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ACTA ORTOPÉDICA BRASILEIRA

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

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Levels of Evidence for Primary Research Question[a]

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

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

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

SUMMARY

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COMPARATIVE ANALYSIS OF THE EFFECTIVENESS OF CLINICAL DATA COLLECTION THROUGH ONLINE AND PHYSICAL ELECTRONIC QUESTIONNAIRE IN ORTHOPEDIC PATIENTS

ANÁLISE COMPARATIVA DA EFETIVIDADE DA COLETA DE DADOS CLÍNICOS POR MEIO DE QUESTIONÁRIOS ELETRÔNICOS ONLINE E FÍSICOS EM PACIENTES ORTOPÉDICOS

Andre Vitor Kerber Cavalcanti Lemos[1], *Lucas Plens de Britto Costa*[1], *Eduardo Souza Maciel*[1], *Nacime Salomão Barbachan Mansur*[1], *Moises Cohen*[1]

1. Universidade Federal de Sao Paulo, Centro de Traumatologia do Esporte, Departamento de Ortopedia e Traumatologia, Sao Paulo, SP, Brazil.
2. Hospital Israelita Albert Einstein, Grupo de Ortopedia Pediatrica, Sao Paulo, SP, Brazil.

ABSTRACT

The collection of clinical data is an essential step for the development of any scientific research. Online digital data collection can optimize this step. Objective: To compare the response rate and the accuracy of the clinical data collection date through the online and physical digital questionnaire in orthopedic patients. Methods: Comparative study, level III of evidence, with forty patients who had ankle sprains were evaluated, followed up for a period of 12 weeks with the application of physical and digital Visual Analogue Scale, Foot Function Index and Cumberland Ankle Instability Tool questionnaires, and data were collected about the moment of collection of each questionnaire. Results: We obtained a response rate of 83.3% in the digital collection group and 60% in the physical collection group ($p < 0.05$), and the response rate in the digital collection group was higher at all times of collection (3, 6 and 12 weeks). Analysis of the time of collection shows greater variability in the larger physical collection group at all times of the study (2.8 vs 1.5; 4.0 vs 2.4; 8.6 vs 1.5). Conclusion: Digital data collection is effective for obtaining clinical data in patients with ankle sprains. ***Level of Evidence III, Comparative, Prospective, Longitudinal Study in Parallel Groups.***

Keywords: Sprains and Strains. Ankle. Internet. Data Collection.

RESUMO

A coleta de dados clínicos é etapa essencial para o desenvolvimento de qualquer pesquisa científica, e a coleta de dados digital online pode otimizá-la. Objetivo: Comparar o índice de resposta e a precisão da data de coleta de dados clínicos por meio de aplicação de questionário digital online e físico a pacientes ortopédicos. Métodos: Estudo comparativo realizado com 40 pacientes que apresentaram entorse de tornozelo, acompanhados pelo período de 12 semanas, com aplicação dos questionários escala visual analógica, foot function index e Cumberland ankle instability tool físicos e digitais. Além disso, foram recolhidos dados sobre o momento da coleta dos questionários. Resultados: Obtivemos índice de resposta de 83,3% no grupo de coleta digital e 60% no grupo de coleta física ($p < 0,05$), sendo que o índice de resposta no grupo de coleta digital foi maior em todos os momentos de coleta (3, 6 e 12 semanas). A análise do momento da coleta apresenta maior variabilidade no grupo de coleta física em todos os momentos do estudo (2,8 vs 1,5; 4,0 vs 2,4; 8,6 vs 1,5). Conclusão: A coleta de dados digital é efetiva para a obtenção dos dados clínicos de pacientes que apresentam entorse do tornozelo. ***Nível de Evidência III, Estudo Comparativo, Prospectivo, Longitudinal em Grupos Paralelos.***

Descritores: *Entorses e Distensões. Tornozelo. Internet. Coleta de Dados.*

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INTRODUCTION

The collection of clinical data is an essential step for the development of any scientific research[1,2]. However, the loss of data from clinical follow-up in research is a concern in the literature, occurring in up to 89% of studies, and in around 48% of these studies, data loss greater than 10%[1-3] was reported. Recruiting patients to research centers to obtain this data can represent a great difficulty in some situations, especially when collecting frequent or long-term data.[3,4]

The use of information technologies such as the internet can optimize the application of questionnaires, reduce the time to obtain data and reduce the loss of follow-up data.[5-11] The use of these questionnaires

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

The study was conducted at Universidade Federal de Sao Paulo, Centro de Traumatologia do Esporte, Departamento de Ortopedia e Traumatologia.
Correspondence: Andre Vitor Kerber Cavalcanti Lemos. Rua Estado de Israel, 636, Sao Paulo, SP, Brazil, 04022001. cirurgiaodope@gmail.com

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has already been validated in clinical research[12] and presents reliable information,[10,13-16] and can even be used in orthopedic patients.[17-21] Ankle sprains are among the most prevalent injuries in the population,[22,23] account for up to 14% of emergency consultations, and have a high impact on the healthcare system[24] in addition to progressing to chronic ankle instability in up to 30-40%.[25,26]. Adequate clinical follow-up of these patients is important to assess the possible unfavorable evolution of the condition,[27,28] although it is common for patients themselves to abandon orthopedic follow-up early, as soon as their pain improves.[26]

The objective of this study is to compare the proportion of responses to the self-administered questionnaires Visual Analogue Scale (VAS),[29] FFI (Foot Function Index)[30] and CAIT (Cumberland Ankle Instability Tool)[31] in two different ways: physically at a medical appointment and applied with a digital online form remotely.

METHODS

A comparative, prospective, longitudinal study in parallel groups, approved by the Research Ethics Committee of the Universidade Federal de São Paulo (CEP-UNIFESP) and included in Plataforma Brasil under number 1541/2018, following the recommendations of Strengthening the Reporting of Observational Studies in Epidemiology – STROBE. The study was carried out at the Centro de Traumatologia Esportiva of the Departamento de Ortopedia e Traumatologia (DOT-UNIFESP).

Patients with acute ankle ligament sprain/injury (< 15 days) between July and October 2018, with clinical signs of ankle ligament injury, aged between 14 and 65 years, were included. Exclusion criteria were fractures or previous surgeries on the affected limb, associated injuries, difficulty accessing the internet, difficulty understanding the questionnaires, refusal to participate in the study or not agreeing with the consent form, signs of reflex sympathetic dystrophy. Regardless of the group selected for follow-up, all patients followed the same treatment protocol: protection of the limb with immobilization with a semi-rigid ankle brace for a period of 6 weeks, use of analgesic medication as necessary and early rehabilitation.

Patients were instructed on how to use the ankle brace (with socks and lace-up sneakers, nighttime use, and removal only for bathing), relative rest (for heavy physical and work activities) and outpatient follow-ups at 3, 6 and 12 weeks. The patient was allowed partial or total weight bearing with immobilization, as tolerated by the pain, and instructed to begin rehabilitation with physiotherapy, which should be maintained over the 12 weeks.

Physical/in-person questionnaire group

The first 20 patients included had their data collected through physical questionnaires from the initial assessment to the proposed final follow-up.

This first group responded to questionnaires during outpatient follow-ups scheduled at 3 weeks, 6 weeks and 12 weeks after their initial trauma. At the 3-week follow-up, the VAS and FFI questionnaires were applied, with a tolerance of 1 week (14 to 28 days post-sprain) for data collection. At the 6-week follow-up, the tolerance for data collection was 2 weeks (29 to 56 days post-sprain). At the 12-week follow-up, the tolerance for data collection was set at 3 weeks (63 and 105 days post-sprain). At that moment, in addition to the application of the VAS and FFI, the patient was instructed to answer the CAIT questionnaire. Whenever the patient had an appointment scheduled, attempts were made to contact them by phone and texting to remind them of the appointment.

Online questionnaire group

The subsequent 20 patients had their data collected through online questionnaires from the initial assessment to the proposed final follow-up. Patients filled out the online questionnaire in the presence of the researcher, during the initial assessment, so that any doubts regarding completion or access could be clarified.

They were informed that they would receive links via cell phone message via the WhatsApp® application or SMS, in addition to an email message, with access to online digital questionnaires on the date to be answered through a cell phone, tablet or computer. When the response to the digital questionnaire was not observed on the set date, patients were contacted via telephone calls or new messages. Patients received a reminder by texting and email on the exact days they completed 3, 6 and 12 weeks, with links to access the questionnaires. Responses were considered valid only when they respected the tolerance periods determined for data collection, similar to the physical data collection group.

Patients selected for the digital questionnaire group responded using an online form created for the study, containing exactly the same questions as the physical questionnaires, with the possibility of answering via smartphone or computers connected to the Internet. In the 3-week and 6-week messages, patients received the following attached link: https://goo.gl/forms/vedkf1SkK982YqF03.

The questionnaire developed on Google Forms for free is a combination of VAS and FFI (translated into Portuguese), in addition to basic identification data (full name, date of birth and email), partially shown here in Figures 1, 2 and 3. In the 12-week message, in addition to the above-mentioned link, patients received the following link: https://goo.gl/forms/Sia2Iy62wbRF51jx2, which gives access to the questionnaire also developed on Google Forms, with the CAIT questions (translated into Portuguese) partly shown here in Figure 4

Statistical analysis was carried out with parametric tests using the

Figure 1. Online questionnaire – identification

Figure 2. Online questionnaire – VAS

<< SUMÁRIO

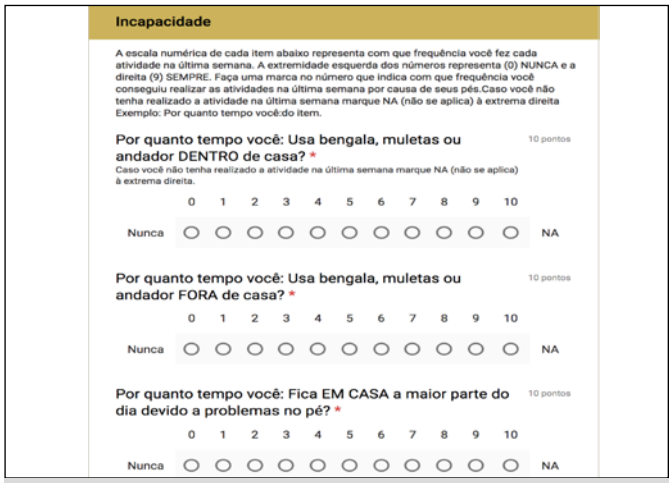

Figure 3. Online questionnaire – FFI (part).

Figure 4. Online questionnaire – CAIT (part).

programs SPSS V20, Minitab 16 and Excel Office 2010, having established a significance level of 5% ($p < 0.05$), and adjusted confidence interval (95% CI).

RESULTS

Comparison of response rates

In the digital collection group, responses were collected in 50 (83.3%) of the 60 possible questionnaires, while in the physical collection group the response rate was 36 (60%) of the questionnaires ($p = 0.005$). When segmenting the analysis of the response rate, we noticed that, at the three moments, it was always higher for the Digital Collection group, but statistically significant only in the 6-week collection (80% for digital collection versus 50% for physical collection, $p = 0.047$) (Table 1).

Comparison of days for data collection

When evaluating the collection day for each questionnaire, we analyzed the collection days in relation to the proposed ideal day. We observed that the mean collection day is very close to the ideal collection day in both groups. The Mann-Whitney test did not indicate any difference in group means, as observed in Table 2. When analyzing the appropriate patterns, we noticed that these, at all times of collection, are higher in the physical collection group, which means a greater variability of days in relation to the ideal collection day. With this observation, we performed the homoscedasticity analysis. When comparing the variability of collection days between the groups in relation to the ideal day, we observed that there is a difference in the variability of collection days between the groups at 3 weeks ($p = 0.003$) and also at 12 weeks ($p < 0.001$) (Table 3).

Table 1. Response rates.

Collection days	Digital collection		Physical collection		P-value
	N	%	N	%	
3 weeks	18	90%	13	65%	0.058
6 weeks	16	80%	10	50%	0.047
12 weeks	16	80%	13	65%	0.288
Total	50	83.3%	36	60%	0.005

Table 2. Compares groups for "collection days" by moment.

Collection days		Mean	Median	Standard deviation	N	P-value Group
3 weeks	Digital collection	21.5	21	1.5	18	0.663
	Physical collection	22.2	23	2.8	13	
6 weeks	Digital collection	42.3	43	2.4	16	0.669
	Physical collection	41.9	42	4.0	10	
12 weeks	Digital collection	84.7	85	1.5	16	0.387
	Physical collection	83.2	81	8.6	13	

Table 3. Compares groups for "collection days" variability

Collection days		Mean	Standard deviation	P-value
3 weeks	Digital collection	21.5	1.54	0.003
	Physical collection	22.2	2.82	
6 weeks	Digital collection	42.3	2.39	0.071
	Physical collection	41.9	4.01	
12 weeks	Digital collection	84.7	1.54	<0.001
	Physical collection	83.2	8.57	

Patient evolution

No statistically significant differences were found in the VAS, FFI and CAIT measurements between the physical and online collection groups. Regarding the evolution of scores in each group, we concluded that there was a significant reduction in the VAS and a significant progressive increase in the FFI in both groups, in a similar way between them.

DISCUSSION

Our study compared data collection from online digital questionnaires and physical questionnaires in orthopedic patients. Despite the advantages of using technology to collect clinical data, these tools are little explored in developing countries,[32] including Brazil. Data collection rates were found to be higher when using online digital questionnaires (83.3%) compared to data collected in physical questionnaires (60%). This finding contradicts studies that compare the application of online and in-person physical questionnaires,[33,34] which present mean response rates of 33% and 56%, but none of these studies was carried out in the context of medical monitoring, with the physical questionnaire being applied upon follow-up visits. A possible explanation for the advantage of the online digital questionnaire in our study is the fact that it increases the opportunities to respond to the questionnaire, since the patient could answer

it at any time, and from anywhere with internet access, in addition to new messages being sent in the absence of responses. On the other hand, the response to the physical questionnaire was necessarily carried out during the follow-up visit.

Many factors can influence response rates to questionnaires administered over the Internet, and we observed that depending on the methodology used, these can be very low.[33] In our study, we obtained a response rate of 83.3% to the online questionnaire, and the questionnaire was sent to patients who were undergoing orthopedic treatment for a recent injury, and reminder messages were used. Strategies to increase response rates to online questionnaires have already been found to be effective in previous studies[33] and were used in our study.

In the literature, improvements in obtaining data with online questionnaires had already been observed in studies with geographic obstacles and in remote areas.[9,10] In our study we noticed that routine problems in large urban centers can also make it difficult to carry out face-to-face interviews.

A high rate of abandonment of conservative treatment for ankle ligament injuries is already known in the literature,[22,28] and this may be a factor that has influenced the low response rate to the physical questionnaire.

A new finding from our study was the reduction in the variability of collection dates, providing greater precision in dates using the internet. We found a decrease in standard deviation by 45% (2.8 to 1.54) in week 3, by 40% (4.01 to 2.39) in week 6 and by 82% (8.57 to 1.54) in week 12, and this piece of data is still little explored in the literature. A likely explanation for this reduction in the variability of the collection date in the online digital group is the fact that collection can be carried out on any day, including weekends and holidays, while outpatient data collection depends on the flexibility of the schedule of research centers and researchers.

In our study, we did not find any impact on the comparative evaluation of results between groups regarding the variability of the day on which the questionnaires were collected. Probably, the fact that the average collection dates were close to the ideal date minimized possible changes that could appear in the results. The improvement in collection precision may represent a benefit in the quality of the data obtained, but further studies are needed.

As described in the literature, data collection through digital and physical questionnaires does not significantly alter the results of the data obtained.[13,14] The similarity between the data collected can also be observed when comparing the evolution of VAS and FFI scores between the groups. As previously reported in the literature,[35,36] we described a high rate of residual symptoms in patients with ligament injuries treated with immobilization, which in our study was observed by the CAIT score (mean 22 in the digital group and 20.33 in the physical group) of the injured ankles after 12 weeks of treatment.

The CFM regulation, through resolution number 2,227/2018, allowed health care to make use of advances in technology, and defined telemedicine as the provision of technology-mediated medical services.[37] However, many questions and suggestions for changes were sent to the CFM, which revoked this resolution for a more in-depth study of the topic.[38] With the occurrence of the COVID-19 virus pandemic, this discussion was expanded, and in 2022 the practice of telemedicine was again regulated by the CFM.[39]

Our study's strong point is the observation of the practical effectiveness of successfully using DRPs to collect data with online questionnaires in orthopedic patients.

Negative points are the lack of data collection regarding the reason for loss of follow-up in both groups, difficulty in analyzing the impact of the variability of collection days on the results of the DRPs, and the lack of randomization for assigning patients to the groups.

A future objective is to create an automated tool for collecting follow-up data on orthopedic patients, which could facilitate data collection by reducing errors in filling out questionnaires and increasing precision at specific moments in the follow-up.

CONCLUSION

The use of online digital questionnaires is effective for data collection and can be useful for orthopedic patients' clinical follow-up.

Using the internet not only optimizes information collection but can also increase data accuracy by reducing time of collection variability.

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CLINICAL AND FUNCTIONAL COMPARISON OF TWO DIFFERENT FIXATION TECHNIQUES IN ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION: ALL-INSIDE VERSUS ANTEROMEDIAL

COMPARAÇÃO CLÍNICA E FUNCIONAL DA RECONSTRUÇÃO DO LIGAMENTO CRUZADO ANTERIOR COM DUAS TÉCNICAS DE FIXAÇÃO DIFERENTES: PORTAL ANTEROMEDIAL VERSUS *ALL-INSIDE*

Gökhan Polat[1], *Serkan Bayram*[1], *Önder İsmet Kiliçoğlu*[1]

1. Istanbul University, Istanbul Faculty of Medicine, Department of Orthopaedics and Traumatology, Istanbul, Turkey.

ABSTRACT

Objective: To compare the clinical and functional outcomes of two different graft fixation methods, all-inside and anteromedial (AM), for single-bundle anterior cruciate ligament (ACL) reconstruction techniques. Methods: Comparing the mid-term results of two groups, the prospectively recorded data of patients diagnosed with isolated ACL rupture between 2015 and 2016 were reviewed retrospectively. Two groups of patients who underwent unilateral isolated ACL reconstruction via two different tibial fixation techniques (19 patients with all-inside [Group 1]; 20 patients with AM portal [Group 2]) from the same institution were enrolled as the study group. The patients were called for the final follow-up and evaluated for symptoms, knee stability (Lachman test, pivot shift test, and KT-1000 arthrometer analysis), and functional scores (Tegner and Lysholm knee scoring scale, International Knee Documentation Committee [IKDC] subjective knee score, and visual analog scale [VAS]). Results: The mean age and follow-up period were statistically equal between the two groups. The functional comparison of patients with Tegner and Lysholm knee and IKDC scores, showed no statistical difference at the mid-term follow-up period. In the clinical assessment of the operated knees, based on the Lachman test and KT-1000 arthrometer, the anterior translation results in group 1 were better than those in group 2, which was statistically significant. However, we obtained similar pivot shift test results in both groups. Conclusion: The study showed that ACL reconstruction via the all-inside had functionally better anterior translation and similar rotational stability results compared with the AM portal technique. ***Level of Evidence III, Case Control Study.***

Keywords: Anterior Cruciate Ligament. Knee Joint. Physical Functional Performance. Lysholm Knee Score. Joint Instability.

RESUMO

Objetivo: Comparar desfechos clínicos e funcionais de dois métodos de fixação do enxerto, all-inside e anteromedial (AM), em técnicas de reconstrução do ligamento cruzado anterior (LCA). Métodos: Comparação dos resultados de médio prazo de dois grupos, os dados obtidos prospectivamente de pacientes diagnosticados com ruptura isolada do LCA entre 2015 e 2016 foram retrospectivamente analisados. Dois grupos de pacientes submetidos à reconstrução unilateral isolada do LCA por duas diferentes técnicas de fixação tibial (19 pacientes por all-inside [Grupo 1]; 20 pacientes por portal AM [Grupo 2]) da mesma instituição foram registrados como grupo de estudo. Os pacientes foram convocados para o último acompanhamento e avaliados sobre sintomas, estabilidade do joelho (teste de Lachman, teste de pivot-shift, e análise com artrômetro KT-1000), e escores funcionais (escore de Tegner e Lysholm para joelho, escala subjetiva de joelho do International Knee Documentation Committee (IKDC), e escala visual analógica [EVA]). Resultados: A idade média e período de acompanhamento foram estatisticamente iguais entre os dois grupos. A comparação funcional de pacientes pelos escore de Tegner and Lysholm para joelho e do IKDC, não revelou diferenças estatísticas no acompanhamento de médio prazo. Na avaliação clínica dos joelhos operados, baseada no teste de Lachman e no artrômetro KT-1000, os resultados de translação anterior no grupo 1 foram melhores do que os do grupo 2, o que foi estatisticamente significante. Entretanto, obtivemos resultados similares do teste de pivot-shift em ambos os grupos. Conclusão: O estudo mostro que a reconstrução do LCA pela técnica all-inside apresentou melhor translação anterior functional e resultados de estabilidade rotacional similares aos da técnica do portal AM. ***Nível de Evidência III, Estudo de Caso Controle.***

Descritores: *Ligamento Cruzado Anterior. Articulação do Joelho. Desempenho Físico Funcional. Escore de Lysholm para Joelho. Instabilidade Articular.*

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INTRODUCTION

Reconstruction of the anterior cruciate ligament (ACL) is one of the most common surgeries in sports medicine, and it has undergone numerous innovations over time for better clinical results via different fixation materials and techniques. The literature describes many arthroscopic ACL reconstruction techniques and graft fixation materials.[1] Despite the many graft fixation materials, such as cross pin, interference screws, etc., cortical suspensory fixation devices

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The study was conducted at Istanbul University, Istanbul Faculty of Medicine.
Correspondence: Serkan Bayram. Çapa Fatih Istanbul, 34093, Turkey, 34093. dr.serkanbayram89@gmail.com / serkan.bayram@istanbul.edu.tr

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have superior biomechanical properties, especially for soft tissue grafts, and are currently the most common femoral fixation implants used.[2] The current consensus is that anatomic ACL reconstruction is the main factor for successful ACL reconstruction.[3-6] However, tibial fixation of the ACL graft is still controversial.

