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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed April 2022)

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

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ACKNOWLEDGEMENTS

When applicable, briefly acknowledge the people who have contributed intellectually or technically to the study, but whose contribution does not justify authorship. The author must ensure that people agree to have their names and institutions disclosed. Financial support for the research and fellowships should be acknowledged in this section (funding agency and project number).

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

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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

VOLUME 31 – Nº 3 – Especial – 2023

Original Article

PHYSIATRIST

PHENOL VERSUS LIDOCAINE IN OBTURATOR NERVE NEUROLYSIS FOR HIP JOINT PAIN

FENOL CONTRA LIDOCAINA EM NEURÓLISE DO NERVO OBTURADOR PARA DOR ARTICULAR DO QUADRIL

CHIARA MARIA THA CREMA, LUIZA PREVIATO TREVISAN MAGARIO, WILIAN CARLOS SIENA, NICOLE MARQUES FAVATO, THABATA PASQUINI SOEIRA, MARCELO RIBERTO

DOI: http://dx.doi.org/10.1590/1413-785220233103e266865

SPINE

EPIDEMIOLOGY OF TRAUMATIC FRACTURES OF THE SPINE IN MARIO COVAS HOSPITAL BETWEEN 2015 AND 2020

EPIDEMIOLOGIA DAS FRATURAS TRAUMÁTICAS DA COLUNA NO HOSPITAL MARIO COVAS ENTRE 2015 E 2020

CÁSSIO BOUSADA FRANCO, PEDRO HENRIQUE SWINERD COELHO DA CRUZ, CAIO CESAR LUCCHESE MORENO, IGOR OLIVEIRA MENESES, LARA GUERCIO DOS SANTOS, ANTONIO CARLOS FONTOURA JUNIOR, THIAGO KOLACHINSKI BRANDÃO, LUCIANO MILLER REIS RODRÍGUEZ, ADRIANO MASAYUKI YONEZAKI

DOI: http://dx.doi.org/10.1590/1413-785220233103e267571

TRAUMA

HUMERAL SHAFT FRACTURE WITH AN INTACT WEDGE FRAGMENT: MIPO VS CONVENTIONAL PLATING

FRATURAS DIAFISÁRIAS DE ÚMERO COM CUNHA INTACTA: MIPO X ESTABILIDADE ABSOLUTA COM PLACA

JORGE HENRIQUE HIGASHI, FELIPE CRUZ CAETANO DOS REIS, CAIO FILIPE ANTUNES GUIMARÃES, RICARDO DEBUSSULO DE LIMA, FERNANDO BRANDAO ANDRADE-SILVA, JORGE DOS SANTOS SILVA, KODI EDSON KOJIMA

DOI: http://dx.doi.org/10.1590/1413-785220233103e268121

WEDGE FRAGMENT VARIATIONS OF TIBIAL SHAFT FRACTURES WITH INTRAMEDULLARY NAILING

FRAGMENTO EM CUNHA DAS FRATURAS DA DIÁFISE DA TÍBIA COM HASTE INTRAMEDULAR

MARIO SERGIO BOFF, PEDRO HENRIQUE DE OLIVEIRA PAOLUCCI, GABRIEL MACHADO DE OLIVEIRA, LEONARDO ZANESCO, FERNANDO BRANDAO ANDRADE-SILVA, MARCOS DE CAMARGO LEONHARDT, PAULO ROBERTO DOS REIS, JORGE DOS SANTOS SILVA, KODI EDSON KOJIMA

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DORSALIS PEDIS NEUROVASCULAR FLAP, OUR EXPERIENCE

RETALHO NEUROVASCULAR DORSAL DO PÉ, NOSSA EXPERIÊNCIA

Sérgio Aparecido do Amaral Júnior[1], Bárbara Letícia Ferreira de Carvalho[1], Antonio Clodoildo Andrade Júnior[1], Maurício Benedito Ferreira Caetano[2], Luiz Angelo Vieira[3], Edie Benedito Caetano[3]

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ABSTRACT

Objective: Analyze the donor site morbidity of the dorsalis pedis neurovascular flap in traumatic injuries with hand tissue loss. Material and Methods: The study involved dorsalis pedis neurovascular flaps that were used to reconstruct the hands of eight male patients, between 1983 and 2003, aged between 21 and 53 years (mean 34.6, SD ± 10.5 years). The size of the lesions ranged from 35 to 78 cm2 (mean 53, SD ± 14.4 cm2). Surgical procedures were performed two to 21 days after the injuries had occurred. The patients were followed up for an average of 10.3 years (ranging 8–14, SD ± 2.1 years). Results: Regarding the donor site, in one case there was hematoma formation, which was drained; in another case, the skin graft needed to be reassessed. All patients experienced delayed healing, with complete healing from 2 to 12 months after the surgery (mean 4.3, SD ± 3.2 months). Conclusion: Despite the advantages of the dorsalis pedis neurovascular flap, we consider that the sequelae in the donor site is cosmetically unacceptable. Nowadays, this procedure is only indicated and justified when associated with the second toe transfer. ***Level of Evidence IV; Case series.***

Keywords: Postoperative Complications; Lower Extremity; Upper Extremity; Foot; Surgical Flaps.

RESUMO

Objetivo: Analisar a morbidade da área doadora do retalho neurovascular do dorso do pé em lesões traumáticas com perda de tecido da mão. Material e métodos: O estudo envolveu retalhos neurovasculares do dorso do pé usados para reconstruir as mãos de oito pacientes do sexo masculino, entre 1983 e 2003, com idades entre 21 e 53 anos (média de 34,6, DP ± 10,5 anos). O tamanho das lesões variou de 35 a 78 cm2 (média de 53, DP ± 14,4 cm2). Os procedimentos cirúrgicos foram realizados entre dois a 21 dias após a ocorrência das lesões. Os pacientes foram acompanhados por uma média de 10,3 anos (variando de 8 a 14, DP ± 2,1 anos). Resultados: Quanto ao local doador, em um caso houve formação de hematoma, que foi drenado; em outro caso, o enxerto de pele precisou ser reavaliado. Todos os pacientes apresentaram retardo na cicatrização, com cicatrização completa de 2 a 12 meses após a cirurgia (média de 4,3, DP ± 3,2 meses). Conclusão: Apesar das vantagens do retalho neurovascular do dorso do pé, consideramos que as sequelas no local doador são cosmeticamente inaceitáveis. Atualmente, esse procedimento só é indicado e justificado quando associado à transferência do segundo dedo do pé. ***Nível de evidência IV; Série de casos.***

Descritores: *Complicações Pós-Operatórias; Extremidade Inferior; Extremidade Superior; Pé; Retalhos Cirúrgicos.*

Citation: Amaral Júnior SA, Carvalho BLF, Andrade Júnior AC, Caetano MBF, Vieira LA, Caetano EB. Dorsalis pedis neurovascular flap, our experience. Acta Ortop Bras. [online]. 2023;31(3)Esp.: Page 1 of 4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

It is a challenge to properly cover complicated injuries of the extremities, especially hand lesions and whenever structures such as bones, tendons, nerves, and blood vessels are exposed. Studies have described different types of flaps to cover such injuries[1-3]. The dorsalis pedis artery island flaps were originally introduced by McCraw and Fulow[4]; Ohmori and Harii[5] improved the technique using a neurovascular free flap in hand reconstruction for the restoration of hand sensibility[3-5].

The dorsalis pedis neurovascular flap is a fasciocutaneous flap supplied by branches of the dorsal artery of the foot, which may present anatomical variations[6-10]. In 83% of cases, it originates from the anterior tibial artery[6], which may be absent, or it may originate from the fibular artery[6,8]. The venous return is performed by the principal and internal saphenous veins; the innervation is through the superficial and deep fibular nerves[4,8]. Some advantages of this type of flap make it ideal for coverage of hand wounds as it has the potential benefit of being thin and pliable, the anatomical structure is similar to the soft tissue of the hand, its pedicle is fairly long, and its vascular anatomy is reliable. Moreover, it can be easily harvested, with potential to include vascularized structures such as bones and tendons, as well as the superficial and deep peroneal nerves. It also allows restoration of sensibility in the recipient site[7,11].

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

The study was conducted at the Pontifícia Universidade Católica de São Paulo (PUC), Faculdade de Ciências Médicas e da Saúde, Sorocaba, SP, Brazil.
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However, the use of this flap has been plagued by questions over sequelae in the donor site[12-15]. The aim of this study was to present the results of eight cases in which dorsalis pedis neurovascular flaps were used for the treatment of hand injuries, and to evaluate if this type of flap would be indicated for such cases at the present moment.

MATERIAL AND METHODS

The study evaluated eight hand reconstruction procedures with dorsalis pedis neurovascular flap transfers between the years 1983 and 2003. The mean age of patients was 34.6 ± 10.5 years, ranging from 21 to 53 years old, and they were all male. The hand reconstruction procedures were carried out in six right hands and two left hands. Most of the hand injuries studied were caused by mechanical trauma. Three were caused by a press machine, three were pinch point injuries, one was a crush injury from a motorcycle accident, and one was caused by electrical burn.

The size of the lesions, measured with a millimeter ruler, ranged from 35 to 78 cm2 (mean of 53 ± 14.4 cm2). None of the patients had loss of bone or tendon tissue; one patient had the index finger amputated, and another patient lost the index, middle, ring, and little fingers. The surgical procedures were performed from 2 to 21 days after the injuries occurred.

Regarding the recipient sites, three flaps were used to cover the palm of the hand (Figure 1), two to cover the palm and first commissure, one to cover the radial side of the hand and middle finger (Figure 2), one was associated with the transfer of the second toe (Figure 3), and one was used to cover a completely degloved hand.

In the preoperative period, the patency of the dorsalis pedis artery was examined by the palpation method or by a Doppler test. With a pneumatic tourniquet between the hallux and the second toe, we proceeded with the distal flap elevation. The mechanical separation of the first and second metatarsal bones enabled the visualization of the first dorsal metatarsal artery to start the dissection. The fascia was included in the flap to avoid separation of the flap artery. The pedicle was only detached from the donor site once the recipient site was adequately prepared.

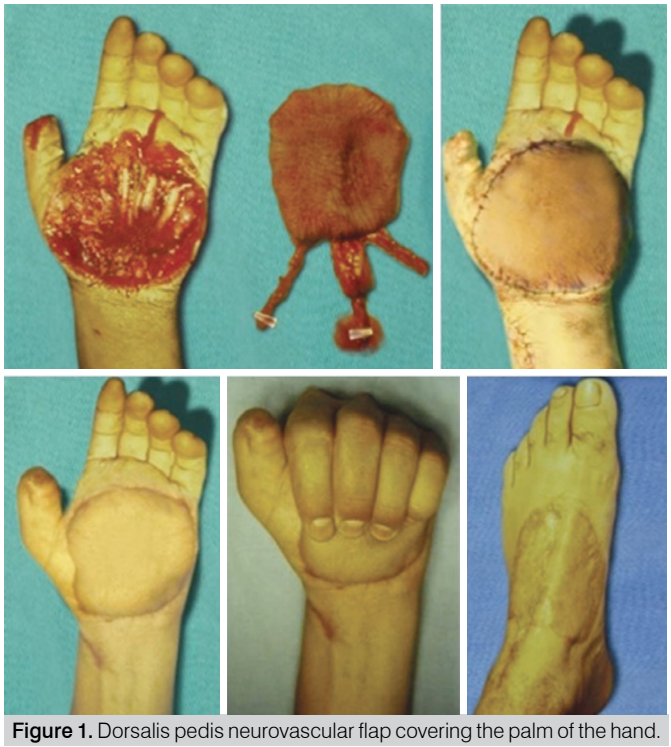

Figure 1. Dorsalis pedis neurovascular flap covering the palm of the hand.

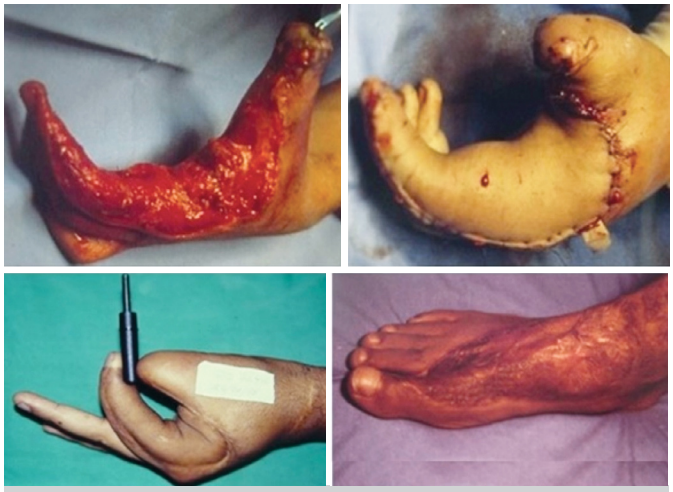

Figure 2. Dorsalis pedis neurovascular flap associated with the first commissure to properly cover the radial side of the hand and middle finger.

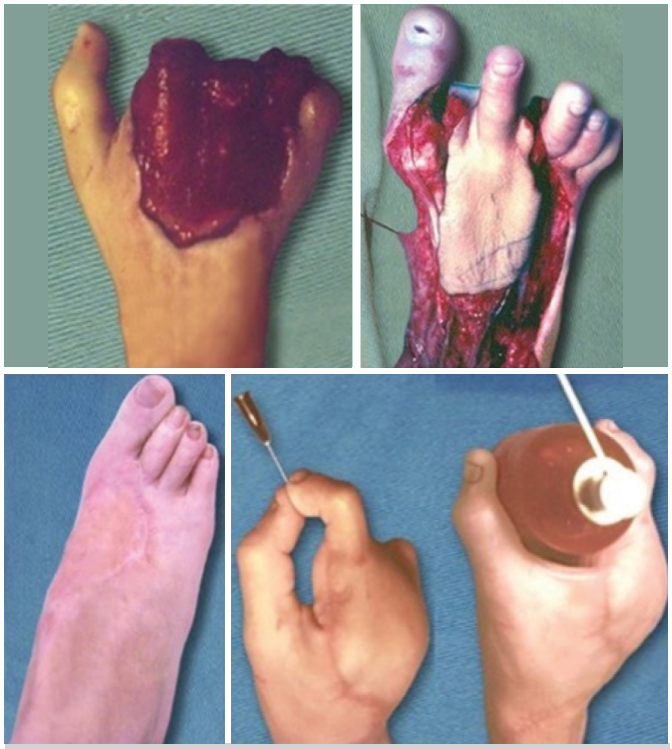

Figure 3. Dorsalis pedis neurovascular flap associated with the transfer of the second toe.

End-to-side anastomosis were performed outside the area of injury. A skin graft was performed immediately after the flap transfer in two limbs, and the other six patients received a graft seven to ten days after the flap transfer. The mean follow up period was 10.3 years (8 to 14 ± 2.1 years).

RESULTS

One patient experienced loss of a small portion of the skin graft by secondary intention healing; another patient had a hematoma that was drained, and all patients had delayed healing beyond 30 days. Healing was completed between 2 and 12 months (mean 4.3 ± 3.2 months).

Restoration of protective sensation was observed in all patients, and all flaps survived. Although no patient had donor or recipient site

infections, all of them experienced significant donor site morbidity, especially delayed healing. Table 1 summarizes the data reported in Methods and Results.

DISCUSSION

In this study we employed the dorsalis pedis neurovascular flap in 8 patients with the purpose of restoring sensibility in critical areas of the hand. We agree that no other flap described in literature provides comparable results regarding the return of sensibility[11]. The protective sensation was restored in all 8 patients; however, we deem the donor site morbidity to be unacceptable. We believe that the use of this flap would be justified only in case 4 of this study, where the flap was transferred along with the second toe for reconstruction of the digital commissure.

Some authors have reported that the sequelae in the donor site are not significant[4,12,15-19], while other authors consider donor site morbidity to be unacceptable[11,12,20-24].

Samson et al.[12] report that donor site morbidity is significant, and they recommend that this flap should only be used when there are no other options available. To avoid more serious sequelae, the authors recommend that the flap should not be extensive, and the distal edge should be at least 2 cm proximal to the digital commissures.

McCraw and Furlow[4] report that 11 patients were treated with a dorsalis pedis neurovascular flap, and the donor site morbidity was negligible. Healing was delayed in some patients, but the cosmetic appearance of the donor site was acceptable. They recommend close attention to the donor site trauma to avoid delayed healing.

Ohmori et al.[5] successfully transferred dorsalis pedis neurovascular flaps in five patients. The cosmetic appearance of the donor site was not mentioned in their study.

Krag and Niegels[15], report that the dorsalis pedis pedicled island flap was used in 13 patients and the intended purpose was achieved in 12 cases (92.3%). They considered the donor site morbidity to be insignificant.

For Ismail[20] the resulting sequelae are significant. To avoid damage to the donor site, the flap should have small dimensions that allow primary closure of the donor site. For the author, the need of a skin graft may cause significant damage due to delayed healing.

On the other hand, Hallok[21] considers that direct donor site closure can be problematic, and the damage could be more significant than those resulting from the use of skin grafts.

For Schlenker et al.[17], who studied 9 free flaps transfers including 3 dorsalis pedis flaps, the damage to the donor site was not significant.

Daniel and Weilan[23] report to have performed 18 free flap transfers for hand reconstruction. Two of the cases involved dorsalis pedis neurovascular flaps and there was restoration of sensibility. Healing in the donor site was delayed in both cases; one of the cases had periodic ulceration, and the healing process occurred after 18 months.

Zuker and Manktelow[11] state that the ideal flap to cover areas must include the superficial and deep peroneal nerves, for sensibility is of utmost importance. For the authors, a careful dissection with preservation of the paratenon of the toe and hallux will minimize donor site damage. They report that the distal edge of the flap must remain at least two centimeters proximal to the digital commissures. Moreover, they observed that the flaps extending to the first commissure did not heal properly.

Caroli et al.[16] used dorsalis pedis neurovascular flaps in three patients. Extensor tendons were incorporated into the flaps to cover areas with loss of skin and tendons on the dorsum of the hand. They report that there was delayed healing in two of the cases because the flaps were long, and the aesthetic result of the dorsum of the foot was not acceptable.

Vila Rovina et al.[22] believe that an extensor tendon transfer combined with a dorsalis pedis flap is an excellent technique to repair hand tissue defects. However, they consider the donor site morbidity to be significant and recommend that such technique is only used when there are no other options available. In one of the cases, the authors transferred the second toe with the dorsalis pedis neurovascular flap for reconstruction of the digital commissure.

Wang et al.[24] used the dorsalis pedis neurovascular flap combined with toe transfer in 15 patients with hand injuries. All flaps survived. At 34.8 months of follow-up, the average subjective satisfaction score was 8. Eleven patients (73.3 %) experienced cold intolerance, dysesthesia, and delayed healing.

Morrison et al.[19], performed toe transfers in 44 patients, and dorsalis pedis flap was used in 6 of the procedures. For the authors, the

Table 1. General summary of the informations contained in Methods and Results.

Donor site	Recipient site	Flap size (cm^2)	Infections	Morbidity	Complications	Healing period(meses) (months)	Sensibility mão	Follow up (years)(anos)
Dorsum of the foot	Palm of the hand	35	N	Y	N	4	Y	10
Dorsum of the foot + hallux	Palm of the hand + middle finger	72	N	Y	N	3	Y	8
Dorsum of the foot	Palm of the hand + 1st commissure	46	N	Y	N	3	Y	10
Dorsum of the foot + 1st commissure	Hand degloving	78	N	Y	Partial lost of the flap	12	Y	12
Dorsum of the foot + 2nd toe	Dorsum qof the hand + digital commissure	50	N	Y	N	3	Y	14
Dorsum of the foot	Palm of the hand	45	N	Y	N	2	Y	9
Dorsum of the foot	Palm of the hand + 1st commissure	48	N	Y	Bruise	5	Y	12
Dorsum of the foot	Palm of the hand	50	N	Y	N	3	Y	8
		53				4,3		10,3
		35				2		8
		78				12		14
		14,4				3,2		2,1

donor site morbidity was not insignificant; delayed healing occurred frequently, but they believe the functional results were beneficial. Han et al.[18] treated 25 patients with hand degloving injury using the dorsalis pedis flap associated with the first commissure flap and other flaps. Although they observed ulcer formation and delayed healing in some of the patients, the results were satisfactory.

Study limitations

Despite the advantages provided by the dorsalis pedis neurovascular flap, we consider that the sequelae in the donor site is cosmetically unacceptable. Nowadays, this procedure is only indicated and justified when associated with the transfer of the second toe, as seen in case 4 of this study.

CONCLUSION

The flap studied proved to be effective for restoration of protective sensation. As for the cosmetic aspect of the donor site, the results are questionable. We considered the best indication to be a combination of the flap with the transfer of the second toe.

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EFFECT OF WRIST WRAP IN HANDGRIP STRENGTH IN CROSSFIT

INFLUÊNCIA DA MUNHEQUEIRA NA FORÇA DE PREENSÃO MANUAL EM PRATICANTES DE CROSSFIT

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ABSTRACT

Objective: Analyze wrist wrap influence on the values of maximum handgrip strength and dynamic resistance. Methods: A controlled randomized cross-over trial including 54 Crossfit participants randomly assigned to two groups. Group 1 began the series of tests with control wrapping, and Group 2 started with functional wrapping. Alternate series of four dynamic grip strength resistance tests were performed, and the resistance and fatigue values were calculated. Results: The values obtained from the grip tests did not indicate any effect from the wrist wrap for an increase in maximum grip strength (35.7 vs. 35.6 kg; p=0.737) or greater endurance (78.2 vs. 77.8%; p=0.549). Fatigue was also equal in both groups (mean differences between the groups: 0.1 kg, CI= -0.7–0.8; p=0.779). Conclusion: The hypothesis that using a wrist wrap increases maximum strength and dynamic handgrip endurance was rejected in this study. ***Evidence Level I; Randomized control trial.***

Keywords: Sports; Sports Equipment; Wrist; Hand Strength.

RESUMO

Objetivo: Analisar a influência do uso da munhequeira no valor máximo de força e na resistência dinâmica de preensão palmar. Métodos: Foi feito um ensaio controlado randomizado cruzado (cross-over) incluindo 54 praticantes de Crossfit. Os participantes foram alocados em dois grupos de forma aleatorizada. O grupo 1 iniciou a bateria de testes com enfaixamento placebo e o grupo 2 iniciou com enfaixamento funcional. Séries alternadas de quatro testes dinâmicos de resistência foram realizadas e os valores de resistência e fadiga foram calculados. Resultados: Os resultados apontaram para uma ausência de efeito do enfaixamento do punho tanto para um suposto aumento da força máxima de preensão (35,7 vs 35,6 kg; p=0,737) quanto para uma maior resistência (78,2 vs 77,8%; p=0,549). A fadiga também foi igual entre os dois grupos (média das diferenças entre os grupos: 0,1kg, CI: -0,7 – 0,8; p=0,779). Conclusão: A hipótese de que o uso da munhequeira aumenta o valor máximo de força e a resistência dinâmica de preensão palmar foram rejeitadas neste estudo. ***Nível de evidência I; Estudo clínico randomizado.***

Descritores: *Esportes; Equipamentos esportivos; Punho; Força da mão.*

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INTRODUCTION

Crossfit is a training and conditioning program that has gained significant recognition and popularity worldwide among the physically active population. It is based on a set of exercises, including running, Olympic weightlifting, Olympic gymnastics and ballistic movement.[1] In this context, having greater manual grip strength would allow lifting more weight, and greater grip resistance would secure the weight longer and increase the number of repetitions of certain movements, improving performance.

Many Crossfit participants use wrist wrap during training because it is believed to increase grip strength. However, despite being widely used by Crossfit participants, little is known about the effects of using wrist wraps on the hand regarding grip strength. The idea that using a wrist wrap can increase grip strength is not new.[2] In 1997 Rettig et al. in a study with young American football athletes, showed that wrapping the wrist did not increase maximum hand grip strength and, considering only the dominant side, even decreased in value[(2)]. Two more recent studies, in 2014 and 2013,[3,4] showed that pressure exerted on the wrist may not influence the maximum grip strength value and may even reduce it, depending on the pressure and the properties of the material used to compress the wrist. As for dynamic grip strength resistance, the most important aspect and one that would directly influence performance, we did not find any data in the literature that measured the influence of the wrist wrap.

The objective of this test is to hypothesize that using a wrist wrap can increase the maximum grip strength and endurance.

METHODS

Study design

A controlled randomized cross-over trial was evaluated and approved by the Institutional Review Board of IGESP Hospital

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

The study was conducted at the Instituto Vita, Department of Hand and Wrist Surgery, São Paulo, Brazil.
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(approval 35643920.3.0000.5450). All participants signed the informed consent form. The mean values and standard deviation previously published[5] were used. The sample size of 54 participants was calculated for this cross-over study to detect a 5kg hand grip difference between the groups in two-sided tests with 80% power and a 5% significance level.

Inclusion and exclusion

Participants were screened in a CrossFit training center. The inclusion criteria were: to be an amateur Crossfit athlete with at least six months of regular sports practice (at least four times a week), between 18 and 40 years, agree to participate in the study, and sign the informed consent form. The exclusion criteria were: active pain on the day of the test (VAS scale pain score higher than 3 out of 10 in the shoulder, forearm, wrist and/or hand), history of wrist injury in the previous six months, previous wrist surgery.

Study groups

Because this is a cross-over study, all participants underwent tests with the control and functional wrapping (intervention; Figure 1). To minimize the confounding effect of the order that would be defined at the beginning of the tests, the participants were randomly separated into two study groups (1:1 ratio): Group 1, performing the test with the control wrapping first, and Group 2, completing the functional wrapping test (intervention) first. The random sequence was generated using the GraphPad online program (GraphPad Software(R), San Diego, USA). A single author was responsible for generating the random allocation sequence and only revealed the allocation of a participant when the other author successfully completed an enrollment. Due to the required procedures, it was not possible to blind neither the researcher nor the participant.

Procedures and data collection

Tests were performed in a CrossFit training center. Fabric wrist wraps 35 inches in length by 3 inches in width (Rogue Fitness®, Columbus, USA) were used as test intervention in both groups in this study. As no user manual is available, the researcher applied them standardized to simulate the conditions under which they are normally used in sports. A mark was made 1 cm distal to the radial styloid, and the wrist wrap was positioned, so the distal edge was aligned with the mark (Figure 2). The wrapping pressure was applied up to a tight enough level but without causing discomfort to the participant. The same wrapping procedure was performed for the control application, but no pressure was applied as recommended above.

