomfort, as observed by thermography and reported by patients.

Data on cardiovascular parameters demonstrated stability over time when comparing the control, amputees, and SCI groups. The stability of these parameters is seen as a positive and beneficial factor since patients with spinal cord injury present cardiovascular and autonomic nervous system changes when positioned in orthostatism.[26] The results of this clinical trial corroborate with previous study carried out by the research group, which analyzed the immediate effect of the use of orthostatic device and observed stability in the parameters analyzed for spinal cord injury.[27]

Study limitations

This study has some limitations, such as the sample size. This population has limitations in locomotion and possibly associated comorbidities that would influence the availability

Table 4. Plantar pressure – Baropodometry.

		Unadjusted Mean (SD)			Inter-group analysis	
		Control (N=15)	Amputees (N=15)	Spinal Cord (N=15)	Diff Average (95%CI) Control - Amputees	Diff Average (95%CI) Control - Spinal Cord
Foot area	Baseline	97.13 (25.18)	141.13 (23.87)	63.60 (20.90)		
	Day 5	84.60 (25.98)	148.47 (06.23)	64.67 (19.56)	19.87 (7.02 to 32.71)*	-13.60 (-26.44 to -0.76)*
	10th day	75.87 (24.54)	149.73 (24.00)	62.80 (03.17)	16.27 (3.42 to 11.29)*	-6.87 (-19.71 to 5.97)
	Day 15 (Follow-up)	95.60 (29.82)	147.07 (26.02)	59.87 (06.20)	7.47 (-5.37 to 20.31)	2.20 (-10.64 to 15.04)
	Intra-group analysis	p=0.3490	p=0.9544	p=0.8506		
Maximum Plantar Pressure	Baseline	887.93 (236.77)	1243.13 (217.98)	1199.80 (437.89)		
	Day 5	987.67 (207.60)	1034.75 (160.56)	1235.80 (392.78)	-219.20 (-376.46 to -61.94)*	63.73 (-93.52 to 220.99)
	10th day	947.20 (171.68)	1125.47 (152.83)	1246.67 (379.91)	-176.93 (-334.19 to -19.68)*	12.40 (-144.86 to 169.65)
	Day 15 (Follow-up)	826.87 (151.52)	1126.73 (220.87)	1269.67 (450.56)	-55.33 (-212.59 to 101.92)	-130.93 (-288.19 to 26.32)
	Intra-group analysis	p=0.1875	p=0.9905	p=0.4869		
Mean Foot Pressure	Baseline	366.53 (77.28)	530 (58.90)	536.47 (221.60)		
	Day 5	396.47 (91.36)	504.93 (66.71)	527.67 (216.18)	-55.00 (-143.25 to 33.25)	38.73 (-49.52 to 126.98)
	10th day	389.60 (73.26)	500.67 (62.37)	501.60 (237.95)	-52.40 (-140.65 to 35.85)	57.93 (-30.32 to 146.18)
	Day 15 (Follow-up)	356.87 (64.87)	515.80 (105.33)	559.67 (225.72)	-4.53 (92.78 to 83.72)*	-32.87 (-121.12 to 55.38)
	Intra-group analysis	p<0.0001	p=0.9973	p=0.5232		
Lateral width	Baseline	3.23 (3.03)	0.65 (0.84)	1.21 (0.94)		
	Day 5	2.77 (2.12)	0.95 (1.03)	1.50 (1.21)	0.77 (-0.65 to 2.18)	-0.75 (-2.16 to 0.67)
	10th day	2.92 (1.89)	0.95 (1.03)	0.97 (0.89)	0.62 (-0.80 to 2.04)	-0.7 (-1.49 to 1.34)
	Day 15 (Follow-up)	3.12 (1.75)	0.63 (0.46)	1.62 (0.97)	0.09 (-1.32 to 1.51)	-0.51 (-1.93 to 0.90)
	Intra-group analysis	p=0.9454	p=0.5963	p=0.2972		
Average Lateral Deviation	Baseline	0.70 (0.63)	0.15 (0.22)	0.26 (0.20)		
	Day 5	0.62 (0.55)	0.24 (0.29)	0.31 (0.30)	0.16 (-0.17 to 0.50)	-0.13 (-0.47 to 0.21)
	10th day	0.61 (0.40)	0.24 (0.29)	0.19 (0.25)	0.18 (-0.16 to 0.52)	-0.03 (-0.36 to 0.31)
	Day 15 (Follow-up)	0.75 (0.49)	0.15 (0.13)	0.33 (0.19)	-0.05 (-0.39 to 0.28)	-0.03 (-0.36 to 0.31)
	Intra-group analysis	p=0.8654	p=0.5597	p=0.3901		
Lateral Velocity	Baseline	1.15 (0.47)	0.27 (0.09)	0.74 (0.18)		
	Day 5	1.15 (0.66)	0.27 (0.08)	0.31 (0.30)	-0.01 (-0.32 to 0.31)	0.43 (0.12 to 0.75)*
	10th day	1.05 (0.19)	0.27 (0.08)	0.83 (0.39)	0.09 (-0.22 to 0.41)	-0.19 (-0.50 to 0.13)
	Day 15 (Follow-up)	0.98 (0.35)	0.01 (0.05)	0.91 (0.39)	-0.13 (-0.19 to 0.44)	-0.34 (-0.66 to -0.02)*
	Intra-group analysis	p=0.6788	p<0.0001	p<0.0001		
Anteroposterior width	Baseline	4.64 (2.55)	2.25 (1.65)	1.45 (0.94)		
	Day 5	3.44 (3.32)	4.65 (3.96)	1.69 (1.06)	3.59 (1.69 to 5.49)*	-1.44 (-3.34 to 0.46)
	10th day	3.73 (1.23)	4.65 (3.96)	1.06 (0.70)	3.31 (1.40 to 5.21)*	-0.53 (-2.43 to 1.37)
	Day 15 (Followup)	3.71 (2.27)	3.17 (2.43)	1.31 (0.76)	1.85 (-0.05 to 3.75)	-0.79 (-2.69 to 1.11)
	Intra-group analysis	p=0.5679	p=0.1113	p=0.2660		
Anteroposterior Mean Deviation	Baseline	1.17 (0.74)	0.54 (0.40)	0.29 (0.20)		
	Day 5	0.79 (0.73)	1.14 (0.99)	0.38 (0.27)	0.97 (0.49 to 1.45)*	-0.46 (-0.94 to 0.02)
	10th day	0.89 (0.30)	1.14 (0.99)	0.24 (0.19)	0.87 (0.39 to 1.35)*	-0.22 (-0.70 to 0.26)
	Day 15 (Follow-up)	0.96 (0.71)	0.79 (0.63)	0.26 (0.20)	0.46 (-0.02 to 0.94)	-0.17 (-0.65 to 0.31)
	Intra-group analysis	p=0.4335	p=0.1185	p=0.3130		
Anteroposterior Velocity	Baseline	0.90 (0.41)	0.78 (0.29)	0.79 (0.32)		
	Day 5	0.85 (0.51)	0.86 (0.20)	0.93 (0.30)	0.13 (-0.17 to 0.42)	-0.19 (-0.49 to 0.10)
	10th day	0.88 (0.28)	0.85 (0.22)	0.80 (0.33)	0.09 (-0.20 to 0.39)	-0.03 (-0.33 to 0.26)
	Day 15 (Follow-up)	0.85 (0.29)	0.80 (0.19)	1.02 (0.52)	0.07 (-0.23 to 0.36)	-0.28 (-0.57 to 0.01)
	Intra-group analysis	p=0.9801	p=0.7330	p=0.2912		

Table 5. Thermography.

		Unadjusted Mean (SD)			Inter-group analysis	
		Control (N=15)	Amputees (N=15)	Spinal Cord (N=15)	*Diff Average (95%CI)* **Control - Amputees**	*Diff Average (95%CI)* **Control - Spinal Cord**
Trunk	Baseline	29.53 (1.30)	30.33 (1.18)	30.92 (0.86)		
	Day 5	29.67 (1.45)	30.27 (1.03)	30.28 (2.11)	-0.21 (-1.32 to 0.89)	0.79 (-0.32 to 1.28)
	10th day	29.65 (0.84)	30.29 (1.18)	30.87 (1.04)	-0.17 (-1.27 to 0.94)	0.17 (-0.93 to 1.89)
	Day 15 (Follow-up)	29.81 (0.99)	30.04 (1.07)	30.48 (1.06)	-0.58 (-1.69 to 0.53)	0.73 (-0.38 to 1.83)
	Intra-group analysis	p=0.9330	p=0.8922	p=0.5131		
Hip	Baseline	28.37 (1.55)	30.27 (1.03)	30.28 (2.11)		
	Day 5	29.10 (1.09)	30.29 (1.18)	30.87 (1.04)	-0.71 (-1.86 to 0.45)	0.14 (-1.02 to 3.04)
	10th day	29.49 (1.22)	30.04 (1.07)	30.48 (1.06)	-1.35 (-2.50 to -0.19)*	0.92 (-0.24 to 1.30)
	Day 15 (Follow-up)	29.19 (1.01)	29.03 (1.29) [ab]	29.21 (1.38) [b]	-2.05 (-3.21 to -0.89)*	1.87 (0.73 to 2.08)*
	Intra-group analysis	p=0.0957	p=0.0113	p=0.0204		
Thigh	Baseline	28.6 (1.76)	28.70 (1.68)	28.29 (1.17)		
	Day 5	28.23 (1.47)	28.60 (0.93)	27.54 (2.05)	-0.27 (-1.62 to 1.08)	0.91 (-0.44 to 2.26)
	10th day	28.42 (0.82)	28.59 (1.13)	28.22 (1.25)	-0.47 (-1.82 to 0.88)	0.43 (-0.92 to 1.78)
	Day 15 (Follow-up)	28.45 (1.53)	28.80 (1.28)	07.28 (1.12)	-0.29 (-1.64 to 1.06)	0.61 (-0.74 to 1.96)
	Intra-group analysis	p=0.9178	p=0.9663	p=0.4864		
Knee	Baseline	29.46 (1.49)	29.59 (1.45)	30.37 (1.46)		
	Day 5	29.83 (1.41)	30.52 (1.55)	29.78 (2.47)	0.56 (-0.61 to 1.73)	0.97 (-0.21 to 2.14)
	10th day	29.98 (1.29)	30.53 (1.17)	07.30 (1.71)	0.43 (-0.75 to 1.60)	0.82 (-0.35 to 1.99)
	Day 15 (Follow-up)	29.44 (1.11)	30.44 (0.83)	30 (1.62)	0.87 (-0.30 to 2.05)	0.35 (-0.83 to 1.52)
	Intra-group analysis	p=0.6081	p=0.1411	p=0.8550		
Leg	Baseline	27.14 (2.09)	08.28 (1.26)	27.53 (1.13)		
	Day 5	26.75 (1.60)	27.77 (1.36)	26.96 (2.22)	0.07 (-1.50 to 1.64)	0.18 (-1.39 to 1.75)
	10th day	27.55 (1.45)	27.93 (1.53)	27.48 (1.05)	-0.56 (-2.13 to 1.01)	0.45 (-1.12 to 2.02)
	Day 15 (Follow-up)	27.32 (1.59)	28.46 (1.16)	27.46 (1.81)	0.20 (-1.37 to 1.77)	0.25 (-1.32 to 1.82)
	Intra-group analysis	p=0.6223	p=0.5362	p=0.7514		
Foot	Baseline	27.63 (1.55)	28.84 (1.43)	29.17 (1.20)		
	Day 5	28.21 (3.19)	28.50 (1.96)	28.62 (2.19)	-0.92 (-2.61 to 0.77)	1.13 (-0.55 to 2.82)
	10th day	28.69 (2.04)	28.81 (1.45)	28.95 (1.62)	-1.09 (-2.78 to 0.59)	1.28 (-0.41 to 2.97)
	Day 15 (Follow-up)	27.11 (1.76)	05.29 (1.33)	28.79 (1.77)	0.73 (-0.95 to 2.42)	-0.13 (-1.82 to 1.55)
	Intra-group analysis	p=0.2441	p=0.8137	p=0.8435		

Table 6. Strength – Dynamometry.

		Unadjusted Mean (SD)			**Inter-group analysis**	
		Control (N=15)	**Amputees (N=15)**	**Spinal Cord (N=15)**	**Diff Average (95%CI) Control - Amputees**	**Diff Average (95%CI) Control - Spinal Cord**
Trunk Extension	Baseline	20.94 (9.78)	18.95 (8.72)	7.74 (4.48)		
	Day 5	23.14 (9.21)	20.23 (7.47)	10.24 (5.19)	0.92 (-7.45 to 5.61)	0.30 (-6.83 to 6.22)
	10th day	25.59 (9.65)	25.73 (11.12)	10.82 (7.51)	2.13 (-4.40 to 8.66)	1.56 (-4.97 to 8.09)
	Day 15 (Follow-up)	08.28 (8.88)	24.56 (10.26)	11.15 (5.76)	1.53 (-8.06 to 5.00)	3.73 (-2.80 to 10.26)
	Intra-group analysis	p=0.1955	p=0.1626	p=0.3784		
Knee Extension	Baseline	24.19 (5.00)	31.99 (8.57)	1.51 (3.73)		
	Day 5	26.35 (8.91)	29.16 (7.36)	1.17 (1.82)	4.98 (-0.53 to -9.44)*	2.48 (-1.96 to 6.94)
	10th day	25.61 (7.00)	31.63 (8.21)	1.01 (1.34)	1.78 (-6.23 to 2.66)	1.91 (-2.54 to 6.36)
	Day 15 (Follow-up)	26.81 (7.66)	32.55 (7.31)	1.58 (1.33)	-2.05 (-6.51 to 2.39)	2.53 (-1.91 to 6.99)
	Intra-group analysis	p=0.7740	p=0.6561	p=0.8864		
Knee Flexion	Baseline	21.59 (5.40)	05.23 (6.19)	0.61 (1.10)		
	Day 5	19.13 (6.12)	23.38 (6.59)	1.30 (1.58)	2.70 (-0.83 to 6.41)	3.15 (-6.78 to 0.47)
	10th day	19.43 (5.55)	24 (6.91)	0.40 (1.53)	3.11 (-0.50 to 6.74)	2.98 (6.61 to 0.64)*
	Day 15 (Follow-up)	18.29 (5.23)	26.68 (6.06)	1.45 (1.48)	6.90 (3.30 to 10.55)*	4.14 (7.70 to 0.51)*
	Intra-group analysis	p=0.4229	p=0.4079	p=0.1371		

of patients to participate in the study, carried out during the COVID-19 pandemic.

CONCLUSION

Long-term use of the orthostatic device appears to be beneficial in improving functionality and reducing pain in amputee and spinal cord injury patients.

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SPORTS MEDICINE

DOPING CONTROL IN MALE SOCCER PLAYERS IN BRAZIL: 10 YEARS OF FOLLOW-UP

CONTROLE DE DOPING NO FUTEBOL MASCULINO NO BRASIL: 10 ANOS DE ACOMPANHAMENTO

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ABSTRACT

Objective: To understand the Adverse Analytical Finding (AAF) that have occurred in Brazilian soccer in a recent 10-year period, comparing them to international data, to know the Brazilian profile. Methods: A review of the AAR in the Doping Control Commission database of the Brazilian Football Association from 2008 to 2017. The AAR in professional male soccer players between 2008 and 2017 were considered. Results: The sample selected in this research was composed of 40,092 doping tests, with 113 AAR, identified in 18 different competitions (0.28%) in the professional category, in Brazilian national and state competitions between 2008 and 2017, flagged in doping control exams through urine samples. Stimulants were detected most frequently (31.0%), followed by glucocorticoids (21.2%), diuretics, and masking agents (19.5%). The Brazilian Championship series did not show a relationship with any of the World Anti-Doping Agency (WADA) groups of substances. Series A showed 0.07% of AAR, Series B 0.21%, Series C 0.75% and Series D 1.49. Conclusion: The rate of AAR in Brazilian soccer was 0.28%, lower than the average for all soccer worldwide, and shows similar percentages among field positions. Stimulants were the most prevalent drugs. The national elite soccer competitions showed significantly fewer cases than the lower divisions. ***Level of Evidence II; Retrospective Study.***

Keywords: Doping in Sports. Soccer. Athlete, Professional. Epidemiology.

RESUMO

Objetivo: Compreender os Resultados Analíticos Adversos (RAA) ocorridos no futebol brasileiro nos últimos 10 anos, comparando-os aos dados internacionais, para conhecer o perfil do futebol brasileiro. Métodos: Revisão dos RAA no banco de dados da Comissão de Controle de Doping da Confederação Brasileira de Futebol de 2008 a 2017. Foram consideradas os RAA entre 2008 e 2017. Resultados: A amostra selecionada nesta pesquisa foi composta por 40.092 exames antidoping com 113 RAA, os quais foram identificados em 18 competições diferentes (0,28%) em atletas da categoria profissional, entre 2008 e 2017, sinalizadas em exames de controle de doping através de amostras de urina. Estimulantes foram detectados com maior frequencia (31%), seguidos de glicocorticoides (21,2%), diuréticos e agentes mascarantes (19,5%). A série do Campeonato Brasileiro não apresentou relação com nenhum dos grupos de substâncias da World Anti-Doping Agency (WADA). A série A apresentou 0,07% da AAR, Série B 0,21%, Série C 0,75% e Série D 1,49%. Conclusão: A taxa de RAA no futebol brasileiro foi de 0,28%, inferior à media do futebol mundial e apresenta percentuais semelhantes entre as posições do campo. Os estimulantes foram as drogas mais prevalentes. As competições nacionais de futebol das Séries superiores apresentaram significativamente menos casos do que as inferiores. ***Nível de Evidência II; Estudo Retrospectivo.***

Descritores: *Doping nos Esportes. Futebol. Atletas Profissionais. Epidemiologia.*

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INTRODUCTION

Soccer is the most popular sport globally, with the most significant number of players. Its professional league is coordinated nationally by its confederations, which report to the continental confederations that, in turn, report to FIFA (*Fédération Internationale de Football Association*). Concerned about ethical aspects, physical and mental health, and equality among competitors, FIFA has been attentive to the doping problem in the sport since 1966. In 1970, regular anti-doping control activities began for international soccer matches and competitions.[1]

In 1999, the International Olympic Committee (IOC) founded the World Anti-Doping Agency (WADA) to organize, coordinate, and promote an international fight against doping, independently and institutionally. Today WADA produces the content, methods, and guidelines that coordinate all anti-doping actions in the main sports played worldwide.[2]

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

The study was conducted at the Sports Traumatology Center of the Paulista School of Medicine, São Paulo, SP, Brazil.
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In Brazil, doping control in soccer is organized and managed by the Commission for Doping Control (CCD) of the Brazilian Football Brazilian Football Association (CBF), in partnership with Brazilian Doping Control Authority (ABCD).