In standard ACL reconstruction with femoral cortical suspensory devices, soft tissue graft is fixated by an interference screw and a common secondary fixation with a staple, a post-tibial screw, or an anchor.[7] This fixation was criticized due to its potential to push the graft material to the tibial tunnel that may loosen the final ACL graft tension or its insufficient fixation strength that may loosen the graft in the rehabilitation period.[8] Some authors identified this limitation as the cause for mild laxities after ACL reconstruction using this method.[9,10] All-inside ACL reconstruction technique became popular for enabling suspensory device fixation in the tibial side. However, ideal tension of the graft is still controversial, and flexibility or elasticity of the graft is another factor considered during ligamentization of the ACL graft. The literature presents no evidence that the cortical suspensory tibial fixation method prevents mild laxities and has superior clinical outcomes.

This study aimed to compare the clinical and functional outcomes of two different tibial graft fixation methods via all-inside and anteromedial (AM) single-bundle ACL reconstruction techniques.

METHODS

Study design

We retrospectively reviewed the prospectively recorded data of patients diagnosed with isolated ACL rupture, who underwent surgery between January 2015 and December 2016 at a single institution, and 40 patients were enrolled in our study group. A patient from the all-inside group was excluded due to unfollow, resulting in 19 patients in all-inside and 20 patients in AM portal groups included in our study group. The institutional review board approved this study (2017/6). The procedures were explained in detail to all the patients, and written informed consent was obtained.

Inclusion criteria: Primary ACL reconstructions using ipsilateral hamstring autografts for isolated unilateral ACL rupture in skeletally mature patients.

Exclusion criteria: Patients with associated meniscal injury for repair requirement, collateral ligamentous injury, posterior cruciate ligament injury, posteromedial or lateral corner injury, associated fractures involving lower limb injuries, significant arthritis, and other articular diseases were excluded from the study.

All surgeries were performed by two surgeons specialized in sports medicine. The surgical technique was selected based on the medical insurance of patients with the same diagnostic instability criteria, such as positive instability tests (Lachman, anterior drawer, and pivot shift tests) and magnetic resonance imaging findings. In the all-inside reconstruction group (Group 1), only the semitendinosus (ST) tendon was harvested and prepared as four strands with both femoral and tibial sides fixated with adjustable cortical suspensory fixation button (TightRope™, Arthrex, Naples, FL, USA). In the AM portal group (Group 2), both ST and gracilis tendons were harvested, and the tendons were prepared as five strands to thicken the autograft. In this group, the femoral side was fixated with an adjustable cortical suspensory device (Ultra-Button, Smith&Nephew, USA), and the tibial side was fixated with an absorbable interference screw and an additional staple or post-screw. In both groups, the femoral and tibial tunnels were prepared according to the anatomic single-bundle ACL reconstruction, with anatomical footprints of the native ACL as reference.[11]

The patients were followed up with the same postoperative physiotherapy protocol. Full load bearing, quadriceps strengthening, and range of motion exercises were immediately started on the first day with closed chain exercises for 3 months. The patients were allowed to participate in sports at the 6th postoperative month.

Outcome measures: Patient demographics, preoperative Tegner and Lysholm knee scoring scale,[12] International Knee Documentation Committee (IKDC) subjective knee score, and visual analog scale (VAS) scores were noted with patient folder, surgery record, and arthroscopy file with retrospective analysis.

All the patients were called for study and underwent functional tests using KT-1000 arthrometer and functional scores. At the last follow-up, all the patients were asked for any symptom regarding knee stability and evaluated for stability of the reconstructed ACL via Lachman and pivot shift tests performed by the same surgeon. To evaluate anterior translation laxity, KT-1000 arthrometer was used (MEDmetric, San Diego, California, USA). This instrument quantifies anterior and posterior tibial dislocation in relation to the femur in the lateral plane by applying a tension system (67 N, 89 N, and 134 N) with quantification of anterior tibial translation.[13] The measurements registered (in mm) were seen through a viewer. The number corresponding to the difference between the operated and unaffected limbs was considered as the degree of knee ligament laxity, and normal values reach up to 3 mm.

At the last follow-up, all patients were examined, and the same author documented the results of the instability Lachman and pivot shift tests according to the KT-1000 arthrometer analysis and modified IKDC criteria (Grade 0 = negative; Grade 1 = subtle glide, but not negative; Grade 2 = glide, Grade 3 = between grades 2 and 4; Grade 4 = clunk; Grade 5 = between grades 4 and 6; Grade 6 = gross).[14] In KT-1000 arthrometer analysis, the operated and contralateral limbs were compared in pairs of repeated tests, with three values for each tension in each knee. The difference in tension for each knee was acquired by subtracting the values for the operated knee from the contralateral knee.

Statistical analyses

All statistical analyses were performed using the SPSS version 24.0 statistics software program (IBM Corp, 2011, Armonk, New York, USA). Student's t-test and Mann-Whitney U test were used to compare the two groups of quantitative data with normal and non-normal distribution, respectively. Pearson's chi-squared test, Fisher-Freeman-Halton exact test, and Fisher exact test were used to compare qualitative data, with significance level set *a priori* at $p < 0.05$, which was considered to be statistically significant. Preoperative demographic data of the groups, including age, graft diameter, preoperative VAS, and functional scores, were compared with Student t-test. Pre- and postoperative functional results were compared with paired t-test, whereas the results between the two groups were compared with Student's t-test. Sample size was not calculated due to the retrospective nature of this study. However, a *post hoc* power analysis showed > 80% power for the subgroup comparisons.

RESULT

The mean age of the patients in the all-inside group (Group 1) was 25.5 ± 7.2 (16–39) years with a mean follow-up of 54.5 ± 5.2 (36–50) months. The mean age of the patients in the AM group (Group 2) was 24.6 ± 6.8 (15–38) years with a mean follow-up of 56.3 ± 5.8 (36–60) months. The mean age and follow-up showed no statistical difference between the two groups.

The mean size of ACL graft was 8.19 ± 0.48 (7.5–9) mm and 7.96 ± 0.39 (7.5–8.5) mm for the all-inside and AM groups, respectively. It showed no significant difference between the two groups.
When each group was compared internally regarding the preoperative status of patients, both groups of patients showed a statistically significant improvement in function. However, functional scores were not significantly different between the two groups (Table 1).
The patients had no complaints or symptoms at the last follow-up. In the clinical assessment of patients in the all-inside group based on the modified IKDC criteria, 9 patients had grade 0 (negative) pivot shift, and 10 patients had grade 1 laxity (subtle glide). By contrast, 5 patients had grade 0 (negative) pivot shift, and 15 patients had grade 1 laxity (subtle glide) in the AM portal group. The pivot shift test results were not statistically different between the two groups ($p > 0.05$). In the clinical assessment of patients in the all-inside group based on the Lachman test, 15 patients had grade 0 laxity (< 3 mm translation), and 4 patients had grade 1 laxity (3–5 mm translation). However, grade 1 laxity was noted compared with the non-operated extremity in all patients in the AM portal group. The results of the all-inside group were better than those in the AM portal group, with statistical significance ($p = 0.027$). The difference in anterior translation for each knee was obtained by subtracting the values for the operated knee from the contralateral knee by using the KT 1000 arthrometer. The 67 N evaluation showed a difference of 0.775 and 1.133 mm from the contralateral knee in the all-inside and AM groups, respectively ($p = 0.038$). The 89 N evaluation showed a difference of 0.8583 and 1.3333 mm from the contralateral knee in the all-inside and AM groups, respectively ($p = 0.035$). The 134 N evaluation showed a difference of 1.4217 and 1.5667 mm from the contralateral knee in the all-inside and AM groups, respectively ($p = 0.0453$). The all-inside group has better anterior translation results compared with the anteromedial group, which was statistically significant in all strength tests (67 N, 89 N, and 134 N) (Table 2).

DISCUSSION

The most important finding of this study was that tibial fixation with adjustable cortical suspensory device via all-inside ACL reconstruction technique had better clinical results regarding anterior translation compared with the interference screw fixation via AM portal technique.

Table 1. Preoperative and postoperative functional results of both groups.

Functional scores	Technique		Mean	Min-Max	Standard deviation	p-value
VAS score	All-inside	Preoperative	5	4-6	0.73855	0.746
	AMP		5.2	4-7	0.88372	
	All-inside	Postoperative	1	0-2	0.60302	0.821
	AMP		1.1	0-2	0.70373	
Subjective IKDC score	All-inside	Preoperative	39.75	25-44	5.13942	0.829
	AMP		37.90	21-50	7.27393	
	All-inside	Postoperative	92.84	88-96	2.15130	0.973
	AMP		90.28	83-96	4.29272	
Tegner Lysholm Knee Scoring Scale	All-inside	Preoperative	43	26-61	10.75343	0.982
	AMP		46.20	26-63	11.71202	
	All-inside	Postoperative	96.25	90-100	3.10791	0.605
	AMP		93.40	76-100	5.65433	

Min: minimum; Max: maximum; AMP: anteromedial portal group.

Table 2. Comparison of KT-100 arthrometer test at tensions of 67 N, 89 N, and 134 N between two groups.

KT-1000	Technique	N	Mean	Standard deviation	p-value
67 N	All-inside single bundle	19	0.775	0.48265	0.038*
	Anteromedial portal single bundle	20	1.1333	0.74322	
89 N	All-inside single bundle	19	0.8583	0.75252	0.035*
	Anteromedial portal single bundle	20	1.3333	0.75277	
134 N	All-inside single bundle	19	1.4217	0.89082	0.0453*
	Anteromedial portal single bundle	20	1.5667	0.97223	

* $p < 0.005$.

The current consensus is that an anatomic ACL reconstruction is the main factor for successful ACL reconstruction, and anatomic single-bundle ACL reconstruction with hamstring autografts has achieved very satisfactory results in clinical and functional aspects and has become the most commonly used surgical technique in most countries.[10] Cortical suspensory devices are the most commonly used implants for femoral fixation in these reconstructions due to superior biomechanical properties, especially for soft tissue grafts.[7] In standard ACL reconstruction with femoral cortical suspensory devices, soft tissue graft is fixated to the tibial tunnel via an interference screw and a common secondary fixation with a staple, a post-tibial screw, or an anchor.[8,9] This fixation was criticized for its potential to push the graft material to the tibial tunnel that may loosen the final ACL graft tension or its insufficient fixation strength that may loosen the graft in the rehabilitation period.[10] Some authors identified this limitation as cause for mild or residual laxities after ACL reconstruction using this method.[15,16] The all-inside ACL reconstruction technique provides an alternative tibial fixation for solving this problem in addition to lower donor site morbidity due to enabling reconstruction with single ST tendon. The all-inside reconstruction technique has better biomechanical results in cadaveric studies, and these advantages have made this technique more popular.[17-19] No evidence shows that cortical suspensory tibial fixation method prevents mild laxities and has superior clinical outcomes compared with interference screw fixation.
Discussions regarding residual laxity following an ideal anatomic ACL reconstruction were focused on the state of secondary stabilizers, such as the anterolateral ligament, meniscal deficiencies, and focused on the graft and ligamentization process during rehabilitation.[16] The current literature shows hamstring autograft as the most common graft used due to its low rate of donor site morbidity and good functional results. In the technical aspect of using soft tissue grafts, such as hamstrings, graft preconditioning has been recommended to remove graft elongation.[20] Despite the recommendation, discussions regarding the amount of applied force and preconditioning time are ongoing.[21]
Ligamentization of the ACL graft is mostly affected by isometry of the reconstruction. To achieve a functional ACL reconstruction and prevent recurrent instability, the final graft tension should not be loose after fixation to maintain stability during the ligamentization period.[22] However, the ideal graft tension is still unknown.[23] Possible risks of graft loosening in the rehabilitation period may have pushed surgeons to use a more tensioned final graft. However, this may cause premature graft rupture or possible secondary ligamentization problems.[24]
Although some studies showed that all-inside ACL reconstruction had good to excellent clinical and functional results, few studies compared these results with interference screw fixation.[25] In this study, the authors compared the functional results of the two groups

of patients with a follow-up of 6 months. With this short-term follow-up, they reported better IKDC subjective knee score, Lysholm knee score, Knee Society scores (KSS), and better Lachman test results in the all-inside group compared with the AM portal group. In our study, both groups had similar functional results with a mean follow-up for the all-inside and AM portal groups, respectively. Similarly, the all-inside group had better anterior translation results, not only with the Lachman test, but also with KT-1000 arthrometer analysis.

The complication rate of all-inside ACL reconstruction was reported at 5.89% in the literature, which was comparable to the other arthroscopic ACL reconstruction techniques.[24] In our study, no major complications required additional surgery or further hospitalization in any group. Similar minor complications were observed in the early follow-up period in both groups ($p > 0.05$). Two patients in the all-inside group had synovitis, whereas one patient in the AM portal group had donor site hematoma not requiring further intervention. Therefore, a single hamstring tendon harvest provides sufficient length to serve as the autograft when quadrupled.[8] However, expensive implant cost and insufficient tendon length (due to the creation of four-fold grafts) are the disadvantages of this technique. The main purpose of ACL reconstruction studies was to investigate function recovery and residual laxity. Kouloumentas et al.[25] reported a large series comparing the all-inside technique for ACL reconstruction by using a short, quadrupled ST tendon (ST4) autograft and suspensory cortical fixation on both femoral and tibial sides compared with a semitendinosus/gracilis (ST/G) autograft fixed with a suspensory device on the femoral side and with an interference screw on the tibial side. In that study, they found no significant differences in the anterior tibial translation between the operative and non-operative knees between the two groups. However, Bressy et al.[26] reported significant residual laxity in 35 patients with 19 months of follow-up, which was attributed to using adjustable loop cortical button. In this study, the all-inside group had less translation in the AM group, but no significant differences were found. The most important finding of this study was that ACL reconstruction with the all-inside technique showed similar improvements in subjective scores and knee stability evaluated at 45 months compared with the AM portal single-bundle ACL technique.

The other main subject was reporting functional result of the clinical study. Buchner, Schmeer and Schmitt[27] reported that the Lysholm score showed good and very good results in 85% of patients, with a mean of 83.6%, and normal or near normal results on the IKDC score in 85% of patients. Benea et al.[5] reported the results of 56 and 23 patients treated with the all-inside and other classical techniques, respectively. In that study, they found that the pain level in the all-inside group seemed lower than that in the classical group. In their most recent study, Kouloumentas et al.[25] reported the results of 90 patients randomized into two groups of 55 patients treated using the all-inside and conventional ACL techniques, respectively, and who were prospectively followed. At 24 months, the Lysholm, IKDC, Knee and Osteoarthritis Outcome Score (KOOS), and KSS scores between the two groups were similar. This study compared the functional scores, Tegner, VAS, and IKDC scores. Both groups showed a significant improvement in all subjective scores postoperatively. However, functional scores were not significantly different between the two groups.

The study had some limitations. First, this is a retrospective, case-control study with a small number of patients. However, all patients were operated by same surgeons and followed up in the same institution. Second, information in the literature is limited, and the mean follow-up of this study was one of the longest follow-up periods, at 44 months. Nevertheless, more detailed data could be obtained with a prospective randomized controlled trial.

CONCLUSION

Surgeons are still searching for advances in ACL reconstruction for better functional results. Many surgeons think that tibial fixation is the drawback of ACL reconstruction, and the all-inside ACL reconstruction technique has closed this gap. This study found that ACL reconstruction via the all-inside technique had functionally better anterior translation results compared with the AM portal technique with tibial interference screw fixation. However, based on the pivot shift tests, the rotational stability of the patients was similar in both groups. Despite the better anterior translation results with the all-inside technique, prospective randomized clinical trials on larger series of patients should be performed to determine the clinical importance of these results.

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DO OLDER PATIENTS "WARN" THAT THEY WILL SUFFER A NEW FRACTURE?

O PACIENTE IDOSO "AVISA" QUE VAI SOFRER UMA NOVA FRATURA?

Samuel Bichara Melin[1], *Marcela Rodrigues Santos do Nascimento*[1], *Alfredo dos Santos Netto*[2,3], *Caio Zamboni*[2,3]

1. Santa Casa de Misericordia de Sao Paulo, Department of Orthopedics and Traumatology, Sao Paulo, SP, Brazil.
2. Santa Casa de Misericordia de Sao Paulo, School of Medical Sciences, Sao Paulo, SP, Brazil.
3. Santa Casa de Misericordia de Sao Paulo, Department of Orthopedics and Traumatology, Trauma Surgery Group, Sao Paulo, SP, Brazil.

ABSTRACT

Objective: To evaluate whether patients older than 60 years admitted for fracture treatment had a history of previous fracture, a diagnosis of osteoporosis, or were under treatment for bone fragility. Methods: Retrospective study including 100 patients older than 60 years with fracture. Fracture location, bone densitometry within the past two years, previous diagnosis and osteoporosis treatment, and previous fracture within the past five years were assessed. Using Fisher's test, it was evaluated whether there was an association between previous fracture and osteoporosis treatment. Results: The most prevalent fracture was in the proximal femur (48%). Of the patients, 18% had fracture in the last five years, with 22% of them diagnosed with osteoporosis, and 22% under treatment. Previous fracture in the last five years was not associated with having a diagnosis of osteoporosis, having had bone densitometry, or being under treatment for osteoporosis. Conclusion: Among patients with previous fracture, only 22% were aware of their diagnosis of osteoporosis, and less than 25% of them were under bone fragility treatment. Previous fracture in the past five years had no association with having a diagnosis of osteoporosis, having had bone densitometry, or being on osteoporosis treatment. ***Level of Evidence III, Retrospective Study.***

Keywords: Osteoporotic Fracture. Osteoporosis. Aged. Secondary Prevention.

RESUMO

Objetivo: Avaliar se os pacientes com mais de 60 anos internados para tratamento de fraturas têm história de fratura prévia, diagnóstico de osteoporose ou se estão em tratamento para fragilidade óssea. Métodos: Estudo retrospectivo que inclui 100 pacientes maiores de 60 anos com fratura. Avaliamos a localização da fratura, a densitometria óssea nos últimos dois anos, o diagnóstico e os tratamentos anteriores de osteoporose, assim como a presença de fratura prévia nos últimos cinco anos. Através de testes de Fisher avaliamos se houve associação entre fratura prévia e tratamento de osteoporose. Resultados: A fratura mais prevalente foi na extremidade proximal do fêmur (48%). Do total de pacientes, 18% tiveram fratura nos últimos cinco anos, sendo que 22% deles tinham diagnóstico de osteoporose e 22% estavam em tratamento. Fratura prévia nos últimos cinco anos não teve associação com diagnóstico de osteoporose, realização de densitometria óssea ou tratamento para osteoporose. Conclusão: Entre os pacientes com fratura prévia, apenas 22% estavam cientes do diagnóstico de osteoporose, e menos de 25% deles estavam em tratamento para fragilidade óssea. Não houve associação de fratura prévia nos últimos cinco anos com diagnóstico de osteoporose, realização de densitometria óssea ou tratamento para osteoporose. ***Nível de Evidência III, Estudo Retrospectivo.***

Descritores: *Fraturas por Osteoporose. Osteoporose. Idoso. Prevenção Secundária.*

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INTRODUCTION

Population's aging is a worldwide phenomenon. This trend leads to a greater concern with diseases related to this age group, including osteoporosis,[1] a disease characterized by decreased bone mass and deterioration of the microarchitecture of bone tissue, with a consequent increase in fragility.[2,3]

Osteoporotic fractures produce serious physical and psychological consequences, affect the quality of life of patients with osteoporosis and their caregivers, and have a high socioeconomic impact. Among these, proximal femur fractures bring with them high morbidity and mortality.[3-5] When individuals suffer their first fracture caused by fragility, they are diagnosed with "established osteoporosis." From this

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Correspondence: Samuel Bichara Melin. Dr. Cesário Mota Júnior, 112, Sao Paulo, SP, Brazil, 01221-010. samu_melin@hotmail.com

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moment it is known that the risk of a new fracture increases considerably compared with patients without previous fracture, emphasizing the importance of osteoporosis treatment in these patients.[2,5-10] However, the lack of diagnostic accuracy and guidance of appropriate osteoporosis treatment remain high, even in patients who have already had a first osteoporotic fracture.[5,7,10-13]

Objectives

Our primary objective was to evaluate whether patients aged over 60 years hospitalized for surgical treatment of fractures had a history of previous fracture in the last five years, and if so, whether they had a diagnosis of osteoporosis or were undergoing treatment to reduce bone fragility. Our secondary objectives were to perform an epidemiological characterization of these patients. In addition, we evaluated whether patients with a history of previous fracture had a greater association with awareness of osteoporosis diagnosis, if they had undergone bone densitometry in the last two years, and were undergoing some type of specific treatment, we compared these data with patients who did not suffer previous fractures.