The tests were conducted 1 hour before the participant's usual training time using the dominant wrist. The participant was given a standardized orientation about the test and performed a warm-up that included wrist mobility and moderate grip strength exercises. We followed the recommendation of the American Society of Hand Therapists for the grip test,[6] using a portable dynamometer (Jamar, 5030J1; Jamar Technologies, Horsham, PA) (Figure 3) calibrated before the study. The participant was seated with shoulders

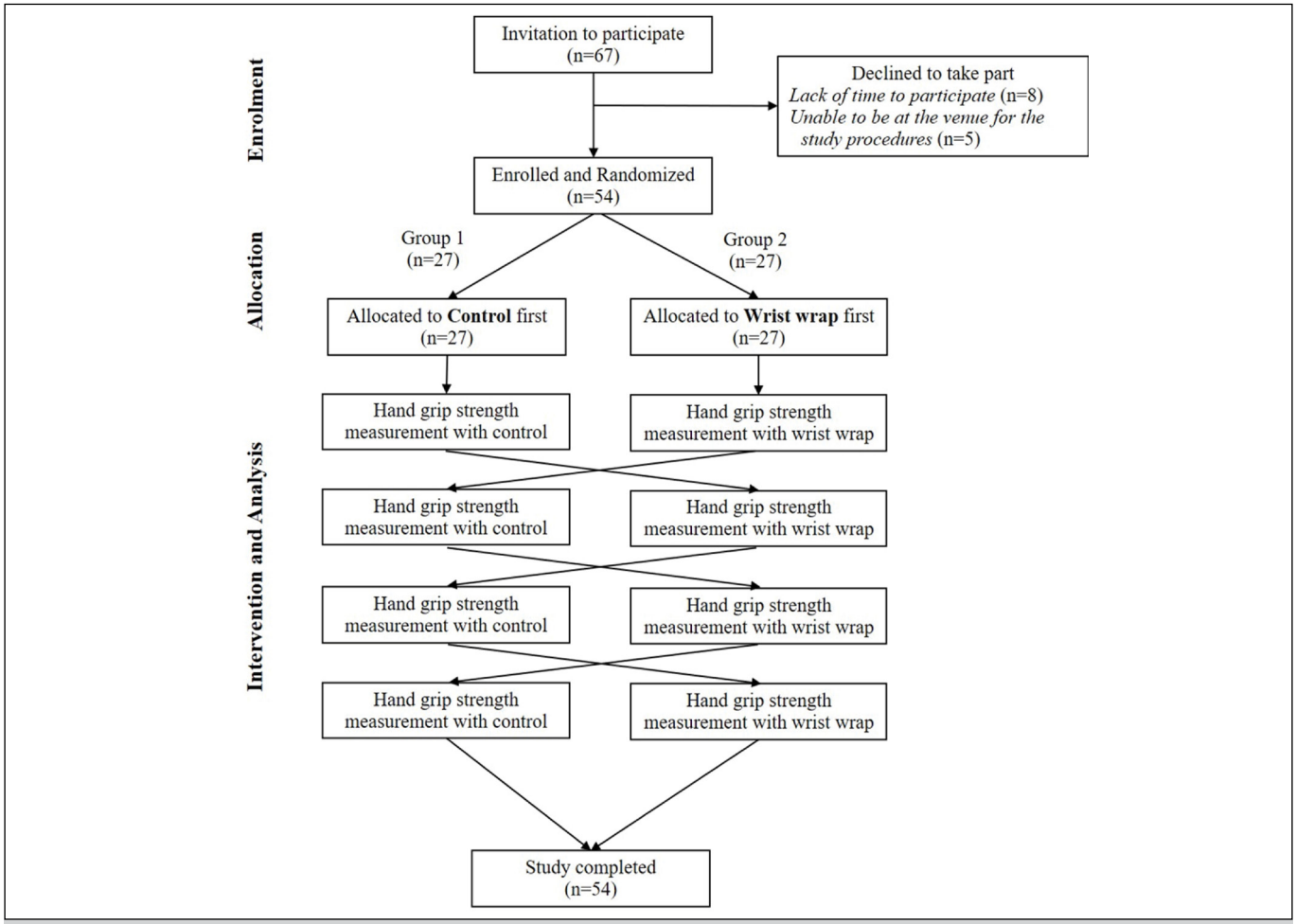

Figure 1. Flow chart diagram of the current study.

<< SUMÁRIO

Figure 2. Wrist warp. On the left, two wrist markings show the radial styloid and the 1 cm distal point; in the center, it is shown the application of the control wrist wrap; and on the right, the application of the functional wrist wrap.

Figure 3. Manual pressure dynamometer used in the tests.

abducted and in neutral rotation, the elbows flexed at 90 degrees, the forearms in a neutral position, and the wrist extended between 0 and 30 degrees (Figure 4). The dynamometer grip position was adjusted to each participant's hand size, and this position was always maintained. Once the participant could distinguish between a loose and tight wrap, it was impossible to blind the volunteers regarding the study group.

The examination was conducted in 4 consecutive tests with a 5-minute wash-out interval spaced using the control and functional wrappings, randomly determining whether the participant would perform the first test under control or intervention conditions (Group 1 or Group 2). Each test consisted of 12 contractions of 3 seconds with 5 seconds of rest between repetitions following the 2016 study by Gerodimos et al.[7]. After each dynamometer reading, the examiner shared the results verbally with the participant for their feedback.

The maximum strength data (kilograms) of the first three and last three contractions in each test were collected. The maximum grip value was the mean of the maximums attained in the three initial movements. The endurance value is the percentage of grip maintenance achieved in the last three movements (fatigue = 100% – endurance). The mean values of the two intervention and the two control tests of each participant were used for data analysis.

Statistical analysis

Statistical analysis was performed using descriptive methods and comparing the control and wrist wrap data. Normality tests were conducted to infer the distribution of the parameters obtained. As a cross-over trial, each participant was the control subject for themselves for all hypothesis testing, so no normalization for body mass index or other parameters was necessary. The Wilcoxon test for paired samples and the Mann-Whitney U test for independent samples was used. Fisher's exact test was used to analyze differences for categorical variables. The data were compiled in Excel tables (Office 16, Microsoft) and analyzed statistically using the SPSS 16.0 software (IBM SPSS).

RESULTS

Fifty-four Crossfit participants were successfully included between September 2020 and February 2021: mean age of 32.9 years old (4.8, standard deviation, SD) and 48% female. Athletes were randomized, resulting in groups with similar baseline parameters. (Table 1)

No volunteers were lost during the study, and all of them completed the series of 4 tests with both wrapping configurations (control and functional wrist wrap; Figure 1).

The results from the tests pointed to the absence of any effect resulting from wrist wrapping (Table 2), either for a supposed increase in initial strength (grip) or for greater resistance/decreased fatigue.

DISCUSSION

In this study, using a wrist wrap did not interfere with maximum strength or grip resistance. The lack of an increase in maximum grip strength is in line with other studies that tested athletes[8] and others that specifically studied wrist use. In a cross-over clinical trial,[9] Johansson et al. demonstrated that maximum grip strength

Figure 4. Positioning of the participant and the examiner during the test.

Table 1. Demographic data and group comparison.

	Group 1	Group 2	p value
Volunteers ("n")	27	27	-
Sex (F/ M)	14/13	12/15	0.786
Age (mean SD)	32.9 ± 5.0	33.4 ± 4.6	0.664
Right hand dominance	25	24	0.999

F: female; M: male; SD: standard deviation

Table 2. Results from test with hand grip.

	Control (n=54)	Wrist Wrap (n=54)	Effect size	p value
	mean ± SD	mean ± SD	mean (95%CI)	
Grip (kg)	35.7 ± 8.6	35.6 ± 8.3	-0.1 (-0.7–0.6)	0.737
Endurance (%)	78.2 ± 6.7	77.8 ± 7.4	0.0 (-0,01–0.02)	0.549

SD: standard deviation; CI: confidence interval. Effect size shown as mean differences

did not vary with a commercial wrist band, similar to Rettig et al.,[2] who used adhesive tape. Although Takahashi et al. demonstrated the possibility of altering hand grip strength by compressing the wrist,[4] this outcome only occurred above a certain pressure level. About muscle fatigue, contractions to measure grip cause blood flow to be intermittent, staying impeded by the pressure during the contraction. According to Pitcher and Mies,[10] this restriction of the blood would contribute to muscle fatigue in the forearm. However, the author reported changes only after two minutes of vascular occlusion, which is longer than the total intervention time of each test. In addition, in our intervention, the compression was generated only in the wrist, where there is less muscle mass, unlike this author, who used an arm cuff.

Another reason the intervention increases fatigue is the greater effort of the wrist extensor muscles, given the limitation of dorsiflexion caused by the wrist wrap. Di Domizio et al. demonstrated that a wrist orthotic increases activation of the extensor muscles when 100% grip strength is required.[11] This fatigue also can interfere with grip strength[(12)], though in our test, there was no increase in fatigue. Certainly, one of the strong points of our study is its cross-over design and randomized allocation for the first trials. Among the confounding factors are the muscle fatigue that interferes progressively in consecutive tests, decreasing the maximum grip strength values, and the learning during the series of tests, since the candidate tends to optimize their strength and therefore have better results in the consecutive tests after being better familiarized with the effort required for the task. In addition, we had any loss of participants for the retest.

We also highlight the pioneering nature of this study, as there is little scientific research involving Crossfit participants. To date, there are only a few clinical trials involving Crossfit.

Not measuring the pressure exerted on the wrist during intervention is a limitation of this study. As previously mentioned, Takahashi and Demura demonstrated that pressure applied to the wrist could interfere with maximum grip strength when above 90hPa.[3] Another limitation of the study is that it did not control pressure on the wrist when submitted to intervention. As pressure adjustment was subjective, allowing the participant to self-adjust according to their comfort level could have caused significant variation among each patient's tests. Also, some participants' unfamiliarity with using the wrist wrap could have increased this variability.

Even though the study demonstrated that the wrist wrap did not impact the maximum grip strength or the dynamic grip resistance, it is not possible to state that it does not affect performance since there are different effects of the wrist wrap that could impact performance. Kauranen et al. proved that wrapping the wrist improves the participant's agility by reducing simple reaction time and choice reaction time in a standardized performance test.[13]

Another possible effect of using wrapping is improved proprioception. Karagiannopoulos et al. demonstrated that the sense of wrist joint positioning, which can deteriorate naturally after exercise-induced muscle fatigue,[14] can be improved with adhesive tape,[15] an intervention similar to our wrist wrap in terms of its positioning on the wrist.

Kim et al. demonstrated how wrapping the wrist could increase the range of motion of wrist extension associated with axial load in individuals with a reduced arc of wrist extension motion.[16] Considering that many Crossfit exercises associate movements of maximum wrist extension with axial load (for example handstand walking, snatch, clean and jerk, etc.), it is possible that the wrist wrap has a similar effect and allows a greater arc of motion in people with reduced wrist mobility, which would have a direct impact on the performance of the participant.

CONCLUSION

We concluded in our study that using a wrist wrap does not affect the maximum hand grip strength and resistance. However, the effect of the wrist wrap on the Crossfit performance was not studied in a more global context, and it may be a topic of investigation in future studies.

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EVALUATION OF OUTCOMES IN INTERVENTION RANDOMIZED CLINICAL TRIALS - DISTAL RADIUS FRACTURES

AVALIAÇÃO DOS DESFECHOS EM ENSAIOS CLÍNICOS RANDOMIZADOS DE INTERVENÇÃO - FRATURAS DISTAIS DO RÁDIO

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ABSTRACT

Objectives: Describe the frequency and types of outcomes in randomized clinical trials (RCT) of intervention for distal radius fractures, analyze how confusing outcome presentations can lead to misinterpretations, and suggest strategies to improve the reader's understanding of the decision-making process. Methods: A retrospective study was conducted through a systematized search on the PubMed® database in the last 10 years, in which only intervention RCT was included for distal radius fractures, and outcomes were analyzed. Results: Of the primary outcomes analyzed in the 75 selected articles, 46.6% were classified as clinical outcomes, 20% as surrogate, 30.6% as composite, 1.3% as complex scales, and 1.3% as safety outcomes. 34.7% of the articles did not report adverse events. Conclusion: The presentation of outcomes with little clinical relevance represented more than half of the sample (53.4%) - such studies can harm the reader since they confuse the interpretation of scientific evidence; the Core Outcome Measures in Effectiveness Trials (COMET) initiative could help health professionals in understanding and selecting the most appropriate therapeutic interventions for patients. ***Level of Evidence III; Retrospective comparative study.***

Keywords: Outcome Assessment, Health Care; Radius Fractures; Randomized Controlled Trials as Topic; Wrist.

RESUMO

Objetivos: Descrever a frequência e os tipos de desfechos em ensaios clínicos randomizados (RCT) de intervenção para fraturas distais do rádio, analisar como apresentações confusas de desfechos podem levar a interpretações equivocadas e sugerir estratégias para melhorar a compreensão do leitor sobre o processo de tomada de decisão. Métodos: Foi realizado estudo retrospectivo mediante busca sistematizada na base de dados PubMed® nos últimos 10 anos, na qual foram incluídos apenas RCT de intervenção para fraturas do segmento distal do rádio, cujos desfechos foram analisados. Resultados: Dos desfechos primários analisados nos 75 artigos selecionados, 46,6% foram classificados como desfechos clínicos, 20% como substitutos, 30,6% como compostos, 1,3% como escalas complexas e em 1,3% como desfechos de segurança. 34,7% dos artigos não reportaram eventos adversos. Conclusão: A apresentação de desfechos com pouca relevância clínica representou mais da metade da amostra (53,4%) - tais estudos podem prejudicar o leitor, uma vez que confundem a interpretação das evidências científicas; a iniciativa Core Outcome Measures in Effectiveness Trials (COMET) auxilia os profissionais de saúde na compreensão e seleção das intervenções terapêuticas mais adequadas para os pacientes. ***Nível de Evidência III; Estudo retrospectivo comparativo.***

Descritores: *Avaliação de Resultados em Cuidados de Saúde; Fraturas do Rádio; Ensaios Clínicos Controlados Aleatórios como Assunto; Punho.*

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INTRODUCTION

The distal radius is the most common fracture site in the upper limbs.[1] The mechanisms of injury range from falls of one's own height to high-energy traumas.[2–4] The distribution of distal radius fractures is bimodal, accompanying the gender and age of the patient's, being more frequent in young adult men (associated with high-energy trauma), and in elderly women due to falls from their own height (osteoporosis-related). Shauver et al.[5] estimated that the cost of hospitalizations for these fractures in the elderly to the U.S. public health system was $170 million in 2007.

Diverse intervention randomized clinical trials (RCT) have been conducted, aiming to achieve better alternatives for the treatment of distal radius fractures. Viergever et al.[6] observed that there has been a substantial increase in the number of RCT, not necessarily accompanied by an increase on quality, underestimating the potential benefits that these studies can promote. It is known that RCT, although located at the top of the evidence pyramid and important in decision-making process, have high associated costs and demands great efforts on the part of research teams.[7,8] Thus, to mitigate expenses and simplify the work, many researchers choose to use few clear outcomes that do not translate into clinical improvement for patients.[9]

Outcomes can be defined as measures of the effects of an intervention. Smith et al.,[10] analyzing the results of an online Delphi survey of 48 UK Clinical Research Collaboration registered Clinical Trials Units, concluded that research into methods to boost recruitment in trials, methods to minimize attrition, and methods for choosing appropriate outcomes to measure are priority topics for methodological research. In this context, we can observe a correlation with the study of Heneghan et al.,[9] that highlights the need to select clinical outcomes in RCT, to promote papers that are capable of translating improvements in patients' health status.

The objectives of this paper are to describe the frequency and types of outcomes in randomized clinical trials (RCT) of intervention for distal radius fractures, to analyze how confusing outcome presentations can lead to misinterpretations, and to suggest strategies to improve the reader's understanding of decision-making.

METHODS

A retrospective study was conducted through a systematized search on the PubMed® database in the last 10 years, being included only intervention RCT for distal radius fractures which outcomes were analyzed. A search was carried out in the PubMed® database using the strategy described in the Table 1, without language restriction. Papers that did not constitute intervention RCT, duplicate papers or which that addressed anatomical sites other than distal radius were excluded. Two independent authors selected the articles by title and abstract using the Rayyan© web applicative according to the inclusion criteria, and possible divergences were resolved by consensus. The selected articles were read in full, and the primary outcomes classified according to the criteria proposed by Heneghan et al.[9]

The search was carried out in PubMed® database on 09/01/2022, and a total of 120 papers were found. After applying the exclusion criteria, 75 articles remained.

Table 1. Search strategy.

N	Search Strategy
#1	Radius Fracture [Title/Abstract] OR Fracture, Radius [Title/Abstract] OR Fractures, Radius [Title/Abstract]
#2	Randomized Controlled Trial [Publication Type]
#3	#1 and #2

RESULTS

Among the 75 selected RCT, we found 35 articles with clinical outcomes (46.6%), 15 articles with surrogate outcomes (20%), 23 articles with composite outcomes (30.6%), 1 article (1.3%) with complex scales and 1 article (1.3%) with safety outcome (Figure 1). 49 articles (65.3%) reported adverse events, and 26 articles (34.7%) did not (Figure 2).

DISCUSSION

The purpose of much of the scientific production in the health area is the validation of practices that promote advances in patient care, thus ensuring an improvement in quality of life.[9,11,12] From this perspective, RCT have the function of testing hypotheses and evaluating them based on chosen outcomes according to the purpose of the study. A choice of outcomes requires a lot of attention, constituting an essential part of the study planning, since according to the objective of the study, whether to analyze the pre-test probability or test the effectiveness of a conduct, certain parameters will be more adequate than others.[10]

Heneghan et al.[9] explicit that one of the reasons why RCT cannot translate benefits for patients is precisely the mistaken choice of outcomes, opting for unclear ones, without relevance in clinical practice. The authors classify the outcomes into clinical, surrogate, composite and subjective, besides mentioning the use of complex scales in the evaluation of interventions. Clinical outcomes are those capable of reflecting real-world configurations and the patients' true needs, being therefore related to quality of life after intervention, of greater relevance in medical practice. Surrogate outcomes are used to infer or predict outcomes of clinical relevance, being useful in the evaluation of pre-test probability in phase 2 studies but should not be used to define medical conducts. Composite outcomes are characterized by the evaluation of factors combined in the measure of the outcome, promoting a reduction in the sample sizes, besides

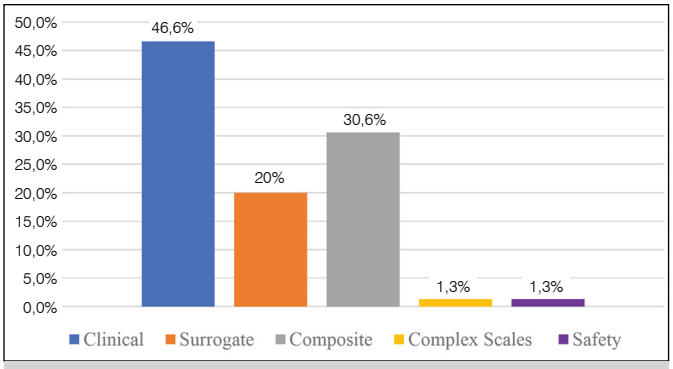

Figure 1. Number of Papers X Primary Outcome Types.

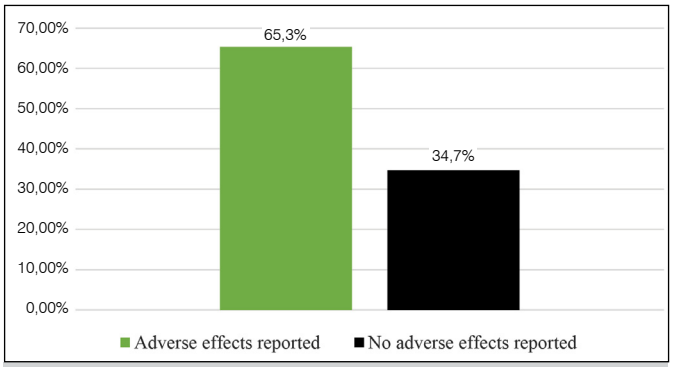

Figure 2. Reporting of adverse effects in the studied sample.

presenting potential for confusing interpretation of the results due to the combination of factors. Subjective outcomes are marked by the need for judgment by the researcher or are reported by patients. The use of complex scales is related to the combination of signs and symptoms in scales created by the authors of the study, which becomes problematic because these are not validated and reliable measurements as the RCT requires.

In our sample, we found that most articles (53.4%) used, in their primary outcomes, measures unable to translate the improvement in patients' health, and, therefore, did not present greater importance in clinical practice. In total, 15 studies (20%) used surrogate outcomes, 23 studies (30.6%) used composite outcomes, one study (1.3%) used safety outcomes and one study (1.3%) used complex scales. This wide range of articles using outcomes that do not adequately assess the patients' clinical condition indicates that most intervention RCT that approaches distal radius fractures are not able to correctly translate an improvement in the patients' health status. However, it cannot be affirmed that these studies are of no scientific importance, since the use of surrogate or composite outcomes may be unique in the early stages of randomized clinical trials, to estimate the pre-test probability, giving the researcher the ability to decide whether to continue with the research, since these outcomes require a shorter follow-up time than clinical outcomes.[12–14]

The surrogate outcomes are indirect measures used in order to estimate a clinical importance, and present as the main quality the fact that they are defined by means of continuous variables, easy to measure and of short-term response, which decreases the follow-up time of the studies.[13,14] To determine the quality of a surrogate outcome, it should present a causal relationship between the intervention and the surrogate outcome and between it and the clinical outcome - this relationship should be the main route of action of the intervention on the clinical outcome.[13,14] In the studied RCT, we can affirm that the surrogate outcomes were well chosen, since, for the most part, measures of joint amplitude and hand strength were used, directly related to limb functionality.

Rupp et al.[15] evidenced that although surrogate outcomes were sufficient for FDA approval of new anti-cancer drugs, these medications were not able to increase patients' survival or improve their quality of life; therefore, caution should be exercised in interpreting such outcomes.

The importance of composite outcomes lies in the decrease in the sample size needed to make statements, thus increasing the statistical power of work.[12,16] Meanwhile, its impairment lies in the confusing interpretation of the results, since we cannot clearly state whether the intervention is effective.[9,16,17] Thus, similarly to surrogate outcomes, compound outcomes contribute to simplify the work, increasing the speed of completion of the study, being useful to formulate hypotheses about the intervention.[16] In the evaluated studies, compound outcomes, in most cases, combined measures of surrogate outcomes, such as range of motion and hand strength, with measures of clinical outcomes, such as limb functionality questionnaires.

The sample also presented two other studies, one evaluating safety outcomes and the other using complex scales in the analysis of outcomes. Safety outcomes are useful in early stages of RCT, when one wants to test whether the intervention can bring harm to the patient's health, being used in small samples composed of healthy individuals, seeking for frequent and serious events, besides being used also in the final phase, in order to make an analysis of the net benefit of the intervention.[18] Moreover, complex scales are used in situations where there are no validated questionnaires to evaluate patients; are related to a great risk of bias, since they are created by the evaluators themselves, tending to a greater positivity of the paper.[9]

As previously mentioned, clinical outcomes are those capable of translating a real improvement in the patient's health status, being clinically relevant *per se* and, thus, RCT that use it are more appropriate to guide medical practice.[9,11,12] In the studied sample, 46.6% (35) of the articles used clinical outcomes, mainly using parameters of limb functionality and quality of life. To access them, validated questionnaires such as DASH, QuickDASH, PRWE, MHQ, SF-36, in addition to analogue pain scale were used. However, the counterpoint of these methods is that they are considered subjective clinical outcomes, since they require the patient's response, appealing to individual subjectivity.[9] Thus, it is a great challenge to evaluate patients clinically and objectively, since the main objective of the interventions is to restore functionality and promote increased quality of life, variables that are difficult to be objectively measured.

Regarding the report of adverse events in the studied sample, we observed that, of the 75 RCT analyzed, 26 did not do it, a number greater than one third of the papers in appreciation. It is essential that the complications resulting from a certain intervention are reported in the RCT, since this information is of great importance in clinical practice, allowing the reader to analyze its benefit-harm ratio.

A solution to the described problems is the Core Outcome Measures in Effectiveness Trials (COMET)[19] - this initiative aims to facilitate the development and application of outcomes that should be measured and reported in clinical trials of a specific disease or experimental population. Its main role is the development of a guideline on how to select outcome measurement instruments for results included in a study. The proposal is of great importance because it recommends outcome measures that represent clinical efficacy, helping the researcher to choose the most appropriate therapeutic interventions. This initiative seeks to standardize such outcomes, facilitating the reader's understanding, as well as the realization of reviews and data joint analysis in a meta-analysis.

CONCLUSIONS

Scientific papers which generate not clear outcomes to readers or have low clinical impact for patients represent an important problem described in the medical literature.

In the studied sample, which included the primary outcomes in 75 intervention RCT for distal radius fractures, 46.6% were considered as clinical outcomes, 20% as surrogate, 30.6% as composite, 1.3% as complex scales and 1.3% as safety outcomes. 34.7% of the articles did not report adverse events. The presentation of outcomes with little clinical relevance represented more than half of the sample (53.4%) - such studies can harm the reader since they confuse the interpretation of scientific evidence and the decision-making process on the part of health professionals, leading them to opt for interventions that do not bring real benefits to patients.

Measures such as those of COMET initiative for the selection of research outcomes could help health professionals in understanding and selecting the most appropriate therapeutic interventions for patients.

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HAND

METACARPAL FRACTURES TREATMENT: COMPARASION BETWEEN KIRSCHNER WIRE AND INTRAMEDULLARY SCREW

TRATAMENTO DE FRATURAS METACARPAIS: COMPARAÇÃO ENTRE FIOS DE KIRSCHNER E FIXAÇÃO INTRAMEDULAR

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ABSTRACT

Introduction: Metacarpal fractures are common and can be treated surgically using Kirschner wires (K-wires) or intramedullary fixation with compression screws (IMCS). Objective: Analyze the postsurgical results from treating the metacarpal extra-articular fractures through the retrograde Kirschner wire technique, and compare it with the intramedullary compression screw fixation. Methods: Retrospective and quantitative studies were to analyze patients' medical records, and a postsurgical evaluation questionnaire was given to the patients, who were divided into K-wire and IMCS. Results: The period of immobilization with a splint took six weeks for the K-wire group and four weeks for the IMCS group. The average time for consolidation took, respectively, fifty-seven days and forty-seven days. The first group could restart their activities twenty-two days after the other, and the average force value of the treated hand, when compared with its contralateral, was 93.9% and 95.4%, respectively. Between the operated hand and its contralateral, there was a difference of 16º in the total measures of the metacarpophalangeal and interphalangeal joint's range of movement among the K-wire group and 5º among the IMCS group. Conclusion: The patients who participated in this study showed excellent results after surgery, and both treatments were proven to be safe and reliable. ***Evidence level III; Retrospective comparative study.***

Keywords: Bone Fracture; Metacarpus; Kirschner Wires; Fracture Fixation, Intramedullary; Trauma.