The data published so far in soccer present only the percentage of adverse analytical results (AAF) by the total samples collected per year and the most prevalent group of drugs. According to this information, the most common drugs in world soccer are anabolic agents (S.1) and Stimulants (S.6), the same characteristic observed in general data of all sports, published annually by WADA[3]. European soccer follows these statistics, with the group of anabolic agents (S.1) as the most prevalent.[4]

In Brazil, the most common drugs are not known, as well as the annual percentages of AAF, so more detailed information about the athlete's profile involved in doping cases is necessary.

The proposal is to understand the AAF in a recent 10-year period, comparing with international data, identifying the most detected agents, the prevalent age, the field position, the division in which the athlete was playing, trying to relate these variables to know the Brazilian profile.

MATERIAL AND METHODS

The study was approved by institutional board under the number 0750/2019. A review of AAFs from 2008 to 2017 was conducted in the CBF CCD database. Data were accessed through an encrypted, exclusive access program, preserving the athlete's anonymity. The information contained: athlete's age, club, competition played at the time of the test, identified substance group, and type of punishment in months. The study considered the AAF that occurred in professional male players in Brazilian soccer between 2008 and 2017.

Inclusion criteria: participants in national soccer competitions (A, B, C, D series and Brazil Cup) and state championships, totaling 20 championships. Exclusion criteria: female soccer athletes, athletes in youth category championships, and international competitions.

The variables considered in the study were: athlete' position - goalkeeper, defender, midfielder, striker -, type of league - national, series A, B, C, D and Brazil Cup, state championships -, class of substance found - from S1 to S9, according to WADA's official list, as shown in Table 1, type of punishment - less than six months, six to 12 months, 12 to 18 months, more than 18 months, acquitted -, demographic analysis - considering the minimum and maximum age, mean, median, standard deviation.

The inferential analyses, used to confirm or refute evidence found in the descriptive analysis, were:

- Student-t-test for independent samples;[5] Analysis of Variance (ANOVA) with a fixed factor,[6] and Mann-Whitney[7] comparing age, according to the use of a forbidden substance, athlete's position in the game, type of competition, and time of punishment.
- Pearson's chi-square and Fisher's exact test[8] (or its extension) to study the association between the use of a forbidden substance and the athlete's position in the game, type of competition, and time of punishment.

In all the conclusions obtained through the inferential analyses, the alpha significance level of 5% was used.

The statistical analysis was done through the mean, median, minimum and maximum values, standard deviation, absolute and relative frequencies (percentage).

The statistical analyses were performed using the program IBM-SPSS Statistics, version 24.[9]

RESULTS

The sample selected in this research was composed of 113 AAF in male soccer athletes, professional category, in Brazilian national and state competitions between 2008 and 2017, caught in doping control exams through urine samples. The average age of these athletes was 27.2 years, ranging from 18 to 41 years; a bit more than half were between 24 and 30 years old (55.8%). Considering the athlete's position in the game, about 41 (36.3%) were defenders, 31 (27.4%) midfielders, 25 (22.1%) strikers, and 16 (14.2%) goalkeepers. Approximately half of the athletes were identified during national competitions (48.7%) and had corresponding punishments, mostly up to six months (42.5%). The stimulants group was most frequently detected (31.0%), followed by glucocorticoids (21.2%), diuretics and masking agents (19.5%), anabolic agents (15.0%), cannabinoids

Table 1. General characteristics of flagged athletes.

Age (years) (n=113)	**Mean**	**27.2**	
	Median	28.0	
	Minimum-maximum	18-41	
	Standard Deviation	4.7	
Age group (n=113)	Up to 23 years old	27	23.9%
	24 to 30 years old	63	55.8%
	31 years old or more	23	20.4%
Year (n=113)	2008	10	8.8%
	2009	9	8.0%
	2010	10	8.8%
	2011	8	7.1%
	2012	7	6.2%
	2013	12	10.6%
	2014	6	5.3%
	2015	11	9.7%
	2016	19	16.8%
	2017	21	18.6%
Position (n=113)	Goalkeeper	16	14.2%
	Defender	41	36.3%
	Midfielder	31	27.4%
	Striker	25	22.1%
Competition (n=113)	Baiano	1	0.9%
	Brazilian A Series	11	9.7%
	Brazilian B Series	24	21.2%
	Brazilian C Series	6	5.3%
	Brazilian D Series	4	3.5%
	Carioca	6	5.3%
	Cearense	2	1.8%
	Gaúcho	8	7.1%
	Goiano	1	0.9%
	Mineiro	4	3.5%
	Paulista A1	9	8.0%
	Paulista A2	8	7.1%
	Paulista A3	9	8.0%
	Paulista Second Division	2	1.8%
	Pernambucano	5	4.4%
	Brazil Cup	10	8.8%
	Northeast Cup	1	0.9%
	Out of competition	2	1.8%
Championship (n=113)	National	55	48.7%
	State	58	51.3%
Punishment (n=113)	Up to six months	48	42.5%
	6 to 12 months	21	18.6%
	12 to 18 months	1	0.9%
	More than 18 months	25	22.1%
	Acquitted	15	13.3%
	No information	3	2.7%

<< SUMÁRIO

(8.0%), growth factors or peptide hormones (4.4%), metabolic modulators or hormones (3.5%), and, finally, beta-2 agonists (0.9%). It is important to note that no athletes tested positive for narcotics. In this research, the relation of age, playing position, competitions grouping the national and state tournaments, the type of championship, and punishment were important objects of investigation, according to doping control tests on the athletes.

Athletes who used substances of the class of metabolic modulators or hormones had higher age when compared to those who did not use them (p=0.008). The athletes' age was not the same, according to the type of competition (p=0.025); athletes from the D series presented a higher age when compared to the A and C series of the Brazilian Championship. Age showed no relationship with the other information described in Table 2.

The position in the game was related only to the use of three groups of substances: growth factors or peptide hormones (p=0.026) among strikers; diuretics or masking agents (p=0.042) among goalkeepers and midfielders, and glucocorticoids (p=0.043) among goalkeepers and defenders (Table 3). The Brazilian Championship series has not shown a relationship with any WADA substance groups. Higher cannabinoid use was confirmed among athletes during state championships compared to national ones. The other relationships were not significant. The distribution of the type of championship, according to substance results, can be seen in Figure 1 and the distribution of the type of championship, according to anti-doping results can be seen in Figure 2.

Athletes with more than 18 months of punishment used anabolic agents more often, than the other ones (p=0.008). The time of punishment did not show a significant relationship with the other substance groups. (Table 4)

There is no relationship between the athlete's position in the game and punishment duration (p=0.831).

Between 2008 and 2017, the lowest rate of AAF occurred in 2014 (0.14%), and the highest rate occurred in 2017 (0.42%). A total of 30,498 samples were collected at national competitions and 9,444 samples at state competitions. Among the AAF, we observed almost half of the cases in national competitions and the other half in state competitions.

Comparing proportionally, the AAF rate obtained was 0.57% in state championships and 0.18% in national championships. In the national competitions, samples collected from the A, B, C, D series and the Brazil Cup were included in the analysis.

It was observed that the A Series presented 0.07% of AAF, followed by B Series (0.21%), C Series (0.75%), D Series (1.49), and Brazil Cup (0.34%).

Within the state competitions, the Paulista Championship, in its various divisions, showed the highest incidence of AAF, with the A3 Series being the most prevalent, followed by the Paulista B Series and the Northeast Cup.

Table 2. Summary measures of athletes' age (years), according to anti-doping use, position, competition, championship and punishment.

	mean	median	minimum	maximum	Standard deviation	p
Anabolic agents						
Have not used (n=96)	27.3	28.0	18.0	41.0	4.8	0.578[a]
Used (n=17)	26.6	26.0	21.0	34.0	3.8	
Growth factors, peptide hormones						
Have not used (n=108)	27.2	28.0	18.0	41.0	4.7	0.955[b]
Used (n=5)	27.6	26.0	26.0	34.0	3.6	
Beta-2 agonist						
Have not used (n=112)	27.3	28.0	18.0	41.0	4.7	0.325[b]
Used (n=1)	23.0	23.0	23.0	23.0		
Metabolic modulators or hormones						
Have not used (n=109)	27.0	27.0	18.0	41.0	4.6	0.008[a]
Used (n=4)	33.3	33.0	30.0	37.0	3.8	
Diuretics or masking agents						
Have not used (n=91)	26.9	27.0	18.0	39.0	4.5	0.171[a]
Used (n=22)	28.5	28.0	19.0	41.0	5.4	
Stimulants						
Have not used (n=78)	27.2	27.0	19.0	41.0	4.5	0.460[b]
Used (n=35)	27.4	28.0	18.0	35.0	5.1	
Narcotics						
Have not used (n=113)	27.2	28.0	18.0	41.0	4.7	-
Used	-	-	-	-	-	
Cannabinoids						
Have not used (n=104)	27.2	27.5	18.0	41.0	4.7	0.887[a]
Used (n=9)	27.4	29.0	22.0	32.0	3.8	
Glucocorticoids						
Have not used (n=89)	27.5	28.0	18.0	41.0	4.7	0.248[a]
Used (n=24)	26.3	26.0	19.0	39.0	4.5	
Total (n=113)	27.2	28.0	18.0	41.0	4.7	
Position						
Goalkeeper (n=16)	25.4	25.0	21.0	33.0	3.9	0.146[c]
Defense (n=41)	27.9	28.0	19.0	35.0	4.0	
Midfield (n=31)	28.1	28.0	18.0	41.0	5.8	
Striker (n=25)	26.2	27.0	18.0	34.0	4.4	
Brazilian Competition						
Series A (n=11)	25.5	26.0	18.0	34.0	4.7	0.025[c]
Series B (n=24)	27.3	28.0	19.0	34.0	4.0	
Series C (n=6)	24.8	23.0	21.0	32.0	4.3	
Series D (n=4)	32.5	33.0	29.0	35.0	2.6	
Championship						
National (n=55)	27.6	28.0	18.0	39.0	4.6	0.392[a]
State (n=58)	26.9	26.0	18.0	41.0	4.8	
Punishment						
0 - 6 months (n=48)	26.7	27.0	18.0	34.0	3.9	0.884[c]
6 - 12 months (n=21)	27.3	27.0	18.0	41.0	5.8	
12 - 18 months (n=1)	28.0	28.0	28.0	28.0	-	
> 18 months (n=25)	27.4	28.0	19.0	37.0	5.0	
Acquitted (n=15)	28.1	29.0	19.0	36.0	5.1	

[a]Student-t-test for independent samples, [b]Mann-Whitney, [c]Analysis of Variance (ANOVA) with a fixed factor.

DISCUSSION

Between 2008 and 2017, 40,092 urine samples were collected, with 113 cases of AAF indicating substances banned in athletes, in or out of competition, by the WADA anti-doping list. There are no studies that compare the number or percentage of AAF between countries in soccer. Al Ghobain et al.[10] analyzed Saudi Arabia's total AAF, including all sports in the country, and noted an average of 3.1% over nine years.

Similarly, Kioukia-Fougia et al.[11] did a similar study in Greece and found an average of 1.42% over seven years. These data may have several biases because they add sports with very different characteristics. Aguilar-Navarro separated team and individual sports in his research; among the individual sports, he obtained an AAF of 1.6% (+/- 0.9%), and among team sports, an AAF of 1.7% (+/- 0.6%), based on worldwide data from WADA.[10]

With an average AAF of 0.28% over ten years, Brazilian soccer is well below the average found in statistical surveys that include several sports. Starting in 2008, Brazilian soccer has always had

Table 3. Distribution of the athletes' field position, according to anti-doping use.

	Position								
	Goalkeeper		Defender		Midfielder		Striker		p
Anabolic agents									
Have not used	13	81.3%	34	82.9%	26	83.9%	23	92.0%	0.733[d]
Used	3	18.8%	7	17.1%	5	16.1%	2	8.0%	
Growth factors, peptide hormones									
Have not used	16	100.0%	40	97.6%	31	100.0%	21	84.0%	0.026[d]
Used	-	-	1	2.4%	-	-	4	16.0%	
Beta-2 agonist									
Have not used	16	100.0%	41	100.0%	30	96.8%	25	100.0%	0.637[d]
Used	-	-	-	-	1	3.2%	-	-	
Metabolic modulators or hormones									
Have not used	16	100.0%	41	100.0%	28	90.3%	24	96.0%	0.137[d]
Used	-	-	-	-	3	9.7%	1	4.0%	
Diuretics or masking agents									
Have not used	11	68.8%	36	87.8%	21	67.7%	23	92.0%	0.042[d]
Used	5	31.3%	5	12.2%	10	32.3%	2	8.0%	
Stimulants									
Have not used	13	81.3%	30	73.2%	21	67.7%	14	56.0%	0.327[e]
Used	3	18.8%	11	26.8%	10	32.3%	11	44.0%	
Narcotics									
Have not used	16	100.0%	41	100.0%	31	100.0%	25	100.0%	-
Used	-	-	-	-	-	-	-	-	
Cannabinoids									
Have not used	15	93.8%	36	87.8%	31	100.0%	22	88.0%	0.159[d]
Used	1	6.3%	5	12.2%	-	-	3	12.0%	
Glucocorticoids									
Have not used	12	75.0%	27	65.9%	27	87.1%	23	92.0%	0.043[e]
Used	4	25.0%	14	34.1%	4	12.9%	2	8.0%	

[d]Fisher's exact test extension, [e]Pearson's chi-square.

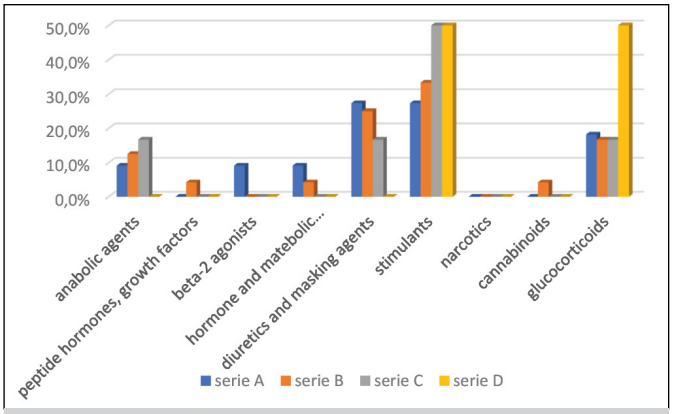

Figure 1. Distribution of the athletes in the Brazilian Championship Series, according to category of WADA banned substance used.

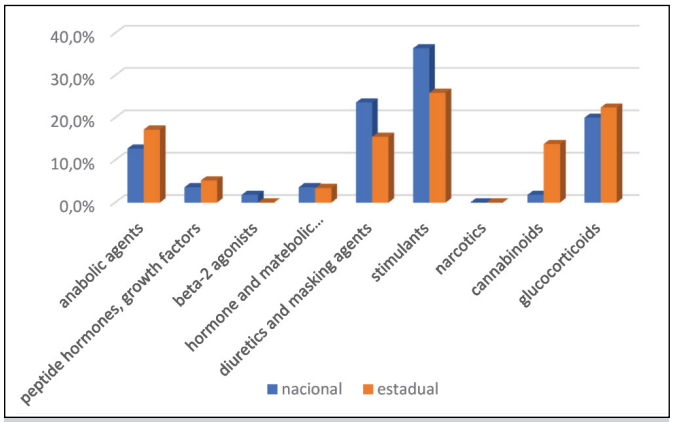

Figure 2. Distribution of the type of championship, according to anti-doping results.

Table 4. Distribution of athletes' punishment period, according to anti-doping results.