METHODS

This is a retrospective cohort study, in which, after approval by the Ethics Committee on Research in Human Beings of the Irmandade da Santa Casa de Misericórdia de Sao Paulo (CAAE: 65619717.1.0000.5479), we evaluated the cases of patients aged over 60 years and diagnosed with fracture, hospitalized for surgical treatment at the Department of Orthopedics and Traumatology of Santa Casa de Misericórdia de São Paulo from January 2021 to December 2021.

After excluding cases of fracture in cancer patients and patients who were unable to answer the questionnaire or who refused to sign an informed consent form, 100 patients were included in the study. The questionnaire applied to the patients included the following information: age, sex, location of the fracture, mechanism of the trauma, place of the fall that resulted in the fracture, performance of bone densitometry in the last two years, previous diagnosis of osteoporosis, use of medications for treating osteoporosis (vitamin D, calcium, and bisphosphonates), previous fracture in the last five years, and the location of such fracture.

The evaluated characteristics were described with absolute and relative frequencies for all older adults evaluated. We also evaluated, using Fisher's exact tests,[14] whether a previous fracture was more associated or not with being aware of the diagnosis of osteoporosis, whether bone densitometry was performed in the last two years and whether the patient is undergoing some type of supplementation with calcium, vitamin D, or bisphosphonate treatment.

The analyses were performed with the IBM-SPSS software for Windows version 22.0 and tabulated with the Microsoft-Excel 2010 software, and the tests were performed with a 95% significance level.

RESULTS

Table 1 shows the detailed description of the data of the 100 patients evaluated. The most prevalent age group was aged from 71 to 80 years (39%). Most participants were females (65%), and the most prevalent fracture was that of the proximal femur (48%), followed by fractures in the distal radius (13%) and proximal humerus (12%). The most frequent trauma mechanism was falling at ground level at home (54%), and the bedroom and bathroom were the rooms with the highest number of accidents (31.5% and 27.9%, respectively). Among the 100 patients (100), only 13% underwent bone densitometry in the last two years, and less than 20% of the patients were being treated with calcium, vitamin D, or bisphosphonates. Only 16% of the patients in our series had a diagnosis of osteoporosis, 16% were under calcium supplementation and 12% were under vitamin D supplementation.

Table 1. Description of the characteristics evaluated for all patients.

Characteristic	Description (N = 100)
Age (years)	
61 to 70 years	33 (33.0)
71 to 80 years	39 (39.0)
> 80 years	28 (28.0)
Sex	
Female	65 (65.0)
Male	35 (35.0)
Fracture	
Clavicle	1 (1.0)
Spine	1 (1.0)
Elbow	6 (6.0)
Distal femur	1 (1.0)
Proximal femur	48 (48.0)
Leg bones	1 (1.0)
Patella	1 (1.0)
Distal tibia	1 (1.0)
Distal radius	13 (13.0)
Sacrum	2 (2.0)
Proximal tibia	2 (2.0)
Ankle	11 (11.0)
Proximal humerus	12 (12.0)
Trauma mechanism	
Fall at ground level at home	54 (54.0)
Fall at ground level on the street	32 (32.0)
Run over by a vehicle	9 (9.0)
Fall of the ladder	5 (5.0)
If a fall at home, which room?*	
Living room	12 (22.2)
Bedroom	17 (31.5)
Bathroom	14 (25.9)
Kitchen	7 (13)
Backyard	4 (7.4)
Bone densitometry in the last two years?	
No	87 (87.0)
Yes	13 (13.0)
Previous diagnosis of osteoporosis?	
No	84 (84.0)
Yes	16 (16.0)
Calcium supplementation	
No	84 (84.0)
Yes	16 (16.0)
Vitamin D supplementation	
No	88 (88.0)
Yes	12 (12.0)
Bisphosphonate treatment	
No	95 (95.0)
Yes	5 (5.0)
Any fractures in the last five years?	
No	82 (82.0)
Yes	18 (18.0)
Which previous fracture?*	
Distal radius	4 (22.2)
Proximal humerus	2 (11.1)
Proximal humerus	7 (38.9)
Other	5 (27.8)

Data expressed as n (%); * Only for valid cases.

<< SUMÁRIO

Among the 100 patients, 18 had previous fractures in the last five years, and the most common were proximal femur (7) and distal radius (5). Among these patients, only 22% had a previous diagnosis of osteoporosis, and less than 25% of them were under calcium (16.7%) or vitamin D (22.2%) supplementation, and none were under bisphosphonate treatment (Table 2).

Previous fracture in the last five years had no statistically significant association with awareness of the diagnosis of osteoporosis, having undergone bone densitometry in the last two years, and undergoing some type of treatment with calcium, vitamin D, or bisphosphonate ($p < 0.05$).

DISCUSSION

The fractures most commonly associated with bone fragility are fractures at the proximal femur, vertebral body, proximal humerus, and distal radius.[9] The most prevalent fracture among our patients was the fracture in the proximal femur and the most frequent trauma mechanism was the fall at ground level at home, with the bedroom and bathroom as the rooms with the highest number of falls. The literature series corroborate our findings that the most common trauma mechanism of these fractures is the fall at ground level at home.[1,3,4,15] Note that the number of fractures of the distal radius was lower than expected, but we noticed that many patients were excluded from the study for being under 60 years of age.

We followed the cases of patients aged over 60 years hospitalized for surgical treatment of fractures in our service for one year. During this period, we had 48 cases of fracture in the proximal femur, a lower number than that presented in other series in the literature that followed similar cases for the same period in the same service.[1,4] One of the possible explanations for this is the social isolation caused by the COVID-19 pandemic. Silva et al.[16] showed a significant reduction in the incidence of hip fractures in individuals aged over 60 years in Brazil during the social isolation due to COVID-19.

Table 2. Description of the cases that had a previous fracture, without statistical association with awareness of the diagnosis of osteoporosis, having undergone bone densitometry in the last two years, and undergoing some type of treatment with calcium, vitamin D, or bisphosphonate.

Parameter	Any fractures in the last five years?		p
	No (N = 82)	Yes (N = 18)	
Bone densitometry in the last two years?			0.699
No	72 (87.8)	15 (83.3)	
Yes	10 (12.2)	3 (16.7)	
Previous diagnosis of osteoporosis?			0.480
No	70 (85.4)	14 (77.8)	
Yes	12 (14.6)	4 (22.2)	
Calcium supplementation			> 0.999
No	69 (84.1)	15 (83.3)	
Yes	13 (15.9)	3 (16.7)	
Vitamin D supplementation			0.221
No	74 (90.2)	14 (77.8)	
Yes	8 (9.8)	4 (22.2)	
Bisphosphonate treatment			0.582
No	77 (93.9)	18 (100)	
Yes	5 (6.1)	0 (0)	

Data expressed as n (%); Fisher's exact test

Only 13% of our patients underwent bone densitometry in the last two years. This data draws our attention, since the decrease in bone mass is happening silently and therefore an active search should be made evaluating patients over 60 years, especially females.[3] The low rate of diagnosis and specific treatment for osteoporosis evinced leads us to a serious problem. Vitamin D plays an important role in calcium metabolism and, consequently, in bone mineralization and osteoporotic conditions. Its deficiency is, therefore, an important risk factor for fractures in older adults. Its use has been recommended as a way to prevent fractures in older adults with osteoporosis.[15] However, this is not always routinely performed in public health, as our findings confirm. Guerra et al.[15] showed that patients with fractures at the proximal femur had significantly reduced serum vitamin D levels compared with patients without fractures of the proximal femur.

Patients aged over 60 years with any fracture have a 50% to 100% higher risk of having another fracture in the future, and the occurrence of fracture at the proximal femur increases the risk of subsequent fracture by six times.[5] In our series, 18% of the patients had a previous fracture in the last five years, and 38% of them were in the proximal femur. Only 22% of them were aware of the diagnosis of osteoporosis, and less than 25% of them were on calcium or vitamin D supplementation, with none of them taking bisphosphonate. Previous fracture in the last five years was not associated with awareness of the diagnosis of osteoporosis, having undergone bone densitometry in the last two years, or undergoing some type of drug treatment or specific supplementation.

These findings are worrisome and demonstrate that the treatment of osteoporosis in patients after fracture, despite the numerous publications warning about the subject in the literature, remains less than ideal.[5,7,10,12,13,17]

A possible explanation for this fact is the low participation of orthopedists in the treatment of osteoporosis. Although orthopedists identify osteoporosis after a fracture, the disease is often treated by other physicians such as generalists, gynecologists, rheumatologists, endocrinologists, and geriatricians. The lack of involvement of orthopedists can be attributed to their reluctance to take responsibility for a chronic disease, their focus on treating the consequences of the disease rather than its causes, or, more possibly, a lack of knowledge about treatment. Zamboni et al.[13] showed that less than half of orthopedists and traumatologists in Brazil make the diagnosis and secondary prevention for osteoporotic fractures, only 0.8% treat these patients correctly, and 47% refer them to clinical specialties. Studies show that the involvement of orthopedic surgeons improves osteoporosis treatment rates.[7]

We believe that the results of this study, which are in line with the literature, show a continuous loss of health promotion opportunity, failing to prevent new fractures in older patients, a situation that, unfortunately, remains common in our health system.

A possible solution is to draw the attention of orthopedic surgeons about the importance and relevance of the topic, and reinforce that they should not only treat the fractures of these patients, but also start the treatment of osteoporosis to prevent new ones.

CONCLUSION

In this study, 18% of patients had a previous fracture in the past five years, with only 22% of them being aware of the diagnosis of osteoporosis, and less than 25% of them were being treated with calcium or vitamin D, with none taking bisphosphonate. The most prevalent fracture was the proximal femur fracture and the most frequent trauma mechanism was the fall at ground level at home,

with the bedroom and bathroom as the rooms with the highest number of accidents. Only 13% of patients underwent bone densitometry in the last two years, and less than 20% were being treated with calcium, vitamin D, or bisphosphonates. Previous fracture in the last five years was not associated with awareness of the diagnosis of osteoporosis, having undergone bone densitometry in the last two years, or undergoing some type of treatment for bone fragility with calcium, vitamin D, or bisphosphonate.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. SBM, MRSN: data collection and bibliographic research; ASN, CZ: review of the article and intellectual concept.

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DISTAL FEMUR HEMIEPIPHYSIODESIS IN KNEE RECURVATUM: A NEW SURGICAL TECHNIQUE

HEMIEPIFISIODESE DO FÊMUR DISTAL NO JOELHO RECURVATO: NOVA PROPOSTA CIRÚRGICA

Nei Botter Montenegro[1], *Talissa Oliveira Generoso*[2], *Bárbara Lívia Corrêa Serafim*[1], *Amâncio Ramalho Júnior*[2]

1. Universidade de Sao Paulo, Faculdade de Medicina, Hospital das Clinicas, Instituto de Ortopedia e Traumatologia IOT HCFMUSP, Grupo de Ortopedia Pediatrica, Sao Paulo, SP, Brazil.
2. Hospital Israelita Albert Einstein, Grupo de Ortopedia Pediatrica, Sao Paulo, SP, Brazil.

ABSTRACT

Introduction: The genu recurvatum is characterized by a hyperextension deformity of the knee in the sagittal plane. Among its causes are conditions such as arthrogryposis, cerebral palsy, poliomyelitis, sequelae of tibial tuberosity fracture and some syndromes with generalized joint hypermobility. Treatment of this deformity can be challenging and, to date, aggressive methods such as femur or tibial osteotomies are the most used for its correction. Objective: This study aimed to describe a new surgical technique for correcting genu recurvatum. Methods: This is a prospective clinical study of children who underwent posterior hemiepiphysiodesis of the distal femur with transphyseal screws. Results: The approach proved to be safe and useful for genu recurvatum deformities, with femoral or articular apex. Conclusion: This approach shows great potential for correcting genu recurvatum in the developing skeleton, being an excellent alternative to the more aggressive methods currently used to treat this deformity. ***Level of evidence IV, Case Series.***

Keywords: Bone Retroversion. Orthopedic Procedures. Minimally Invasive Surgical Procedures. Knee Joint. Growth and Development. Growth Plate.

RESUMO

Introdução: O joelho recurvato é caracterizado por uma deformidade em hiperextensão do joelho no plano sagital. Entre suas causas, estão condições como artrogripose, paralisia cerebral, poliomielite, sequelas de fratura da tuberosidade da tíbia e algumas síndromes com hipermobilidade articular generalizada. O tratamento dessa deformidade pode ser desafiador e, até o momento, métodos agressivos como osteotomias do fêmur ou da tíbia são os mais utilizados para sua correção. Objetivo: Descrever uma nova técnica cirúrgica de correção do genu recurvatum. Métodos: Estudo clínico prospectivo de crianças submetidas à hemiepifisiodese posterior do fêmur distal com parafusos transfisários. Resultados: A técnica se mostrou segura e útil para as deformidades em recurvato do joelho, com ápice femoral ou articular. Conclusão: Essa técnica apresenta grande potencial de correção do joelho recurvato no esqueleto imaturo, sendo uma excelente alternativa aos métodos mais agressivos atualmente utilizados para o tratamento dessa deformidade. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Retroversão Óssea. Procedimentos Ortopédicos. Procedimentos Cirúrgicos Minimamente Invasivos. Articulação do Joelho. Crescimento e Desenvolvimento. Lâmina de Crescimento.*

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INTRODUCTION

Genu recurvatum, also known as knee recurvatum, is characterized as a hyperextension deformity of the knee in the sagittal plane and, when left untreated, is associated with short- and long-term complications such as joint pain and early gonarthrosis. At the extreme end of the spectrum, there may even be anterior dislocation of the knee.[1-3]

Congenital recurvatum, an uncommon deformity of the knee in children, is caused by conditions such as arthrogryposis,[4] cerebral palsy,[5-7] poliomyelitis, sequelae of tibial tuberosity fractures,[8,9] and some syndromes with generalized joint hypermobility.[1,10]

It is important to note that the treatment of genu recurvatum is challenging. When the deformity is significant and surgical correction

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

The study was conducted at Universidade de Sao Paulo, Faculdade de Medicina, Hospital das Clinicas, Instituto de Ortopedia e Traumatologia IOT HCFMUSP and Hospital Israelita Albert Einstein.
Correspondence: Nei Botter Montenegro. Rua Domingos Lopes da Silva, 800, apt. 91, Sao Paulo, SP, Brazil, 05641030. neibottermontenegro@gmail.com
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is indicated, soft tissue surgical procedures can be used, such as quadricepsplasty[11] and hamstring lengthening,[6,12] as well as osteotomies of the distal femur and proximal tibia with internal[13] or external[14-16] fixation to correct bone alignment. The surgical procedures mentioned above are aggressive and require a long recovery time, in addition to risks such as neurovascular injury, compartment syndrome, and infections.

In this context, in search of less aggressive methods with excellent potential for correcting this angular deformity, we used guided growth with posterior hemiepiphysiodesis of the distal femur to correct recurvatum. This article presents a surgical technique using two transphyseal cannulated screws inserted into the posterior portion of the distal femoral physis and the clinical and radiographic results of three patients treated with this method.

METHODS

Casuistry

Three patients were treated, totaling four knees with genu recurvatum, three on the left side and one on the right side. Two had arthrogryposis multiplex congenita (one patient with bilateral recurvatum and one with unilateral recurvatum) and one had a unilateral deformity caused by joint hypermobility.

All the patients' legal guardians signed an informed consent form before the surgical treatment and the procedures followed the norms of the Human Research Ethics Committee with the protocol approved by the Research Ethics Committee of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo under number 4.334.540.

Surgical technique

With the patient in horizontal dorsal decubitus, two 1 cm longitudinal incisions were made on the anterior surface of the distal thigh and blunt dissection was performed through the quadriceps muscle to the anterior surface of the distal femur, in an area proximal to the epiphyseal disc.

Using percutaneous methods and fluoroscopic guidance with images in the coronal and sagittal planes, two guide wires, one for each incision, were passed from anterior to posterior and proximal to distal. They crossed the distal femoral epiphyseal disk in its posterior third, close to the subchondral limit of the medial and lateral femoral condyles.

Two cannulated screws with a diameter of 5.5 mm, threaded along their entire length, were inserted through the guide wires, with the tips of the screws positioned completely within the distal femoral epiphysis (Figure 1A and 1B). The subcutaneous tissue and skin were then sutured.

The patients were released from knee mobilization and limb loading immediately after surgery.

Every four months, the degree of deformity was clinically and radiographically assessed until its complete correction, at which point the screws were then removed.

RESULTS

The surgical treatment was performed and followed clinically and radiographically until the correction of the deformity. The average time to correct the deformity was 15 months, with a minimum follow-up of 1 year. No peri- or post-operative complications or recurrence of the deformity occurred in any of the cases described.

The average correction of the femorotibial angle in the sagittal plane was 26°, with a maximum angle of 32° and a minimum of 18° (Figures 2, 3, and 4).

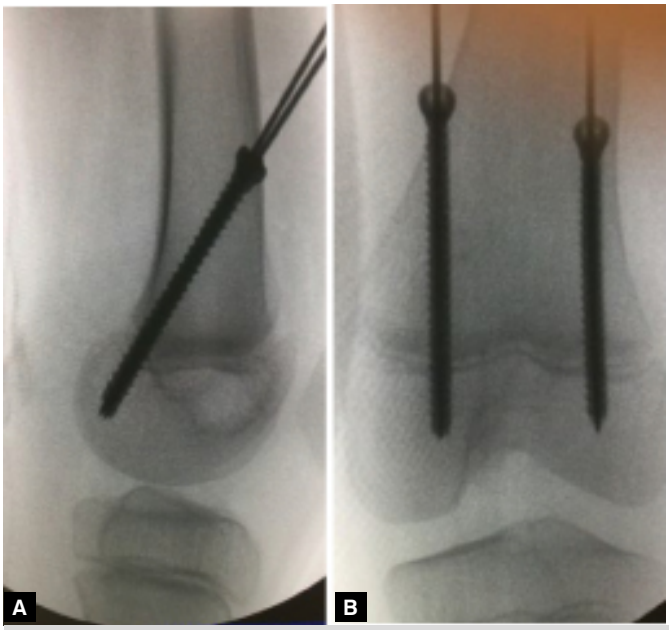

Figure 1. Intraoperative control of the posterior hemiepiphysiodesis of the distal femur, with two cannulated screws guided by metallic wires (A – side view; B – anteroposterior view), for the treatment of genu recurvatum deformity due to joint hypermobility in a 9-year-old patient.

DISCUSSION

The knee recurvatum, or hyperextension (genu recurvatum), can be caused by bone deformities affecting the tibia or femur, neuro-orthopaedic diseases,[6] traumatic anterior tibial fractures or epiphysiodesis, infections, iatrogenies,[9] capsular-ligament malformations due to arthrogryposis and syndromes with joint hypermobility.

The treatment for this deformity is indicated based on the clinical implications for gait and joint function, although hyperextension has less impact than a fixed knee in flexion.

The clinical presentation is characteristic, with posterior angulation of the knee, either unilateral or bilateral, depending on the underlying cause. The patient may experience claudication while walking, especially when it is unilateral or asymmetrical. The orthostatic radiographic analysis with the knees in maximum extension defines the origin of the deformity (bone, joint or mixed) and allows the calculation of the tibiofemoral deformity angle using a goniometer. The indications for surgical correction depend on this analysis.

The non-surgical treatment modalities for knee recurvatum include physical therapy, serial casting, and orthoses.[17,18] Surgery is reserved for situations in which the deformity is more resistant and also as part of the overall treatment plan, which may include correcting deformities in the foot[19] and hip.[6] Among the surgical options available, quadriceps tenotomies, quadricepsplasty, and shortening or opening wedge osteotomies with the addition of bone graft can be considered. In cases of bone deformities, supracondylar osteotomies of the femur with the removal of a posterior wedge, aimed at normalizing the angle between the diaphysis and the intercondylar groove, is a described surgical option. Another treatment option used is anterior opening wedge tibial osteotomy, above the tibial tuberosity, and the insertion of bone graft.[8] In the latter, it is important to avoid distal displacement of the patella by reinserting the patellar tendon proximally. Osteotomies can be combined with posterior capsular repair,[20] indicated mainly in cases that present premature closure of the anterior portion of the epiphyseal disc.[9,15]

The most used surgical treatment for knee recurvatum is osteotomies of the distal femur or proximal tibia.[13] However, these procedures

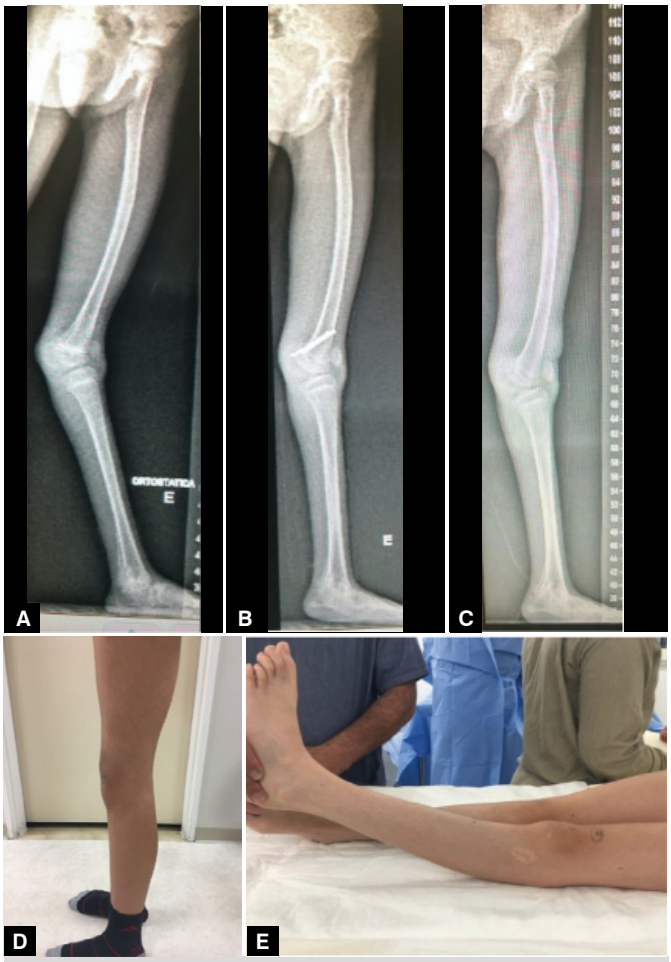

Figure 2. (A) Panoramic radiograph of the left lower limb in profile, a 9-yearold female patient, demonstrating a 32-degree knee recurvatum deformity due to joint hypermobility; (B) Panoramic radiograph of the left lower limb in profile, 1 year and 1 month after surgical treatment with posterior epiphysiodesis of the distal femur, showing correction of the knee recurvatum deformity; (C) Panoramic radiograph in profile, 1 year and 2 months after the removal of the screws from the posterior epiphysiodesis of the distal femur, with maintenance of the correction of the left knee recurvatum deformity; (D) Preoperative photograph of the left lower limb in profile, demonstrating the left knee recurvatum deformity; (E) Photograph taken 1 year after the correction of the left knee recurvatum deformity by posterior epiphysiodesis of the distal femur.

have higher morbidity and risk of complications, requiring a search for less invasive, safer, and more effective methods.