RESUMO

Introdução: Fraturas dos metacarpos são frequentes e podem ser tratadas de forma cirúrgica com os fios de Kirschner (FK) e Fixação Intramedular com Parafuso de Compressão (FIPC). Objetivo: Analisar os resultados pós-operatórios do tratamento das fraturas extra-articulares dos metacarpos pela técnica retrógrada com fios de Kirschner e comparar com a fixação intramedular utilizando parafuso de compressão. Métodos: Estudo retrospectivo, quantitativo, com análise de prontuários, utilizando questionários de avaliação pós-operatória em dez pacientes divididos em dois grupos: FIPC e FK. Resultados: O período de imobilização com tala nos grupos FK e FIPC foram de seis e quatro semanas respectivamente, já o tempo médio para consolidação foi de 57 e 47 dias respectivamente. O grupo FK retornou as atividades laborais após os FIPC. O valor médio de força na mão acometida comparada a contralateral foi de 93,9% no grupo FK, e no FIPC de 95,4%. Medidas da soma de amplitude de movimento das articulações metacarpofalangeanas e interfalangeanas no grupo FK obtiveram diferença média entre as mãos operada e a contralateral de 16°, já na FIPC observou-se 5°. Conclusão: Os pacientes estudados apresentaram excelentes resultados pós-operatórios e ambos os tratamentos provam ser seguros e confiáveis. ***Nível de evidência III; Estudo retrospectivo comparativo.***

Descritores: *Fratura; Metacarpo; Fios de Kirschner; Fixação Intramedular de Fraturas; Trauma.*

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INTRODUCTION

Metacarpal fractures are very frequent and account for 36 to 42% of all hand injuries.[1-2] Conservative treatment can be administered in cases where the fractures are stable. However, surgery is recommended when fractures show a rotational deviation of more than 5º, shortenings of more than 6mm, pseudo-clawing, or a variable angular deviation (depending on the injured metacarpus), because these deformities are related to significant biomechanical constraints on the efficiency of the flexor tendon and on the extensor mechanism of the fingers, and therefore can leave the patient with sequelae or other limitations in case these injures are not properly attended.[3-4]

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

The study was conducted at the Faculdade de Medicina do ABC (FMABC).
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Several surgical techniques are employed to heal these fractures, among which the Kirschner wires are the most popular implants not only for intra-articular fractures, but also for extra-articular ones. Some of the advantages of this technique are its low cost (when compared with other alternatives), and the fact that it is a percutaneous procedure. Besides, it also shows a lower rate of tendon adhesion.[5] Nevertheless, it is still necessary to immobilize the affected area after surgery in order to protect it, but this prevents fracture from early rehabilitation.[6-7]

Regarding the intramedullary compression screws, it is agreed that they have proven to be a promising technique to treat diaphyseal fractures as well as stable fractures of the metacarpal neck without comminution.[8-9] In addition to being a low-complexity method, they are also minimally invasive and, due to their steadiness, they do provide an early rehabilitation avoiding possible stiffness.[10-11]

Consequently, the objective of this study is to analyze the postsurgical results obtained from the treatment of the metacarpal extra-articular fractures through the retrograde Kirschner wire technique, and compare it with the intramedullary compression screw fixation.

METHODS

This is a retrospective, comparative, descriptive and quantitative study, which offers an evaluation of medical records through the administration of clinical tests and surveys to assess the postsurgical condition of the patients who presented metacarpal fractures and were then treated surgically at the same medical center from 2019 to 2021. All the patients signed an Informed Consent Form, and the research was approved by the Local Research Ethics Committee (CAAE: 56459722.0.0000.0082).

The epidemiological data, which were descriptively analyzed, included the variables: age, gender, occupation, and the characteristics of both the fracture and the main limb. The time span for the radiological consolidation of the fracture was examined, as well as the time needed for patients to return to their habitual activities, and the time allocated for immobilization and possible postoperative complications. Postsurgical assessments were performed in order to examine function, mobility and strength flaws.

Ten patients who presented extra-articular metacarpal deviated fractures participated in this study and were divided in two groups, according to the surgical treatment to be administered: five of them joined the Kirschner wires (K-wire) group and the other five joined the intramedullary compression screw fixation (IMCS) group.

Patients who presented open metacarpal fractures, pathologic fractures, previous upper-limb injuries that showed sequelae, articular fractures or bilateral fractures, and patients who refused to be submitted to any of the procedures mentioned above were excluded from this research.

Surgical Technique

In patients belonging to the IMCS group, a longitudinal incision of approximately 1cm was made in dorsal topography of the head of the fractured metacarpus. Another longitudinal incision was made in the extensor tendon, which provided a clear view of the metacarpal distal articulation. After that, a close reduction of the fracture was also made by longitudinal traction associated to the Jahss maneuver, followed by the introduction of the guide wire into the medullary canal, milling with a 2.7mm cannulated drill and the insertion of a 3.5mm medullary compression screw, placed 2mm below the articular surface. The patients were immobilized with a palmar splint for a few weeks, depending on their recovery process, and then sent to rehabilitation.

In patients belonging to the K-wire group, the retrograde introduction technique was employed. At first, a close reduction of the fracture was made by traction associated to the Jahss maneuver, followed by the medullary and crossed insertion of two Kirschner percutaneous wires measuring from 1 to 1.5mm. Due to the protocol on avoiding the risk of losing fracture reduction, patients of the K-wire group were immobilized with a splint for six weeks.

The patients were evaluated at least six months after the operation. The extension and flexion range of motion of the metacarpophalangeal joints, and of the proximal and distal interphalangeal joints (Total Active Motion – TAM) of all fingers was tested. Due to individual variation of finger extension and flexion, a comparison with the range of motion of the same contralateral finger, which was healthy, was made. Based on the criteria proposed in other studies,[12] an excellent range of motion after surgery consists of less than 40º of the finger flexion's total loss, and less than 10º of the proximal interphalangeal joint's total loss (when compared with the healthy contralateral finger). A good range of motion presents a finger flexion's total loss varying from 40º to 80º, and a proximal interphalangeal joint's total loss between 10º and 30º. A poor range of motion includes a finger flexion's total loss higher than 80º, whereas the loss of the proximal interphalangeal joint is higher than 30º (when compared with the healthy contralateral finger).

The average handgrip strength of the injured limb and its contralateral was measured after three tests were carried out using a handgrip dynamometer (SAEHAN), then the strength was corrected by dominance.[13] The rotational deformity was measured individually for each one of the injured fingers. In order to make an assessment of the upper limbs' functionality after surgery, the following questionnaire was used: *Disabilities of the Arm, Shoulder and Hand Questionnaire* (DASH).[14]

Statistical Treatment

All data were recorded using the software *Microsoft Excel,* and because there were not many samples, they were considered nonparametric. Therefore, they were described according to their proportion, median and interval – depending on the nature of the variables. Inferential tests were done through the χ^2 – Mann-Whitney test – again, depending on the nature of the variables. These variables are represented in box plot graphs.

RESULTS

For better understanding of the results, table 1 was prepared.

In the K-wire group, patients were, on average, 30 years old (ranging from 15 to 47 years of age), whereas patients in the IMCS group were 32 years, on average (ranging from 23 to 39 years of age) (p.0.69). The K-wire group consisted exclusively of men, but one woman participated in the IMCS group. The samples from both groups revealed four isolated fractures of the fifth metacarpus, and one isolated fracture of the fourth metacarpus. These fractures were present in the dominant hand in 40% of the patients of the K-wire group, and in 80% of the patients of the IMCS group (p 0.167).

The immobilization period with a splint was the same for all the patients in the K-wire group and lasted six weeks. On the other hand, the average period lasted 33.4 days for patients of the IMCS group (0-90 days). The average time span for the consolidation of the fractures in the first group lasted 57 days, but lasted 10 days less in the second group (p 0.643).

Seven months after the surgery, all the patients who participated in this research had already been back to their jobs, except for one patient who was unemployed. A K-wire patient who used to work in logistics took 210 days to get back to their activities, because their return was delayed due to Social Security issues at the Brazilian Social Security Institute (INSS). The fracture of this patient took 83 days to be consolidated. As sensitivity analysis, the assessment was carried out again excluding this specific case. As a result, the time

Table 1. Comparison between the groups.

	K-wire	IMCS
Age (interval)	30 years (15-47 years)	32 years (23-39 years)
Gender (Men:Women)	05:00	04:01
Trauma of the dominant hand	40%	80%
Smoker	40%	60%
Average duration of immobilization after surgery	6 weeks (±0)	4 weeks e 4 days (± 30 days)
Average time span for radiographic	57 days (±16)	47 days (±7,6)
Average time span for patients to go back to work*	2 months e 22 days (±13 days)	2 months (±36 days)
Results of limb functionality (0-100 points in DASH)	2 (±2,1)	2,5 (±2,8)
Rotational deviation	0	0
% of postsurgical handgrip strength (interval)**	93,9% (84,9-99,9%)	95,4% (87,9-110%)
Number of patients presenting loss in the range of motion (TAM)***	2	1
Evaluation results of the range of motion (TAM)****		
Normal hand	280 (±13,6)	286 (±10,2)
Postsurgical hand	264 (±15)	281 (±12,8)
% of patients who showed an excellent recovery after surgery	80% (4/5)	100% (5/5)

* One member of the K-wire group went back to work seven months later because of Social Security-related issues at the Brazilian Social Security Institute (INSS); One member of the IMCS group was unemployed when she got the injury. ** % of postsurgical handgrip strength when compared with the contralateral hand, having corrected its strength bearing in mind the limb dominance. *** Patients belonging to the K-wire group showed losses of 30º and 48º; the only patient belonging to the IMCS group who showed a loss of 25º had a surgery-related complication (intra-articular screw fixation). **** TAM – total range of motion (extension and flexion) of the metacarpophalangeal joints, and of the proximal and distal interphalangeal joints.

needed for patients of the K-wire group to return to their activities was, on average, 22 days longer than the ICMS group (p 0.771).
The assessment of the upper limb's functionality was made through the DASH questionnaire, and its average result was 1.99 points (0-5.83) for the K-wire group, and 2,48 points (0-7.5) for the IMCS group (p 0.952). Regarding the percentage of handgrip strength of the operated hand when compared with its contralateral after the strength correction, the K-wire group showed 93,9% strength on the injured hand. In the other group, however, it was 95,4%, also when compared with its contralateral.
In patients of the K-wire group, the total measures of the range of movement of the metacarpophalangeal, and the proximal and distal interphalangeal joints (TAM) were 264º on the injured hand, an 280º on the contralateral hand, which suggests an excellent outcome in terms of postsurgical range of motion in 80% of the patients. In the IMCS group, the result of the total active motion was 281º on the injured hand, and 286º on the contralateral hand, which also suggests and excellent outcome in terms of postsurgical range of motion in 100% of the patients (p 0.444).
Next, the FK and IMCS techniques will be represented, respectively, in figures 1 and 2. The images represent the right hand in both cases of the figures.

DISCUSSION

Most diaphyseal fractures and fractures of the metacarpal neck can be treated conservatively, as the angle between them and the dorsal apex can be functionally compensated by a 20º-30º motion of the ring and little fingers carpometacarpal joints. There is no consensus on the acceptable degree of an angular deviation for metacarpal neck fractures of these two fingers.

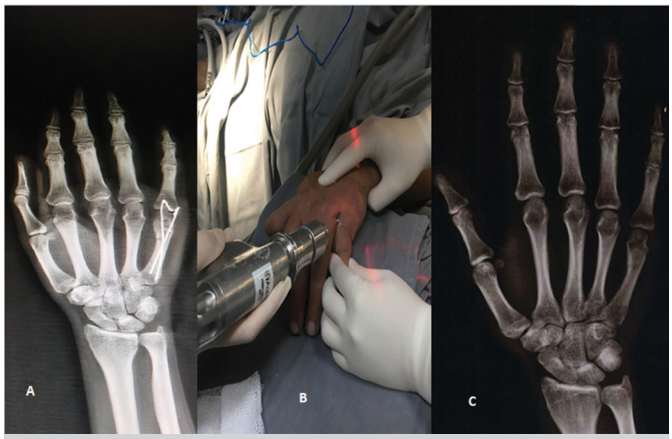

Figure 1. A) Anteroposterior radiograph in the immediate postoperative period of fixation of the 5º metacarpal diaphyseal fracture with FK. B) Retrograde intramedullary fixation technique with FK. C) Anteroposterior radiograph - Consolidation of the 5º metacarpal diaphyseal fracture.

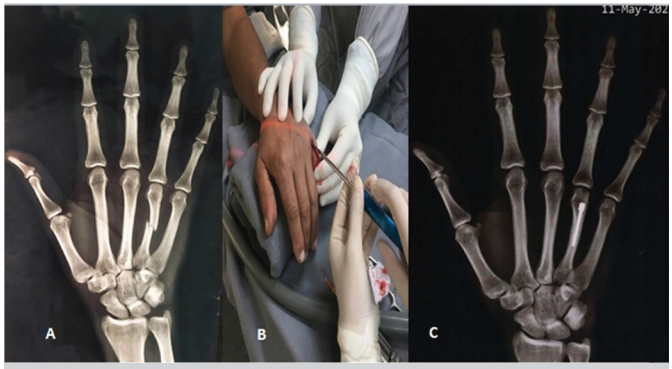

Figure 2. A) Anteroposterior radiograph – Diaphyseal fracture of the 4º metacarpal. B) IMCS surgical technique. C) Anteroposterior radiograph – Consolidation of the 4º metacarpal diaphyseal fracture.

Previous researches, however, have reached satisfactory clinical results for conservative treatments showing volar angulations between 30 to 70 degrees.[15] Nevertheless, research done on corpses have suggested that a flaw on the metacarpal neck whose dorsal apex is higher than 30º cause a decrease in length and function of the intrinsic muscles, and reduce the efficiency of the flexor system throughout the metacarpophalangeal joints mobility.[16] As for the middle and index fingers, a reduction in and stabilization of diaphyseal fractures, and of fractures of the metacarpal necks that present abnormalities higher than 10º-15º in their sagittal plane are essential, since their carpometacarpal joints are rigid. Pseudo-clawing and rotational deformities are also suitable for surgical treatment in order to reduce and stabilize the fracture.
Several surgical techniques have been applied to treat diaphyseal fractures, metacarpal subcapital fractures and fractures of the metacarpal neck that present significant deviations. It has not been decided on which surgical technique is the best, though nowadays one should take the characteristics of the fracture and the surgeon's preference into consideration before opting for a particular treatment.
Concerning the percutaneous Kirschner-wire technique, it avoids tissue lesion, but demands postsurgical immobilization for a period that varies from four to six weeks, so that any loss in reduction can be prevented. In this study, no complications involving K-wire patients were brought to our attention. Nonetheless, two in-depth studies have shown predominance of 16% in postoperative complications

after treatments that resorted to Kirschner wires.[17] Some of these complications included: osteomyelitis, rupture of the extensor tendon, neurological lesion and pin-tract infection. In addition to that, a randomized clinical trial did not reveal any differences in clinical results after comparing the conservative treatment of the metacarpal neck fracture on the fifth metacarpal bone with the percutaneous fixation with Kirschner wires.[18] On the other hand, another randomized clinical trial concluded that there are no differences between the treatment of boxer's fractures with either the Kirschner wires or the intramedullary screw fixation, as excellent results were achieved and there were just few complications in both groups.[19]

This research, however, manifests a surgical complication in one of the IMCS group patients, who complained about the pain and who had a significant decrease in the range of motion two months after the surgery that treated a diaphyseal fracture in the fifth metacarpal bone on their right hand. After six months, this patient was submitted to another surgery to remove the screw, which was found in intra-articular position. By doing so, there was a considerable improvement in the range of motion, and an ease of the pain. In spite of this, the present research also demonstrates that, after more than six months, the patients who underwent either the treatment with Kirschner wires or with intramedullary screw fixation showed good results in terms of range of motion, strength, pain relief and functionality (according to the DASH questionnaire). Besides, all fractures healed properly, and patients could go back to their daily activities and to their jobs. No significant differences relevant to statistics were identified among the patients of the two groups.

It is believed that intramedullary compression screws are better suited for cases where there is no comminution, for the introduction of the screws into comminuted fractures can lead to bone shortening. Screw fixation usually present good results in patients who have demanding jobs and need to return to their activities shortly. However, this synthesis can be a support,[20] but will not provide the same level of stability that the fixation of locking plates does. For this reason, it is important to be wary of the postsurgical rehabilitation protocol, in order to avoid rotational deviation and fracture reduction loss. In addition to that, studies on long-term prospective monitoring to assess metacarpophalangeal joints sequelae are inexistent, which makes it hard to establish how safe this technique really is. In order for one to recommend this technique to treat metacarpal fractures, then head, neck and diaphyseal fractures that are not comminuted should be its main indicators.

This study also has some shortcomings, such as the difficulty to follow the postsurgical rehabilitation protocol due to patient's unavailability to attend physiotherapy sessions. Furthermore, the samples used in this research contained only fractures of the ring and little fingers, which interferes with the projection of other results related to extra-articular fractures of the other metacarpi; thus, the amount of samples is limited.

CONCLUSION

In conclusion, this study demonstrates that patients who underwent osteosynthesis to treat a metacarpal extra-articular fracture with the retrograde Kirschner wire technique or intramedullary compression screws fixation showed great postsurgical results in their range of motion and strength, and all of them could return to their usual activities and jobs. Consequently, taking the positive outcomes into consideration, new studies on this matter are strongly suggested, specially to assess these patients in the long term.

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PRIMARY TOTAL HIP ARTHROPLASTIES UNDER BRAZILIAN PUBLIC HEALTH SYSTEM (2012-2021)

ARTROPLASTIAS PRIMÁRIAS TOTAIS DO QUADRIL NO SISTEMA PÚBLICO DE SAÚDE (2012-2021)

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ABSTRACT

Objectives: To describe the regional distribution of hospital admission authorizations (HAA), hospitalization costs (HC), the average length of stay (LOS), and mortality rates (MR) related to primary total hip arthroplasties (THA) funded by the Brazilian Health Unic System (SUS) from 2012 to 2021. Methods: Descriptive cross-sectional study using secondary data of public domain obtained from the Department of Informatics of SUS (DATASUS) database website. Results: A total of 125,463 HAA were released with HC of 552,218,181.04 BRL in the evaluated period. The average LOS was of 6.8 days. MR was 1.62%. Conclusion: The regional distribution of HAA was 65,756 (52%) in the Southeast; 33,837 (27%) in the South; 14,882 (12%) in the Northeast; 9,364 (8%) in Midwest; and 1,624 (1%) in North - in 2020 there was a sharp decrease of the released HAA, probably due to the COVID-19 pandemic. HC was 293,474,673.20 BRL in the Southeast; 144,794,843.11 BRL in the South; 61,751,644.36 BRL in the Northeast; 45,724,353.80 BRL in the Midwest; and 6,472,666.57 BRL in the North. The average LOS was 6.7 in the Southeast; 5.3 in the South; 9.2 in the Northeast; 7.6 in the Midwest; and, 13.6 in the North. MR was as follows: Southeast=1.88%; South=1.07%; Northeast=1.83%; Midwest=1.44%; and North=1.47%. ***Evidence Level III; Retrospective Comparative Study.***

Keywords: Arthroplasty, Replacement, Hip; Hip Fractures; Hospital Costs; Length of Stay; Mortality; Regional Health Planning.

RESUMO

Objetivos: Descrever a distribuição regional das autorizações de internação hospitalar (AIH), custos de internação (CI), tempo médio de permanência (TMP) e taxa de mortalidade (TM) relacionados às artroplastias totais de quadril (ATQ) primárias financiadas pelo Sistema Único de Saúde (SUS) de 2012 a 2021. Métodos: Estudo transversal descritivo utilizando dados secundários de domínio público obtidos no site do banco de dados do Departamento de Informática do SUS (DATASUS). Resultados: Foram liberadas 125.463 AIH com CI de R$ 552.218.181,04 no período avaliado. O TMP foi de 6,8 dias. A TM foi de 1,62%. Conclusões: A distribuição regional de AIH foi de 65.756 (52%) no Sudeste; 33.837 (27%) no Sul; 14.882 (12%) no Nordeste; 9.364 (8%) no Centro-Oeste; e, 1.624 (1%) no Norte - em 2020 houve queda acentuada das AIH liberadas, provavelmente devido à pandemia COVID-19. Os CI foram de R$ 293.474.673,20 no Sudeste; R$ 144.794.843,11 no Sul; R$ 61.751.644,36 no Nordeste; R$ 45.724.353,80 no Centro-Oeste; e R$ 6.472.666,57 no Norte. O TMP foi de 6,7 no Sudeste; 5,3 no Sul; 9,2 no Nordeste; 7,6 no Centro-Oeste; e 13,6 no Norte. A TM foi como se segue: Sudeste=1,88%; Sul=1,07%; Nordeste=1,83%; Centro-Oeste=1,44%; e, Norte=1,47%. ***Nível de Evidência III; Estudo Retrospectivo Comparativo.***

Descritores: *Artroplastia de Quadril; Fraturas do Quadril; Custos Hospitalares; Tempo de Internação; Mortalidade; Regionalização da Saúde.*

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INTRODUCTION

Total hip arthroplasty (THA) is one of the most performed orthopedic surgical procedures in the world and considerably improves the patients' quality of life, besides presenting a relatively short recovery period. Jones et al. (2000)[1] pointed out to improvement in pain and functional status in more than 75% of cases, with patient's satisfaction rate reaching 91%. The main indications for THA in the elderly are advanced hip osteoarthritis (OA) and femoral neck fractures (FNF).

OA is one of the main degenerative diseases affecting the elderly population - a chronic and disabling condition, associated with pain, stiffness and, in the most severe cases, deformities. In Brazil,

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The study was conducted at the Departamento de Cirurgia Experimental e Especialidades Cirúrgicas, Faculdade de Medicina da Bahia, Universidade Federal da Bahia.
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OA is the most prevalent musculoskeletal disease, affecting 4% of the population, being associated with falls, depression and obesity.[2] The treatment is initially symptomatic, focused on the approach of pain and function preservation, based on the use of analgesics, anti-inflammatory drugs, weak opioids and physiotherapy. In more advanced cases, with greater joint involvement and pain worsening, it is necessary to replace the affected joint.

Hip fractures are among the most common lesions treated by orthopedists and especially prevalent in the geriatric population. In 2014, more than 320,000 hip fractures were treated in emergency rooms in the United States (US), most of them in women aged 65 and over. Each year, more than a third of adults aged 65 and over fall. The higher number of falls, combined with the higher prevalence of osteoporosis, makes the geriatric population particularly susceptible to fractures. Hip fractures reduce patient independence and mobility and are associated with increased mortality risk. There are several treatment options for FNF; non-deviated fractures can be treated by internal *in situ* fixation with screws, although several studies demonstrate that this approach is not ideal, especially in the elderly population, being preferably to perform hip arthroplasty, especially the partial (PHA) one. THA has historically been reserved for younger and more active patients with a history of hip OA; many studies, however, have shown that the functional results of THA are superior of those of PHA in the treatment of FNF.[3]

Moreover, THA can be divided into two large groups: cemented and not cemented. The first is based on the use of polymethylmethacrylate (PMMA) to fix the prosthetic components; this method has historically been associated with a high rate of aseptic loosening, demanding studies to improve the quality of the PMMA, in addition to the development of other fixation methods,[4] emerging the concept of non-cemented prostheses, which fixation is based on press fit and osteointegration potential, presented and widely disseminated in the 1970s and 1980s, with the objective of improving of THA durability, avoiding loosening and bone destruction; however, it was found that non-cemented prostheses have loosening rates of 1.3% to 9% in femoral component and from 3% to 15% in acetabular component.[4]

Data on the regional distribution of performed primary THA in Brazil are scarce,[5] even in view of the high prevalence of hip OA and FNF in this country. It becomes relevant to know about the volume of these procedures performed over the years, in addition to its associated costs, average length of stay (LOS) and mortality rates (MR), so that the health system can define appropriate strategies to deal with this reality, enabling improvement in the quality of care to the population affected by these conditions.

The purpose of this paper is to describe the regional distribution of hospital admission authorizations (HAA), hospitalization costs (HC), average LOS, and MR related to primary THA funded by the Brazilian Health Unic System (SUS) from 2012 to 2021.

METHODS

This is a descriptive cross-sectional study dealing with the regional distribution (Midwest, North, Northeast, Southeast and South) of HAA, HC, average LOS, and MR related to primary THA funded by the Brazilian Health Unic System (SUS) from 1 January 2012 to 31 December 2021.

The secondary data were obtained from the database site of the Department of Informatics of the SUS (DATASUS), Ministry of Health. All hospitalizations for primary THA coded under the records 04.08.04.008-4 (primary cemented THA) and 04.08.04.009-2 (primary non-cemented/hybrid THA) of the Unified Table of Procedures, Medications, Orthotics, Prostheses and Synthesis Materials Management System (SIGTAP) were included.

For the calculations that required population data, we used the 2010 census, conducted by the Brazilian Institute of Geography and Statistics (IBGE). The Microsoft 365® Excel ® program was used to data tabulating and statistical calculations.

Due to the design of the study, in accordance with the National Health Council Resolution (CNS) no. 466/2012, no approval by the institutional research ethics committee was required, because we used secondary information from a public domain database.

RESULTS

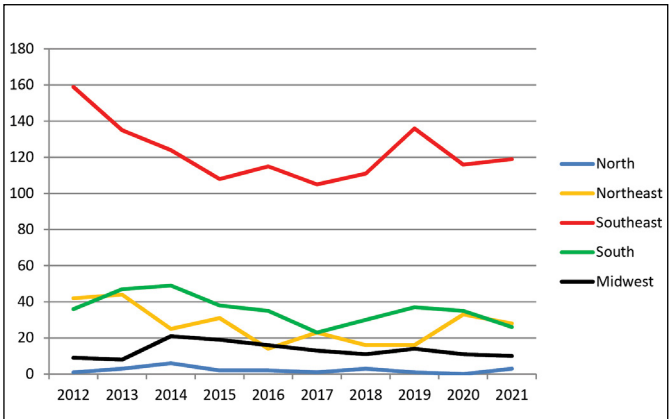
In the evaluated decade (2012-2021), the SUS funded 125,463 THA, of which 42,113 (33.6%) were cemented and 83,350 (66.4%) were non-cemented/hybrid (Figure 1). The Southeast Region performed approximately 52% (65,756) of these procedures, followed by the South Region, with 27% (33,837); the Northeast Region, with 12% (14,882); the Midwest Region, with 8% (9,273); and the North Region, with 1% (1,624) (Table 1).

Most of primary THA (59.36%) were performed as elective procedures, presenting an increase of 41.1% in number from 2012 to 2019; however, between 2019 and 2020, occurred an expressive fall (46.3%) of elective THA. The urgency procedures experienced a percentage increase of 13.9% between 2012 and 2019, remaining stable in number between 2019 and 2020. There was no information on hospitalization regimen in 3,949 of the performed procedures (Figure 2).

The total expenditure made by the SUS for primary THA in the evaluated period was of 552,218,181.04 BRL. The Southeast region obtained the largest investment (293,474,673.20 BRL, 53.14% of the total amount spent), followed by the South, Northeast, Midwest and North Regions (Table 2). Moreover, the mean value per hospitalization was of 4,394.92 BRL; the Midwest Region obtained the greater mean value per hospitalization (4,820.00 BRL) (Table 3).

The average LOS for primary THA in the evaluated period was of 6.8 days (Table 4). The North Region presented the highest average LOS (13.6 days), while the South Region presented the lowest (5.3 days) for primary THA.

The absolute number of deaths in the evaluated period was of 2010 (Figure 3) - the Southeast region had the highest absolute number of deaths (1228, 61.1%) and the North Region had the lowest (22 deaths, 0,01%). Regarding the MR, we observed a lower value in South Region, which presented 1.07 deaths per 1,000 inhabitants; the Southeast Region had the highest MR, reaching 1.88 deaths per 1.000 inhabitants (Table 5).



