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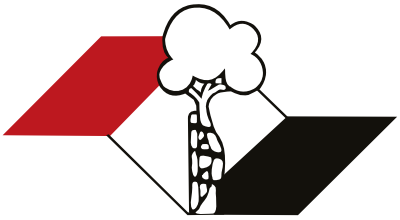

ISSN 1413-7852

Acta Ortopédica Brasileira

Volume 32 – Number 3 – Year 2024

ISSN 1413-7852

Acta Ortopédica Brasileira

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

Affiliated with Associação Brasileira de Editores Científicos

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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

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c) Book chapters: Author(s) of the chapter. Chapter heading. Publisher (s) of the book and other related data according to previous item. Ex.: Chapman MW, Olson SA. Open fractures. In: Rockwood CA, Green DP. Fractures in adults. 4th ed. Philadelphia: Lippincott-Raven; 1996. p.305-52.

d) Summaries: Author(s). Title, followed by [abstract]. Journal year; volume (supplement and corresponding number, if applicable): page(s) Ex.: Enzensberger W, Fisher PA. Metronome in Parkinson's disease [abstract]. Lancet. 1996;34:1337.

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f) Thesis: Author, title (master, PhD etc.), city: institution; year. Ex.: Kaplan SJ. Post-hospital home health care: the elderly's access and utilization [dissertation]. St. Louis: Washington Univ.; 1995.

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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 32 – Nº 3 – 2024

Original Article

DOI: http://dx.doi.org/10.1590/1413-785220243203e282286

PATHOPHYSIOLOGY OF POSTTRAUMATIC ANKLE OSTEOARTHRITIS: A MULTICENTER PERSPECTIVE

FISIOPATOLOGIA DA OSTEOARTRITE PÓS-TRAUMÁTICA DO TORNOZELO: PERSPECTIVA MULTICÊNTRICA

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ABSTRACT

Besides the acute injury and trauma-induced macroscopic alterations, the evolution to posttraumatic ankle osteoarthritis (PTOA) is a complex process progressing at the tissue and molecular level. Furthermore, changes in the molecular pathways affect chondrocyte viability. Treatment modalities for PTOA focal or confined disease include innovative techniques. Objective: Our purpose is to increase medical awareness based on scientific evidence of pathophysiology, molecular biology, and treatment of post-traumatic ankle osteoarthritis. Methods: To support the perspectives of the experts, evidence from the scientific literature respected the PRISMA guidelines and the PICOS search strategy was used. We included case-control, cohort, experimental studies and case reports, written in English. Results: The authors were homogeneously exposed to 282 selected abstracts and 114 full articles directly related to post-traumatic osteoarthritis after malleolar fractures. Conclusion: The pathophysiological factors involved in posttraumatic ankle osteoarthritis, such as biological, structural, mechanical, and molecular changes must be studied together, as the interaction between these factors determines the risk of progression of PTOA. Inhibition of a single catabolic molecule or cascade probably is not sufficient to alter the natural progression of the pathological process. ***Evidence level V, expert opinion.***

Keywords: Ankle Osteoarthritis. Pathophysiology. Molecular Biology.

RESUMO

A evolução para a osteoartrite pós-traumática do tornozelo (PTOA) a partir da lesão aguda e das alterações macroscópicas induzidas pelo trauma é um processo complexo, que progride em nível tecidual e molecular. Além disso, as alterações nas vias moleculares afetam a viabilidade dos condrócitos. As modalidades focais ou confinadas de tratamento para PTOA incluem técnicas inovadoras. Objetivo: Nosso objetivo é aumentar a conscientização médica, com base em evidências científicas de fisiopatologia, biologia molecular e tratamento da osteoartrite pós-traumática do tornozelo. Métodos: Para o embasamento das perspectivas dos autores experts, as evidências da literatura científica respeitaram as diretrizes Prisma e a estratégia de busca Picos foi empregada. Incluímos estudos de caso-controle, de coorte, experimentais e relatos de caso, escritos em inglês. Resultados: Os autores foram expostos de forma homogênea a 282 resumos e 114 artigos completos, diretamente relacionados à osteoartrite pós-traumática após fraturas maleolares. Conclusão: Os fatores fisiopatológicos envolvidos na osteoartrite pós-traumática do tornozelo, como alterações biológicas, estruturais, mecânicas e moleculares, devem ser estudados em conjunto, pois a interação entre esses fatores determina o risco de progressão da PTOA. A inibição de uma única molécula catabólica ou cascata provavelmente não é suficiente para alterar a progressão natural do processo patológico. ***Nível de evidência V, opinião do especialista.***

Descritores: *Osteoartrite do Tornozelo. Fisiopatologia. Biologia Molecular.*

Citation: Godoy-Santos AL, Cesar Netto C, Santini S, Herrera-Pérez M, Valderrabano V, Rammelt S. Pathophysiology, molecular biology and treatment of posttraumatic ankle osteoarthritis – a multicenter perspective. Acta Ortop Bras. [online]. 2024;32(3):Page 1 of 6. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Besides the acute injury and trauma-induced macroscopic alterations, the evolution to posttraumatic ankle osteoarthritis (PTOA) is a complex process progressing at the tissue and molecular level.[1-6] Furthermore, changes to apoptosis pathways, like caspase inhibition, or necrosis progression via antagonist of reactive oxidant species (anti-ROS) are thought to affect chondrocyte viability.[7-15]

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

The study was conducted at Universidade de São Paulo, Faculdade de Medicina, Hospital das Clinicas HC-FMUSP, Laboratório Prof Manlio Mario Marco Napoli, São Paulo, SP, Brazil. Correspondence: Alexandre Leme Godoy-Santos. Rua Dr Ovídio Pires de Campos, 333, Cerqueira Cesar, São Paulo, SP, 05403-010. alexandrelemegodoy@gmail.com

Article received on 01/15/2024, approved on 03/15/2024.

Although animal studies have shown some progress in pharmacologic therapies, current non- surgical therapies for PTOA of the ankle are mostly palliative and limited to significant adaptation of lifestyle.[16-20] Progression of early stage PTOA associated with malalignment or instability of the ankle mortise may be successfully halted with corrective osteotomies and ligament reconstruction in carefully selected patients.[6] As the disease progresses, salvage options are limited to either joint distraction, arthrolysis, fusion or joint replacement.[19] Treatment modalities for focal or confined disease include bone marrow stimulation techniques, cartilage transplantation, osteochondral grafts, collagen membranes, and autologous chondrocyte implantation. The results of these techniques have been reported mainly for osteochondrosis dissecans, not PTOA, and repeated histological analyses have mostly revealed the formation of "hyaline like" fibrocartilage.[6,19,20] Our purpose is to increase medical awareness based on scientific evidence of pathophysiology, molecular biology, and treatment of post-traumatic ankle osteoarthritis.

METHODS

The study was approved by the institutional review board of our institutions and did not involve animals nor humans. To support the perspectives of the experts, evidence from the scientific literature respected the Prisma guidelines, and the Picos search strategy was employed as follows: we conducted a search of the relevant scientific literature from January 1, 1977, to September 21, 2023, using databases, including PubMed, MedLine, and Scopus, and gray literature sources. Searched terms were "posttraumatic osteoarthritis" AND "ankle fractures", "posttraumatic osteoarthritis" AND "cartilage", "posttraumatic osteoarthritis" AND "synovia", "posttraumatic osteoarthritis" AND "synovial fluid" NAD "molecular" AND "biology". Table 1 lists the keywords used in the search. We included case-control, cohort, experimental studies, and case reports, written in English. The selected references were reviewed by all authors and judged on their contribution to the body of knowledge of this topic. A total of 282 abstracts were screened, 114 of which were directly related to the posttraumatic osteoarthritis after malleolar fracture (Table 2). Different aspects of ankle PTOA were extensively detailed below.

Table1. Keywords used to search the PUBMED database.

Keywords for PUBMED, MedLine and Scopus literature search		
Malleolar fracture	Ankle Fracture	Posttraumatic osteoarthritis
Cartilage	Chondral tissue	Synovia
Synovial fluid	Joint damage	Histological changes
Subheadings used for PUBMED, MedLine and Scopus literature search		
Cytokine	Matrix metalloproteinases	Physiopathology
Inflammatory cells	Etiology	Collagen
Metabolism	Diagnosis	Chondrocyte
Viability	Treatment	Outcomes

Table 2. Types of studies and casuistic resulting of database search.

Animal studies (in vivo/ in vitro)	32
Cadaveric studies	4
Case series	37 (total cases: 1158)
Case control studies	8 (total test cases: 418)
Cohort studies	3 (total patients: 4827)
Review of literature	31
Total selected studies	114
Total patients	6.403

Understanding the pathophysiology and associated injuries of ankle PTOA

Hintermann et al[7]. Evaluated the arthroscopic findings in acute fractures of the ankle in 288 consecutive patients. Cartilage lesions were found in 228 ankles (79.2%), more often on the talus (69.4%) than on the tibial plafond (45.8%), the fibula (45.1%), and the medial malleolus (41.3%). The frequency and severity of the lesions increased from Weber type-B to type-C fracture. A possible explanation for the disparity between prevalence of chondral defects and the development of ankle arthritis might be that ankle joint cartilage has the higher glycosaminoglycan (GAG) content compared with cartilage on other locations, which yields a high stiffness to the borders of chondral lesions. Furthermore, ankle joint cartilage is the metabolically most active cartilage in the human body, having the highest turnover of aggrecan proteins. Although several in vitro studies have demonstrated that an organ system response to acute intraarticular fracture, no established gold-standard is available to identify patients at high risk of PTOA development following an intraarticular fracture. A recent in vivo study showed that synovitis scores and CD68+ macrophages abundance were significantly greater in tissue from patients with ankle fracture compared with normal ankles. More importantly, pro-inflammatory cytokines TNFα, IFNγ, IL-6, IL-8, IL-10, and IL-1β were increased in synovia from patients with ankle fracture in comparison with knee OA, showing that acute inflammation could be more pronounced soon after an ankle fracture than an already installed OA. Notably, IL-6 concentration was significantly increased in the serum of patients with ankle fracture compared with normal serum. Its level also correlated positively with the IL-6 intraarticular concentration, suggesting that it may be a candidate for monitoring early local and systemic inflammatory changes following ankle fractures.

The damage of cracks to the adjacent chondrocytes have been shown in a canine model through the expression of pro-inflammatory markers such as TNFα and IL1β, loss of proteoglycan, and cell cloning immediately after impaction and up to 1 year, at which time some repair has been observed. In a human study, traumatic fracture of an articular surface resulted in significant chondrocyte death and apoptosis, with cells along the edges of the disrupted articular cartilage showing decreased viability and increased apoptosis when compared to those located away from this site. Importantly, a privileged area of viable cells is generally present in the middle and deep zones away from the fracture edge, which suggests that attempts to anatomically reconstruct traumatized joints are reasonable, as vital tissue is present in those areas and might heal the fracture or osteotomy site.

Chondrocyte death – necrosis or apoptosis?

Chondrocyte dysfunction and death are critical findings of articular degeneration. However, there is questioning on whether there is necrosis or apoptosis of the cell. Increased incidence of chondrocyte death has been found in various forms of joint arthrosis and has been shown to occur in response to mechanical injury. Necrosis is marked by increased uptake of fluids by the cell, with decrease of proteoglycan biosynthesis and increase in water content. The resultant swelling causes rupture of the cell membrane and release of the cell contents. Necrosis of impacted chondrocytes has been linked to overproduction of reactive oxidant species (ROS). It was hypothesized that the chondrocyte mitochondria were the most likely source of the damaging acute impact- related ROS.

Apoptosis results in chromatin condensation, DNA fragmentation, cell shrinkage, and plasma membrane blebbing. In most cases, once the cell membrane integrity is lost, these nuclear and cytoplasmic fragments are taken up by phagocytic cells in the area. The final

pathway for apoptosis involves a complex proteolytic system identified as caspases. These proteases activate pro-inflammatory cytokines and ultimately depend on activation of Caspase-3 to complete the autophagic process.

Apoptosis rates in normal cartilage are less than 1% and in osteoarthritis these rates have been reported to average 15%. In the first study to evaluate chondrocyte death after in vivo impact and fracture in humans, the apoptosis rates were more than twice this value, in fact up to 35%. A classic correlation between chondrocyte apoptosis and PTOA includes the production of nitric oxide (NO) and nitric oxide synthase (NOS). As chondrocytes age, there is an increase in the production of NOS, which catalyzes the formation of NO. NO has been shown to decrease chondrocyte production of proteoglycan and type II collagen, making the cartilage less efficient at damage repair and disrupting normal homeostasis. NO has also been shown to cause damage to DNA strands and to trigger apoptosis.

There are investigations of the relationship between cartilage injury and chondrocyte apoptosis. A dose-response was present between the incidence of apoptosis and loading magnitudes. Some investigators also found little apoptosis in their human specimens in the first 3 hours after injury. However, beginning at 6 hours and continuing until 96 hours after injury, there was a consistent increase in apoptosis. Although there is evidence to support the concept that chondrocytes can be stimulated to undergo apoptosis in response to injury, so far little evidence exists to support the claim that chondrocyte apoptosis contributes significantly to the development of posttraumatic osteoarthrosis.

Subchondral bone thickening, severe erosion of the cartilage at the fracture site and acute synovitis within 7 days were also observed. Some authors have investigated chondrocyte death in intraarticular fractures created with realistic impulses in explanted whole joints from cows, pigs, and humans. They reported that the majority of chondrocyte deaths occurred in proximity to the fracture lines in all three species. Remarkably, human ankle joints exhibited dead chondrocytes along the crack lines.

The mechanisms involved in the development of ankle PTOA - focus on molecular biology

Proprioception normally provided by afferences from the ankle capsule and ligaments may further impair the ability of dynamic stabilizing structures, such as peroneal muscles, thus leading to functional ankle instability. In the further course, disuse atrophy and residual muscle weakness will add to the kinematic disbalance. Pain and fear of re-injury may also inhibit muscle function and lead to stiffness and capsular fibrosis. Alterations in this microenvironment have been shown to induce changes in chondrocyte gene expression and ultimately propagate the initial injury. Other factors beyond alterations in cartilage loading patterns, like adaptability of chondrocytes to the action of inflammatory cytokines in the joint space, must be taken into account in the development of PTOA.

Immediately after the initial trauma, articular chondrocytes are influenced by various inflammatory chemokines, including TNF-*a*, IL-1*b*, and MMP-13. Chondrocyte apoptosis continues to increase in the days following trauma and the percentage of dead chondrocytes demonstrated a progressive increment from 6 hours to 5 days post-injury. The caspase apoptotic phenomenon is linked, among others, to high intraarticular levels of TNF-*a*. In a pioneer study, proteoglycan synthesis was markedly suppressed after intraarticular injections of IL-1*b* in naive mice, whereas higher doses of TNF-*a* were needed for this. Notably, normalization of PG synthesis was shown by blocking of IL-1 with anti-IL-1, thus minimizing cartilage damage. Catabolin/IL-1 preparation caused extensive loss of proteoglycan, and later collagen, from the cartilage explant while proteoglycan appeared in the culture medium. It was concluded that the role of Catabolin/IL-1 in vivo is similar to its effects in vitro on cartilage in organ culture. In an earlier study, the same author also stated that synovium affected the cartilage in two ways: first, by a direct action on the matrix, possibly by secreted proteinases, like collagenase, and second, by an indirect action mediated through the living chondrocytes which produce acidic proteinases of the lysosomal system.

Besides activation of inflammatory response, mechanical damage during traumatic injury has been shown to change gene expression in chondrocytes, activating various degradative enzymes such as MMPs. These MMPs degrade extracellular matrix (ECM) proteins like collagens and GAGs, which in turn accumulate and cause a positive feedback cycle, with further MMP release and progressive cartilage loss, even after cessation of the mechanical injury. Adams et al. demonstrated that pro-inflammatory cytokines IL-6, IL-8, MMP-1, MMP-2, and MMP-3 were significantly elevated in the synovial fluid of fractured ankles when compared to matched contralateral uninjured side, even 6 months after the initial fracture[14]. Godoy et al. recently analyzed cellularity and synovial profile in patients with acute ankle fractures in comparison with fresh cadaveric ankles. Cytokine concentrations in synovial fluid samples were significantly higher in the fracture group, especially for IL-2, IL-6, IL-10, and IL-17. Synovial tissue of study group showed an accumulation of collagen and proteoglycan. Another auhor revealed significant elevation of 19 amino acids metabolites in fractures ankles in comparison to the contralateral sides. Among these, glutathione metabolism exhibited the most elevated increase, indicating a possible role for oxidative stress in ankle fractures. A decrease in synovial fluid SF lubricin was also associated with elevation of inflammatory cytokines in human knees after ligament injuries, which may play the joint at a risk of wear-induced damage.

PTOA can be considered a “whole joint” disease in which synovial reaction can lead to synthesis and release of a wide variety of cytokines and chemokines. Some of these inflammatory mediators are detected in joint tissues and SF in OA and have catabolic effects on chondrocytes. The synovial membrane is also a source of pro-inflammatory and catabolic products, including metalloproteinases and aggrecanases, which contribute to articular matrix degradation. The influence of the synovium on chondrocytes is triggered by the release of cytokines and growth factors such as IL-1, IL-6, and TNF, stimulated primarily by direct contact of SF and bone marrow. These factors are produced in the synovial membrane and diffuse into the cartilage via the SF and, among other mechanisms, lead to increased apoptosis of chondrocytes. Consequently, synovitis is associated with greater symptoms such as pain and degree of joint dysfunction. Two potential innate inflammatory mechanisms that may lead to synovitis in OA have been suggested: toll-like receptors (TLR) pathways and the complement cascade.

Matrix fragments and products released during cellular stress like PGs and GAGs can activate the innate immune response via pattern-recognition receptors known as TLR. The following cellular response culminates in activation of specific transcription factors, with nuclear-factor κB (NF-κB) playing a prominent role. Many MMP, particularly MMP-13, implicated in OA-related cartilage damage are dependent on the activity of NF-κ B as well.

TLR activation in the synovium is an important stimulus for NFκB activation and subsequent production of chemokines (e.g. IL-8 and CCL5) and cytokines (e.g. IL-1, IL-6, and TNF), which recruit and activate macrophages, granulocytes and lymphocytes. In cartilage, TLR-2 and TLR-4 are up-regulated specifically in damaged areas in patients with PTOA. A more specific study demonstrated that TLR2 and TLR4 signals are important in mediating catabolic responses

and in increasing MMP-3 and MMP-13 production, also stimulated by the synovium.

The second pathway to synovitis damage involves complement activation, which is physiologically essential for effective clearance of many pathogens and damaged host components. When complement activity is dysregulated it can lead to extensive tissue damage. Clinically, increased synovial complement component deposition (C3a and C5b-9) in the setting of acute flare-ups of symptomatic OA has been demonstrated, suggesting that complement activation occurs early in the joint during PTOA development.

Activation of both TLR and the complement cascade in the synovium results in transcriptional activation of genes involved in the development of inflammation, most notably genes for soluble mediators such as cytokines and chemokines. These mediators may be produced by a variety of cell types, including macrophages, chondrocytes and synovial fibroblasts. IL-1, IL-7, and TNF are some of the dominant activators of chondrocyte-mediated catabolic protease production, leading to production of MMPs and PG loss via chondrocyte specific receptors. Consequently, these inflammatory mediators represent a potential target for therapeutic interventions against structural joint damage.

Up-regulation of genes encoding acute pro-inflammatory markers has been observed both after acute traumatic injury and PTOA development. Enriched pathways associated with the up-regulated genes include heme biosynthesis and complement cascade. Sebastian et al. investigated the genetic basis of enhanced OA susceptibility in three mouse strains with varying susceptibility to OA: STR/ort (highly susceptible), C57BL/6J (moderately susceptible), and MRL/MpJ (not susceptible). They identified 944, 2330, and 2702 genes differentially regulated in MRL/MpJ, C57BL/6J, and STR/ort, respectively, in response to ACL injury, including B4galnt2 (beta-1,4-N-acetyl-galactosaminyl transferase 2) and Tpsab1 (tryptase alpha/beta 1). Up-regulation of genes encoding both acute pro-inflammatory markers, such as inducible nitric oxidesynthase (iNOS), IL-6, and IL-17, and matrix degrading enzymes, such as ADAMTS-4 (A-disintegrin and metalloproteinase with thrombospondin motif 4) and MMP3, was detected in femoral cartilage, concomitant with extensive cartilage damage and bone remodeling over 21-days post-injury. In injured knees, iNOS, ADAMTS-4, MMP-3, and IL-6 were elevated 19.5-fold, 7.7-fold, 10.2-fold, and 36-fold, respectively at 4 hours post-ACL rupture.

In vitro cartilage injury models have provided much of our basic understanding of the acute effects of impact load on cartilage. However, these models are limited, as they neither represent a natural physiologic environment nor investigate cartilage response to injury over time.

Detection of early PTOA

Due to the complexity of mechanical, inflammatory, and molecular factors involved in the ankle PTOA and their interactions, it is difficult to allocate the patient into an isolated phenotype. Rather than treating PTOA of the ankle as a single disease, a more holistic approach may overcome different individual evolution and guide clinicians to better target their patient. (Figure 1)

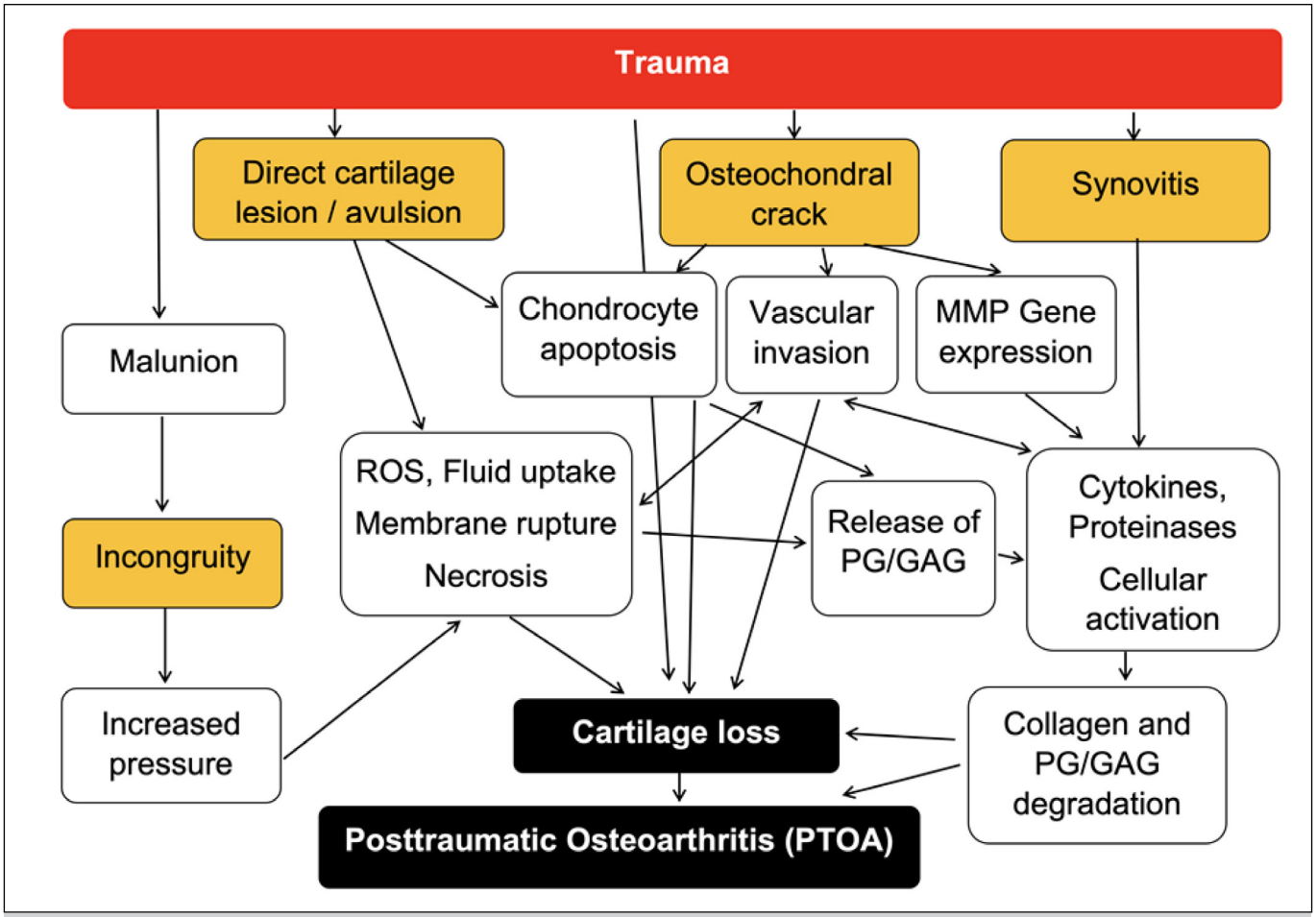

Figure 1. *The holistic approach for understanding different individual evolution and guiding clinicians to an individualized treatment target.*

The most appropriate modality for early detection of OA in younger patients is magnetic resonance imaging (MRI). Newer techniques like cartilage mapping are capable to detect early alterations in cartilage microstructure, composition of extracellular matrix and biomechanical of chondrocytes. T1ρ is an important modality for evaluation of proteoglycan content, while collagen organization is better visualized in T2 relaxation times.[6] T2 mapping has reduced sensitivity to evaluate deep layers of cartilage, since its highly organized structural properties results in extremely short T2 relaxation times. In this context, ultrashort echo time (UTE)–T2 is more sensitive to accurately visualize collagen integrity and cartilage degeneration.

Single-photon emission computed tomography/computed tomography (SPECT-CT) to evaluate the extent of degenerative changes and their biological activities has been used in patients with PTOA of the ankle. This imaging modality is a combination of bone scanning and CT imaging data and has demonstrated significantly higher interobserver and intraobserver reliability than measurement using CT alone or CT and bone scanning together. Also, SPECT-CT imaging allows to accurately verify the effects of mechanical malalignment on cartilage. Malaligned ankles into varus showed significantly higher radioisotope uptake in the medial joint compartment than in the lateral compartment, whereas malaligned ankles into valgus showed significantly greater uptake in the lateral areas.

Since OA is an inflammatory disease process, biomarkers of inflammation may be the earliest signs of PTOA. They can be measured in blood, urine, and synovial fluid. TNF-*a*, IL-1, and MMP have all been targeted but the best predictor is yet to be established. However, the same markers are expressed in the wake of an acute fracture as measured with gene expression analysis, and more recently proteomics and metabolomics from microdialysis sampling may also be quantified. Collagen II precursors and metabolites are more specific markers of chondrocyte metabolism. In spite of all that, there is a need for reliable biomarkers to provide prognostic information and to monitor clinical response. Prospective studies correlating patient outcomes with changes in biomarkers profile would be beneficial to guide OA treatments.

Perspectives on systemic treatment

Unfortunately, options to treat PTOA are mostly limited to late procedures such as bone marrow stimulation, bulk osteochondral grafting, arthrodesis or joint replacement. Ways of modulating the physiologic response to trauma and potentially preventing chondrocyte death are further described.

In early stages of asymmetric arthritis resulting from malunions, joint-preserving osteotomies can avoid the need for arthrodesis or arthroplasty. Dislocations should be reduced promptly because they increase the soft tissue damage and there is a close correlation between the length of joint dislocation with apoptosis of chondrocytes. In an experimental OA model, intermittent treatment with teriparatide (parathyroid hormone) was found to improve the microstructure, remodel the subchondral bone, and prevent progression of cartilage damage, which may prevent joint collapse by suppressing osteoclastic activity in the subchondral bone.

Statins can potentially modulate the function of chondrocytes. Lovastatin significantly promoted proliferation and inhibited the IL-1b induced apoptosis in rabbit chondrocyte. In contrast, NSAIDs inhibit in vitro chondrogenesis from mesenchymal stem cells. Once chondrocytes are exposed to NSAIDs, their cell cycle was found arrested in the G(0)/G(1) phase. However, under inflammatory conditions the response is different. Celecoxib and indomethacin significantly reduced the number of trauma-induced apoptotic chondrocytes in a study with human articular impacted cartilage. Hyaluronan (HA) protects against chondrocyte apoptosis during the development of OA. Low molecular weight hyaluronan, binds to its specific anti-apoptosis receptors and exerts high expression levels of COL2A1 and AGG genes in OA cartilage.