This study reports on the surgical treatment of the knee recurvatum using guided growth with posterior hemiepiphysiodesis of the distal femur using two screws. This method is indicated for deformities caused by capsuloligamentous hyperextension and arthrogryposis. This treatment is not indicated when premature closure of the anterior physeal plate is observed, femoral or tibial, due to any etiology.[15] Occasionally, in these situations, the posterior epiphysiodesis of the distal femur could only be indicated to reduce the progression of the deformity during the residual growth of the patient.

For the provisional posterior epiphysiodesis of the distal femur surgery, two transphyseal cannulated screws were inserted in the sagittal plane to allow anterior growth of the distal femur. This was based on the reports by Métaizeau et al.[21] on the guided growth techniques described for correcting deformities in the coronal plane (varus and valgus).

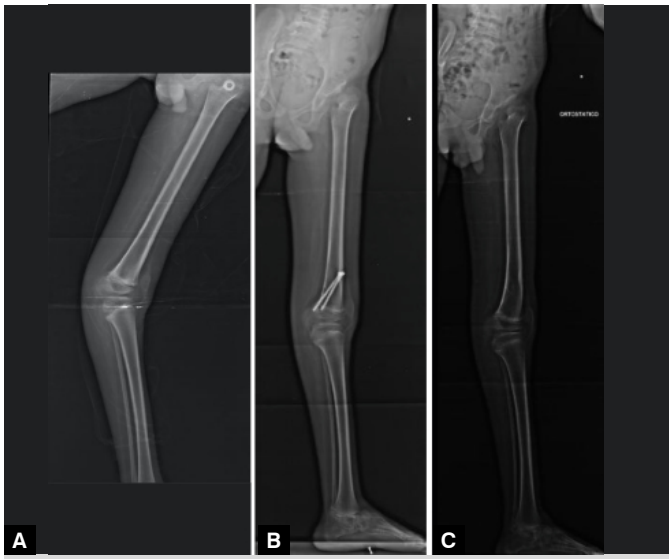

Figure 3. (A) Panoramic radiograph of the left lower limb in profile, a 10-year-old male patient, with a 33-degree knee recurvatum deformity due to arthrogryposis; (B) Panoramic radiograph of the left lower limb in profile, 1 year and 5 months after surgical treatment with posterior epiphysiodesis of the distal femur, showing correction of the deformity; (C) Panoramic radiograph in profile, 1 year and 1 month after the removal of the epiphysiodesis, with maintenance of the correction.

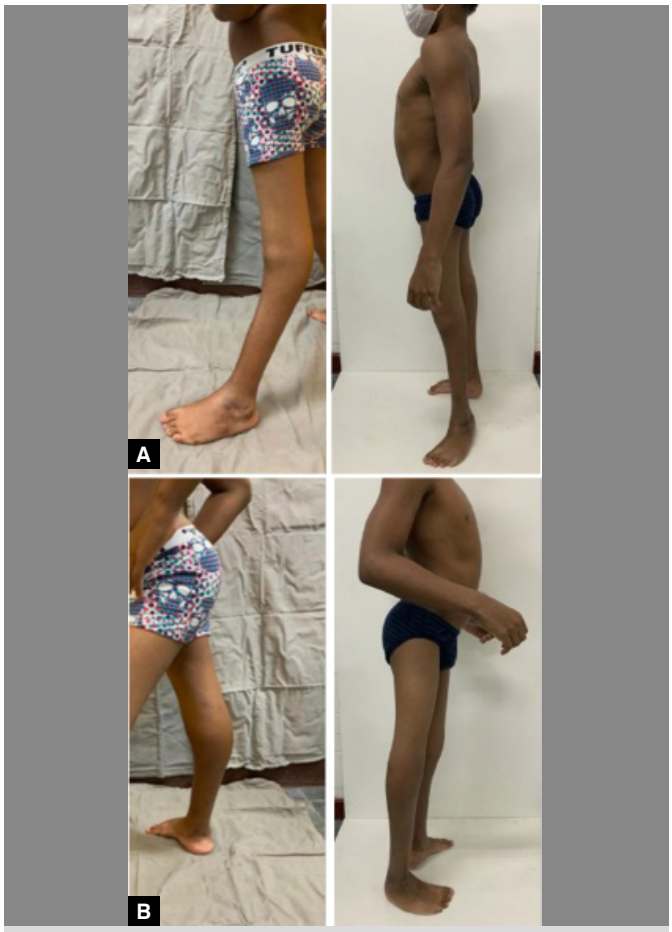

Figure 4. Pre- and post-operative clinical photographs of the left (A) and right (B) lower limbs in profile, showing correction of the recurvatum deformity by posterior epiphysiodesis of the distal femur in a patient with artrogiposys and mild hemiparetic cerebral palsy.

The patients were released for immediate loading. Deformities were monitored by clinical and radiographic evaluations every four months until the recurvatum deformities of the treated knees reached full correction; then, the screws were removed to release the linear growth of the distal femur. It is a minimally invasive, reversible method with a low rate of complications, does not require post-operative immobilization, and most patients are able to walk after the procedure and return to their normal activities. It is important to emphasize the need for follow-up at short intervals, to define the exact moment when the screws should be removed, avoiding overcorrection with inversion of the deformity.

Among the causes of this deformity, which can be treated by the method described in this article, arthrogryposis is a condition that is present from birth and is seen in different diseases, all of which have in common the presence of stiffness and multiple joint deformities. The clinical presentation is diverse and the functional prognosis depends on the etiology, which differentiates the therapeutic options from case to case. In arthrogryposis, knee involvement is very common (38-90% of patients with amyoplasia), ranging from soft tissue contractures (in flexion or hyperextension) to instability, subluxation, or femorotibial dislocation. Flexion contractures are more common and disabling, with significant resistance to treatment and a high recurrence rate.[4]

The prognosis for ambulation is better with recurvatum deformities. According to the literature, nonoperative treatment of knee recurvatum in arthrogryposis with passive mobilization and orthoses fails in about one third of cases. Surgical intervention is recommended, particularly when the knee flexion is limited to 35° or less. According to Lampasi, Antonioli, and Donzelli,[17] the most used methods to date are quadricepsplasty and femoral shortening and flexion osteotomies, procedures with a higher complication rate than the percutaneous hemiepiphysiodesis using transphyseal screws described in this study, with which we have obtained good results.

Patients with knee recurvatum due to ligament laxity have few options for physical therapy or surgical soft-tissue correction, and osteotomy is reserved for patients with significant gait limitations. The posterior femoral hemiepiphysiodesis presented in this study is undoubtedly a less aggressive surgical alternative with lower risks and a progressive and permanent correction after screw removal.

Guided growth is used as a treatment method for lower limb deformities in the sagittal plane. Jorneau,[22] Klatt and Stevens,[14] and Stevens, Stephens, and Rothberg[23] described correction of the knee in flexion with guided growth by anterior hemiepiphysiodesis of the distal femur with two plates (Eight Plate).

In 2021, Stevens, Stephens, and Rothberg[23] also described guided growth of the tibial recurvatum by posterior epiphysiodesis of the proximal tibia using the Eight-Plate, with excellent results. Kievit, van Duijvenbode, and Stavenuiter[24] reported a case of knee recurvatum as a complication of treatment of lower limb length discrepancy with temporary epiphysiodesis of the distal femur and proximal tibia using Eight-Plate. The hypothesis is that the recurvate was caused by a very anterior positioning of the plates, and then the correction of the recurved deformity was obtained with the surgical reapproach and posterior replacement of the plates in the distal femur.

No studies have been found on treatment of genu recurvatum using posterior hemiepiphysiodesis of the distal femur with transphyseal screws, as described in this study.

CONCLUSION

Posterior hemiepiphysiodesis of the distal femur with transphyseal screws proved to be a safe and very useful approach for recurvatum deformities of the knee whose apex is in the femur or associated with joint hypermobility. This approach shows great potential for correcting the knee recurvatum in the developing skeleton and serves as an excellent alternative to the more aggressive methods currently employed to treat this deformity.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. NBM, ARJ: intellectual concept, performing the surgeries, writing and revising the article; TOG, BLCS: writing and revising the article.

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CORRELATION BETWEEN TYPES OF MINDSET AND QUALITY OF LIFE EVALUATION IN PATIENTS WITH SCOLIOSIS

CORRELAÇÃO ENTRE OS TIPOS DE MENTALIDADE E AVALIAÇÃO DA QUALIDADE DE VIDA EM PACIENTES COM ESCOLIOSE

Wesley Wilian Costa Martins[1], Leonardo Sardas[1], Rodolfo Guedes Pereira Nunes Barbosa[1], Rodrigo Góes Medéa de Mendonça[2], Alberto Gotfryd[2], Maria Fernanda Silber Caffaro[1,2], Patrícia Maria de Moraes Barros Fucs[1], Robert Meves[2]

1. Irmandade da Santa Casa de Misericordia de Sao Paulo, Department of Orthopedics and Traumatology "Pavilhao Fernandinho Simonsen", Sao Paulo, SP, Brazil.
2. Irmandade da Santa Casa de Misericordia de Sao Paulo, Departamento de Ortopedia e Traumatologia "Pavilhao Fernandinho Simonsen", Spine Surgery Group, Sao Paulo, SP, Brazil.

ABSTRACT

Scoliosis is a pathology with multiple etiologies that leads to aesthetic changes, increased morbidity and, especially, psychological damage. Objective: This work aims to compare two mindset types (fixed and growth) and assess levels of quality of life in individuals with scoliosis. Methods: Two questionnaires, Scoliosis Research Society-30 (SRS-30) and Early-Onset Scoliosis-24 Questionnaire (EOSQ-24), associated with the "Health Mindset Scale," were used. We applied the SRS-30 to patients who were independent or whose diagnosis of spinal deformity occurred after the age of 10 years. For patients diagnosed before the age of 10 or who presented dependence due to cognitive impairment, caregivers were subjected to the "Health Mindset Scale" and EOSQ-24 questionnaires. Results: The sample consisted of 35 patients aged from 4 to 46 years, the majority aged from 15 to 18 years old (42.9%), female (71.4%), and with neuromuscular scoliosis (28.6%). The only significant result ($p = 0.060$) was the increase in pain/discomfort scores in the EOSQ-24 for a patient with a growth mindset. Lastly, there was no statistical difference between groups, however, in patients with a growth mindset, there was a tendency ($p = 0.060$) to have a higher pain/discomfort score, assessed via the EOSQ-24 score, reported by the caregiver. ***Level of Evidence III, Retrospective Comparative Study***.

Keywords: Scoliosis. Spine. Quality of Life. Behavior. Patient Health Questionnaire.

RESUMO

A escoliose é uma patologia com múltiplas etiologias e que acarreta alterações estéticas, aumento de morbidade e principalmente danos psicológicos. Objetivo: Comparar dois tipos de mindset (fixo e construtivo) e o nível de qualidade de vida. Métodos: Foram utilizados dois questionários, o Scoliosis Research Society-30 (SRS-30) e o Early-Onset Scoliosis-24 Questionnaire (EOSQ-24), associados à escala Health Mindset Scale. Aplicamos o SRS-30 em pacientes independentes ou cujo diagnóstico de deformidade na coluna ocorreu após os 10 anos. Já no caso de pacientes com diagnóstico antes dos 10 anos ou que apresentassem dependência devido a dificuldades cognitivas, os cuidadores foram submetidos à Health Mindset Scale e ao EOSQ-24. Resultados: A amostra foi composta por 35 pacientes com idades entre 4 e 46 anos, sendo a maioria entre 15 e 18 anos (42,9%), do sexo feminino (71,4%) e com escoliose do tipo neuromuscular (28,6%). O único resultado com significância ($p = 0,060$) foi o aumento dos escores de dor/desconforto nos questionários EOSQ-24 em paciente com mindset de crescimento. Por fim, não houve diferença estatisticamente significante entre os grupos, porém, em pacientes com mindset construtivo, houve tendência ($p = 0,060$) de maior escore de dor/desconforto avaliado por meio do EOSQ-24 e referido pelo cuidador. ***Nível de Evidência III, Estudo Retrospectivo Comparativo.***

Descritores: *Escoliose. Coluna Vertebral. Qualidade de Vida. Comportamento. Questionário de Saúde do Paciente.*

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INTRODUCTION

Scoliosis is defined as a deformity with a 3D deviation of the spine.[1] Based on its etiology, it can be divided into four very distinct groups: neuromuscular; syndromic; congenital; and idiopathic.[2,3] Regardless of the etiology, this comorbidity is generally associated with body changes, long-term morbidity, and significant psychological damage, which means it can be considered a psychosocial challenge for patients and caregivers.[4,5] In this context, patient-centered questionnaires are important for treatment evaluation, care protocols and definition of policies by paying entities.[6]

The Scoliosis Research Society-30 (SRS-30) questionnaire, modified by Asher et al. from the original questionnaire created by Haher et al.,[7] which proved, through internal consistency, planned score distribution and confidence level, to be an appropriate instrument

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

The study was conducted at Irmandade da Santa Casa de Misericordia de Sao Paulo, Department of Orthopedics and Traumatology "Pavilhao Fernandinho Simonsen".
Correspondence: Leonardo Sardas. Rua General Jardim, 595, apt. 144, Sao Paulo, SP, Brazil, 01223011. leonardosardas@gmail.com

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for patients with scoliosis, measuring patients' quality of life and the outcome of surgical procedures in the spine. Oliveira, Meves and Avanzi[8] translated and validated this questionnaire for its application in Brazil. They presented a final translated version of the SRS-30 questionnaire after testing it with 20 patients, clarified how it should be scored and suggested that, in Brazil, the completion of the questionnaire should be assisted by a professional, preferably a health professional, since some patients had difficulty understanding the questions.

In addition to this questionnaire, we can use the Early-Onset Scoliosis-24 Questionnaire (EOSQ-24), developed by Corona et al.,[9] in the United States, and applied to caregivers of children with early-onset scoliosis (EOS), that is, scoliosis with onset before the age of 10 years. This questionnaire consists of 24 items, with 11 domains designed to assess the quality of life of children with EOS and the burden of care on their caregivers. It also has a translated and validated version for the Brazilian population, which presents excellent reliability for the application to patients with EOS, as presented by Mendonça et al.[6]

New ways of classifying and indicating treatments for this type of comorbidity find, in social psychology, the concept of "mindset" (an individual's assumption about the source of their own capacity), which has recently been applied to healthcare in the United States and was formulated by Dweck in 2006.[10] There are two divergent types of mindsets that fundamentally change how individuals respond to similar circumstances: the "fixed" mindset and the "growth" mindset. The "fixed" mindset is the belief that attribute is essentially immutable, and the "growth" or "constructive" mindset is the belief that this attribute can be improved through consistent effort. This research on mindset and its potential to influence behavioral outcomes was conducted and validated for the first time in the realm of intelligence, specifically on children attending school. It was observed that the growth mindset was associated with better performance and with the tendency to seek new challenges. Furthermore, simple interventions to promote constructive mindset have been shown to improve both performance during classes and students' grades.[10]

The mindset theory has recently been applied to the medical field, also in the United States, through a questionnaire formulated with four questions and with answers ranging from 1–6, in which "1" would be to completely agree and "6" to completely disagree. According to the final score, individuals were then divided into two groups: fixed or constructive mindsets.[10-12] While individuals with a "constructive" mindset tended to see health as something that could be improved through their behaviors, those with a "fixed" mindset regarded health as something immutable. This was observed through contrasting responses to the disease in terms of behaviors and treatment outcomes. It has been found that constructive-minded patients typically have better adaptive responses to their diseases, both in cases in which they were previously healthy and in cases of chronic diseases.[12]

Postoperative patients with constructive mindsets consistently present lower scores on pain scales, as in cases of tonsillectomy and pectus excavatum corrections.[13,14] In the case of chronic diseases, patients with diabetes bearing this mindset present better glycemic control, and constructive-minded individuals who receive renal transplant show better quality of life.[15,16] For healthy individuals, constructive mindset is associated with better eating habits and physical activity, both in eutrophic individuals and those with obesity.[17,18]

Given the effects of the mindset on various health areas, we applied this 4-question questionnaire, that is, the "Health mindset scale" after translation into Brazilian Portuguese and cross-cultural validation,[19] to patients with spinal deformities, comparing rates of quality of life, which will be measured through the SRS-30 and EOSQ-24 questionnaires. The hypothesis was that patients with constructive mindsets would report a higher quality of life than patients with fixed mindsets.

METHODS

The study took place in a tertiary hospital located in the capital city of the state of São Paulo, with the approval of the Research Ethics Committee of the Irmandade de Misericórdia da Santa Casa de São Paulo (Opinion No. 5,114,313).

All patients and caregivers who participated in the study were adequately informed and signed an informed consent form, which included appropriate specifications about the study and the role of the participant.

The "Health Mindset Scale"—translated into Brazilian Portuguese, according to the international guideline for cross-cultural adaptation—was used.[20] Along with the "Health Mindset Scale," the SRS-30 was applied to independent patients and to those whose spinal deformity diagnosis occurred after the age of 10 years. In the case of patients diagnosed before the age of 10 years or who presented dependence due to cognitive impairment, the "Health Mindset Scale" and EOSQ-24 questionnaires were answered by the caregivers. The evaluators contacted patients both in person, during outpatient visits, and by telephone call, for data collection. Subsequently, results were compared to evaluate the profile of the groups studied.

Statistical analysis

Continuous variables are expressed as mean, standard deviation, median, and interquartile range. The categorical variables, in turn, are expressed by their absolute number of occurrence and their percentages. For internal consistency analysis, Cronbach's alpha reliability test was used in each group of questions that characterized a questionnaire domain, in addition to the global internal consistency index involving the entire questionnaire. For the analysis of the ceiling and floor effects, it was considered that 15% of patients who obtained the lowest or the highest possible score determined the effect. Data analyses were performed using the SPSS 23.0 program for MAC (IBM SPSS Inc., Chicago, IL). A $p < 0.05$ value was considered statistically significant.

For discriminative validity, comparisons between categorical variables were performed using non-parametric tests (Kruskar-Wallis and Mann Whitney U) and Spearman's correlation coefficients were used for continuous variables.

RESULTS

The translated and cross-culturally adapted questionnaires were applied to the patients included in the study. The sample consisted of 35 patients aged from 4 to 46 years($M = 15.48$; $SD = 7.12$), most of them being aged from 15 to 18 years (42.9%), female (71.4%), and with neuromuscular scoliosis (28.6%). Table 1presents details on the profile of the sample regarding gender, age group, and type of scoliosis.

Internal consistency of the instruments

Internal consistency of the Health Mindset Scale

The internal consistency of the three items was satisfactory ($\alpha = 0.723$). Table 2 presents descriptive statistics for each item and α for excluded items.

In addition, Table 3 presents bivariate inter-item correlations.

<< SUMÁRIO

Table 1. Sample profile.

Characteristic	f	%
Sex		
Female	25	71.4
Male	10	28.6
Age group		
4 to 10 years	6	17.1
11 to 14 years	9	25.7
15 to 18 years	15	42.9
Over 18 years	5	14.3
Type of Scoliosis		
Spinal cord abnormality	1	2.9
Congenital or structural	7	20.0
Idiopathic	7	20.0
Neuromuscular	10	28.6
Syndromic	4	11.4
Missing information	6	17.1

Table 2. Descriptive statistics and α if the item is excluded from the Health Mindset Scale.

Item	M	SD	α if the item is deleted
1. Your body has a defined health condition or level and you cannot do much to change that.	3.68	1.77	0.75
2. You cannot quite change your health.	4.22	1.61	0.45
3. You can try to feel better, but you cannot change your health.	4.74	1.52	0.68

M = mean; SD = standard deviation.

Table 3. Inter-item correlations and item-total of the Health Mindset Scale.