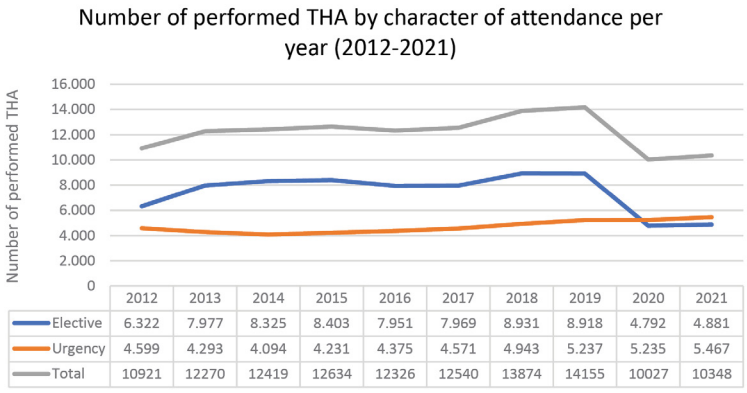
Source: Produced by the authors based on DATASUS information (BRASIL. Datasus. Available at: http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/piuf.def).

Figure 1. Absolute number of cemented and non-cemented/hybrid THA per year (2012-2021).

Table 1. Hospital Admission Authorizations (HAA) Distribution for THA by Brazilian region per year (2012-2021).

Region	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Total
North	113	164	208	213	146	196	194	139	121	130	1,624
Northeast	1,472	1,529	1,519	1,443	1,314	1,506	1,606	1,476	1,464	1,553	14,882
Southeast	6,254	6,817	6,735	6,628	6,751	6,683	7,251	7,577	5,352	5,708	65,756
South	3,041	3,357	3,510	3,771	3,630	3,359	3,916	4,134	2,616	2,503	33,837
Midwest	641	819	845	964	889	1,162	1,265	1181	801	797	9,364
Total	11,521	12,686	12,817	13,019	12,730	12,906	14,232	14,507	10,354	10,691	125,463

Source: Produced by the authors based on DATASUS information (BRASIL. Datasus. Available at: http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/piuf.def).



Source: Produced by the authors based on DATASUS information (BRASIL. Datasus. Available at: http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/piuf.def).

Figure 2. umber of performed THA by character of attendance per year (2012-2021).

Table 2. Distribution of the total amount spent in BRL with hospitalizations for THA by Brazilian region per year (2012-2021).

Region	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Total
North	274,827.13	552,218.37	871,571.68	933,070.22	452,995.56	707,935.75	914,676.08	682,713.52	565,458.13	517,200.13	6,472,666.57
Northeast	5,190,104.72	5,953,644.26	5,976,891.83	5,680,239.12	5,519,094.07	6,518,046.77	7,093,242.93	6,705,893.97	6,338,972.86	6,775,513.83	61,751,644.36
Southeast	22,995,168.75	29,154,816.93	29,448,373.28	30,093,439.86	29,329,746.77	29,677,185.98	34,432,053.73	36,530,191.69	25,071,105.81	26,742,590.40	293,474,673.20
South	10,771,406.54	13,890,234.17	14,561,727.83	15,890,478.00	15,200,258.03	14,157,902.47	17,364,872.23	19,180,027.15	12,088,572.61	11,689,364.08	144,794,843.11
Midwest	2,139,227.27	3,544,996.30	4,008,112.30	4,933,774.71	4,985,483.17	6,231,197.26	5,979,867.13	5,987,737.13	3,911,088.10	4,002,870,43	45,724,353.80
Total	41,370,734.41	53,095,910.03	54,866,676.92	57,531,001.91	55,487,577.60	57,292,268.23	65,784,712.10	69,086,563.46	47,975,197.51	49,727,538.87	552,218,181.04

Source: Produced by the authors based on DATASUS information (BRASIL. Datasus. Available at: http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/piuf.def).

Table 3. Average BRL value of hospital admissions for THA by Brazilian region per year (2012-2021).

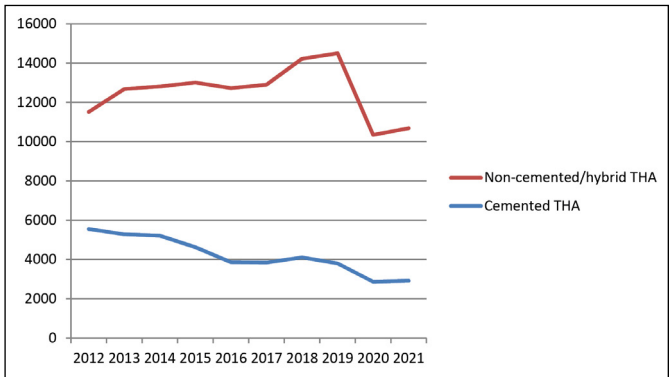
Region	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Average
North	2,432.10	3,367.19	4,190.25	4,380.61	3,102.71	3,611.92	4,714.83	4,911.61	4,673.21	4,420.51	3,980.49
Northeast	3,525.89	3,893.82	3,934.75	3,936.41	4,200.22	4,328.05	4,416.71	4,543.29	4,329.90	4,362.86	4,147.19
Southeast	3,676.87	4,276.78	4,372.44	4,540.35	4,344.50	4,440.70	4,748.59	4,821.19	4,684.44	4,685.11	4,459.10
South	3,542.06	4,137.69	4,148.64	4,213.86	4,187.40	4,214.92	4,434.34	4,639.58	4,621.01	4,670.14	4,280.96
Midwest	3,337.33	4,328.44	4,743.33	5,118.02	5,607.97	5,362.48	4,727.17	5,070.06	4,882.76	5,022.42	4,820.00
Average	3,590.90	4,185.39	4,280.77	4,419.00	4,358.80	4,439.20	4,622.31	4,762.29	4,633.49	4,657.01	4,394.92

Source: Produced by the authors based on DATASUS information (BRASIL. Datasus. Available at: http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/piuf.def).

Table 4. Average length of stay (LOS) in days for THA by Brazilian region per year (2012-2021).

Region	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Average
North	11,6	12,3	15,4	13,2	13,9	13,9	16,6	13,4	12,2	13,1	13,6
Northeast	9,1	9,5	9,2	9,7	10,5	9,2	9,2	8,6	9,1	7,8	9,2
Southeast	7,2	7	6,9	6,9	6,8	6,5	6,4	6,3	6,6	6,3	6,7
South	5,9	5,9	5,8	5,5	5,2	5,2	5	4,7	5	4,7	5,3
Midwest	9,9	8,7	7,6	7,2	7,6	6,9	8,2	7,1	6,4	6,1	7,6
Average	7,3	7,2	7,1	7	6,9	6,7	6,6	6,2	6,6	6,2	6,8

Source: Produced by the authors based on DATASUS information (BRASIL. Datasus. Available at: http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/piuf.def).



Source: Produced by the authors based on DATASUS information (BRASIL. Datasus. Available at: http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/piuf.def).

Figure 3. Absolute number of deaths during THA hospitalizations by Brazilian region per year (2012-2021).

DISCUSSION

The number of primary THA performed in the US in 2014 was 370,770[6] being projected about 500,000 procedures for the year 2021.[7] In Brazil, between January 2012 and December 2021, 125,463 procedures were performed under the SUS – the total number of procedures is considerably lower than that projected in the US, because our study did not include the procedures paid privately or funded by health insurance.

Between 2012 and 2019, there was an increase (25.9%) in the number of primary THA performed under the SUS. However, in 2020, the first year in which the COVID-19 pandemic significantly affected the Brazilian health system, there was a significant decrease in the total number of primary THA (28.6%). This decline was even higher when elective procedures (46.3%) were considered - the number of emergency procedures remained stable in the same period (Figure 2), which can be explained by the redefinition of the orthopedic care model during the COVID-19 pandemic, that modified the approach

Table 5. Mortality rate (%) during THA hospitalizations by Brazilian region per year (2012-2021).

Region	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Average
North	0,88	1,83	2,88	0,94	1,37	0,51	1,55	0,72	0,00	2,56	1,47
Northeast	2,85	2,88	1,65	2,15	1,07	1,53	1,00	1,08	2,25	1,80	1,83
Southeast	2,54	1,98	1,84	1,63	1,70	1,57	1,53	1,79	2,17	2,08	1,88
South	1,18	1,40	1,40	1,01	0,96	0,68	0,77	0,90	1,34	1,04	1,07
Midwest	1,40	0,98	2,49	1,97	1,80	1,12	0,87	1,19	1,37	1,25	1,44
Average	2,14	1,87	1,76	1,52	1,43	1,28	1,20	1,41	1,88	1,74	1,62

Source: Produced by the authors based on DATASUS information (BRASIL. Datasus. Available at: http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/piuf.def).

Table 6. Values funded by the SUS for services (hospital and professional) and implant materials used in cemented (SIGTAP CODE 04.08.04.008-4) and non-cemented/hybrid (SIGTAP CODE 04.08.04.009-2) THA. Updated values in September 2022.

Primary Cemented Total Hip Arthroplasty (SIGTAP CODE 04.08.04.008-4)	
Type of Service	**Amount Paid per Service**
Hospital (5 daily; maximum stay of up until more 2 daily is allowed, ICU daily are funded separately)	1,924.25 BRL
Professional Service	417.46 BRL
Total amount paid for hospitalization expenses	2,341.71 BRL
Implant Materials	Amount paid per implant
Cemented Femoral Modular Component Centralizer (Maximum Quantity: 1)	104.44 BRL
Cement With Antibiotic (Maximum Quantity: 2)	109.62 BRL
Primary/Revision Cemented Acetabular Polyethylene Component (Maximum Quantity: 1)	282.87 BRL
Cephalic Component for Total Hip Arthroplasty (Includes Prosthesis) (Maximum Quantity: 1)	463.48 BRL
Primary Cemented Modular Femoral Component (Maximum Quantity: 1)	1,008.00 BRL
Cephalic Component for Total Hip Arthroplasty (Includes Prosthesis) (Maximum Quantity: 1)	463.48 BRL
Primary Cemented Modular Femoral Component (Maximum Quantity: 1)	1,008.00 BRL
Cemented Charnley type Monoblock Femoral Component (Maximum Quantity: 1)	850.01 BRL
Femoral Cement Restrictor (Maximum Quantity: 1)	28.80 BRL
Cement Without Antibiotic (Maximum Quantity: 2)	60.59 BRL
Total amount paid for implant materials	1,850.78 to 2,167.42 BRL
Primary Non-Cemented/Hybrid Total Hip Arthroplasty (SIGTAP CODE 04.08.04.009-2)	
Type of Service	**Amount Paid per Service**
Hospital (5 daily; maximum stay of up until more 2 daily is allowed, ICU daily are funded separately)	1,924.25 BRL
Professional Service	417.46 BRL
Total amount paid for hospitalization expenses	2,341.71 BRL
Implant Materials	**Amount paid per implant**
Cemented Femoral Modular Component Centralizer (Maximum Quantity: 1)	104.44 BRL
Cement With Antibiotic (Maximum Quantity: 1)	109.62 BRL
Primary/Revision Metallic Acetabular Component of Biological Fixation (Maximum Quantity: 1)	1,027.28 BRL
Cephalic Component for Total Hip Arthroplasty (Includes Prosthesis) (Maximum Quantity: 1)	463.48 BRL
Primary Cemented Modular Femoral Component (Maximum Quantity: 1)	1,008.00 BRL
Primary Non-Cemented Modular Femoral Component (Maximum Quantity: 1)	1,695.27 BRL
Primary/Revision Polyethylene Acetabular Component for Metallic Component Biological Fixation (Maximum Quantity: 1)	372.78 BRL
3.5 MM Cortical Screw (Maximum Quantity: 3)	15.34 BRL
Acetabular Component Screw (Maximum Quantity: 3)	109.67 BRL
Femoral Cement Restrictor (Maximum Quantity: 1)	28.80 BRL
Cement Without Antibiotic (Maximum Quantity: 1)	60.59 BRL
Total amount paid for implant materials	3,394.38 to 3,887.82 BRL

Source: Produced by the authors based on DATASUS-SIGTAP information (BRASIL. Sigtap. Available at: http://sigtap.datasus.gov.br/tabela-unificada/app/sec/procedimento/publicados/consultar).

of certain procedures, especially those electives, to provide greater security for patients and health professionals besides to save vital resources, given the reality that was coming.[8] In the US, in March 2020, 66% of the states have already issued limitation guidelines for elective surgeries. In Poland, there was a drop of 29% to 33% in primary THA numbers between 2019 and 2020.[9] In Scotland, there was a drop of 53.6%, and after the resumption of elective surgical procedures, Scottish hospitals reached only 40% to 50% of the previous monthly volume.[10]

In the evaluated decade, the total amount spent by the SUS on hospitalizations for primary THA was of 552,218,181.04 BRL. The Southeast Region (the most populous in Brazil) received the largest investment (293,474,673. 20 BRL), corresponding to 53.14% of the total. Proportionally to the number of procedures carried out, there was an increasing trend in spending between the years 2012 to 2019; in the pandemic period (2020-2021) the spending decreased, being lower than the cash spent in 2013 for primary THA hospitalizations (Table 2).

In US (2015), the expenditure associated with THA and total knee arthroplasty (TKA) combined was of 65 billion USD. Between 2003 and 2009, 1.4 to 1.6 billion EUR were spent on primary THA in Germany.[11] The difference in HC by country, however, can be expressive - in a comparative study between three Canadian hospitals and three US hospitals conducted in 2004, HC averages of US$ 6,766 and US$ 13,339 ($p<0,0001$), respectively, were found.[12] In an aggregate study, evaluating 2.8 million THA admissions between 2002 and 2013 in the US, there was an increase in the spent value from 15,792 USD (95% CI, 15,706 to 15,878 USD) in 2002 to 23,650 USD (95% CI, 23,544 to 23,755 USD) in 2013.[13] In our study, the mean value per hospitalization for primary THA was of 4,394.92 BRL, with an increase of 29.69% in the evaluated period, being lower in the North Region (3,980. 49 BRL) and higher in the Midwest Region (4,820.00 BRL) (Table 3).

Carducci et al. (2020)[14] found that implant prices were the most dispendious components of total cost across all types of joint arthroplasty, accounting for an average of 53.8% of these expenses and that the increase in hospitalization time would not play a significant role in the value spent to perform these procedures. The amounts paid by the SUS for implants used in cemented THA and non-cemented/hybrid THA may represent, respectively, between 44.14 and 48.06% (1,850.78 to 2,167.42 BRL), and between 66.05 and 69.08% (3,394.38 to 3,887.82 BRL) of the total cost of each hospitalization (Table 6). On the other hand, the literature points out to cost reduction strategies that include reducing the average LOS minimizing preoperative and perioperative risks and investing in postoperative care,[15] which may constitute alternatives to decrease the burden to the Brazilian public health system.

In the US, the average LOS for primary THA decreased from 4.06 to 2.75 days between the years 2002 and 2013,[13] reaching 2.28 days in 2018, demonstrating a downward trend in that country.[14] Foote et al. (2009),[16] analyzing 675 patients submitted to primary THA at a regional hospital in Great Britain, identified an average LOS of 8 days.[16] Kim et al. (2003),[17] reviewing the literature on the efficacy of clinical pathways for TKA and THA identified that the standardization of care processes, together with the surgical approach, was associated with a lower average LOS when compared to that observed in patients treated exclusively by surgery. Mertes et al. (2013) demonstrated that integrated care pathways in THA were effective in reducing average LOS (from 6.9 to 5.5 days); elderly and male patients had greater benefits with this strategy.[18] In our study, the daily average LOS for THA was of 6.8 days; the North Region had the highest average hospital stay (13.1 days) and the South Region presented the lowest average LOS (5.3 days) (Table 4). Factors that are often associated with increased daily LOS include delays or cancellations of surgical procedures, clinical destabilization, nosocomial infection, and waiting for complementary diagnostic tests, vacancies in semi-intensive or intensive care unities or home care – socioeconomic differences may therefore justify the discrepancy observed between distinct Brazilian Regions. The Southeast and South Regions, which have lower average LOS, have higher GDP *per capita,* while the most deprived regions (North and Northeast) have higher average LOS. However, the increase in hospitalization time observed in North and Northeast Regions did not translate into a proportional increase in HC and MR.

In a study of 10,244 patients undergoing primary THA and TKA for a decade, the perioperative MR was less than 2% in patients under 70 years of age, 4% in patients aged 70 to 79 years, and 21% in patients aged 80 years or older.[19] In an epidemiological study conducted in the US, which evaluated 2,182,121 primary THA between the years 1998 and 2008, the mean MR was 1.8% or equivalent to 0.44 events per 1,000 days of hospitalization.[20] In our study, we found an average MR of 1.62% in a decade, slightly below, therefore, of that observed in the literature. The South Region had the lowest (1.07%) average MR and the Southeast Region, the highest (1.88%) (Table 5). The absolute number of deaths in the evaluated period was of 2,010; the Southeast Region presented the highest number (1,228, 61.1%), and the lowest (22 deaths) occurred in the North Region (Figure 3).

The limitations of the current study are in line with other retrospective database studies reviews. Most of them are related to underreporting of cases, lack of information on the socio-demographic characteristics of the affected population, unavailability of specific data concerning underlying hip pathologies, comorbidities and death causes. In addition, we deal with absolute numbers, which does not allow scrutinizing details regarding, for example, to specific expenses with prolonged hospital stay, ICU stay, among other aspects related to primary THA hospitalizations.

CONCLUSION

The total number of released HAA for primary THA between 2012 and 2021 was of 125,463. The regional distribution occurred as it follows: 65,756 (52%) in Southeast; 33,837 (27%) in South; 14,882 (12%) in Northeast; 9,364 (8%) in Midwest; and 1,624 (1%) in North. Regarding HC, we detected a total expenditure of 552.218.181,04 BRL in the evaluated period, with the following regional distribution: 293,474,673.20 BRL (53.1%) in Southeast; 144,794,843.11 BRL (26.2%) in South; 61,751,644.36 BRL (11.2%) in Northeast; 45,724,353.80 BRL (8.3%) in Midwest; and 6,472,666.57 BRL (1.2%) in North. The mean value spent by the SUS from 2012 to 2021 per hospitalization was of 4,394.92 BRL - regionally, we observed the expenditure of 4,459.10 BRL in Southeast; 4,280.96 BRL in South; 4,147.19 BRL in Northeast; 4,820.00 BRL in Midwest; and 3,980.49 BRL in North.

The average LOS of the evaluated period was of 6.8 days. Regionally, we observed 6.7 in Southeast; 5.3 in South; 9.2 in Northeast; 7.6 in Midwest; and 13.6 in North.

Regarding the regional distribution, we noted that MR was of 1.88% in Southeast; 1.07% in South; 1.83% in Northeast; 1.44% in Midwest; and 1.47% in North.

After a rise of 25.9% on the number of performed primary THA from 2012 to 2019, there was the impact of the COVID-19 pandemic leading to a reduction of 28.6% from 2019 to 2020, even higher (46.3%) when elective procedures were considered, suggesting the need to evaluate what happened with other elective orthopedic procedures carried out under the SUS in that period.

The data from this study may also assist the government authorities to define appropriate strategies to cope with the socioeconomic impact of the performance of primary THA in the distinct Brazilian Regions.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. TMNTF, BKM, AAS: Substantial contributions to the conception or design of the work and the acquisition, analysis, or interpretation of data for the work; CAAA: Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved and final approval of the version to be published; ESRM: Drafting the work or revising it critically for important intellectual content and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved and final approval of the version to be published; AG: Substantial contributions to the conception or design of the work AND drafting the work or revising it critically for important intellectual content AND agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved AND final approval of the version to be published AND final approval of the version to be published.

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PEDIATRIC ORTHOPEDICS

TREATMENT OF OSTEOGENESIS IMPERFECTA USING THE FASSIER-DUVAL TELESCOPIC ROD

TRATAMENTO DA OSTEOGÊNESE IMPERFEITA COM A HASTE TELESCÓPICA FASSIER-DUVAL

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ABSTRACT

Objectives: This study aimed to assess the treatment of patients with Osteogenesis Imperfecta (OI) operated on with a telescopic Fassier-Duval (FD) rod in a querterenario hospital from 2010 to 2020. Methods: We analyzed indication for surgical treatment, causes of reoperation, complications and the effectiveness of telescoping rod. Results: The results were compared with the literature and with the same parameters from a previous study which a different telescopic rod developed by the same authors. This was a retrospective study based on the analysis of digital and radiographic clinical records. Fifteen patients with 21 FD rods were evaluated, most were used on the femur (18 rods or 85.7%), eight patients were female (53.3%), with a mean age of 10.47 (3.92 to 16.44) years, most of whom had type III Sillence (46.7%), with a mean follow-up of 5.22 (1.43 to 7.02) years. Seven rods (33.3%) had complications. The main indication was for fracture (57.1%). Regarding the ability to telescope, we observed that 15 rods (71.4%) followed the child's growth. Conclusion: We had good results using FD rods, similar to the data found in the literature and the data obtained with our rod. ***Level of Evidence III, Retrospective comparative study.***

Keywords: Osteogenesis imperfecta; Osteotomy; Joint Deformities, Acquired.

RESUMO

Objetivos: O objetivo deste estudo foi avaliar o tratamento de pacientes com Osteogênese Imperfeita (OI) operados com a haste telescopada de Fassier-Duval (FD) num hospital quaternário no período de 2010 a 2020. Métodos: Analisamos a indicação cirúrgica do tratamento, as causas de revisão, suas complicações e a eficácia na telescopagem da haste. Resultados: Os resultados foram comparados com a literatura e com os mesmos parâmetros de um artigo anterior no qual foi utilizada uma haste telescopada desenvolvida pelo nosso grupo. O estudo foi retrospectivo baseado na análise dos prontuários clínicos digitais e radiográficos dos pacientes. Quinze pacientes com 21 hastes de FD foram avaliados, sendo a maioria no fêmur (85,7%), oito pacientes eram do sexo feminino (53,3%), com média de 10,47 (3,92 a 16,44) anos, a maioria do tipo III de Sillence (46,7%), com tempo de seguimento médio de 5,22 (1,43 a 7,02) anos. Deste total, sete hastes (33,3%) apresentaram complicações. A principal indicação cirúrgica foram fraturas (57,1%). Em relação à telescopagem, observamos que 15 hastes (71,4%) acompanharam o crescimento da criança. Conclusão: No presente estudo verificamos bons resultados com as hastes de FD, à semelhança dos dados encontrados na literatura e dos dados encontrados com a haste do nosso serviço. ***Nível de Evidência III; Estudo retrospectivo comparativo.***

Descritores: *Osteogênese Imperfeita; Osteotomia; Deformidades Articulares Adquiridas.*

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INTRODUCTION

Osteogenesis imperfecta (OI) is a disease characterized by quantitative and/or qualitative changes in type I collagen. These changes lead to fragility of the bone that predisposes it to deformities and a greater number of fractures in these patients, even when low-energy trauma is involved.[1,2] Vitamin D replacement, calcium and especially bisphosphonates are used in the clinical treatment of moderate and severe cases, having a positive impact upon the prognosis of the disease.[3] For its surgical treatment, the use of telescopic intramedullary rods is recommended as the gold standard.[4-12] The objective of this study was to assess the effectiveness of the Fassier-Duval (FD) rod by conducting a retrospective analysis of patients with Osteogenesis Imperfecta operated by our team.

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

The study was conducted at the Irmandade da Santa Casa de Misericórdia de São Paulo, Department of Orthopedics and Traumatology, Sao Paulo, SP, Brazil.
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METHODS

This is an observational, retrospective, longitudinal study in which the physical or electronic medical records and radiographic examinations of patients with OI who had undergone intramedullary alignment and stabilization with the FD rod between January 2010 and January 2020 were analyzed.

All patients with OI who had undergone surgical treatment using FD rods were included. Those patients who did not have an appropriate outpatient follow-up, for whom there were no radiographic records, and those with other bone and metabolic diseases were excluded from the study. All patients or caregivers signed a consent and/or assent form.

The follow-up visits for each patient, the immediate postoperative images following FD rodding and the latest images that were made available within the study period were evaluated. Each rod was then checked for telescoping in millimeters by comparing the rod's measurements in the immediate postoperative period and those taken from the patient's latest radiograph, by employing the digital measurement capability provided along with the software used to perform the radiographs (Enterprise ImagingXero® Viewer – AgfaHealthCare, version 8.1.2).

The current study was approved by the ethics committee.

Data were fed to two Microsoft Excel® spreadsheets. The first included the patients' identification data, including sex, date of birth, age at the end of data analysis, OI clinical type, date of surgery using the Fassier-Duval rod, age at the time of surgery, laterality, and whether there were surgical revisions of the implants. The second spreadsheet had data for each rod, also analyzing sex, clinical type, laterality, date of surgery, surgical indication, segment undergoing surgery, follow-up time, positive or negative telescoping, and percentage of telescoping; where pertinent, rod revision surgery and indication.

The data were statistically correlated by using the Kolmogorov-Smirnov, paired T-Student and ANOVA tests, with the SPSS V20, Minitab 16 and Microsoft Excel Office 2010 programs.

RESULTS

Seventeen patients with OI who underwent FD rodding were considered eligible for the study. However, two were excluded due to lack of outpatient follow-up and recent radiographs. Among the 15 patients included, eight (53.3%) were female and seven (46.7%) were male. An average of 1.4 rods was obtained for each patient, totaling 21 rods. Six of them had two FD rods; five had rods bilaterally in the femurs; and one patient had one rod in the left tibia and one rod in the right femur. (Table 1)

The mean age at the time of surgery was 10.47 years (minimum of 3.92 and maximum of 16.44 years). Seven (46.7%) patients underwent surgery between five and ten years of age, six (40%) patients were older than ten years, and only two (13.3%) patients underwent surgery before five years of age.

Regarding the Sillence Classification, three patients (20%) were classified as type I, seven (46.7%) as type III, and five (33.3%) as type IV. (Table 2)

Of the 21 rods studied, 11 (52.4%) were found in female patients. With respect to laterality, eleven was on the left side (52.4%).

The main surgical indication was the occurrence of fractures (57.1%), followed by rod migration in 23.8% and correction of deformities in 19% of the cases. The mean postoperative follow-up time was 5.22 years (1.43 to 7.02 years).

Seven rods (33.3%) had postoperative complications (Table 1). Three cases of peri-implant fracture (14.3%); three cases of loosening distal component (14.3%) and one case of metallosis (4.8%).

Table 1. Distribution of FD rods.

FD rods		N = 21	Proportion (%)
Sex	Female	11	52.4%
	Male	10	47.6%
Age at rodding procedure	< 14 years	16	76.2%
	> 14 years	5	23.8%
Complications	Fracture	3	14.3%
	Loosening	3	14.3%
	Metallosis	1	4.8%
Laterality **	Right-side	10	47.6%
	Left-side	11	52.4%
Bone	Femur	18	85.7%
	Tibia	3	14.3%
Surgical indication	Deformity	4	19.0%
	Fracture	12	57.1%
	Migration	5	23.8%
Clinical Type	Type 1	4	19.0%
	Type 3	9	42.9%
	Type 4	8	38.1%

Table 2. Qualitative distribution of patients according to the Sillence classification and number of FD rods.