	Punishment										
	Up to 6 months		6 to 12 months		12 to 18 months		More than 18 months		Acquitted		p
	N	%	N	%	N	%	N	%	N	%	
Anabolic agents											
Have not used	45	93.8	20	95.2	1	100.0	16	64.0	13	86.7	0.008[d]
Used	3	6.3%	1	4.8	-	-	9	36.0	2	13.3	
Growth factors, peptide hormones											
Have not used	44	91.7	21	100.0	1	100.0	25	100.0	15	100.0	0.281[d]
Used	4	8.3	-	-	-	-	-	-	-	-	
Beta-2 agonist											
Have not used	47	97.9	21	100.0	1	100.0	25	100.0	15	100.0	>0.999[d]
Used	1	2.1	-	-	-	-	-	-	-	-	
Metabolic modulators or hormones											
Have not used	47	97.9	21	100.0	1	100.0	24	96.0	13	86.7	0.221[d]
Used	1	2.1	-	-	-	-	1	4.0	2	13.3	
Diuretics or masking agents											
Have not used	38	79.2	17	81.0	-	-	23	92.0	10	66.7	0.109[d]
Used	10	20.8	4	19.0	1	100.0	2	8.0	5	33.3	
Stimulants											
Have not used	36	75.0	14	66.7	1	100.0	14	56.0	11	73.3	0.498[d]
Used	12	25.0	7	33.3	-	-	11	44.0	4	26.7	
Narcotics											
Have not used	48	100.0	21	100.0	1	100.0	25	100.0	15	100.0	-
Used	-	-	-	-	-	-	-	-	-	-	
Cannabinoids											
Have not used	41	85.4	20	95.2	1	100.0	25	100.0	15	100.0	0.150[d]
Used	7	14.6	1	4.8	-	-	-	-	-	-	
Glucocorticoids											
Have not used	38	79.2	13	61.9	1	100.0	23	92.0	11	73.3	0.132[d]
Used	10	20.8	8	38.1	-	-	2	8.0	4	26.7	

lower AAF percentages than the sum of soccer results from the rest of the world, according to data published by WADA. This may be related to the extensive testing work carried out in Brazil and the strict punishments for athletes and professionals involved in flagged and judged cases. Still comparing Brazilian soccer to the world soccer concerning the types of substances most commonly found, we noticed that, in the data provided by WADA from 2014, when the publications specifying the groups of drugs by sports began, it was possible to stratify, within soccer, which substances were the most common.[3] In contrast to our research, Brazilian soccer obtained the presence of stimulants (S6) as the most common group of substances, followed by glucocorticoids (S9) and diuretics or masking agents (S5). It was also observed that diuretics represent double the incidence in Brazilian soccer, compared to data from soccer worldwide, according to WADA.[3]

Age

The average age found in the study was 27.2 years. A greater concentration at the extremes of the ages was expected, due to

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immaturity among younger athletes or the search for performance among older athletes. In the 4th division of Brazilian soccer, a greater presence of positive tests amongst athletes over 30 years old was observed, possibly related to the end of their career, corroborating the hypothesis of an alternative search for performance.
Similarly, the substances most commonly found in athletes over 30 years old are metabolic modulators or hormones (S4). Thevis et al. correlate this class of drugs to the treatment of sarcopenia, loss of muscle mass, and bone mass, which could attract older athletes seeking high performance.[11] We believed that younger athletes would be more affected by social drugs, such as stimulants (S6) and cannabinoids (S8), which was contradicted by the study.

Substance

In Brazilian soccer, the class of drugs most identified in the study was stimulants, more specifically group 6A, in which cocaine is found, with 56% of the total AAF, demonstrating a problem of social order, which interferes directly in the practice of soccer. Cocaine has the ability to stimulate adrenergic neurotransmitters and can generate performance improvement. However, its use is more related to social problems than searching for better sports performance.[12]
By discussing the presence of drugs of abuse as a cause of AAF, other actors identified Tetrahydrocannabidiol (THC) as the main drug.[13] Kiouki-Fougia et al,[11] when studying the prevalence of substances in doping tests in Greece between 2005 and 2011, found THC in second place among total substances, representing 10% of cases, losing to anabolic agents, which accounted for 31%. Strano Rossi et al.[14] noted the highest prevalence of THC and secondarily cocaine among drugs of abuse in his study, which included 100,000 urine tests of young athletes in Italy over ten years.[11] All these studies demonstrate the real gravity of Brazilian soccer concerning the abuse of cocaine, the main drug found in the tests done in Brazil.
An important factor is that there were no flagrant cases of substance use in the narcotics class in this 10-year period.

Position

The statistically significant presence between drug classes by position is not clear.
Hormone peptides and growth factors (S2) were observed, statistically related to strikers, diuretics or masking agents (S5) among midfielders and goalkeepers, and glucocorticoids (S9) among goalkeepers and defenders. There is no relationship in the literature between position played on the field and the demand for a particular class of drugs. Attention is drawn to the proportion of positive cases among goalkeepers, due to a smaller number of athletes per team, in this group of analysis, in comparison with the other groups of positions in the field.

Punishment

There are four main reasons for an athlete to be acquitted after having an AAF in a doping test: negative counterevidence for identified substance, the existence of Therapeutic Authorization (TRA) for the use of the caught substance, proof of administration of the drug without the athlete's knowledge, and contamination or error in sample handling.
In our analysis, the most common type of punishment includes a period of absence, around six months, enough time to generate a financial loss to the club, physical and sportive loss to the athlete, as well as social inconveniences with the public disclosure of a "positive" case.
Anabolic agents (S1) were responsible for the longest time away from the sport, around 18 months. Doping in sport shows how complex it is to combat. Geographic and cultural differences are fundamental to an understanding and better control of these cases, as well as the professionals involved, who support the athletes. Pielke, in an editorial, discusses how demographic and social factors should be considered to understand the risk factors in athletes involved with doping.[15]
In their study, Morente-Sánchez et al.[16] applied a questionnaire to 237 soccer professionals in Spain and found that 57.6% did not know what WADA meant and 84.9% did not know the list of banned substances. According to Hon et al.[17], the low percentage rate of AAF surveilled by WADA annually is underestimated. Their study, researching the "real number" of doping through interviews with athletes, estimates a number around 14% to 39%. Ulrich et al.[18], with a similar survey, estimated a figure around 43.6%. Until now, no statistical survey on doping control has been seen that analyzes the variables of a single sport discipline, as described in this article in detail, which can serve as a first step to investigate triggering factors and an epidemiological profile. This article analyzes athletes with substantial social, geographical, and financial distinctions, presenting biases in the comparison between tournaments with low annual testing and tournaments testing in all rounds, which may increase the percentage value, even in a few cases.

Limitations

The presence of 113 AAFs is a small number for definitive statistical correlations, especially taking into account the various analysis variables used in this study. We understand that many alerts were given with this information, and that the continuity in the collection of this information and the constant analysis could represent more significant results.

CONCLUSION

In the analysis between 2008 and 2017, the rate of AAF in Brazilian soccer is 0.28%, lower than the summed average of all soccer worldwide, and shows similar percentages among the positions on the field. The average age is around 27 years old. Stimulants are the most prevalent drugs, followed by glucocorticoids and diuretics and masking agents. The elite national soccer competitions have far fewer cases compared to the lower divisions.

AUTHORS' CONTRIBUTION: Contributorship: HFM: evaluated the samples and prepared the article; PHSL: reviewed the article; FAGS: evaluated the samples and prepared the article; MC: concept of the article and reviwed the article; JP: concept of the article and reviwed the article; GGA: concept of the article and reviwed the article.

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SPORTS MEDICINE

INJURY EPIDEMIOLOGY IN BEACH TENNIS: INCIDENCE AND RISK FACTORS

EPIDEMIOLOGIA DAS LESÕES NO BEACH TENNIS: INCIDÊNCIA E FATORES DE RISCO

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ABSTRACT

Introduction: Due to the growing increase in beach tennis practice in Brazil and the lack of studies on the injuries that occur in this sport, it has become necessary to develop more research on the subject. Objective: to identify risk and protection factors for injuries in beach tennis, in order to generate prevention strategies for musculoskeletal injuries. Method: A cross-sectional epidemiological study, level 3 of evidence, was carried out through an electronic form with 698 Beach Tennis players, who answered questions about their relationship with the practice of the sport and occurrences of injuries. We researched the prevalence of injuries, their types, and their relation with personal physical characteristics and the practice of other sports. Results: We found a positive relationship between injuries when associated with longer exposure time and the presence of a previous injury. We did not find differences regarding BMI, gender, and stretching and muscle strengthening performance. Conclusion: the most frequent non-traumatic injuries were to the elbow and shoulder (tendonitis) and traumatic (sprain) injuries to the knee and ankle. ***Level of Evidence II; Cohort Study.***

Keywords: Wounds and Injuries. Epidemiology. Athletes. Musculoskeletal System.

RESUMO

Introdução: Devido ao crescente aumento da prática de Beach Tennis no Brasil e a carência de estudos sobre as lesões que ocorrem nesse esporte se faz necessário o desenvolvimento de mais pesquisas sobre o tema. Objetivo: identificar fatores de risco e de proteção para lesões no Beach Tennis, afim de gerar estratégias de prevenção às injurias musculoesqueléticas. Método: realizado estudo epidemiológico transversal nível 3 de evidência através de um formulário eletrônico com 698 praticantes de Beach Tennis, que responderam questionamentos sobre sua relação com a prática do esporte e ocorrências de lesões. Pesquisamos a prevalência das lesões e seus tipos, assim como sua relação com as características físicas pessoais e prática de outros esportes. Resultados: encontramos relação de positividade para lesões quando associadas a maior tempo de exposição e presença de lesão prévia. Não encontramos diferença quanto ao IMC, sexo e a realização de alongamento e fortalecimento muscular. Conclusão: as lesões mais frequentes não traumáticas foram no cotovelo e ombro (tendinite) e traumáticas (entorse) de joelho e tornozelo. ***Nível de Evidência II; Estudo de Coorte.***

Descritores: *Ferimentos e Lesões. Epidemiologia. Atletas. Sistema Musculoesquelético.*

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INTRODUCTION

Beach Tennis (BT) was created in 1987 in the province of Ravennana, Italy. In 1996 the sport began to become professionalized. The modality arrived in Brazil in 2008 in the state of Rio de Janeiro and since then the sport has been growing rapidly to other Brazilian cities, including non-coastal cities.[1]

Despite the numerous studies involving injuries that occur in tennis players around the world,[1] we found available in the literature only one epidemiological study addressing BT players.[2] This is a cross-sectional epidemiological study that analyzed practitioners of different levels of BT in the French island of Réunion, where the sport was raised to professionalism in the 1990s.[4]

With the recent increase in the practice of BT, especially in Brazil,[1] the possible injuries associated with its practice are not known. Research to better understand them is important to develop preventive and therapeutic programs, and to minimize their impact, such as discouragement.

The objective of this study is to characterize the BT players, the prevalence of injuries, identify risk and protection factors for sports-related musculoskeletal disorders, and their impact on the player performance.

METHODS

Cross-sectional epidemiological study in BT players, invited to complete a questionnaire with the use of a virtual application. The participation in this study was voluntary and all individuals who agreed to participate signed an informed consent form to follow up on the application of the questionnaire.

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

The study was conducted at the Centro Universitário Saúde ABC, ABC Medical School, Department of Orthopaedics and Traumatology, Santo André, SP, Brazil.
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This study was approved by the Research Ethics Committee, CAAE 60292822.5.0000.0082 on August 15, 2022, and does not require CONEP review.

We asked the following information in the questionnaire: identification and anthropometric data (age, height, weight, gender, dominant limb), time of BT practice (over the years, weekly frequency, how many sets), if they do any concomitant physical preparation (Beach Tennis classes, practice of other sports), players' level (participation in competitions, category); physical injuries: previous or current with the time away, type of injury, affected limb, professional who made the diagnosis, pain during and after the match, and whether stretching or physical strengthening is done before or after training and matches. With the data obtained we will evaluate the prevalence and relationship of injuries with gender, BMI, frequency of games, practice of other sports, physical conditioning (weight training, stretching, and strengthening), and previous injuries. Also the correlation between the affected area and type of injury.

For these data descriptive and inferential statistical methods will be applied. Qualitative variables will be presented by distribution of absolute and relative frequencies. In the inferential part will be applied: (a) To compare the proportional distribution of nominal variables will be applied the G Test of independence; (b) To evaluate the distribution of the location of the lesion will be applied the Chi-square test of adherence. The alpha error will be previously set at 5% for rejection of the null hypothesis and the statistical processing will be performed in the BioEstat version 5.3 and STATA release 17 programs.

RESULTS

The data collection time was 30 days, with a total number of 698 participants.

Participants of different ages filled out the survey and we identified that the older the age group, the higher the risk of the patient to suffer an injury, being that among the players under 30 years old 26.10% had injuries, between 30 and 50 years old 51.2%, and over 50 years old 61.8%.

The questionnaire was filled out by a majority of females (67.3%), but this variable does not represent a significant difference for the occurrence of injuries (p-value=0.5871) when compared to males.

In the anthropometric data evaluation, we verified that most of the practitioners (66.8%) present BMI less than 25 kg/m^2 (normal value). The correlation of the presence of injuries among individuals with BMI below or above 25 also showed no significant difference (p-value=0.1865).

Regarding the time of practice, it was shown that the most common is from 1 to 2 years (28.5%) and that this has a significant difference with the appearance of injuries (p-value<0.0001*), showing also that for players who play from 3 to 5 years the occurrence of injuries is 75%.

When we evaluated the weekly frequency of games, most of the players play from 2 to 3 times a week (40.4%), and this data also presents a significant difference for the occurrence of injuries (p-value=0.0004*), and for players who play from 5 to 7 times a week the occurrence of injuries reaches 66.2%.

Another variable that presented significant difference (p-value<0.0001*) was the time practiced per game with the presence of injury, being that the most common time of game (66.8%) was 2 hours (3 to 5 sets), and a time of game longer than 3 hours is related to 67.1% of injuries. (Table 1)

We evaluated the relationship between the practice of other sports concomitant to the BT (74.5%) and the occurrence of injuries, obtaining no significant difference (p-value=0.1452) between those who practice or not.

A stretching routine before and after games is not performed in 53.7%, and these had no significant difference with the number of injuries when compared to those who perform (p-value=0.0926).

The practice of physical conditioning and weight training is accomplished by most of the practitioners (73.6%), but it was not shown as a protective factor for injuries, also not presenting significant difference (p-value=0.5926).

There is a positive correlation between the existence of a previous injury and the appearance of a new one (p-value<0.0001*), for of those who had already suffered an injury, 74.9% had a new one in the BT. (Table 2)

Table 1. Site affected by the injury in n=698 beach tennis practitioners. Year 2022.

Affected location	n	%
Elbow	163	23.4
Shoulder	98	14.0
Knee	82	11.7
Feet	62	8.9
Ankle	62	8.9
Calf	52	7.4
Cervical spine	48	6.9
Lumbar spine	48	6.9
Hand	44	6.3
Fist	44	6.3
Hips	26	3.7

p-value <0.0001, Chi-square grip.

Table 2. Sex, BMI, Practice time, How many times per week and Playing time according to the presence of injury in n=698 beach tennis practitioners. Year 2022.

	Injury						
	Present		Absent		General		
	n	%	N	%	n	%	p-value
Sex							**0.5871**
Female	250	53.2	220	46.8	470	67.3	
Male	127	55.7	101	44.3	228	32.7	
IMC							**0.1865**
Greater than 25	134	57.8	98	42.2	232	33.2	
Less than 25	243	52.1	223	47.9	466	66.8	
Practice time							**<0.0001***
Less than 1 year	44	34.1	85	65.9	129	18.5	
1 to 2 years	86	43.4	113	57.1	199	28.5	
2 to 3 years	70	55.1	57	44.9	127	18.2	
3 to 5 years	87	75.0	29	25.0	116	16.6	
More than 5 years	90	70.9	37	29.1	127	18.2	
How many times a week							**0.0004***
1 time	48	38.4	77	61.6	125	17.9	
2 to 3 times	151	53.5	131	46.5	282	40.4	
3 to 5 times	130	59.9	87	40.1	217	31.1	
5 to 7 times	47	66.2	24	33.8	71	10.2	
Not once	1	33.3	2	66.7	3	0.4	
Playing time							**<0.0001***
Up to 1 hour (Approx. 3 sets)	55	38.5	88	61.5	143	20.5	
Up to 2 hours (Approx. 3 to 5 sets)	263	56.4	203	43.6	466	66.8	
More than 3 hours (More than 6 sets)	57	67.1	28	32.9	85	12.2	
Not informed	2	50.0	2	50.0	4	0.5	

*G test of independence, comparing Presence x Absence of Injury.

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When we researched which limbs were most frequently injured we found that with a significant difference (p-value <0.0001*) the elbow was the most affected (23.4%), followed by the shoulder (14.0%). Among the types of injuries reported we have elbow tendinitis (80.26%) as the most prevalent, followed by knee sprain and contusion (61.90%) and shoulder tendinopathy (60.52%). Excluded from these results the patients who had multiple injuries (20.63%). (Table 3)

DISCUSSION

According to data from the Brazilian Tennis Confederation,[1] currently the BT is practiced by more than 500 thousand people spread all over the continents, regardless of sex and age. Data from the International Tennis Federation also point out that Brazil is the second biggest force in the world in this sport, second only to Italy, the country that created the modality.[1]

All the questions about the longest time of exposure to the sport presented statistical relevance as risk factors for injury. The longer the time of practice, the higher the risk of injury. Up to 75% of players with 3 to 5 years of practice, 66.2% of those who play 5 to 7 times a week, and 67.1% of those who play for more than 3 hours per game can present injuries. These data match those collected when studying injuries in tennis players,[3] where training overload generates a cumulative effect, and repetitive micro traumas were one of the main triggering factors for musculoskeletal injuries.

When asked about the places already injured the participants mentioned: cervical spine, lumbar spine, elbow, knee, hand, shoulder, calf, foot, wrist, hip, and ankle, being the most affected limbs the elbow (23.4%), followed by the shoulder (14%). Results were also found in Tennis and Badminton players, because they are racquet sports and have been demonstrated in previous studies with competitive tennis players,[4] which indicated elbow and shoulder as the most affected joints, followed by the knee.