First evidence exists that bisphosphonates can inhibit chondrocyte apoptosis and degradation of cartilage secondary to corticosteroid-induced apoptosis. Growth factors are important in the physiology of chondrocytes and transforming growth factor (TGF-b) and IGF-1 were found to have anti-apoptotic effects. Similarly, bone morphogenetic protein (BMP-)2 prevents apoptosis of chondrocytes via inhibition of caspase-3 and -9 and increase in Bcl-xL expression.

Anti-inflammatory interleukins such as IL-4, IL-10, and IL-13 are expressed by articular chondrocytes and have chondroprotective effects. IL- 10 stimulates COL-II and PG expression, and inhibits cytokine induced MMP and NO expression. IL-10 further antagonizes the apoptotic pathways of IL-1b and TNF-*a* and inhibits the levels of pro-inflammatory cytokines. In vitro experiments on chondrocytes have shown that caspase-1 selective inhibitor Z-YVAD blocked chondrocyte apoptosis when exposed to collagenase. The intra-articular application of the pan-caspase inhibitor Z-VAD-FMK in vivo significantly reduced cartilage degradation both macroscopically and microscopically. Similarly, when chondrocytes were subjected to high mechanical stresses or after impaction injuries, caspase inhibitors were found to prevent their apoptosis.

Diacerein, an inhibitor of IL-1b, reduced OA chondrocyte DNA fragmentation and death through a decrease in the level of caspase-3 expression, levels of iNOS, and secondarily to NO production. Diacerein was found to reduce the pain and symptomatology in patients with PTOA and had an impact on the abnormal subchondral bone metabolism by reducing the synthesis of resorptive factors and osteoclast formation. Curcumin inhibited IL-1b-induced apoptosis and caspase-3 activation in chondrocytes. Recent work has shown that curcumin protects human chondrocytes from the catabolic actions of IL-1b, including MMP-3 upregulation, inhibition of collagen type II, and downregulation of beta1-integrin expression. Resveratrol reduced the SNP-induced apoptosis rate of chondrocytes and level of NO in the synovial fluid. The combination of curcumin and resveratrol had a more potent effect as compared to monotherapy with each drug individually.

Lastly, platelet rich plasma (PRP) significantly increased the proliferation of chondrocytes and decreased their apoptosis in an in vitro study. PRP application resulted in a dose-dependent significant decrease in MMP-3, MMP-13, ADAMTS-5, IL-6, and COX-2, while TGF-b, aggrecan, and collagen type 2, TIMPs and intracellular anti-inflammatory interleukins IL-4, IL-10, IL-13 were increased.

CONCLUSION

The pathophysiological factors involved in posttraumatic ankle osteoarthritis, such as biological, structural, mechanical, and molecular changes must be studied together, as the interaction between these factors determines the risk of PTOA progression. Inhibition of a single catabolic molecule or cascade probably is not sufficient to alter the natural progression of the pathological process. Developing methods to prevent the advancement of PTOA may delay or eliminate the necessity for arthrodesis or arthroplasty, which occurs undesirably earlier in patients with ankle PTOA.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. ALGS conception, study design and article writting. CCN conception, study design and article writting. SS conception, study design, interpreted the results, and drafted the article. MHP conception, study design and article writting. VV conception, study design and article writing, acquired data. SR conception, study design and article writting. critically reviewed the article. All authors contributed to the intellectual concept of the study and approved the final version of the manuscript.

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DOI: http://dx.doi.org/10.1590/1413-785220243203e276755

SHORT-TERM EVALUATION BETWEEN POLYETHYLENE THICKNESS IN PRIMARY TOTAL KNEE ARTHROPLASTY

AVALIAÇÃO A CURTO PRAZO ENTRE A ESPESSURA DO POLIETILENO NA ARTROPLASTIA TOTAL PRIMÁRIA DO JOELHO

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ABSTRACT

Objective: The objective of the research was to carry out a comparative study between Smith & Nephew ® or Zimmer ® prostheses with thick versus thin polyethylene, in patients undergoing primary total knee arthroplasty, during a short-term follow-up. Thus, the objective was to analyze the survival of the implants in question under the clinical and radiographic aspect. Methods: The sample was divided into two groups: Group 1 with thick polyethylene and group 2 with thin polyethylene. A clinical analysis of the patients was carried out and the implants were checked for loosening. Results: The groups were similar when compared. According to the Ahlbäck classification, 83% of the patients were in groups IV and V. The median functional score in the postoperative period was similar between the two groups. Postoperatively, the tibiofemoral angle fluctuated between 5 and 6^0 valgus on average. Two complications were observed in each group. None of the evaluated patients presented implant loosening Conclusion: Patients treated with thick polyethylene had the same functional score as the control group, as well as the absence of radiographic changes in this short-term follow-up, with implant survival and a similar rate of complications between both groups. ***Level of evidence III, Retrospective study***.

Keywords: Knee Arthroplasty. Joelho. Prosthesis Failure.

RESUMO

Objetivo: O objetivo desta pesquisa foi realizar um estudo comparativo entre as próteses Smith & Nephew ® e Zimmer ®, com polietileno espesso versus o fino, em pacientes submetidos à artroplastia total primária do joelho, durante um seguimento de curto prazo. Dessa forma, foi analisada a sobrevida dos implantes em questão sob o aspecto clínico e radiográfico. Métodos: A amostra foi dividida em dois grupos: grupo 1 com polietileno espesso e grupo 2 com polietileno fino. Foi realizada análise clínica dos pacientes e verificado se ocorreu soltura dos implantes. Resultados: Os grupos tiveram resultados semelhantes quando comparados. Segundo a classificação de Ahlbäck, 83% dos pacientes eram dos grupos IV e V. A mediana do escore funcional no pós-operatório foi similar entre os grupos. No pós-operatório o ângulo tíbio-femoral oscilou na média entre 5 e 6^0 de valgo. Foram observadas duas complicações em cada grupo. Nenhum dos pacientes avaliados apresentou soltura do implante. Conclusão: Os pacientes tratados com o polietileno espesso apresentaram o mesmo escore funcional do grupo controle, assim como ausência de alterações radiográficas nesse seguimento de curto prazo, com sobrevida do implante e índice de complicações similar entre ambos os grupos. ***Nível de evidência III, Estudo retrospectivo.***

Descritores: *Artroplastia do Joelho. Joelho. Falha de Prótese.*

Citation: Pires e Albuquerque RS, Pizziolo TR, Silva OAT, Monteiro MAG, Minamoto STN, Mozella AP. Short-term evaluation between polyethylene thickness in primary total knee arthroplasty. Acta Ortop Bras. [online]. 2024;32(3):Page 1 of 4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

The longevity of the population and the higher prevalence of patients with osteoarthritis have increased the frequency of indication for total knee arthroplasty (TKA).[1] TKA can be defined as a highly complex surgical procedure for the treatment of osteoarthritis, which can have satisfactory and lasting impacts on the improvement of pain, quality of life and patient function, in addition to the correction of deformities and instabilities of origins related to degenerative processes that affect the knee joint.[2] TKA presents excellent postoperative outcomes, in relation to implant survival, with rates of more than 95%, in at least 10 years of follow-up.[3]

High molecular weight polyethylenes are the most used in TKAs. Their success is due to various properties such as abrasion resistance, impact strength, low coefficient of friction, and to being chemically inert.[4]

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

The study was conducted at Centro de Cirurgia do Joelho do Instituto Nacional de Traumatologia e Ortopedia.
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Article received on 07/19/2023, approved on 11/03/2023.

The factors that affect polyethylene wear in TKA include polyethylene properties, imperfections and thickness, contact area, level, type of stress, coefficient of friction on joint surfaces and prosthesis conformity.[5] The fundamental mechanisms of polyethylene wear are adhesion, abrasion and fatigue and, in turn, with increasing stress, a greater amount of debris is produced, causing, in the long term, osteolysis and aseptic loosening of the TKA.[6]

Polyethylene thickness relates directly to stress distribution. As a result, the size of this component has become increasingly important.[7] Thick polyethylene can show greater wear due to the change in the articular interline.[8]

In TKA, polyethylene thickness has a multifactorial character. The size of this component is secondary to factors such as preoperative deformity, bone resections and ligament releases of the knee.[9] Therefore, there is no way to predict polyethylene thickness preoperatively.

In primary TKA, the literature is scarce and seeks to correlate polyethylene thickness, functional outcome of joint replacement, and aseptic failure rate.[10,11]

The main objective of the research is to conduct a comparative study between Smith & Nephew® or Zimmer® prostheses with thick versus thin polyethylene in patients submitted to primary total knee arthroplasty during a short-term follow-up. Thus, the objective is to analyze the survival of the implants in question from the clinical and radiographic perspective.

MATERIAL AND METHODS

This is an observational, cross-sectional and retrospective study. The participants were identified by using data from the implant sector of our hospital. By identifying patients associated with the specific implant, it was possible to have access to the medical records of those submitted to posterior-stabilized (PS) primary TKA with thick and thin polyethylene. Thus, we conducted a comparative study, observing the radiographic analysis of patients submitted to PS primary TKA, Smith & Nephew® or Zimmer® during a minimum follow-up of 2 years postoperatively. The sample was divided into two groups: group 1 with thick polyethylene (> 14 mm) and group 2 with thin polyethylene (< 14 mm)[11] (Figures 1 and 2).

Figure 1. Total knee arthroplasty with thick polyethylene.

Figure 2. Total knee arthroplasty with thin polyethylene.

The sample consisted of patients of both sexes and all ages, who had been submitted to primary TKA in the hospital with the Smith & Nephew® and Zimmer® prosthesis type and who had been admitted for treatment during the years 2017 to 2020.

The Smith & Nephew® and Zimmer® prostheses, during this study period, were the implants tendered in our hospital. Thus, the choice of prostheses for analysis is justified, without any type of conflict of interest in the evaluation.

Inclusion criteria: patients submitted to primary arthroplasty performed at the research hospital, with Smith & Nephew® and Zimmer® type prosthesis. Exclusion criteria: failure to document data from the medical record, use of another prosthesis model and non-agreement to participate in the research. The research was approved by the Institutional Ethics Committe (57720022.5.0000.5273) according to the established ethical standards.

Postoperatively, with a minimum of two years of follow-up, clinical evaluations were performed by a single physician, a member of the Brazilian Society of Knee Surgery and with a graduate degree (doctorate) in Medicine. During the evaluation, patient demographic data were collected, in addition to functional *Knee Society Score (*KSS).[12] The KSS form evaluates six variables: pain, function, range of motion, muscle strength, flexion deformity and instability. Subtractions occur in the use of crutches or cane, loss of active knee extension, and instability in varus and valgus. The maximum score is 100 points, of which: 85 points or more is considered excellent; 70 to 84, good; 60 to 69, regular; and 60 or less, unsatisfactory.

Radiographic analysis of the PS Smith & Nephew® and Zimmer® implants were performed by another orthopedic physician participating in the study, without prior knowledge of the functional indices obtained during the initial evaluation. The radiographs were performed with bipodal support in the anteroposterior, lateral and axial views of the patella. Radiographic analysis evaluated implant loosening through the criteria used by the *Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System*.[13] The evaluation of osteolysis consisted in observing the presence of a radiolucent line in the region of the prothesis-cement or bone-cement interface, which was quantified in millimeters of thickness and subsequently analyzed at each radiographic view for comparison. In addition, the degree of osteoarthritis was analyzed by the Ahlbäck classification,[14] the type of deformity of the lower limb, as well as

the tibio-femoral angle. This angle was calculated by drawing lines between the anatomical axes of the femur and tibia, preoperatively and postoperatively.[15] Radiographic data were analyzed using mDicomViewer 3.0 software (Microdata, RJ-Brazil, 2007).

Medical records were analyzed by a single physician member of the Brazilian Society of Knee Surgery, and patient demographic data, body mass index (BMI) and *American Society of Anesthesiology (ASA) Classification* were collected. Body mass index was calculated by dividing body mass by height squared. This ratio was recorded in kilograms per square meter (kg/m^2) as described by Adolphe Quelet.[16]

Statistical analysis was performed using Microsoft Excel 2016 and GraphPad Prism 5 software. Implant survival was defined as the need for revision for any cause, and survival was determined through the analysis of the Fischer test with a 95% confidence interval. In addition, the Student's T test of equality of variance was used to calculate the outcomes analyzed with the two independent samples of the population, with a significance level of 0.05.

RESULTS

A total of 90 patients were evaluated postoperatively after primary total knee arthroplasty, from 2017 to 2020. Patients were divided into two groups: thin polyethylene (49 patients) versus thick polyethylene (41 patients). All patients had been diagnosed with primary osteoarthritis of the knee.

In relation to males, 14 patients with use of thin polyethylene and 11 patients with use of thick polyethylene; in relation to females, 35 patients with use of thin polyethylene and 30 patients with use of thick polyethylene. The distribution by sex was similar between the two groups ($p = 0.958$).

The mean age of the thin polyethylene group was 70.59 years (standard deviation 7.32) and, of the thick polyethylene group, 67.39 years (standard deviation 7.06). The mean age of the thick polyethylene group was lower than that of the thin polyethylene group ($p = 0.038$).

We evaluated laterality, right side, there were 25 (56.82%) thin polyethylenes and 19 (43.18%) thick polyethylenes, in relation to the left side, 24 (52.17%) thin polyethylenes and 22 (47.83%). Regarding laterality, the groups were similar to each other ($p = 0.818$).

In the case of preoperative deformity, it was evaluated and classified according to the Ahlbäck classification, finding with grade II 2 thin and 1 thick polyethylenes, grade III 8 thin and 4 thick polyethylenes, grade IV 18 thin and 10 thick polyethylenes, and grade V 21 thin and 26 thick polyethylenes.

In the thin polyethylene group, BMI was distributed as follows: Normal 6 patients, overweight 19 patients, grade I obesity 18 patients, grade II obesity 5 patients, grade III obesity 1 patient. In the thick polyethylene group, we obtained: Normal 1 patient, overweight 13 patients, grade I obesity 12 patients, grade II obesity 8 patients, grade III obesity 8 patients.

The ASA classification was graded as follows in the thin polyethylene group: Grade I 1 patient, Grade II 44 patients, Grade III 4 patients. In the thick polyethylene group we obtained: Grade I 4 patients, Grade II 33 patients, Grade III 4 patients.

Regarding the preoperative axis, the median of the thick polyethylene group was -8 degrees quartile interval (QI) = (-15.0 – 12.5) and the median of the thin polyethylene group was -5 degrees QI = (-12.0 – 7.0). The groups were similar in relation to the preoperative axis ($p = 0.567$). The varus axis was considered negative and the valgus axis was considered a positive number.

Regarding the postoperative axis, the median of the thick polyethylene group was 6 degrees QI = (5.0 – 7.0) and the median of the thin polyethylene group was 5 degrees QI = (5.0 – 6.0). The groups were similar in relation to the postoperative axis ($p = 0.063$). The varus axis was considered negative and the valgus axis was considered a positive number.

Regarding complications, each group presented two complications, totaling four complications. In the thin polyethylene group, one patient presented paresthesia in the operated knee and leg and one patient presented joint stiffness and had to undergo manipulation under anesthesia. In the thick polyethylene group, one patient had infection and one patient had wound dehiscence. None of the patients evaluated had implant loosening.

The mean preoperative objective KSS was similar between the two groups ($p = 0.672$), and that of the thin polyethylene group was 39.84 (standard deviation = 16.92) and that of the thick polyethylene group was 38.37 (standard deviation = 15.85). The mean preoperative subjective KSS was similar between the two groups ($p = 0.253$), with the thin polyethylene group being 41.02 (standard deviation = 20.66) and the thick polyethylene group being 35.61 (standard deviation = 23.40).

The median objective KSS in the postoperative period was similar between the two groups ($p = 0.938$), and that of the thin polyethylene group was 88.00 QI = (84.00 – 92.00) and that of the thick polyethylene group was 88.00 QI = (80.00 – 92.00). The median subjective KSS in the postoperative period was similar between the two groups ($p = 0.292$), and that of the thin polyethylene group was 82.00 QI = (70.00 – 90.00) and that of the thick polyethylene group was 80.00 QI = (62.50 – 90.00).

DISCUSSION

There is no study in Brazil that evaluates the thickness of polyethylene and correlates with the functional result of primary TKA, as well as implant survival. In addition, there are few studies in the literature on this topic. We believe that in some developed countries there is no waiting list for surgery; therefore, these patients are operated on at the earliest stage of osteoarthritis and consequently cases have less complexity. As a result, our research becomes extremely relevant. Ligament balance, bone resection and polyethylene thickness are interconnected variables.[7] As a result, we obtained the preoperative radiographic analysis trying to determine the degree of deformity and correlate with polyethylene thickness.

Polyethylene wear can produce debris that influence the loosening of prosthetic components.[3] Several variables can influence the frictional wear behavior of polyethylene, such as prosthesis design, raw material used, surgical technique applied, and patient morbidities, such as level of activity and body mass.[3] We agree with these statements, therefore, we used two types of prostheses established in the international market. In addition, we assessed BMI. Garceau et al. concluded that there were no differences in TKA revision indices, as well as in the clinical follow-up of thick versus thin polyethylene implants.[10] Our study is consistent with this literature; however, these authors analyzed implants with various degrees of constrictions. In addition, they reported that their multicenter study could have generated a lack of standardization. In contrast, Berend et al. observed a higher rate of TKA failure with thick polyethylene.[9] Greco et al. also found no difference between the group with thick versus thin polyethylene.[11]

Preoperative factors such as degree of deformity, bone loss and ligament insufficiency may affect the choice of polyethylene thickness.[10] In addition, this patient profile may present a low functional score. We ratified these statements; however, our research showed a similar postoperative KSS between the two groups.

Our study was based on the study of Greco et al., who used the 14 mm polyethylene thickness cutoff limit. Below this limit, it was considered thin, and, above it, thick.[11]

Our analysis had a short-term follow-up (2 years) and was based on the study of Greco et al.[11]

In the research of Greco et al., the thick polyethylene group was composed of 3.5% of the sample.[11] Our study sought to obtain a more homogeneous and proportional population between the two groups (49 thin polyethylenes versus 41 thick polyethylenes). The use of thicker polyethylene was frequent in less experienced surgeons.[11] In contrast , our study was composed only of experienced surgeons and members of the Brazilian Society of Knee Surgery, trying to standardize the group.

Survival analysis of this study demonstrated that "thinner" polyethylenes (< or = 14 mm) had the same short-term performance compared to "thicker" polyethylenes (> 14 mm), assessed on postoperative follow-up imaging and clinically.

Previously, there were concepts that very "thin" polyethylene in TKAs are associated with higher failure rates, mainly due to wear; however, current studies have shown that "thicker" polyethylenes (≥ 14 mm) are also associated with higher failure rates in medium- to long-term follow-up.[17] The surgical variables associated with the implant should be carefully evaluated and may be associated with higher failure rates.[17] As a result, we note the controversy on the subject and the relevance of the study.

In our study, it was observed that most patients were female, but there was no statistical difference between males and females in relation to polyethylene thickness used (thick versus thin); therefore, it is assumed that it is not possible to determine polyethylene thickness in relation to sex.

When evaluating preoperative deformities and the postoperative axis, there was similarity between the groups in our study, with no statistical difference between the groups in relation to polyethylene thickness used.

Our research presents as limitations being retrospective and having a short-term follow-up.

CONCLUSION

Patients treated with thick polyethylene had the same functional score as the control group, as well as no radiographic changes in this short-term follow-up, with implant survival, complication rate similar between the groups.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. RS: writing and performing surgeries; TR: data analysis and performing surgeries; OA: data analysis and performing surgeries; MAG: data analysis and performing surgeries; STN: data analysis and performing surgeries; AP: article review and intellectual concept of the article.

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DOI: http://dx.doi.org/10.1590/1413-785220243203e277781

ULTRASOUND-GUIDED GENICULAR NERVE BLOCK FOR KNEE OSTEOARTHRITIS: A CASE SERIES

BLOQUEIO DO NERVO GENICULAR GUIADO POR ULTRASSOM PARA OSTEOARTROSE DO JOELHO: UMA SÉRIE DE CASOS

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ABSTRACT

Objective: Knee genicular nerve blocks have been a topic of discussion among various types of treatment for knee osteoarthritis. This study aims to evaluate the pain and function of patients diagnosed with knee osteoarthritis after undergoing ultrasound-guided genicular nerve blockade using pharmacological agents. Methods: The study included 36 patients diagnosed with knee osteoarthritis, comprising 17 bilateral cases, totaling 53 knees undergoing UGNB using a mixture of triamcinolone, ropivacaine, and lidocaine under ultrasound guidance. Epidemiological data, pain outcomes measured by the Visual Analog Scale (VAS), and function assessed using the Western Ontario and McMaster Universities (WOMAC) score were evaluated before and after 12 weeks of the procedure. Results: The mean age was 75.5 years (standard deviation of 9.4 years), with a predominance of females and right-sided involvement. There was a mean reduction of 3.0 points in VAS ($p < 0.001$) and 15.4 points in WOMAC ($p < 0.001$). Two cases reported only minor and transient complications related to the procedure (skin anesthesia and edema). Conclusion: Ultrasound-guided genicular nerve blockade using pharmacological agents demonstrated pain reduction and improved function with a low complication rate after 12 weeks in patients with knee gonarthrosis. ***Level of Evidence IV, Case Series.***

Keywords: Nerve Block. Pain. Knee Osteoarthritis. Ultrasonography. Anesthetics.

RESUMO

Objetivo: Os bloqueios geniculares do joelho têm sido tema de discussão entre os diversos tipos de tratamento da gonartrose. Este estudo tem por objetivo avaliar a dor e a função dos pacientes com diagnóstico de osteoartrose do joelho, após realização do procedimento de bloqueio farmacológico dos nervos geniculares (BFNG) guiado por ultrassom. Métodos: O estudo incluiu 36 pacientes com diagnóstico de gonartrose, sendo 17 casos bilaterais, totalizando 53 joelhos submetidos ao BFNG, com a mistura de triancinolona, ropivacaína e lidocaína guiado por ultrassom. Avaliou-se dados epidemiológicos, desfechos de dor pela Escala Visual Analógica (EVA) e função com escore Western Ontario and Mcmaster Universities (WOMAC) antes e após 12 semanas do procedimento. Resultados: A idade média encontrada foi de 75,5 anos (desvio padrão de 9,4 anos), com predominância do sexo feminino e do lado direito. Houve uma redução média na EVA de 3,0 pontos ($p < 0,001$) e no WOMAC de 15,4 ($p < 0,001$). Em dois casos, relataram apenas complicações menores e transitórias relacionadas ao procedimento (anestesia da pele e edema). Conclusão: O bloqueio farmacológico dos nervos geniculares guiado por ultrassom demonstrou redução da dor e melhora na função, com baixa taxa de complicação após 12 semanas nos pacientes com gonartrose. ***Nível de evidência IV, Série de Casos.***

Descritores: *Bloqueio Nervoso. Dor. Osteoartrite do Joelho. Ultrassonografia. Anestésicos.*

Citation: Ramalho RC, Fernandes TD, Peraro FF, Pugliese GM, Arliani GG, Ferreira GF. Ultrasound-guided genicular nerve block for knee osteoarthritis: a case series. Acta Ortop Bras. [online]. 2024;32(3):Page 1 of 5. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Knee osteoarthritis or gonarthrosis is the main cause of knee pain, affecting about 10% of the world population aged over 60 years, mainly women.[1] It is characterized by continuous mechanical stress associated with the local inflammatory process, causing wear in the intra-articular structures of the knee. As a result, the knee can be swollen, with limited range of motion, and in more advanced cases even evolve with deformities.[2]

Total knee arthroplasty can be a successful surgical option for cases that do not respond to conservative treatments, but with risks and complications already well described in the literature

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

The study was conducted at Instituto Prevent Senior.

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Article received on 08/21/2023, approved on 10/20/2023.

and, thus, patients often request less invasive interventions before accepting arthroplasty.[3]

The diagnosis is clinical and is complemented by imaging exams, with weight-bearing knee radiography being the main exam. In this examination, there is usually a decrease in joint space, osteophytes and subchondral sclerosis.[4] To monitor the progression of the disease and aid in treatment, the Ahlbäck radiographic classification can be used.[5]

The initial treatment is conservative through weight loss, physical therapy and the use of pain relievers. In advanced cases, where patients have functional limitation and no improvement with lifestyle changes, more invasive interventions such as infiltrations, blocks and surgery are indicated. Even after all these procedures, patients may still develop refractory pain.[6]

Current studies demonstrate that genicular nerve blocks (GNB) using pharmacological agents, such as corticosteroid and anesthetic solutions, can relieve pain and improve the patient's functional capacity.[7] In patients with gonarthrosis, the intervention is performed on the sensory branches of genicular nerves: superomedial, superolateral and inferomedial.[8]

The objective of the study was to compare the clinical pain and function outcomes of patients with knee osteoarthritis submitted to ultrasound-guided genicular nerve block using pharmacological agents.

MATERIAL AND METHODS

The present study is a retrospective case series of patients diagnosed with knee osteoarthritis submitted to ultrasound-guided GNB.

The project was approved by the Local Ethics Committee (Brazil Platform - CAAE: 72636023.0.0000.8114). The research followed the principles of the Declaration of Helsinki and was based on the guide on good clinical practices at all stages.

Inclusion and exclusion criteria

Inclusion criteria: patients with diagnosis of gonarthrosis, clinical and radiographic, refractory to conservative treatment and who were submitted to pharmacological ultrasound-guided genicular nerve block by the senior author (G.F.F.) between June 2022 and February 2023.

Exclusion criteria: patients with previous knee surgeries or fractures; individuals with autoimmune diseases such as rheumatoid arthritis, lupus, among others.

Evaluated outcomes and follow-up

Patients were clinically evaluated through the pain score using the Visual Analogue Scale (VAS)[9] and the *Western Ontario and McMaster Universities* (WOMAC) function score.[10] Patients were evaluated at two times: before the procedure and 12 weeks after the block.

The Ahlbäck classification was used to measure the degree of knee osteoarthritis before the intervention. This classification was initially published by Ahlbäck in 1968[11] and later revised in 1992 by Keyes et al.[12]

This stratification is based on the weight-bearing radiographic view of the knee.. The score ranges from grade 1 to grade 5. Grade I: decreased joint space; Grade II: obliteration of joint space; Grade III: anteroposterior view indicates tibial plateau wear of less than 5.0 mm and profile view shows intact posterior part of tibial plateau; Grade IV: anteroposterior view shows tibial plateau wear between 5.0 and 10.0 mm, and profile view shows extensive wear of posterior margin of plateau; Grade V: anteroposterior view shows severe tibial subluxation, and profile view shows anterior tibial subluxation greater than 10.0 mm.

Data collection

Data were collected from patient medical records and also included information such as age, sex, laterality, height, weight, presence of occurrences or complications resulting from the procedure, and calculated Body Mass Index (BMI).

Study data were entered and managed using Research Electronic Data Capture (REDCap) tools hosted at the Prevent Senior Institute. REDCap is a secure, web-based application designed to support data capture for research studies by providing: 1) an intuitive interface for validated data entry; 2) audit trails for data manipulation tracking and export procedures; 3) automated export procedures for continuous data downloads for common statistical packages; and 4) procedures for importing data from external sources.[13]

Procedure and intervention

The entire procedure was performed exclusively in an outpatient setting. For GNB, patients were initially positioned in horizontal dorsal decubitus on the stretcher with a pad in the popliteal region to leave in slight flexion and the knee asepsis and antisepsis were performed.

The pharmacological solution used was composed of 2.5 mL ropivacan (7.5 mg/ml), 2.5 mL lidocan (2%) without vasoconstricting component and 1.0 mL triamcinolone. The solution totaled 6.0 mL and 2.0 mL were applied to each genicular nerve: superolateral, superomedial and inferomedial.

The entire procedure was guided by Toshiba Aplio300® Ultrasound with linear transducer, protected by sterile cover. Initially, we located the joint on the long axis, and then we looked for the genicular bundle, best visualized by pulsing each genicular artery. Using a 22G spinal anesthesia needle, the drug was delivered to the correct region by needling in plane and direct visualization.