Sillence's Clinical Type	Patients (n = 15)	Patient proportion (%)	Rods (n = 21)	Rod proportion (%)
Type I	3	20.0%	4	19.0%
Type III	7	46.7%	9	42.9%
Type IV	5	33.3%	8	38.1%

Eighteen rods were implanted in the femur (85.7%), and only three in the tibia (14.3%). Regarding age, 16 rods (76.2%) were implanted in children under 14 years of age and the remaining five (23.8%) were implanted in children over this age. For the telescoping analysis, patients were divided into these two groups in order to better assess the growth potential of younger patients. (Table 1)

Analyzing the data related to telescoping we found that 15 rods (71.4%) showed an increase in length (Table 3), whereas the other six rods (28.6%) showed no difference between their initial and final radiographic measurements.

The overall telescoping mean was 24 mm, that corresponded to a 9.9% increase (Figures 1 and 2). When considering patients who underwent surgery under 14 years of age, the mean telescoping was 30 mm (p-value<0.001) or 11.4% (263 - 293 mm). The greatest telescoping value was 71 mm, accounting for a 27.9% increase. Data from patients for whom no telescoping was observed (three rods) were disregarded. When considering patients over 14 years of age, telescoping was not statistically significant (p-value = 0.293).

According to the Sillence classification, all three clinical types showed increased radiographic measurements of Fassier-Duval rods. Type I patients had a mean of 19mm (297 - 316mm); type III had a mean of 28mm (294 - 322mm); and type IV had a mean of 22mm of lenght (272 - 294mm). A statistically significant difference was found with respect to the laterality: the mean telescoping on the left side was 35.9 mm (14.4%) versus 10.9 mm (4.9%) on the right side (p-value = 0.016). (Table 4)

There was no statistically significant difference in telescoping with respect to the specific postoperative period. (Table 5) Six patients did not show positive telescoping: three of them were over 14 years old at the time of surgery, whereas the other three, despite their young age, did not show bone growth, the reasons for which will be discussed below. (Table 6)

<< SUMÁRIO

Table 3. Telescoping rate of FD rods.

Rods		N = 21	Proportion (%)	P-value
Telescoping	Yes	15	71.4%	<0.001
	No	6	28.6%	

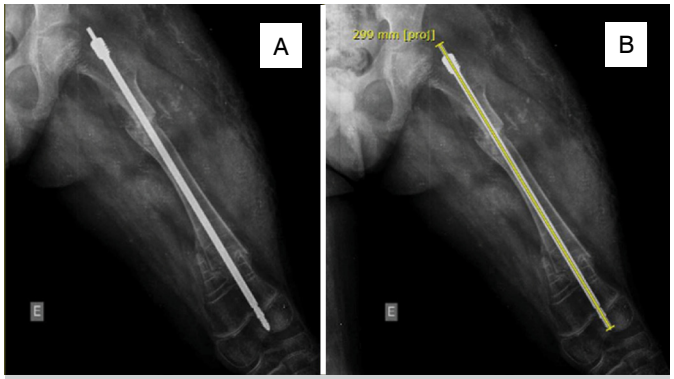

Figure 1. A) Anteroposterior (AP) radiograph of the left femur with fracture in its proximal and distal thirds fixed with FD rod in the immediate postoperative period (IPO). B) The same radiograph showing initial length of 299 mm in the IPO (2016).

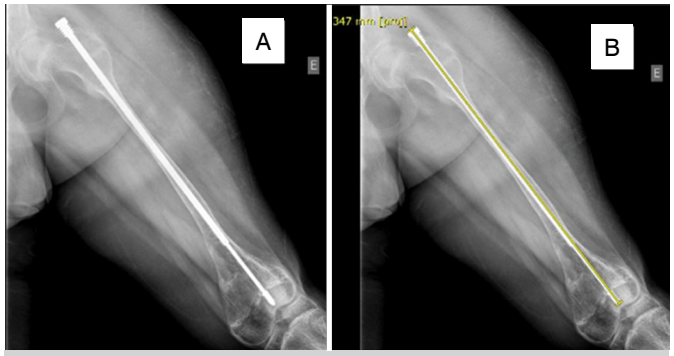

Figure 2. A) Anteroposterior (AP) radiograph of the left femur showing the treatment progression four years following FD rod surgery; B) The same radiograph with a final length measurement of 347mm (2020).

Table 4. Assessment of percentage telescoping increase.

Telescoping (%)		Mean increase (%)	P-value
Sex	Female	12.2%	0.300
	Male	7.3%	
Laterality	Right-side	4.9%	0.037
	Left-side	14.4%	
Bone	Femur	8.7%	0.220
	Tibia	17.0%	
Age range	< 14 years	12.4%	0.053
	> 14 years	1.8 %	
Follow-up time interval	0.5-3 years	1.3%	0.118
	3-5 years	13.4%	
	5-10 years	12.0%	
Surgical indication	Deformity	5.1%	0.640
	Fracture	11.1%	
	Migration	10.8%	
Clinical Type	Type I	7.0%	0.788
	Type III	11.6%	
	Type IV	9.3%	

Table 5. Telescoping analysis of the FD rod at the initial and final postoperative time interval.

Postoperative time interval	0.5-3 years	3-5 years	5-10 years	p-value
Telescoping mean (mm)	5.2	32.2	28.5	0.142
Telescoping mean %	1.3	13.4	12	0.118

Table 6. Description of patients who did not show telescoping.

Age at surgery (years)	Sex	Clinical Type	Bone	Surgical indication	Postoperative follow-up time (years)	Cause of the lack of telescoping
12.3	Female	III	Femur	Fracture	5.61	No bone growth
14.22	Female	IV	Femur	Migration	6.73	No bone growth
7.77	Female	IV	Femur	Deformity	0.88	Postoperative time
6.15	Male	IV	Femur	Deformity	1.65	No bone growth
18.31	Male	III	Femur	Migration	2.52	No bone growth
15.28	Male	III	Femur	Fracture	6.59	No bone growth

DISCUSSION

One of the main advantages of the telescopic FD rod is its ability to lengthen in synchronization with the child's bone segment. This reduces the number of revision surgeries over time and as the patient grows, thereby resulting in lower morbidity for the child with OI. Another advantage lies in the biomechanical principle of intramedullary rods in general, which work as an internal template, preventing deformities and promoting increased "resistance" against fractures due to the structure of the material itself. As disadvantages, there are difficulties in performing the percutaneous technique that includes a surgeon's long learning curve and the high cost of the material that limits its use in the public health system.[14]

Among the technical difficulties encountered in surgical procedures, the following ones can be recited: the need for multidisciplinary care, starting with the proper handling and positioning of the patient in order to prevent fractures provoked both by the nursing team and the surgical team in the room; special caution during anesthesia so as to avoid the use of anesthetics that can potentially cause hypermetabolic reactions or intubation-related mandibular and cervical fractures;[15] and the caution and attention needed when performing the surgical technique proper, which involves inserting the intramedullary rods into very thin and commonly obliterated bones.

With regard to this last aspect, it is not uncommon to find bowing deformities, as if these bones had assumed a "rib-shaped" appearance (Figure 3), especially when the tibia and femur are involved. The posterior aspect (concavity) of such bones is rigid and hard, which renders it difficult to receive a reamer or guide wire, whereas on the other hand, their anterior aspect (convexity) is fragile and offers nearly no resistance, which increase the occurrence of false path of the rods. During the surgical procedure, the correction of these deformities often requires an anterior wedge-shaped shortening to better acquire a rectilinear bone pattern. In the femur another challenge is the subtrochanteric deformity that forms a proximal fragment flexed and in varus – muscle force makes intraoperative reduction difficult by forcing the rod into an anterior and lateral position, often "tearing" the bone due to the continuous muscle tension exerted. (Figure 4)

In Brazil, a telescopic intramedullary rod was developed by our team in 2000. Its creation was based on the principles of previous rods[7-12], but now aiming at joint preservation as well as the Fassier-Duval rods' features. It was centrally attached into the distal epiphysis through its internal rod by means of a thread, and the trochanteric stabilization was achieved by the external rod through transosseous suturing of the greater trochanter. It yielded satisfactory results, both

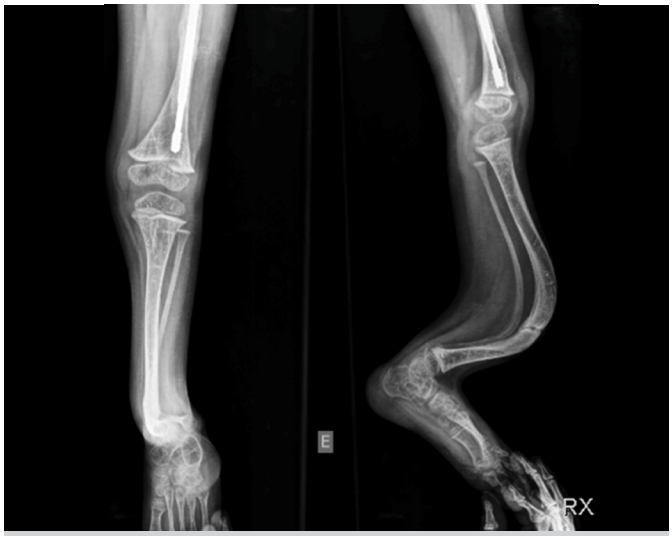

Figure 3. AP and lateral radiograph of the left leg showing the "rib-like" appearance of the tibia and fibula in a patient with osteogenesis imperfecta. Note the anterior convexity, with a lower bone density, compared to the posterior concavity, which is denser and more rigid, with obliterated marrow.

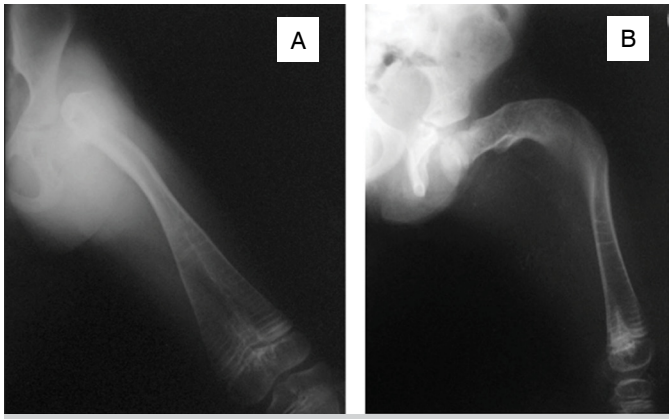

Figure 4. A) AP radiograph of the left thigh of a nine-year-old patient with OI and extreme varus of the proximal femur and bone overlap. B) Lateral radiograph of the same patient showing the flexion deformity.

in terms of cost-effectiveness and complication rates.[12] Its main limitation, though, is that its use was restricted to the femur, since only the greater trochanter allowed for proximal fixation by suturing. The main indication of surgery with the Fassier-Duval rod in this study was the occurrence of fractures (57.1%), a result similar to that found with the rod developed by SCSP.[12] This piece of data differs from most studies in which the main surgical indication observed was the correction of deformities.[16,17] A particularity of the health care service institution where this two studies were carried out is the large volume of emergencies, making it difficult to prioritize elective surgeries, which may have influenced the indication.

Another possible bias of this study is that all patients were treated in a public hospital, at which neither the costs of FD rodding nor the procedure itself is standardized by Brazil's Ministry of Health. In the cases included in this study, the implants were obtained via donations or lawsuits.

In the seven cases (33.3%) in which there were late complications, reoperation was performed in one patient (4,8%) with removal of the FD internal component after trauma with a peri-implant fracture. The patient remained with the complete rod (two components) for 2.55 years. The other patients had conservative treatment with a plaster cast, due to the unavailability of a new FD rod. Two of them sustained perisynthesis fracture, three patients had loosened the distal tip of the FD rod, and one had metallosis. There was no relationship with the Sillence classification, given that all types included in the study presented with the aforementioned complications.

One patient had clinical signs suggestive of metallosis, but this complication is not directly related to the rod. This patient progressed to a femoral neck fracture 2 years thereafter, at which point she underwent treatment with a locking plate and due to likely incompatible materials, she started to present local symptoms of inflammation. It was opted to remove the plate. (Figure 5) The problem was resolved after the implants were removed. Until the end of this study, the postoperative follow-up of this patient was 6.39 years, with the FD rod still in place and no local changes.

In this study, in addition to a longer mean follow-up time, longer than some follow-up time series found in the literature, we observed lower complication rates. Birke et al.,[4] in a 12-month follow-up, found a complication rate 40%, and 13% of the cases required rod revision, which also happened mainly due to fractures and/or migration of one of the components. This result was similar to that found by Sulko et al.,[16] who recorded a follow-up period of 18 months. It is worth mentioning that, in the literature, the average surgical revision rate varies between 3-14%.[3] These data may be related to the difficulties pertaining to the surgical technique proper and the long learning curve involved in the treatment of children with fragile bones. Despite this, some of the published are much higher, like those in the study by Azzam et al.,[17] in which 46% of the rods had to be revised, mainly due to fractures. This high rate can be explained by the greater number of patients analyzed and the long mean follow-up time (9 years).[17] In this way, also in the series corresponding to the implant developed at SCSP, a revision rate of almost 50% was observed, mainly due to fractures.[12]

The main advantage advocated for modern rods is their ability to telescope immature skeletons, thereby reducing the number of surgical reinterventions.[6,7,12,] In this study, 71.4% of the rods showed positive telescoping, with an average increase of 24 mm (9.9%) relative to the initial size. Considering patients under 14 years of age, the mean absolute lengthening achieved with telescoping was 30 mm, corresponding to an 11.4% increase. In the series recorded with the rod developed at SCSP, we observed positive telescoping in 60% of the rods, similarly to what was found in the current study. In the previous study with the SCSP rod, the mean increase was 23.57% – in absolute figures, the mean increase was 48.3 mm.[12] These results are probably attributable to the longer follow-up time (about nine years versus five years). In the literature, when telescoping failure is observed, the results are similar, however such

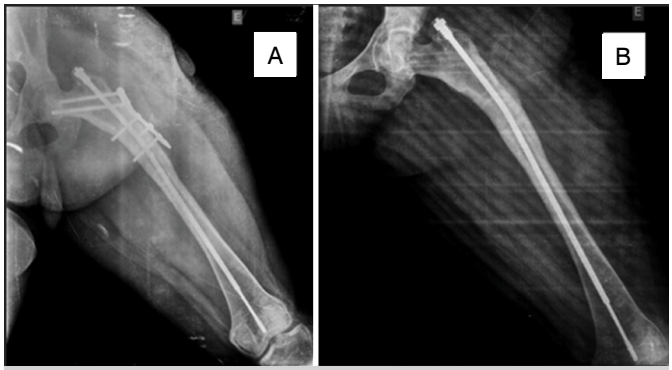

Figure 5. A) AP radiograph of the left femur of the patient with suspected metallosis in the proximal third of the left thigh due to likely incompatible synthesis materials. B) AP radiograph of the left femur of the same patient after removal of the plate in the IPO.

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studies do not present quantitative data, either as percentages or absolute values, that might allow for a comparative analysis.[4,12,18] Both the technical difficulty in assessing size and proportionality with the software used to view the radiographs by different health care services and the lack of parameter standardization when taking the measurements of the rods during the follow-up period make the analysis of these data difficult. We hope that further studies can provide advances in ensuring the reliability of this important piece of data on the main feature of telescopic rods in the future.

Of the six patients who did not show positive telescoping, four had reached skeletal maturity at the time they underwent surgery, one with 12.3-year-old female patient and three others who were older than 14 years of age. The other two patients were under 14 years of age and did not show bone growth, whereas the postoperative time was insufficient for growth analysis. (Table 5)

In the literature, the main cause indicated for telescoping failure is internal component migration of the FD rod (with distal fixation), with rates ranging from 13% to 41%.[4,12,13] In this study, the main reason for the lack of telescoping was the absence of bone growth among the patients. Lack of telescoping was also seen in a child with less than 1 year follow-up and one 6.15-year-old patient, despite a follow-up of 1.65 years, did not show bone growth in the period when comparing the radiographs.

Despite the good results found in both this study and the previous one carried out by our work group, our biggest limitation is the small series (15 patients in the current study and 22 patients in the previous one), given that osteogenesis imperfecta is a rare disease.

CONCLUSION

We found good effectiveness of surgical treatment in OI patients with the FD rod, with telescoping success rates like those reported in the literature, and with our rods[12], as well as similar complication rates.[4,12,18]

Other studies with specific data on telescoping, i.e., absolute values and percentages, are still scarce, which does not allow for a better comparison of either growth parameters or results.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. EOG: writing, data analysis, performing surgeries and intellectual concept of the article; MA: performing surgeries and article review; PHC: data analysis and writing; MRM: data tabulation and analysis; CS: intellectual concept of the article and performing surgeries.

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PHYSIATRIST

PHENOL VERSUS LIDOCAINE IN OBTURATOR NERVE NEUROLYSIS FOR HIP JOINT PAIN

FENOL CONTRA LIDOCAINA EM NEURÓLISE DO NERVO OBTURADOR PARA DOR ARTICULAR DO QUADRIL

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ABSTRACT

Introduction: For patients with severe hip osteoarthritis without clinical or socioeconomic conditions for total hip replacement, the obturator nerve block may serve for pain control and functional improvement. Either lidocaine or phenol are used, although the latter is expected to last longer. Objectives: Compare hip pain and functional performance after obturator nerve block with phenol versus lidocaine in patients with severe hip osteoarthritis who failed conservative treatment. Methodology: Forty-four patients scheduled for total arthroplasty due to severe osteoarthritis were randomized to the anterior branch of the obturator nerve with phenol (PG) or 1% lidocaine (LG), guided by electrical stimulation. Patients were evaluated with VAS, WOMAC, and pressure pain dolorimetry before the procedure and in the first and fourth months afterward. Results: Both groups improved significantly in pain control, pressure dolorimetry and functioning in the first month with reduced effect after 4 months, although the scores were still better than baseline. No statistical difference could be noticed between the groups. Severe adverse effects were not reported. Conclusion: Both lidocaine and phenol are equally effective and safe in the obturator nerve block for the control of pain and improvement in functioning in patients with severe hip OA. ***Evidence Level I; Randomized control trial, double-blind.***

Keywords: Phenol; Lidocaine; Osteoarthritis, Hip; Chronic Pain; Nerve Block.

RESUMO

Introdução: Em pacientes com osteoartrite grave do quadril, sem condições clínicas ou socioeconômicas para a substituição total do quadril, o bloqueio do nervo obturador pode servir para o controle da dor e ganho funcional. Pode-se usar lidocaína ou fenol, embora seja esperado que o último apresente maior duração. Objetivo: Comparar a dor no quadril e o desempenho funcional após o bloqueio do nervo obturador com fenol versus lidocaína em pacientes com osteoartrite grave do quadril que não obtiveram sucesso no tratamento conservador. Metodologia: Quarenta e quatro pacientes programados para artroplastia total devido à osteoartrite grave foram randomizados para o ramo anterior do nervo obturador com fenol (PG) ou lidocaína a 1% (LG), guiados por estimulação elétrica. Os pacientes foram avaliados com EVA, WOMAC e dolorimetria de dor por pressão antes do procedimento e no primeiro e quarto meses seguintes. Resultados: Ambos os grupos apresentaram melhora significativa no controle da dor, na dolorimetria por pressão e na funcionalidade no primeiro mês, com efeito reduzido após quatro meses, embora as pontuações ainda fossem melhores do que a linha de base. Não foi possível observar nenhuma diferença estatística entre os grupos. Não foram relatados efeitos adversos graves. Conclusão: Tanto a lidocaína quanto o fenol são igualmente eficazes e seguros no bloqueio do nervo obturador para o controle da dor e melhora da funcionalidade em pacientes com OA grave de quadril. ***Nível de evidência I; Estudo clínico randomizado,duplo cego.***

Descritores: *Fenol; Lidocaína; Osteoartrite do Quadril; Dor Crônica; Bloqueio Nervoso.*

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INTRODUCTION

The main symptom of osteoarthritis (OA) is joint pain, tipically worsened by movement or load, but also present at rest, and accompanied by joint stiffness that lasts less than thirty minutes or joint instability, limitation of the range of motion, and physical disability. These may lead to a compromised functional capacity of the affected individual and give rise to changes in gait and activities of daily living (ADLs).[1]

Comprehensive rehabilitation therapy aims to control pain, improve mobility, and bring functional restoration. Therapeutic resources may include non-pharmacological strategies such as exercise, modalities, walking aids, and drugs such as analgesics, anti-inflammatories, opiates, capsaicin cream, injections with glucocorticoids or hyaluronic acid.[1] Despite not being present in the therapeutic guidelines for this clinical condition, nerve blocks are a valuable interventionist resource, particularly when clinical treatment fails and

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

The study was conducted at the Hospital das Clínicas, Faculdade de medicina da USP de Ribeirão Preto, SP, Brazil.
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the surgical indication for total hip arthroplasty is restricted due to the clinical conditions related to high surgical risk in the elderly patient with multiple comorbidities,[2] or socioeconomic conditions.[3] In this context, the obturator nerve block can be an analgesic therapeutic alternative that enables the rehabilitation process.[4-6]

Nerve blocks interrupt the nociceptive input at its origin, blocking conduction by the spinal, cranial nerves, or afferent fibers that accompany the autonomic nerves. It is an indication for the relief of multiple painful syndromes, of nociceptive or neuropathic nature.7 Among the substances used in the practice of these blocks are lidocaine and phenol, which share the immediate local anesthetic action, which is more prolonged in the later due to their immediate selective effect on smaller nerve fibers, resulting from the destruction of small vessels, which initially saves large fibers.[8] John Monagle and Joanne Ee described the use of intra-articular phenol in hip osteoarthritis, where they achieved better pain control and improved functioning[6] and a previous study by our group, carried out only with the use of phenol in a series of patients,[4] there was an improvement in pain, especially during the first two months after the block.[9]

This study aims to evaluate the effectiveness of a pain treatment done by applying phenol to the anterior branch of the obturator nerve in comparison with the application of lidocaine in patients with hip osteoarthritis, who did not improve with the conservative treatment.

METHODS

This study was approved by the institution Internal Review Board (CAAE: 66553517.8.0000.5440), all subjects were instructed on the risks and benefits and signed an informed consent form prior to the start of the study.

This was a randomized, double-blind clinical trial. Participants were recruited from the rehabilitation center of a tertiary general hospital from Brazil's public health system. Inclusion criteria for this study were: 1) both sexes, 2) adults, 3) diagnosis of severe hip OA, based on the stage of joint degeneration(Kellgren Lawrence class 3 or 4), 4) failed conservative treatment such as drugs, physical therapy exercises, injections with glucocorticoids or hyaluronic acid, pain intensity assessed by the Visual Analog Scale (VAS) greater than six, 5) no known phenol allergy or uncontrolled coagulopathy. Exclusion criteria consisted of the presence of generalized pain, inability to undergo the block procedure under electrical stimulation guidance, due to pacemakers or other implanted devices sensitive to electrical currents, and difficulty in understanding the assessment instruments. Figure 1 shows the flowchart of allocation of individuals.

Forty-four severe hip OA patients were randomized in blocks of four participants with a computer-generated list (website *www.randomization.com*)for the blockade in the anterior branch of the obturator nerve (BABON)either with phenol (group PG) or lidocaine (group LG). In this study, patients were evaluated immediately after randomization and before the nerve block, follow up assessments were done one and four months after the intervention. Assessment used pain intensity VAS, which consisted of a 100 mm straight line anchored at the extremities to the expressions 'no pain' and 'worst possible pain' on which the patient is asked to indicate the intensity of the painful symptom during the day of evaluation. Dolorimetry consisted in the use of a pressure dynamometer with a cylindrical and rubberized tip of 1 cm^2 to inflict progressive pressure on myofascial trigger points until the patient manifested pain[10] – the painful pressure threshold indicate the sensibilization of that specific trigger point, thus lower scores indicated more sensitive points which needed less pressure to cause pain. The questionnaire Western Ontario and McMaster Universities Arthritis Index (WOMAC) was used to assess pain, stiffness, and physical function specifically for hip conditions, having already been used in several RCTs for drug and surgical treatment of hip OA.[11]

Using manual palpation, the interval between muscles adductor longus and brevis was identified, and needles were inserted 3 to 5 centimeters distal to their upper extremity. The anterior branch of the

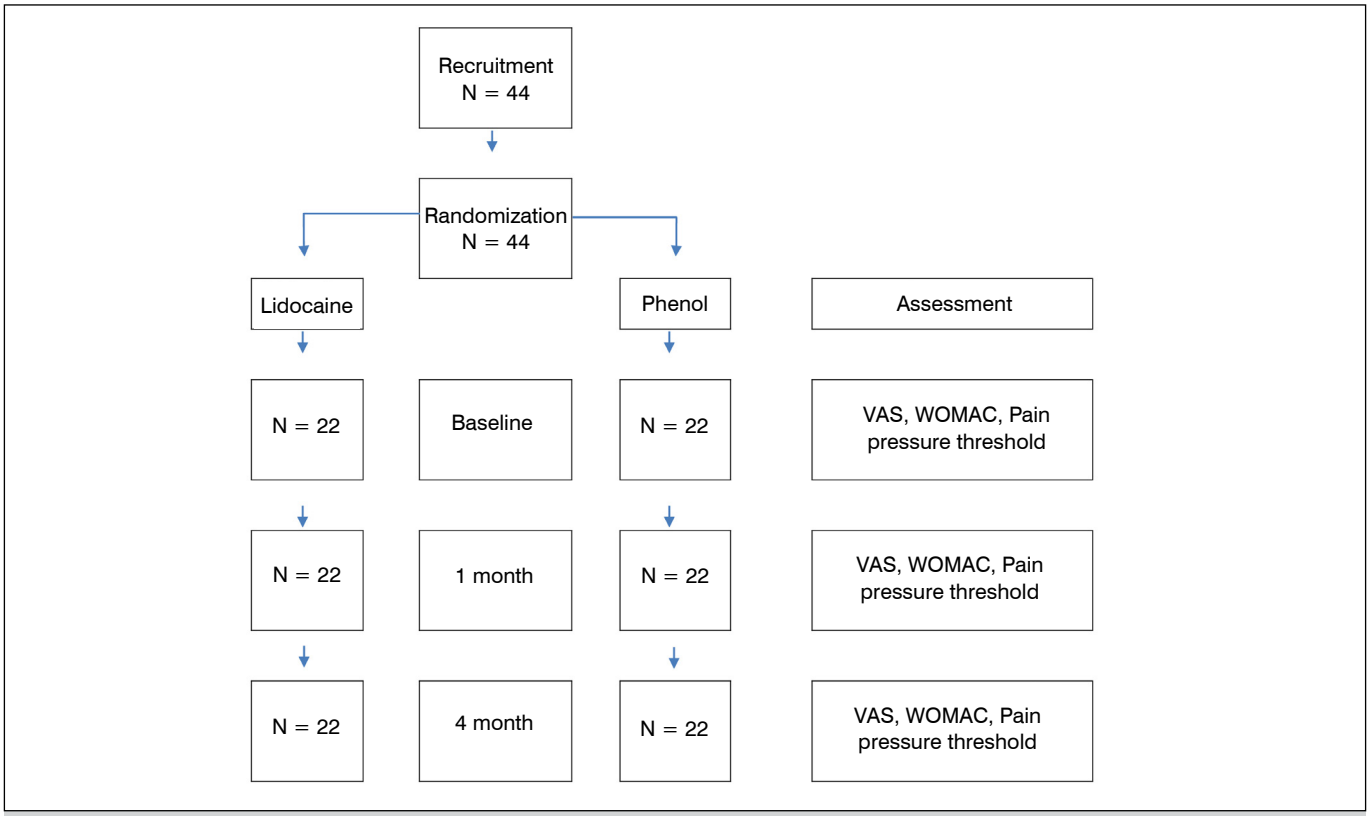


Figure 1. Flowchart of allocation of subjects.