And as for the most common type of injury, we found data consistent with those shown in the work base of this study,[4] where tendinopathies are more common in the upper limbs (elbow 80.26%, shoulder 60.52%, and wrist 45.45%), while traumatic injuries such as sprains are more common in the lower limbs (ankle and foot 37.93%), followed by muscle injuries (calf 93.75%).

When we analyzed the relationship between the physical conditioning of the practitioners and the incidence of injuries, we believed that those who did the preparation would have this habit as a factor for preventing injuries, but we did not find the expected results, because there is no statistically significant difference between injured practitioners with more or less physical conditioning. As well as stretching, which is not performed by most of the practitioners (53.7%), before and after the games also did not present relevance as a risk factor. In a literature review available on these relations,[5] we also did not find statistical relevance regarding the practice of muscle stretching before and after exercise and the decrease in injury risk, although they state that better physical conditioning, which is defined in the article[7] as higher neuromuscular fiber recruitment, higher capacity of fibers to absorb energy and transfer it to the bone system, and higher amount of energy substrate is related to a lower incidence of injuries.

When the anthropometric factors such as weight, BMI, age, and sex were evaluated, we found significant relevance only for age, and after 50 years 61.8% of the patients had injuries; the other data showed no statistical relevance as risk factors or prevention of possible injuries. We also did not find in other studies with throwing sports, such as handball,[6] significant relevance for such relations.

Most (74.5%) of the BT practitioners also participate in other sports, but this data did not show statistical relevance as a risk or protection factor. The practice of weight-training, which in our study was not presented as a prevention factor for the appearance of injuries, is advocated for the prevention of injuries and for the improvement of physical conditioning in studies aimed at the correct practice of weight-training,[7] where the authors argue that when well performed and supervised, strength training acts as a protection factor against musculoskeletal injuries due to the improvement of body perception, muscle and joint strengthening, and physical conditioning.

We tried to find out if BT practitioners with previous injuries would have greater chances of suffering a new injury, finding a positive relation for this. However the study was limited for not being able to relate the place of the previous injury with the new injury, not being possible to define if it occurred in an already fragile place or if it affected a different area.

Table 3. Do you practice another sport, Do you have any stretching/strengthening routine before and after training/games?, Do you do any physical conditioning/bodybuilding work? and Previous injury according to the presence of injury in n=698 beach tennis practitioners. Year 2022.

	Present		Absent		General		p-value
	n	%	n	%	n	%	
Practice another sport							**0.1452**
Yes	272	52.3	248	47.7	520	74.5	
No	105	59.0	73	41.0	178	25.5	
Do you have any stretching/strengthening routines before and after workouts/games?							**0.0926**
Yes	186	57.6	137	42.4	323	46.3	
No	191	50.9	184	49.1	375	53.7	
Do you do any fitness/bodybuilding work?							**0.5908**
Yes	274	53.3	240	46.7	514	73.6	
No	103	56.0	81	44.0	184	26.4	
Previous injury							**<0.0001***
Yes	274	74.9	240	25.1	514	47.9	
No	127	34.9	237	65.1	364	52.1	

*G test of independence, comparing Presence x Absence of Injury.

CONCLUSION

Among the practitioners of BT, those individuals older than 50 years, who practice the sport for a longer time, with a greater weekly frequency, for more hours in each game and who already presented a previous injury at the beginning of the practice are more prone to injuries, being able to infer that the greater exposure increases the risk of injury.

Actions that promote the adequate preparation and physical conditioning to the players of BT showed no difference in this study for the prevention of sports-related injuries and also in the time away from the game.

The prevalence of injuries showed no difference in relation to gender, nor to BMI.

The most common injuries were those of the elbow and shoulder, both due to inflammatory diseases of the tendons, followed by traumatic injuries (sprain) in the knee and ankle.

AUTHORS' CONTRIBUTION: All the authors had very important contributions for the development of this article. PSB: development of the application for data collection through the questionnaire. FLR: conception of the study hypothesis, development, data analysis, writing and critical review. RSP: conception of the study hypothesis, data analysis and paper writing. IPF: conception of the study hypothesis, data analysis and paper writing.

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ORTHOPEDIC TRAUMA

ASSESSMENT OF INTEROBSERVER RELIABILITY FOR THE LETOURNEL AND JUDET CLASSIFICATION

AVALIAÇÃO DA CONFIABILIDADE INTEROBSERVADORES PARA A CLASSIFICAÇÃO DE LETOURNEL E JUDET

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ABSTRACT

Introduction: The Judet and Letournel classification is the most widely used classification system for acetabular fractures. Some complex fractures couldn't be classified according to this classification. The main purpose of this study was to evaluate the reliability of the Letournel and Judet classification system for acetabular fractures. Material and methods: 10 acetabular fractures were analyzed among 17 orthopedic surgeons. The surgeons were asked to classify the fractures according to the Judet and Letournel classification. Their experience, the number of surgeries, and the incision type that the surgeon uses for the anterior part of the acetabulum were recorded. Results: The overall interobserver agreement for the Letournel classification was found to be poor, with a Kappa value of 0.287. The Kappa value for interobserver agreement was 0.224 for plain radiographs, 0.293 for 2D-CT, and 0.321 for 3D-CT scans. There was no significant difference between the incision types used by the surgeons. The highest reliability was determined among the surgeons who operate on 10-20 acetabular fractures per year, with a Kappa value of 0.309. Conclusion: This results revealed that the Judet and Letournel Judet classification is not sufficient to classify acetabular fractures because of unclassified fractures and the complex algorithm of the system. ***Level of Evidence III; Comparative Retrospective Study.***

Keywords: Acetabulum. Orthopedic Surgeons. Pelvis. Fractures, Bone.

RESUMO

Introdução: A classificação de Judet e Letournel é o sistema de classificação mais amplamente utilizado para fraturas acetabulares. Algumas fraturas complexas, porém, não puderam ser classificadas de acordo com esta classificação. O principal objetivo deste estudo foi avaliar a confiabilidade do sistema de classificação de Judet e Letournel para fraturas acetabulares. Material e métodos: Foram selecionadas aleatoriamente 10 fraturas acetabulares de um banco de dados. Participaram do estudo 17 cirurgiões ortopédicos. Foi solicitado aos cirurgiões que classificassem as fraturas de acordo com a classificação de Judet e Letournel. Suas experiências, o número de cirurgias e o tipo de incisão que o cirurgião utiliza para a parte anterior do acetábulo foram registrados. Resultados: A concordância interobservadores geral para a classificação de Judet e Letournel foi considerada fraca, com um valor de Kappa de 0,287. O valor de Kappa para a concordância interobservadores foi de 0,224 para radiografias simples, 0,293 para tomografias computadorizadas em 2D e 0,321 para tomografias computadorizadas em 3D. Não houve diferença significativa entre os tipos de incisão utilizados pelos cirurgiões. A maior confiabilidade foi determinada entre os cirurgiões que operam de 10 a 20 fraturas acetabulares por ano, com um valor de Kappa de 0,309. Conclusão: Os resultados revelaram que a classificação de Judet e Letournel não é suficiente para classificar fraturas acetabulares devido a fraturas não classificadas e ao algoritmo complexo do sistema. ***Nível de Evidência III; Estudo Comparativo Retorpectivo.***

Descritores: *Acetábulo. Cirurgiões Ortopédicos. Pelve. Fracturas Óseas.*

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INTRODUCTION

The treatment of acetabular fractures is one of the most complicated situations in orthopaedic surgery. There has been a progressive increase in the number of cases, resulting from high-energy accidents and due to the improvement of emergency rescue systems, which are able to save the life of a polytrauma patient.[1] Accurate classification of acetabular fractures is very important when selecting the correct surgical approach to enable the most effective surgical treatment.[2] The need for an accurate and precise classification system has been long established as a cornerstone in modern fracture treatment.[3] Judet and Letournel, whose treatise analyses fractures of the acetabulum, named the columns in reference to their double embryological origin. The iliopubic column (anterior column) extends from the superior iliac crest to the pubic symphysis. The thicker structure of the ilioischial column (posterior column)

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The study was conducted at the Pamukkale University, Faculty of Medicine, Departament of Orthopaedics, Denizli, Turkey.
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extends from the inferior sacroiliac joint and sciatic notch to the ischial tuberosity. Letournel and Judet developed a classification system which divides fracture types into one of five elementary (simple) and five associated (complex) patterns based on the column system. The Letournel and Judet classification requires 3 plain radiographs of the pelvis: an AP view, an obturator oblique view, and an iliac oblique view. The evaluation of acetabular fractures is difficult and the classification systems of Letournel[4,5] and AO/OTA[6] are complex. There is a current trend towards increased utilization of computed tomography (CT) imaging both in the general population and specifically in the emergency care setting.[7] The integration of CT scans into common medical care of trauma patients has increased our ability to detect fractures of the quadrilateral surface, sacrum, acetabular roof, and posterior acetabular wall, to identify loose bodies in the hip, and provides a more complete understanding of acetabular fracture characteristics.

The reliability of the Letournel and Judet classification was investigated previous studies. Beaule et al. stuied the reliability wtihin the different experience levels of surgeons but the fracture types did not selected randomly.[8] Hutt et al. classified the fractures according to the Letournel and Judet classification. They used a hundred radiograps three observers and they put a tab as unclassified.[9]

The main purpose of this study was to evaluate additional information for the reliability of the Letournel and Judet classification system with randomly selected radiograms offered to observers who had variable degrees clinically. Each observer was familiar with the Letournel classification. Evaluations and comparisons were made in respect of Kappa values for interobserver reliability, according to the type of incision used for anterior part fractures, the experience of the surgeons, using plain radiographs and the additional effect of two-dimensional CT (2D-CT) and three-dimensional CT (3D-CT) scans and the complexity of the fracture type.

MATERIAL AND METHODS

In this study the reliability of the Letournel and Judet classification was investigated according to the participants' experience, the number of acetabular fracture surgeries performed per year, the incision type that the surgeon uses for the anterior part of the acetabulum and the effect of 2D and 3D CT scans. The Judet and Letournel classification divides acetabular fractures into 2 groups: elementary (simple) and associated (complex). The elementary fracture group includes anterior and posterior wall fractures, anterior and posterior column fractures, and transverse fractures. The associated acetabular fracture group includes both column fractures, anterior column posterior hemitransverse fractures, T-type fractures, and transverse or posterior column with posterior wall fractures. (Figure 1)

A total of 10 patients, aged >18 years, with 10 acetabular fractures were randomly selected from the hospital database. For each patient there was a complete set of radiographs, CT scans and 3D-CT scans taken within the last 3 years. The CT scans and the 3D-CT scans were uploaded to the internet in video format. A total of 17 orthopedic surgeons, all of whom were familiar with the Letournel and Judet classification and who were variable degrees in treating acetabular fractures, participated in the study. Standard forms were created and sent to the personal e-mail addresses of the participating observers. The participants were not given any clinical information regarding the demographic data, treatment methods or results of the patients. A schema and written explanation of the Letournel and Judet classification were given in the introduction of the Form (Figure 1). Each item in the survey had 10 different response options, comprising the types of acetabulum fracture according to the Letournel and Judet classification. The observers were asked to mark only one option in response to each item.

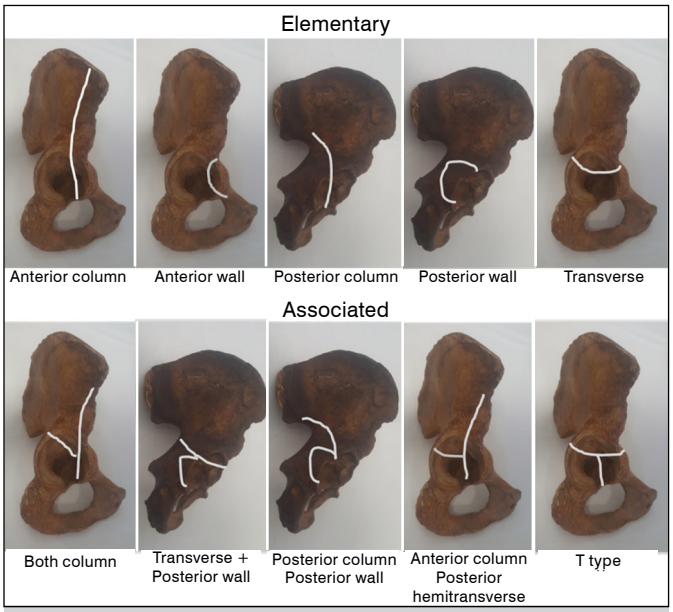

Figure 1. Elementary and associated types of acetabular fractures according to the Letournel classification.

The first 3 items were related to the experience of the surgeon, the number of acetabular fracture surgeries performed and the incision type that the surgeon uses for the anterior part of the acetabulum. The next item included three plain radiographs of the first patient and the participants were asked to classify the type of acetabulum fracture according to the Letournel and Judet classification. In the next item, the CT scans of the same patient were presented and the participants were again asked the type of acetabulum fracture according to the Letournel and Judet classification. The following item presented the 3D-CT scans of the same patient and the respondents were asked if there was any change to the diagnosis and if so, which fracture type did they now consider it to be. Ten patients radiographs, CT scans and 3D-CT scans of 10 patients were presented in this way. All the answers were collected and analysed statistically. Fleiss Kappa analysis was applied to analyse agreement between the surgeons. Statistical analysis was performed using R (version 3.4.3, Vienna, Austria) in RStudio software (Version 1.1.463 – © 2009-2018 RStudio, Inc.). The package used for the analysis was "irr". According to Landis and Koch, a Kappa value of 0.00–0.20 indicates slight agreement, 0.21–0.40 fair agreement, 0.41–0.60 moderate agreement, and Kappa 0.81 is considered to be almost perfect. [10]

RESULTS

In this study, 17 orthopaedic surgeons who had variable degrees clinically classified acetabular fractures according to the Letournel and Judet classification. The overall interobserver agreement for the Letournel classification was found to be poor with a Kappa value of 0.287 [Kappa (95 % CI), $p<0.001$]. When evaluating the interobserver agreement according to the selected incision, for ilioinguinal incision the Kappa value was found to be 0.282 [Kappa (95 % CI), $p<0.001$] and for modified medial Stoppa 0.281 [Kappa (95% CI), $p<0.001$]. The interobserver agreement according to the years of experience of the physician, was Kappa 0.262 for experience of 1-5 years [Kappa (95% CI), $p<0.001$], 0.303 for 5-10 years [Kappa (95% CI), $p<0.001$] and 0.238 for 10-20 years [Kappa (95% CI), $p<0.001$]. The interobserver agreement according to the physicians practice that the number of operated acetabular fracture per year, for 5-10 the kappa value was found 0.262 [Kappa (95% CI),

<< SUMÁRIO

p<0.001] for 10-20 0.309 [Kappa (95 % CI), p<0.001] and for 20 and over 0.278 [Kappa (95 % CI), p<0.001] (Table 1). The interobserver agreement for plain radiographs was Kappa value 0.224 for plain radiographs, 0.293 for 2D-CT, and 0.321 for 3D-CT. After the answers were collected the senior author classified the fracture types according to the Letournel classification (Table 2). The senior author's diagnostics were two posterior wall, two posterior column, one transverse, two t type, two anterior column posterior hemitransverse and one both column. Agreement percentage was 90% for posterior wall fractures, 68% for posterior column fractures. One t type fracture the agreement percentage was 49%. Another t type fracture the agreement percentage was 17%. (Table 2, Figure 2).

Table 1. The results of incision type, years of experience of the surgeon, number of operations performed per year, and the Kappa values.

	n	Kappa
Ilioinguinal	7	0.282
Modified medial Stoppa	10	0.281
1-5 years	7	0.262
5-10 years	7	0.303
10-20 years	3	0.238
5-10 operations per year	7	0.262
10-20 operations per year	6	0.309
20 + operations per year	4	0.278

DISCUSSION

In this study the overall Kappa for the Letournel and Judet classification was found to be poor at 0.287. The study results also showed that the incision type preferred by the surgeon for anterior part fractures of the acetabulum did not change the reliability of the Letournel and Judet classification. In 2D CT, and 3D CT scans the kappa vale were increased and more importantly the agreement percentages were İncreased (Table 2, Figure 2). The experience of the surgeon partially increased the reliability but not to a significant degree. In the study by Beaulé et al., the senior author had originally classified the fractures at the time of surgery and patient radiographs were selected to include every type of fracture.[8] The study was conducted with three groups of three orthopaedic surgeons: group 1, surgeons who had studied under Letournel, group 2, surgeons who specialized in acetabular fracture surgery, and group 3, general trauma surgeons. The interobserver

Table 2. Senior author's diagnosis and percentages of the most given answers to the patients X-ray, 2-D CT, 3-D CT sans.