Item	1.	2.	3	Item-total correlation
1. Your body has a defined health condition and you cannot do much to change that.	1			0.45
2. You cannot quite change your health.	0.51	1		0.69
3. You can try to feel better, but you cannot change your health.	0.29	0.60	1	0.50

Strong correlations were observed between items 1 and 2 and between items 2 and 3. However, a poor correlation was observed between items 1 and 3. Item-total correlations ranged from 0.45 (item 1) to 0.69 (item 2).

Internal Consistency of SRS-30

Table 4 shows the internal consistency of each dimension of the SRS-30.

Internal Consistency of EOSQ-24

Table 5 presents the internal consistency of each EOSQ-24 dimension.

Bivariate correlations between scores on the Health Mindset Scale and SRS-30 (Table 6), and between scores on the Health Mindset Scale and EOSQ-24 (Table 7) are presented below:

The Pain/Discomfort score of EOSQ-24 was significant and the Health Mindset Scale score was moderate and positive. That is, the higher the pain score on this scale, the greater its disparity with the items of the Health Mindset Scale.

Comparison between SRS-30 and EOSQ-24 by types of mindset types

Mann-Whitney tests were performed to compare SRS-30 and EOSQ-24 scores by types of mindset (Table 8).

Table 4. Cronbach's alpha coefficients of the Scoliosis Research Society-30 (SRS-30) domains.

Domain	α
Function/Activity	0.54
Pain	0.85
Self-Image/Appearance	0.61
Mental Health	0.50
Satisfaction with Management	0.80

The alphas ranged from 0.50 (mental health) to 0.85 (pain). Two dimensions presented a coefficient below recommendations (Function/Activity and Mental Health).

Table 5. Cronbach's alpha coefficients of the Early-Onset Scoliosis-24 Questionnaire (EOSQ-24) domains.

Domain	α
General Health	0.26
Pain/Discomfort	0.78
Pulmonary Function	0.08
Transfer	Singular Item
Physical Function	0.74
Daily Living	0.44
Fatigue/Energy Levels	0.42
Emotion	0.51
Parental Impact	0.57
Financial Impact	Singular Item
Satisfaction	0.77

Coefficients ranged from 0.08 (Pulmonary Function) to 0.78 (Pain/Discomfort). Six dimensions presented alphas below recommendations (< 0.60).

Table 6. Correlation coefficients between the Health Mindset Scale and Scoliosis Research Society-30 (SRS-30).

Domain	Spearman's Rho	p-value
Function/Activity	−0.16	0.512
Pain	−0.17	0.501
Self-Image/Appearance	0.16	0.515
Mental Health	0.07	0.775
Satisfaction with Management	−0.009	0.972

Table 7. Correlation coefficients between the Health Mindset Scale and Early-Onset Scoliosis-24 Questionnaire (EOSQ-24).

Domain	Spearman's Rho	p-value
General Health	0.04	0.832
Pain/Discomfort	0.44*	0.034
Pulmonary Function	−0.07	0.746
Transfer	0.02	0.900
Physical Function	0.09	0.654
Daily Livings	−0.25	0.247
Fatigue/Energy Levels	−0.14	0.515
Emotion	−0.18	0.402
Parental Impact	−0.05	0.810
Financial Impact	−0.14	0.515
Satisfaction	0.05	0.790

* Significant correlation ($p < 0.05$).

The results indicated only a marginally significant difference in the pain/discomfort score in the EOSQ-24 ($p = 0.060$), indicating that patients with a growth mindset scored higher in this dimension.

DISCUSSION

Scoliosis is a condition that limits the daily living of those who suffer from it, causing a relevant impact on their quality of life and that of their caregivers[6]. In our study, we obtained a sample of 35 patients aged from 4 to 46 years (M = 15.48; SD = 7.12), with most individuals aged from 15 to 18 years (42.9%), female (71.4%), and with neuromuscular scoliosis (28.6%).[11]

Satisfactory internal consistency was observed for the three items (α = 0.723) of the "Health mindset scale." Strong correlations were observed between items 1 and 2 and between items 2 and 3. However, poor correlation was observed between items 1 and 3. Item-total correlations ranged from 0.45 (item 1) to 0.69 (item 2), as observed in the translation of the scale into Brazilian Portuguese.[20]

Table 8. Non-parametric comparison between the Scoliosis Research Society-30 (SRS-30) and Early-Onset Scoliosis-24 Questionnaire (EOSQ-24) scores, considering differences between fixed and growth mindset types.

Domain	Fixed	Growth	p-value Mann-Whitney
SRS-30			
Function/Activity	3.00 0.54	3.10 0.54	0.798
Pain	3.60 1.48	3.55 0.98	0.798
Self-Image/Appearance	3.55 0.52	3.47 0.65	0.721
Mental Health	3.68 0.84	3.40 0.58	0.574
Satisfaction with management	3.25 0.64	3.55 1.07	0.442
EOSQ-24			
General Health	56.25 13.11	61.02 13.89	0.443
Pain/Discomfort	39.58 22.93	65.44 25.59	0.060
Pulmonary Function	79.16 23.27	72.79 21.75	0.450
Transfer	62.50 30.61	70.58 26.86	0.533
Physical Function	62.48 30.62	63.22 32.28	0.832
Daily Living	72.91 22.93	53.67 38.72	0.254
Fatigue/Energy Levels	62.50 28.50	61.76 23.58	0.943
Emotion	64.58 25.51	51.47 28.25	0.394
Parental Impact	55.83 23.54	61.47 17.02	0.698
Financial Impact	58.33 25.81	54.41 23.77	0.881
Satisfaction	50.00 27.38	57.35 24.62	0.428

Mean ± standard deviation.

The pain/discomfort scores were significant (p = 0.060) for the EOSQ-24 questionnaires in patients with a growth mindset. This finding contradicts the literature—for example, Joseph et al.[11]—since constructive-minded patients are expected to obtain lower pain perception scores. The reason for this incongruity may be related to the fact that answers were given by caregivers, therefore, their perceptions of their own fatigues, emotional impacts and economic burdens might have been reflected in responses.

There was no statistically significant difference between patients with different mindset types and the SRS-30 and EOSQ-24 quality of life scores (8 and 27 patients, respectively). As a limitation of this study, we mention the difficulty of patients to accurately understand the concepts of growth mindset, even though such concepts were explained during the questionnaires application. Patients who attend to outpatient clinics in our service generally have low socioeconomic and educational levels. It was noteworthy that the interviewees needed further clarification about what was being requested to understand the context of statements or assign them scores: we observed that some individuals gave opposite evaluations (agree or disagree) to statements with similar contexts. Moreover, some caregivers/patients were concerned about the negative influence of their responses on the treatment, especially when they agreed with statements that corresponded to the fixed mindset. This apprehension continued even after the interviewer explained that the results of the questionnaires would not interfere in future follow-up. These factors may have influenced responses and results.

A study by Joseph et al.,[11] in which 110 individuals were evaluated—mostly women (85.5%), mean age of 13.1 ± 1.4 years, participants of a program for treatment with orthosis, and who were able to complete the questionnaire with a good understanding—demonstrated that patients with growth mindsets generally had greater well-being than those with fixed mindsets, especially during treatment, and accepted such treatment better. In a study by Krain et al.,[13] 1,005 caregivers and their children were interviewed during the postoperative periods of tonsillectomy and adenoidectomy. The study population had no significant difference between genders, a mean age of 6.24 ± 2.93 years with, respectively, 72% and 79.9% of mothers and fathers, and these had attended school at least up to high school. Results demonstrated that caregivers with fixed mindsets reported higher pain scores and greater use of painkillers in the recent postoperative period, even though the pain scores were not significantly different between patients.

Comparing both studies to ours, we observed that these maintained a single type of treatment, only interviewed participants before the use of the orthosis and in the recent postoperative period, and had larger and more homogeneous samples. Meanwhile, our study included different types of scoliosis, treatments and stages (surgical or not, pre- and post-medical intervention) and various age groups, producing a more heterogeneous sample. It is also important to indicate that the total number of patients in our study can also be considered as a limiting factor (35 patients). These variables may have impacted the results found, which differ from the reviewed literature.[21]

CONCLUSION

The application of the mindset scale divided subjects into two groups: fixed and constructive mindset (8 and 27 patients, respectively)

The correlation showed no statistical difference between the groups, however, a higher pain/discomfort score tended (p = 0.060) to be found in patients with a constructive mindset, as assessed by the EOSQ-24 through caregivers' reports.

This study opens a new perspective in the understanding of the referred capacity of psychometric questionnaires and their dependency toward patients or caregivers. However, our study still requires further development: changes such as increasing the study sample and selecting a homogeneous population to be evaluated are necessary.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. WWCM, LS, RGPNB: collected the data and wrote the article; RGMM: designed the study; RM: coordinated the execution; AG, MFSC, PMMBF: reviewed and approved the final version of the article..

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EFFECTIVENESS OF VISCOSUPPLEMENTATION IN THE TREATMENT OF HEMOPHILIC ARTHROPATHY: A SYSTEMATIC REVIEW

EFETIVIDADE DA VISCOSSUPLEMENTAÇÃO NO TRATAMENTO DA ARTROPATIA HEMOFÍLICA: UMA REVISÃO SISTEMÁTICA

Samilly Conceição Maia Martins[1], Erion Junior de Andrade[2], Mayara Branco e Silva[1], Margareth Castro Ozelo[3,4], Gustavo Constantino de Campos[1], Rodrigo Gonçalves Pagnano[1]

1. Universidade Estadual de Campinas, Faculdade de Ciencias Medicas, Departamento de Ortopedia e Traumatologia, Campinas, SP, Brazil.
2. Universidade Estadual de Campinas, Faculdade de Ciencias Medicas, Departamento de Neurologia e Neurocirurgia, Campinas, SP, Brazil.
3. Universidade Estadual de Campinas, Centro de Hematologia e Hemoterapia, Unidade de Hemofilia "Claudio Luiz Pizzigatti Correa", Campinas, SP, Brazil.
4. Universidade Estadual de Campinas, Faculdade de Ciencias Medicas, Departamento de Medicina Interna, Campinas, SP, Brazil.

ABSTRACT

Objective: To describe the efficacy of using viscosupplementation in patients with hemophilic arthropathy (HA), on pain, limb functionality, and quality of life. Methods: A systematic review of the literature was performed following the PRISMA guidelines without limitations of language or year of publication. The search was performed on the following medical databases: PubMed, Cochrane Library, EMBASE, BVS/BIREME, Scopus, Web of Science, EBSCOhost, and PROQUEST in April 2020. The search used the following word: (hemophilia AND joint diseases) OR (haemophilic arthropathy OR hemophilic arthropathy) AND viscosupplementation. Results: The systematic review identified 127 articles, 10 of which were selected for data extraction and qualitative analysis. The 10 selected articles included 297 joints with HA in 177 hemophilic subjects. Our review showed positive results in alleviating pain and improving functional capacity, and quality of life. No major adverse effects were observed. Conclusion: There is a lack of scientific evidence regarding viscosupplementation with hyaluronic acid, but the results presented in this research suggest that it is an effective and safe therapeutic option to alleviate pain and improve functional capacity in patients with HA. ***Level of Evidence II, Systematic Review.***

Keywords: Hyaluronic Acid. Viscosupplementation. Hemarthrosis. Pain Management. Arthropathy. Hemophilia.

RESUMO

Objetivo: Descrever o uso da viscossuplementação com ácido hialurônico em pacientes com artropatia hemofílica (HA), sua eficácia na dor, a funcionalidade do membro e a qualidade de vida após sua aplicação. Métodos: Revisão sistemática da literatura (RSL) que seguiu as diretrizes PRISMA, sem limitação de idioma ou ano de publicação. A pesquisa foi realizada em abril de 2020 nas seguintes bases de dados médicas: PubMed, Cochrane Library, EMBASE, BVS/BIREME, Scopus, Web of Science, EBSCOhost e ProQuest. A estratégia de pesquisa foi: (hemofilia AND joint disease) OR (artropatia hemofílica OU artropatia hemofílica) E viscossuplementação. Resultados: A RSL identificou 127 artigos, dos quais 10 foram selecionados para extração de dados e análise qualitativa. Os 10 artigos selecionados incluíram 297 articulações com AH em 177 indivíduos hemofílicos. Nossa revisão mostrou resultados positivos na melhora da dor, na capacidade funcional e na qualidade de vida. Não foram observados efeitos adversos importantes. Conclusão: A evidência científica atual a respeito da viscossuplementação com ácido hialurônico é escassa, mas os resultados apresentados nesta pesquisa sugerem que é uma opção terapêutica eficaz e segura para diminuir a dor e melhorar a capacidade funcional em pacientes com AH. ***Nível de Evidência II, Revisão Sistemática.***

Descritores: *Ácido Hialurônico. Viscossuplementação. Hemartrose. Manejo da Dor. Artropatia. Hemofilia.*

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INTRODUCTION

Hemophilia is a congenital bleeding disorder marked by frequent episodes of bleeding throughout life, particularly in the muscles and joints, called hemarthrosis.[1,2] Hemarthrosis is responsible for about 80% of all bleeding episodes. The direct action of iron and blood into joints leads to specific changes in the periarticular environment resulting in chronic synovitis, cartilage damage, and bone destruction, leading to irreversible changes.[3] This process, called hemophilic arthropathy (HA), is multifactorial and a particular type of secondary osteoarthritis.[4,5] It usually affects young patients clinically presenting chronic pain, decreased range of motion, deformities, muscle atrophy, and functional impairment.[2,6] Therefore, HA has a high negative impact on the quality of life of patients with hemophilia.[3,7,8]

Hyaluronic acid is a molecule physiologically found in synovial fluid and cartilage matrix.[9] Viscosupplementation, injection of hyaluronic acid, is an accepted treatment that can benefit patients

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The study was conducted at the Universidade Estadual de Campinas.
Correspondence: Samilly Conceição Maia Martins. Rua Carlos Gomes, 241, Campinas, SP, Brazil, 13083970. samilly.maia@hotmail.com

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with osteoarthritis through several different in vivo mechanisms by changing and decreasing the inflammatory and degenerative components, responsible for cartilage degeneration.[10,11] Among the described benefits are anti-inflammatory, anabolic, analgesic, and chondroprotective effects and their effect on the viscosity and elasticity of synovial fluid, thus reducing pain symptoms and contributing to lubrication, shock absorption, elasticity, hydration, and nutrition of joint tissues.[12,13] The clinical and biological similarity of the pathophysiology of osteoarthritis and HA led to the investigation of hyaluronic acid in patients with hemophilia that have HA. This study aimed to evaluate the efficacy of viscosupplementation in patients with hemophilic arthropathy regarding pain control, impact on limb functional capacity, and quality of life.

METHODS

Study selection

The search was performed in accordance with the Cochrane Model[14] and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) recommendation.[15] The "PICOT" methodology was used to define the clinical research issue and the search for evidence. The systematic search in eight electronic databases (PubMed, Cochrane Library, EMBASE, BVS/BIREME, Scopus, Web of Science, EBSCOhost, and PROQUEST)[13] in April 2020. The research string was as follows: [medical subject descriptor terms (MeSH) and free terms] including (hemophilia AND "joint diseases") OR ("hemophilic arthropathy" OR "haemophilic arthropathy") AND viscosupplementation.
To include the studies in the final analysis the following inclusion criteria were used: only studies on humans, randomized or non-randomized clinical trials, case-controlled studies, or case series, with no restrictions on year or language to minimize any risk of bias. Studies that included animal and in-vitro studies, literature reviews, case reports, duplicate papers, interviews, or comments were excluded. The retrieved studies were processed by reference management programs. Afterward, two independent reviewers (SCM and EJA) managed the remaining articles in the Rayyan program. Any discrepancies were resolved by discussion amongst the authors and consultations with the senior author (RCP) were made to revise the entire process.

Outcomes of interest

The primary outcome assessed was clinical improvement in pain alleviation and function of the affected limb, and patient's quality of life based on specific criteria and validated questionnaires. Visual Analog Pain Scale (VAS) was used to evaluate pain control.[16] Regarding functional capacity, the Western Ontario and McMaster Universities Arthritis Index (WOMAC) was used,[17,18] and to assess patients quality of life, the 36-item Short-Form Survey (SF-36) scores was used.[19] The secondary outcome was the occurrence of adverse effects.

Statistical methods and analysis

As our search resulted in studies with different methodologies, including study designs, participants, interventions, and reported outcome measures it was not possible to perform a meta-analysis. Therefore, a qualitative synthesis of the data will be described.

RESULTS

Study search results

The systematic search resulted in 127 articles. The retrieved studies were processed by reference management programs, where 61 papers were duplicates, and then automatically excluded. Afterward, two independent reviewers (SCM and EJA) managed the remaining articles in the Rayyan program, and three papers were excluded due to duplication. Also, 49 papers were excluded for the following reasons: inadequate study design (case reports, literature reviews, comments, interviews, or news); inappropriate population (not with hemophilic arthropathy), inappropriate intervention (studies that did not use intra-articular hyaluronic acid as a treatment method). The reviewers independently read the remaining 20 manuscripts in full and evaluated them according to the aforementioned eligibility criteria. Finally, we selected 10 articles for data extraction and qualitative analysis that evaluated intra-articular viscosupplementation in hemophilic patients, with regular follow-up with a hematologist and clotting factor replacement before performing the procedure. Figure 1 shows a flowchart outlining the selection process.

Patient population

Altogether, the 10 selected articles evaluated the procedure in 297 joints in 177 subjects, with eight shoulders, 31 elbows, one hip, 181 knees, and 76 ankles. When reported, most subjects included in the studies were patients with severe hemophilia A. Table 1 summarizes the demographic data and clinical follow-up of the studies analyzed. The clinical protocol, therapeutic doses and interval of clinical evaluation of the results varied according to the administered product, location to be performed, and the availability of the patient, as shown in Table 2.

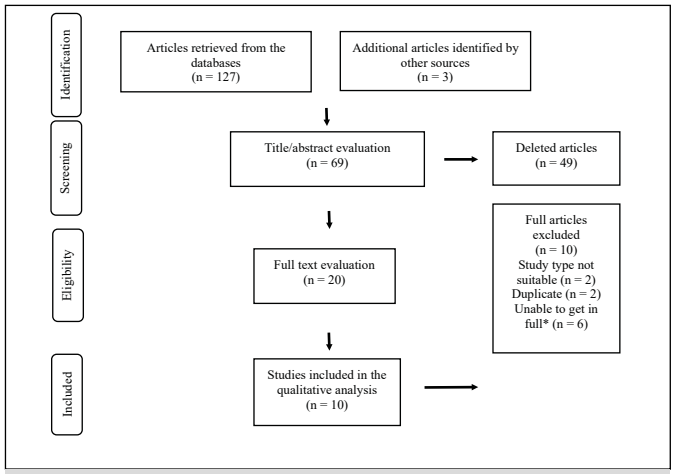

Figure 1. Research flowchart in the databases after applying the eligibility criteria.

Table 1. The demographic data and clinical follow-up.

Study	Year	N	Age in years (mean)	BMI (mean)	Clinical Evaluation Timeframe	Follow-up range
Carulli et al.[7]	2012	46	39	26.7	0, 6, 12, 24 m	24–132 m
Carulli et al.[20]	2013	27	42	26.45	0, 6, 12, 24 m	60 m
Rezende et al.[21]	2015	14	23.7	NR	0, 1, 3, 6, 12 m	12 m
Zelada et al.[22]	2013	14	23.7	NR	0,1,3 m	3 m
Li et al.[23]	2019	11	38.8	25.4	0, 1, 3, 6, 12 m	6 m
Carulli et al.[24]	2020	14	45.8	NR	0, 1, 3, 6, 18 m	20 m
Li et al.[25]	2019	20	38.2	24.2	0, 1, 3, 6 m	6 m
Fernández-Palazzi et al.[26]	2002	25	29.7	NR	1–10 m	1–12 m
Wallny et al.[27]	2000	20	35-56	NR	0, 3, 24 m	26 m

BMI: body max index; m: month; NR: no results.

<< SUMÁRIO

Table 2. Description of intervention protocols.

References	Description of Intervention Protocols
Carulli et al.[7]	3–5 intra-articular HAc administrations 1 to 4 weeks apart.
Carulli et al.[20]	5 Intra-articular low molecular weight HAc applications 2 weeks apart. 3 Applications of high molecular weight HAc 4 weeks apart
Rezende et al.[21]	In single intra-articular administration: joint lavage with 0.9% SF followed by infiltration with HAc (1 ampoule/2 ml) + triamcinolone (1 ml) diluted in ropivacaine (5 ml for knees and 2 ml for ankles, elbows, and shoulders).
Zelada et al.[22]	In single intra-articular administration: joint lavage with saline solution, followed by emptying and application of HAc (6 ml to the knee or 2 ml to the ankles, elbows, and shoulders) + triamcinolone (1 ml) + ropivacaine (5 ml to the knees or 1 ml to the ankles, elbows, and shoulders).
Li et al.[23]	5 intra-articular applications of 2.5 ml of HAc with a 1-week interval.
Carulli et al.[24]	3 intra-articular applications of HAc with monthly intervals in the knees and 2 applications with monthly intervals in the ankle.
Li et al.[25]	3 Intra-articular applications of HAc (2 ml) with weekly intervals,
Fernández-Palazzi et al.[26]	3 Intra-articular HAc administrations through standard portals, at weekly intervals.
Wallny et al.[27]	5 applications of HAc (01 ampoule of 20 mg) intra-articular, with a weekly interval.

Clinical Outcomes

The clinical outcomes evaluated were pain and functional capacity, as summarized in Table 3.