<< SUMÁRIO

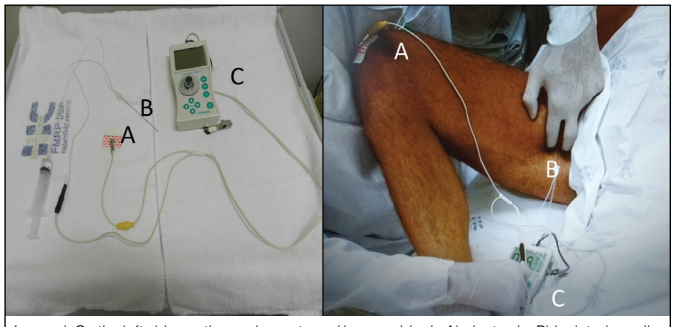
obturator nerve could be localized with 100mm-long isolated needles connected to an electrostimulator.[12] Figure 2 shows the arrangement of this localization system: the electrical current produced by the stimulator would travel from an electrode to the tip of the needle. Electrical current as low as 2 mA can produce muscle contraction. When the best contraction of adductor muscles was obtained with 1 mA, which is the rheobase for peripheral nerves, successful localization was accomplished. Treatment was performed with an application of 2.5 ml of phenol 6% or lidocaine 1% to the anterior branch of the obturator nerve according to a randomization list. Immediate effect is the interruption of muscle contraction.

Both lidocaine and phenol solutions are transparent liquids, but the later exhalates a pungent smell and could be easily differentiated from the first. To warrant blinding, the therapeutic solutions were prepared by a research nurse who was the only one in contact with the randomization sequence. She would bring the syringes with an open bottle of phenol, thus the injection would always be performed in a phenol smelling environment.

The sample size calculation was based on the result of a previous study published by Crema et al., in which a series of patients with severe hip OA underwent neurolysis in the anterior branch of the obturator nerve to control pain, having the mean pain intensity (VAS) varied from 8.2 ± 0.9 at baseline to 6.6 ± 1.7 at the end of one month, 6.5 ± 1.7 at the end of two months, and 7.3 ± 1 at six months (p= 0.0094). Considering an effect size of 10%, the statistical power of 80% and the significance level of 0.05, twenty participants would be needed in each study group, to which a margin of 10% was added (four more participants) for the case of follow-up losses. Quantitative variables were evaluated with mean and standard deviation, whereas in categorical variables, percentages were evaluated. After verifying the normality of the distribution of variables, the evaluation of the results of pain assessment in patients with the VAS (primary outcome), WOMAC and its subscales and dolorimetry, the ANOVA test for repeated measures was used to assess the evolution of the values of these variables. As the dolorimetry was always evaluated in a group of six muscles, adductor magnus, short and long, gluteus minimus, medius and piriformis, we preferred to create an index of mean value of these points rather than study them individually. The analysis of the results was based on the intention to treat.

RESULTS

Forty-four patients were included in the study according to the flowchart shown in Figure 1, 22 (50%) of whom were men. The mean age of the entire sample is 54.6 ± 15.7 years. Table 1 presents the biodemographic and clinical data.



Legend: On the left side are the equipment used in nerve block: A) electrode, B) isolated needle, C) electrostimulator. On the right side the electrode (B) is positioned in the knee and connected to the stimulator (C) which is operated by the physician while positioning the needle (A) between the the muscles adductor brevis and longus.

Figure 2. Equipment and positioning of lower leg for blocking of the anterior branch of the obturator nerve.

Idiopathic hip OA was responsible for 50%, followed by avascular necrosis of the femoral head (22.7%). Other etiologies of hip disease were Legg-Perthes and rheumatoid arthritis.

Figure 3 shows pain intensity reported by VAS during the study. Baseline pain intensity was similar in both groups (phenol: 87.0 ± 15.0 x lidocaine90.0 ± 11.0; p>0.05). After one month of a single nerve block, pain intensity reduced in both groups, although slightly more in those subjects injected with phenol, without statistical difference (phenol: 58.0 ± 29.0 x lidocaine: 70.0 ± 27.0; p>0.05), and both groups finished the follow-up period with very similar pain intensities (phenol: 59.0 ± 29.0 x lidocaine: 60.0 ± 32.0; p>0.05). A significant decrease in pain levels over the course of follow-up was demonstrated by ANOVA.

Similar results concerning functioning can be observed in Figure 4. Again, both groups had similar baseline scores and decreased the compromise in quality of life after one month and four months, without statistical difference.

Table 1. Biodemographic and clinical data.

	All	Phenol	Lidocaine
N	44	22	22
Men (%)	22	11	11
Age (Years)	54.6 15.7	55.9 16.8	53.2 14.7
RX Classification			
Class 3	21 (47.7%)	11 (50.0%)	10 (55.5%)
Class 4	23 (52.3%)	11(50.0%)	12 (54.5%)

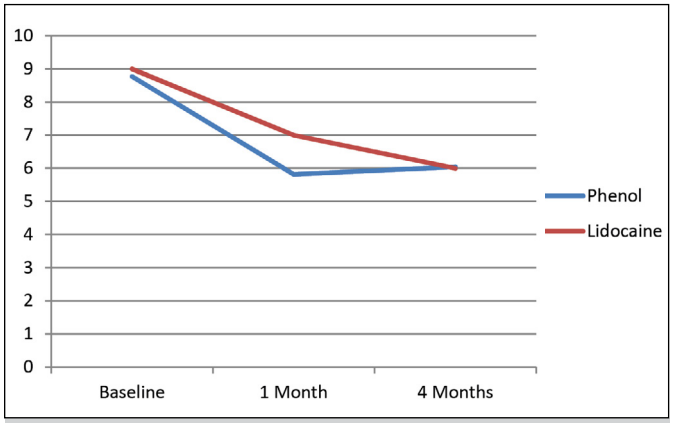


Figure 3. Evolution of pain intensity assessed by VAS during the study in patients blocked with phenol and lidocaine.

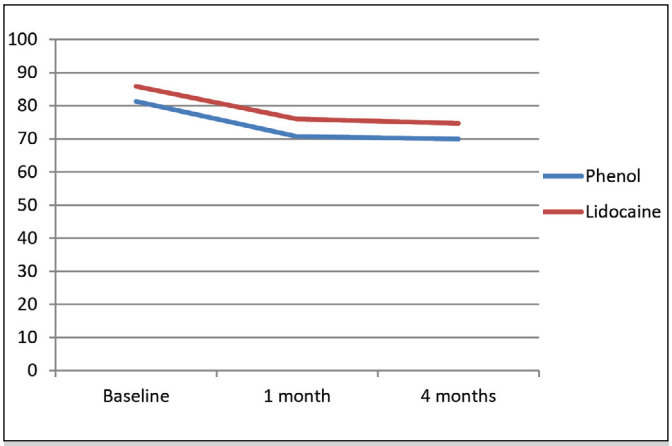


Figure 4. Evolution of functioning assessed by WOMAC during the study in patients blocked with phenol and lidocaine.

Table 2 shows the evolution of the mean values of each domain of the WOMAC questionnaire. For the pain component, no differences were identified between the groups. For the group with phenol, there was pain reduction at the end of one month, but with resumption of pain levels in the fourth month; on the other hand, in the lidocaine group, the reduction in the pain component values of this questionnaire obtained at the end of the first month was maintained until the end of the observation period. The ANOVA test to verify the interaction of the type of treatment with the temporal evolution of this component was not significant. For the 'stiffness' and 'function' components, both groups had improved indices at the end of the first month of the segment, with stability of gains at the end of four months for both variables in the group in which phenol was used, while for 'stiffness' there was a progressive improvement in the lidocaine group, but this was not the case for the 'function' component. Again, the ANOVA test did not identify a statistically significant interaction between treatment and evolution over the observation period for these two questionnaire components.

Mean dolorimetry values were calculated from the pain pressure theshold obtained in the medial gluteus medius, lateral gluteus medius, gluteus minimus, and piriformis. Although the curves in Figure 5 are inverted in comparison to figures 3 and 4, the meaning is the same, baseline pain pressure thresholds were similar and improved after one and four months, but without statistical difference among the groups. Patients did not report adverse effects after the procedure, such as paresthesia, bruising or pain.

DISCUSSION

This randomized controlled trial was successful in comparing the effect of blocking the anterior branch of the obturator nerve with lidocaine and phenol in patients with severe hip OA. Overall, it was possible to demonstrate a reduction of about 33% in pain intensity assessed by the VAS for up to sixteen weeks in these patients who were candidates for surgical treatment, accompanied by an improvement in quality of life and functioning measured by WOMAC. However, there was no significant change in pressure dolorimetry. The two pharmacological agents produced very similar results in all parameters evaluated, with minimal differences. Alternatively, Silva et al. describe a case report in which they performed an obturator nerve block with 10 ml of 0.25% bupivacaine, resulting in 100% improvement of pain and improvement in the patient's functioning, who started presenting independence for daily activities. The analgesic effect persisted for 40 days.[14]

The initial hypothesis that the effects of phenolblock would last longer was not confirmed. Contrasting to lidocaine, which effect of neural block lasts 2 to 4 hours, the effects of phenolic blocks are based in the local anesthetic action on gama fibers, reducing the spastic reflex associated to pain. Also, this substance can produce axoniotmesis, which is the disorganization of the structure of myelin sheath of axons, without injury to endoneural tubes, which may reduce motor inputs and cause relaxation. Its effect in muscle relaxation and spasticity control is well known.[9] The effects of chemical neurolysis with phenol are not permanent, since functional reinnervation may occur in a period of months. or years.[8] The time of action of this procedure may vary with the concentration of phenol, injected volume, duration of exposure, and injection technique. In a study carried out by Felsenthal, the degree of conduction block differed with different concentrations and volumes of phenol injected up to eight weeks after the nerve block, which could explain the variation in duration.[15]

The WOMAC questionnaire showed that, in an unified way, up to the fourth month there was an improvement of joint stiffness, feeling of instability or joint insecurity, limited range of motion, and physical incapacity leading to impairment of activities such as walking, sitting, standing, and performing physical activities.

None of the individuals in this study developed sensory changes or neuropathic pain pattern in the sensory territory of this nerve branch - the medial face of the thigh, although it is expected that, when injected close to nerves with a predominance of sensory fibers, phenol may cause dysesthesia or anesthesia for up to four months, and eventually this sensation can be described as neuropathic pain, with terms such as shock and burning and with constant or paroxysmal presentation. The most frequent adverse effects in phenolysis are: dysesthesia and pain resulting from a local inflammatory process, ranging from 0.4% to 5% in children and 2-32% in adults.[13]

This study has some limitations, such as the evaluation of functionality through a questionnaire to be answered by the patient and not through physical tests; the patients had multiple comorbidities and presented arthritis in other joints as a confounding factor in the perception of improvement; and also the presence of periarticular pain pathologies should be investigated. Special attention should be directed to muscular affections, such as myofascial pain, as its treatment can represent a significant symptomatic relief.[16] The most frequently involved muscles are the piriformis, iliopsoas, adductor longus, gluteus medius and minimus, adductors, and the piriformis muscle, which is related to pain over the buttock, along with its insertion in the greater trochanter and radiating to the posterior surface of the thigh. The iliopsoas muscle, in turn, presents a distribution of pain associated with its trigger points on the anterior and proximal surface of the thigh, as shown in an unpublished study by Magário et al.[17]

Given that there is a lack of studies on blocks aimed at improving pain in hip osteoarthritis, the positive aspects of this study include the assessment of methods based on blocks to relieve pain and improve the quality of life or functionality for patients with few resources.

Table 2. Detailed evolution of WOMAC components during the study in patients blocked with phenol and lidocaine.

	Treatment	Baseline	One month	Four months
WOMAC		83.6 ± 18.3	81.3 ± 12.9	85.9 ± 5.5
Pain		17.4 ± 2.7	16.8 ± 3.1	18.0 ± 2.0
	Phenol	16.8 ± 3.1	13.9 ± 3.6*	16.5 ± 12.5
	Lidocaine	18.0 ± 2.0	15.4 ± 3.0*	15.1 ± 2.9*
Stiffness		5.8 ± 1.8	5.6 ± 2.1	6.1 ± 1.6
	Phenol	5.6 ± 2.1	4.2 ± 2.3*	3.2 ± 2.7*
	Lidocaine	6.1 ± 1.6	4.4 ± 2.2*	3.0 ± 2.5*§
Function		60.6 ± 6.8	59.1 ± 8.2	62.2 ± 4.7
	Phenol	59.1 ± 8.2	52.3 ± 11.5*	52.7 ± 10.4*
	Lidocaine	62.2 ± 4.7	56.5 ± 7.7*	57.1 ± 5.2*

Legend: *p<0.05 in relation to the initial value, and §p<0.05 in relation to the value one month after the beginning of the treatment.

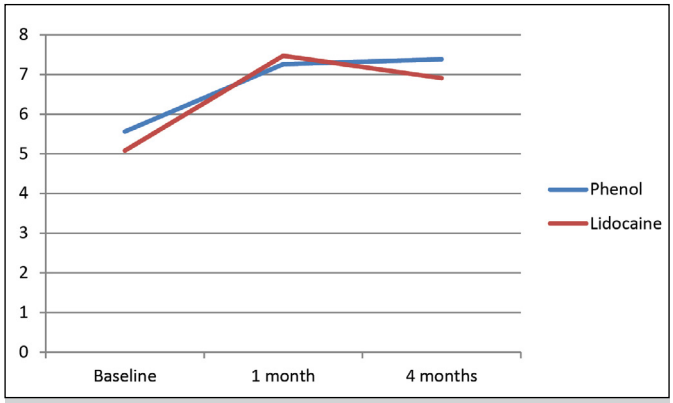


Figure 5. Dolorimetry evolution.

CONCLUSION

The application of phenol or lidocaine in the anterior branch of the obturator nerve can alleviate pain and improve the functionality of patients with hip OA, and may be an alternative treatment for patients who have not undergone THA surgery, either because they are not in clinical condition or because of the queue waiting for the procedure.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to this paper's development. CMTC: writing of the article, review, statistical analysis and performance of obturator nerve neurolysis procedures; LPTM: literature review and obturator nerve neurolysis procedures, article review; WCS: literature review and performance of obturator nerve neurolysis procedures, revision; NMF: performing obturator nerve neurolysis procedures, writing and reviewing the article; TPS: writing and reviewing the article; MR: writing and reviewing, statistical analysis and performance of obturator nerve neurolysis procedures.

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SPINE

EPIDEMIOLOGY OF TRAUMATIC FRACTURES OF THE SPINE IN MARIO COVAS HOSPITAL BETWEEN 2015 AND 2020

EPIDEMIOLOGIA DAS FRATURAS TRAUMÁTICAS DA COLUNA NO HOSPITAL MARIO COVAS ENTRE 2015 E 2020

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ABSTRACT

Objective: Analyze the epidemiological profile of patients with traumatic spinal fractures treated at Mário Covas State Hospital between 2015 and 2020. Methodology: This is an epidemiological, descriptive, retrospective, quantitative, comparative, medical records review-type study. Data collection was carried out between May and June 2022 at the Mário Covas State Hospital, the following characteristics being evaluated: age, sex, lesion topography, trauma mechanism, origin and treatment. Results: Data from 252 patients with traumatic spinal fractures were analyzed. The mean age of patients was 48.7 years, 74.7% were male. The mechanism of trauma from falls from a height and the topography of the lumbar vertebrae have a highly significant trend. The most affected vertebrae are lumbar L1, thoracic T12 and cervical C6. The crossing of the age group with the male sex is higher than expected in those over 60 years of age. The crossing of the age group with the trauma mechanism is higher than expected, between 20 and 39 years. Conclusion: There are few published works on the epidemiology of traumatic fractures of the spine, which points to the need for further studies on the subject. ***Level of Evidence III; Retrospective comparative study.***

Keywords: Fracture; Spine; Trauma.

RESUMO

Objetivo: Analisar o perfil epidemiológico dos pacientes com fratura traumática de coluna vertebral atendidos no Hospital Estadual Mário Covas entre os anos de 2015 e 2020. Metodologia: Trata-se de um estudo epidemiológico, descritivo, retrospectivo, quantitativo, comparativo, do tipo revisão de prontuário médico. A coleta de dados foi realizada entre maio e junho de 2022 no Hospital Estadual Mário Covas, sendo avaliadas as características: idade, sexo, topografia da lesão, mecanismo de trauma, procedência e tratamento. Resultados: Foram analisados dados de 252 pacientes com fratura traumática da coluna vertebral. A média da idade dos pacientes foi de 48,7 anos, 74,7% eram do sexo masculino. O mecanismo de trauma tipo queda de altura e a topografia das vértebras lombares têm tendência altamente significativa. As vértebras mais afetadas são lombar L1, torácica T12 e cervical C6. O cruzamento da faixa etária com sexo masculino está acima do esperado nos maiores de 60 anos. O cruzamento da faixa etária com mecanismo do trauma está acima do esperado, entre 20 a 39 anos. Conclusão: São poucos os trabalhos publicados a respeito da epidemiologia das fraturas traumáticas de coluna vertebral, o que aponta para a necessidade de novos estudos acerca da temática. ***Nível de evidência III; Estudo retrospectivo comparativo.***

Descritores: *Coluna Vertebral; Fratura; Trauma.*

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INTRODUCTION

Currently, traumatic spinal fractures are important causes of morbidity and mortality and represent a gradual increase in incidence. Thus, it is notable the growth in the number of patients who arrive at the emergency room with severe traumatic spinal injuries, victims of falls from heights, automobile accidents, firearm wounds, and being run over by a car.[1]

Falling from a balcony has been found to be the most frequent cause among trauma mechanisms associated with traumatic fracture of the spine. Housing with balconies is related to the shift in construction to masonry houses in large population areas and pockets of poverty. Given its correlation with the state of social vulnerability of the individual, it is understood as a modifiable causal factor.[2]

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

The study was conducted at the Faculdade de Medicina do ABC, Santo André, São Paulo, Brazil.
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Traumatic spine injury occurs predominantly in males, and is four times more frequent in the 15-40 age group,[3] that is, at an age of high productivity. Given the risk of irreversible sequelae, the consequences affect not only the patient, but also the family and society, and thus have a major impact on public health in Brazil.[2]
It is emphasized that few studies have been published in the Brazilian literature on the epidemiology of traumatic spine fractures, which justifies the need for new studies on the subject. In this sense, recognizing the scarcity of such data, this study aims to analyze the epidemiological profile of patients with traumatic spine fractures treated at the Mário Covas State Hospital between 2015 and 2020.
Thus, the intention is, based on the results, to evaluate possible techniques for improving treatment, as well as prevention strategies. In addition to analyzing the impact of the COVID-19 pandemic on the incidence of spinal trauma during the years 2020 in relation previous years, disseminating these data as a form of scientific contribution.

METHODS

This is an epidemiological analysis, descriptive, retrospective, quantitative, comparative study, with a direct and observational approach, of the medical record review type. Data collection was performed by analyzing clinical and epidemiological data of patients seen at Hospital Estadual Mário Covas (HEMC), during the months of May and June 2022. Thus, the characteristics evaluated were age, gender, topography of the injury, trauma mechanism, origin, and treatment. It is noteworthy that the HEMC is the trauma reference center of the ABC Paulista macro region, receiving patients regulated from other cities in greater São Paulo, through the CRUE (Central Regulatory Urgency and Emergency).
The data studied were divided into groups: year of attendance, age group, sex, trauma mechanism (auto accident, motorcycle accident, domestic accident, auto vs. motorcycle accident, running over, FAF, diving, fall, and fall from own height), topography (odontoid, cervical/odontoid vertebra, lumbar vertebra, thoracic vertebra, thoracic/cervical vertebra, thoracic/cervical/odontoid vertebra, thoracic/lumbar vertebra, thoracic/lumbar/cervical vertebra, others). Surgical and conservative management was also addressed.
The data were expressed with their respective confidence intervals, and the statistical treatment was performed using SPSS software. For comparison of proportions, the chi-square test was used with a 5% significance level and, finally, the variables: age group and gender, cause and gender, cause and age group.[4]
Regarding data collection from medical records, criteria were established. As inclusion criteria, patients with a diagnosis of traumatic spine fracture were selected for this study, having undergone surgical treatment or not, performed at the HEMC during the period from 2015 to 2020, as these were the years with the highest prevalence of medical care. The exclusion criteria were non-traumatic fractures and patients about whom it was not possible to collect adequate information by studying the medical records.

RESULTS

Data from n=252 patients with traumatic spine fracture from 2015 to 2020 were analyzed. Patients were aged between 9 years (youngest) and 91 years (oldest), mean age is 48.7 ±18 years, median = 50 years (34 to 62, 1st Quartile and 3rd Quartile). The age group 40 to 59 years (34.9%) was significantly more frequent. Of the patients are 74.7% were male (p-value <0.0001*, statistically significant).
To facilitate the inspection of the results, Figures 1 to 8 were elaborated, which cover the year, age range, gender, trauma mechanism,

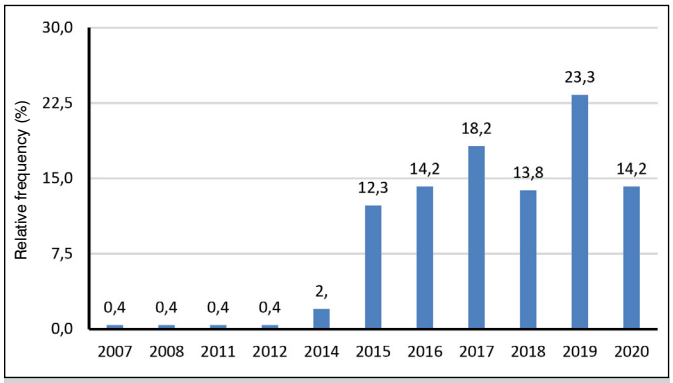

Figure 1. Year of the traumatic spine fractures of 252 patients.

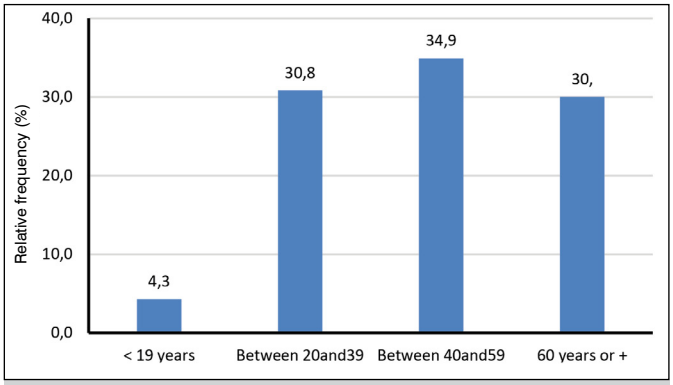

Figure 2. Age range of the 252 patients with traumatic spinal fracture.

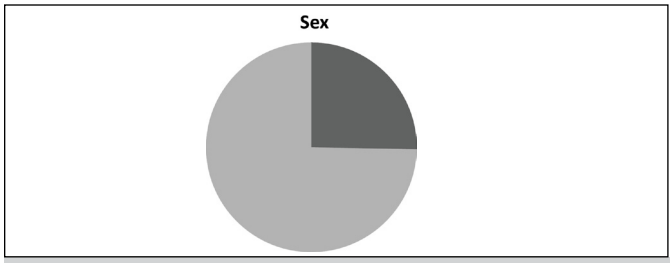

Figure 3. Sex of the 252 patients with traumatic spinal fracture.

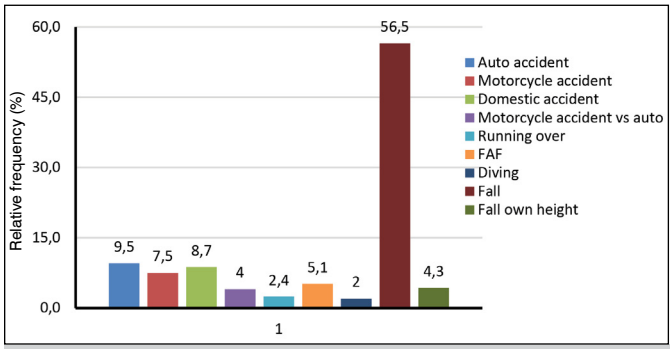

Figure 4. Mechanism of trauma of the 252 patients with traumatic spinal fracture.

topography, cervical vertebrae and thoracic vertebrae of the patients with traumatic fractures, respectively.
Table 1 shows the intersection of the age range data with the following variables:
a. Sex: male (57.9%) is above expected in the 60 years and older age group, (p-value=0.0006*, highly significant).

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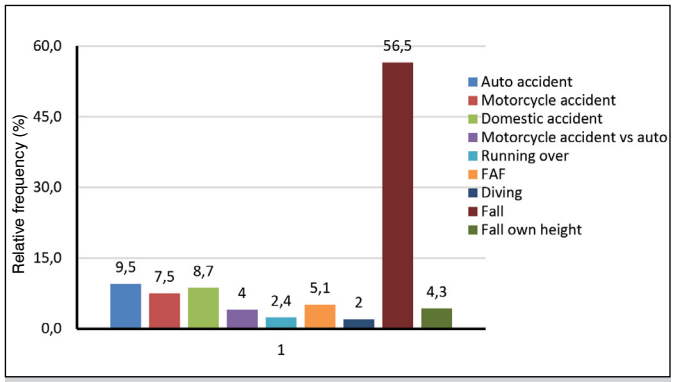

Figure 5. Topography of the 252 patients with traumatic spinal fracture.

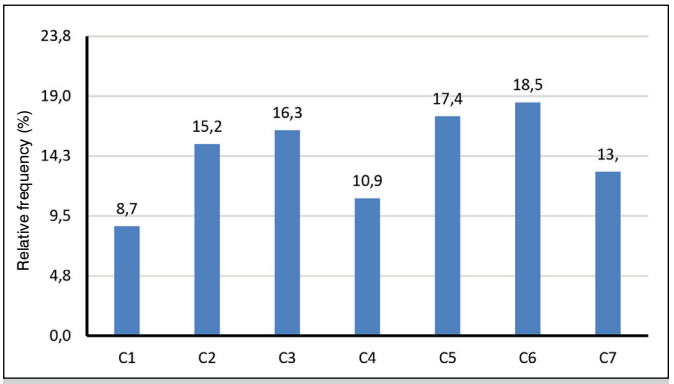

Figure 6. Affected cervical vertebrae of the 252 patients with traumatic spinal fracture.