The procedure was always performed by the same physician, experienced in guided intervention (G.F.F.), following the standard of medication and application for all patients in the study. Inferolateral genicular nerve block was not performed in order to avoid iatrogenic injury or block of the common peroneal nerve

After the procedure, the patient was immediately referred for a consultation and evaluation by the physiotherapy team to guide the entire rehabilitation process specific to each patient.

Statistical analysis

Statistical data analysis was performed through the continuous variables that passed the Shapiro-Wilk normality test. For comparisons of data distributed in a non-parametric way, the Wilcoxon test was used. For normally distributed data, the paired Student's t-test was used. Categorical variables were evaluated by their proportion. Subgroup analysis was performed through a linear regression comparing the pain scale (VAS) and the degrees of arthrosis (Ahlbäck). All statistical evaluations were performed using the R software. Statistical evidence was considered when p-value ≤ 0.05.

RESULTS

The present study analyzed 36 patients, totaling 53 knees (17 bilateral), most on the right side (52.8%) and with a predominance of females with 83% of the sample. The mean age of the patients analyzed was 75.5 years, with a minimum age of 57 years and a maximum age of 95 years, with a standard deviation (SD) of 9.4 years. The mean BMI of the included patients was 29.7 (SD 4.2).

Regarding the degree of knee osteoarthritis, most patients (38%) were classified as grade II, 34% as grade III, 18% as grade IV and 10% as grade V.

Regarding the clinical evaluation, there was a mean reduction of 3 points in the visual analogue scale of pain after pharmacological block. The mean initial value was 8.0 points (SD 1.6) and after the block with 12 weeks of follow-up the VAS decreased to 5.0 (SD 1.2), obtaining a 3.0-point reduction in the mean in relation to the initial value ($p < 0.001$), as shown in Figure 1.

Regarding the WOMAC score, there was a 15.4-point reduction ($p < 0.001$). In this same score, sub-items were analyzed with a reduction of 4.1 points for pain ($p < 0.001$), a reduction in joint stiffness of 1.1 point ($p < 0.05$) and in function of 7.2 ($p < 0.001$), showing a positive impact on the different dimensions evaluated by the WOMAC score (Table 1).

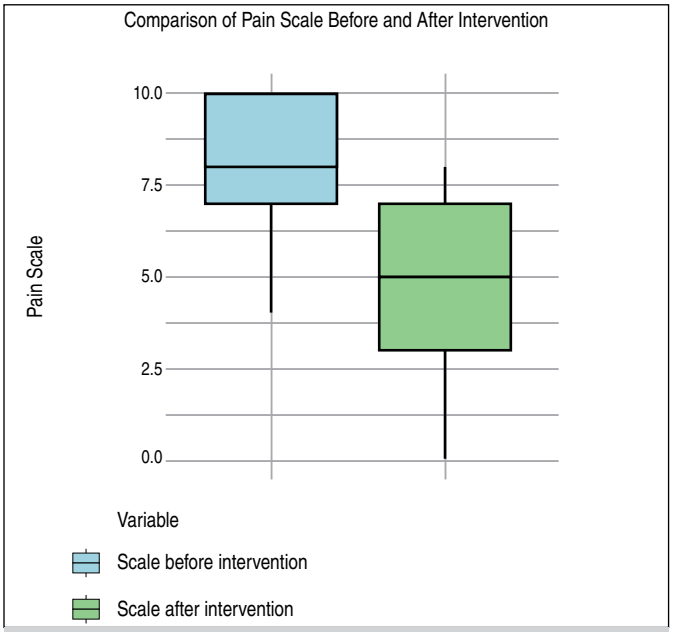

Figure 1. Comparison of VAS before and after intervention

Table 1. Pre- and post-intervention clinical evaluation results.

Outcome	Pre-intervention (mean, standard deviation, minimum and maximum)	Post-intervention (mean, standard deviation, minimum and maximum)	Pre- and post-intervention mean difference	p-value
VAS*	8,0 ± 1,6 [4,0-10,0]	5,0 ± 2,1 [0-8,0]	-3,0	p < 0,001
WOMAC**	64,1 ± 16,7 [25,6-93,7]	48,7 ± 25,1 [2,0-93,8]	-15,4	p < 0,001
WOMAC (Pain)	12,7 ± 3,2 [6,0-18,0]	8,6 ± 5,1 [9-20,0]	-4,1	p < 0,001
WOMAC (Joint Stiffness)	4,1 ± 2,1 [0-8,0]	3,0 ± 1,4 [0-6,0]	-1,1	p < 0,05
WOMAC (Function)	45,3 ± 12,3 [15,0-67,0]	35,4 ± 18,6 [0-68,0]	-7,2	p < 0,001

* Visual Analogue Scale; **Western Ontario and McMaster Universities

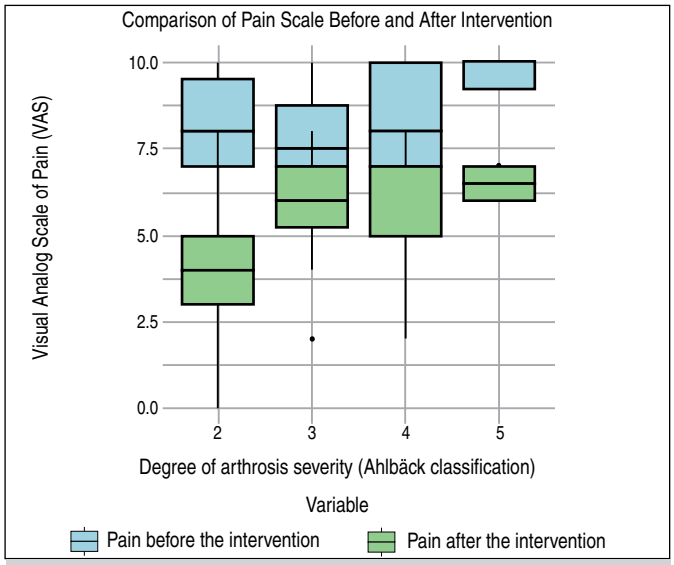

Figure 2. Comparison of VAS before and after intervention considering the degree of Ahlbäck

Subgroup analysis

The subgroup analysis of VAS before and after intervention stratified by the degree of osteoarthritis (Ahlbäck classification) showed that the coefficient for the degree of osteoarthritis is statistically significant ($p = 0.00467$). This suggests a significant relation between degree of osteoarthritis (Ahlbäck) and VAS 12 weeks after genicular nerve block, suggesting that the severity of osteoarthritis may influence the response to therapy (Figure 2). In this case, the lower the severity of arthrosis, the greater the reduction in pain 12 weeks after genicular nerve block.

Complications

Of the 53 cases where block was performed, only two (3.8%) presented complications, and the two complications were considered minor. One patient had edema in the knee region and another had loss of sensation on the lateral face of the knee, both temporary. There were no major complications.

DISCUSSION

It is known that the initial treatment of knee osteoarthritis is conservative, with physiotherapy, non-steroidal anti-inflammatory drugs (NSAIDS) and analgesics.[6]

NSAIDS and analgesics are indicated for patients with mild to moderate osteoarthritis, while physiotherapy is indicated for strengthening the quadriceps, flexibility and improvement of physical fitness, serving as an aid for drug treatment.[14,15]

As the condition becomes more complex, other therapeutic methods are employed, such as injectable corticosteroids, intra-articular hyaluronic acid, and, more recently, genicular nerve block.[16-19]

Injections are reserved for patients with low response to oral medication, and joint infiltrations with hyaluronic acid have seen

increasing adoption over the years.[20] However, the outcome in more advanced cases of knee osteoarthritis is often insufficient to relieve symptoms.

Thus, GNB is a therapeutic option for knee osteoarthritis in order to relieve pain and allow a window of opportunity for rehabilitation, often compromised by pain.

Patients in our sample reported an important reduction in pain symptoms 12 weeks after the procedure, with a 3-point decrease in the mean value of the visual analogue scale of pain ($p < 0.001$) and in the WOMAC score of pain ($p < 0.001$).

There was also a relation between the power to reduce pain and the degree of osteoarthritis, that is, the greater the joint destruction, the lower the power of GNB. This reinforces the fact that advanced degrees of knee osteoarthritis have a worse result when compared to milder degrees.

In addition, we observed an improvement in relation to the stiffness measured in the WOMAC score, with lower significance when compared to other sub-items ($p < 0.05$). This is probably due more to the perception of improved pain than to an increased range of motion, as GNB does not reach the joint region.

In these 12 weeks, with improved pain and function, patients have the ideal time to perform intense and individualized physiotherapy rehabilitation, avoiding the recurrence of symptoms and the need for a new block. However, it is important, before the intervention, to explain this concept to the patient and the need for rehabilitation programs that should be followed subsequently.

Some studies on GNB have been published. In the article of Kim et al.[2] the combination of GNB with lidocaine and corticosteroids provided short-term pain relief, although the contribution of corticosteroids was not clear compared to local anesthesia alone (control group). In the present study, the findings are similar, emphasizing the effectiveness in relieving pain in patients with knee osteoarthritis.

In the study conducted by Shanahan et al.[16] the authors published a 12-week placebo-controlled clinical trial to investigate the effects of GNB in patients with knee osteoarthritis. In the study group, patients received corticosteroid and bupivacaine block. Comparing those results with our findings, there was also an improvement in pain and function after genicular nerve block.

Tan et al.[21] conducted a systematic review on ultrasound-guided GNB for chronic knee osteoarthritis. They analyzed nine studies that included a total of 280 patients with symptoms or characteristics of the disease for at least 3 months.

The studies used different block techniques and pharmacological agents, such as local anesthetics, corticosteroids and alcohol. The review showed sustained improvements in knee pain and function for up to 6 months after the procedure, regardless of the choice of pharmacologic agents.

Although it was not possible to perform a meta-analysis due to the heterogeneity of the studies, techniques and agents, it was concluded that there is solid evidence to target the upper medial and lower medial genicular nerves with local anesthetics, corticosteroids or alcohol, resulting in reduced pain and improved function in patients with chronic knee osteoarthritis under ultrasound guidance.

Generalization

This study was conducted with a population with a mean age of 75.5 years and the generalization of the results for younger ages should be performed with caution.

Study limitations

First, it is a case series without a control group. Second, the study was retrospective and with data collected from patient medical records. Finally, the mean age of the study was above the population with osteoarthritis, limiting the result in younger populations.

Summary of evidence

The present study demonstrated that ultrasound-guided genicular nerve block in patients with knee osteoarthritis showed improved pain and function in the short term with a low rate of complications.

CONCLUSION

Ultrasound-guided genicular nerve block demonstrated a reduction in pain and improvement in function with low rate of complications after 12 weeks in patients with knee osteoarthritis.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of the manuscript and was in agreement with the final version. GFF, RCR and TDF and GGA were the main contributors in the writing of the manuscript. GFF performed all procedures and evaluated the data from the statistical analysis. GFF, RCR and FFP assessed patients. GFF, RCR, TDF, FFP, GMP, GGA carried out the bibliographic research, review of the manuscript and contributed to the intellectual conception of the study.

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DOI: http://dx.doi.org/10.1590/1413-785220243203e266917

EFFECTS OF TREADMILL GAIT TRAINING ON BALANCE IN PARKINSON'S PATIENTS AFTER DEEP BRAIN STIMULATION

EFEITOS DO TREINO DE MARCHA EM ESTEIRA NO EQUILÍBRIO POSTURAL DE PACIENTES COM PARKINSON APÓS ESTIMULAÇÃO CEREBRAL PROFUNDA

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ABSTRACT

Objective: After deep brain stimulation (DBS), patients with Parkinson's disease (PD) typically still present significant gait and postural stability problems, and thus additional interventions are needed. In this way, our purpose was evaluate the comparative effectiveness of treadmill training, with and without body weight support, on balance outcomes among patients with PD after DBS. Methods: Eleven patients with PD that were using bilateral subthalamic nucleus DBS were evaluated using Time Up and Go test (TUG); Berg Balance Scale (BBS) and Static Posturography. In phase 1, all subjects participated in 8-weeks of treadmill training in conjunction with conventional physiotherapy. After six weeks (wash-out), each patient then participated in a subsequent 8-weeks of treadmill training with partial body weight support. Results: After the phase 1, there were improvements on the cognitive TUG performance (Before: 15.7 ± 1,8 sec; After: 13.7 ± 3.1 sec; $p < 0.01$) and an increase of anteroposterior and medio-lateral body oscillation with eyes closed. After the phase 2, there were improvements in conventional (Before: 12.3 ± 2.0 sec; After: 10.7 ± 1.7 sec; $p < 0.01$) and cognitive (Before: 14.6 ± 3.5 sec; After: 12.5 ± 1.6 sec; $p < 0.05$) TUG performances. There were no significant changes in the Berg Balance Scale following either training protocol. Conclusion: Both trainings improved static and dynamic balance and had similar results; however, supported treadmill training seemed to be a potentially superior option, as patients tended to feel safer. ***Level of Evidence II, therapeutic studies - investigation of treatment outcomes.***

Keywords: Parkinson Disease. Deep Brain Stimulation. Postural Balance. Neurological Gait Disorders. Neurological Rehabilitation.

RESUMO

Objetivo: Mesmo após a estimulação cerebral profunda (ECP), os pacientes com doença de Parkinson (DP) muitas vezes ainda apresentam problemas significativos de marcha e estabilidade postural, e, portanto, intervenções adicionais são necessárias. Avaliar a eficácia comparativa do treinamento em esteira, com e sem suporte de peso corporal, nos resultados de equilíbrio de pacientes com DP após ECP. Métodos: Onze pacientes com DP em uso de ECP bilateral do núcleo subtalâmico foram avaliados pelos testes Time Up and Go (TUG), escala de equilíbrio de Berg (EEB) e posturografia estática. Na fase 1, todos participaram de oito semanas de treinamento em esteira em conjunto com fisioterapia convencional. Após seis semanas (wash-out), cada paciente participou de oito semanas subsequentes de treinamento em esteira com suporte parcial de peso corporal. Resultados: Depois da fase 1, houve melhora no desempenho cognitivo do TUG (antes: 15,7 ± 1,8 s; depois: 13,7 ± 3,1 s; $p < 0,01$) e aumento da oscilação anteroposterior e médio-lateral do corpo com os olhos fechados. Após a fase 2, os resultados do TUG convencional (antes: 12,3 ± 2,0 seg; depois: 10,7 ± 1,7 seg; $p < 0,01$) e cognitivo (antes: 14,6 ± 3,5 s; depois: 12,5 ± 1,6 s; $p < 0,05$) demonstraram melhora. Os protocolos de treinamento não causaram mudanças significativas na EEB.. Conclusão: Ambos os treinos melhoraram o equilíbrio estático e dinâmico e tiveram resultados semelhantes; no entanto, o treinamento em esteira com suporte é uma opção potencialmente superior, uma vez que os pacientes tendiam a se sentir mais seguros. ***Nível de Evidência II, estudos terapêuticos - investigação de resultados de tratamento.***

Descritores: *Doença de Parkinson. Estimulação Cerebral Profunda. Equilíbrio Postural. Transtornos Neurológicos da Marcha. Reabilitação Neurológica.*

Citation: Andrade VCS, Alonso AC, Luna NMS, Rogatto FBT, Brech GC, Bocalini DS, Greve JMD. Effects of treadmill gait training on balance in Parkinson's patients after deep brain stimulation. Acta Ortop Bras. [online]. 2024;32(3): Page 1 of 6. Available from URL: http://www.scielo.br/aob.

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

The study was conducted at Universidade de São Paulo, Faculdade de Medicina, Hospital das Clínicas HC-FMUSP.
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Article received on 08/16/2022, approved on 11/22/2022.

INTRODUCTION

Subthalamic nucleus deep brain stimulation (DBS) has been regularly used in Parkinson's Disease (PD) to reduce the severity of hallmark symptoms such as bradykinesia,[1] rigidity and tremor,[2,3] however, its effect on postural instability and gait disorders (axial symptoms) is less well-understood.[1,4]

Gait disorders and balance dysfunction in PD increases risk and frequency of falls,[5,6] and both parameters worsen during dual task (motor or cognitive) demands.[7] Among aging adults with PD, falls can lead to incapacity, morbidity, reduction on quality of life, and even early mortality.[8,9] Because DBS interventions have uncertain results on axial symptoms and the progressive aspects of the disease, it is important to explore potential adjuvant therapeutic approaches that may provide adaptations for maintaining or even improvements of surgical results in such abilities.

Standard physiotherapy interventions are well-known to improve strength, the range of motion, balance, and gait in patients with PD.[6,9] Moreover, treadmill training with[9-12] or without body weight support may be an alternative strategy to improve the axial symptoms of PD[13-20] lthough treadmill unsupported training is certainly more biomechanically specific to free-living ambulatory conditions, the supported training may provide an advantage by allowing for better a perception of safety and comfort, and thus greater progression in training dose (e.g., treadmill velocity, incline, etc.). Moreover, Luna et al.[21] conclude that the body weight supported treadmill training promote significative changes in kinematics variables of gait. Therefore, the purpose of this study was to evaluate the benefits of treadmill training and the comparative effectiveness of treadmill training with and without body weight support on mobility and balance in patients with PD after DBS.

MATERIALS AND METHODS

Study design

This study is a Prospective, longitudinal, controlled study. The study was approved by ethics committee of Clinical Hospital, School of Medicine, University of Sao Paulo under number 0105/10, and all the participants have signed statements of informed consent.

Participants

Patients with idiopathic PD that were using subthalamic nucleus bilateral DBS were recruited for this investigation. Inclusion criteria were: (1) ≥ 12 months post-surgery, (2) an ability to walk 10 meters without assistance, (3) PD disease stage II-III according to Hoehn & Yahr classification,[22] (4) a Mini-Mental State Examination (MMSE) score ≥ 25, (5) stability of medications and DBS parameters, (6) no history of treadmill training in the previous six months, (7) no concomitant physiotherapy interventions, and (8) no other existing neurological disorders. Moreover, patients were excluded if they were not able to perform the evaluations. Of the twenty-nine patients that met inclusion criteria, only 17 were able to participate. Among these patients, six were excluded (2 changed DBS devices, 3 for excessive absence, and 1 for not finishing the evaluation due to a freezing episode). Eleven patients finished protocol, six men and five women. As for the Hoehn and Yahr Classification:[22] one patient was classified as 3, seven as 2,5 and three as 2. At table 1 are described the sample characteristics.

Table 1. Sample characteristics.

Parameters	Mean DP
Age (years)	61 ± 2
H&Y	2 ± 1
MMSE	27 ± 1
Diagnostic (years)	20 ± 7
Time after DBS (months)	20 ± 4

Procedures

Included patients were submitted to functional tests one hour after taking the medication and with the DBS dispositive active. The evaluation was applied pre and post unsupported treadmill training as well as pre and post body weight supported treadmill training, by the same examiner. The figure 1 present all phases of study.

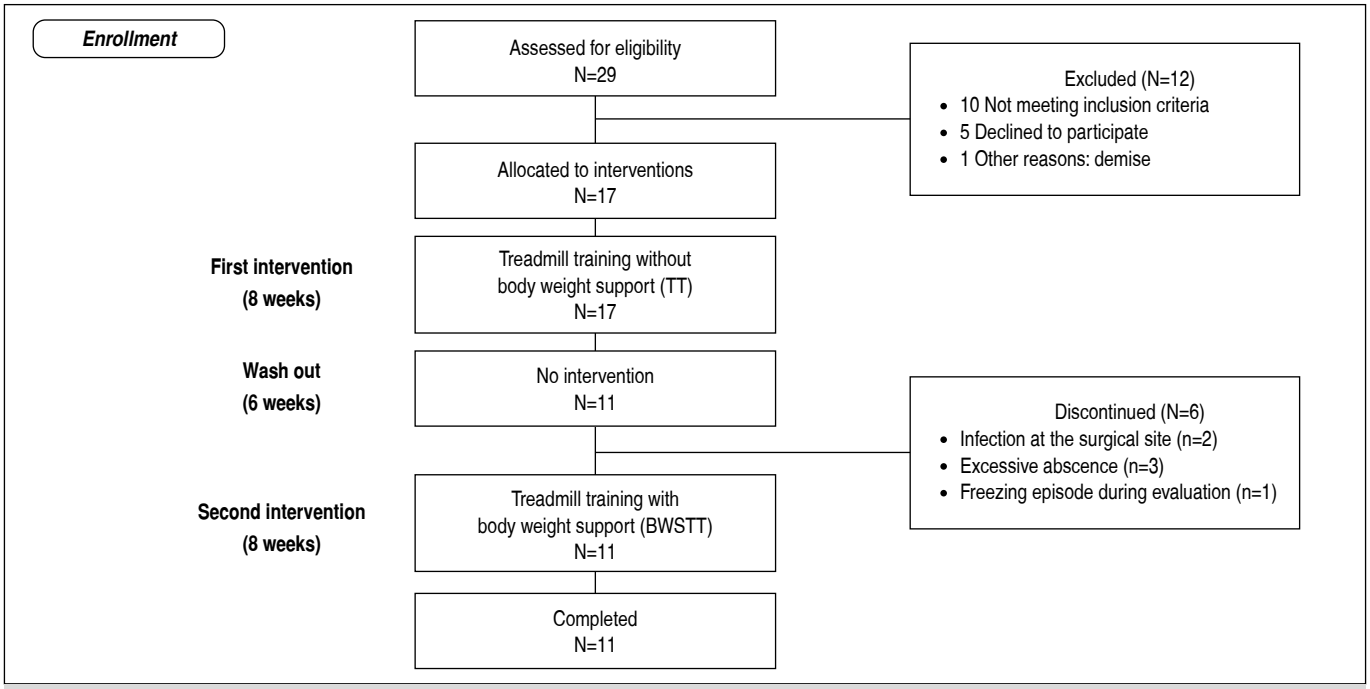

Figure 1. Enrollment and retention of study participants.

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Intervention

Patients underwent two different treatment phases:

Phase 1

Phase I consisted of treadmill training without body weight support or body belt. It was conducted in conjunction with a standard physiotherapy intervention that involved stretching, strengthening and balance exercises. Training took place twice per week for a duration of eight weeks (i.e., 16 total sessions). Each session lasted 90 minutes. Treadmill training lasted 30 minutes, in which the initial speed was determined individually for each patient coincident at a comfortable pace, and then gradually increased as each patient improved gait performance. During the bout of walking, patients were carefully monitored for fatigue. In the event that a patient complained of fatigue or any symptom related to overexertion (e.g., shortness of breath, etc.), walking speed was gradually reduced to a comfortable pace. Patients were oriented to hold on treadmill lateral or anterior bars, but during the training, they were encouraged to release hands and increase step length. After phase 1, each patient was re-evaluated on all mobility and balance assessments.

Wash out

Following the first phase of training, all patients underwent six weeks of wash out. During this period, they were instructed to not participate in any type of physical exercise. The third evaluation of all mobility and balance measures was administered after the washout and before Phase 2.

Phase 2

During phase 2, each patient participated in treadmill training with body weight support (BWST), which was again in conjunction with the same physiotherapy program as during phase 1. At the beginning of phase 2, BWST was administered at 30% of body mass support and thereafter was reduced to 20% by the sixth session, and to 10% by the eleventh session. The BWST required the use of a body belt with straps to allow body suspension. The number of sessions, training time, and all exercises were similar to that of phase 1.

EVALUATED PARAMETERS

Berg balance scale

The Berg balance scale (BBS) is a balance evaluation, and is comprised of 14 items performed during sitting, standing, and postural transitions.[23] The scale is scored from 0 (unable to perform) to 4 (normal performance)[24] and has documented high inter-reliability and internal consistency among patients with PD.[23]

Time up and go test

The time up and go test (TUG) measures the time it takes for the individual to get up from a chair to a standing height, walk three meters, return to the chair, and sit back down. This test has a high test-retest reliability and inter-rater reliability in the PD population.[25] Patients were instructed to carry out the task at their normal movement speed. The test was applied in three situations: (1) conventional (i.e., the standard test); (2) cognitive – dual task (i.e., the standard test plus answering subtraction calculations); and (3) motor – dual task (i.e., the standard test carrying a tray with a glass of water), as previously described.[25] Each test was completed three times and the average times were calculated for the analysis.

Static posturography

The postural balance assessment (posturography) was performed on a portable force platform (AccuSway Plus, AMTI, MA, USA). For data acquisition, the force platform was connected to a signal-amplifying interface box (PJB-101) that was linked to a computer by means of an RS-232 cable. The data were gathered and stored using Balance Clinic software, configured to a frequency of 100 Hz with a fourth-order Butterworth filter and a cutoff frequency of 10 Hz. All subjects underwent the test with standardized positioning in relation to the maximum width of the support base (smaller than hip width), with arms along the body and head facing a target. The base of support was drawn on a paper on a fixed position on the force platform, corresponding to the anatomical points of distal hallux phalanx, fifth metatarsal head, and lateral and medial malleolus for each foot. Three measurements were made with the eyes open (EO) and three made with the eyes closed (EC) for 60 s each. The arithmetic means of the results were calculated from the three tests conducted under each condition and were processed using the Balance Clinic software. The parameters used to measure the subjects' stability with eyes open and closed were the root mean square of the displacement amplitude from the COP in the mediolateral axis (XSD), anteroposterior (YSD) and the mean velocity calculated from the total displacement of the COP in all directions (VAvg).

Statistical analysis

The data were described by medians, means, and standard deviation. The Shapiro-Wilk test was used to determine whether the continuous variables presented a normal distribution. The following comparisons were made: (1) pre versus post unsupported treadmill training evaluation (i.e., phase 1), (2) before versus after BWST evaluation (i.e., phase 2), and comparisons between phases for absolute and relative (%) changes in outcomes. Student t-Test was used for the comparison of TUGT and Berg Balance Scale results. Regression analysis with post-intervention outcomes as the dependent variable and baseline values as covariates were also used to assess the between-group differences in TUGT and Berg tests. The models included a group indicator with two levels and baseline values as covariates. This model is equivalent to an analysis of covariance (ANCOVA) but has the advantage of providing estimates for each group, adjusted for baseline characteristics that are potentially associated with the primary outcomes. A coefficient of the unsupported treadmill group indicator was employed to estimate the mean post-intervention outcome (e.g. conventional TUG) associated with unsupported treadmill, compared with BWST. Regression assumptions were checked. Posturography variables were analyzed using the Wilcoxon Test. All data were stored and analyzed on SPSS v20.0 and statistical significance was set at $p < 0.05$.

RESULTS

The conventional TUG decreased significantly from baseline, following the BWST, but no differences were seen after unsupported treadmill training (Table 2). Despite the pre to post-intervention differences, after adjusting for baseline values there were no differences between phases for post-intervention values ($p > 0.05$); however, there was a non-significant trend of greater improvements in conventional TUG for BWST (11.9%) as compared to unsupported training (3.4%) ($p = 0.08$). The cognitive TUG decreased significantly following both unsupported treadmill training (13.1%; $p = 0.01$) and BWST (11%; $p = 0.04$), but there were no differences between phases after adjusting for baseline values ($p = 0.48$). There were no changes in the performance of the motor TUG following either intervention and no differences between phases. Berg Balance Scale results demonstrated no differences from pre and post-intervention for unsupported treadmill training and BWST, nor when comparing interventions.

Static Posturography evaluation with opened eyes showed no differences to anterior-posterior and mediolateral amplitude,

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or in velocity of the pressure center displacement following unsupported treadmill training and BWST (Table 3). During the closed eyes evaluation, the anterior-posterior and medio-lateral amplitude increased after the unsupported treadmill training, but there were no changes in the velocity of the pressure center displacement. There were no differences in any outcomes following the BWST, and there were no differences between treatments.

Table 2. Conventional, cognitive and motor Time Up and Go test and Berg balance scale outcome measures before and after the treadmill training without and with body weight support in Parkinson's disease patients using deep brain stimulation device.