Patient	Senior author's diagnosis	X ray; most given answer/ percentage		2-D CT; most given answer/percentage		3-D CT most given answer/percentage	
1	Transverse	Transverse	47.1	Transverse	29.4	Transverse	47.1
2	T type	Anterior column	52.9	Both column	52.9	Both column	35.3
3	T type	T type	47.1	T type	47.1	T type	52.9
4	Posterior wall	Posterior wall	88.2	Posterior wall	100	Posterior wall	100
5	Anterior column posterior hemitransverse	Anterior column	29.4	T type	35.3	Anterior column posterior hemitransverse	35.3
6	Posterior column	Posterior column	41.2	Posterior column	52.9	Posterior column	47.1
7	Anterior column posterior hemitransverse	Posterior column	23.5	Anterior column posterior hemitransverse	29.4	Anterior column posterior hemitransverse	29.4
8	Posterior column	Posterior wall	70.6	Posterior column	58.8	Posterior column	76.5
9	Posterior wall	Posterior wall	70.6	Posterior wall	94.1	Posterior wall	88.2
10	Both column	Posterior column	47.5	Both column	47.5	Both column	59

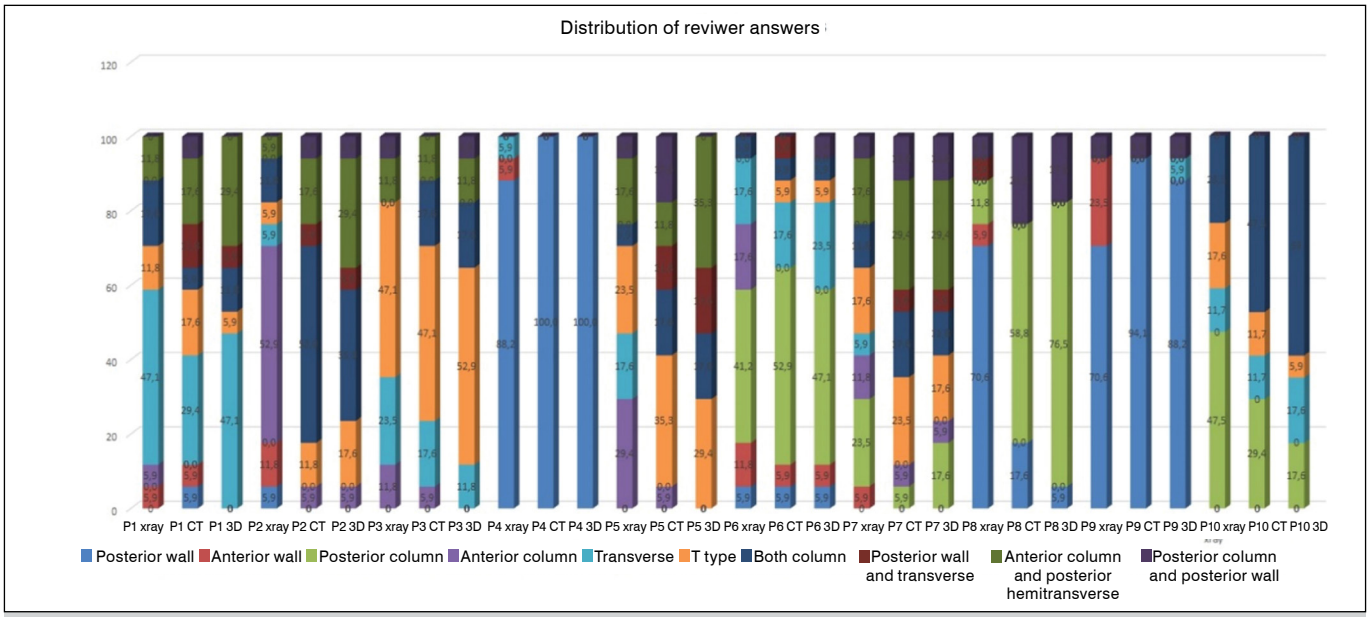

Figure 2. Distribution of observers answers.

reliability without and with CT during the first session was 0.70 and 0.74, respectively; 0.71 for group 1, 0.69 for group 2, and 0.51 for group 3. In the current study, radiographs and CT scans of randomly selected patients were used and after the observers results were collected, the senior author classified the fractures. The Kappa value was determined for overall, plain radiographs, 2D CT, and 3D CT scans and the questions were studied separately. In this study the kappa values was lower than Beaule study but the percent agreement was similar among elementary fracture types; posterior wall fractures was % 92 in Beaule, in this study was was % 90. For the associated fracture types they found percent agreement for t type 49 %, in this study percent agreement for one t type fracture which could be classify with Letournel was 49 % but another t type fracture percent agreement was % 17, the observers classified that as both column 35 % (Figure 3). In a study by Hutt et. al, 4 surgeons experienced in acetabular fracture surgery classified acetabulum fractures according to the Letournel and Judet classification and if they thought a fracture could not be classified, it was noted as unclassifiable. In that study, the overall Kappa value was 0.43 for plain radiographs and 0.54 for CT. When the unclassifiable fracture patterns were removed, inter-observer agreement was substantially improved to $\kappa = 0.65$ for radiographs alone, and near perfect $\kappa = 0.80$, with the addition of CT scans. In total, 63% of cases were recorded as unclassifiable by at least one surgeon, and 46% by at least two in the Hutt et al. Study.[9] The Letournel and Judet classification system could be fail with acetabulum fractures which do not match the fracture lines described by Letournel and Judet, especially when quadrilateral surface fracture is included.[9] Although the quadrilateral surface is an important anatomic structure and essential in the surgical reduction of fractures of the acetabulum, it is not a part of the systems developed for classifying these fractures.[11,12] In the current study the overall Kappa value was found to be poor at 0.287 in comparison with the Hutt et al. study, in which 4 surgeons worked together, whereas the current study included 17 surgeons from 10 different centers and so it can be considered that their practices may be different. And as the Fleiss kappa methods when the observer number increased the kappa value decraese, kappa coefficient is highly affected by the number of observers.[10] Herman et al. described a novel classification system as the vectors of trauma with 6 fracture patterns and according to their study, 20% of fractures could not be classified according to the Letournel and Judet classification system.[13] The novel classification described by Herman et al. requires studies of interobserver agreement, additional data from 3D CT, and assessments of the overall effect on clinical outcomes. Ohashi et al. reported Kappa values of 0.42 for interobserver agreement of the classification of 101 acetabular fractures when only radiographs were viewed and 0.70 when only multidetector CT images were viewed.[14] It was concluded in that study that plain radiographs

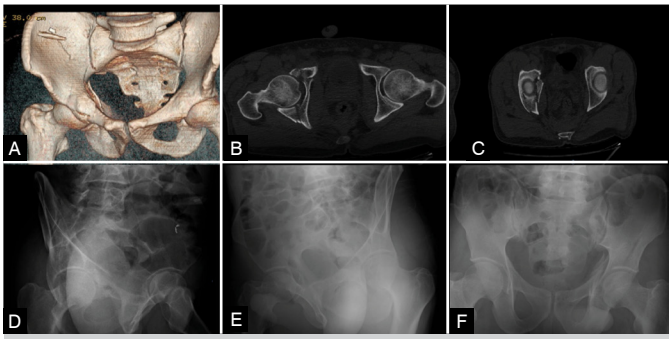

Figure 3. Patient eight radiograms; A: 3D-CT scan; B,C: 2D-CT scan; D: obturator oblique xray; E: iliac oblique xray; F: AP pelvis xray.

are not necessary and CT scans are sufficient for classification. However, plain radiographs can detect a fracture line more frequently using AP pelvis radiographs, so patients can avoid unnecessary CT imaging with radiation exposure. In a study by Ohashi et al, there were only two radiologist observers, and it was stated that with a higher number of observers, agreement could change. Consistent with the findings of the current study, Visutipol et al. found that the addition of a 3D CT scan did not improve the inter- or intraobserver reliability of the Letournel classification with Kappa values reported of 0.42 for plain radiographs and 0.44 for 3D CT evaluation.[15] But in the current study despite the non significant kappa increasing for CT images the percentage of agreement increse more. In the patient eight series the senior author's diagnosis was posterior column and the 70 % was posterior wall according to x rays, 58.8 % was posterior column according to 2D-CT scans and 76.5 % was posterior column according to 3D-CT scans.

Prevezas et al. used the iliopectineal and ilioischial lines to group fractures according to integrity and to then classify them according to the Letournel and Judet classification, yet they failed to demonstrate any significant improvement in concordance.[16] Petrisor et al. conducted a comparative study between orthopaedic surgeons in training and those who had already graduated. Interobserver concordance using the Letournel and Judet classification was found to increase in direct relation to the surgeon's experience, regardless of the addition of oblique views.[17] However, that study used four elementary fracture types and roof fracture and tear drop disruption, so the agreement would be expected to be higher and anterior wall fracture agreement poorer among all trained observers. In the current study, the maximum agreement was found between surgeons who performed 10-20 acetabular fracture operations per year.

Boudissa et al. studied semi-automatic bone-fragment segmentation through orthopaedic residents and found that agreement improved with semi-automatic bone-fragment segmentation but in the study, only fractures which could be classified were used.[18] Riouallon et al. developed an application based on the Letournel and Judet classification. In that method, 8 radiographic landmarks were systematically examined for fracture lines, including 3 anterior landmarks (iliac wing, linea arcuata, and anterior wall of the acetabulum), 3 "no man's land" landmarks (roof of the acetabulum, quadrilateral surface, and obturator ring), and 2 posterior landmarks (posterior border of the iliac bone and posterior wall of the acetabulum). According to the study results, using the application improved reliability among 14 observers with different degrees of experience. However, the study was monocentric and there could have been selection bias in terms of the examiners.[19] Clarke et al, the overall interobserver agreement for the Letournel and Judet classification was found to be moderate with a Kappa value of 0.52 in 4 four trauma centres and the highest Kappa value of 0.60 in the 3D CT set.[20] In that study, a single set of images was evaluated but in the current study all 2D CT and 3D CT images were presented in video format and therefore, whole sets of images were given to the observers, who comprised 17 trauma surgeons from 10 different trauma centres. The plain radiographs, 2D CT and 3D CT videos were given in the same set and the participants were asked not to change the previous answers following 2D CT and 3D CT images. Thus the additional effect on interobserver reliability could be studied.

In conclusion, the results of this study revealed that the Letournel and Judet classification is not sufficient for the classification of acetabular fractures because of unclassified fractures and the complex algorithm. Even among experienced surgeons, interobserver raliability was found to be poor. Therefore, a clearer classification system is required for acetabular fractures

AUTHORS' CONTRIBUTION: MY: Concept: The idea for research or article/hypothesis generation; Design: Planning the methods to generate hypothesis; Resources: Supplying financial resources, equipment, space, and personnel vital to the project; Data collection and/or processing: Responsibility for conducting experiments, management of patients, organizing and reporting data; Literature search: Responsibility for conducting literature Search; Writing manuscript: Responsibility for creation of an entire or the substantial part of the manuscript. ANA: Materials: Biological materials, reagents, referred patients; Analysis and/or interpretation: Responsibility for presentation and logical explanation of results. AFD: Supervision: Supervision and responsibility for the organization and course of the project and the manuscript preparation; Critical review: Reworking the final, before submission version of the manuscript for intellectual content, not just spelling and grammar check.

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ORTHOPEDIC TRAUMA

LEADERSHIP DEVELOPMENT TRAINING FOR BRAZILIAN ORTHOPEDIC SURGEONS

TREINAMENTO DE DESENVOLVIMENTO DE LIDERANÇA PARA CIRURGIÕES ORTOPÉDICOS BRASILEIROS

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ABSTRACT

Objective: To report on the experience and impressions of the Brazilian orthopedic trauma surgeons attending the Leadership Development Program (LDP) hosted by the Sociedade Brasileira do Trauma Ortopédico (SBTO) in Sao Paulo, Brazil on November 4, 2022. Methods: Forty-eight orthopedic trauma surgeons from five different regions throughout Brazil were provided a link to complete The Big Five Test, a validated online personality assessment. The questionnaire was available in Portuguese and was intended to provide a background on individual personality traits and their influence on interpersonal interactions. The LDP integrated content from literature reviews specific to Latin America, established leadership programs from leading business schools, and various subject matter experts. Prior to the start of the LDP, participants received a pre-course survey evaluating demographic information, a needs assessment, and the prioritization of leadership topics utilizing a 5-point Likert-scale. Attendees participated in the one-day, interactive LDP focusing on the fundamental principles of leadership development, communication, personal development, emotional intelligence and negotiation. Following the LDP, a post-course evaluation was administered to determine the participants' overall experience, and suggestions for LDP improvement. Results: Forty-one of the forty-eight course participants completed the pre-course evaluation, whereas forty-six of the forty-eight participants completed the post-course evaluations. Overwhelmingly, the lack of opportunity

RESUMO

Objetivo: Relatar a experiência e as impressões de cirurgiões de trauma ortopédico brasileiros participantes do Programa de Desenvolvimento de Liderança (PDL), organizado pela Sociedade Brasileira do Trauma Ortopédico (SBTO), em São Paulo, Brasil, em 4 de novembro de 2022. Métodos: Quarenta e oito cirurgiões de trauma ortopédico de cinco regiões diferentes do Brasil receberam um link para preencher o The Big Five Test, uma avaliação de personalidade on-line validada. O questionário estava disponível em português e pretendia fornecer informações básicas sobre traços de personalidade individuais e sua influência nas interações interpessoais. O PDL integrou conteúdo de análises de literatura específicas da América Latina, e programas de liderança estabelecidos pelas principais escolas de negócios e por vários especialistas no assunto. Antes do início do PDL, os participantes receberam uma pesquisa pré-curso solicitando informações demográficas, uma avaliação de necessidades e a priorização de tópicos de liderança utilizando uma escala Likert de 5 pontos. Os participantes participaram do PDL interativo de um dia com foco nos princípios fundamentais de desenvolvimento de liderança, comunicação, desenvolvimento pessoal, inteligência emocional e negociação. Após o PDL, foi realizada uma avaliação pós-curso para determinar a experiência geral dos participantes e sugestões para melhoria do PDL. Resultados: Quarenta e um dos quarenta e oito participantes do curso concluíram a avaliação pré-curso, enquanto quarenta e seis dos quarenta e oito participantes concluíram a avaliação pós-curso. A falta de oportunidade foi relatada com maior prevalência como o principal

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The study was conducted at the University of California, Orthopaedic Trauma Institute, Department of Orthopaedic Surgery, San Francisco, School of Medicine, Zuckerberg San Francisco General Hospital, San Francisco, California, USA.
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was most prevalently reported as the main obstacle to attending a leadership course, as cited by 56% of respondents. Conclusion: Expanding the accessibility, diversity, and customizability of leadership programs can facilitate the development of personal tools needed to move healthcare forward. Critical topics include emotional intelligence and other differentiating leadership qualities that distinguish true transformational and servant leaders. Advancing leadership skills can stimulate networking, expose learners to experiential learning styles, inspire others to create positive change, and engender creative solutions for systematic improvements and health outcomes. ***Level of Evidence III; Individual Case-Control Studies.***

Keywords: Orthopedic Surgeons. Program Development. Latin America. Lower-Middle-Income Countries.

obstáculo para frequentar um curso de liderança, conforme citado por 56% dos entrevistados. Conclusão: Expandir a acessibilidade, a diversidade e a personalização dos programas de liderança podem facilitar o desenvolvimento de ferramentas pessoais necessárias para fazer avançar os cuidados de saúde. Os tópicos críticos incluem inteligência emocional e outras qualidades de liderança diferenciadas, que distinguem verdadeiros líderes transformacionais e servidores O avanço das competências de liderança pode estimular o networking, expor os alunos a estilos de aprendizagem experiencial, inspirar outros a criar mudanças positivas e gerar soluções criativas para melhorias sistemáticas dos resultados na saúde. ***Nível de Evidência III; Estudos de caso-controle individuais.***

Descritores: *Cirurgiões Ortopédicos. Desenvolvimento de Programas. América Latina. Países de Baixa e Média Renda.*

INTRODUCTION

There is increasing value in the awareness and enhancement of cognitive and social skillsets. Such cognitive skills include decision-making, planning, and situational awareness, while the social component encompasses leadership, teamwork, and communication skills.[1] In the general clinical setting, it has been shown that these skillsets are highly associated with the capacity of a physician to practice medicine according to standards of intellectual and moral excellence, bearing the responsibility for patient care, medical education and research, and cultural organization.[2] In the context of orthopedic trauma, these non-technical skills have profound implications on patient outcomes and the performance of healthcare systems.[3-7] Human behaviors relating to these skillsets have been implicated in nearly 50-80% of errors or adverse events in medicine.[7,8] This reinforces that these abilities are fundamental to clinical expertise and the delivery of high-quality,[8] safe, effective, and patient-centered care.[9]

While the assessment and training of these non-technical skills have become more accessible in high-income countries (HICs), there remains a need for further development and incorporation of these tools into the medical education throughout low- and middle-income countries (LMICs),[1] particularly throughout Latin America.[10] Given the direct association between national income and spending, a significant portion of the care delivered in LMICs is often greatly hindered by the lack of requisite healthcare funding. The burden of disease is greater, advanced technology is limited, the supply of human and material resources is inconsistent, and the healthcare systems remain less integrated than in many HICs. As a result, the individual and collective disharmony, dissatisfaction, and disappointment often experienced in the doctor-patient relationship is commonly attributed to this adverse environment.[11] The effect that human behavior may have on patient safety and health outcomes may thus be more substantial in LMICs than in HICs.[1] Despite their classification as upper middle-income countries, Brazil and other Latin American countries are characterized by unequal wealth distribution, thereby having significant proportions of their populations to conditions that are more commonly found in countries with a lower gross domestic products.[12] These healthcare challenges are further in situations where non-technical skillsets assist in improved management of the available resources, prompting further interest in understanding and improving these skills.

In 2019, a cross-sectional, multinational survey was administered to the Asociación de Cirujanos Traumatólogos de las Americas (ACTUAR) network, an international collaborative consortium established to enhance research capacity among orthopedic trauma surgeons in Latin America.[12] The survey was designed to determine the interest in and relative importance of various leadership topics and other non-technical skills. The survey was completed by 144 orthopedic surgeons from 18 Latin American countries.[10] The results characterized region-specific perspectives, desired competencies, and existing barriers to leadership development participation and formed the basis for a novel Leadership Development Program (LDP) curriculum for Latin American orthopedic trauma surgeons.[10] Through this collaborative effort, an inaugural LDP was actualized in 2019 in Hermosillo, Mexico; followed by Havana, Cuba; Veracruz, Mexico; and most recently, Sao Paulo, Brazil. This paper will report on the experience and impressions of the Brazilian orthopedic trauma surgeons attending the LDP hosted by the Sociedade Brasileira do Trauma Ortopédico (SBTO) in Sao Paulo, Brazil on November 4, 2022.