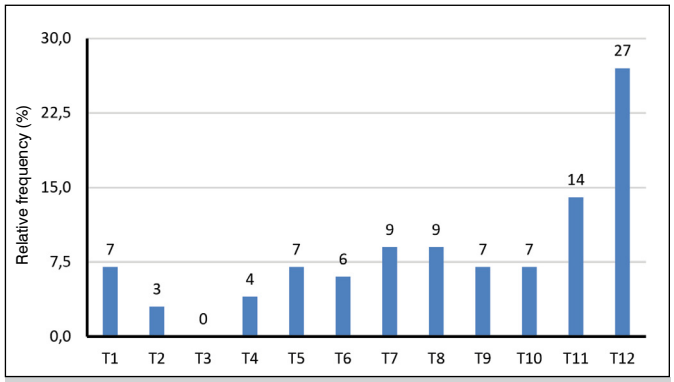

Figure 7. Thoracic vertebrae affected in the 252 patients with traumatic spinal fracture.

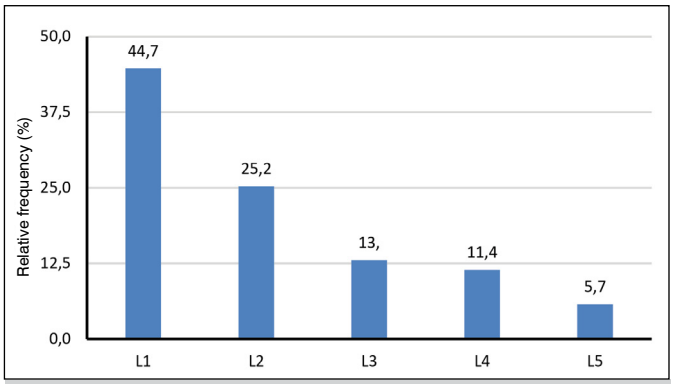

Figure 8. Affected lumbar vertebrae of n=252 patients with traumatic spinal fracture.

b. Mechanism of trauma: above expected in the 20 to 39 age group: motorcycle accident (17.9%), motorcycle vs auto accident (11.5%), FAF (14.1%).
c. Conduct: Surgical (52.3%) in the 40 to 59 age group, the most prevalent.
Table 2 shows that the intersection of the data on the trauma mechanism in relation to gender, with motorcycle accidents being the most prevalent in males (10.1%) and falls from height in females (10.9%).
Table 3 shows that there is no statistical difference between the trauma mechanism and the type of treatment adopted.
Table 4 shows that the trauma mechanism automobile accident (19.5%) and diving (7.9%) are common causes of cervical vertebra fracture, but falls are more prevalent in both cervical (42.9%) and lumbar vertebra fractures (69.3%).
Table 5 shows that as with lumbar vertebral fractures, the trauma mechanism of falling is the most common in thoracic vertebral fractures (52.8%).
Table 6 shows that most fractures of lumbar vertebrae were treated surgically, while fractures of the odontoid process were almost entirely treated conservatively.

Table 1. Evaluation of age group according to sex, trauma mechanism, management and follow-up of n=252 patients with traumatic spine fracture.

	< 19 years		20 e 39		40 e 59		60 years or +		
	n=11	%	n=78	%	n=88	%	n=76	%	p-value
Sex									**0.0006***
Feminine	2	18,2	11	14,1	19	21,6	32(z)	42,1(z)	
Masculine	9	81,8	67	85,9	69	78,4	44(x)	57,9(x)	
Trauma mechanism									**<0.0001***
Auto accident	2	18,2	6	7,7	9	10,2	7	9,2	
Motorcycle accident	1	9,1	14(x)	17,9(x)	2(z)	2,3(z)	2	2,6	
Domestic accident	2	18,2	5	6,4	9	10,2	6	7,9	
Motorcycle accident vs auto	0	0,0	9(x)	11,5(x)	1	1,1	0(z)	0,0(z)	
Running over	1	9,1	0	0,0	2	2,3	3	3,9	
FAF	1	9,1	11(x)	14,1(x)	0(z)	0,0(z)	1	1,3	
Diving	0	0,0	3	3,8	2	2,3	0	0,0	
Fall	4	36,4	29(z)	37,3(z)	61(x)	69,3(x)	49	64,6	
Fall own height	0	0,0	1	1,3	2	2,3	8	10,5	
Conduct									**0,4897**
Arthrodesis	4	36,4	39	50,0	46	52,3	32	42,1	
Conservative	7	63,6	39	50,0	42	47,7	44	57,9	

*Independence chi-square. (x) Above expectations. (z) Lower than expected.

Table 2. Evaluation of gender according to trauma mechanism and management of n=252 patients with traumatic fracture of the spine.

	Feminine		Masculine		
	n=64	%	n=189	%	p-value
Trauma mechanism					**<0.0001***
Auto accident	9	14,1	15	7,9	
Motorcycle accident	0	0,0	19	10,1	
Domestic accident	3	4,7	19	10,1	
Motorcycle accident vs auto	0	0,0	10	5,3	
Running over	1	1,6	5	2,6	
FAF	2	3,1	11	5,8	
Diving	0	0,0	5	2,6	
Fall	42	65,6	101	53,5	
Fall own height	7	10,9	4	2,1	
Conduct					**0,3681***
Arthrodesis	27	42,2	94	49,7	
Conservative	37	57,8	95	50,3	

*Independence chi-square.

Table 3. Evaluation of Management according to Mechanism of trauma and of n=252 patients with traumatic fracture of the spine.

Conduct	Arthrodesis		Conservative		
	n=121	%	n=132	%	
Auto accident	12	9,9	12	9,1	
Motorcycle accident	9	7,4	10	7,6	
Domestic accident	12	9,9	10	7,6	
Motorcycle accident vs auto	6	5,0	4	3,0	
Running over	3	2,5	3	2,3	
FAF	5	4,1	8	6,1	
Diving	2	1,7	3	2,3	
Fall	68	56,2	75	56,7	
Fall own height	4	3,3	7	5,3	
p-value					0,9738*

*Independence chi-square.

Table 4. Evaluation of Topography according to Mechanism of trauma and of n=252 patients with traumatic spinal fracture.

Topography*	Odontoid		Cervical		Cervical/ Odontoid		Lumbar	
	n=6	%	n=63	%	n=2	%	n=101	%
Auto accident	1	16,7	10(x)	15,9(x)	0	0,0	3	3,0
Motorcycle accident	1	16,7	4	6,3	0	0,0	6	5,9
Domestic accident	1	16,7	7	11,1	1(x)	50,0(x)	7	6,9
Motorcycle accident vs auto	0	0,0	2	3,2	0	0,0	4	4,0
Running over	0	0,0	2	3,2	0	0,0	3	3,0
FAF	0	0,0	4	6,3	0	0,0	5	5,0
Diving	0	0,0	5(x)	7,9(x)	0	0,0	0	0,0
Fall	3	50,0	27	42,9	1	50,0	70(x)	69,3(x)
Fall own height	0	0,0	2	3,2	0	0,0	3	3,0

*p-value <0.0001. Chi-square of independence. (x) Above expectations.

Table 5. Evaluation of Topography according to Mechanism of trauma and of n=252 patients with traumatic spine fracture.

Topography	Thoracic		Thoracic/ Cervical		Thoracic/Cervical/ Odontoid	
	n=53	%	n=7	%	n=1	%
Auto accident	5	9,4	2	28,6	1	100,0
Motorcycle accident	7	13,2	0	0,0	0	0,0
Domestic accident	3	5,7	0	0,0	0	0,0
Motorcycle accident vs auto	3	5,7	1	14,3	0	0,0
Running over	0	0,0	1	14,3	0	0,0
FAF	2	3,8	1	14,3	0	0,0
Diving	0	0,0	0	0,0	0	0,0
Fall	28(x)	52,8(x)	1	14,3	0	0,0
Fall own height	5	9,4	1	14,3	0	0,0

*p-value <0.0001. Chi-square of independence. (x) Above expectations.

Therefore, from the statistical analysis performed by means of the information collected from the medical records regarding spinal fractures that occurred at the HEMC in the aforementioned study period, the following predominant characteristics can be stated: mean age is 48.7 +/- 18 years, age range 40 to 59 years (34.9%) is the most frequent, and 74.7% are male. The trauma mechanism of falling from height and lumbar vertebrae topography (39.8%) have a highly significant trend.

The most affected vertebrae are: lumbar L1 (44.7%), followed by thoracic T12 (27.0%) and cervical C6 (18.5%). The crossover of age group with male gender (57.9%) is higher than expected in the 60 and older age group. The intersection of age with the trauma mechanism is above what is expected in the 20 to 39 age group:

Table 6. Evaluation of Management according to Topography of n=252 patients with traumatic spine fractures.

Conduct	Surgical		Conservative	
	n=121	%	n=132	%
Topography *				
Odontoid	1	0,8	5	3,8
Cervical	28	23,1	35	26,5
Cervical/Odontoid	1	0,8	1	0,8
Lumbar	49	40,6	52	39,3
Thoracic	29	24,0	24	18,2
Thoracic /Cervical	5	4,1	2	1,5
Thoracic /Cervical/Odontoid	0	0,0	1	0,8
Thoracic /Lumbar	3	2,5	6	4,5
Thoracic /Lumbar/Cervical	0	0,0	1	0,8
Sacrum	5	4,1	5	3,8

*p-value: 0.5517. Chi-square of independence.

motorcycle accident (17.9%), motorcycle vs auto accident (11.5%), gunshot wound (14.1%) and in the 40 to 59 age group, fall (69.3%). Figure 1 shows a drop in the incidence of traumatic spine fractures between 2019 and 2020, which corresponds to the period when the new coronavirus pandemic begins. It is also noted that conservative management (52.2%) was the most common approach to spinal fractures, but without a large percentage of difference with respect to surgical management (47.8%).

DISCUSSION

An increase in the number of patients who are victims of spinal trauma has been noted, with a significant socioeconomic impact.[5] The male gender with the highest prevalence has also been observed by other authors, which corroborates the findings of this study. Regarding the age range, the age of higher prevalence was around 40 years, varying in most cases from 20 to 60 years of age,[3,5-10] being an age range close to the patients seen at the HEMC.

It is noteworthy that, besides trauma from falls from heights, which are very prevalent,[5] traffic accidents deserve attention, since its high prevalence has been observed, as well as the involvement of victims in an even younger age range when compared, reaching a decade less age in traffic accidents when compared to the trauma caused by this type of fall mentioned above.[6]

Other studies have shown the presence of different etiologies of spinal injury by trauma, such as automobile accidents (25%-50%), falls from a slab (20-23%), firearm wounds (7%), diving in shallow waters (3%), sports practice, aggression (2%) and other acts of violence (15%).[5-7] The causes vary according to the region studied, in view of the percentages of these indices contrasting with those found in patients seen at the HEMC.

Furthermore, it was verified that the lumbar spine L1 is also usually the most affected, with the thoracic spine T12 having a relevant prevalence.[6] In females, a greater prevalence of the cervical spine was verified, at a ratio of 6:1 in relation to males, even though the latter are the ones who suffer more spinal injuries as a result of traumatic events.[7]

In a study carried out in Saudi Arabia, the prevalence of cervical injuries was also higher in males, with 85.6% of the cases and a mean age of 36.6 years.[9]

No less important is the presence of neurological injury as a result of the trauma.[6] A European study observed that among the patients assisted, (9.6%) suffered spinal fractures/dislocations alone and 4,489 (1.8%) suffered spinal cord injury with or without fractures/dislocations. The age of patients with spinal cord injury was 44.5 years, and 64.5% of these patients were male.[10]

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However, even with these important indexes, the incidence of spinal cord injury due to spinal trauma is not elucidated in Brazil.[7] In this sense, the understanding of these data, as well as in relation to other types of spinal injuries, is essential for the planning of health services and for the establishment of injury prevention priorities.[11] With the high prevalence of spinal injuries, improvements in management were required to achieve effective treatment. Thus, the development and training of teams specialized in the care of these patients was expanded, in order to provide a greater expectation of survival, even in the most severe cases, in addition to reducing complications. However, the prognosis depends on the rehabilitation process to reintegrate the individual into society, which is a long process, and emphasizes the importance of prevention.[7]

It is also emphasized that with the drop in traumatic spinal fractures in 2020 mentioned in Figure 1, it is assumed that this fact may be related to social isolation due to the pandemic of COVID-19, in view of the growth in incidence in relation to the years before the onset of the global health crisis.

CONCLUSIONS

Thus, traumatic spinal injuries commonly affect young adults and males. In addition, fractures of the lumbar and thoracic spine have become more frequent. It is noteworthy that the epidemiology, etiology, and mechanism of injury can vary according to the location studied, with high-impact traffic accidents and occupational accidents being an important cause. Besides the physical and financial incapacitation, spinal injuries interfere with the patient's quality of life.

However, there are still few studies published on the epidemiology of traumatic spine fractures, and therefore, we suggest the need for further research on the subject for better knowledge and planning of necessary interventions.

AUTHORS' CONTRIBUTION: Each author has individually and significantly contributed to the development of this article. CBF and CPHSC: made substantial contributions to the conception or design of the work, or acquisition, analysis or interpretation of data for the work. They also contributed to the writing of the work and provided critical review of its intellectual contente. Additionally, They provided final approval of the manuscript version to be published; CCLM, IOM and LGS: made substantial contribution to the conception or design of the work, or acquisition, analysis or interpretation of data for the work. They also contributed to the writing of the work and provided critical review of its intellectual content; ACFJr and TKB: made substantial contributions to the conception or design of the work, or acquisition, analysis or interpretation of data for the work. They provided final approval of the manuscript version to be published; LMRR: contributed to the writing of the work and provided critical review of its intellectual content. Also provided final approval of the version of the manuscript to be published; AMY: contributed to the writing of the work and provided critical review of its intellectual contente. Also provided final approval of the manuscript version to be published.

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HUMERAL SHAFT FRACTURE WITH AN INTACT WEDGE FRAGMENT: MIPO VS CONVENTIONAL PLATING

FRATURAS DIAFISÁRIAS DE ÚMERO COM CUNHA INTACTA: MIPO X ESTABILIDADE ABSOLUTA COM PLACA

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ABSTRACT

Objective: Evaluate bone healing time, consolidation, and the complication rate between the minimally invasive plate osteosynthesis and open reduction with plate osteosynthesis in humeral diaphyseal fractures with an intact wedge (AO 12B2). Methods: A retrospective study was carried out between 2016 and 2020. The medical records and radiographs of 18 patients were analyzed, and data were collected regarding the time of consolidation, age, sex, plate size, number of screws, complications such as iatrogenic injury damage to the radial nerve, material failure, and postoperative infection. Results: No statistically significant differences were observed in the variables of age, sex, plate size, and number of screws used or in the RUSHU index (Radiographic Union Score for Humeral fractures). There were no postoperative infections, material failure, or need for reoperation, nor cases of secondary radial nerve injury. After one year, all patients had a consolidation index analyzed by RUSHU >11. Conclusion: both techniques showed similar results, with a high consolidation rate and low rates of complications or iatrogenic damage to the radial nerve. ***Evidence level III; Retrospective comparative study.***

Keywords: Humerus; Diaphysis; Bone Consolidation; Complications.

RESUMO

Objetivo: Comparar o tempo de consolidação e o índice de complicações entre os métodos de osteossíntese com placa minimamente invasiva e estabilidade absoluta através da placa nas fraturas diafisárias do úmero com cunha intacta (AO 12B2). Métodos: Foi realizado um estudo retrospectivo entre os anos de 2016 e 2020. Foram analisados os prontuários e radiografias de 18 pacientes e coletados dados referentes a: tempo de consolidação, idade, sexo, tamanho da placa, número de parafusos, presença de complicações como lesão iatrogênica do nervo radial, falha do material e infecção pós operatória. Resultados: Não foram observadas diferenças estatisticamente significativas nas variáveis de idade, sexo, tamanho da placa e número de parafusos utilizados, ou no índice de RUSHU (Radiographic Union Score for Humeral fractures). Não houve casos de infecção pós-operatória, falha do material ou necessidade de reoperação, nem casos de lesão secundária do nervo radial. Após 1 ano todos os pacientes tiveram índice de consolidação analisado pelo RUSHU >11. Conclusão: Ambas as técnicas se mostraram com resultados similares, com alta taxa de consolidação e baixas taxas de complicações ou lesão iatrogênica do nervo radial. ***Nível de evidência III; Estudo retrospectivo comparativo.***

Descritores: *Úmero; Diáfise; Consolidação Óssea; Complicações.*

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INTRODUCTION

Humeral fractures account for 5% to 8% of all fractures, and the shaft segment comprises approximately 20% of the humeral fractures and 3% of all long bone fractures.[1,2]

Besides the historically used conservative treatment, many surgeons tend to prefer the operative treatment based on the reported non-union rate, residual deformity, and joint stiffness.[3-5] Currently the open reduction with plate osteosynthesis (ORPO) remains the gold standard for the operative treatment,[6,7] which has the advantage of the anatomical reduction, early range of motion, high rate of bone healing and possibility to explore and visualize the radial nerve.[8,9] In the other hand to minimize the extensive dissection of the ORPO the minimally invasive plate osteosynthesis (MIPO) has emerged as a procedure which preserves the soft tissue envelope and periosteal circulation.[10,11] Intramedullary nailing (IMN) is also another less invasive technique, but recent studies have reported high rates of re-operation and insertion site morbidity.[12,13]

The humeral shaft fractures are classified according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) / Orthopaedic Trauma Association (OTA) combined classification[14] in simple type fractures

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

The study was conducted at the Universidade de Sao Paulo, Faculdade de Medicina, Hospital das Clinicas HC-FMUSP, Sao Paulo, SP, Brazil.
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(A), fractures with wedge fragment (B) and complex (C). In simple type A fractures Kim et al. have shown that MIPO is equivalent to ORPO as a safe and effective method of fixation.[15] Jiang et al. and Livane and Belangero have published better results with the MIPO for comminuted fractures.[10,16]

In type B shaft fractures with intact wedge is not clear whether is better to do the ORPO technique to achieve absolute stability or MIPO technique to achieve relative stability.

The incidence of type B shaft fractures is around 29% of the humeral shaft fractures,[1] causing possible limitation in the number of patients to be included, leading the authors to a more modest goal: to evaluate the difference in healing and complication rate between the ORPO and MIPO for the treatment of the AO/OTA 12B2 type fractures.

PATIENTS AND METHODS

This retrospective study was performed at an urban university-based level 1 trauma center, between 2016 and 2020. Data were collected through a retrospective chart review and review of existing radiographs. Ethical approval was provided by the Scientific and Ethical Committee of the university under the protocol 52567121.5.0000.0068. Written informed consent was obtained from all included patients.

The inclusion criteria were as follows: humeral shaft fractures (5 cm bellow the surgical neck and 5 cm above the olecranon fossa) with an intact wedge fragment (AO/OTA 12B2), with less than two weeks, an age older than 16 years with completion of growth, signed informed consent and at least 12-month follow-up with all necessary radiographs for the healing assessment.

The exclusion criteria included fractures with more than two weeks, AO/OTA types A and C, open fractures Gustilo type IIIB and C, any treatment other than plate fixation with ORPO or MIPO, pathologic fracture, refracture, proximal and distal humeral fractures, and incomplete follow-up.

Demographic data on the following were collected: age, sex, mechanism of trauma, associated injuries, primary radial nerve injury, AO/OTA classification, and Gustilo classification [17] for open fractures.

In the ORPO group were included all the fractures where the intact wedge fragment was anatomically reduced, interfragmentary compression achieved and a rigid fixation applied following the AO principle of absolute stability.[19] In the MIPO group were included shaft fractures where indirect reduction was applied correcting the alignment, length and rotation and the fixation was done with long plates and a flexible construct.[18]

The data relative to the surgical procedure collected were the length of the plate, number of screws in each side of the fracture, fixation working length and presence or not of a lag screw.

The variables collected in the follow up were secondary radial nerve injury, infection as defined by Metsemakers et al.[19], and bone healing using the RUSHU (Radiographic Union Score for Humeral fractures) [20]. In this score each cortex (anterior, posterior, lateral and medial) receives points from one to three, based on the healing stage, being one point for absence of callus formation, two points for presence of a non-bridging callus and three points for a bridging callus. A score less than seven points was considered nonunion (≥ 8 was considered healed).

Descriptive statistics included means and standard deviations for continuous variables and counts (percentages) for categorical variables. Statistical analysis of infection and nonunion was performed using the chi-square test or Fisher's exact test. Comparative analysis was performed according to the outcome and compared using Student's t-test. Odds ratios were estimated with the respective 95% confidence intercal and adjusted with the model of multiple logistic regression with the variables that presented with a descriptive level of bivariable analysis less than 0.10 ($p<0.10$). Statistical analysis was performed using IBM SPSS software for Windows version 22.0, with a significant level of 5%.

RESULTS

A total of 93 patients with humeral shaft fracture were treated between 2016 and 2020, and we could get data from 66 patients, because 26 lost follow-up and did not complete the one-year follow-up and one patient died due to cause nonrelated to the fracture. After applying the inclusion and exclusion criteria, 18 patients (27.2%) were included. The group was composed by 7 (38.9%) men and 11 (61.1%) women, with a mean age of 45.1 years. Of the 18 patients, 10 (55.5%) were treated with open reduction and plate osteosynthesis (ORPO) and the remaining 8 (44.5%) were treated with minimally invasive plate osteosynthesis (MIPO). There was no significant difference in age ($p = 0.911$) and gender ($p = 0.802$) between the ORPO and MIPO groups (Table 1).

In the ORPO group, one patient (10%) had open fracture, compared with two patients in the MIPO group (25%). Primary injury of the radial nerve occurred in two patients (20%) in the ORPO group and in three (37.5%) in the MIPO group. Both parameters showed no statistical difference between the two groups, respectively $p = 0.512$ and $p = 0.476$ (Table 1).

The plate length was defined by the number of screw holes of the plate and in the ORPO group the average length was 9.4 ± 1.3 (7 – 12) holes and in the MIPO group 11.8 ± 2.0 (10 – 16) holes, showing a significant difference between the groups ($p=0.009$). The average number of screws in each side of the plate did not have statistical difference between the groups, being 3.5 ± 0.5 screws in the ORPO group and 3.0 ± 0.8 screws in the MIPO group (Table 2).

There was no infection, nor plate failure or reoperation in any of the groups. There was also no secondary radial nerve injury in neither group.

The mean RUSHU in the six-month follow-up was 10.6 ± 2.3 in the ORPO group, with one case with RUSHU > 7. In the MIPO group it was 9.1 ± 2.9, with three patients with score > 7. There was no statistically significant difference between the groups (Table 2).

The 12-month follow-up RUSHU was 11.4 ± 8.4 in the ORPO group and 11.5 ± 0.7 in the MIPO group ($p=0.798$). All patients had score > 11 in both groups (Table 2).

Table 1. Demographic data.

	ORPO (n= 10)	MIPO (n=8)	p
Mean age	45.2 ± 17.5	45.0 ± 13.2	0.911
Sex			0.802
Female	6 (60%)	5 62.5%)	
Male	4 (40%)	3 37.5%)	
Open fracture	1 (10%)	2 (25%)	0.512
Primary injury radial nerve	2 (20%)	3 (37.5)	0.476

Table 2. Plate and screws.

	ORPO (n= 10)	MIPO (n=8)	p
Mean plate length	9.4 ± 1.3 (7 – 12)	11.8 ± 2.0 (10 – 16)	0.009*
Number of screws in each side of the plate	3.5 ± 0.5 (3 – 4)	3.0 ± 0.8 (3 – 4)	0.118
Infection (superficial / deep)	0 (0%)	0 (0%)	
Plate failure	0 (0%)	0 (0%)	
Reoperation	0 (0%)	0 (0%)	
Secondary radial nerve injury	0 (0%)	0 (0%)	
Mean RUSHU (6m)	10.6 ± 2.3	9.1 ± 2.9	0.247
Mean RUSHU (12m)	11.4 ± 8.4	11.5 ± 0.7	0.798

RUSHU - Radiographic Union Score for Humeral fractures.

DISCUSSION

Fractures of humeral shaft is defined as the segment distal to the surgical neck and proximal to the epicondyles and make up 5 to 8% of all fractures [1,2]. The most common fracture type is type A (simple, including spiral, oblique, or transverse fractures), followed by type B (including intact wedge or fragmented wedge) and type C (complex, including segmental or complex).[21]

Historically nonoperative treatment with functional brace has been used, however, due to the high rate of non-union, residual deformity and joint stiffness many orthopedic surgeons tend to prefer the operative treatment[3,22], particularly in severely displaced, comminuted, or segmented; demands for improved functional results and earlier rehabilitation.[23]

Operative treatment options include plate fixation or intramedullary nailing. Fixation with intramedullary nail has biomechanical advantages and good rates of bone healing, but recent studies have reported higher rates of reoperation and insertion site morbidity when compared to plate fixation, thus, plate fixation is considered gold standard for operative treatment.[24,25]

Fixation with plate can be done with absolute stability with anatomical reduction, interfragmentary compression and rigid fixation, also known as open reduction and plate fixation (ORPO), which has the advantage of multiple surgical approach, possibility to explore the radial nerve and a perfect reduction of the fracture and but the disadvantage of potential higher risk of infection, non-union and secondary injury to the radial nerve caused by the more extensive soft tissue dissection and periosteal blood supply.[15]

Plate fixation can also be done with a minimally invasive technique (MIPO) with functional reduction and flexible fixation.[18,19] This bridge plate technique has the potential to minimize the complications due to smaller incisions and the percutaneous method to insert and fix the plate.[15,26]

Following the mechanical thinking simple type fracture due to high strain would do better with ORPO and on the other hand multifragmented fractures with low strain would do better with MIPO. Nevertheless, Kim et al. (2015) [15] have done a prospective randomized study to compare ORPO and MIPO applied in simple type fracture of the humerus and found equivalent overall union rate and excellent functional outcomes in both groups.

Wang et al (2015) [23] focused their study on the evaluation of the comparison of the malrotation and functional results of the MIPO technique and ORPO. Both groups exhibited satisfactory union results and final shoulder function scoring. A significant incidence of malrotation (> 20º) was observed in the MIPO group (40.9% vs. 0%; $p < 0.01$). The malrotation significantly impacted the range of motion of the shoulder.

Esmailiejah et al. (2015)[28] in a prospective randomized study with 68 patients, have found a shorter median time to union in the MIPO group (4 months vs. 5 months). Varus deformity > 5º was more common in the MIPO group (18.7% vs. 6.0%). There haven't found significant difference in the functional result and complications (infection, non-union and iatrogenic radial nerve injury).

Hu et al. (2016) [27] in a meta-analysis did not detect any significant difference in terms of operative time, fracture union rate, and fracture union time. The total complication rate was 20.1% in the ORPO group, compared with 5,1% in the MIPO group with a statistically significant difference ($p<0.01$). The main factor impacting this difference was the rate of iatrogenic radial nerve palsy that was lower in the MIPO (2.2% vs 10.4%).

All these studies analyzed all types of shaft fracture, including simple (type A), wedge (type B) and complex (type C) fractures. To our knowledge this is the first study to compare ORPO and MIPO in humeral fractures with intact wedge fragment (type B2).

The presence of an intact wedge allows the surgeon to opt for the absolute stability because it is possible to anatomically reduce the wedge and produce interfragmentary compression with lag screws. The concern is the dissection needed to manipulate the wedge fragment if this can affect the biology enough to impair the healing rate or to produce higher complication rate like infection and reoperation.