Parameters	Phase 1 Treadmill training without body weight support			Phase 2 Body weighted supported treadmill training			After Phase 1 vs Phase 2
	Before	After	P*	Before	After	P*	P*
Conventional TUG (sec)	11.8 ± 2.1	11.4 ± 2.6	< 0.25	12.3 ± 2.0	10.7 ± 1.7	< 0.01	< 0.28
Cognitive TUG (sec)	15.7 ± 1.8	13.7 ± 3.1	< 0.01*	14.6 ± 3.5	12.5 ± 1.6	< 0.05	< 0.26
Motor TUG (sec)	13.9 ± 3.0	13.3 ± 3.8	< 0.19	13.3 ± 3.0	11.9 ± 1.6	< 0.14	< 0.15
Berg balance scale	50.7 ± 3.0	51.9 ± 3.1	< 0.22	50.0 ± 4.4	51.7 ± 1.6	< 0.18	< 0.83

Values expressed in mean ± DP. TUG: time up and go.

*Test t student

Table 3. Static posturography parameters with opened and closed eyes evaluation before and after the treadmill training without and with body weight support.

Parameters	Phase 1 Treadmill training without body weight support			Phase 2 Body weighted supported treadmill training			After Phase 1 vs Phase 2
	Before	After	P*	Before	After	P*	P*
Opened eyes							
Med. lateral amp (cm)	1.34	1.54	< 0.13	2.24	2.43	< 0.79	< 0.24
Ant. posterior amp (cm)	1.60	3.24	< 0.11	2.98	2.75	< 0.79	< 0.47
Mean velocity (cm/s)	0.70	0.98	< 0.37	1.04	1.01	< 0.37	< 0.42
Closed eyes							
Med. lateral amp (cm)	1.38	3.28	< 0.01*	2.33	2.07	< 0.72	< 0.42
Ant. posterior amp (cm)	2.15	3.71	< 0.04	3.22	3.16	< 0.79	< 0.47
Mean velocity (cm/s)	1.21	1.22	< 0.18	1.24	1.20	< 0.53	< 0.59

Values expressed in median. Med. lateral amp: medio lateral amplitude of dislocation of the pressure center in centimeter. Ant. posterior amp: anteroposterior amplitude of dislocation of the pressure center in centimeters

Wilcoxon Test.

DISCUSSION

Treadmill training could also be associated with neuroplasticity and neuroprotection, as experimental animal studies have previously demonstrated.[26] The unsupported treadmill training improved cognitive TUG and improved certain aspects of static posturography, i.e., anterior-posterior and medial-lateral amplitude of dislocation of the pressure center with eyes closed, but not with eyes opened. Body weight supported treadmill training improved conventional and cognitive TUG performance; however, it did not promote changes in posturography outcomes. Likewise, outcomes from the Berg Balance Scale were not changed from either intervention.

Performance in the TUG is highly correlated to mobility, the risk of fall and severity of the PD symptoms,[27] and is moderately correlated to gait velocity.[28] Each second increase in the TUG is associated with a 2.3% increase in the odds of a fall.[29] We have demonstrated that treadmill gait training both with and without body weight support can improve performance in the TUG among persons with PD, and these improvements could be related to the increase in gait velocity and step length promoted by the direct effect of the treadmill.[29,30]

A reduction of TUG could also be associated with a balance and motor control improvement, facilitating the execution of the movement and the preparation to turn and sitting to stand.[30] Some experts have described such a reduction in conventional TUG after unsupported treadmill training,[14,19,31] however, we demonstrated this only in conjunction with BWST. The absence of differences after unsupported treadmill training may have been due to less training sessions per week, less duration of treadmill training sessions in comparison to previous studies, and/or a higher pre-training functional status due to the DBS treatment among our patients.

The reductions in conventional TUG were seen only after the body weight support treadmill training, which could be due to the increase of the gait velocity and step length in this particular kind of training, thus making this a more effective strategy than the unsupported treadmill training. It is also possible that because body weight support treadmill training provides more safety and confidence, patients can release hands earlier in the intervention and reinforce balance recruitment. These factors could contribute to the long-term effectiveness of the treadmill gait training in PD.

Cognitive TUG decreased after both training protocols, which could be associated with an improvement in gait automaticity. Dual-task affects PD gait performance reducing velocity, step length, swing time and increasing double stance due to a competition for neurological available resources.[32,33] Treadmill gait training, particularly with body weight support, can elicit improvements in balance and mobility, demanding less attentional resources during these tasks and probably facilitating cognitive requirement and motor performance.

Despite being a dual task, motor TUG did not change following either type of training. The dual motor task could be easier than the cognitive task because involves two motor tasks demanding lower attentional sources.[34]

Previous studies have shown improvements in BBS after treadmill training without and with body weight support.[10,13] However, the present study did not find the same results and this could be due to a higher baseline BBS capacity among our patients. Our small sample size is another potential factor limiting the ability to detect significant differences in BBS parameters.[10,15]

Following the unsupported treadmill training, the oscillation of the pressure center (COP) increased with closed eyes. The increase of the anterior-posterior and medial-lateral amplitude of dislocation of the COP with eyes closed could suggest the increase of the limits of stability. Some previous work, however, has described this increase in body oscillation as a worsening in balance, with a higher risk of fall.[35-39] However, these findings are controversial in PD, because as patients have a rigidity and flexed posture, this decreased the COP oscillation.[40]

The reduction of the compensatory dynamic postural responses, as well as the range of motion of the COP, could lead to a loss of balance during dynamic conditions.[36] Moreover, the increase of the COP amplitude oscillation, seen after treadmill training may well be associated with improvements in balance, as it means a large limit of stability that could be favorable on daily activities as well as in regards to reduction of falls risk.

Despite not observing differences between training protocols, the use of the body belt promoted more safety and it allowed patients to release hands from handrails, thus increasing balance stimulus during the BWST. This type of treadmill training appears to be more effective among patients that require greater assistance. Some limitations should be mentioned. First, we had a very small sample to detect multiple outcomes from various tests. Future, prospective studies with larger sample sizes are necessary to better understand the trajectory of changes between unsupported and supported treadmill training. Moreover, and despite the 6-week wash-out period, there may have been a training effect from using unsupported prior to supported training for all subjects. It would be interesting for future efforts to examine these in a random assignment, as well as to examine the effectiveness of varying doses of the treatment. Despite these limitations, we provide some of the very first evidence to document the comparative effectiveness of supported versus unsupported treadmill training among patients with PD, following DBS therapy.

CONCLUSION

Treadmill training and body weight supported treadmill training is safe and effective strategies to improve balance and mobility among patients with PD; however, patients seem to feel more confidence during body weight supported treadmill training. Both types of training can be used as an adjuvant treatment of the DBS surgical procedure, for improving physical capability, balance and gait stability and reducing the risk of fall.

ACKNOWLEDGMENTS

The authors thanks to Fundação de Amparo à Pesquisa do Espírito Santo (grant number 84417625/2018). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. VCS, NMSL: writing, data analysis and performing surgeries; FBT: review of the article and intellectual concept of the article, final approval of the version of the manuscript to be published; ACA: data analysis and performing surgeries, substantial contribute to the concept of the work, data analysis and performing surgeries, final approval of the version of the manuscript to be published; GCB: data analysis and performing surgeries; DSB: review of the article and intellectual concept of the article, final approval of the version of the manuscript to be published; JMDG: substantial contribute to the concept of the work, data analysis and performing surgeries, review of the article and intellectual concept of the article.

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DOI: http://dx.doi.org/10.1590/1413-785220243203e273510

ORTHOPEDIC INJURIES IN MEN'S PROFESSIONAL SOCCER DURING THE CORONAVIRUS DISEASE PANDEMIC

LESÕES ORTOPÉDICAS NO FUTEBOL PROFISSIONAL MASCULINO DURANTE A PANDEMIA DO CORONAVÍRUS

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ABSTRACT

Objective: To assess the incidence and characteristics of injuries that occurred in the 2020 season of the Paulista Football Championship during the novel coronavirus disease pandemic. Methods: We conducted a prospective study using an electronic questionnaire developed by the Medical Committee of the Paulista Football Federation. Results were sent to the team doctors of series A1 and A2 after each round of the Paulista Football Championship. Results: Series A1 and A2 presented 12.17 and 15.6 injuries, respectively, per 1000 gaming hours. The strikers were the most affected, with muscle injuries being the most frequent and the lower limbs being the most affected. Most injuries occurred within 31-45 minutes of playing; only 4.5% of injuries required surgery. Conclusion: There was no statistical difference in the comparison between pre- and post-pandemic conditions. In relation to the variables studied, the most injuries occurred in the lower limbs; the most common type of injury was muscle strain, followed by sprain and contusion. The most requested exam was MRI; most injuries were classified as moderate (8-28 days). There was no difference between pre- and post-pandemic conditions. ***Level of Evidence IV, Case Series.***

Keywords: Soccer. Injuries. COVID-19.

RESUMO

Objetivo: Avaliar a incidência e as características das lesões ocorridas na temporada 2020 do Campeonato Paulista de Futebol durante a pandemia de covid-19. Métodos: Foi realizado um estudo prospectivo por meio de questionário eletrônico desenvolvido pela Comissão Médica da Federação Paulista de Futebol. Os resultados foram enviados aos médicos das equipes das séries A1 e A2 após cada rodada do Campeonato Paulista de Futebol. Resultados: As Séries A1 e A2 apresentaram 12,17 e 15,6 lesões, respectivamente, por 1.000 horas de jogo. Os atacantes foram os mais acometidos, sendo as lesões musculares as mais frequentes e os membros inferiores os mais afetados. A maioria das lesões ocorreu dentro de 31 a 45 minutos de jogo; apenas 4,5% das lesões necessitaram de cirurgia. Conclusão: Não houve diferença estatística na comparação entre as condições pré e pós-pandemia. Em relação às variáveis estudadas, a maioria das lesões ocorreu nos membros inferiores; o tipo de lesão mais comum foi distensão muscular, seguida de entorse e contusão. O exame mais solicitado foi a ressonância magnética; a maioria das lesões foi classificada como moderada (8-28 dias). Não houve diferença entre as condições pré e pós-pandemia. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Futebol. Lesões. COVID-19.*

Citation: Arliani GG, da Silva EHR, Fares H, Lara PHS, Pagura JR, Cohen M. Treatment of supracondylar fractures of the humerus in children with crossed and lateral kirschner wires: a systematic review. Acta Ortop Bras. [online]. 2024;32(3):Page 1 of 7. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Football is complex and involves considerable risk of injury with associated material, economic, and sports-related impact. In one month, placing a professional footballer on reserve due to injury translates to an average loss of € 500,000 and compromises the success of the team during football matches.[1] Therefore, because of physical and emotional stress, professional football is considered a sport with a high risk for injury.[2] Epidemiological studies revealed an incidence rate of 16-28 and 2-11 injuries during matches and practices, respectively, for every 1,000 hours of exposure at the professional level.[3] According to an epidemiological study on men's professional football, the average injury rate is approximately 6-8 injuries per 1000 hours of exposure.[2]

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

The study was conducted at Centro de Traumatologia do Esporte da Escola Paulista de Medicina, Rua Estado de Israel 713, São Paulo.
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Article received on 03/27/2023, approved on 07/13/2023.

The majority of football injuries affect the lower limbs; more specifically, the ankles, knees, and thighs.[4] Susceptibility to specific types of injuries varies depending on the athlete's position in the field. Significant differences found in the incidence rates possibly occur due to changes in game style and intensity. Moreover, the overall mood of the match also plays an important role in the specificities of each injury.[5] A study on elite athletes suggested that the different roles in each position require specific technical, physiological, and tactical demands from the players. For instance, central defense players are more likely to jump for the ball than external defenders, whereas external midfielders generally cover greater distances than those by central midfielders when running.[6]

Injuries largely influence the final team results in both national and European tournaments. Such findings have revealed the importance of preventing injuries to increase the chances of awards and success.[7] Implementing prevention strategies for a given population requires obtaining and understanding evidence of a specific pattern. As such, several epidemiological investigations have been conducted worldwide. These patterns have been found to be common practices in main leagues, world tournaments,[2,8] and world cups.[9,10] Although football is the most popular sport in Brazil, there are only a few epidemiological studies and datas pertaining to the regional and national leagues. The purpose of this investigation was to compare the incidence and specificities of injuries to establish preventive measures and policies.

At the beginning of March 2020, the World Health Organization announced the coronavirus disease (COVID-19), an infection caused by the SARS-CoV-2 virus. Subsequently, it was declared a pandemic. As a result, most players had to train from home while following the routines provided by the teams' strength and conditioning staff.[11] Despite these efforts, many players have shown signs of detraining,[12] thereby resulting in an increased risk of injury upon their return to playing.[13] The objectives of this study were to assess the incidence and characteristics of injuries that occurred in the 2020 season of the Paulista Football Championship before and after the pandemic.

METHODOLOGY

This study was approved by the Ethics Committee of the (number 1.660.701). This was a prospective study conducted via an electronic form developed by the Medical Committee of the São Paulo Football Federation (Federação Paulista de Futebol). Results were sent to the team physicians of series A1 and A2 after each round of the 2020 São Paulo State Football Championship.

The above-mentioned form was developed to analyze the incidence of injuries and their characteristics. The form comprised 15 questions on the specificities of the match, athlete, and injury (Appendix 1). The definition used to determine a football injury was the statement set out by Fuller et al.[14] for the 2005 FIFA consensus, and was as follows: "Any physical complaint sustained by a player that results from a football match or football training, irrespective of the need for medical attention or time loss from football activities". A form was filled out by the athlete after returning from the field and used to analyze the outcome of each reported injury. There were eight questions structured in the form of complementary tests, exams, and final diagnoses (Appendix 2). The Football Federation was asked to record the events to obtain the time of each match; classifications are as follows: morning (matches beginning before 12 p.m.), afternoon (matches before 6 p.m.), and night (matches after 6 p.m.). The first 10 and 12 matches in the A1 and A2 series were played prior to the COVID-19 lockdown, respectively. Moreover, the remaining six and nine matches in the A1 and A2 series, respectively, were played after the break.

The incidence of injuries was calculated to assess the risk, expressed as the number of injuries per 1000 hours of exposure (14, 15). The following formula was used to calculate the exposure: Exposure = number of matches x number of players starting the match (22) × duration of the match in minutes (90) / 60. The following formula was used to calculate incidence at matches: Incidence = number of injuries at matches x 1000 hours/time of Exposure

Statistical analysis

Parametric statistics were used for data that were both quantitative and uninterrupted. The two-portion test was used to characterize the relative frequency distribution of the qualitative variables. Differences were considered statistically significant at $p < 0.05$. SPSS V17 software was used to perform the analyses.

RESULTS

Mapping of the injuries

The average age of the injured players was 26.6 years, whereas the average time loss caused by injuries was 20.6 days. Most matches occurred at night (47%). Furthermore, 9.5% were held in the morning and 43.6% in the afternoon. A total of 118 injuries were described during all 256 matches, with an average of 0.46 injuries per match. In terms of the playing position, 26.9% of the injuries were sustained by forwards, 22.7% by external defenders, 21.8% by central defenders, 16% by external midfielders, 10.9% by central midfielders, and 1.7% by goalkeepers (Figure 1).

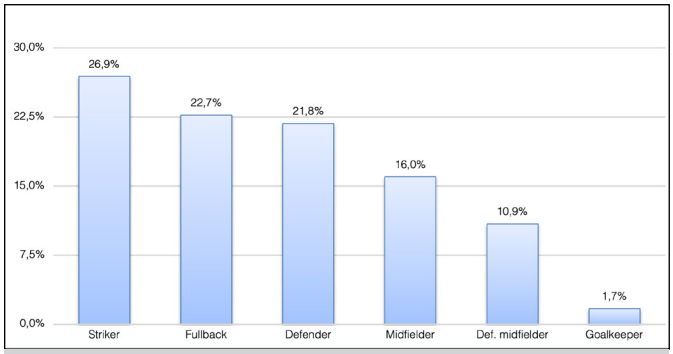

Figure 1. Position distribution

Most injuries occurred during the first half of the match, and within 31-45 minutes (23.5%), followed by 61-75 minutes (21%), 16-30 minutes, and 76-90 minutes (16%). Most injuries were deemed moderate based on the severity scale, with time loss ranging from 8 to 28 days (35.3%). The results are shown in Figure 2.

In terms of site of injury, the most common injuries were on the following sites: thigh (42.9%), ankle (13.4%), knee (12,6%), and head (11,8%). Injuries occurred most often on the right side (49.6%); the side did not apply in 12.6% of the cases. The most common injury type was muscle strain (45.8%), followed by sprains (19.5%), and contusions (17.8%) (Figure 3). With respect to the final diagnosis, the most frequent injuries were as follows: hamstring strain (22.4%), adductor muscle strain (10.4%), lateral ankle sprain (10.4%), quadriceps muscle strain (9%), and foot contusion (6%). There were 12.17 injuries per 1000 hours of matches in the A1 Series, and 15.6 injuries per 1000 hours of matches in the A2 Series. When summed, 13.96 injuries occurred in 1000 hours of matches in both series.

<< SUMÁRIO

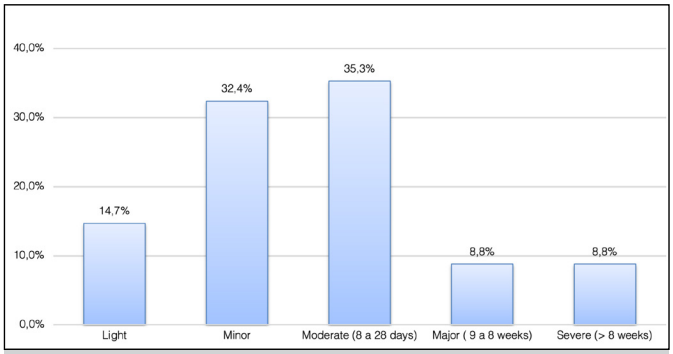

Figure 2. Severity distribution

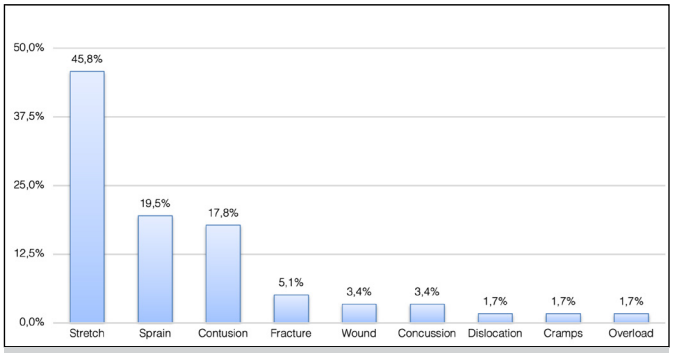

Figure 3. Type of injury distribution

Treatment of the injuries

When requested, the most common complementary tests and exams were magnetic resonance imaging (MRI) (42.6%) and ultrasonography (22.1%), followed by radiography (13.2%) and computed tomography (CT) (4.4%). No tests were necessary for 13.2% of the injuries. Surgery was required in 4.5% of all recorded injuries. Most injuries were deemed moderate according to the severity scale, with a time loss ranging from 8 to 28 days (35.3%). (Figure 3)

Before and during the pandemic

The main results are presented in Table 1. There were no statistical differences between the two periods for the variables studied.

DISCUSSION

In this study, the incidence and characteristics of the injuries were similar to the data in the literature.[3,15,16-19] Muscle strains, sprains, and contusions were the most prevalent types of injuries, as was the case in several other investigations in the literature.[2,20-22] Only 4.5% of the injuries required surgery; most diagnoses required non-surgical treatment. In addition, fractures and severe ligament injuries were conservatively managed.

Similar to other studies developed by our group, MRIs were the most commonly requested exams.[21-23] As most cases were muscular injuries, MRI was deemed the most useful. Most injuries occurred within the first 31-45 minutes of the first half of the matches.[21-23] In other studies, the incidence was higher during the last 30 minutes of the match.[16,23,24] However, in some of these studies, the tournament was organized as a single-elimination system, which may have subsequently enhanced the motivation of the athletes. Recent studies have shown the impact of the lockdown on the physical qualities of athletes. Rampini et al.[25] showed that home-based training during lockdown was effective in improving aerobic fitness, although it did not allow players to maintain their usual strength levels. Grazioli et al.[26] showed that 63 days of quarantine impaired several physical performance capabilities as compared with during regular off-season. Special attention should be given to body composition-, speed-, and power-related capabilities after long-term detraining. Moreno-Perez et al.[11] showed that during isolation at home, eccentric hamstring strength decreased; this magnitude of muscle weakness might indicate a higher risk of injury according to a previous study.[27] Despite showing increased risk for injuries, we found no statistical difference between the incidence and type of injuries and the moment at which these injuries occurred. Regarding the incidence of injuries, the percentage of injuries before and after the lockdown was at 26.3% and 21.7%, respectively. In both periods, muscle strain was the most common injury, accounting for almost half of the cases; this condition showed that the lockdown did not alter the characteristics of the injuries. Moreover, differences in the occurrence of the injuries were observed. Before the lockdown, injuries were most common between 31-45 min of the match. After the return from the lockdown, they were most common at 16-30 min. This condition might be attributable to a decrease in muscle strength, thereby increasing the risk of injury and decreasing player endurance.

The greatest limitation of this study was the reliability of the information provided by the clubs' medical personnel, as well as the lack of official records on injuries sustained during the matches. Moreover, it was not possible to accurately measure each athlete's exposure.

CONCLUSION

Most injuries occurred in the lower limbs; muscle strains were the most common type of injury, followed by sprains and contusions. MRIs were the most commonly requested test; most injuries were classified as moderate. Approximately 4.5% of injuries evolved to require surgery. The results were similar before and after the lockdown due to the COVID-19 pandemic.

ACKNOWLEDGEMENTS

We would like to thank the Football Federation for all the support given to the development of this study.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. Contributorship: GGA: collected the data, prepared the article and reviewed the article; EHRS: collected the data and prepared the article; HF: collected the data and prepared the article; PHSL: collected the data, prepared the article and reviewed the article; JRP: concept of the article and reviewed the article; MC: concept of the article and reviwed the article.

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APPENDIX 1: MAPPING OF THE INJURIES SUSTAINED IN THE 2020 SÃO PAULO STATE FOOTBALL CHAMPIONSHIP

REPORT ON ORTHOPEDIC INJURIES SUSTAINED DURING THE 2020 SÃO PAULO STATE FOOTBALL CHAMPIONSHIP

1) THIS REPORT REFERS TO THE FOLLOWING MATCH:

.....

2) WHAT WAS THE WEATHER LIKE AT THE TIME OF THE MATCH?

- SUNNY
- CLOUDY
- RAINY
- SUN SHOWER
- RAIN AND LIGHTNING
- NIGHT – CLEAR SKY
- NIGHT –RAINY

3) TEMPERATURE MEASURED AT THE TIME OF THE MATCH:

.....

4) LOCATION

- HOME GAME
- UP TO 200KM AWAY
- FROM 200 TO 400KM AWAY
- MORE THAN 400KM AWAY

5) WERE THERE INJURIES SUSTAINED DURING THE MATCH?

- YES
- NO

FILL OUT THE FOLLOWING ITEMS ONLY IF INJURIES WERE SUSTAINED

6) NAME OF THE INJURED ATHLETE: .....

DATE OF BIRTH: .....

7) ATHLETE'S POSITION:

- GOALKEEPER
- CENTRAL DEFENDER
- EXTERNAL DEFENDER
- EXTERNAL MIDFIELDER
- CENTRAL MIDFIELDER
- FORWARD

8) WHEN WAS THE INJURY SUSTAINED?

- 0-15 MIN
- 15-30 MIN
- 30-45 MIN
- 45-60 MIN
- 60-75 MIN
- 75-90 MIN
- OVERTIME – 1ST HALF
- OVERTIME – 2ND HALF

9) DID THE INJURY OCCUR AFTER CONTACT OR COLLISION WITH THE BALL, GOAL OR WITH ANOTHER ATHLETE?

- YES
- NO

10) IF YES, IN WHICH CIRCUMSTANCES?

- ANOTHER PLAYER
- BALL
- GOAL
- OTHERS

11) DID THE REFEREE CONSIDER THE INJURY MECHANISM A MISCONDUCT?

- YES
- NO

12) WHAT PUNISHMENT WAS APPLIED?

- FOUL, NO CARD.
- FOUL AND YELLOW CARD
- FOUL AND RED CARD
- NO PENALTY

13) WHERE WAS THE INJURY SUSTAINED?

- HEAD
- TRUNK
- UPPER LIMBS/EXTREMITIES
- LOWER LIMBS/EXTREMITIES
- N/A

14) SIDE OD THE INJURY

- RIGHT
- LEFT
- N/A
- BILATERAL

15) TYPE OF INJURY

- Strain
- Sprain
- Contusion
- Fracture
- Joint Dislocation
- Wound (with contusion)
- Concussion
- Cramp
- Others

PROBABLE FINAL DIAGNOSIS:

.....

APPENDIX 2: INJURY REPORT: 2020 SÃO PAULO STATE FOOTBALL CHAMPIONSHIP

REPORT ON ORTHOPEDIC INJURIES SUSTAINED DURING THE 2020 SÃO PAULO STATE FOOTBALL CHAMPIONSHIP

1) NAME OF THE INJURED ATHLETE

.....

DATE OF BIRTH:.....

POSITION.....

INJURY:.....

DATE OF THE INJURY:.....

2)COMPLEMENTARY TESTS/EXAMS REQUESTED:

- NONE
- RADIOGRAPHY (RX)
- ULTRASOUND (US)
- CAT SCAN
- MRI
- OTHERS:.....

3) DID THE INJURY REQUIRE SURGERY?

- YES
- NO

4) IF YES, SPECIFY:

.....

5) ATHLETE'S RETURN DATE TO SPORTS ACTIVITIES:

.....

6) DAYS OF TIME LOSS:

.....

7) INJURY SEVERITY SCALE:

- SLIGHT (UP TO 3 DAYS OF TIME LOSS)
- MINOR (3 TO 7 DAYS OF TIME LOSS)
- MILD (7 TO 28 DAYS OF TIME LOSS)
- MAJOR (7 DAYS TO 8 WEEKS OF TIME LOSS)
- SEVERE (MORE THAN 8 WEEKS OF TIME LOSS)

8) DID THE FINAL DIAGNOSIS CONFIRM THE INITIAL DIAGNOSIS?

- YES
- NO

FINAL DIAGNOSIS:

.....

DOI: http://dx.doi.org/10.1590/1413-785220243203e269705

3D PRINTING IN COMPLEX TIBIAL FRACTURE CLASSIFICATION & PLANNING

IMPRESSÃO 3D PARA A CLASSIFICAÇÃO E PLANEJAMENTO DE FRATURAS TIBIAIS COMPLEXAS

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ABSTRACT

Objective: Tibial plateau fractures are common intra-articular fractures that pose classification and treatment challenges for orthopedic surgeons. Objective: This study examines the value of 3D printing for classifying and planning surgery for complex tibial plateau fractures. Methods: We reviewed 54 complex tibial plateau fractures treated at our hospital from January 2017 to January 2019. Patients underwent preoperative spiral CT scans, with DICOM data processed using Mimics software. 3D printing technology created accurate 1:1 scale models of the fractures. These models helped subdivide the fractures into seven types based on the tibial plateau's geometric planes. Surgical approaches and simulated operations, including fracture reduction and plate placement, were planned using these models. Results: The 3D models accurately depicted the direction and extent of fracture displacement and plateau collapse. They facilitated the preoperative planning, allowing for precise reconstruction strategies and matching intraoperative details with the pre-printed models. Post-surgery, the anatomical structure of the tibial plateau was significantly improved in all 54 cases. Conclusion: 3D printing effectively aids in the classification and preoperative planning of complex tibial plateau fractures, enhancing surgical outcomes and anatomical restoration. ***Level of Evidence IV, Prospective Study.***

Keywords: 3D Printing. Tibial Plateau Fracture. Anatomic Landmarks. Preoperative Care

RESUMO

Objetivo: As fraturas do planalto tibial são fraturas intra-articulares comuns de classificação e tratamento desafiadores aos cirurgiões ortopédicos. Objetivo: Este estudo investiga o uso de impressão 3D para classificar e planejar a cirurgia de fraturas complexas do planalto tibial. Métodos: 54 fraturas complexas do planalto tibial tratadas em nosso hospital de janeiro de 2017 a janeiro de 2019 foram revisadas. Os pacientes foram submetidos a tomografias computadorizadas em espiral pré-operatórias, com dados DICOM processados usando o software Mimics. A tecnologia de impressão 3D gerou modelos precisos em escala 1:1 das fraturas. Estes modelos ajudaram a subdividir as fraturas em sete tipos com base nos planos geométricos do planalto tibial. As abordagens cirúrgicas e as operações simuladas, incluindo a redução da fratura e a colocação de placa, foram planejadas utilizando estes modelos. Resultados: Os modelos 3D representaram com precisão a direção e a extensão da deslocação da fratura e do colapso do planalto. Os modelos facilitaram o planejamento pré-operatório, viabilizando estratégias de reconstrução precisas e a correspondência dos detalhes intraoperatórios com os modelos pré-impressos. Após a cirurgia, a estrutura anatômica do planalto tibial melhorou significativamente em todos os 54 casos. Conclusão: A impressão 3D ajuda na classificação e no planejamento pré-operatório de fraturas complexas do planalto tibial, melhorando os resultados cirúrgicos e a restauração anatômica. ***Nível de Evidência IV, Estudo Prospectivo.***

Descritores: *Impressão 3D. Fratura do Planalto Tibial. Marcos anatômicos. Cuidados pré-operatórios.*

Citation: Chen F, Huang C, Ling C, Zhou J, Wang Y, Zhang P, et al. 3D printing in complex tibial fracture classification & planning. Acta. Ortop. Bras. [online]. 2024;32(3):Page 1 of 6. Available from URL: http://www.scielo.br/aob.