Pain assessment

Pain was assessed by the VAS[16] with a pre-procedure mean score of 5.6 (range: 4.1–8.7). Carulli et al.,[7,20] in a long-term follow-up study demonstrated maximum benefit six months after the intervention compared to the pre-intervention ($p < 0.05$). Carulli et al.[7] reported in their series, including 46 patients with hemophilia, that eight out of 10 evaluated elbows showed marked alleviation of pain, with only two patients needing additional analgesia or complementary physical therapy to control pain. The same author reported 15 out of 24 joints assessed had improvement on pain scores in the knee. Of 25 patients whose ankles were evaluated only three required analgesia or physical therapy to control pain, and one was indicated for ankle arthroplasty due to poor improvement. The same author concluded that viscosupplementation was able to delay aggressive treatment for up to 2 to 4 years after the first cycle with 91.4% of patients exhibiting good results. However, in a different study, Carulli et al.,[20] without differing joints, observed that all patients found pain alleviation in the short term compared to the pre-treatment assessment ($p < 0.05$) up to the first year and with a subsequent gradual decline, nonetheless still better than pre-intervention values.

Table 3. Clinical scores using the scales EVA, WOMAC, and SF-36 applied pre- and post-treatment with HAc.

STUDY	VAS		WOMAC		SF-36	
	Pre	Post	Pre	Post	Pre	Post
Carulli et al.[20]	5.52	1 m: 2.45 12 m: 2.98 24 m: 3.12	64.45	6 m: 21.2 12 m: 54.2 24 m: 56.6 36 m: 56.8	52.57	1 m: NR 2 m: NR 3 m: NR 6 m: 72.5 12 m: 72.5 24 m: 66.1 36 m: 47.4
Rezende et al.[21]	4.57	1 m: 3.56 3 m: 4.2 6 m: 4.23 12 m: 3.82	34.4	1 m: 24.1 2 m: NR 3 m: 23.5 6 m: 23.5 12 m: 22,4 24 m: NR 36 m: NR	NR	1 m: NR 2 m: NR 3 m: NR 6 m: NR 12 m: NR 24 m: NR 36 m: NR
Zelada et al.[22]	44.6	1 m: 4.4 2 m: NR 3 m: 4.6 6 m: NR 12 m: NR	38,4	1 m: 23.5 2 m: NR 3 m: 26.5 6 m: NR 12 m: NR 24 m: NR 36 m: NR	32	1 m: 62.4 2 m: NR 3 m: 92.4 6 m: NR 12 m: NR 24 m: NR 36 m: NR
Li et al.[23]	Knee: 4,1	1 m: 1.8** 2 m: 1.6** 3 m: 2.3** 6 m: NR 12 m: NR	38.3	1 m: 19.1 2 m: 21.3 3 m: 27.1 6 m: 35.8 12 m: NR 24 m: NR 36 m: NR	54.4	1 m: 58.5 2 m: 63.5 3 m: 63.3 6 m: 58.3 12 m: NR 24 m: NR 36 m: NR
Carulli et al.[24]	8	1 m: 1* 2 m: NR 3 m: NR 6 m: NR 12 m: NR	NR	1 m: NR 2 m: NR 3 m: NR 6 m: NR 12 m: NR 24 m: NR 36 m: NR	NR	1 m: NR 2 m: NR 3 m: NR 6 m: NR 12 m: NR 24 m: NR 36 m: NR
Li et al.[25]	Knee: 5.7	1 m: 2.7 2 m: 1.8 3 m: 2.5 6 m: 3.2 12 m: NR	38.1	1 m: 22.3 2 m: 21.3 3 m: 24.8 6 m: 26 12 m: NR 24 m: NR 36 m: NR	48.8	1 m: 58.8 2 m: 63.2 3 m: 64.8 6 m: 60.6 12 m: NR 24 m: NR 36 m: NR
Fernández-Palazzi et al.[26]	Shoulder: 7,67 Elbow: 10 Knee: 8.47 Ankle: 8	1 m: 3.7 2 m: NR 3 m: NR 6 m: NR 12 m: NR	NR	1 m: NR 2 m: NR 3 m: NR 6 m: NR 12 m: NR 24 m: NR 34 m: NR	NR	1 m: NR 2 m: NR 3 m: NR 6 m: NR 12 m: NR 24 m: NR 36 m: NR
Wallny et al.[27]	Knee: 5.4	1 m: 4.7 2 m: NR 3 m: NR 6 m: NR 12 m: NR	NR	1 m: NR 2 m: NR 3 m: NR 6 m: NR 12 m: NR 24 m: NR 36 m: NR	NR	1 m: NR 2 m: NR 3 m: NR 6 m: NR 12 m: NR 24 m: NR 36 m: NR

VAS: Visual Analog Pain Scale; WOMAC: The Western Ontario and McMaster Universities Osteoarthritis Index; SF-36: 36-item Short-Form Survey; m: month; NR: no results.

Fernández-Palazzi et al.,[26] observed complete pain relief in 13.7% of the injected joints and partial improvement in 62%, which means that 75% of the results were classified as excellent or good outcomes. Three-quarters of the patients improved, and only 10.3% were considered to have a poor outcome, wherein there was no improvement in the joint condition, requiring another procedure.

Wallny et al.,[27] reported that the VAS[16] for the subjective experience of pain dropped from 5.4 to 3.8 points, improving after three months in 70% of their patients. They also observed that the positive effect of viscosupplementation was maintained for up to two years in half of the patients.
Li et al.,[23] obtained a significant reduction in pain from hemophilic arthropathy of the knee, observed for up to six months ($p < 0.01$). The authors followed the maximum benefit two months after injection.

Functional capacity and quality of life

Functional capacity was evaluated using the WOMAC score, that is a disease-specific measure to evaluate limb function in arthritis and arthropathies with values from 0 (best) to 100 (worst). Carulli et al.,[20] reported pre-treatment mean value of 64.45 and observed a maximum benefit in six months (mean value = 21.2) with a gradual increase in their values (mean value of 56.8 in 36 months). Subsequently, Rezende et al.[21] observed an average decrease of 8.29 points compared to pre-treatment after one month. Zelada et al.,[22] in a study with 3 months of follow-up, found a greater difference in the total value in one month, up to minus 14.7 points, mainly at the expense of function improvement, with an average decrease of 11.4 points ($p < 0.05$). The other papers selected did not assess WOMAC scores.
Among the 10 papers, quality of life assessment using the SF-36 was reported in five papers. The SF-36 is a 36-item assessment tool that aims to perform a generic measure of health status evaluating physical functioning, social functioning, and role limitation due to physical health or mental problems, with higher scores indicating better health-related quality of life. Carulli et al.,[20] presented a pre-treatment mean score of 52.57 points and a significant difference with improved functional capacity compared to the pre-intervention at six months (mean score = 72.5, $p < 0,05$), reaching better levels and associated with substantially positive effects in the long-term follow-up at 36 months (mean score = 47.4). It can be noted that an increase in the self-reported questionnaire values were observed after three months of treatment, followed by a slow decline over time. In Li et al.,[23] the total result was not statistically significant with pre-treatment mean scores of 54.4 and the largest increase in scores was observed in 2 months with mean score of 63.5. In another study, Li et al.[25] described a mean pre-treatment score of 68.8 and the stronger benefit was recorded 3 months post-treatment with mean score of 64.8 with scores slightly decreasing at the 6-month follow-up (mean score = 60.6) In the studies whose scores were stratified by the components of SF-36, it was observed that most of the improvement in scores was due to the mental health component [7,20,22,23,25,28].

Adverse effects and procedure complications

The viscosupplementation in the evaluated studies showed that the patients had good tolerance to the intra-articular injections. Some minor and transient adverse effects at the injection site, such as pain after injection and local bruising, have been reported by Li et al.[25] In this review, there was no joint bleeding related to the intra-articular application of hyaluronic acid, post-procedure infection, or acute inflammation. The studies in this review reported no major adverse effects.

DISCUSSION

As the life expectancy of patients with hemophilia has increased, the management of its consequences, such as pain and decreased functional capacity, has become a central issue in the comprehensive treatment because of its impact on patients' quality of life. Clinical data of patients with hemophilia shows that joint pain is the most common painful manifestation and a substantial problem, where patients often feel that their pain has been sub-optimally managed despite medical treatment.[24,25,28,29]
Pain management strategies for patients with hemophilia involve a multimodal approach, focusing on physical and psychological aspects, and suggesting a gradual process according to pain intensity. Whenever possible, the underlying condition should be treated in a staggered manner, such as by physical therapy, analgesic and anti-inflammatory treatment, radioisotope synovectomy, and surgical interventions.[30]
Analgesic medical therapy in hemophilia patients shows additional challenges due to the need for long-term use, comorbidities, and the potential of some medications to increase the risk of bleeding.[31]
Several studies confirm that intra-articular hyaluronic acid is effective in treating osteoarthritis and supports its use.[32-38] Rodrigues-Merchan,[39] in a literature review on intra-articular injections of hyaluronic acid in the hemophilic knee, emphasizes the similarities and differences between primary osteoarthritis (OA) and HA and provide a rationale for defending the use of viscosupplementation in patients with hemophilia. The author emphasizes that, as in OA, there is joint destruction associated with pain, loss of range of motion, deformities, and functional incapacity of the affected limb. However, in hemophilic arthropathy, these characteristics are more intense and occur at an earlier age. Fernández-Palazzi et al.,[26] are among the first authors to propose the efficacy and safety of hyaluronic acid administration in chronic hemophilic arthropathy. In their study, with a mean follow-up of two years, most patients had positive and persistent effects, such as pain relief and improvements in range of motion and functional capacity. Only 10% of patients were considered to have a poor outcome requiring new treatments. The authors' main conclusion was that viscosupplementation is effective and a better physiological treatment than corticosteroid therapy without the harmful effects on the articular cartilage known to be caused by the latter.
Carulli et al.,[7] proposed viscosupplementation as a primary approach to HA. With changes in lifestyle and rehabilitation, it can be recommended for all patients with hemophilia with initial radiological signs of arthropathy associated with pain and functional impairment. The authors showed that injections with hyaluronic acid were positive, in the short term, in modulating pain and functional capacity in the knees, ankles, and elbows. An average six-year follow-up showed a reduction in the degeneration of joint function. In their series, some patients required more than two injections over the years, with a positive and lasting impact on pain control and range of motion, reducing the need for a more invasive approach. In two other papers from the same group, Carulli et al.,[20,24] showed the same positive results when comparing HA patients treated with viscosupplementation to a nontreated hemophilic population; they also suggest the use and the benefits of hyaluronic acid for severe arthropathy with the intention to postpone an invasive procedure. More than half of hemophilic patients with arthropathy report mobility problems, especially those with bleeding despite prophylaxis.[28]
The WOMAC was developed in the early-1980s as a disease-specific measure for lower limb arthritis and arthropathy.[17,18] Our selected studies[20-23] verified that viscosupplementation can improve functional capacity, based on the WOMAC score, in the short term with a subsequent slow decline in the scores, but still showing better values than pre-treatment, especially those related to joint stiffness and range of motion, with more persistent positive effects on these areas. In agreement with the available literature,[39] we did not observe major adverse effects in the evaluated studies.
Hoorfar and Mobaraky[40] used the SF-36 tool to assess their patients. The authors reported that patients with hemophilia and HA have a self-perceived physical disability with especially low scores in physical domains related to pain. Zelada et al.,[22] were able to verify the same results. When analyzing the post-treatment scores,

the aforementioned studies reported that the physical component of the SF-36 showed improvement by the procedure, but the mental component of the SF-36 was the one that improved the most, mainly after three months of the procedure.

Despite the beneficial results being more expressive in the short term, especially in the first six months, it is essential to highlight that for those living with hemophilia, less invasive procedures to the musculoskeletal system are especially interesting. Therefore, as a less invasive procedure, viscosupplementation provides benefits such as pain relief and joint protection, with improved load distribution and reduced impact. Thus, especially in the studied population, it can enable adequate rehabilitation and serve the purpose of a less invasive treatment, adding to an improvement in the long-term quality of life.

Our study has some limitations. The quality of the studies varied, with most being marked by low-level evidence as descriptive or case series (level of evidence III or IV). Also, the studies selected showed marked methodological variations, including study designs, participants, intervention protocols, and reported outcome measures making the statistical analysis impossible. Therefore, we describe the studies, their results, applicability, and limitations in the qualitative synthesis. Concerning the results of the review, this article highlights the scarcity of publications on hemophilic arthropathy and the consequent restriction in data analysis.

CONCLUSION

According to the available literature, viscosupplementation can be a useful therapeutic option in hemophilic arthropathy, with positive results in alleviating pain and improving functional capacity and quality of life, especially in the first six months, and with no major adverse effects. Those results are especially important in this specific population that presents a fast disease progression at an early age.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the authors upon reasonable request.

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LOW BACK PAIN ESTIMATES IN PROFESSIONAL SOCCER: A SYSTEMATIC REVIEW AND META-ANALYSIS

ESTIMATIVAS DA DOR LOMBAR NO FUTEBOL PROFISSIONAL: REVISÃO SISTEMÁTICA E METANÁLISE

Juliano Bergamaschine Mata Diz[1], *Maria Theresa Pereira Dutra*[1], *Isabella Cheremetta Feijóo*[1], *Ana Luíza Morais Sogno*[1], *Fernanda Rezende Silva*[1], *Giovanna de Faria Carnevale*[1], *Bruno de Souza Moreira*[2], *Carlos Fernando Moreira Silva*[1]

1. Faculdade de Medicina de Barbacena, Barbacena, MG, Brazil.
2. Universidade Federal de Minas Gerais, Belo Horizonte, MG, Brazil.

ABSTRACT

Objective: To evaluate the epidemiological and clinical characteristics of low back pain (LBP) in adult professional soccer players. Methods: Systematic review and meta-analysis. Results: The review included 44 studies. The pooled prevalence of LBP during ≤ 1 season was 1% (95%CI = 0–4%) in men. The pooled point prevalence of LBP was 25% (95%CI = 16–36%) in men and 28% (95%CI = 20–37%) in women. The pooled past-year prevalence of LBP was 34% (95%CI = 24–44%) in men. The pooled lifetime prevalence of LBP was 32% (95%CI = 25–39%) in men and 50% (95%CI = 32–69%) in women. The pooled frequency of LBP/total number of injuries was 2% (95%CI = 1–3%) in men and 4% (95%CI = 2–5%) in women. The pooled incidence rate of LBP/1,000 player-hours of exposure was 0.30 (95%CI = 0.17–0.53) in men and 0.32 (95%CI = 0.06–1.87) in women. The recurrence of LBP ranged from 3% to 63% in men. The intensity of LBP ranged from 1.68 (2.39) to 4.87 (2.14) points on a 0-10 scale (minimum = 0 and maximum = 8 points). The severity of LBP (days absent from professional activities due to pain) ranged from 2 (0) to 10 (19) days (minimum = 1 and maximum = 28 days). Conclusion: Adult elite soccer players have a substantial prevalence of LBP. The frequency and incidence of LBP (compared with other conditions and sports) seems to be low. Estimates of the recurrence, intensity, and severity of LBP are uncertain. ***Level of Evidence II, Systematic Review of Level II Studies.***

Keywords: Low Back Pain. Epidemiology. Prevalence. Sports. Soccer. Professional Athletes.

RESUMO

Objetivo: Investigar as características epidemiológicas e clínicas da lombalgia em jogadores profissionais de futebol. Métodos: Revisão sistemática e metanálise. Resultados: A revisão incluiu 44 estudos. A prevalência combinada de lombalgia em até uma temporada foi de 1% (IC95% = 0-4%) em homens. A prevalência pontual combinada de lombalgia foi de 25% (IC95% = 16-36%) em homens e 28% (IC95% = 20-37%) em mulheres. A prevalência combinada de lombalgia no último ano foi de 34% (IC95% = 24-44%) em homens. A prevalência combinada de lombalgia ao longo da vida foi de 32% (IC95% = 25-39%) em homens e 50% (IC95% = 32-69%) em mulheres. A frequência combinada de lombalgia/número total de lesões foi de 2% (IC95% = 1-3%) em homens e 4% (IC95% = 2-5%) em mulheres. A taxa de incidência combinada de lombalgia/1.000 jogador-horas de exposição foi de 0,30 (IC95% = 0,17-0,53) em homens e 0,32 (IC95% = 0,06-1,87) em mulheres. A recorrência de lombalgia variou entre 3-63% em homens. A intensidade da lombalgia variou entre 1,68 (2,39)-4,87 (2,14) pontos em uma escala de 0-10 (mínimo = 0; máximo = 8 pontos). A gravidade da lombalgia (ausência das atividades profissionais devido à dor) variou entre 2 (0)-10 (19) dias (mínimo = 1; máximo = 28 dias). Conclusão: Jogadores de futebol profissional apresentam alta prevalência de lombalgia substancial. A frequência e a incidência da lombalgia parecem ser baixas comparadas a outros esportes e condições. As estimativas de recorrência, intensidade e gravidade da lombalgia são incertas. ***Nível de Evidência II, Revisão Sistemática de Estudos de Nível II****.*

Descritores: *Lombalgia. Epidemiologia. Prevalência. Esportes. Futebol. Atletas Profissionais.*

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INTRODUCTION

Low back pain (LBP) is a common complaint in the general population and represents one of the main causes of seeking medical care worldwide.[1] It is associated with high rates of physical disability and work absenteeism, and therefore has a huge negative socioeconomic effect on patients and health systems, both public and private.[2] This condition has a multifactorial etiology, and a wide range of biopsychosocial factors may contribute to the onset and improvement or worsening of patients' signs/symptoms.[3]
Professional athletes, regardless of their sport, often experience LBP, since the level of physical and psychological demand in training and competitions is significantly higher than in non-athletes.[4] Previous

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The study was conducted at Faculdade de Medicina de Barbacena.
Correspondence: Juliano Bergamaschine Mata Diz. Praça Presidente Antonio Carlos, 8, Barbacena, MG, Brazil, 36202336. julianodiz@gmail.com

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systematic reviews on the epidemiology of LBP in sports showed point prevalence estimates ranging from 10% to 67% and 12-month prevalence estimates ranging from 17% to 94%.[4,5] Thus, the clinical approach to athletes with back complaints involves permanent care that goes beyond relieving symptoms and restoring functionality. Screening for potential risk factors that may predispose to back pain during sports practice is necessary in order to suppress or attenuate causal mechanisms and prevent recurrences.[6]

Moreover, when professional athletes have a musculoskeletal problem, they need to recover as quickly as possible, fully restoring their physical and functional capabilities to train/compete at the highest levels of performance.[7] However, besides the need for athletes to fully recover in time for their professional commitments, institutions (e.g., clubs and federations) impose burdens arising from the absence of athletes in their activities, whether financial costs or burdens directly related to the inability of athletes to perform in commitments on the official calendar.[8]

Soccer, one of the most popular sports in the world, exposes its players to high mechanical stress, such as repetitive movements, excessive loads, and high-energy trauma. This can easily affect the musculoskeletal system, especially the lumbar spine, which is one of the body regions most susceptible to dysfunction due to traumatic, overuse, and/or degenerative mechanisms.[6,9] Especially considering professional soccer and the level of performance it has reached in the contemporary sports world, studying LBP in this context can evidence its negative repercussions for athletes and institutions and provide important support for pain prevention and management strategies. Thus, this study aimed to evaluate the epidemiological (prevalence and incidence) and clinical (recurrence and severity) characteristics of LBP in professional soccer players.

METHODS

Study design and guidelines

This is a systematic review and meta-analysis. Its methods were based on recommendations of the JBI Manual for Evidence Synthesis,[10] the Meta-analysis of Observational Studies in Epidemiology (MOOSE) group,[11] and the Cochrane Handbook for Systematic Reviews of Interventions.[12] The review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist[13] and the Prisma in Exercise, Rehabilitation, Sport Medicine and Sports Science (PERSiST) guidance.[14] PROSPERO No. CRD42021271942.

Search strategy and inclusion criteria

Searches for original studies were conducted in the Embase, LILACS, PubMed/MEDLINE, SciELO, Scopus, SPORTDiscus, and Web of Science databases, without date or language restrictions. A manual search was also performed in Google Scholar, specialized scientific journals, and reference lists of previous studies. Moreover, professionals/researchers in the field were consulted to identify additional relevant records. Search strategies were elaborated using combinations of descriptors/terms for each database, using English words such as "epidemiology," "prevalence," "incidence," "backache," "spine," "injury," "sport," "football," "soccer," "athlete," "professional," and "elite." Supplementary Table 1 presents detailed search strategies.

Studies with data on LBP in adult professional soccer players of both sexes, regardless of academic type (e.g., conference abstract, dissertation/thesis, or article) and design (e.g., observational or experimental), were the inclusion criteria. Anatomically, LBP is any pain and/or discomfort in the region between the costal margin and the inferior gluteal folds, with or without radiation to the lower limbs, regardless of the cause (specific or non-specific) and evolution (acute or chronic).[15,16] The sport assessed was the traditional field soccer[17] in professional contexts involving seasons, training, and/or competitions (e.g., matches, tournaments, championships, leagues, and cups). No minimum sample size was considered as an inclusion criterion in order to increase the number of eligible studies. Studies with other types of soccer (e.g., indoor, beach, and Paralympic), different age groups (e.g., children and young people), and non-professional levels (e.g., amateur athletes) were excluded.