With the MIPO technique usually the reduction is indirect and closed, preserving the fracture hematoma. Care should be taken to have the wedge fragment close enough to the main fragments to have its healing.

The plate length was shorter in the ORPO group than in the MIPO group (mean 9.4 holes vs. 11.8 holes). In the ORPO the plate to be shorter was expected because with the open reduction the tendency is to use the shortest place possible to avoid long incisions, the plate should have enough length to bridge the area of the wedge and have three screws in each side of the fracture. To avoid invading the fracture hematoma in the MIPO plate the surgical incisions are placed more proximal and distal, thus, the need for a longer plate. Shorter plates have a shorter leaver arm and because of this the need for more screws, the longer the plate less screws are needed, this explain why in the ORPO the mean number of screws were higher than in the MIPO (3.5 vs. 3.0).

The mean RUSHU with 6 months didn't show a statistically significant difference between the two groups and were higher than 8, the threshold to consider the fracture healed (10.6 vs. 9.1; $p=0.247$). Although one can consider all healed, analyzing the absolute number of cases with RUSHU < 8 in each group, the results show 1 case out of 10 in the ORPO group, and 3 cases out of 8 in the MIPO group. This difference might be explained by the fact that a well done ORPO heals primarily without callus formation, so it is easier to interpret the x-ray as having higher RUSHU score.

After one-year follow-up all fractures were healed in both groups, all having RUSHU score 11 and 12 (mean 11.4 vs. 11.5; $p=0.798$), without any reoperation or intervention. Implant failure was also zero in both groups.

The iatrogenic secondary radial nerve injury was also absent in both groups. This shows that both methods are safe if done properly. In the ORPO a careful dissection and exposition of radial nerve must be done in all procedures and car should be taken to protect it all the time. With the MIPO the radial nerve is not dissected, but the anterior placement of the plate is safe for the nerve.

There was no superficial or deep infection in both groups.

The main limitation of this study is the number of included patients (18), ten in the ORPO and 8 in the MIPO group. This can be explained by the fact that the humeral shaft fracture is not as common as lower extremity fractures and the study addressed only a subgroup of those fractures, only humeral shaft fractures with an intact wedge (OA/OTA 12B2), which represents less than 30% of the humeral fractures. [1] This low number of patients influenced the statistical analysis. A larger number of patients could provide more information to validate the results. Radiographic analysis has always a subjectivity when giving score in the RUSHU method. Another limitation is to only have radiographic evaluation without a functional result.

In conclusion, the study shows that ORPO and MIPO have similar results in the surgical treatment of the humeral shaft fractures with an intact wedge, with high healing rates and low complications, including infection and iatrogenic radial nerve injury.

CONCLUSION

In the surgical fixation of humeral shaft fracture with intact wedge (AO/OTA 12B2), open reduction and plate fixation (ORPO) produces similar result as minimally invasive plate osteosynthesis (MIPO), with high healing rates assessed by the RUSHU score and low infection and iatrogenic secondary radial nerve injury.

AUTHORS' CONTRIBUTION: EJHH and FCCR: Writing and preparation of the study model and method. CFAG: Data collection. RDL and FBAS: Development of the discussion and theoretical framework. Literature review and incorporation into the work. JSS: Supervision, review, and contribution to the discussion and conclusion of the article. KEK: Text and discussion elaboration, supervision, review, and contribution to the discussion and conclusion of the article.

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TRAUMA

WEDGE FRAGMENT VARIATIONS OF TIBIAL SHAFT FRACTURES WITH INTRAMEDULLARY NAILING

FRAGMENTO EM CUNHA DAS FRATURAS DA DIÁFISE DA TÍBIA COM HASTE INTRAMEDULAR

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ABSTRACT

Introduction: Tibial shaft fracture is the most common long-bone fracture, and the standard treatment is intramedullary (IM) nail fixation. Regardless of the development of this technique pseudoarthrosis remains prevalent. Objective: Evaluate the correlation between wedge fragment size and displacement, displacement of the main fragments of the 42B2 type, and pseudoarthrosis incidence. Methods: We retrospectively assessed all patients with 42B2 type fracture treated with IM nailing between January, 2015 and December, 2019. Six radiographic parameters were defined for preoperative radiographs in the anteroposterior (AP) and lateral views. Another six parameters were defined for postoperative radiographs at three, six, and 12 months. The Radiographic Union Score for Tibial Fractures score was used to assess bone healing. Results: Of 355 patients with tibial shaft fractures, 51 were included in the study. There were 41 (82.0%) male patients, with a mean age of 36.7 years, 37 (72.5%) had open fractures, and 28 (54.9%) had associated injuries. After statistical analysis, the factors that correlated significantly with nonunion were wedge height > 18 mm, preoperative translational displacement of the fracture in the AP view > 18 mm, and final distance of the wedge in relation to its original anatomical position after IM nailing > 5 mm. Conclusion: Risk factors for nonunion related to the wedge and42B2 fracture are wedge height > 18 mm, initial translation in the AP view of the fracture > 18 mm, and distance > 5 mm of the wedge from its anatomical position after IM nailing. ***Evidence level III; Retrospective comparative study.***

Keywords: Tibial Fractures; Pseudarthrosis; Risk factors; Prognostic Factors; Nailing, Intramedullary.

RESUMO

Introdução: A fratura da diáfise da tíbia é a fratura mais comum dentre os ossos longos, sendo o tratamento padrão a fixação com haste intramedular (HIM). Independentemente do desenvolvimento da técnica cirúrgica, a pseudoartrose continua prevalente. Objetivo: Avaliar a associação entre o tamanho e o desvio da cunha, os desvios dos fragmentos principais do tipo 42B2 e a incidência de pseudoartrose. Métodos: Avaliamos, retrospectivamente, todos os pacientes com fraturas tipo 42B2 tratados com hastes intramedulares entre janeiro de 2015 e dezembro de 2019. Seis parâmetros radiográficos foram definidos para as radiografias pré-operatórias nas incidências anteroposterior (AP) e perfil. Outros seis parâmetros foram definidos para as radiografias pós-operatórias em 3, 6 e 12 meses de acompanhamento pós-operatório. O Escore Radiográfico de União para as Fraturas da Tíbia (RUST) foi o instrumento usado para avaliar a consolidação óssea. Resultados: Dos 355 pacientes com fraturas da diáfise da tíbia, 51 foram incluídos no estudo. Os pacientes incluídos foram 41 (82,0%) do sexo masculino, com idade média de 36,7 anos, 37 (72,5%) com fraturas expostas e 28 (54,9%) com lesões associadas. Após análise estatística, os fatores que se correlacionaram significativamente com a não consolidação foram a altura da cunha > 18 mm, o deslocamento translacional pré-operatório da fratura na incidência AP > 18 mm e a distância final da cunha em relação à sua posição anatômica original após a cravação do MI > 5 mm. Conclusão: Os fatores de risco para a pseudartrose relacionada com a fratura em cunha e42B2 são a altura da cunha > 18 mm, a translação inicial na vista AP da fratura > 18 mm e a distância > 5 mm da cunha em relação à sua posição anatômica após a fixação IM. Nível de evidência III; estudo comparativo retrospectivo. ***Nível de evidência III; Estudo retrospectivo comparativo.***

Descritores: *Fraturas da Tíbia; Pseudoartrose; Fatores de risco; Fatores Prognósticos; Haste Intramedular.*

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INTRODUCTION

Tibial shaft fractures are the most common fractures of the long bones, accounting for 36.7% of long bone fractures and over 2% of all fractures[1]. It affects young working-age patients and commonly results from high-energy trauma such as transport accidents (motor vehicle or motorbike) and fall from height[2].

For displaced tibial shaft fractures, the most indicated treatment is fixation with an intramedullary (IM) nail because it ensures rapid bone healing and expedites patient's functional recovery.[3,4] Despite this reliable treatment method, a considerable number of patients experience failure during the healing process. The incidence of nonunion after IM nailing varies widely, ranging from 3% to 48%[5] to a more accepted range of 15–19%.[6-8]

Nonunion affects the patient's quality of life by causing physical (pain, disability) and mental hardship[9,10]. There is often a need for secondary intervention or additional treatment to stimulate bone union[11]. The ability to promptly identify fractures at risk would help to implement preventive strategies to avoid nonunion, improve information given to the patient, and better anticipate the likely healing course [8,12].

Some clinical risk factors for nonunion after tibial shaft fracture nailing have been identified in previous studies, such as open fracture, sex, smoking, and fracture of the distal third of the tibia.[13] There are also some scores to use as predictors for nonunion: Radiographic Union Score for Tibial fractures (RUST), modified RUST, and Non-union Risk Determination score (NURD).[14] Comminution is considered to be a risk factor [7]. To our knowledge, no study has evaluated the influence of the size and displacement of an intact wedge fragment in tibial shaft fractures on the development of nonunion.

The aim of this study was to analyze the influence of wedge fragment size and its preoperative and post-fixation displacement as predictors of nonunion of the third fragment after treatment of AO/OTA 42B2 type fractures treated with IM nailing.

PATIENTS AND METHODS

This retrospective case series was conducted at an urban university-based level 1 trauma center between January, 2015 and December, 2019. Clinical and radiographic data were collected from patient charts. Written informed consent was obtained from all patients included in this study. Ethical approval was provided by the Scientific and Ethical Committee of the University under protocol 53172921.6.0000.0068 and was performed in accordance with the principles of the Declaration of Helsinki.

The inclusion criteria were as follows: tibial shaft fracture classified as 42B2 according to the AO/OTA classification[15] treated with IM nailing, age ≥18 years, closed or open Gustilo type I to IIIA,[16] no previous fracture in the same leg, a minimum of 12 months of follow-up, complete radiographic examination, and signed informed consent. The exclusion criteria included AO/OTA types A, B3, and C; treatment with anything other than IM nailing; Gustilo type IIIB and IIIC open fractures; contraindication for anesthesia or surgery; infection prior to internal fixation; articular extension of the fracture; pathologic fracture; stress fractures; age <17 years; and follow-up <12 months. Baseline demographic data on the following were collected: age, sex, associated injuries, AO/OTA classification, and Gustilo classification of open fractures. Infection was defined according to the criteria for fracture-related infection.[17]

Radiographs used to measure the fracture parameters were the preoperative radiograph and 3-, 6-, and 12-month post operative radiographs. In the preoperative radiograph, the size of the wedge fragment was measured as follows: b = length of the cortical bone measured at the base of the wedge and h = height of the wedge measured with a line perpendicular to the base to the apex of the wedge (Figure 1a). The displacement of the wedge fragment was defined as the vertical distance from its original position in the proximal fragment (Dv) and the horizontal distance (Dh) from the apex of the wedge fragment (Figure 1b). Fracture displacement (x) was measured as the angle between the anatomical axis of the proximal fragment and anatomical axis of the distal fragment; and fracture translation (y) was measured as the distance between the most distal point of the proximal main fragment and most proximal point of the main distal fragment (Figure 1c).

Three months postoperatively, the reduction of the wedge fragment was measured as the distance between the proximal (s), apex (w), and distal (t) points to its original position in reduced and fixed fractures (Figure 2a). Angulation of the wedge fragment (r) was measured as the angle between the line parallel to the cortical bone of the base of the wedge and the anatomical axis of the tibia (Figure 2b). Reduction of the anatomical axis of the tibia (x) and the final gap "y" in the fracture site were also measured (Figure 1c). Radiographic fracture healing was evaluated using the RUST, which assigns points based on the assessment of healing visible in anteroposterior (AP) and lateral (L) radiographs, with 1 point assigned if there is a fracture line with no callus, 2 points if there is callus present but a fracture line is still visible, and 3 points if there is a bridging callus with no evidence of a fracture line. Individual

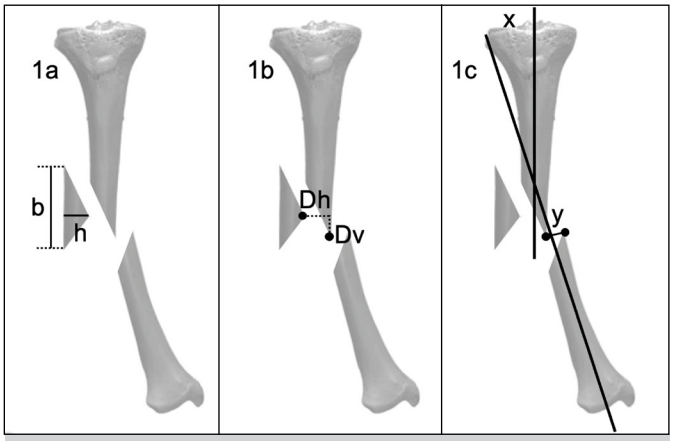

Figure 1. Radiographic measurements of the wedge size and displacement and the initial fracture displacement.

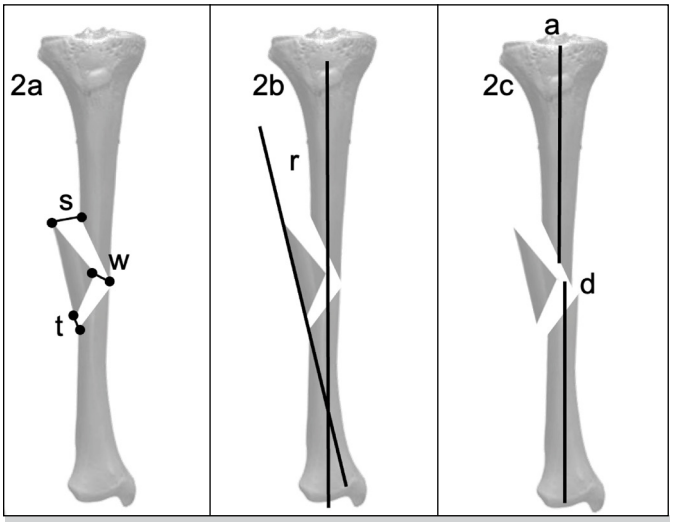

Figure 2. Post operative radiographic measurements of the wedge and the fracture displacement.

cortical scores are added to obtain a total score. A minimum of 9 points is used to exclude nonunion and 12 points to consider the fracture definitively healed.[18] This was done using the radiographs obtained at 6 and 12 months.

The healing status of the wedge to the tibial main fragments was also recorded if the wedge was completely healed on both sides, or only proximal or distal.

All radiographic measurements and assessments of healing (RUST) were performed independently by three authors. For the measurements, the mean was accepted for the analysis, and for the RUST, a consensus was reached after the first evaluation.

Statistical analyses were performed using SigmaPlot software (version 11.0; SPSS, Richmond, CA, USA). Descriptive statistics included means and standard deviations for continuous variables and counts (percentages) for categorical variables. The correlation between the aforementioned radiographic parameters and RUST was analyzed using a linear regression test. Similarly, the correlation with wedge fragment healing was analyzed using the Pearson and Hosmer-Lemeshow tests. Statistical significance was set at 0.05.

RESULTS

Between January, 2015 and December, 2019, 355 patients were diagnosed with tibial shaft fracture. According to the AO/OTA classification, 51 fractures (14%) were classified as type B2 (presence of an intact wedge fragment) and fulfilled the inclusion criteria. Of these patients, 41 (82%) were male and 10 (18%) were female, with a mean age of 36.7 years (range, 17–70) years. The left side was fractured in 31 (60.8%) patients. The fracture was open in 37 (72.5%) patients and associated injuries were present in 28 (54.9%) patients. During the follow-up, five (9.8%) patients developed infection (Table 1).

The measurements of the wedge were a mean height (h) in the AP view of 18.6 ± 7.4 mm and in the L view 19.9 ± 9.1 mm. The base length (b) in the AP view was 57.4 ± 25.3 mm and in the L view 54.7 ± 26.9 mm.

Regarding the initial displacement of the wedge from its original position in the AP view was a horizontal distance (Dh) of 11.3 ± 10.4 mm and a vertical distance (Dv) of 12.8 ± 14.9 mm. In the L view Dh was 9.7 ± 9.6 mm, and Dv was 10.5 ± 11.3 mm.

In the AP view, the fracture's initial displacement measured by the mechanical axis (x) was 8.0° ± 6.8 in the AP view and 6.0° ± 4.9 in the L view. The translational displacement (y) was 18.3 ± 11.9 mm in the AP view and 15.7 ± 10.8 in the L view.

The displacement of the wedge from its original position after reduction and IM nailing of the tibia were measured three times. The distance from the apex of the wedge to the proximal fragment (w) in the AP view was 4.9 ± 7.2 mm and 4.6 ± 3.7 mm in the L view. The distance of the most proximal point to the proximal fragment (s) in the AP view was 4.8 ± 4.3 mm and 6.4 ± 4.7 mm in the L view. The distance of the most distal point to the distal fragment (t) was 5.4 ± 4.9 mm in the AP view and 6.5 ± 6.9 mm in the L view. The angulation of the wedge to the mechanical axis (r) was 6.0° ± 6.8 in the AP view and 5.3° ± 4.9 in the L view.

The final tibial mechanical axis alignment (a) was 1.5° ± 1.5 in the AP view and 2.4° ± 2.7 in the L view. The final gap at the fracture site (d) was 0.9 ± 1.5 mm in the AP view and 2.0 ± 3.0 mm in the L view.

Results of the radiographic measurements are presented in the Table 2.

The mean RUST at the 6-month follow-up was 8.1 ± 1.6 (range, 5–11), with 24 (47.1%) fractures with a score higher than 9 and none with a score of 12. At the 12-month follow-up, the mean RUST was 10.1 ± 1.5 (range, 6–12), with a total of nine (17.6%) patients with a score of 12, and 32 (62.7%) with a score of 9 to 11. At the completion of the follow-up, 10 (19.7%) patients were considered to have a nonunion with RUST between 6 and 8.

Table 1. Demographic characteristics of the patients.

Variable	Description (n = 51)
Age (years)	
Mean ± SD	36.7 ± 13.6
Gender, n (%)	
Female	10 (19.6)
Male	41 (80.4)
Side, n (%)	
Right	20 (39.2)
Left	31 (60.8)
Associated injuries, n (%)	
No	23 (45.1)
Yes	28 (54.9)
Open fractures, n (%)	
No	14 (27.4)
Yes	37 (72.6)
Post op infection, n (%)	
No	46 (90.2)
Yes	5 (9.8)

Table 2. Statistical analysis of the radiographic parameters of the wedge size and displacement and fracture displacement pre and post operative in the AP and L view.

Parameters	Mean and SD (mm)	Correlation with RUST 12 month		Correlation with healing 12 month	
		R	p	OR [I.C. 95%]	p
b (AP)	57,4 (25,3)	0,050	0,232	0,991 [0,965-1,018]	0,501
b (L)	54,7 (26,9)	0,029	0,423	0,995 [0,967-1,024]	0,738
h (AP)	18,6 (7,4)	0,144	0,039	0,888 [0,781-1,009]	0,068*
h (L)	19,9 (9,1)	0,245	0,014	0,875 [0,727-0,964]	0,042*
Dv (AP)	12,8 (14,9)	0,078	0,135	0,969 [0,918-1,023]	0,252
Dv (L)	10,5 (11,3)	0,081	0,175	0,948 [0,872-1,031]	0,214
Dh (AP)	11,3 (10,4)	0,071	0,156	0,994 [0,931-1,061]	0,852
Dh (L)	9,7 (9,6)	0,051	0,291	0,937 [0,850-1,033]	0,191
x (AP)	8,0 (6,8)	0,000	0,918	1,000 [0,909-1,101]	0,998
x (L)	6,0 (4,9)	0,024	0,473	1,068 [0,914-1249]	0,406
y (AP)	18,3 (11,9)	0,157	0,016	0,929 [0,865-0,997]	0,042*
y (L)	15,7 (10,8)	0,041	0,342	0,984 [0,886-1,092]	0,761
s (AP)	4,8 (4,3)	0,022	0,483	1,002 [,825-1,216]	0,985
s (L)	6,4 (4,7)	0,00	0,741	1,017 [0,871-1,186]	0,833
w (AP)	4,9 (7,2)	0,000	0,904	1,066 [0,773-1,471]	0,695
w (L)	4,6 (3,7)	0,003	0,815	1,064 [0,828-1,368]	0,626
t (AP)	5,4 (4,9)	0,223	0,020	0,815 [0,658-0,941]	0,032*
t (L)	6,5 (6,9)	0,006	0,689	1,023 [0,926-1,143]	0,595
r (AP)	6,0 (6,8)	0,099	0,118	1,215 [0,987-1,494]	0,066
r (L)	5,3 (4,9)	0,001	0,903	1,178 [0,963-1,440]	0,111
a (AP)	1,5 (1,5)	0,004	0,744	1,416 [0,844-2,377]	0,188
a (L)	2,4 (2,7)	0,009	0,611	1,299 [0,918-1,840]	0,140
d (AP)	0,9 (1,5)	0,036	0,307	0,630 [0,299-1,325]	0,223
d (L)	2,0 (3,0)	0,008	0,618	0,949 [0,739-1,219]	0,684

SD: standard deviation; AP; anteroposterior view; L: lateral view; b: base length of the wedge; h: height of the wedge; Dh: horizontal distance wedge-original location; Dv: vertical distance wedge-original location; x: preop mechanical axis displacement; y: preop translational displacement; s: distance between the most proximal point of the wedge to its anatomical position after fixation; t: distance between the most distal point of the wedge to its anatomical position after fixation; w: distance between the apex of the wedge to its anatomical position after fixation; r: angle between the wedge and the mechanical axis after fixation; a: mechanical axis after fixation and d: gap at the fracture site after fixation. Correlation with RUST: linear regression test; correlation with healing: Pearson and Hosmer-Lemeshow test. * statistically significant.

In the analysis of the wedge union in the 10 patients with nonunion, five (50%) fractures presented with nonunion of the wedge both proximally and distally, one (10%) showed healing only in the proximal part of the wedge, and four (40%) showed healing only in the distal part of the wedge.

The statistical analyses are presented in Table 2. After the linear regression test to find out the correlation of the measurements and RUST and the Pearson Hosmer-Lemeshow test for the correlation with healing of the wedge both at 12-month follow-up, we could find correlation with only three parameters: "h" height of the wedge fragment in the both AP and L view (OR = 1.183 [1.014-1.422] / p = 0.048), 'y" preoperative translational displacement in the AP view (OR = 1.111 [1.013-1.218] / p = 0.025) and "t" distance of the most distal point of the wedge in post operative radiographs (OR 1.311 [1.126-1.504] / p = 0.004)). The impact of these three parameters on the RUST ranged from 14% to 24%, as depicted in Table 2.

DISCUSSION

The tibial shaft is the most frequently fractured long bone,[19] and despite the introduction of minimally invasive intramedullary nail fixation, complications remain prevalent.[11] Nonunion can be a devastating complication to patients and a burden to the public health system[9,20,] with an incidence varying from 15% to 19%.[7]

The ability to predict fractures that develop nonunion could allow surgeons to anticipate the problem and institute prevention strategies in the early management, define an appropriate surveillance during follow-up and early intervention to promote healing, and ultimately decrease both the patient suffering and cost to the health system [3,6,8.]

Several studies have been conducted to identify risk factors for nonunion in tibial shaft fractures fixed with IM nails. These studies found factors related to the patient: ASA physical status score, Injury Severity Score, smoking status, comorbidities, and gender [3,5,8,21.] Factors related to the fracture included open injuries, high energy, comminution, AO/OTA type B or C, fibular fracture, and associated injuries.[7,8,22] Recently, more focus has been placed on fracture gap as a high-risk factor[23,24.]

Some scores were also developed to assess healing evolution and predict nonunion, such as the RUST, modified RUST, and NURD.[14]

As cited above, comminuted fracture is a risk factor for nonunion, and AO/OTA types B and C are considered comminuted but have different characteristics. On the one hand, type B has less soft tissue injury than type C, but the wedge fragment in type B can be totally avascular.

The incidence of AO/OTA type B fractures is considerable and varies between 22% and 40%[25,26]; therefore, it is worth evaluating wedge size and displacement in the development of nonunion as risk factors. We decided to include only type B2 fractures because they had an intact wedge. Type B3, with a fragmented wedge, may behave as a type C fracture. As we could not find any study similar to this, we defined radiographic measurements as shown in figures 1 and 2 to understand the most relevant measurements that could lead to nonunion.

Our findings in the 3-month radiograph with very few patients showing signs of bone healing corroborate the findings of other authors, such as Mundi et al.[27] and Wojahn et al.,[28] who found that the median time to radiographic union after tibial nailing was approximately 20 weeks, and little healing occurred within the first 8 weeks after surgery.

The RUST objectively determines the extent of healing by scoring the degree of fracture healing from 1 to 3 points for each of the four cortices, as viewed from AP and L radiographs. The sum of 12 points is a completely healed fracture in the four cortices, and points 9–11 indicate bone healing in three cortices, which can be considered a good result.[18]

At the 6-month follow-up, close to half of the patients (47.1%) had RUST higher than 9 points and could have been considered to be healed. By 12 months, the number had increased to 80.3%, with a score higher than 9 points. This is an indication that the healing of a 42B2 fracture can take between 6 and 9 months, and not performing surgery for nonunion in all fractures not healed within 6 months may be a wise decision.

In our series, 10 (19.7%) patients were diagnosed with nonunion after 12 months. The statistical analysis of the correlation between radiographic measurements and nonunion revealed positive correlation with three parameters: "h," height of the wedge; "y," preoperative translational displacement; and "t," post operative distance of the wedge to its anatomical position.

These results indicate that the height of the wedge is more important than its length. This may be because a wedge with a larger height compromises the diameter of the tibial shaft, leaving less contact area between the two main fragments of the tibia. This is consistent with the finding that less bone contact leads to nonunion[7,24.]

Many articles cite high energy trauma as a risk factor without being more specific. Our results showed that the risk factor was the initial translational displacement between the main proximal and distal fragments of the tibia in the AP view. Translational displacements > 18 mm in the AP view may be considered a risk factor for nonunion. This may be related to soft tissue injury and vascular compromise of the fracture site, worsening, and delaying the healing process.

Another risk factor was the final distance of the wedge to its original anatomical position, which was measured in this study as the distance between the apex of the wedge and original position (t). An average distance of 5 mm showed a positive correlation with the development of nonunion.

Our study has several limitations. The first limitation is its retrospective design. The second limitation was the small number of patients, which influenced the statistical analysis. Any radiographic measurement may be inconsistent because of the magnification of the image and imprecise measurements. Even if the RUST is only 3 points for each cortex, it is a subjective assessment and is capable of being erroneous. The lack of analysis of some variables may also interfere with the results.

In conclusion, in AO/OTA 42B2, risk factors for nonunion are size of the wedge, especially its height (> 18 mm); initial translation of the fracture (> 18 mm); and final reduction of the wedge fragment (> 5 mm). In the presence of these factors, one can consider either initiating a different strategy or not waiting long to perform surgery to ensure bone healing.

CONCLUSIONS

The risk factors identified in this study for nonunion in 42B2 tibial shaft fractures treated with IM nailing are as follows:

Wedge height > 18 mm

Translational displacement on AP preoperative radiograph > 18 mm

Distance of the wedge from its original position on postoperative radiograph > 5 mm

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