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

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Article received on 11/21/2022, approved on 02/15/2024.

INTRODUCTION

Tibial plateau fracture is one of the common intra-articular fractures in the clinic. And its accurate classification and treatment is a complex problem for orthopedic surgeons.[1] At present, the commonly used clinical classification method of tibial plateau fracture was put forward by Schatzker et al.[2] in 1949, which is based on X-ray. It does not consider the displacement of fracture in the sagittal position. So sometimes, the classification can not effectively guide the formulation of the treatment plan, especially in the case of the posterior tibial plateau. In 2009, Professor Luo Congfeng[3] proposed a three-column classification method of tibial plateau fractures based on CT, which divides the tibial plateau into lateral column region, medial column region, and posterior column region. However, this classification method can not directly reflect the degree of comminution and collapse of the articular surface of the fracture. Also, this classification method can not guide the design of preoperative operation well. Complex tibial plateau fractures are often associated with two-column or three-column fractures. Good preoperative planning can significantly shorten the operation time and improve the restoration effect. With the emergence of 3D printing digital medical technology, accurate and individualized treatment has become the trend of orthopedic trauma surgery.[4] Different literature reviews have revealed an increasing use of 3D-printed models in surgery,[5] orthopedics[6] and orthopedic trauma,[7] interventional radiology,[8] surgical teaching and assessment,[9] etc. The reported advantages of 3DP-based approaches refer to the robust capabilities of customization based on patient imagistic data (computer tomography (CT), magnetic resonance imaging (MRI)), improved visualization of the anatomy allowing better diagnosis evaluation, a decrease in operating time, and radiologic exposure during surgery, improved intervention accuracy, and enhanced communication among physicians and with patients.[5,7]

METHODS

Inclusion and exclusion criteria for cases

Inclusion criteria: ①cases of unilateral closed tibial plateau fracture treated by surgery in the department of orthopedics of our hospital during 2017.01-2019.01. ② complex tibial plateau fractures with double-column or three-column injuries. ③The time from injury to operation was less than 14 days.

Exclusion criteria: ①patients with chronic lesions of knee joint and knee joint dysfunction before the injury. ②complicated with vascular and nerve damage on the affected side. ③those with serious underlying diseases or unable to cooperate with treatment.

General information

A total of 54 patients were included in this study, including 36 males and 18 females, with an average age of 50.2 ± 2.8 years old. According to the theoretical basis of the three-column classification of the tibial plateau, combined with 3D printing model classification, there were 18 cases of type IV fracture, 13 cases of type V fracture, 8 cases of type VI fracture, and 15 cases of type VII fracture. All cases were treated with internal fixation. The time from injury to operation was 12 days, with an average of 6.4 ± 1.5 days. The Ethics Committee has approved this study of our hospital. All patients have signed the informed consent form for the operation.

Ethics approval and consent to participate

All procedures performed in studies involving human participants were by the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Using 3D printing model to refine the classification of plateau fractures from the geometric plane 3-column 3-zone typing method

3D model printing: all the 54 cases underwent 64-slice spiral CT thin-slice scanning (0.6mm) before the operation, and the DICOM data were input into the computer. The Mimics software was used to process the data. And the 3D printing technique was used to print the three-dimensional model of the fracture (1:1).

Based on the classification of the geometric plane of the platform (figure 1), the overlooking view of the tibial plateau shows that the O point is the midpoint of the tibial spine line. The A' point is the tibial tubercle. The B' point is the medial crest of the tibial plateau. And the C 'point is the anterior edge of the fibular head. The tibial plateau is divided into three plane parts by OA', OB' and OC,' which are defined as A zone, B zone, and C zone, respectively. (Table 1)

Table 1. Three-column and three-zone classification of tibial plateau fractures.

Classification	Zone	Position	Approach
I	A	Supine position	Anterolateral approach
II	B	Supine position	Anterior medial approach
III	C	Prone position	Posterior approach
IV	A+B	Supine position	Combined medical and lateral approach
V	A+C	Supine position	Anterolateral peroneal approach
VI	B+C	Supine position	Posteromedial approach
VII	A+B+C	Floating position	Anterolateral approach + posteromedial approach

Type IV-VII are included in this project.

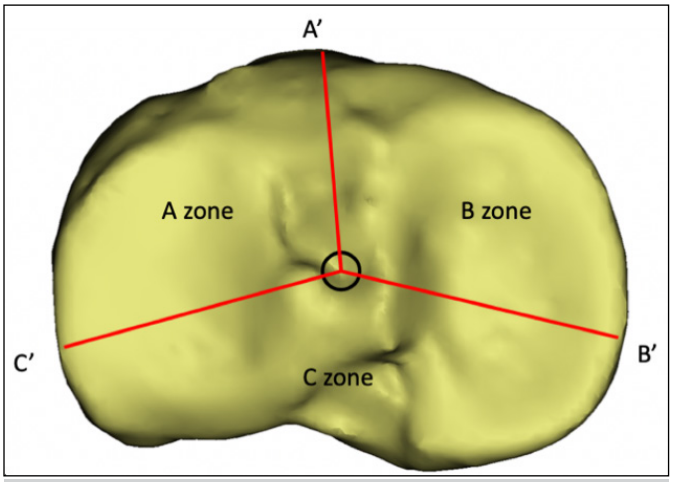

Figure 1. Classification of the 3 zones.

O: Midpoint of tibial spine line A':tibial tuberosity;

B':Medial spine of tibial plateau;

C': Anterior margin of the fibular head.

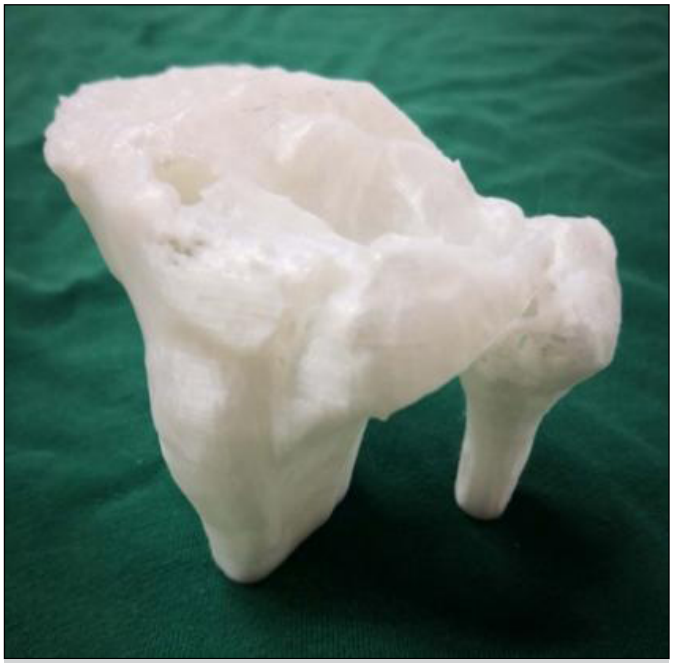

Figure 2. 3D printed tibial plateau fracture model.

Preoperative planning and surgical simulation steps

① The CT data of patients with quasi-fracture were processed on a particular computer platform. And then, the tibial plateau fracture model was printed 1:1 (figure 2). The printing machine is the selective laser sintering equipment Farsoon401. The printing material is nylon powder material for laser sintering.
② The fractures were re-classified by three-column classification according to the fracture imaging data and 3D visual model to achieve accurate classification according to the principle.
③ Evaluate the displacement direction of the bone fracture block. And through the direction, distribution, and movement of the fracture block, we can accurately evaluate the displacement direction of the bone fracture block.
④ Evaluate the collapse site of the articular surface. And through the detailed analysis and observation of the articular surface, we can determine the actual collapse site of the articular surface.
⑤ Establish the surgical approach. By analyzing the fractured mass and articular surface of the complex tibial plateau fracture, the intraoperative approach can be established to create conditions for reducing trauma injury.
⑥ Determine the position and the number of steel plate implantation. Predicting the position and number of steel plate implantation and the pre-bending data of steel plate before operation can effectively reduce the operation time, trauma injury, and the use of anesthetic drugs.
⑦ Simulate the operation. The reduction of the fracture block and the placement of the steel plate can be performed on the 3D model according to the operation plan to improve the operation's proficiency.

Preoperative scheme design of complex tibial plateau fracture (type IV-VII)

Type IV: supine position, choice of surgical approach: combined medial and lateral approach. (figure 3).
Type V: supine position, choice of surgical approach: an anterolateral peroneal head approach to fix the lateral column, and whether to fix it according to the stability of the posterior column (figure 4).
Type VI: supine position, choice of surgical approach: modified posterior medial approach (figure 5).
Type VII: floating position, choice of surgical approach: the meniscus was repaired by the anterolateral approach, the anterolateral approach fixed the lateral column, and the posteromedial approach fixed the medial column and the posterior column. (figure 6)

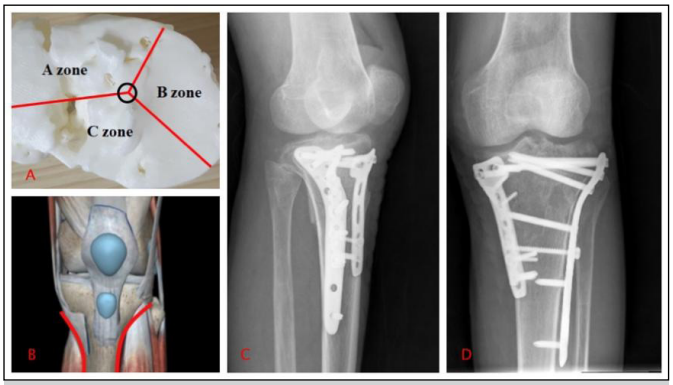

Figure 3. Type IV tibial plateau fracture.

A: 3D printed model; B: Approach; C, D: X-rays after the operation.

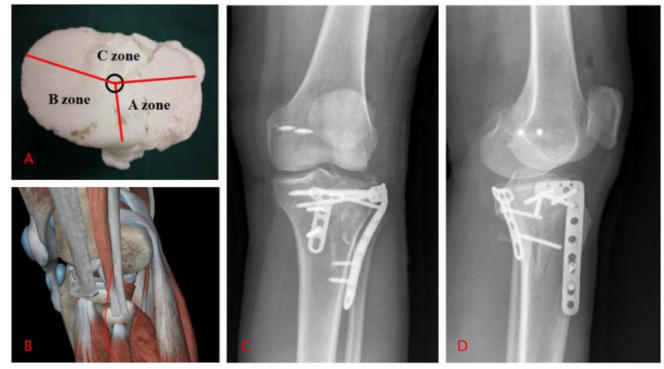

Figure 4. Type V tibial plateau fracture.

A: 3D printed model; B: Approach; C, D: X-rays after the operation.

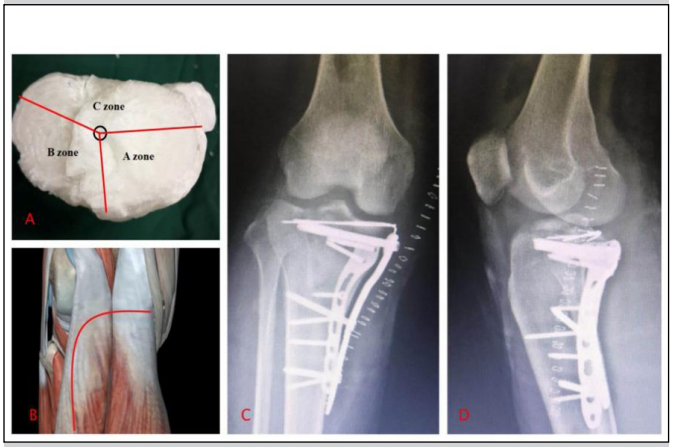

Figure 5. Type VI tibial plateau fracture.

A: 3D printed model; B: Approach; C, D: X-rays after the operation.

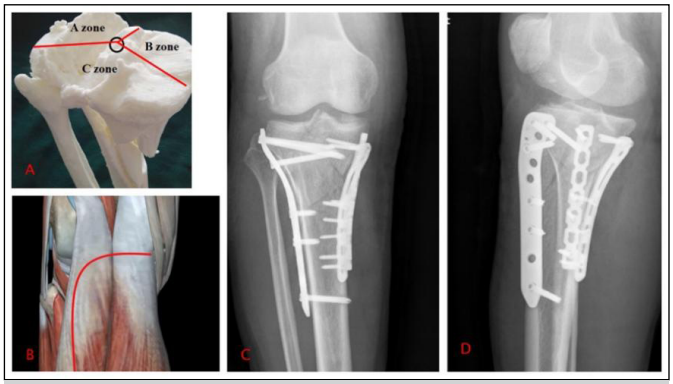

Figure 6. Type VII tibial plateau fracture.

A: 3D printed model; B: Approach; C, D: X-rays after the operation.

Surgical methods and postoperative management

All patients were treated with general anesthesia or combined block anesthesia. After successful anesthesia, the affected limb was bound with a tourniquet with a pressure of 50KPA for 90 minutes. Antibiotics were routinely used before operation. Combined with preoperative classification, the operation was performed according to the surgical approach, fracture reduction mode, plate preshaping, screw direction, and length designed before operation. During the operation, the mode and amount of bone graft were determined according to the collapse of the articular surface. Explore the articular surface to repair meniscus and ligament injuries that need one-stage surgical repair as far as possible.[10] Intraoperative C-arm fluoroscopy confirmed the degree of fracture reduction and articular surface elevation. After the operation, the negative pressure drainage tube was routinely indwelled and removed within 48 hours. Prophylactic use of antibiotics was used within 48 hours after the operation. The contraction exercise of the quadriceps femoris was performed on the 3rd day after the operation. The flexion and extension function of the knee joint began to exercise 1 week later, and partial weight-bearing began to be carried out six weeks after the operation. And after the fracture healing was confirmed by X-ray, three months after the operation, patients began to bear weight completely gradually.

Observation indicators

The coincidence rate between the preoperative planning and the final surgical plan

Each case of complex platform fracture was designed according to the 3D printing model before operation. The specific surgical approach and implant scheme were designed. The specific operation plan was recorded. The consistency rate between the final operation plan and the preoperative plan was obtained.

Knee joint function score

The patients were followed up for one year. During the follow-up, the anterior and lateral films of the knee joint were taken, and the knee joint function was evaluated by HSS score.[11] HSS score > 85 was excellent, 70-84 was good, 60-69 was fair, and < 59 was poor.

Fracture healing time and postoperative complications

The fracture healing time of each case was recorded in the follow-up. And whether there were postoperative complications such as infection, screw fracture, and other complications were recorded.

Statistical processing

The above data were analyzed by SPSS18.0 statistical software. $\chi 2$ test was used for the Comparison of counting data. T-test was used for the Comparison of measurement data. The difference was statistically significant ($P < 0.05$).

RESULTS

The coincidence rate between the preoperative planning and the final surgical plan

The classification of tibial plateau fracture combined with 3D printing is basically consistent with what was seen during the operation. The fracture type and articular surface collapse seen during the operation are basically the same as the model, which is of great help to the understanding and operation of the operation. In all 54 cases, the final operation plan of 51 cases was consistent with the design before operation. And 3 cases of them are type VII fracture. Before the operation, the lateral column was fixed by anterolateral approach, and the medial column and posterior column were fixed by the posteromedial approach. The bone mass of the lateral column was reduced and fixed by an anterolateral approach. It was found that the stability of the posterior column was good. The coincidence rate between the preoperative planning and the final surgical plan was 94.4% (the final plan was consistent with the preoperative planning and design of the number of cases / total number of cases * 100%). The postoperative CT results showed that the collapse of the articular surface of the platform was well reduced in all 54 patients.

Knee joint function score

During the follow-up six months after the operation, the excellent and good rate of knee joint function was 87.0%. And the excellent and good rate of knee joint function 12 months after the operation was 90.7%. Only one patient had poor knee joint function six months after the operation. And his knee joint function was improved after functional rehabilitation exercise. (Table 2)

Table 2. Comparison of knee joint function.

		Six month after the surgery	12 months after surgery
Case numbers		54	54
HSS score		88.1±6.1	88.4±6.9
knee joint function	Excellent	38(70%)	44(80%)
	Good	9(17%)	5(10%)
	Average	6(11%)	5(10%)
	Bad	1(2%)	0

($P > 0.05$).

Fracture healing time and postoperative complications

Postoperative follow-up showed that all 54 patients healed well. And the average healing time was 3.4±0.5 months. All 54 patients had no infection and no internal fixation loosening.

DISCUSSION

The importance of correct classification of tibial plateau fractures and preoperative planning

The treatment of complex tibial plateau fractures has always been a difficult problem in orthopedics.[12] It is often accompanied by ligament, meniscus injury, and serious damage of nerve, blood vessel, and soft tissue, making fracture treatment more difficult.[13] Patients often have varying degrees of dysfunction after the operation, which seriously affects their ability to work. How to deal with complex tibial plateau fractures, reduce fracture complications, and make a good recovery of knee joint function.

The correct classification and preoperative planning of tibial plateau fractures are very important for selecting surgical approaches and fixation methods. CT scanning can scan the tibial plateau in axial, coronal, and sagittal planes to show the full picture of the tibial plateau.[14-16] At the same time, 3D printing can have a more intuitive understanding of the whole tibial plateau and the details of the fracture, which makes various measurements more convenient. Thus, we can have a quantitative understanding of the degree of fracture collapse and splitting. Also, it can provide a better reference for surgical approach and internal fixation placement.[17]

Development of classification methods for tibial plateau fractures

A good classification method of tibial plateau fracture not only needs to accurately reflect the degree of fracture injury but also needs to guide clinical treatment. Hohl-Moore classification is a classification method based on X-ray, which divides tibial plateau fractures into five kinds of primary fractures and five kinds of fracture and dislocation. However, this method can not accurately reflect the degree of soft tissue injury during fracture, and it is difficult to guide clinical treatment. Schatzker classification increases the type of VI fracture with separation of metaphysis and diaphysis, widely used in the clinic. However, it also has disadvantages. In practical clinical Applications, simple collapse fracture is rare and can not be effectively distinguished. The fracture of the posterior lateral column of the tibial plateau is not distinguished, which is easy to cause missed diagnosis and affect the choice of surgical treatment. The content of the AO classification is detailed, which is conducive to academic research and communication. However, the content is too complex to remember. Also, it can not accurately reflect the relationship between articular surface collapse and fracture severity. Thus, it is not competent to guide the choice of clinical treatment and prognosis.[18] Based on the above, Luo Congfeng et al. suggested the classical three-column classification method based on three-dimensional CT. They analyzed the shape and location of the fracture from a three-dimensional point of view for the first time.[3] According to the division, it is divided into internal, external, and posterior three columns, which can accurately guide the surgical approach. But this classification did not put forward the concept of posteromedial and posterolateral tibial plateau fractures. Mao Yujiang et al. put forward the theory of "four columns and four quadrants" based on three columns. This classification distinguishes the morphological differences between posteromedial and posterolateral column fractures and is of great significance for the guidance of clinical posterior column fractures.[19]

With the emergence of 3D printing technology, we can better obtain the solid model of the fracture site before operation. Compared with the solid model, the surgeon has a deeper understanding of the local structure of the fracture. Based on the accurate classification, it is of greater significance to guide clinical surgery.[20-22]

Advantages of 3D printing technique in classification and preoperative planning of complex tibial plateau fractures

Compared with CT scanning, 3D printing provides more details about proximal tibial bone and fracture, even the internal details of fracture.[6-7] 3D printing can intuitively classify and fix the fracture as a more detailed preoperative plan, guide the mode of operation, surgical approach, and fixation, providing better preoperative guidance for clinical practice.[23] And it can provide the possibility to better improve the classification of tibial plateau fracture. It has the following three advantages:

Psychological advantage: After printing the 3D model of complex tibial plateau fracture, the operator can intuitively understand the fracture state and displacement. So that the surgeon can have more time and more intuitive to design the operation plan, to get twice the result with half the effort.

Operational advantages: According to the operation on the simulated 3D model before the operation, the plates and screws can be implanted smoothly during the operation. For medial and lateral plateau fractures, we can often see the articular surface of the plateau; the reduction of the articular surface is not very difficult. Still, it may not be easy to see the posterior articular surface during operation in complex plateau fractures involving posterior column fractures. Therefore, the preoperative surgical design, the preshaping of the steel plate, and the direction and length of the screw are of great help to the operation. It greatly simplifies the difficulty of the operation, shortens the operation time, and reduces surgical trauma injury.[24-25]

Communication advantages: before the operation, we use 3D printed models to communicate with patients. So that patients have a better understanding of the severity of their fractures and a certain understanding of the surgical plan and the expected effect of treatment. In this way, it can also eliminate the patients' fear. And the compliance will be better.

With the combination of digital medicine and orthopedics, 3D printing technology can transform virtual 3D images into realistic three-dimensional objects, facilitating precise treatment for surgeons. 3D printed models applied to tibial plateau fractures have the characteristics of optimizing preoperative planning, providing individualized and precise treatment, which can reduce the difficulty of surgery and improve the accuracy of surgery.

Before surgery, the surgeons can accurately gauge the plate and screw, design the relevant angle and length with the aid of a computer. Simulated surgical operations can increase the operator's operational proficiency. At the same time, it can intervene in advance to deal with the operation's key areas and difficult points, which can reduce the risk of damaging blood vessels and nerves during the nail placement. The anatomical structure of the patient's tibia and the adjacent relationship can be clarified by comparing and observing the physical model in real-time during surgery, reducing errors in judgment and surgery-related complications due to anatomical deformities and individual differences. The number of secondary surgeries is reduced, and the difficulty and risk of surgery are reduced. Only one verification fluoroscopy is required after nail placement, which greatly reduces operative time, x-ray fluoroscopy, and surgical bleeding.

In summary, 3D printing technology can further refine the classification of complex tibial plateau fractures. The surgical approach and internal fixation plan are planned through the solid model, which is intuitive and accurate. And the preoperative planning scheme is feasible, which greatly simplifies the operation and reduces surgical trauma injury. Also, it can be used as a routine item of preoperative preparation. In the future, under the guidance of a 3D printing template, the optimized preoperative planning of tibial plateau fracture and accurate internal fixation operation will be better applied to the clinic.

DECLARATION:

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

FUNDING

National Natural Science Foundation of China(81771985), Key Projects of Medical Science and Technology Development of Nanjing(ZKX18029), Science and Technology Projects of Nanjing(201715073)

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. CYH and CFY: contributed to the study design and the drafting of the article; JMZ: contributed to the implementation; BZ, HJ and XMX: collected CT data and CAD; BJ and FYM: performed 3D printing; XJ, FYC and LMW: contributed to all surgical procedures. The authors read and approved the final manuscript.

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DOI: http://dx.doi.org/10.1590/1413-785220243203e267630

TREATMENT OF PEDIATRIC FEMUR FRACTURES WITH FLEXIBLE STAINLESS STEEL INTRAMEDULLARY NAIL

TRATAMENTO DE FRATURAS DO FÊMUR PEDIÁTRICO COM HASTE INTRAMEDULAR FLEXÍVEL DE AÇO INOXIDÁVEL

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ABSTRACT

Objectives: To identify the characteristics of patients and femur fractures treated with a stainless steel intramedullary nail (ESIN) in children under 15 years of age. Know the results of using the ESIN of related steel in the service. Methods: Retrospective study with review of hospital records and organization of data in spreadsheets. Result: 24 cases were identified, 17 male cases and 7 female cases. A minimum age of 4 years and a maximum of 11 years were observed (average of 7 years). The 3 most common trauma mechanisms were being run over (n:8, 33%) and falling from a height (n:8, 3%). The most common location of the fractures was in the mid-diaphyseal region (n: 20, 88%), only one case presented a bilateral femur fracture. The most common associated trauma was traumatic brain injury. The observation period observed several months between 2 and 5. With regard to complications, 3 cases were observed (12.5%) being bursitis, vicious construction and loss of reduction. Conclusion: Steel HIF shows similar good results. As the study includes the retrospective profile, the absence of a group and the small sample size. ***Level of Evidence IV, Case series.***

Keywords: Stainless Steel. Child. Femur Fractures. Intramedullary Fixation of Fractures.

RESUMO

Objetivos: Identificar as características dos pacientes e das fraturas de fêmur tratadas com haste intramedular flexível (HIF) de aço inoxidável em menores de 15 anos. A partir disso, conhecer os resultados relacionados ao uso da HIF de aço inoxidável no serviço. Métodos: Estudo retrospectivo, com revisão de prontuários hospitalares e organização dos dados em planilhas. Resultado: Identificados 24 casos, sendo 17 do gênero masculino e sete do gênero feminino. Foram observadas idade mínima de 4 anos e máxima de 11 anos (média de 7 anos). Os mecanismos de trauma mais comuns foram atropelamento (n: 8, 33%) e queda de altura (n: 8, 33%). A localização mais comum das fraturas foi na região médio diafisária (n: 20, 88%), apenas um caso apresentou fratura de fêmur bilateral. O trauma associado mais comum foi traumatismo crânio-encefálico. O período de consolidação observado variou entre 2 e 5 meses. No que se refere a complicações, foram observados três casos (12,5%), sendo estes: bursite, consolidação viciosa e perda de redução. Conclusão: A HIF de aço apresenta bons resultados, semelhantes aos das hastes de titânio. As limitações do estudo incluem o perfil retrospectivo, a ausência de grupo controle e o número pequeno da amostra. ***Nível de evidência IV, Série de casos.***

Descritores: *Aço Inoxidável. Criança. Fraturas do Fêmur. Fixação Intramedular de Fraturas.*

Citation: Brandão MAB, Arantes JES, Chueire AJFG, Carvalho Filho G. Surgical treatment of femur fracture with flexible stainless steel intramedular nail in children. Acta Ortop Bras. [online]. 2024;32(3):Page 1 of 5. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Trauma is a leading cause of morbidity and mortality in children and femoral fractures have a significant impact on the patients' entire medical-familial care network.[1] Femoral diaphyseal fractures represent 1.4% to 1.7% of all fractures in the pediatric population, with males being the most affected. The incidence distribution is bimodal: first peak at 2-4 years of age and the second in adolescence.[2] Traffic accidents comprise the most frequent trauma mechanism, with the exception of children under 3 years of age.[3]

The preferred method for treating femoral fracture in children can vary according to age.[4] Conservative treatment with plaster after a period of traction has been one of the most

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

The study was conducted at Faculdade de Medicina de São José do Rio Preto, Hospital de Base, Departamento de Ortopedia e Traumatologia.
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Article received on 09/20/2022, approved on 02/15/2024.

used options in the past, but during the last decades new techniques have been developed.[5] For children aged 18 months to 6 years, conservative methods of treatment still predominate, represented by temporary traction and immobilization by pelvipodal plaster.[6] For children aged 6 to 16 years, fracture treatment depends on good reduction, not compromising areas of growth or blood irrigation and reducing complications, and it is possible to opt for elastic stable intramedullary nailing (ESIN) with favorable outcomes.[1,6] In addition, even for children aged under 6 years, there are current studies that recommend the use of ESIN and show good results.[7] Other surgical treatment methods include submuscular plates, external fixators and locked intramedullary nails.