Study selection and data extraction

Two reviewers independently screened the titles and abstracts of the original studies obtained from the searches. The full texts of potential studies were accessed and assessed for eligibility. The studies that met the inclusion criteria were included in the review. Data were extracted by two independent reviewers to avoid the omission of relevant data. Disagreements were resolved by consensus.[10] The following information was extracted: study (author and date); location (country); design (cross-sectional or longitudinal) sample (size and sex and age of participants); assessment time [during a season (≤ 12 months), for longer than a season (> 12 months), or during a given time (e.g., point) and/or period (e.g., past year)]; exposure (total hours of exposure in training and/or matches); injury (total number of soccer-related injuries); and outcome (prevalence and/or incidence). The authors of original studies were contacted via email to clarify unclear/missing information and/or provide additional data.

Risk of bias assessment

Two reviewers independently assessed the risk of bias of each included study, using a tool developed by Loney and Stratford[18] and Loney et al.,[19] which has eight items that address methodological issues of prevalence/incidence studies. This tool was chosen because it best applies to the scope of this review (considering its condition, context, and population).[10] Items 1 and 2 refer to the study design, the description of the setting, and the characteristics of participants. Items 3 and 4 refer to sample selection and size. Items 5 to 7 refer to diagnostic methods, data collection, and statistical analysis, and item 8 refers to the response rate and the follow-up period.[18]

For evaluation purposes, in item 1, a cross-sectional design was considered adequate for prevalence studies and a longitudinal design (prospective or retrospective) for incidence studies.[18,19] In item 2, the clear presentation of the origin, affiliation, and characteristics of participants was considered adequate.[18,19] In item 3, a sample selection by convenience from professional soccer settings, such as clubs, national teams, and/or competitions, was considered acceptable.[20] In item 4, a sample size of ≥ 25 participants was considered adequate, as this is the average number of players at a professional soccer club during a season and/or competition.[21,22] In items 5 and 6, the identification of LBP cases/events using standardized records with sufficient information on the assessment, exposure, and outcome, according to the definitions of injury resulting from soccer suggested by Fuller et al.,[20] Hägglund et al.,[23] and Timpka et al.[24] (e.g., inability to play/train; need for medical care; detectable tissue damage; or self-reported complaint resulting from injury) was considered adequate. In item 7, an explicit reporting of prevalence/incidence results with confidence intervals (CI) was considered adequate.[18,19] In item 8, a response rate ≥ 70% was considered acceptable,[18,19] while for incidence studies, the acceptable follow-up period should cover at least one full official tournament,[20] with a sample loss < 20%.[25]

For each item in the assessment tool, the answer was "yes," "unclear," or "no," depending on whether the information in the included studies was sufficiently clear, obscure, or absent,

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respectively. The answer "yes" was classified as "low risk of bias;" "unclear" as "unknown risk of bias;" and "no" as "high risk of bias." Disagreements were resolved by a third reviewer.[10] The authors of original studies were contacted via email if additional information was required. The frequency of answers for each item was estimated and presented in a bar chart. A total average of "low risk of bias" answers was provided without, however, using it as a selection or judgment criterion.

Data analysis and evidence synthesis

The data from each included study were initially described using descriptive statistics. Study-level prevalence estimates were obtained using the formula:[26]

$$\text{Prevalence} = \frac{\text{number of positive LBP cases}}{\text{total number of players in the study}} \times 100$$

Study-level injury frequencies were obtained by the formula:[26]

$$\text{Frequency} = \frac{\text{number of positive LBP events}}{\text{total number of injuries in the study}} \times 100$$

Study-level incidence rates were obtained by the formula:[20,26]

$$\text{Incidence} = \frac{\text{number of positive LBP events}}{\text{total exposure (in hours) in the study}} \times 1{,}000 \text{ hours of exposure}$$

For prevalence and injury frequency estimates, a 95%CI was estimated using the Wilson method for $n \leq 40$ and the Agresti-Coull method for $n > 40$, while for incidence rates, a 95%CI was estimated using the Clopper-Pearson exact method.[27] All descriptive analyses were performed using the EpiTools epidemiological calculator (Ausvet, 2018; https://epitools.ausvet.com. Au/ciproportion).

The meta-analysis of injury prevalence and frequency was conducted by pooling the proportions obtained in the included studies, using the inverse variance heterogeneity (Ivhet) model, which estimates the variance of the pooled effect by a quasi-likelihood framework.[28,29] This model has shown better performance in reducing the observed variance and improving the accuracy of estimates compared with the traditional DerSimonian-Laird random effects model,[30] especially when the number of pooled studies is small (e.g., $k < 10$) and the heterogeneity is substantially high (e.g., $I^2 > 50\%$).[28,29] Moreover, the proportions were normalized using the Freeman-Tukey double arcsine transformation in order to stabilize the variance within/between studies when estimating study weights.[31] This approach improves variance estimation in analyses that include studies with small sample sizes and proportions close to 0.0 or 1.0.[10,31]

The meta-analysis of incidence was conducted by pooling the rates and their respective standard errors obtained in the included studies, using the DerSimonian-Laird random effects model.[30] Rates were expressed per 1,000 player-hours of exposure, according to the formula:[32]

$$\text{Incidence} = \frac{\text{number of positive LBP events}}{\text{number of matches} \times \text{number of players} \times \text{match length}} \times 1{,}000 \text{ hours of exposure}$$

Data on exposure in training and/or matches were obtained from the included studies. When an incidence rate was not provided in the studies that reported injuries during competitions, the number of positive LBP events, the number of matches, the number of exposed players (11 or 22), and match length in hours (90 minutes = 1.5 hours), were used to obtain incidence rates, as in the formula above.[20,32]

Heterogeneity between pooled studies was assessed using Cochran's Q test. A large Q value with $p < 0.10$ suggests the presence of significant heterogeneity. Quantification of variability (%) was assessed using the I^2 statistic, and a value $\geq 75\%$ showed considerable heterogeneity.[12] Publication bias was assessed for meta-analyses with $k \geq 10$ studies using the Doi plot method.[33] For quantification of asymmetry, the LFK index was used. A value less than or equal to ± 1 represented "absent asymmetry" (absent publication bias), a value between ± 1 and ± 2 represented "minor asymmetry" (present publication bias), and a value greater than ± 2 represented "major asymmetry" (significant publication bias). Moreover, Egger's test with $p < 0.10$ was used as an additional inference of significant asymmetry.[33] All meta-analyses were performed using MetaXL software version 5.3 (EpiGear International Pty Ltd., Sunrise Beach, Queensland, Australia, 2016).

The quality of evidence for prevalence estimates, injury frequencies, and incidence rates was rated by two independent reviewers using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system.[34] The levels of quality of evidence were: high quality (the pooled estimates/rates are very close to the actual estimates/rates, and differences are unlikely); moderate quality (the pooled estimates/rates are close to the actual estimates/rates, but may differ); low quality (the pooled estimates/rates are uncertain and likely to differ from the actual estimates/rates); and very low quality (the pooled estimates/rates are very uncertain and probably very different from the actual estimates/rates).

The overall quality of evidence for each pooled result was initially rated as high and then downgraded by one, two, or three levels (up to very low) if one of the following criteria were present: $\geq 50\%$ of pooled studies were classified as "high risk of bias" in items 4, 5, or 6 of the tool (serious risk of bias); $\geq 50\%$ of pooled studies did not use valid/reliable methods to identify LBP in soccer settings[20] (serious indirectness); $\geq 50\%$ of pooled studies did not have a sample of 25 participants or more (serious imprecision); the I^2 of the pooled analysis was $\geq 75\%$ (serious inconsistency); and the analysis of publication bias showed "major asymmetry" and Egger's test with $p < 0.10$ (serious publication bias).[34] For meta-analyses with $k < 10$ studies, the analysis of publication bias was not conducted and therefore not used as a criterion for rating the quality of evidence. Finally, the clinical features of LBP were described as follows: recurrence rate (%); pain intensity (average points on a 0–10 scale and categorization into three levels: ≤ 3 points = mild; 4–7 points = moderate; 8–10 points = severe); and pain severity (average number of days a player is absent from professional activities due to pain, from the first day absent until full return to training/matches, and categorization into four levels: ≤ 3 days = minimal; 4–7 days = mild; 8–28 days = moderate; > 28 days = severe).[15,20]

RESULTS

Study selection process

The searches identified 9,959 studies. We removed 1,632 duplicates and excluded 8,148 based on their titles/abstracts. We read 179 original studies in full and assessed their eligibility. Finally, we excluded 135 for six different reasons and included 44 in this review[22,35-79] (Figure 1). The study by van Beijsterveldt et al.[75] used data from the same sample as the study by Stubbe et al.[71] The PhD dissertations by Hägglund[52] and Netto[61] only provided additional data on their respective original articles.[51,60]

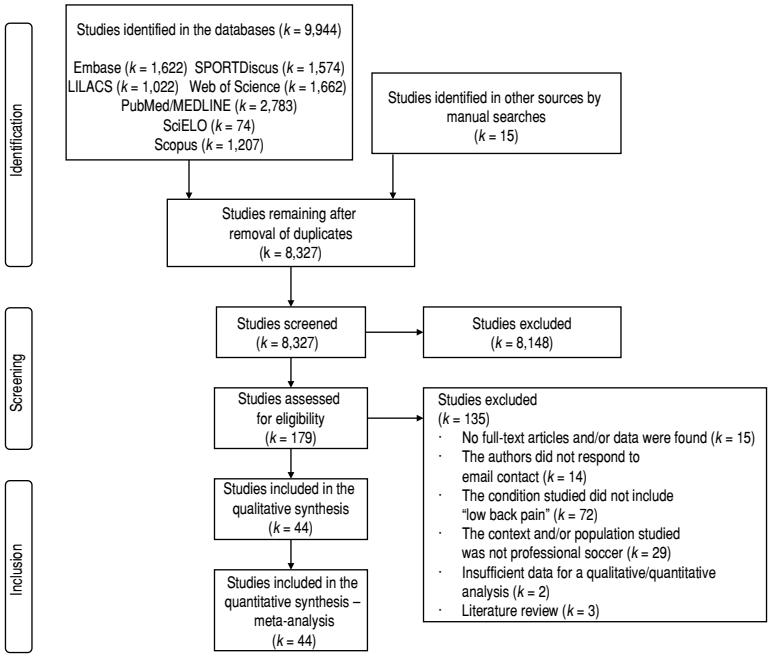

Figure 1. PRISMA flowchart of studies in the review (k = 44).

Study description

The included studies were published from 1991 to 2021 and conducted in Europe (k = 27),[22,35-40,44,46-48,50,51,54-57,64,67,68,71,73-75,77-79] South, Central, and North America and the Caribbean (k = 12),[42,43,49,59,60,63,65,66,69,70,72,76] Asia (k = 2),[45,62] Oceania(k = 2),[53,58] and Eurasia (k = 1),[41] using data from about 13,960 men and 2,083 women (Table 1). Regarding the design, the studies were cross-sectional (k = 12)[38,40-43,50,53,54,59,72,74,76] or longitudinal (k = 32).[22,35-37,39,44-49,51,55-58,60,62-71,73,75,77-79] Regarding the outcome, the studies provided data on the prevalence of LBP (k = 19),[36,38-42,45,49,50,53,54,60,62,67,68,72,74,76,78] the frequency of LBP according to the total number of injuries (k = 34),[22,35-37,40,42-49,51,55-60,63-71,73,76-79] and the incidence of LBP according to 1,000 player-hours of exposure (k = 24).[22,35,36,44-47,49,51,55-57,60,63-66,68,69,71,73,77-79]

Table 1. Characteristics of the studies included in the review (k = 44).

Study Author Date	Location Country(ies)	Design Cross-sectional, longitudinal	Sample Men/women (n) Mean age (variability)	Assessment Season*, period	Exposure Men/women (h) Total†	Injury Men/women (n) Total‡	Outcome Prevalence§, incidence
Arnason et al.[36] 1996	Iceland	Longitudinal	84/0 25 (18–35) years	Apr–Sep/1991, during ≤ 1 season	6,850¶/0	85/0	Prevalence, incidence
Bjørneboe et al.[37] 2011	Norway	Longitudinal	296/0 NA	Jul–Nov/2007, during ≤ 1 season	NA	174/0	Prevalence
Brynhildsen et al.[38] 1997	Sweden	Cross-sectional	0/361 21 (14–36) years	At the time of the study (point), lifetime	NA	NA	Prevalence
Brynhildsen et al.[39] 1997	Sweden	Longitudinal	0/261 21 (15–28) years	6–8 months, during ≤ 1 season	NA	NA	Prevalence
Cabral[40] 2017	Portugal	Cross-sectional	48/0 24 (16–38) years	Past year	NA	36/0	Prevalence
Çali et al.[41] 2015	Turkey	Cross-sectional	121/0 24 (16–34) years	Past year	NA	NA	Prevalence
Cesca et al.[42] 2012	Brazil	Cross-sectional	20/0 NA (18–40) years	Jan–May/2011, during ≤ 1 season	NA	58/0	Prevalence
Coelho[43] 2011	Brazil	Cross-sectional	67/0 NA	May–Aug/2011, during ≤ 1 season	NA	66/0	Prevalence
Dupont et al.[44] 2010	Scotland	Longitudinal	32/0 26 (4) years	Jul/2007–May/2009, during > 1 season	18,495/0	165/0	Prevalence, incidence

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Table 1. Characteristics of the studies included in the review (k = 44).

Study Author Date	Location Country(ies)	Design Cross-sectional, longitudinal	Sample Men/women (n) Mean age (variability)	Assessment Season*, period	Exposure Men/women (h) Total†	Injury Men/women (n) Total‡	Outcome Prevalence§, incidence
Eirale et al.[45] 2012	Qatar	Longitudinal	36/0 24 (NA) years	Jun/2007–Oct/2008, during > 1 season	10,043/0	78/0	Prevalence, incidence
Ekstrand et al.[46] 2011	Several[A]	Longitudinal	2,299/0 25 (5) years	June/2001–Dec/2009, during > 1 season	1,175,000/0	2,908/0	Prevalence, incidence
Ekstrand et al.[47] 2011	Several[B]	Longitudinal	613/154 25 (16–38) years 23 (15–38) years	Feb/2003–Oct/2008, during > 1 season	198,071/48,404	1,791/314	Prevalence, incidence
Ekstrand et al.[22] 2013	Several[C]	Longitudinal	1,743/0 NA	Jul/2001–Jun/2012, during > 1 season	1,057,201/0	8,029/0	Prevalence, incidence
Ekstrand et al.[48] 2020	Several[D]	Longitudinal	NA/0 NA	2001–2017, during > 1 season	NA	19,926/0	Prevalence
Escobar[49] 2018	Guatemala	Longitudinal	28/0 > 20 years	Jan–Jun/2017, during ≤ 1 season	396¶/0	25/0	Prevalence, incidence
Grosdent et al.[50] 2016	Belgium	Cross-sectional	43/0 18 (1) years	At the time of the study (point); past year	NA	NA	Prevalence
Hägglund et al.[51] 2009	Sweden	Longitudinal	239/228 25 (16–37) years 23 (15–41) years	Jan–Oct/2005, during ≤ 1 season	71,361/54,156	548/299	Prevalence, incidence
Hides et al.[53] 2016	Australia	Cross-sectional	25/0 24 (6) years	At the time of the study (point)	NA	NA	Prevalence
Junge et al.[54] 2000	Czech Republic	Cross-sectional	81/0 24 (18–33) years	Lifetime	NA	NA	Prevalence
Kristenson et al.[55] 2013	Norway and Sweden	Longitudinal	1,507/0 25 (5) years	Jan/2010–Nov/2011, during > 1 season	229,456/0	2,241/0	Prevalence, incidence
Krutsch et al.[56] 2022	Germany	Longitudinal	1,800§/0 NA	Aug/2014–May/2018, during > 1 season	855,000¶/0	551/0	Prevalence, incidence
Larruskain et al.[57] 2018	Spain	Longitudinal	50/35 25 (4) years 25 (5) years	Jul/2010–Jun/2015, during > 1 season	28,878/25,395	323/160	Prevalence, incidence
Lu et al.[58] 2020	Australia	Longitudinal	421/0 NA	Oct/2012–Apr/2018, during > 1 season	NA	917/0	Prevalence
Martín-San Agustín et al.[35] 2021	Spain	Longitudinal	0/123 23 (4) years	Jul/2016–Jun/2017, during ≤ 1 season	0/30,959¶	0/113	Prevalence, incidence
Nascimento et al.[59] 2015	Brazil	Cross-sectional	25/0 24 (4) years	Jan–May/2013, during ≤ 1 season	NA	11/0	Prevalence
Netto et al.[60] 2019	Brazil	Longitudinal	864/0 22 (NA) years	May–Dec/2016, during ≤ 1 season	12,507¶/0	312/0	Prevalence, incidence
Noormohammadpour et al.[62] 2020	Iran	Longitudinal	37/0 19 (16–23) years	6 months, during ≤ 1 season	NA	NA	Prevalence
Pangrazio et al.[63] 2016	Several[E]	Longitudinal	506/644 NA	2015–2016, during ≤ 1 season	1,914¶/1,584¶	115/151	Prevalence, incidence
Papacostas et al.[64] 2009	Greece	Longitudinal	105/0 26 (5) years	Jul–May, during > 1 season	11,491/0	51/0	Prevalence, incidence
Paus et al.[65] 2003	Argentina	Longitudinal	86/0 27 (17–37) years	1995–2001, during > 1 season	3,237/0	2,536/0	Prevalence, incidence
Pedrinelli et al.[66] 2013	Several[F]	Longitudinal	276/0 NA	Jul/2011, during ≤ 1 season	2,430/0	63/0	Prevalence, incidence
Peterson et al.[67] 2000	Czech Republic	Longitudinal	51/0 NA	Past year	NA	99/0	Prevalence
Poulsen et al.[68] 1991	Denmark	Longitudinal	55/0 26 (21–30) years	1986, during ≤ 1 season	6,445/0	57/0	Prevalence, incidence
Santos et al.[69] 2009	Brazil	Longitudinal	35/0 NA	2007, during ≤ 1 season	1,007¶/0	49/0	Prevalence, incidence

Risk of bias

The assessment of the 44 included studies showed the following results: 93% to 98% of studies had "low risk" in items 1, 3, and 4; 75% and 71% of studies had "low risk" in items 5 and 6, respectively; and 68% and 64% of studies had "low risk" in items 2 and 8, respectively. The main methodological problem was in item 7, as 86% of studies had "high risk," mainly because they did not provide a CI for prevalence/incidence values (Figure 2). In item 5, which refers to the diagnosis of the condition, 62% of studies ($k = 27$)[22,36,37,44-48,50,51,55-58,60,62,64,65,68-71,73,75,77-79] used the definition of soccer-related injury proposed by Fuller et al.[20] in their consensus statement (i.e., time-loss injury) (Supplementary Table 2). The total average of "low risk" answers was 5.7 (2–8) (Table 2).

Table 1. Characteristics of the studies included in the review (k = 44).

Study Author Date	Location Country(ies)	Design Cross-sectional, longitudinal	Sample Men/women (n) Mean age (variability)	Assessment Season*, period	Exposure Men/women (h) Total†	Injury Men/women (n) Total‡	Outcome Prevalence§, incidence
Silva et al.[70] 2005	Brazil	Longitudinal	30/0 NA	Jan–Dec/2003, during ≤ 1 season	NA	49/0	Prevalence
Stubbe et al.[71] 2015	Netherlands	Longitudinal	217/0 25 (4) years	Jul/2009–May/2010, during ≤ 1 season	46,194/0	286/0	Prevalence, incidence
Todeschini et al.[72] 2019	Brazil	Cross-sectional	39/0 23 (5) years	Lifetime	NA	NA	Prevalence
Torrontegui-Duarte et al.[73] 2020	Spain	Longitudinal	71/0 27 (3) years	Aug/1999–May/2017, during > 1 season	50,140¶/0	356/0	Prevalence, incidence
Tunås et al.[74] 2015	Norway	Cross-sectional	0/277 22 (18–32) years	At the time of the study (point); past year; lifetime	NA	NA	Prevalence
van Beijsterveldt et al.[75#] 2015	Netherlands	Longitudinal	217/0 25 (4) years	Jul/2009–May/2010, during ≤ 1 season	46,194/0	286/0	Prevalence, incidence
Vasconcelos Jr. et al.[76] 2010	Brazil	Cross-sectional	19/0 27 (4) years	May–Nov/2009, during ≤ 1 season	NA	20/0	Prevalence
Waldén et al.[77] 2005	Several[G]	Longitudinal	266/0 26 (4) years	Jul/2001–May/2002, during ≤ 1 season	69,707/0	658/0	Prevalence, incidence
Waldén et al.[78] 2007	Several[H]	Longitudinal	368/0 NA	Jun–Jul/2004, during ≤ 1 season	4,742/0	45/0	Prevalence, incidence
Waldén et al.[79] 2013	Several[I]	Longitudinal	1,357/0 NA	Aug/2001–May/2010, during > 1 season	773,563/0	5,949/0	Prevalence, incidence

n = absolute number; h = hour; NA = not available
*Assessment period in each included study: during ≤ 1 season (≤ 12 months) or > 1 season (> 12 months); or during a given time (e.g., point) and/or period (e.g., past year).
†Total hours of exposure in training and/or matches in each included study.
‡Total soccer-related injuries in each included study.
§Prevalence of LBP according to the total sample (cases/total sample) and/or frequency of LBP according to the total number of injuries (cases/total number of injuries) in each included study.
¶Estimated exposure based on data provided in the included study, in another study with the same sample, and/or in the literature.
#This study used data from the same sample as the study by van Stubbe et al.[71]
[A]Data from 51 European teams from several countries such as England, Italy, Germany, Spain, France, the Netherlands, Sweden, among others.
[B]Data from 20 European teams from Sweden, the Netherlands, Finland, Switzerland, Ireland, Norway, Austria, and Scotland.
[C]Data from 27 European teams from 10 countries, such as England, Italy, Netherlands, Spain, Germany, among others.
[D]Data from 116 European teams from 24 countries, such as France, Spain, Germany, Italy, England, Portugal, the Netherlands, Belgium, Norway, Sweden, Switzerland, Denmark, among others.
[E]Data from 12 Latin American teams and 16 national teams from Argentina, Brazil, Bolivia, Chile, Colombia, Peru, Ecuador, Paraguay, Uruguay, Venezuela, Costa Rica, Panama, Haiti, Jamaica, Mexico, and the United States.
[F]International tournament with national teams from Argentina, Brazil, Peru, Colombia, Costa Rica, Uruguay, Ecuador, Bolivia, Chile, Venezuela, Mexico, and Paraguay.
[G]Data from 11 European teams from England, France, Italy, Netherlands, and Spain.
[H]International tournament with national teams from Bulgaria, Croatia, Czech Republic, Denmark, England, France, Germany, Greece, Italy, Latvia, Netherlands, Portugal, Russia, Spain, Sweden, and Switzerland.
[I]Data from 24 European teams from Scotland, England, France, Netherlands, Belgium, Germany, Italy, Portugal, and Spain.