MATERIALS AND METHODS

Forty-eight orthopedic trauma surgeons from five different regions throughout Brazil were invited to attend a 1-day LDP on the basis of their experience and/or leadership responsibilities. The course was attended by 92.7% males and 7.3% females, having an average of 10 years of practice experience since training. All participants were board certified members of the Sociedade Brasileira de Ortopedia e Traumatologia (SBOT) and active members of the SBTO. According to the official division of Brazilian regions, 10.5% lived in the south, 87.5% in the southeast, and 2% in the northeast of the country.

In preparation for the course, participants were provided a link to complete The Big Five Test,[13] a validated online personality assessment. The questionnaire was available in Portuguese and was intended to provide a background on individual personality traits and their influence on interpersonal interactions. Prior to the start of the course, participants received a link to complete a pre-course evaluation to determine their general interest and experience in leadership development opportunities as well as their prioritization of various leadership topics.[14-16] Upon course completion, a post-course evaluation was administered to assess course efficacy, obtain suggestions for improvement, and capture the overall experience of attendees.

The LDP integrated content from literature reviews specific to Latin America, established leadership programs from leading business schools, and various subject matter experts.[13] In addition to illustrating the fundamental principles of leadership development, the curriculum cultivated various social and cognitive skillsets, including personal learning styles, communication, team dynamics, personal development, emotional intelligence, strength deployment inventory, and negotiation. To accommodate diverse learning styles, these concepts were presented using hands-on learning activities,

case studies, real-world applications, interactive group activities, and formal didactic instruction. The course content and course materials were primarily provided in English.
The 2022 board of the SBTO fully supported the course and was actively present throughout its administration. The original study was deemed "exempt" by UCSF and given the study number 19-28517.

RESULTS

Pre-Course Evaluation

Forty-one (85%) of the forty-eight course participants completed the pre-course evaluation. Respondents reported a current leadership position (97.6%), most commonly within the hospital setting (92.7%), with an equal distribution among different ranges of leadership experience (0-2 years, 3-5 years, and 6+ years). Despite 100% of respondents expressing interest in attending a leadership course, only 14.6% reported previous leadership course attendance. Overwhelmingly, the lack of opportunity was most prevalently reported as the main obstacle to attending a leadership course, as cited by 56% of respondents. (Table 1)
Respondents were asked to evaluate the most important leadership topics utilizing a 5-point Likert scale, assigning items a rank between 1- indicating "strongly agree" and 5- indicating "strongly disagree". Decision-making ability, professional etiquette, and conflict management were ranked among the most important topics (Figure 1). Notably, when respondents were asked to propose additional leadership topics, a common thread emerged around introspective development, which included continued personal and professional growth, adaptability, self-improvement, open mindedness, and support for emerging leaders. Many of these commonly identified leadership qualities were universally acknowledged social and cognitive skills and well represented throughout the LDP content. When asked to preferentially rank various learning styles, lecture-based and simulation exercises were rated most favorably. (Table 2)

Post-Course Evaluation

Post-course evaluations were completed by forty-six (96%) of the forty-eight participants, 96% of whom attended the full duration of the course. Respondents unanimously agreed that the course material was enthusiastically communicated, that it had clearly articulated goals, and that the course design was conducive to achieving these goals. Furthermore, 100% of respondents concurred that the course encouraged active participation through discussions and group activities. Commonly cited course strengths included the novel and dynamic content as well as the interactive exercises. Suggestions for improvement included providing pre-course and other written materials for added background, expanding and referencing the various topics covered, and providing simulation and group activity instructions in Portuguese.
Collectively, these course evaluations demonstrate that orthopaedic trauma surgeons have a variety of leadership responsibilities. These evaluations also showed that there was a perceived paucity of leadership development opportunities available to Brazilian orthopedic trauma surgeons, confirming an interest in pursuing such opportunities.

DISCUSSION

The role of an orthopedic trauma surgeon requires specialization, expertise, and the assumption of various responsibilities that

Table 2. Pre-Course Evaluation Results: Learning Style Preferences (Reported as Frequency Cited).

Learning Style	Preference
Lecture	26
Simulation Exercises	21
Interactive Plenary Session/Panel Discussion	15
Small Group Work	18

Source: Sociedade Brasileira do Trauma Ortopédico and University of California at San Francisco, 2022.

Table 1. Pre-Course Evaluation Results: Leadership Position and Leadership Course Attendance (Reported as % of Respondents).

Currently in Leadership Position	Leadership Setting	Years of Experience in Leadership Position	Previous Leadership Course Attendance	Barriers to Leadership Course Participation
97.7%	Clinic – 29.3%	0-2 years – 31.7%	14.6%	Limited Opportunities – 56%
	Hospital – 92.7%	3-5 years – 29.3%		Early in Career – 29.3%
	Regional Society – 14.6%	6+ years – 36.6%		Schedule Conflicts – 12.2%
	National Society – 9.6%			Cost – 4.9%
	International Society – 0%			Work Schedule Conflicts – 17%
				Other – 2.4%

Source: Sociedade Brasileira do Trauma Ortopédico and University of California at San Francisco, 2022.

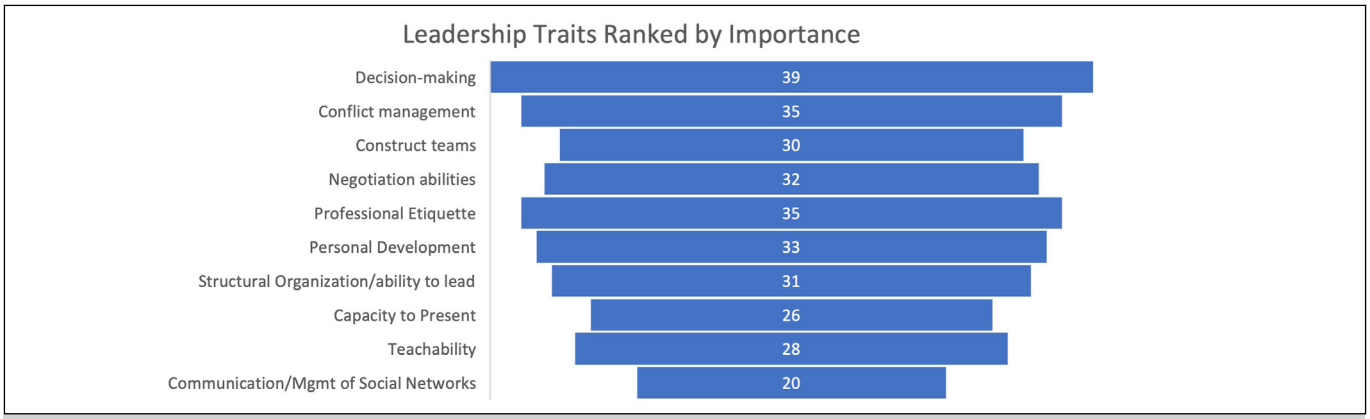

Figure 1. Leadership Traits Ranked

require intrinsic leadership qualities. Properly developed leadership knowledge and skills are pivotal to protecting the patient's interests, organizational direction and requirements, and professional integrity.[2-17] Leadership development has been identified as one of the most important priorities for medical education this century;[18] however, the inclusion of this subject in medical training curricula remains inconsistent and lacks standardization across countries.[18,19] According to Brazil's national curriculum guidelines for medical education, leadership skills are considered a component of the basic knowledge a physician must have to work in interdisciplinary teams with responsibility, empathy, effective communication, decision making, and the assumption of leadership positions.[20,21] Nevertheless, most medical schools don't formally integrate these expected these subjects into the curriculum.[20] Historically, surgeons haven't been trained to focus on leadership or reflect on their personal behavioral style.[22] By the nature of their profession, they tend to focus on outcomes rather than the processes involved in achieving those outcomes.[23] Consequently, physician leaders are often selected on the basis of their success in the core activities of medical centers: research, education, and patient care; yet they may often lack sufficient training and experience in administration, management, and leadership.[24] Only by understanding this longstanding cultural reality, medical doctors will be able to develop an expansive new framework for prioritizing societal health care needs and expectations, instead of exclusively focusing on the individual patient.[25]

Furthermore, there are limited studies reporting on leadership education in Brazil or evaluating the efficacy of leadership integration in medical practices.[19] A systematic review evaluating leadership development programs for U.S.-based physicians demonstrated that physician leadership has focused on imparting technical and conceptual knowledge, customarily through lectures and seminars.[25] These teaching tools often take precedence over efforts to build self-awareness, for which action-based learning, feedback, and self-development activities may be more appropriate.[25] Notably, studies documenting favorable organizational outcomes were characterized by the use of multiple learning methods, including lectures, seminars, group work, and action learning projects in multidisciplinary teams.[23-26] Incorporating diverse learning formats, adapting for the personality types of different learners, and teaching concepts over time are more likely to become part of their daily behavior such that they become second nature.[21] Moreover, an extended program duration can cultivate valuable networking opportunities, as participants who spend significant periods of time learning together often develop a special camaraderie, which encourages ongoing collaboration and synergy among colleagues and institutions for the encouragement of leadership behavior.[21] As collaboration continues to progress, participants must adapt and embrace roles of leadership.[2]

As teamwork and collaboration are increasingly fundamental to healthcare operations, there is a growing need to include self-awareness and emotional intelligence as fundamental competencies within LDPs.[24] The most successful emerging healthcare models will effectively address the shift from individualism to a culture of collaboration and interaction – a transition largely driven by emotional intelligence.[26] From the boardroom and chairman's office to the ward and bedside, emotional intelligence is ubiquitous throughout clinical settings[25] and represents an element of leadership that ultimately influences individual and collective efforts to accomplish shared objectives.[27] Emotional intelligence and its concomitant skills are valued non-technical abilities within the personal development toolkit and have been identified as the most essential competency for leaders to succeed in academic institutions and other organizations.[28] To this end, two essential components of emotional intelligence must be present in a leader; social skill, or the talent to propagate others in a desired direction; and empathy, the sensitivity to feelings and emotions of others.[29] The introspective leadership qualities proposed by SBTO leadership course participants in the pre-course evaluations reflect a high sensitivity and capacity for prioritizing and further developing these abilities. Cultivating leadership skills to empower self-aware, empathetic, altruistic, and authentic leaders who demonstrate commitment to the growth of people and communities can have profound systemic implications on healthcare.[21] Leadership skill education has been an eclectic activity, recently moving away from a hierarchical and exclusively empirical process, towards the lived experience of the leader.[30]

CONCLUSION

Expanding the accessibility, diversity, and customizability of leadership programs can facilitate the development of personal tools needed to move healthcare forward. Critical topics include emotional intelligence and other differentiating leadership qualities that distinguish true transformational and servant leaders. Advancing leadership skills can stimulate networking, expose learners to experiential learning styles, inspire others to create positive change, and engender creative solutions for systematic improvements and health outcomes.

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ORTHOPEDIC TRAUMA

THE EFFECTS OF DRAINAGE TUBE ON PAIN AND FUNCTIONAL RECOVERY AFTER UNICOMPARTMENTAL KNEE ARTHROPLASTY

EFEITOS DO TUBO DE DRENAGEM NA DOR E RECUPERAÇÃO FUNCIONAL APÓS ARTROPLASTIA UNICOMPARTIMENTAL DO JOELHO

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ABSTRACT

Objective: The objective of this study was to evaluate the impact of drainage tube placement on postoperative pain, recovery, and opioid consumption within a 72-hour period following unicompartmental knee arthroplasty (UKA). Methods: Patients with medial knee osteoarthritis who underwent UKA from January 2019 to August 2020 were enrolled in the study and divided into two groups based on whether they received a drain postoperatively. Results: The drainage group had significantly lower VAS scores on day 1, day 2, and day 3, in addition to significantly smaller changes in the circumference of the knee joint within 3 days postoperatively (P <0.05). The ROM in the drainage group significantly increased at 3 days and 1 month post-surgery, with a statistically significant difference in morphine consumption between the two groups at 3 days (P<0.05). The incidence of postoperative nausea and vomiting (5 cases) and wound bleeding (1 case) was lower in the drainage group compared to the non-drainage group (P<0.05). Conclusions: The placement of a drainage tube in UKA may reduce the swelling of knee joint and pain, which not only reduces the use of Opioid but also facilitates early functional activities of the knee joint. ***Level of Evidence III; Retrospective Comparative Study.***

Keywords: Arthroplasty, Replacement, Knee. Drainage. Knee Joint. Morphine.

RESUMO

Objetivo: O objetivo deste estudo foi avaliar o impacto da implantação do tubo de drenagem na dor pós-operatória, na recuperação e no consumo de opioides em um período de 72 horas após a artroplastia unicompartimental do joelho (UKA). Métodos: Pacientes com osteoartrite medial do joelho submetidos à UKA de janeiro de 2019 a agosto de 2020 foram incluídos no estudo e divididos em dois grupos com base no fato de terem ou não recebido um dreno no pós-operatório. Resultados: O grupo de drenagem apresentou escores EVA significativamente menores no dia 1, no dia 2 e no dia 3, além de alterações significativamente menores na circunferência da articulação do joelho em 3 dias de pós-operatório (P <0,05). A ADM no grupo de drenagem aumentou significativamente em 3 dias e 1 mês após a cirurgia, com uma diferença estatisticamente significativa no consumo de morfina entre os dois grupos em 3 dias (P<0,05). A incidência de náuseas e vômitos no pós-operatório (5 casos) e sangramento da ferida (1 caso) foi menor no grupo de drenagem em comparação com o grupo sem drenagem (P<0,05). Conclusão: A utilização de tubo de drenagem na UKA pode reduzir o edema articular do joelho e a dor, reduzindo o uso de opioides e facilitando as atividades funcionais iniciais da articulação do joelho. ***Nível de Evidência III; Estudo Comparativo Retrospectivo.***

Descritores: *Artroplastia do Joelho. Drenagem. Articulação do Joelho. Morfina.*

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INTRODUCTION

Unicompartmental knee arthroplasty (UKA) is one of the effective treatments for medial compartment osteoarthritis of the knee. When compared with total knee arthroplasty, UKA is minimally invasive that promotes faster postoperative functional recovery and shortens hospital length of stay.[1-4] During UKA surgery, soft tissue incision and intraoperative osteotomy result in bleeding. Blood may then accumulate in the joint capsule and penetrate the soft tissue around the wound, leading to postoperative hematoma and swelling around the knee joint. Therefore, most surgeons would place a drainage tube in UKA surgery to prevent such complications.

In recent years, the application of multi-modal blood management in the perioperative period.Measures to reduce postoperative bleeding include the intraoperative controlled hypotension, tourniquet use, and the application of anti-fibrinolytic drugs.[5,6] Due to the small size of the incision and relatively little bleeding in UKA, the need for placing a drainage tube has been debated.[7,8] To date, few studies have examined the effects of drainage tubes

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The study was conducted at the Fuyang People's Hospital, Fuyang, Anhui, China.
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after UKA on postoperative consumption of analgesics and early functional recovery. Therefore, this retrospective study investigated the impact of drainage tubes after UKA on postoperative pain, Opioid consumption during hospitalization, and early postoperative functional recovery in patients undergoing UKA for osteoarthritis of the medial compartment of the knee.Two main objectives drive this research. First, to investigate the effects of drainage tubes on pain and functional recovery after UKA. Second, to assess Opioid consumption over the first 3 days after surgery.

METHODS

This was a single center, retrospective cohort study. The study was approved by the ethics committee of Fuyang People's Hospital (2021-43), and written informed consent was obtained from patients and their family members. A total of 78 patients who had undergone medial single-compartment knee arthroplasty for osteoarthritis at our hospital from January 2019 to August 2020 were included. Other inclusion criteria were: (1) complete case and postoperative follow-up data; (2) osteoarthritis of the medial compartment of the knee,Primary UKA; (3) patients had normal coagulation profile, without hematological disorder and not consuming long-term oral hormones. Exclusion criteria included: (1) Incomplete case or follow-up data; (2) Inflammatory arthritis, which had an infection prior to surgery. Patients were assigned into two groups: Group A with a post-operative closed-suction drainage tube and Group B without a drainage tube. Preoperative basic and clinical demographics of patients are shown in Table 1. All patients were evaluated by the American Society of Anesthesiologists Classification Standards before surgery.

Surgical technique

Surgery was performed by the same treatment group and the same anesthetic team. All patients underwent combined spinal and epidural anesthesia. At 30 minutes before surgery, all patients received intravenous tranexamic acid 1.0 g. An oblique incision measuring approximately 6 cm in length was made on the medial side of the knee joint, and the parapatellar medial approach was taken. The skin, subcutaneous tissue, deep fascia and nodular capsules were incised in turn, the anterior and inner sides of the tibial plateau were exposed. The LINK unicondylar operation steps were followed, whereby the tibial osteotomy guide plate was placed for tibial osteotomy and the excised medial plateau bone block was completely removed. The thickness of the anterior and posterior margins was measured, and the meniscus remained after the removal. Then, the knee joint was straightened, the upper edge of the femoral side osteotomy was marked, the distal femur and posterior condyle cartilage were cut off in turn, and the tibial prosthesis trial model was installed. The flexion-extension gap and flexion-extension activity were measured to ensure no impact and the prosthesis looseness was appropriate before taking out the test model. After washing and drying, the cement was mixed, and the prosthesis was installed. The LINK®Sled unicondylar knee prosthesis was used in all patients. The activities of the knee joint flexion and extension and soft-tissue balance were tested after the solidification of the bone cement. The wound was then thoroughly rinsed, removed excess bone cement was removed, and hemostasis was ensured. In the drainage group, a negative pressure drainage tube was placed on the inner side of the knee. Finally, the wound was closed in layers with sutures.