The use of ESIN has reported complication rates ranging from 33-62%, mostly related to soft tissues with no need for surgical intervention, mainly involving pain and/or inflammation at nail insertion.[8]

The objectives of this study were: trace the evolution of cases and complications of femur fractures treated with stainless steel elastic stable intramedullary nailing (ESIN) in children aged under 15 years. Find the outcomes related to the use of stainless steel ESIN in relation to titanium nailing.

MATERIALS AND METHODS

This is a retrospective study with review of hospital records carried out in a reference Children and Maternity hospital in the non-metropolitan area of São Paulo. We analyzed data for the period from May/2016 to October/2020.

The present study was submitted to the Ethics Committee under opinion number 51363421.0.0000.5415 and its implementation was approved.

Inclusion criteria were: patients aged under 15 years, with a diagnosis of femur fracture, undergoing surgical treatment with stainless steel elastic stable intramedullary nailing (ESIN) technique. Exclusion criteria were: patients with follow-up for less than 12 months and pathological fractures. Patients with incomplete medical records were not included. The informed consent form was not required due to the study being only a review of medical records.

The authors analyzed data from hospital medical records and used the following epidemiological information: gender, age, and trauma mechanism. Based on the initial radiographs, the fractures were classified according to fracture line location (diaphyseal or metaphyseal region), laterality and pediatric AO classification.[9]

The surgeries were performed with the patient in horizontal dorsal decubitus on a radio-transparent operating table under general anesthesia. Fractures were reduced in a closed manner. Nail diameter was chosen to occupy 80% of medullary cavity diameter. The two nail were always chosen with the same thickness to avoid incorrect positioning and varus or valgus imbalance. The retrograde route was performed with two surgical steel flexible nails inserted with insertion point 2 cm proximal to the distal physis of the femur. The medial nail inserted up to 2 cm of the proximal femur and the lateral nail up to 1 cm of the greater trochanter. Skin incisions were made 3-4 cm distal to the planned insertion site depending on child size. The nails underwent molding with three times the diameter of the medullary channel, the arch vertex was placed at the level of the fracture zone. The nail was inserted with the aid of a "T" guide with the tip aligned with the medullary axis. The second nail was inserted by the same technique. The fracture was reduced and the nails were progressed. When the fracture was firmly fixed the rotation was checked before final anchoring. The nails had their end cut off and impacted. In cases with anterograde nails, the insertion was anterolateral in the subtrochanteric area. The nails were separated vertically by approximately 1–2 cm and horizontally by 0.5–1 cm. The reduction and positioning of the nails was checked by intraoperative scoping. Subcutaneous and skin were sutured with simple stitches (Figure 1).

Figure 1. Immediate pre- and postoperative radiography of diaphyseal femur fracture.

In the immediate postoperative period, anteroposterior and lateral thigh radiographs were taken. Patients were discharged from hospital on the first day after surgery, except in some cases where polytrauma patients required further evaluation by other specialties. At discharge, patients were instructed to maintain

zero load, keep the limb elevated and perform exercises to gain active and passive range of motion in the hip, knee and ankle joints. The first follow-up visit was one week later for surgical wound evaluation. The second follow-up visit was three weeks later for removal of stitches, control radiography. In the sixth week, new radiographs were taken and progressive load was allowed with the help and under the supervision of a physiotherapy team. Subsequently, patients had follow-up visits every two months for clinical and radiographic evaluation (Figure 2).

Figure 2. Preoperative and postoperative radiographs (4 months after fracture).

Complications found included bursitis, vicious consolidation, and asymmetry of lower limbs (Clavien-Dindo type I and II).[10,11] Nailing removal was indicated to patients and their guardians after fracture consolidation, medullary canal reossification with return of the cortical layers of the femur, return of the ability to walk without pain, gain of range of motion and symmetrical muscle trophism to the contralateral limb. In selected cases, the removal procedure was performed in an operating room under general anesthesia with a one-day hospitalization (Figure 3).

Figure 3. Radiography after nailing removal (12 months after surgery). Same patient as Figure 2.

RESULTS

We traced 24 cases of femoral fracture treated with ESIN, of which 17 cases of males (71%) and 7 cases of females (29%), compatible with the distribution described in the literature. We observed a minimum age of 4 years and a maximum age of 11 years, with a mean of 7 years.

The most common trauma mechanisms traced were being hit by a car (n: 8, 33%) and falling from a height (n: 8, 33%), followed by car accidents (n: 6, 25%). Two of the cases evaluated were related to objects falling on the lower limbs. The most common associated injury was traumatic brain injury traced in 4 cases, one of which required a neurosurgical approach (Table 1).

Table 1. Distribution of cases

Gender	
Male: 17	
Female: 7	
Age	
0 to 6 years: 9	
7 to 10 years: 13	
>10 years: 2	
Trauma mechanism	
Hit by a car: 8	
Fall from a height: 8	
Car accident: 6	
Other (2)	
Fracture level	
Proximal metaphysis: 4	
Diaphyseal: 20	
Distal metaphysis: 0	
Complications	
Bursitis: 1	
Asymmetry: 1	
Vicious consolidation: 1	

The most common fracture location was the mid-diaphyseal region (n: 20, 88%). Fractures were classified by AO criteria with 11 32-D/4.1 pattern fractures (42%) and 10 32-D/5.1 fractures. Four cases of fracture in the proximal metaphyseal region were observed. The left side was predominant, occurring in 13 cases (54.5%), only one case presented bilateral femur fracture.

The consolidation period ranged from 2 to 5 months, with an average of 2.9 months.

Regarding complications, 3 cases (12.5%) were observed. One case presented bursitis, another case had vicious consolidation and a third case had reduction loss.

ESIN removal occurred in 7 cases. However, 10 cases of the total had a loss of follow-up after 18 months, and it was not possible to determine the need for removal. These cases are represented by patients who did not return to the outpatient clinic for the scheduled visits.

DISCUSSION

The definition of surgical treatment of femur fractures in children depends on variables such as age, patient weight, bone exposure or comminution, and availability of materials. For children aged 6–16 years, ESIN is an excellent treatment choice as it enables early load, quick return to activities of daily living, small incisions and low rates of serious complications.

ESIN allows a slight movement in the focus of the fracture end, being beneficial for the formation of bone callus and characterizing the mechanism of relative stability, with the technique being widely used in the treatment of fractures of long limb bones, such as femur, tibia and humerus.[12]

The treatment of femoral fractures in children is still the subject of discussions. The analysis of postoperative benefits makes ESIN a favorable option. Increasingly, our service opts for the use of ESIN as a therapeutic plan in cases with indication for such.

The most common fracture patterns found in our study were simple transverse diaphyseal (46%) and simple oblique diaphyseal (42%). Buechsenscheutz et al. (2002) described 17 transverse fractures (41%) and 11 oblique fractures (26%), with 25 of the cases (60%) with diaphyseal line.[13] Hoffman in 2012 presented an index of 89.6% of single line fractures.[2]

In 1982 the concept of ESIN was introduced by a group in Nancy and described by Ligier in 1988. In this study, 123 fractures were observed in 118 children and 13 cases of superficial inflammation (9.8%) and 14 cases with deviation were identified (only one of the cases with rotational deviation).[14] Luhmann et al.[15] concluded that the most common complication was skin injury caused by the nails and it can be avoided by leaving only 2.5 cm of the nail external to the bone. They also observed that fixation of femoral fractures in overweight patients with ESIN is associated with increased sagittal angulation.[15] Flynn et al.[16] described in 2001 an analysis of 58 cases finding 7% of superficial infections and no cases of osteomyelitis.[16] Narayanan et al.[17] evaluated 78 cases of pediatric femoral fracture finding 58% of complications, the most common being pain or irritation at the nail insertion site. Poor consolidation was found in 8 cases, reduction loss in 5 cases, and refracture in 2 cases. Among these, 10 cases required re-approach. [17] In our study, the complication rate was 12.5%, one case of bursitis that occurred late due to friction of the prominent point of the lateral nail with the soft parts of the knee, requiring removal of nails that already had clinical radiographic criteria of consolidation. Another case with vicious consolidation evolves with valgus deviation of the femur and a third case with asymmetry of 4.0 cm, with conservative treatment by family decision. The case with reduction loss showed asymmetry of 4.1 cm between the lower limbs and epiphysiodesis in the contralateral distal femur was indicated.

The use of anterograde nail may present complications such as valgus deformity, narrowing of the femur and alteration in the epiphyseal plate.[18] In the study carried out, no lesion related to the use of anterograde nail was found in the analysis period.

Compared to other types of surgical approach such as submuscular plates, chosen in the treatment of fractures that present comminution of the femur diaphysis, heavier patients and fractures of the bone ends, ESIN presents good results with reduced operative time, less blood loss during surgery and lower cost of hospitalization.[19]

The main limitations and difficulties in the use of flexible nails are found in patients with unstable, comminuted lines, in metaphyseal regions and in obese patients; however, there are new articles that even in these cases ESIN can be well indicated.[8] In relation to external fixation of closed fractures, ESIN is associated with earlier load, better range of motion, faster return to activities of daily living and lower incidence of discrepancy in limb length.[20] Our patients presented no case of refracture, even in cases where the nails were removed, demonstrating a positive result in relation to a previous study carried out in our service with a rate of 17% of refracture with the use of an external fixator.[21]

Differently from what is found in much of the literature on ESIN, the material of the nails available in the service is stainless steel. Wall et al.[22] showed that the rate of major complications (for example, irritation caused by nail requiring revision surgery, infection, delayed union, nail breakage) was higher in titanium nails than in stainless steel nails (35.7% and 16.7%, respectively).[22] In a study also in 2008 Soni et al. [23] evaluated two-dimensional computerized models with qualitative analysis favorable to the use of titanium nails, but quantitative analysis with statistically similar values between titanium and steel.[23] Comparative studies with

results of equivalent or even superior quality for the use of steel nails were found. In addition, the cost of steel ESIN can be up to three times lower than titanium ESIN.[24,25]

There is no agreement in the literature regarding the removal of implant material, and it is mentioned that it is necessary only in symptomatic patients or when the implant may compromise the physis.[26] In our service, the nails were removed in 7 patients, but in 10 cases of the total there was loss of follow-up after 18 months and it was not possible to trace the need for nail removal.

The study presents the bias of loss of follow-up, as some patients do not return for scheduled visits. In addition, there was a large number of incomplete medical records, which leads to a reduced total number for analysis.

CONCLUSION

Our service uses steel ESIN and presents good results compatible with the literature. Study Limitations include the retrospective profile with insufficient information in some medical records with loss of follow-up, the lack of a control group, and the small sample size. In addition, formal measurements of angular changes were not performed in all patients, only in patients with clinical complaints. The complication rate found was lower than that presented in the literature. We conclude and demonstrate with our described cases that the use of stainless-steel elastic stable intramedullary nailing is an option that is viable, cheaper, with a low complication rate, and accessible for the treatment of pediatric patients with diaphyseal femur fracture.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. MADB: research project design, data collection, medical record analysis, article drafting. JESA: data collection and analysis. AJFGC: article drafting, article review, intellectual conception, research project design. GCF: article review and intellectual conception contribution.

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DOI: http://dx.doi.org/10.1590/1413-785220243203e276513

RANDOMIZED EXPERIMENTAL STUDY OF TOPICAL VASODILATORS IN MICROSURGERY WITH COST ANALYSIS

ESTUDO EXPERIMENTAL RANDOMIZADO DE VASODILATADORES TÓPICOS EM MICROCIRURGIA COM ANÁLISE DE CUSTO

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ABSTRACT

Objective: Throughout microsurgical anastomosis, many surgeons use topical vasodilators in order to reduce pathological vasospasm. It was carried out an experimental study comparing the effectiveness of topical use of Nitroglycerin, Papaverine, Magnesium sulfate over a control group in the femoral artery and vein of rats, in reducing prolonged vasospasm. Methods: Randomized comparative experimental study in 15 rats, divided into four groups. The external diameter of the vases soaked in the randomized solution was measured. For statistical analysis, it was calculated the percentual increase in the external diameter of the vessels. Results: A statistically significant increase in arterial dilation was observed after 10 minutes of topical application of 10% magnesium sulfate compared to the control group, with $p = 0.044$. No other drug showed a vasodilator effect superior to the control group. Magnesium sulfate at 10% is still not used in microsurgery and costs 15 times less than papaverine, the standard drug for topical vasodilation in clinical cases at our service. Conclusion: Magnesium sulfate had better vasodilating effects over the control group after 10 minutes of arterial microanastomosis. None of the tested drugs have presented superior vasodilating effects over each other nor the control group after venous microanastomosis. ***Level of evidence II, Experimental study, Randomized Trial.***

Keywords: Microsurgery. Vasodilator Agents. Animal Models. Experimental Study. Complications.

RESUMO

Objetivo: Durante a anastomose microcirúrgica, muitos cirurgiões utilizam vasodilatadores tópicos para reduzir o vasoespasmo prolongado patológico, assim reduzindo o risco de complicações vasculares. Entretanto, ainda faltam dados experimentais para identificação da droga padrão-ouro para vasodilatadores tópicos em microcirurgia e sua avaliação de análise de custo, já que a droga geralmente utilizada para este objetivo é baseada, na maior parte dos casos, na experiência do cirurgião. Métodos: Foi realizado um estudo experimental comparativo randomizado, avaliando a eficácia do uso tópico de Nitroglicerina, Papaverina e Sulfato de Magnésio em relação a um grupo controle, na redução do vasoespasmo na artéria e veia femoral de ratos. Foram avaliados o diâmetro externo dos vasos embebidos em solução randomizada dos fármacos para vasodilatação. Após cálculo do aumento percentual no diâmetro externo dos vasos, foi realizada análise estatística. Resultados: Observou-se aumento estatisticamente significativo da dilatação arterial após 10 minutos de aplicação tópica de sulfato de magnésio a 10% em relação ao grupo controle, com p = 0,044. Nenhuma outra droga apresentou efeito vasodilatador superior ao grupo controle. O sulfato de magnésio a 10% ainda não é utilizado em microcirurgia e apresenta custo até 15 vezes menor quando comparado com a papaverina, droga padrão para vasodilatação tópica em casos clínicos em nosso serviço. Conclusão: O sulfato de magnésio apresentou melhor efeito vasodilatador quando comparado ao grupo controle, após 10 minutos da microanastomose arterial. Nenhum dos fármacos testados apresentou efeito vasodilatador superior após a microanastomose venosa. ***Nível de Evidência II, Estudo experimental, Ensaio Randomizado.***

Descritores: *Microcirurgia. Complicações. Dilatação. Eficácia. Custo e Análises de Custo.*

Citation: Rusig RP, Alves DYYO, Nascimento AOL, Santos GB, Mattar R Jr, Iamaguchi RB. Randomized comparative experimental study of topical vasodilators in microsurgery with cost analysis. Acta Ortop Bras. [online]. 2024;32(3):Page 1 of 5. Available from URL: http://www.scielo.br/aob.

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

The study was conducted at Universidade de São Paulo, Faculdade de Medicina, Hand Surgery and Reconstructive Microsurgery Group, Instituto de Ortopedia e Traumatologia Hospital das Clínicas HC-FMUSP.

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Article received on 07/11/2023, approved on 11/03/2023.

INTRODUCTION

Microsurgical free flaps currently have a high success rate in reconstructive surgeries, but complications may be present in 5-10% of cases.[1] One of the main causes of complications is vascular thrombosis, which can be caused by prolonged vasospasm of the vascular pedicle[2-4] due to a significant reduction in flow velocity. Decreased intraluminal flow promotes the formation of intraoperative thrombi, reduced blood supply to the tissue to be transferred and consequently: flap loss due to ischemia, ischemia-reperfusion injury, microcirculation thrombosis and altered consumption of coagulation factors.[4,5,6]

The use of vasodilators to control vasospasm in microsurgery is widely adopted; however, there is no drug defined as the gold standard for topical or systemic intraoperative use.[7,8] In current microsurgery, vasospasm is treated according to personal or institutional experience, there are few studies comparing the available drugs and the vasodilating potential of each drug.[7,8,9]

The objective of this experimental study is to find which topical vasodilating drug would be the most effective and least costly for use in microsurgery, including the effect on arterial and venous anastomoses. The following topical vasodilators were compared with the control group with physiological solution: papaverine, currently used as the medication of choice in our service; 10% magnesium sulfate, as it is a vasodilator with good efficacy in experimental studies and with antithrombotic effect by decreasing platelet aggregation;[10,11] and nitroglycerin, a drug widely used in cardiac surgery as an arterial vasodilator.[12,13] Quantitative effects were analyzed with the topical use of each drug in the femoral artery and vein of rats by measuring the external diameter of the vessels with a micrometer ruler, before and after microanastomosis. The secondary objective was to provide cost analysis of the drugs tested and availability in the context of Brazilian public health care, for intraoperative use in clinical occurrence.

MATERIAL AND METHOD

Fifteen male Wistar rats weighing 376–432 grams were included in this study. The study was submitted to and approved by the Animal Research Ethics Committee (CEUA) number 1752/2022 and CAAE number 29539719.8.0000.0068. The rats were kept in the vivarium and in a musculoskeletal research laboratory according to the principles of care and use of animals in laboratory.

The animals were submitted to pre-anesthetic medication using tramadol hydrochloride at a dose of 0.3 mg/100 g associated with meloxicam at a dose of 0.02 mg/100 g intramuscularly and placed in an inhalational anesthetic induction box with Isoflurane (equipamento Bonther, Ribeirão Preto - SP). After confirmation of the anesthetic plan, the animals were placed in a nebulization mask with 2% Isoflurane, with bilateral trichotomy of the inguinal region and the specimen was positioned in horizontal dorsal decubitus on a surgical platform under a surgical microscope with magnification of up to 20x. The experimental tests were performed by the first author, under supervision and monitoring for the measurements and annotations of the data by the other authors. Surgery was always initiated on the right side with oblique inguinal incision, cauterization of vascular branches and microscopic dissection of the femoral artery, nerve and vein bilaterally, in its middle third. Transverse arteriotomy and microanastomosis were performed, followed by transverse venotomy and microanastomosis. Using a 10 mm optical glass eye ruler with a 100 micrometer scale, the external diameter of the femoral artery was measured distally to the microanastomosis, in favor of arterial flow, and the external diameter of the femoral vein was measured proximally to the microanastomosis, in favor of venous flow, and the values were recorded as time zero (t_0), under magnification of 20x. We continued with topical application of vasodilators, all at room temperature, according to the following groups:

Group 1: Nitroglycerin (50 mg/mL ampoule diluted in 0.9% sodium chloride to 0.4 mg/mL concentration - Tridil® Cristália Químico, Itapira - SP)

Group 2: Papaverine (50 mg/mL ampoule diluted in 0.9% sodium chloride to 30 mg/mL concentration - Hypoverin® Hypofarma, Ribeirão das Neves - MG)

Group 3: Magnesium sulfate (10% ampoule used at 100 mg/mL concentration - Samtec Biotecnologia Limitada, Ribeirão Preto - SP)

Group 4 (Control): 0.9 % sodium chloride

According to the groups described, we performed topical application of 4 ml of one of the solutions immediately after the measurement at the initial time (t_0), in a order that was randomized through a platform (https://www.random.org/) from 1 to 30, with the odd numbers referring to the right side and the even numbers referring to the left side. The vessels were kept soaked in the solution for 30 minutes and the external diameter of the femoral arteries and veins was measured with 3 min (t_3), 5 min (t_5), 10 min (t_{10}) and 30 min (t_{30}) counted from the application of the drugs (t_0). Concomitantly with the measurement of the diameter of the vessels on the right side, the same procedure was performed on the left side and the measurements were recorded. Soon after the experimental phase described, the animals were euthanized using the anesthesia protocol and, after further confirmation of the anesthetic plan, 20% potassium chloride was administered intracardially. Figure 1

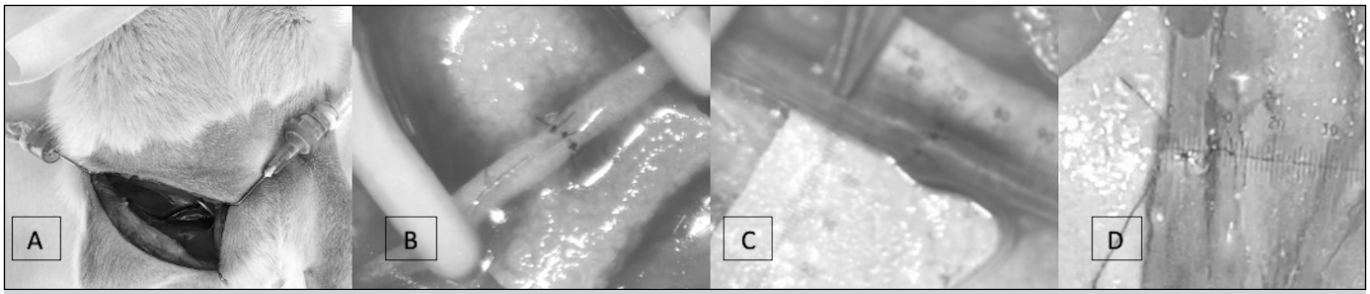

Figure 1. Demonstration of the stages of the experimental study. A: Surgical access of the inguinal region of the rat; B: Microanastomosis with the aid of Clamps; C: Measurement at initial time; D: Measurements after topical application of the drug.

Quantitative analysis of artery vasodilation was performed separately from the vein, following the same protocol for both: we calculated the difference in the external diameter of the artery (Δ_{artery}) and vein (Δ_{vein}) at the evaluated times (t_3, t_5, t_{10} and t_{30}) in relation to the initial measurement (t_0) [$\Delta_t = x_t - x_{t0}$], just before administering the drug, and their representation in relation to t_0 expressed as a percentage. For statistical analysis, the SPSS version 20.0 program (SPSS Inc ®, Chicago, IL, USA) was used, with descriptive statistics

and statistical analysis. After Levene's test, the Kruskal Wallis test was used for quantitative variables, being considered statistically significant $p < 0.05$. After identifying a statistically significant result, the Mann-Whitney test was used to determine which drug analyzed produced greater vasodilation compared to the different drug groups and in relation to the control group, for the artery or for the vein.

The cost of papaverine, nitroglycerin and magnesium sulfate was researched in the regulations of the National Health Surveillance Agency (ANVISA) on the price of medicines defined by the Chamber of Regulation of the Drug Market (CMED) published between August 2022 and January 2023.[14] The factory price (FP) with Tax on Circulation of Goods and Services (ICMS) at 18% of each drug was used as a reference for comparative purposes.[15]

RESULTS

We performed 26 tests on 15 rats. We obtained Group 1: Nitroglycerin n = 6, Group 2: Papaverine n = 7, Group 3: Magnesium Sulfate n = 7, Group 4: Control n = 6. The mean values of the external diameter of the arteries and veins are exemplified in Tables 1 and 2, respectively. Four cases were excluded due to cardiorespiratory arrest of the rat during the procedure, before the measurement at 10 minutes (3 cases in the Papaverine group and 1 case in the Nitroglycerin group).

Table 1. Mean arterial external diameter measurements, in micrometers (μm) according to the time (t) evaluated after drug administration.

Group	Drug	Time									
		t_0		t_3		t_5		t_{10}		t_{30}	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
1	Nitroglycerin	7.40	1.14	8.20	0.84	8.20	0.84	8.20	1.10	8.50	1.29
2	Papaverine	6.75	1.26	7.75	0.50	7.75	0.50	7.75	0.50	7.50	1.29
3	Magnesium sulfate	6.14	1.77	7.83	2.23	8.29	2.06	8.57	1.90	7.83	1.72
4	Control	8.50	1.87	8.60	2.07	8.67	1.86	8.50	1.64	8.50	1.64

Table 2. Mean venous external diameter measurements, in micrometers (μm) according to the time (t) evaluated, after drug administration.

Group	Drug	Time									
		t_0		t_3		t_5		t_{10}		t_{30}	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
1	Nitroglycerin	9.60	1.14	9.80	1.10	9.80	1.10	10.00	1.63	9.75	1.26
2	Papaverine	8.75	1.26	9.5	0.58	9.5	0.58	9.25	0.50	8.50	1.92
3	Magnesium sulfate	7.86	2.12	8.83	1.94	9.29	2.06	9.57	1.99	9.67	1.75
4	Control	9.17	1.47	8.40	1.67	8.83	1.84	9.50	1.76	9.83	1.94

According to the measured values, the percentage of variation (Δ) in the diameter of the arterial and venous vessels was calculated in relation to the initial measurement at t_0 (just before application of the drug) and the mean dilation value of each drug was calculated, used as a basis for statistical tests.

After analyzing data homogeneity, a non-parametric Kruskal Wallis test was performed, between the different drugs and the control group, for the mean variation (Δ) in arterial external diameter according to the evolution of each group according to the time (Graph 1), observing no statistically significant difference in artery dilation values measured 3 minutes (p = 0.099), 5 minutes (p = 0.207) or 30 minutes (p = 0.183) after application of the drug. Statistically significant difference was observed for arterial dilation after 10 minutes with p=0.044.

In a comparative analysis between the different drugs and the control group, analyzing case by case, through the Mann-Whitney statistical test, it was observed that the only drug with a statistically significant increase in external diameter (vasodilation) was Magnesium sulfate when compared to the control group with p = 0.017. (Figure 2)

The analysis was repeated for the measurements of variation (Δ) in venous external diameter after topical application of the drugs and the control group, and no statistically relevant difference was observed in vein dilation values measured 3 minutes (p = 0.112), 5 minutes (p = 0.214), 10 minutes (p = 0.401) or 30 minutes (p = 0.243) after drug application. (Figure 3)

Magnesium Sulphate had a cost (FP) of R$ 219.07 per 200 ampoules (price per ampoule R$ 1.10), Papaverine R$ 177.45 per 10 ampoules (price per ampoule R$17.70) and Nitroglycerin R$ 364.71 per 10 ampoules (price per ampoule R$ 36.47)

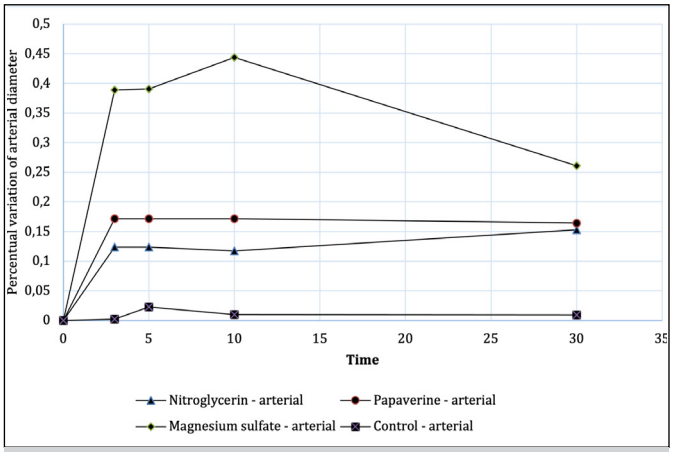

Figure 2. Evolution of the mean percentage change in arterial diameter as a function of time.

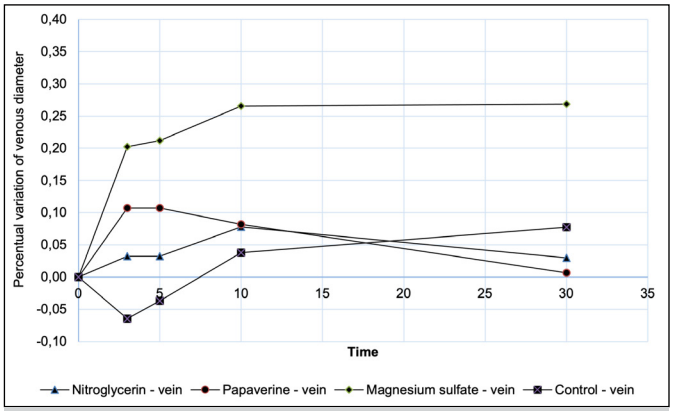

Figure 3. Evolution of the mean percentage change in venous diameter as a function of time.

DISCUSSION

This study was designed to assist in the choice of the most effective topical vasodilator drug in microsurgery, which is easily applicable at the intraoperative time and capable of controlling vasospasm, ischemia and thrombogenic factors at the intraoperative time of microanastomosis.[16] Vasodilation promotes an increase in the velocity of microanastomosis flow, better vascularization of the microsurgical flap and is correlated with a higher tissue survival rate.[17] Therefore, the hypothesis of this experimental study is that the greater and more prolonged the vasodilation caused by the drug, the greater the reduction of vasospasm and flow turbulence, as one of the factors of Virchow's triad, consequent platelet activation with the endothelial surface and thrombus formation,[18,19] leading to an increased risk of vascular complications of the microsurgical flap. When we observe, in our clinical practice, the impairment of flap perfusion parameters during the microsurgical procedure after the release of vascular clamps, one of the causative factors is arterial vasospasm with reduced flow to the transplanted tissue and the surgical tactic is the use of topical vasodilators, described in the medical literature and seen in the clinical practice of microsurgeons, with the objective of reducing the risk of anastomotic thrombosis and microcirculation immediately or late, with possible need for revision of the anastomoses, prolongation of the operative time, and increased complications.[20]

Although in the literature there are articles studying the options of vasodilating drugs for use in arterial vasospasm, there are no studies evaluating their effect on venous anastomosis, with venous thrombosis being one of the main complications observed in microsurgical flaps in limbs.[21,22] The comparative evaluation of venous vasodilation in our study did not demonstrate statistically relevant superiority of any of the drugs studied in relation to the control group, with no isolated influence on the success of venous microanastomosis. We emphasize that the main isolated clinical factor for success of microanastomosis is refined surgical technique.[23] We do not recommend the use of drugs to reduce venous vasospasm in our clinical practice.

In our study, the only drug that produced arterial vasodilation with a statistically significant result, when compared to the control group, was 10% Magnesium Sulfate, a drug used in cardiology, neurology and neurosurgery to treat vasospasm; however, its efficacy in microsurgery has not been confirmed.[4,24] In experimental microsurgery, magnesium sulfate is used as a drug with an antithrombotic effect ,[10] its main side effects start at a plasma concentration of 7 Mg/dL^{-1} and there may be electrocardiographic changes and, at higher plasma concentrations, areflexia, apnea and cardiac arrest, when above 24 Mg/dL^{-1}. Its use is safe at doses of 30 to 50 mg/kg intravenously,[24-27] therefore the use of 10% magnesium sulfate in reconstructive microsurgery with topical application of the drug is safe and has a serum concentration well below the safe dose by intravenous administration; however, in vivo studies should be performed to confirm its safety and efficacy in microanastomoses. The choice of drugs and their corresponding doses was based on the best vasodilating outcomes of other studies[4,13,16,28] and on the availability of the drug in our setting. Magnesium sulfate is a drug widely available in Brazil's Unified Health System and is included in the National List of Essential Medicines (RENAME 2022).[29] Papaverine or nitroglycerin are not included in RENAME 2022.

In our daily clinical practice, we routinely use papaverine as an arterial vasodilator after microanastomoses; however, this choice is based on personal choice and previous studies have not demonstrated consensus or level I clinical evidence for the use of vasodilators. Based on this lack of scientific basis to support the choice of the best arterial and venous vasodilating drugs[7,8,9] and the concern with public health care costs, we carried out this work with the inclusion of cost analysis of the drugs tested, all available in clinical-surgical practice. We observed that Magnesium Sulfate was the only drug that presented statistical superiority as an arterial vasodilator when compared to the control group and has an ampoule cost about 15 times lower than papaverine.[14,15] therefore, we suggest further experimental and clinical studies to confirm our results, which may provide sufficient evidence for review of the drug used as the gold standard for vasodilation in microsurgery.

Magnesium Sulfate may be a promising drug in reducing vasospasm in microsurgery, and may have superior effectiveness when compared to currently popular agents in use[7,30] being economically viable and widely available.[29]

The limitations of this study include the costs of drugs and animals for experimental work, being randomized according to the availability for the work, being ideal the inclusion in future studies of a greater number of experimental tests.

CONCLUSION

No drug studied exhibited a better topical vasodilating effect after venous microanastomosis. Magnesium sulfate showed a better arterial vasodilating effect when compared to the control group and the cost of this drug is the lowest among those tested in the Brazilian Health Care System. Further studies are needed to prove clinical evidence of the use of topical vasodilators for the reduction of intra- and postoperative complications of free flaps and microsurgical reconstruction in humans, induced by vasospasm and confirm what would be the gold standard drug for this purpose.

AUTHORS' CONTRIBUTIONS: RPR: Conception, methodology, surgeries, writing of the original article; RBIC: Conception, methodology, review of the original article, statistical analysis, supervision; DYYOA: writing of the original article, cost analysis, statistical analysis; AOSN: academic in scientific training; GBS: Surgeries, animal preparation na supervision of the experimental study in animals; RMJ: Supervision.

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DOI: http://dx.doi.org/10.1590/1413-785220243203e274165

REPLANTATION OF THE THUMB OR REVISION OF AMPUTATION: AN EPIDEMIOLOGICAL STUDY

REIMPLANTE DE POLEGAR OU REVISÃO DA AMPUTAÇÃO: UM ESTUDO EPIDEMIOLÓGICO

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ABSTRACT

Objetive: This article presents a retrospective cohort study analyzing patients from IOT-FMUSP who underwent replantation or revision amputation procedures for traumatic thumb amputation between 2013 and 2020. Methods: The study included 40 patients in the replanted group and 41 patients in the amputed group. The patients were divided according to the level of amputation and their medical records were analyzed. Results: A total of 81 patients with digital amputation were analyzed, consisting of 79 males and 2 females, with mean ages of 43 and 49 for the amputed and replanted groups, respectively. According to the Biemer classification, 28.4% had proximal amputation, while 71.6% had distal amputation. The most common occupation was bricklayer (19.75%), and 80.24% were manual workers. Of the patients, 65% returned to their previous work, with 77.77% of them having amputation on their non-dominant hand, mostly caused by circular saw accidents (77.77%). The replantation success rate was 78%, with an average ischemia time of 9 hours and door-to-room time of 2 hours. Conclusion: the study findings revealed that traumatic thumb amputation predominantly affects working-age males with a low education level and the success rate of replantation was high in this ischemia time and door-to-room conditions. ***Level of Evidence II, Retrospective study.***

Keywords: Epidemiology. Replantation. Thumb. Amputation. Microsurgery.

RESUMO

Objetivo: Este artigo consiste em um corte retrospectivo que analisou vítimas de amputação traumática do polegar submetidas a reimplante ou procedimentos de regularização da amputação no Instituto de Ortopedia e Traumatologia do Hospital das Clínicas da Faculdade de Medica da Universidade de São Paulo (IOT-FMUSP). Métodos: Foram analisados 40 pacientes reimplantados e 41 pacientes regularizados, que foram separados conforme o nível da amputação e, após, tiveram seus prontuários médicos analisados. Resultados: Foram analisados 81 pacientes com amputação digital (79 homens e 2 mulheres), com idade média de 43 anos e 49 anos (Grupo Amputado e Grupo Reimplante, respectivamente) e 28,4% deles tinham amputação proximal, de acordo com a classificação de Biemer, enquanto 71,6% tinham amputação distal. A ocupação mais comum foi a de pedreiro (19,75%), mas 80,24% eram trabalhadores manuais. 65% dos pacientes retornaram ao trabalho anterior. 77,77% dos pacientes afetaram a mão não dominante, e a serra circular causou 77,77% das amputações. A taxa de sucesso para reimplantes foi de 78%. O tempo de isquemia foi de 9 horas e o tempo de porta-quarto foi de 2 horas. Conclusão: O estudo revelou que as taxas de reimplante foram altas nas condições de isquemia e tempo porta-sala, e a maioria dos pacientes vítimas de amputação traumática do polegar são homens em idade de trabalho e com baixa escolaridade. ***Nível de Evidência II, Estudo retrospectivo.***

Descritores: *Epidemiologia. Reimplante. Polegar. Amputação. Microcirurgia.*

Citation: Mattar TGM, Matalani CFA, Silveira HB, Sargaço AK, Pessa MMN, de Pontes FV, et al. Replantation of the thumb or revision of amputation: an epidemiological study. Acta Ortop Bras. [online]. 2024;32(3):Page 1 of 5. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Since the first successful thumb replantation,[1] several authors have reported excellent survival rates,[2,3] in addition to a detailed surgical technique.[4] The initial objective of finger replantation is to maintain the viability of the finger.[5] Another equally important

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

The study was conducted at Universidade de São Paulo.
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Article received on 04/23/2023, approved on 08/01/2023.

objective is to achieve the most satisfactory function. However, replantation is a complex, expensive procedure that requires a high degree of investment on the part of the patient and society.
Amputations of fingers and thumbs are prevalent traumatic injuries affecting North Americans every year. However, replantation rates have gradually dropped in hospitals in the United States of America, due to the challenges of aligning: staff with training in microsurgery, logistics, infrastructure, financial and labor issues.[6,7]
The national literature is scarce in publications of studies on thumb amputation and replantation, with a lack of large series of clinical cases and comparative studies, whether prospective or retrospective.[8] Such studies could better illustrate the national reality, and their findings could be confronted with those reported internationally.
Therefore, we can argue that a descriptive study of thumb replantations and amputations carried out in a large national center with a team trained in Microsurgery, whose patients are part of a different context from other international series of thumb replantations, was necessary.

OBJECTIVE

The objective of this study was to describe the epidemiological data of patients who were victims of traumatic thumb amputation treated at the Institute of Orthopedics and Traumatology of HC-FMUSP through the procedure of replantation or revision amputation of the amputation stump.

MATERIALS AND METHODS

The study carried out consists of a retrospective cohort with cross-sectional analysis of patients from the Institute of Orthopedics and Traumatology of FMUSP, victims of traumatic thumb amputation and submitted to replantation or thumb revision amputation procedures, in their different forms and levels, in the period between 2013 and 2020, after the creation and organization of CEMIM (Center for Emergency Care in Reconstructive Microsurgery and Hand Surgery).
The article had the approval of the Committee of Ethics of IOT-FMUSP and it was registered in the Brazil Platform (CAAE: 56255216.4.0000.0068).

Population studied – Sample Group

After convocation, 81 patients who underwent replantation or amputation of the thumb returned to the outpatient clinic to be evaluated in this research and signed an informed consent form. 40 of these patients underwent thumb replantation (Replanted Group) and 41 underwent thumb amputation with revision of the amputation stump (Amputated Group).

Table 1. Sample Groups

Replanted Group	Amputated group
N=40	N=41

All patients who attended the IOT-HC-FMUSP in response to the invitation to participate in the research and who completed all the evaluations included in the research methodology and signed an informed consent form were included.

Review of medical records and anamnesis

The following parameters were recorded: patient's age at the time of the surgical procedure, gender, presence of comorbidities, trauma mechanism, time elapsed from trauma to assessment, laterality, ischemia time, type of ischemia, door-to-surgical room time, surgical tactic adopted (including graft use and number of repaired structures), presence of intercurrences and patient habits.
Data related to work occupation, manual activities performed before and after surgery and return to work were recorded.
We adopted the Biemer[9] classification to determine the amputation level: Zone 1= nail level; Zone 2 = interphalangeal joint; Zone 3 = proximal phalanx; Zone 4 = Metacarpophalangeal joint; Zone 5 = metacarpus.[9]
We assessed the handedness of the injured thumb and classified distal injuries by unifying Biemer levels 1, 2 and 3 and proximal injuries by unifying Biemer levels 4 and 5.

RESULTS

Of the total number of patients, 79 are male (97.53%) and 2 are female (2.47%). The level distribution of the level of the injury according to the Biemer Classification[9] is shown in Table 2.

Table 2. Distribution of lesion level in patients according to Biemer's classification.

	I	II	III	IV	V	Total
Amputated Group	2	2	20	5	12	41
Replanted Group	3	9	22	3	3	40
Total	5	11	42	8	15	81

Regarding the age of the patients, those who underwent thumb revision amputation had a mean age of 43 years-old and those who underwent thumb replantation had a mean age of 49 years-old (Table 3).

Table 3. Distribution of average, minimum and maximum ages of patients.

	Age (average)	Minimum age	Maximum age
Amputated Group	43 years-old	16 years-old	73 years-old
Replanted Group	49 years-old	21 years-old	71 years-old

The most common occupation of thumb amputation patients was Bricklayer – Construction Assistant (19.75%). At the time of the accident, out of the total number of patients, 80.24% of the patients were manual workers and 7.4% of the patients were retired.
Evaluating Return to Work after the procedure, 28 patients returned to previous work in the Replanted Group (70%) and 25 patients returned to work in the Amputated Group (60.97%) (Table 4).

Table 4. Distribution of patients according to return or absence from work.

	Return to work	Absence from work	Total
Replanted Group	28 (70%)	12 (30%)	40
Amputated Group	25 (61%)	16 (39%)	41
Total	53 (65%)	28 (35%)	81

In terms of education, 53.67% of the patients who underwent thumb revision amputation had incomplete secondary education, and 66.67% of the patients who underwent thumb replantation had incomplete secondary education.
The distribution found for Trauma Laterality is shown in Table 5.

Table 5. Distribution of the affected side and patient dominance.

	Left	Right	Total	Dominant	Non-dominant	Total
Amputated Group	28	13	41	13	28	41
Replanted Group	35	5	40	5	35	40
Total	63	18	81	18	63	81

We found 12 patients with comorbidities in the Replanted Group (8 with Systemic Arterial Hypertension, 3 Diabetes Mellitus, 1 Bowel Neoplasm), and 5 in the Amputated Group (5 Systemic Arterial Hypertension + Diabetes Mellitus). Arterial Hypertension and Diabetes mellitus were the most frequent comorbidities (20.98% of patients).
Evaluating the habits of the patients, we found a percentage of 19.75% of smokers, totaling 16 smokers, 10 in the Amputated Group (24.29%) and 6 in the Replanted Group (15%). The number of alcoholics in the sample was 11 (13.58%), 6 in the Amputated Group (14.63%) and 5 in the Replanted Group (12.5%).
Of the total number of Amputated patients (n = 41), 10 patients were previously submitted to the replantation procedure, but without success. When analyzing all of the cases in this sample that were submitted to replantation with success or not (n = 50), compared with the cases of successful replantation (Group Replanted = 40), we obtained a success rate of 80% of the replantations performed.
Out of the complications observed which led to the loss of the replantation, there were 4 cases of venous congestion (9.76%), 5 of arterial ischemia (12.20%), 2 of distal cutaneous necrosis that evolved into non-viability of the thumb (4.88 %) and 1 late necrosis of the thumb (2.44%).
The most common trauma mechanism was amputation by circular saw (n = 63, 77.77%), with 26 cases of Amputated thumbs (63%) and 37 cases of reimplanted thumbs (92.5%). Trauma mechanisms with worse prognosis (explosion, avulsion and crushing) were more common in the Amputated Group (n = 14) (34.14%) than in the Replanted Group (n = 1) (2.5%).
Ischemia time had an average of 8.72 hours in the Amputated Group (MIN = 4, MAX = 19, SD = 3.83, MD = 8) and an average of 8.81 hours in the Replanted Group (MIN = 3, MAX = 16, SD = 3.15).
Door-to-Surgical Room Time had an average of 2.21 hours in the Amputated Group (MIN = 0.5, MAX = 10, SD = 1.5) and an average of 2.18 hours in the Replanted Group (MIN = 1, MAX = 5, SD = 1.2).
The type of ischemia used to preserve the amputated thumb was warm ischemia in 24 cases (30%) and cold ischemia in 56 cases (70%). In the Amputated Group, there were 31 cases of cold ischemia (75.61%) and 10 cases of warm ischemia (24.39%). In the Replanted Group, there were 25 cases of cold ischemia (64.10%) and 14 cases of warm ischemia (35.9%).
Analyzing the surgical technique in the Replanted Group, 2 venous anastomoses were performed in 17 patients (42.5%), 1 venous anastomosis in 9 (22.5%) and in 14 patients there was no data on the number of veins repaired in the surgical description of the procedure (35%). Two arterial anastomoses were performed in 3 patients (7.5%), 1 arterial anastomosis in 31 patients (77.5%) and in 6 patients (15%) there was no data on the number of repaired arteries noted in the medical records. 2 neurorrhaphy procedures were performed in 18 cases (56.25%), 1 neurorrhaphy procedure in 1 case (37.5%) and 0 neurorrhaphy procedures in 2 cases (6.25%). In only 1 case was a vascular graft used and, likewise, in only 1 case was a nerve graft used.
Most patients were operated on during the Night period (n = 60, 75%). Of the Amputated thumbs, 9 were operated on during the day (21.95%) and 32 at night (78.05%). Of the Replanted thumbs, 11 were operated on during the day (27.5%) and 29 operated on at night (72.5%) (Table 6).

Table 6. Distribution of patients according to the period of care.

	Night duty	Daytime duty	Total
Replanted Group	29 (72,5%)	11 (27,5%)	40
Amputated Group	32 (78%)	9 (22%)	41
Total	61 (75,3%)	20 (24,7%)	81

The average length of hospital stay was 4.68 days in the Amputated Group (MIN = 1, MAX = 21, SD = 5.33), and 6.54 days in the Replanted Group (MIN = 3, MAX = 14, SD = 2, 35).
The average time from the trauma to the functional evaluation in the Amputated Group was 26.27 months (MIN = 12, MAX = 48, SD = 12.08) and in the Replanted Group it was 30.05 months (MIN = 12, MAX = 108, SD = 20.34).

DISCUSSION

After calling the patients submitted to procedures for replantation and revision amputation of the thumb, 81 patients responded to the request, agreed to participate in this research and signed the free and informed consent form. Out of these patients, 41 had been submitted to revision amputation and 40 to reimplantation. This is the largest series of cases that evaluates, in the same time and service, patients with thumb amputation and replantation.
When evaluating our series, we identified that most of our patients were male (79 of the 81 patients). The higher incidence of traumatic thumb amputation in males is notorious, due to a higher prevalence of this injury in manual workers who use industrial machines (circular saw) which offers an increased risk of these injuries.
Regarding the level of the amputation, we observed a higher relative prevalence of levels 2 and 3 of Biemer in the Replanted Group and levels 4 and 5 in the Amputated Group. We can infer that in lesions at level 2 and 3 (near the interphalangeal region of the thumb) replantation is usually possible, and that probably at level 4 and 5 (metacarpophalangeal region or proximal to it) replantation is less indicated because it is related to crushing or avulsion (mechanisms of greater severity). However, when evaluating these data, it was not possible to demonstrate a statistical difference between amputation levels in the Replanted and Amputated Groups. In our series, level 3 was the most frequent in both the Amputated and Replanted Groups, corresponding to more than half of the cases.
When comparing the average age of our series with others published in the literature, we observed that our patients are slightly older than most publications (average 43 years-old in the Amputated Group and 49 years-old in the Replanted Group). Glickman et al[10] found a mean age of 32.5 years-old and Ciclamini et al[11] of 35 years-old. This data is difficult to interpret, however it leads to a reflection on the social conditions of workers in this age group, characteristics of our geographic region (City of São Paulo – Brazil) and of our hospital (university service with high demand for care for patients with high complexity). On the other hand, Chang et al[12] found an age group for digital replantations in Taiwan more frequently between 45 and 54 years old. These authors also observed that machines and motorized manual tools caused 68.8% of digital amputations and that higher rates of replantation attempts occurred in thumb amputations (OR: 1.35; $p = 0.01$), in consultations performed in private hospitals (OR: 1.40; $p = 0.01$), in specialized medical centers (OR: 2.38; $p < 0.001$), in regional reference hospitals (OR: 2.41; $p < 0.001$) and in hospitals with annual volume greater than 20 digital amputations (OR: 4.23; $p < 0.001$).
The most common occupation of thumb amputation patients in our series was Bricklayer – Construction Assistant (19.75%). Of the total number of patients, 80.24% of the patients were manual workers at the time of the accident. At the time of the accident, 7.4% of the patients were retired. Other authors[6,7] draw attention to the incidence of traumatic amputations in the underprivileged population and workers who perform functions related to greater risk. When evaluating the education of our patients, we observed that 53.67% of the patients who underwent revision amputation and 66.67% of the patients who underwent thumb replantation had incomplete secondary education, with no statistically significant difference between the groups, demonstrating a profile like previous literature.

Mahmoudi et al[6] assess that reimplantation rates have gradually fallen in US hospitals, which makes this procedure less accessible to minorities and the vulnerable population. Unfortunately, we can consider that this is a persistent situation in Brazil, where the opportunity for a patient to undergo a replantation procedure in the public system has always been very low. Mahmoudi et al[6] and Hustedt et al[13] suggest that the establishment of regional centers for the referral of complex trauma can considerably increase the success of digital replantation in the United States. These authors consider that patients victims of traumatic amputation treated by a surgeon with a high volume of microsurgical procedures in a high-volume center have a 2.5 times greater probability of obtaining a successful replantation. Brazil does not have a regionalized system for caring for patients who are victims of amputations. There is a great lack of high-volume care centers for procedures in reconstructive microsurgery and there is a lack of public policies in this sector.

Approximately 30 months after the procedure, 28 patients returned to their previous work in the Replanted Group (70%) and 25 patients returned to work in the Amputated Group (60.97%). Janezic et al[14] found a return to the same job as before the thumb replantation procedure in 67% of their patients. Unglaub et al[15] reported that most of their 24 treated patients returned to their previous occupation after thumb replantation. Therefore, our results regarding the return to work are like those found by other authors.

The most common trauma mechanism in our patients was the circular saw (n = 63) (77.77%), with 26 cases of amputated thumbs (63%) and 37 cases of replanted thumbs (92.5%). Trauma mechanisms with worse prognosis (explosion, avulsion and crushing) were more common in the Amputated Group (n = 14) (34.14%) than in the Replanted Group (n = 1) (2.5%). These findings were expected since the mechanism of amputation by circular saw is usually related to a higher rate of indication and success for the replantation procedure. When assessing handedness, 13 patients who underwent revision amputation (31.72%) and 5 who underwent replantation (12.5%) had the dominant side affected. We did not observe studies related to the side and dominance in the literature, but when analyzing our data, we can infer that there is a slightly more frequent occurrence of amputation of the dominant side in cases of revision amputation. Considering that the circular saw was the most frequent mechanism of amputation, mainly in the Replanted Group (92.5%), it is usually the non-dominant side that approaches the machine in a more dangerous way (holding the object to be cut) being therefore the most vulnerable side. The worst prognosis mechanisms (avulsion and crushing), more frequent in the Amputated Group, occur more frequently in the dominant limb. Despite the differences pointed out, it was not possible to demonstrate statistical differences between the groups.

Of all patients, 12 had comorbidities in the Replanted Group (SAH: 8 and DM: 3) and 5 had comorbidities in the Amputated Group (SAH and DM: 5). Hypertension (SAH) and Diabetes Mellitus (DM) were the most frequent comorbidities. Hustedt et al[13] consider that patients with more than 3 comorbidities and those with a history of alcohol abuse, anemia, electrolyte imbalance, obesity, peripheral vascular disease, or psychotic disorders, are at greater risk of replantation failure and post-operative complications.

Assessing the patients' habits, we found 16 smokers (19.75% of smokers), 10 in the Amputated Group (24.29%) and 6 in the Replanted Group (15%). The number of alcoholics was 11 (13.58%), 6 in the Amputated Group (14.63%) and 5 in the Replanted Group (12.5%). Despite the higher prevalence of smokers and alcoholics in the Amputated Group, it was not possible to demonstrate statistical difference between the groups in relation to these variables.

Of the total number of amputated patients (n = 41), 10 were previously submitted to the replantation procedures, but without success in terms of viability. In this series, of the 51 patients who underwent the replantation procedures, 40 were successful. Therefore, in this series we obtained a success rate of 78.43% for thumb replantations performed during the study period. We found a wide variation in the success rate of thumb replantations noted in the medical literature. Schlenker et al[2] reveal a survival rate of 73%, Arakaki and Tsai[16] 71%, Zumiotti et al[17] 68.75%, Mattar Jr et al[8] of 64 % of replantations in amputations caused by avulsion mechanism, Zumiotti et al[17] of 73% of replantations in the topography of the distal phalanx of the thumb, Janezic et al[14] of 66%, Sharma et al[3] of 91.30%, Agarwal et al[18] 92%, Mahmoudi et al[6] 74% between 2004 and 2006, and 65% between 2010-2012. When comparing our data with those in the literature, considering that our service is university-based, with high demand, where replantations are more frequently indicated, our survival rate can be considered like that of most publications.

Out of the complications observed, which led to the loss of the reimplantation, there were 4 cases of venous congestion (9.76%), 5 of arterial ischemia (12.20%), 2 of distal cutaneous necrosis that made the reimplantation unfeasible (4.88%). and 1 late necrosis of the thumb (2.44%). Arakaki and Tsai[16] reported the need for re-exploration in 16.3% of the reimplanted thumbs due to vascular impairment, and nine of these were recovered (45%). Sharma et al [3] emphasize that early re-exploration of vascular problems generates a high recovery rate, and should be performed in all cases, and recommend the use of vein grafts in more severe injuries due to crushing and avulsion. In our sample, the number of arterial and venous vascular complications was similar. Although we constitute a hospital with a high volume of microsurgical procedures, in our series there are no cases of success in re-exploration due to vascular complications. We consider that we have difficulties in carrying out re-explorations in our public service, which faces infrastructure problems.

Ischemia time had an average of 8.72 hours in the Amputated Group (MIN = 4, MAX = 19, SD = 3.83) and an average of 8.81 hours in the Reimplanted Group (MIN = 3, MAX = 16, SD = 3.15). There is no difference between the groups, and this time can be considered adequate for an urban center of a metropolis like São Paulo. However, it is still a long time by international standards, revealing a lack of infrastructure in the care of these patients.

In our series, we found a door-to-surgical room time with an average of 2.21 hours in the Amputated Group (MIN = 0.5, MAX = 10, SD = 1.5) and an average of 2.18 hours in the Replanted Group (MIN = 1, MAX = 5, SD = 1,2). Therefore, we did not observe differences between the groups regarding the waiting time between the patient's arrival at the hospital and the arrival in the operating room. This time of approximately 2 hours and 20 minutes could certainly be reduced with the improvement of the infrastructure in our hospital.

Evaluating our patients, we observed that the ischemia of the amputated part until arrival at the hospital was warm in 24 cases (30%). This data also clearly reveals the lack of adequate infrastructure to the care for this type of trauma in our country.

We can state that the surgical techniques and tactics for treating thumb amputations in our group are standardized and may vary in the indication criteria for the use of vascular grafts and peripheral nerve repair techniques. In most cases, the repair of vascular, nervous, tendinous and osteoarticular system structures depends on the anatomy of the injury and the trauma mechanism. In the group of replanted patients, 2 venous anastomoses were performed in 17 patients (42.5%), 1 venous anastomosis in 9 (22.5%) and in 14 patients (35%) we did not find data in the medical records on the number of veins repaired. Efanov et al[19] draw attention to the fact that all efforts should be made to favor the repair of two veins, since, in this condition, they find a better survival of replanted fingers. The approach adopted in our group is to repair as many vascular structures as possible, whether arterial or venous.

In our patients, 2 arterial anastomoses were performed in 3 patients (7.5%), 1 arterial anastomosis in 31 patients (77.5%) and in 6 patients (15%) we did not find data in the medical records about the number of repaired arteries.

In the same way as Schlenker et al,[2] we used a vein graft connecting the radial artery (proximally) to the thumb arteries (distally) to circumvent a traumatized area in 1 patient. In injuries that do not involve an avulsion mechanism, this procedure may be unnecessary, being bone shortening for bone revision amputation usually sufficient to allow vascular and nerve anastomosis with no tension in preserved and viable structures. This tactic was used in most patients in this study. However, we agree with Barbato and Salsak[4] on the need to follow a flow of procedures depending on the type of traumatic thumb amputation, including the use of anastomosed vascular graft in the amputated segment as the initial procedure in more complex traumatic amputations (especially in avulsion injuries).

In our series, 2 neurorrhaphy procedures were performed in 18 cases (56.25%), 1 neurorrhaphy procedure in 1 case (37.5%) and 0 neurorrhaphy procedures in 2 cases (6.25%). In only 1 case, a vascular graft was used, and in 1 case, a nerve graft was used in the acute phase of reimplantation.