Table 1. Preoperative basic and clinical demographics between the two groups.

	Gender	Age (year of age)	BMI (kg/cm^2)	HSS score	VAS score	ROM (°)
GroupA (n=40)	16/24	65.66±4.94	24.45±2.40	58.79±2.72	5.45±1.12	116.55±4.97
GroupB (n=38)	14/24	65.71+5.29	24.53±1.91	58.39±2.85	5.58±1.11	116.10±4.91
c^2/F	0.082	0.094	2.286	O.001	0.26	0.17
P	0.774	0.871	0.796	0.628	0.605	0.519

Postoperative management

All patients received anticoagulation and antibiotics postoperatively, with an intravenous drip of Parecoxib 40mg twice a day for 3 days. Opioid(Morphine hydrochloride)injection was administered according to the patient's pain level. The drainage tube was removed 24 hours after surgery. Following the recovery of anesthesia, quadriceps active contraction exercise and straight leg elevation exercise were commenced, which encouraged early mobilization of patients after 1-2 days.

Outcome measurements

The operative time (min), the postoperative pain level was assessed using the visual analog scale (VSA), and the VAS scores at day-1 to day-3 days after surgery in addition to the total consumption of morphine hydrochloride injection (mg) in the first 3 days were determined. The circumference of the knee joint and the knee joint mobility were measured on day-3 and day-6 following surgery. The number of patients requiring postoperative blood transfusion and incidences of nausea and vomiting were recorded. The knee function was assessed using the Hospital for Special Surgery (HSS) score at 1, 3, 6, and 12 months after surgery.

Statistical analysis

All analyses were performed using IBM SPSS Statistics 24.0. Continuous variables were expressed as mean ± standard deviation with comparisons performed using the independent sample t-test. Categorical variables were presented as numbers (counts) with comparisons performed using the chi-square test. The correlation between the variables was analyzed by using the Pearson correlation. A P-value of <0.05 was considered statistically significant.

RESULTS

There was no statistically significant difference between the two groups in gender, age, body mass index (BMI), preoperative knee HSS function score, VAS score, and the preoperative knee range of motion (ROM) ($P>0.05$) (Table 1).

Post-operative results are shown in Table 2. However, the drainage group had significantly lower VAS scores on day-1, day-2, and day-3, in addition to significantly smaller changes in the circumference of the knee joint within 3 days postoperatively ($P<0.05$). Also, the ROM of the knee joint at day-3 and 1 month was significantly higher in the drainage group but no difference was observed at 6 months following surgery when compared with the non-drainage group. The knee HSS function scores were significantly higher in the drainage group at 1 month and 3 months after surgery but no difference was observed at 6 months and 12 months after surgery. The incidence of postoperative nausea and vomiting was significantly higher in the nondrainage group, but no significant difference was observed between the groups in the requirement for blood transfusion, the incidence of wound infection, subcutaneous ecchymosis, or fat liquefaction. All the complications are shown in Table 3. The amount of morphine hydrochloride used within 3 days postoperatively was significantly different in either group ($t=3.801$, $P<0.05$) (Figure 1) . Although the overall number of these adverse events was low, they were more apparent in the non-drainage group. All wound complications were resolved resolved without serious adverse consequences.

<< SUMÁRIO

Table 2. The operation time, total blood loss and postoperative outcomes between the two groups.

	Group A (n=40)	Group B (n=38)	F	P
Operation Time (min)	40 5.16	38 4.32	0.827	0.942
VAS score (postoperative)				
Day-1	3.67±0.67	4.23±0.88	0.031	0.004
Day-2	3.02±0.58	3.66±0.74	10.07	P < 0.001
Day-3	2.18±0.38	2.61±0.55	19.82	P < 0.001
Changes in the circumference of the knee joint on day-3 to baseline (cm)	2.95±0.30	3.45±0.29	0.075	P < 0.001
ROM (°)				
Day 3	100.42±5.22	91.53±3.43	4.439	P < 0.001
1st month	113.15±3.93	109±4.71	0.104	0.001
6th month	121.23±3.29	119.80±3.26	2.353	0.057
HSS score				
1st month	67.03±2.22	64.50±2.33	0.118	P < 0.001
3rd month	85.68±1.69	82.68±2.56	5.949	P < 0.001
6th month	89.80±1.78	89.13±1.53	0.012	0.08
12th month	93.18±1.71	92.89±1.64	0.011	0.463

Table 3. Postoperative blood transfusion, wound complications and nausea and vomiting between the two groups.

	Requirement for blood transfusion	Nausea and vomiting	Wound infection	Ecchymosis	Fat liquefaction
Group A (n=40)	1	5	0	1	0
Group B (n=38)	0	15	1	3	2
c^2	0.000	7.436	0.001	0.321	0.568
P	1.000	0.006	0.979	0.571	0.451

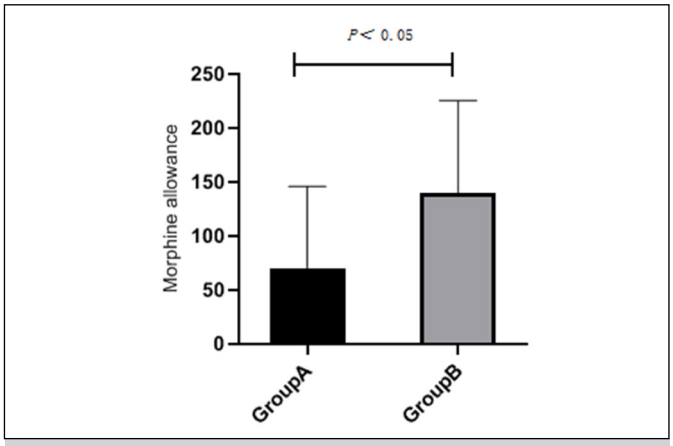

Figure 1. The amount of morphine hydrochloride between the two groups.

DISCUSSION

Placement of a drainage tube in joint replacement surgery is common and widely practiced, which aimed to drain the blood in the joint cavity, reduce local tension, reduce inflammatory exudation and mitigate the risk of wound infection. The study by Kim et al[9] has shown an increased risk of postoperative wound bleeding and potential wound infection if a drainage tube is not placed after knee arthroplasty.Li et al[10] conducted a prospective randomized controlled study on 100 patients with total knee arthroplasty, showing that postoperative wound indwelling drainage tubes have no advantage in knee function recovery. However, patients without the drainage tube were more likely to experience blood stasis, tissue swelling, and blood extravasates .Anton et al[11] conducted a randomized controlled study on 146 patients[12] with total knee arthroplasty, and found no significant difference in blood loss, length of hospitalization,knee ROM, and KOOS score among patients with drainage tube placement. However, the value of a drainage tube after the UKA operation remains a controversy at present. In 2004, Confalonieri et al[13] reported no clinical benefits of placing a drainage tube after UKA surgery but increased the cost of hospitalization. Nicola et al[14] demonstrated placing a drainage tube did not provide substantial benefit in the management of blood loss after total knee arthroplasty or UKA. Furthermore, the study by Zhang et al[15] has found that the blood loss and postoperative drainage volume of UKA were very low. Therefore, using drainage tubes in UKA did not confer any clinical advantages but increased the costs. On the other hand, Ares et al[12] have conducted a study involving 234 patients undergoing knee arthroplasty and reported that the drainage tube could be used in patients with a large amount of intraoperative blood loss and a high risk of bleeding, and it should be removed at 24 hours after surgery. In our study, we found that patients in the drainage group had significantly better early knee ROM and the knee HSS function scores in the first and third months after surgery when compared with those in the non-drainage group. .These could be attributed to the placement of a drainage tube that reduces blood accumulation in the knee joint, leading to a reduction in the swelling around the knee joint. These would result in the low pressure in the capsule of the knee joint during training and the tension of soft tissue around the knee, contributing to reduced pain that is conducive to the patient's early rehabilitation training. In recent years, the promotion and practice of the rapid rehabilitation concept in perioperative management have successfully accelerated the postoperative functional recovery by reducing pain and postoperative complications, and consequently shorten the hospital length of stay and improve patient satisfaction.[16-18] Early active functional exercise contributes to postoperative proprioception recovery that is vital for the daily activities of the knee joint. Hematoma in the joint capsule after UKA is one of the main causes of swelling around the knee. Joint swelling will then increase the tension around the knee joint and therefore, the patient will increase the muscle strength when completing the limb activity, resulting in increased pain at the knee joint, which then limits the active flexion and reduce the confidence of patients performing exercise during the early postoperative rehabilitation period. Pain is known as the "fifth-largest vital sign", and patients experiencing

significant pain postoperatively may have increased fear and reluctant to participate in the rehabilitation training, leading to delayed recovery, increased length of hospital stay, and decreased patient satisfaction.[19,20] Our analyses revealed that the pain level and usage of opioid usage were significantly lower in patients having a drainage tube than those without. Furthermore, a significantly higher incidence of postoperative nausea and vomiting was observed in the non-drainage group, which may result in patients' poor oral intake, leading to hydro-electrolyte imbalance and increasing the need for intravenous fluid administration. Studies have shown that postoperative nausea and vomiting increase the length of hospital stay and the economic burden.[21]

The results show that the placement of a drainage tube after UKA reduces swelling of the knee joint swelling, lessens postoperative pain and opioid usage, facilitates early knee joint functional activities, and increases patient comfort and confidence in early rehabilitation training.Therefore, we recommend the placement of a drainage tube after UKA.However,there were limitations to this study. This was a retrospective study that included a relatively small sample size from a single center. Also, postoperative knee pain and nausea/vomiting might be multi-factorial and not solely due to the swelling of the knee joint or consumption of opioid-based analgesics, respectively. Therefore, a randomized control study is warranted to validate our findings.

AUTHORS' CONTRIBUTION: FT, RSZ, NY, FZQ, analyzed and interpreted the patient data regarding the hematological disease and the transplant. FT was a major contributor in writing the manuscript. All authors read and approved the final manuscript.

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PEDIATRIC ORTHOPEDIC

OSTEOCHONDRITIS DISSECANS OF THE HIP IN LEGG-CALVÉ-PERTHES DISEASE: CASE REPORT AND REVIEW

OSTEOCONDRITE DISSECANTE DO QUADRIL NA DOENÇA DE LEGG-CALVÉ-PERTHES: RELATO DE CASO E REVISÃO

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ABSTRACT

Introduction: Legg-Calvé-Perthes disease (LCPD) is the idiopathic osteonecrosis of the capital femoral epiphysis in children. It is a self-healing condition, and the morphology of the hip may vary according to the severity of the disease, among several other factors. The treatment focuses on attempts to prevent femoral head collapse, obtain functional hip motion recovery, and reduce pain. Osteochondritis Dissecans (OCD) of the femoral head has been reported in 2% to 7% of patients diagnosed with healed LCPD. Although OCD may remain asymptomatic, the osteochondral fragment has the potential to become unstable, evolving into symptoms of pain, locking, catching, and snapping. Case report: We present a case report of a ten-year-old boy with an OCD lesion following LCPD who underwent effective osteochondral fixation through the surgical hip dislocation approach. The patient evolved to excellent functional recovery at 1 year post-operatively. Discussion: The surgical hip dislocation approach allows anatomical fixation of the OCD fragment, as well as improvement of hip biomechanics, decreasing pain, improving range of motion and joint congruency, and preserving the native articular cartilage. It also gives the surgeon the opportunity to assess hip stability, femoroacetabular impingement and labral tears, allowing a wide variety of options for the treatment of the healed LCPD. ***Level of Evidence IV; Type of study Case Report.***

Keywords: Orthopedics. Orthopedic Procedures. Growth And Development. Growth Plate. Legg-Calve-Perthes Disease. Osteochondritis Dissecans.

RESUMO

Introdução: A Doença de Legg-Calvé-Perthes (DLCP) é a osteonecrose idiopática da epífise femoral proximal em crianças. É uma condição auto resolutiva, porém a morfologia final do quadril pode variar de acordo com a gravidade da doença. O tratamento concentra-se na tentativa de prevenir o colapso da cabeça femoral, obtendo recuperação funcional do movimento do quadril e redução da dor. A osteocondrite dissecante (OCD) da cabeça femoral foi relatada em 2% a 7% dos pacientes diagnosticados com DLCP já curada. Embora a OCD possa permanecer assintomática, o fragmento osteocondral tem potencial para se tornar instável, evoluindo para sintomas de dor, bloqueio, impacto e estalido. Relato de caso: Apresentamos o relato de caso de um menino de 10 anos com OCD da cabeça femoral após DLCP, submetido à fixação osteocondral do fragmento por meio da abordagem cirúrgica de luxação do quadril. O paciente evoluiu com excelente recuperação funcional 1 ano após a cirurgia. Discussão: A abordagem cirúrgica da luxação do quadril permite a fixação anatômica do fragmento da OCD, bem como a melhora da biomecânica do quadril, diminuindo a dor, melhorando a amplitude de movimento e a congruência articular e preservando a cartilagem articular nativa. Também dá ao cirurgião a oportunidade de avaliar a estabilidade do quadril, impacto femoroacetabular e lesões labrais, permitindo uma ampla variedade de opções para o tratamento das sequelas da DLCP. ***Nível de evidência IV; tipo de estudo Relato de Casos.***

Descritores*: Ortopedia. Procedimentos Ortopédicos. Crescimento e Desenvolvimento. Lâmina de Crescimento. Doença de Legg-Calve-Perthes. Osteocondrite Dissecante.*

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INTRODUCTION

Legg-Calvé-Perthes disease (LCPD) refers to idiopathic osteonecrosis of the capital femoral epiphysis in children.[1-4] It is a self-healing condition in which the blood supply to the capital femoral epiphysis spontaneously recovers by means of recanalization of pre-existing vessels that occurs precociously within weeks after the necrosis, or eventually formation of new vessels over a period of months to years.[1,4-7] The clinical onset of LCPD usually occurs in children

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The study was conducted at the Núcleo de Ortopedia Especializada in São Paulo, São Paulo, SP, Brazil.
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between ages of four and eight years, with the condition being five times more common in males than females.[1,2,5] During the healing process, abnormal proximal femoral growth results in varying deformities, which predisposes to hip joint incongruity, femoroacetabular impingement, chondrolysis and labral tears.[8-11] The clinical management of Perthes' disease focuses on attempts of preventing femoral head collapse, obtaining functional recovery of the hip motion and reduction of pain.[2,8,12] The prognosis of the hip joint affected by LCPD depends on the age of the patient at the time of onset, patient weight, the stage of the disease, the extent of epiphyseal involvement, height of the lateral pillar and the extrusion of the femoral head.[5,8,10,13]

Osteochondritis Dissecans (OCD) of the femoral head has been reported in 2% to 7% of patients diagnosed with LCP disease.[9,14] These lesions often remain asymptomatic, although the osteochondral fragment may become unstable and release articular loose bodies, producing symptoms of pain, locking, catching and snapping.[2,9,12,14] Patients with osteochondral lesions of the femoral head are at risk of rapid progression to symptomatic osteoarthritis of the hip joint.[15-17] The surgical hip dislocation approach has been used to assess both intra-articular and extra-articular abnormalities around the hip joint as it is capable of addressing residual deformities of the proximal femur in patients with healed LCPD.[6,8-11]

In this case report, we present a patient with an OCD lesion following Perthes disease treated through a surgical hip dislocation approach. It was possible to effectively treat the OCD lesions and preserve the native articular cartilage, avoiding alternative cartilage substitution techniques as salvage procedures.

This report was structured according to the CAse REport (CARE) guidelines checklist, in order to capture useful clinical information and key components from the case.[18]

Case report

We present the case of a boy who developed a right-sided limp at the age of ten (April, 2017). He was diagnosed with LCPD and underwent conservative treatment with physiotherapy, and weight bearing restrictions using a wheelchair followed by two crutches during 28 months. At the reossification stage (IIIB) of the disease, the boy was asymptomatic, although the radiographs showed an abnormal hip morphology with flattening of the femoral head, coxa magna and brevis. Four years after the beginning of the symptoms (June, 2021, at the age of fourteen), he presented with hip pain, limping and a limited range of motion of the right hip (flexion up to 90 degrees, internal rotation up to 15 degrees, abduction up to 15 degrees).

Radiographs showed a possible loose osteochondral fragment inside the joint, detached from the central part of the femoral head (Figure 1). The contrast-enhanced magnetic resonance imaging (MRI) showed an unstable osteochondral fragment measuring 28 x 22 mm with surrounding bone edema (Figure 2). In addition, flattening of the femoral head, shortening of the femoral neck and synovitis were noted. The computed tomography (CT) scan evidenced an unstable osteochondral fragment with similar proportions as shown by the MRI. (Figure 3)

Conservative treatment for the OCD was instituted with partial weight bearing, non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy for eight weeks with no improvement. Therefore, open reduction and internal fixation of the osteochondral fragment was indicated. At this time point, his Harris Hip Score (HHS)[19] was 64,325.