Most of our cases were operated during the Night duty period (n = 61) (75.3%). We can infer that most patients suffer the accident during the day and that, after just over 8 hours of ischemia, they are submitted to the replantation or revision amputation procedure at night. Of the amputated thumbs, 9 were operated on during the day (21.95%) and 32 at night (78.05%). Of the replanted thumbs, 11 were operated on during the day (28.21%) and 28 operated on at night (71.79%), with no statistically significant difference between the groups.

Regarding patient satisfaction with the procedure performed, 32 patients declared themselves satisfied with the revision amputation procedure (72%) and 38 satisfied with the replantation (95%). When comparing the satisfaction index of our patients who underwent thumb replantation with those presented in other publications, we again found similar values.

CONCLUSIONS

The epidemiological data evaluated in this study revealed that most patients who are victims of traumatic thumb amputation are males in working age and with low education level. About 20% of patients have comorbidities. The most frequent amputation level was at the proximal phalanx. More proximal amputations were more frequent in the amputated group. The circular saw was the most frequent mechanism, and the most common occupation was Bricklayer-Construction Assistant. Most amputations occurred in the non-dominant thumb. Ischemia time was approximately 9 hours and door-to-room time 2 hours. The type of ischemia was cold in 70% of patients and hot in 30%. Most replantation and revision amputation procedures occurred during the night duty period (75%). The success rate for replantations was 78%. The most frequent complications were arterial and venous thrombosis (20%). Hospitalization time was approximately 6 days in the replanted group and 4 days in the amputated group. The satisfaction rate was higher in the replanted group (95%) than in the amputated group (78%). Most patients returned to their previous work: 70% in the replanted group and 60% in the amputated group.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. TGM: redação e realização de cirurgias; TH: revisão do artigo e realização de cirurgias; RM: revisão do artigo e realização de cirurgias; MR: revisão do artigo e realização de cirurgias; CFA: redação e análise dos dados; HB: redação e análise dos dados; MMN: aquisição e interpretação de dados; FV: aquisição e interpretação de dados.

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DOI: http://dx.doi.org/10.1590/1413-785220243203e278420

SUPRACONDYLAR FRACTURES IN CHILDREN: A SYSTEMATIC REVIEW OF TREATMENT OPTIONS

FRATURAS SUPRACONDILIANAS INFANTIS: REVISÃO SISTEMÁTICA DE OPÇÕES DE TRATAMENTO

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ABSTRACT

Objective: To compare the outcomes of surgical stabilization of pediatric supracondylar humeral fractures with the use of crossed Kirschner wires versus divergent lateral pinning wires. Methods: This is a systematic review with meta-analysis carried out by searching the MEDLINE/PubMed, Science Direct and Scielo databases. In these, the search for journals was carried out between January and August 2023, where 695 studies were found. To assess the quality of the studies, the Jadad and the MINORS scales were used.. The selection and reading of relevant articles were carried out by the researchers and 11 studies met the selection criteria. Results: From the 11 selected studies, 963 patients who met the criteria for the surgical treatment of these fractures were grouped. After the statistical analysis, we found that the ulnar nerve injury had a higher incidence when the crossed-K wire technique was used; and the lateral fixation is safer for the ulnar nerve. Conclusion: Both fixation techniques determine good functional results. However, fixation with lateral Kirschner wires proves to be safer considering the risk of iatrogenic injury to the ulnar nerve. Crossed-K wire fixation is more effective in terms of stability and maintenance of fracture reduction. ***Level of Evidence II, Systematic Review of Level II or Level I Studies with discrepant results.***

Keywords: *Humeral Fractures. Child. Fracture Fixation. Orthopaedic Fixation Devices. Postoperative Complications.*

RESUMO

Objetivo: Comparar os desfechos da estabilização cirúrgica das fraturas supracondilianas do úmero pediátricas com o uso de fios de Kirschner cruzados versus fios laterais divergentes. Métodos: Trata-se de uma Revisão Sistemática com metanálise realizada pela pesquisa nas bases de dados MEDLINE/PubMed, Science Direct e Scielo. Nessas, a busca dos periódicos foi realizada entre janeiro e agosto de 2023, e foram encontrados 695 estudos. Para a avaliação da sua qualidade, foram utilizadas a escala de Jadad e a escala MINORS. A seleção e a leitura dos artigos pertinentes foram realizadas pelos pesquisadores e 11 estudos preencheram os critérios de escolha. Resultados: Dos estudos selecionados, agrupamos 963 pacientes que preenchiam os critérios para o tratamento cirúrgico das fraturas. Após a análise estatística, observamos que maior incidência de lesão do nervo ulnar quando foi utilizada a técnica de pinagem cruzada; e a fixação lateral demonstrou ser mais segura para tal. Conclusão: Ambas as técnicas de fixação determinam bons resultados funcionais. Entretanto, a fixação com fios de Kirschner laterais demonstra ser mais segura, considerando o risco de lesão iatrogênica do nervo ulnar. A fixação com fios cruzados é mais eficaz, levando em conta a estabilidade e a manutenção da redução das fraturas. ***Nível de evidência II, Revisão sistemática de Estudos de Nível II ou Nível I com resultados discrepantes.***

Descritores: *Fraturas do Úmero. Criança. Fixação de Fratura. Dispositivos de Fixação Ortopédica. Complicações Pós-Operatórias.*

Citation: Higuchi DH, de Oliveira GA, Alves JP, Lebedenco L, Dobashi ET. Treatment of supracondylar fractures of the humerus in children with crossed and lateral kirschner wires: a systematic review. Acta Ortop Bras. [online]. 2024;32(3):Page 1 of 6. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Supracondylar fractures of the humerus (SFH) account for about 3 to 15% of all bone lesions affecting the immature skeleton, especially in children under seven years of age.[1] It is the fracture that most requires surgical treatment in the pediatric population,[2] with an estimated incidence of 1.7 per 1,000 individuals.[3]

In general, these lesions are treated by closed reduction associated with percutaneous fixation with Kirschner wires (KW). This osteosynthesis method offers several configurations that can arrange implants in various ways, typically by cross (two lateral and one medial or one medial and one lateral wires) or lateral entries (three or two divergent or two parallel wires).[4]

Successfully treating pediatric SFH depends on achieving and maintaining an acceptable reduction until the fracture consolidates itself, avoiding potential complications.[5]

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

The study was conducted at Universidade Federal de São Paulo, Escola Paulista de Medicina, Departamento de Ortopedia e Traumatologia.
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Artigo recebido em 09/11/2023, aprovado em 02/16/2024.

Therapeutic advances and improvements in the care of SFH have undoubtedly contributed to the success of the treatment (which depends on obtaining and maintaining an adequate and stable reduction until the fracture consolidates itself).[6]
The possible complications of these fractures especially include nerve and vascular injuries, compartment syndrome, malunion, and functional impairment (including reduced range of motion and angular deformities).[1,5]
Controversy persists regarding the choice of the ideal fixation technique for these fractures. Although the literature describes many pin configurations with KW, the two most common refer to cross-fixation and osteosynthesis with a lateral entry. However, despite its many articles, this review acknowledges the persisting controversies on this topic.[7]
Based on this problem, the authors of this study aim to analyze the existing literature, carry out a secondary systematic review with a meta-analysis, and compare the efficiency of several configurations of osteosynthesis with KW regarding their stability and reduction of complications in pediatric SFH.

METHODOLOGY

This systematic review was carried out with a targeted protocol using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[8]
Primary cross-sectional, cohort, and randomized studies and case reports on the use of wires in children with SFH in all languages that were published in the last 10 years were considered as inclusion criteria.
The guiding question of this research followed the PICO strategy (P – population, I – intervention, C – comparison, and O – outcome).[8] Its study population consisted of children with SFH; its intervention, of osteosynthesis with cross-arranged KW in comparison to other techniques (such as lateral fixation); and its outcome, of consolidation, function, and complication rates. Thus, this study elaborated the following clinical question: "What fixation technique for supracondylar fractures offers the best stability and complication rates?"
Searches were conducted from January to August 2023 on the following databases: Medical Literature Analysis and Retrieval System Online/National Library of Medicine (MEDLINE®/PubMed®), Science Direct, and Scientific Electronic Library Online. Additional searches were performed on the reference list of the studies of interest to refine the search and include research that had been missed.
The search strategy in this study considered descriptors that were selected from the DeCS/MeSH (Descritores em Ciências da Saúde/Medical Subject Headings) in Portuguese and English, which were combined by the Boolean operator AND: "distal humeral fractures" AND "fracture fixation" AND "child" or "humeral fractures, distal" AND "fracture fixation" AND "children."
All retrieved studies were independently evaluated by two authors, who screened them by reading their titles and abstracts. Potentially eligible texts were reviewed and then fully read. Disagreements regarding article choice were solved by a discussion among the involved researchers. However, a third author was consulted to resolve possible discrepancies, whenever necessary.
The quality of the trials was assessed by the Jadad scale[9] for randomized clinical trials and by the Methodological index for non-randomized studies (MINORS),[10] for observational studies.
The data collected during the search were detailed in a spreadsheet in which all the information was made available as tables.

RESULTS

Of the 695 retrieved studies, this research excluded 659 for failing to meet its pre-established inclusion criteria or for being duplicates. Thus, 36 studies underwent a detailed analysis. Finally, the final evaluation included 11 clinical studies: nine from electronic searches, [11-19] and two from manual searches of the references of other articles.[20-21] Figure 1 details the process of sorting the articles in a flow diagram.

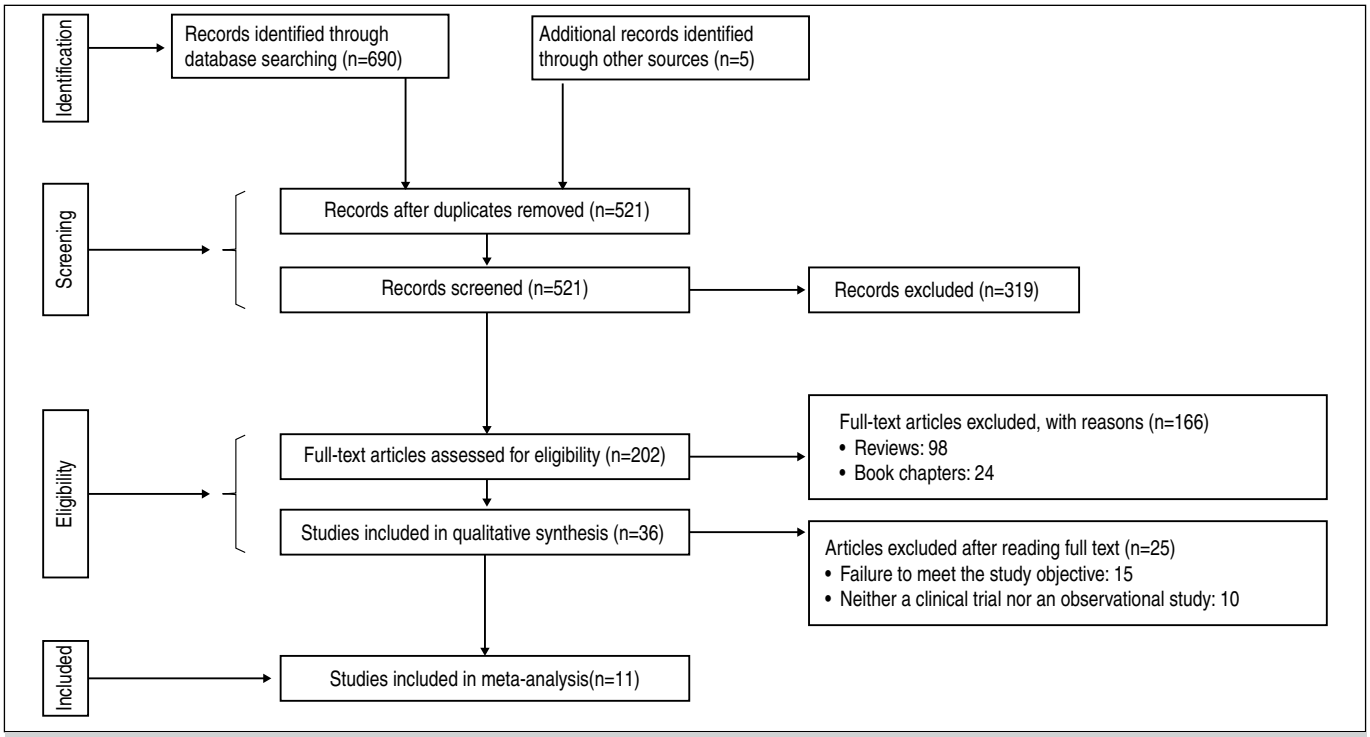

Figura 1. Diagrama de fluxo conforme recomendação PRISMA.

According to Table 1, only Afaque et al.[12] showed good methodological quality in the Jadad scale.[9]

Table 1. Jadad[9] evaluation of the studies.

Jadad Evaluation.[9]	Afaque et al.[7]	Jain et al.[11]	Natalin et al.[12]	Othman et al.[13]
Was the study described as randomized?	1	0	0	0
Was randomization described and was it adequate?	1	1	1	1
Was the study described as double-blind?	0	0	0	0
Was blinding described and was it appropriate?	0	0	0	0
Were losses and exclusions been described?	1	1	1	1
Total:	3	2	2	2

≥ 3: low risk of bias; < 3: High risk of bias.
Source: Jadad et al.[9]

Items on the MINORS[10] scale are rated as 0 (unreported), 1 (reported but inadequate), or 2 (reported and adequate). This analysis showed that Claireaux et al.[11] and Trung et al.[18] obtained the lowest scores (Table 2).

Table 2. Classification of study quality and risk of bias according to the MINORS[21] tool.

Author/ Year	Study follow-up time	MINORS Score[21]
Claireaux et al.[10]	24 weeks	6
Yawar et al.[14]	24 weeks	9
Rutuarama and Firth[15]	24 weeks	12
Trung et al.[16]	48 weeks	6
Agrawal et al.[17]	24 weeks	10
Moratelli et al.[18]	8 weeks	10
Li et al.[19]	60 weeks	11

Source: Slim et al.[10]

Table 3 lists the general characteristics of the studies in this systematic review.

Table 3. Summary of the studies in this systematic review.

Author/ Year	Sample	Type of Fracture	Intervention	Follow-up (weeks)	Outcome
Claireaux et al.[10]	N: 209 patients 52.0% girls 6.4 years on average	Gartland Type II or III	Different diameters Kirschner crossed wires	24	Significant loss of reduction and neurological deficit were observed.
Afaque et al.[7]	N: 84 patients 70.0% boys 6.8 years on average	Gartland Type III	Crossed fixation Lateral fixation	12	Both techniques provided stable fixation and good functional results without iatrogenic injuries to the ulnar nerve.
Jain et al.[11]	N: 168 patients 70.2% boys 6.8 years on average	Gartland Type III	Crossed fixation Lateral fixation	24	Both groups showed a significant loss of range of motion and the cross-fixation group, iatrogenic nerve injuries.
Natalin et al.[12]	N: 43 65.0% boys 6.5 years on average	Gartland Type III	Crossed fixation Lateral fixation	8	Observed neither compartment syndrome, vascular or treatment-related nerve injuries nor pin infections.
Othman et al.[13]	N: 47 Sex: unreported 5.5 years on average	Gartland Type II or III	Dorgan's Cross Lateral Fixation Medial-lateral cross fixation Parallel or divergent side fixation	28	The aesthetic clinical result was satisfactory for the three techniques in more than 90% of the cases.
Yawar et al.[14]	50 patients 52.0% boys 6.3 years on average	Gartland Type II or III	Crossed fixation Lateral fixation	24	Both lateral and crossed wire configurations led to good radiological stability.
Rutuarama and Firth[15]	N: 38 66.0% boys 7.5 years on average	Gartland Type III	Closed reduction and Kirschner crossed percutaneous wires	24	Most children regained full range of motion after closed reduction and fixation of crossed wires without physical therapy.
Trung et al.[16]	N: 42 70.0% boys 6.0 years on average	Gartland Type II or III	Cross-pining technique with a Kirschner wire inserted medially and another laterally	48	Closed reduction and percutaneous fixation proved to be an effective treatment with good therapeutic results.
Agrawal et al.[17]	N: 70 65.4% boys 8.0 years on average	Gartland Type II or III	Closed reduction and fixation by two Kirschner crossed wires.	24	Satisfactory functional results, brief hospital stays, and few complications of percutaneous fixation with Kirshner crossed wires.
Moratelli et al.[18]	N: 129 59.7% boys 6.3 years on average	Gartland Type II or III	Crossed fixation Lateral fixation	8	Lateral or cross fixation and time to surgery failed to influence the functional outcomes of supracondylar fracture in children but lateral fixation decreases the risk of ulnar nerve injuries.
Li et al.[19]	N: 83 73.5% boys 10.0 years on average	Gartland Type III	Small medial approach and cross-fixation with three Kirschner wires.	60	Low incidence of complications in older children.

The sample consisted of 963 children, of whom 453 underwent fixation using the cross-wire technique and 410, osteosynthesis with lateral wires or other techniques. Samples ranged from 38[15] to 209 patients in the included studies.[11] About six articles included Gartland type II and III fractures, whereas five, only type III fractures. Most studies showed a higher prevalence in boys, with percentages ranging from 52.0 to 73.5%.[15-20] Only one study had a higher prevalence of girls(52.0%).[11]

Except for one study,[17] which only used cross-KW, the distribution of fixation techniques ranged from 48.05[11] to 66%[14] for lateral wires and from 34[15] to 51.95% for cross-wire.[12]

Nerve injury incidence reached 11.11% at most in two studies[12,13] and that of infection in pin path, 31.20%[22] in one study and zero in another study.[13] Only one study[21] reported vascular injuries.

All studies employed crossed KW or lateral fixation, with follow-ups ranging from eight to 60 weeks. All studies showed satisfactory results, regardless of osteosynthesis technique. Considering complications, this study highlights the risk of ulnar nerve injuries and loss of reduction.

Statistical analysis first carried out a meta-analysis with studies that included control groups.[7,12-15,19] This model used a meta-analysis of binary outcomes (occurrence or absence of complications in both groups and crossed or side wires). This research considered both common and randomized effects and returned the hazard ratio to compare the chosen studies. The results of this meta-analysis (Figure 2) indicated no differences between the complications in the group that received cross-fixation and that which received lateral fixation (RR 1.19 and 1.24; CI-0.77; 1.9; p = 0.69) and no evidence of heterogeneity between studies (I^2 = 0%, τ^2 = 0).

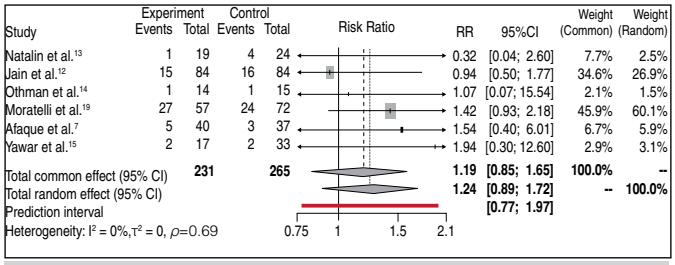

Figure 2. Forest plot showing the proportion of complications between cross and lateral fixation.

The second meta-analysis used individual proportions by combining the proportions or probabilities of an event across studies to calculate an overall proportion or probability. The results of this meta-analysis (Figure 3) indicated differences between the complications in each study (RR 0.22 and 0.17; CI −0.02; 0,72; p = 0.01) and a high evidence of heterogeneity between studies (I^2 = 90%, τ^2 = 1,0751).

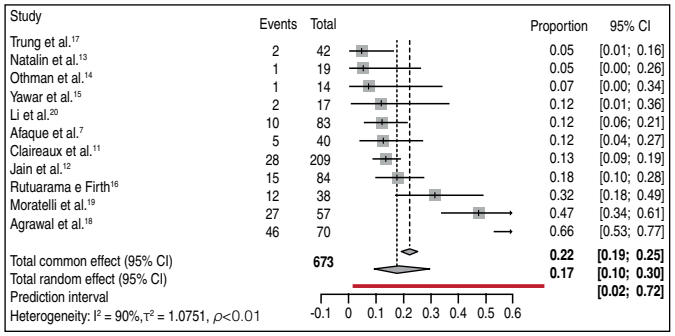

Figure 3. Forest plot showing the proportion of complications in the included studies.

DISCUSSION

The successful treatment of SFH with deviations depends on maintaining an acceptable reduction until the fracture heals, avoiding complications.

Controversy persists regarding the optimal technique of fixation with KW. So, this systematic review was carried out to try to ascertain the most efficient surgical technique of osteosynthesis.

The analysis of the stability of several fixation configurations retrieved the biomechanical study by Zionts et al.,[23] who measured the rotational resistance of the SFH distal fragment by simulating and fixating them in four configurations. The authors concluded that the configuration of crossed wires placed from the medial and lateral condyles configured the arrangement with the greatest mechanical stability. However, two parallel lateral KW could serve to treat significant swelling of the upper limb to be operated despite it being an inferior but acceptable biomechanical option. More recently, Lee et al.[3] used a bone model and concluded that the use of two divergent lateral pins was comparable to crossed wires in extension and varus and valgus loading but would be biomechanically inferior in axial rotation tests. Stability using parallel or divergent lateral fixation can be improved by maximally separating the pins at the fracture site and adding a third pin in the middle in cases of significant movement at the fracture focus. This review considers that inserting KW through the olecranon fossa adds two more cortices, increasing stability.[5]

Other biomechanical studies show that the medial portion of the distal humerus suffers from greater stress and deformation under axial loads than the middle portion. Therefore, the internal rotation of the distal fragment is considered the main factor for varus deformity.[4] Therefore, adequate reduction and stable fixation should be achieved to avoid distal fragment deviation and postoperative deformity.[14] The displacement of SFH is more likely to occur in older children, as shown by some studies.[22]

The most significant findings of this study, considering stabilization with crossed wires, refer to its higher risk of infection and ulnar nerve injuries. However, this technique has greater biomechanical stability. Lateral fixation offers a greater risk of loss of reduction.

These findings resemble those in a systematic review with a meta-analysis by Kwok et al. (which included 11 studies), which reported that lateral fixation is associated with greater loss of reduction and lower risk of iatrogenic ulnar nerve injuries.[6]

However, this review deems that these findings should be carefully interpreted due to the poor methodological quality of most of the included studies and the divergent opinions on this topic. This study found a systematic review with a meta-analysis of randomized clinical trials that aimed to evaluate SFH stabilization techniques considering elbow function, risk of neurological injury, and loss of reduction. It evaluated results for certain aspects that resemble those in this study. It should be noted that this review included studies with a poor methodological quality.[4]

Claireaux et al.[11] found no significant differences in the incidence of neurological deficits and iatrogenic nerve injuries related to the care of patients treated with cross-sectional KW and other techniques. However, they observed that the maintenance of the reduction was significantly better in patients treated with the three Kirschner-wire configuration (two lateral and one medial) than those under other configurations. Moreover, patients treated in this way showed a smaller change in Baumann angle.

Similarly, according to Natalin et al.,[13] 56.0% of patients received fixation with lateral wires and 44.0%, with crossed wires. Overall, four had neurological injuries in their first consultation (which completely and spontaneously regressed during follow-up). Observed neither compartment syndrome, vascular or treatment-related nerve injuries nor pin infections. The authors also found that the elbow flexion

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amplitude decreased in the group of patients who underwent fixation with crossed wires, but no change in the Baumann angle between the different types of fixation.

Afaque et al.[7] also compared cross and lateral fixation and observed no differences regarding radiographic and clinical results between groups. Overall, two patients who underwent cross-fixation developed tardy ulnar nerve palsy. However, after statistical analysis, both techniques provided stable fixation, union, and good functional results without iatrogenic injuries to the ulnar nerve after small incisions were performed to find the medial epicondyle.

Queiroz et al.'s systematic review showed that percutaneous fixation with lateral wires for type II and crossed wires for type III and IV fractures associated with a minimal medial approach to protect the ulnar nerve would offer significantly lower chances of iatrogenic nerve injuries. The longer duration of the procedure configures a disadvantage of medial surgery but fails to discourage this approach due to its greater stability.

On the other hand, Moratelli et al.[19] stated that KW medial fixation increases the risk of ulnar nerve injuries.

Othman et al.[14] evaluated Dorgan's lateral cross fixation by osteosynthesis with medial and lateral cross fixation associated with parallel or divergent lateral fixation. They observed that all three methods stabilized the fracture and maintained reduction. However, lateral pins are safer for the ulnar nerve than medial pins. However, the results by Jain et al.[11] and Moratelli et al.[19] suggest that the cross-fixation method is better than the lateral fixation method. These authors considered biomechanical stability, which avoids secondary angular deviation and the resulting vicious consolidation. However, they mention that the lateral fixation method may be safer as it shows no risk of injury to the ulnar nerve.

Similarly, Yawar et al.[15] found that lateral and crossed wire configurations led to good radiographic stability, preserving the Baumann angle without any loss of reduction or risk of iatrogenic nerve injuries.

Rutuarama and Firth's[16] findings indicate that most children with grade III Gartland SFH completely recovered their elbow range of motion and had good functional results 24 weeks after closed reduction and fixation with percutaneous crossed KW. On the other hand, older children or those with associated neurovascular and soft tissue lesions had poor functional results. Corroborating these findings, Li et al.[20] found that open reduction by a medial approach and cross-fixation with three KW for severely displaced type III Gartland fractures is safe and effective, with a low incidence of complications in older children.

Agrawal et al.[18] found that infection in the pin path (31.2%) and pin malposition (27.8%) were the most frequent complications. However, after wire removal, a daily periodic dressing and the use of appropriate oral antibiotic therapy helped treat infections. Trung et al.[17] reported that some patients had secondary osteomyelitis and iatrogenic injuries of the ulnar nerve due to cross-pinning. According to Moratelli et al.[19] loss of reduction (3.9%) and iatrogenic ulnar nerve palsy (2.3%) occurred after fixation with crossed pins

Iatrogenic nerve injuries may stem from local irritation, pressure, twisting or penetration of the medial pin, iatrogenic constriction of the cubital tunnel by a medial pin, and nerve transection.

Thus, some surgical techniques can reduce the rates of ulnar nerve injury associated with medial fixation. Initially, inserting the lateral pin enables elbow extension to a flexion below 90° so that the ulnar nerve can be displaced in a more posterior direction before the insertion of the medial pin. A small incision over the medial epicondyle serves to isolate the ulnar nerve, especially under pronounced swelling.[6,14,20,24] Ultrasound-guided intervention and intraoperative nerve monitoring[13-15] are also mentioned as options. However, this review stresses that the analysis the overall probability of iatrogenic nerve injuries (including the radial and median nerves) shows an about 2% probability of neural damage even under a lateral entry point for KW affixation. This can occur due to the reduction maneuver and the penetration of the pins through the medial or anterior cortex.

This study has a number of limitations, some of which are inherent to all systematic reviews. The studies in this review show methodological variations, including fixation techniques between and in studies; various institutions, and surgeons' particularities. Clearly defined technical guidance and precise adherence to certain principles, such as making a small incision and ensuring that a medial KW is inserted directly into the bone, can determine the lowest likelihood of iatrogenic nerve injuries. Careful placement of lateral entry pins, proper fixation of all three columns, bicortical fixation, and fluoroscopy can provide a lower rate of fracture displacement after fixation. Most included studies used retrospective case series with weaker empirical evidence than randomized controlled trials or prospective studies. Moreover, improvements in surgical techniques and radiographic technology likely affected results. The limited number of studies with a greater degree of scientific relevance negatively affected this research.

This review agrees with Avenkar et al.[21] and Wang et al.[24] who stress the common frequency of complications after SFH in children. Moreover, Rutuarama and Firth[16] emphasize that these fractures can cause physical disability in children due to such potential complications.

CONCLUSION

The articles this review analyzed and included showed that both cross and lateral fixation techniques provide good functional results but fixation with lateral wires more safely avoided ulnar nerve injuries, whereas fixation with crossed wires more effectively maintained this reduction, conferring greater stability in infantile SFH.

Despite the findings of this study, the definition of the best method of fixation of these fractures in children (whether with crossed or lateral KW) remains uncertain. Thus, this review stresses the need for more randomized clinical trials to analyze the EXISTING osteosynthesis techniques and determine the best treatment for these fractures. Level of Evidence I, systematic review.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. DHH; GAO; JPA; LL and ETB.

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