Surgical Technique

The patient underwent OCD fragment fixation using the surgical dislocation approach as described by Ganz et al.[11] The patient was positioned in left lateral decubitus stabilized with cushions. An incision was made over the greater trochanter in its central axis, going from 30 mm above its tip to 50 mm below its bottom part. The approach was carried through the subcutaneous tissue, sectioning the fascia lata and blunch division of gluteus maximus. The bursa was divided. The piriform tendon was identified at its trochanteric insertion. A straight trigastric osteotomy was performed at the greater trochanter with an oscillating saw, preserving the attachments of the vastus lateralis, gluteus medius and minimus. The greater trochanter was retracted anteriorly and the capsule was exposed. A "Z" shaped capsulotomy was performed, the

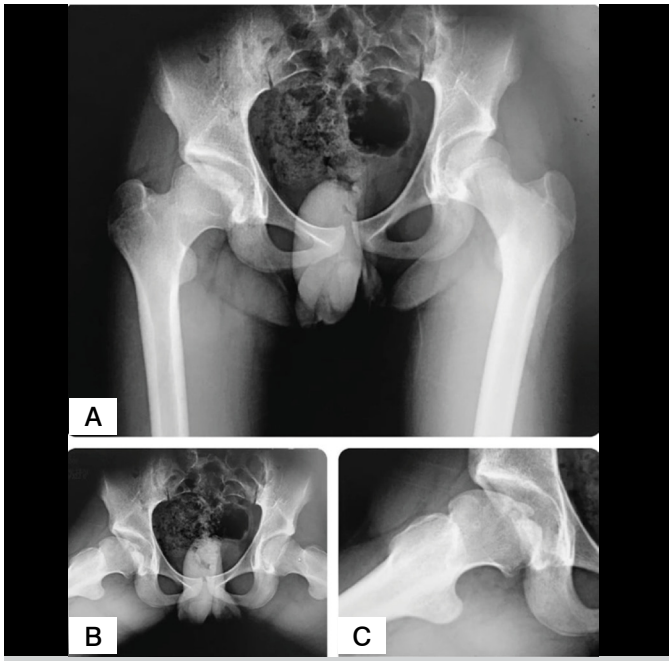

Figure 1. Pelvis AP (A), Frog-leg (B) and close view (C) of the right hip in the Frog-leg view radiographs. Note an osteochondral fragment in the central part of the femoral head. In the Frog-leg view, the fragment appears to be detached from its bony base.

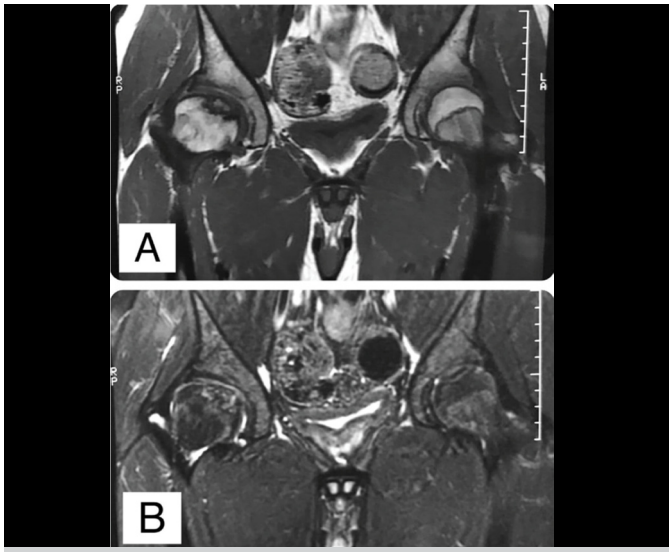

Figure 2. Magnetic Resonance Images (MRI) of both hips in the coronal view. A. T1-weighted MRI showing a non-perfused area surrounding the osteochondral fragment. B. T2-weighted MRI showing intra articular synovitis and edema around the OCD fragment. Note that the articular cartilage has a step-deformity due to a slight elevation of the unstable OCD fragment.

ligamentum teres was sectioned and the hip was successfully dislocated. (Figure 4)
The second part of the procedure involved the treatment of the OCD lesion. (Figure 5) First, the osteochondral fragment was gently freed from its bony base using a Freer elevator, then the underlying bony bed was debrided using a curette and multiple micro perforations were made using a 0.88 mm guidewire in order to enhance bleeding and facilitate anatomic reduction and healing of the osteochondral fragment (Figure 6). The fragment was temporarily secured using guidewires and then fixed definitively with three 1.5 mm cannulated headless compression screws (Acutrak; Acumed, Hillsboro, OR) below the surface of the joint (Figure 7). Anatomic reduction and stability were visually assessed and confirmed radiographically after the fixation. There were no labral tears or impingement following reduction of the femoral head into the acetabulum.
The capsule was loosely repaired with absorbable sutures. The greater trochanter was advanced about 1 cm and fixed with two 6.5 mm partially threaded cannulated screws with washers. The wound was closed in a standard fashion and the patient was immobilized with an abduction cushion after the procedure.

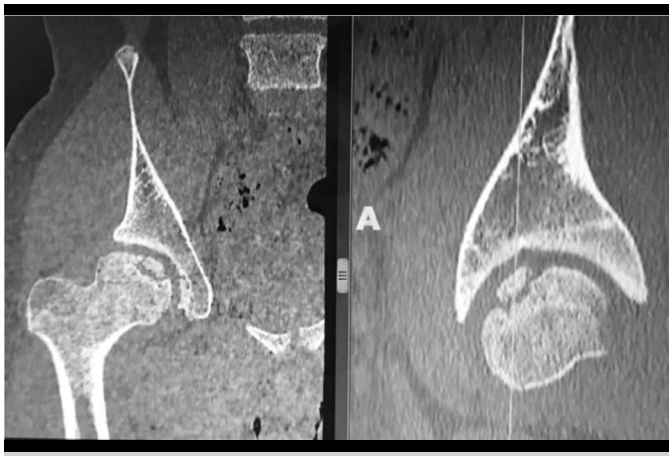

Figure 3. Computed tomography (CT) scan in the coronal (left) and axial (right) views. Note the elevation of the osteochondral (OCD) fragment in both views. There is no visible bone connection between the OCD fragment and the remaining of the femoral head.

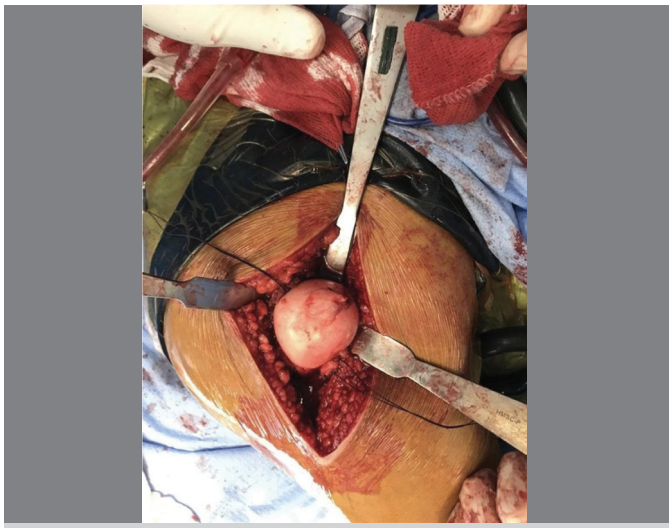

Figure 4. Femoral head after surgical hip dislocation. Note the ovoid shaped head and the limits of the central unstable Osteochondral Fragment. The osteochondral fragment is connected with the stable cartilage tissue.

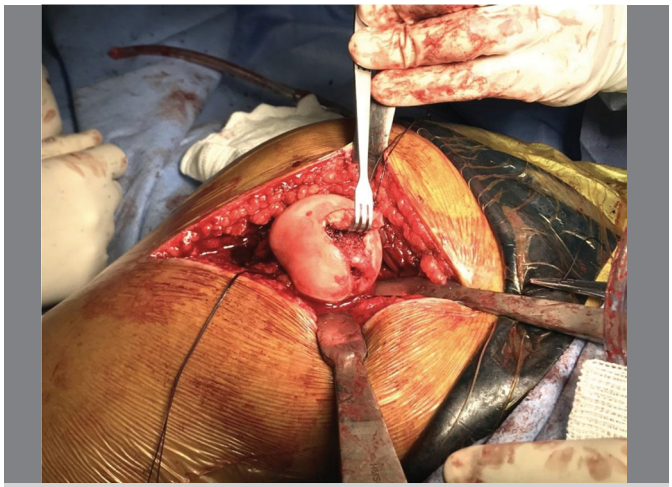

Figure 5. Picture showing the Osteochondral Fragment detached from its bony base after dissection with a Freer elevator, preserving the cartilage bridge connection.

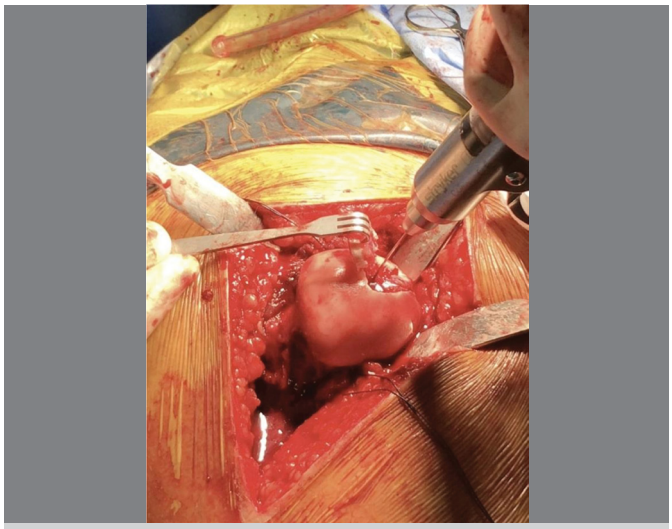

Figure 6. Multiple micro perforations were carried out using a 0.88 mm guidewire. Note the presence of blood at the deepest part of the lesion, showing adequate blood supply coming from the metaphysis for the healing of the Osteochondral Fragment after fixation.

Post Operative Care

The patient was discharged from the hospital 1 day after the procedure, immobilized in an abduction wedge cushion. Physiotherapy was initiated immediately with passive range of motion of the right hip, with exception of adduction and external rotation to protect against unwanted capsule suture failure and joint dislocation . Sitting was allowed as tolerated and no weight bearing was allowed for 8 weeks.
The patient was seen in a 2 week interval during the first 8 weeks. After that, the patient was seen monthly until the 6th month postoperative. Radiographs were taken in each one of these visits. After great trochanter healing at the 6th week after surgery, active range of motion exercises and hip external rotation were initiated. The patient began partial weight bearing around the 8th week and gradually transitioned to full weight bearing until the 12th week. The OCD fragment healing was visible at 12th week postoperative. The physiotherapy program was continued through the first 6 months postoperative and no impact sports, running or jumping

were allowed during this period. After the 6th month postoperative the patient was allowed to resume his physical activities as he used to practice before the onset of symptoms. (Figure 8)
At the latest follow-up visit 1 year postoperative, the patient presented improvement of the range of motion of the right hip (flexion up to 110 degrees, internal rotation up to 30 degrees, abduction up to 30 degrees), and was asymptomatic. His Harris Hip Score (HHS)[19] at the final follow-up improved from 64,325 to 97, and the Trendelenburg test improved from positive to leveled.

Patient Perspective

To evaluate the patient's quality of life, the Harris Hip Score (HHS)[19] was applied before surgical treatment and after complete rehabilitation. It was assessed pain, function, deformity and mobility.

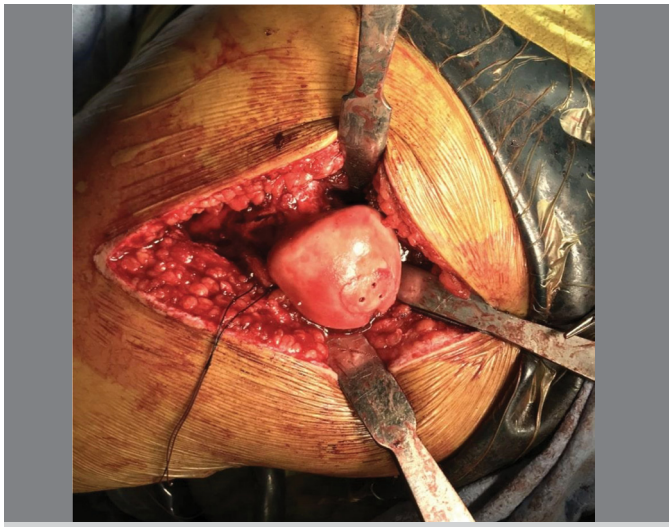

Figure 7. Final clinical picture after fixation of the Osteochondral Fragment with three 1.5 mm cannulated headless compression screws (Acutrak; Acumed, Hillsboro, OR). The fixation was stable and the borders of the lesion were smooth, demonstrating a good reduction.

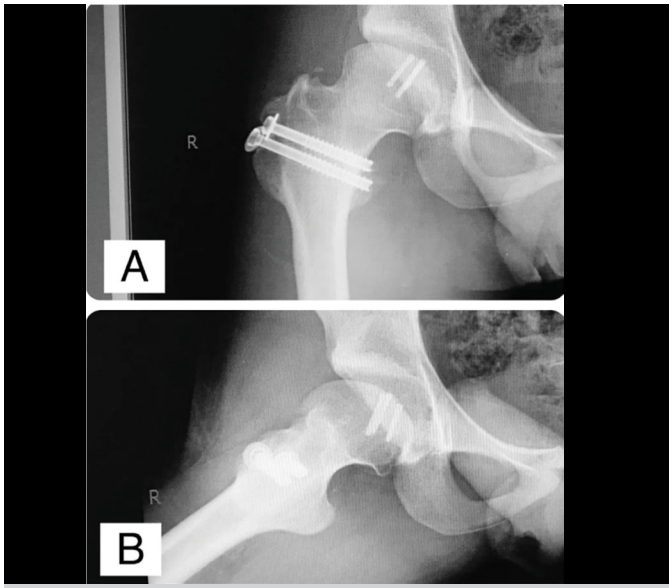

Figure 8. AP view (8A) and Frog-leg view (8B) of the right hip, in the 10th month postoperative. There's complete healing of the Osteochondral Fragment. The great trochanter was also healed and distalized. The implants did not bother the patient and were not removed.

At 1 year postoperative, he scored a total of 97 out of 100 with a leveled Trendelenburg gait. The patient reported no pain, no difficulty in walking, being able to walk unlimited distance and to go up and down stairs without support. He also reported being able to put on his shoes without difficulty and to sit comfortably in a chair for an hour.

DISCUSSION

LCPD is characterized by unilateral or bilateral necrosis of the femoral head, which results from a proximal femoral epiphysis ischaemia of unknown etiology and affects the range of motion of the hip.[1-4,6,7,9] Age at disease onset and diagnosis, sex, range of motion of the hip and severity of the disease / necrosis are considered potential prognostic factors in LCPD. Despite early treatment efforts, many patients evolve with residual femoral head deformity that may be symptomatic with a residual limp and decreased hip motion[1-3,10,12,13]
OCD is rare as an isolated cause of late pain following LCPD. It has been reported to occur in 2% to 7% of the patients that present with LCPD.[9,14] These lesions often remain asymptomatic and require nonoperative treatment, unless the fragment is loose, causing locking, catching, pain, limping and limited range of motion.[6,8-10] The symptoms were observed in our patient four years after the onset of LCPD. For these symptomatic patients, there are basically four treatment options: OCD fragment fixation, osteochondral autograft transfer (OAT), fresh osteochondral allograft and OCD fragment arthroscopic resection.[14-17]
Lamplot et al,[9] in a study of 64 patients treated with hip preservation surgery for LCPD, reported that the 7 patients (7 hips) who underwent surgical hip dislocation and ORIF of femoral head OCD had significant improvement in internal rotation in flexion at final follow-up. The authors observed radiographic healing without evidence of implant failure and no progression of osteoarthritis. All 7 patients also reported marked clinical improvement with resolution of pain and mechanical symptoms at final follow-up.
Surgical hip dislocation has been used to address both intra-articular and extra-articular abnormalities around the hip joint as it is capable of addressing residual deformities of the proximal part of the femur in patients with healed LCPD.[8-12]
In this report, the patient underwent a surgical dislocation approach as described by Ganz et al,[11] who developed the technique after remarkable understanding of the blood supply to the femoral head and the ability to safely dislocate the hip. The surgical hip dislocation approach permitted assessment and treatment of the OCD lesion with reduction of the osteochondral fragment, as described by Lamplot et al.[9] A relative neck lengthening is also possible by means of distalization of the trochanteric flap, providing improvement in hip biomechanics, as this last restored both abductor tension and abductor lever arm.
This case report has several strengths. To the best of our knowledge, this is the 8th case reported in the literature performing this technique, following its description by Lamplot et al.[9] Our results also support the hypothesis that, when possible, surgical interventions for cartilage restoration should first attempt to preserve the patient's native articular cartilagem.[9,15,16] Furthermore, we included an objective quality of life questionnaire (HHS) that showed a good clinical outcome at final follow-up.
A limitation of this report is related to its retrospective nature and all the biases associated with it. Also, we didn't have the opportunity to collect a new scanogram to analyze a possible leg length discrepancy at final follow-up, which could be related to the mild improvement in his Trendelenburg Gait. MRI and CT scans at his last visit were also not available. In addition, the follow-up time was relatively short (one year), although the patient had already reached a healed stage of the disease and showed improved outcomes.

In conclusion, the surgical hip dislocation and OCD fragment fixation technique has been found to be beneficial in many aspects. The surgery allowed simultaneous approach to the intra-articular lesion, as well as it restored the proper hip biomechanics, decreasing pain, improving range of motion and joint congruency, while preserving the original cartilage of the patient's hip. It also gives the surgeon the opportunity to assess hip stability, the presence of femoroacetabular impingement and labral tears, allowing a wide variety of options for the treatment of the healed LCPD.

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