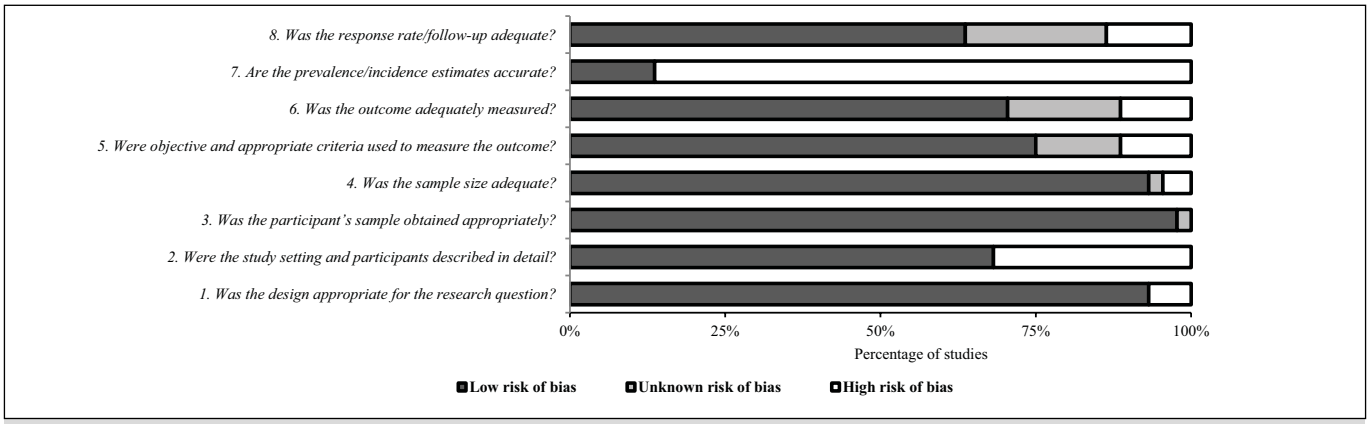

Figure 2. Risk of bias summary of the included studies ($k = 44$).

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Table 2. Risk of bias assessment of the included studies (k = 44).

	Item								
	1	2	3	4	5	6	7	8	Total
Study	*Study design*	*Setting/ participants*	*Sampling method*	*Sample size*	*Diagnosis*	*Data collection*	*Statistical approach*	*Sample losses*	**0–8**
Arnason et al.[36]	Y	Y	Y	Y	Y	Y	N	Y	7
Bjørneboe et al.[37]	Y	Y	Y	Y	Y	U	N	Y	6
Brynhildsen et al.[38]	Y	Y	Y	Y	U	Y	N	Y	6
Brynhildsen et al.[39]	Y	Y	Y	Y	Y	N	N	U	5
Cabral[40]	Y	Y	Y	Y	Y	Y	N	Y	7
Çali et al.[41]	Y	Y	Y	Y	N	Y	N	N	5
Cesca et al.[42]	N	Y	Y	N	U	Y	N	Y	4
Coelho[43]	Y	N	Y	Y	N	N	N	Y	4
Dupont et al.[44]	Y	Y	Y	Y	Y	Y	Y	Y	8
Eirale et al.[45]	Y	Y	Y	Y	Y	Y	N	Y	7
Ekstrand et al.[46]	Y	Y	Y	Y	Y	Y	N	U	6
Ekstrand et al.[47]	Y	Y	Y	Y	Y	Y	N	U	6
Ekstrand et al.[22]	Y	N	Y	Y	Y	Y	N	Y	6
Ekstrand et al.[48]	Y	N	Y	U	Y	U	N	U	3
Escobar[49]	Y	N	Y	Y	N	Y	N	Y	5
Grosdent et al.[50]	Y	Y	Y	Y	Y	Y	N	Y	7
Hägglund et al.[51]	Y	Y	Y	Y	Y	Y	N	Y	7
Hides et al.[53]	Y	Y	Y	Y	N	Y	N	Y	6
Junge et al.[54]	Y	Y	Y	Y	U	U	N	Y	5
Kristenson et al.[55]	Y	Y	Y	Y	Y	Y	Y	Y	8
Krutsch et al.[56]	Y	N	Y	Y	Y	Y	N	U	5
Larruskain et al.[57]	Y	Y	Y	Y	Y	Y	Y	Y	8
Lu et al.[58]	Y	N	Y	Y	Y	N	Y	U	5
Martín-San Agustín et al.[35]	Y	Y	Y	Y	Y	Y	Y	N	6
Nascimento et al.[59]	Y	Y	Y	Y	N	U	N	Y	5
Netto et al.[60]	Y	N	Y	Y	Y	Y	N	Y	6
Noormohammadpour et al.[62]	N	Y	Y	Y	Y	U	N	Y	5
Pangrazio et al.[63]	Y	N	Y	Y	U	U	N	Y	4

Table 2. Risk of bias assessment of the included studies (k = 44).

	Item								
	1	2	3	4	5	6	7	8	Total
Study	*Study design*	*Setting/ participants*	*Sampling method*	*Sample size*	*Diagnosis*	*Data collection*	*Statistical approach*	*Sample losses*	**0–8**
Papacostas et al.[64]	Y	Y	Y	Y	Y	Y	N	Y	7
Paus et al.[65]	Y	Y	Y	Y	Y	Y	N	U	6
Pedrinelli et al.[66]	Y	N	Y	Y	Y	Y	N	Y	6
Peterson et al.[67]	Y	N	Y	Y	Y	N	N	N	4
Poulsen et al.[68]	Y	Y	Y	Y	Y	Y	N	Y	7
Santos et al.[69]	Y	N	Y	Y	Y	U	N	Y	5
Silva et al.[70]	N	N	U	Y	Y	N	N	U	2
Stubbe et al.[71]	Y	Y	Y	Y	Y	Y	N	N	6
Todeschini et al.[72]	Y	Y	Y	Y	U	Y	N	Y	6
Torrontegui-Duarte et al.[73]	Y	Y	Y	Y	Y	Y	N	N	6
Tunås et al.[74]	Y	Y	Y	Y	Y	Y	N	Y	7
van Beijsterveldt et al.[75]	Y	Y	Y	Y	Y	Y	N	N	6
Vasconcelos Jr. et al.[76]	Y	Y	Y	N	U	U	N	U	3
Waldén et al.[77]	Y	Y	Y	Y	Y	Y	N	Y	7
Waldén et al.[78]	Y	N	Y	Y	Y	Y	N	Y	6
Waldén et al.[79]	Y	N	Y	Y	Y	Y	Y	U	6

Tool developed by Loney and Stratford[18] and Loney et al.[19]
1. Was the design appropriate for the research question?
2. Were the study setting and participants described in detail?
3. Was the participant's sample obtained appropriately?
4. Was the sample size adequate?
5. Were objective and appropriate criteria used to measure the outcome?
6. Was the outcome adequately measured?
7. Are the prevalence/incidence estimates accurate?
8. Was the response rate/follow-up adequate?
Y = yes; N = no; U = unclear.

META-ANALYSES

Prevalence

In total, 10 studies[36,39,42,45,49,60,62,68,76,78] provided the prevalence of LBP during ≤ 1 season (Supplementary Table 3a). The pooled estimate in men was 1% (95%CI = 0–4%) (Figure 3a). The evidence for this estimate was rated as moderate quality due to serious inconsistency (I^2 = 81%). Descriptively, one study[39] showed an estimate in women of 29% (95%CI = 24-35%) (Figure 3b).
Four studies[38,50,53,74] provided the point prevalence of LBP (Supplementary Table 3b). The pooled estimate in men was 25% (95%CI = 16–36%) (Figure 3c). The evidence for this estimate was rated as low quality due to serious risk of bias and indirectness (≥ 50% of pooled studies had "high risk" in item 5 of the risk of bias tool and did not use valid/reliable methods to identify LBP in soccer settings, respectively). The pooled estimate in women was 28% (95%CI = 20–37%) (Figure 3d). The evidence for this estimate was rated as moderate quality due to serious inconsistency (I^2 = 81%).
Five studies[40,41,50,67,74] provided past-year prevalence of LBP (Supplementary Table 3c). The pooled estimate in men was 34% (95%CI = 24–44%) (Figure 3e). The evidence for this estimate was rated as low quality due to serious risk of bias and indirectness (≥ 50% of pooled studies had "high risk" in items 5 or 6 of the risk of bias tool and did not use valid/reliable methods to identify LBP in soccer settings, respectively). Descriptively, one study[74] showed an estimate in women of 57% (95%CI = 51-63%) (Figure 3f).
Five studies[38,54,62,72,74] provided lifetime prevalence of LBP (Supplementary Table 3d). The pooled estimate in men was 32% (95%CI = 25–39%) (Figure 3g). The evidence for this estimate was rated as high quality. The pooled estimate in women was 50% (95%CI = 32–69%) (Figure 3h). The evidence for this estimate was rated as moderate quality due to serious inconsistency (I^2 = 95%).

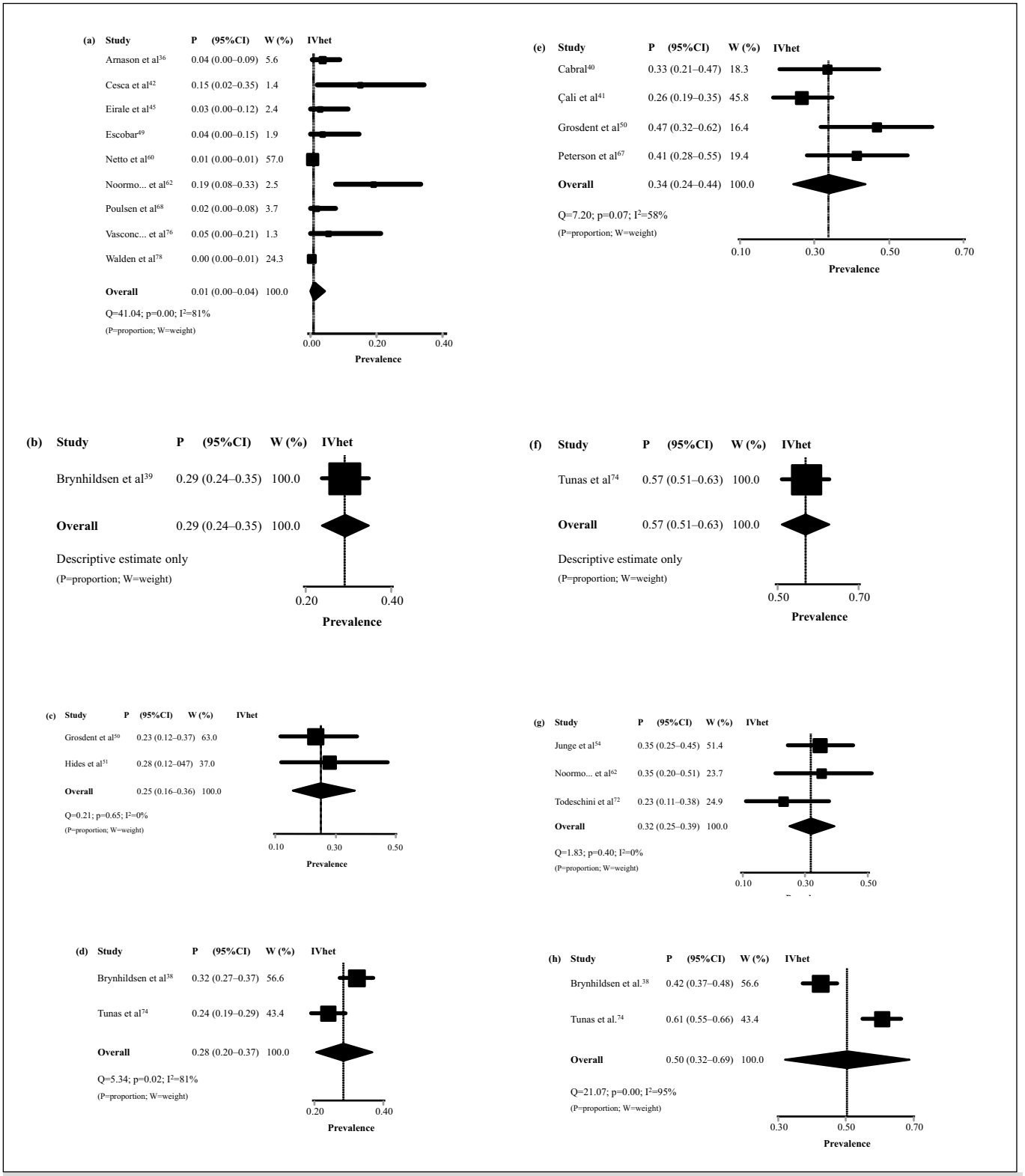

Figure 3. Meta-analyses with pooled prevalence estimates of low back pain in professional soccer players, according to the total number of players, reported in each included study (k = 19).

Injury frequency

In total, 34 studies[22,35-37,40,42-49,51,55-60,63-71,73,76-79] provided the frequency of LBP according to the total number of injuries (Supplementary Table 4). The pooled estimate in men was 2% (95%CI = 1–3%) (Figure 4a). The evidence for this estimate was rated as low quality due to serious inconsistency and publication bias (I^2 = 88% and presence of "major asymmetry," with p = 0.02 according to Egger's test, respectively) (Figure 5). The pooled estimate in women was 4% (95%CI = 2–5%) (Figure 4b). The evidence for this estimate was rated as high quality.

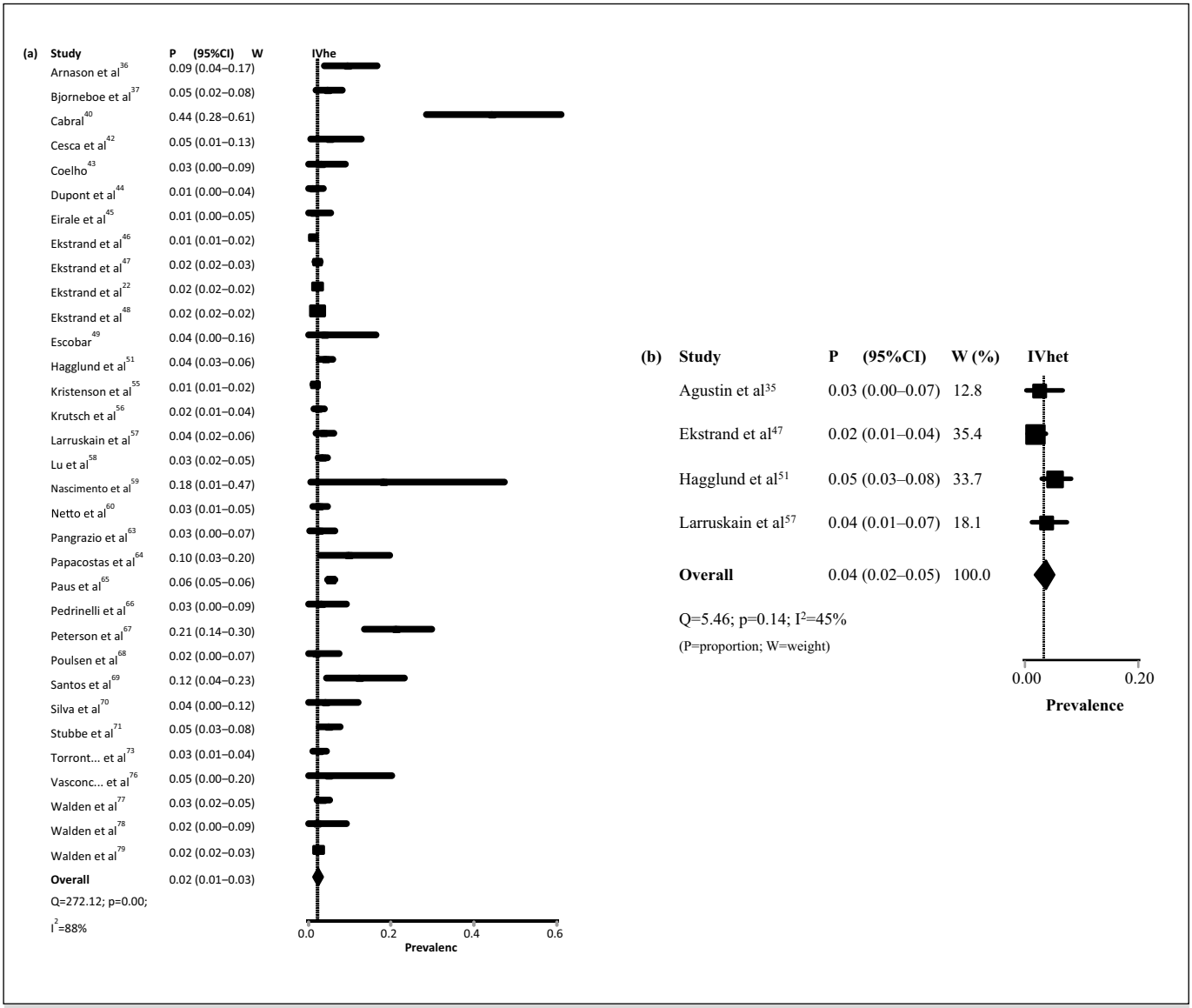

Figure 4. Meta-analyses with pooled frequency estimates of low back pain in professional soccer players, according to the total number of injuries, reported in each included study (k = 34).

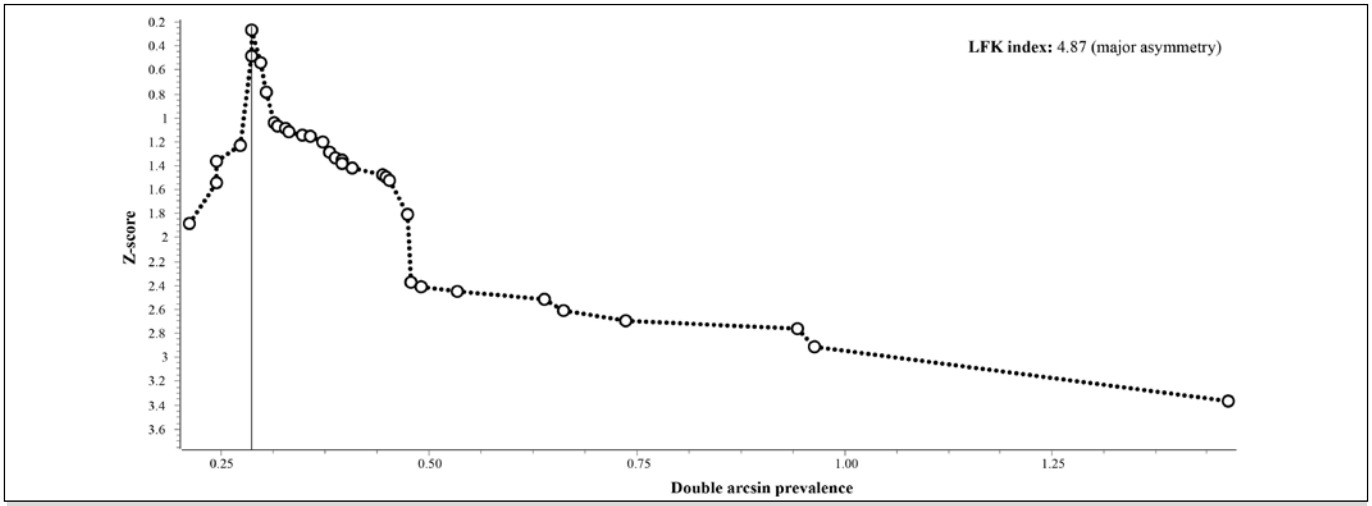

Figure 5. Doi plot of Z-score by double arcsine prevalence (k = 33).

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Incidence

A total of 24[22,35,36,44-47,49,51,55-57,60,63-66,68,69,71,73,77-79] studies provided the incidence of LBP according to 1,000 player-hours of exposure (Supplementary Table 5). The pooled rate in men was 0.30 (95%CI = 0.17–0.53%) (Figure 6a). We excluded one study[65] from this analysis due to its very extreme rate (43.25; 95%CI = 36.50–50.84). The evidence for this rate was rated as low quality due to serious inconsistency and publication bias (I^2 = 100% and presence of "major asymmetry," with $p < 0.01$ according to Egger's test, respectively) (Figure 7). The pooled estimate in women was 0.32 (95%CI = 0.06–1.87%) (Figure 6b). The evidence for this estimate was rated as moderate quality due to serious inconsistency (I^2 = 100%).

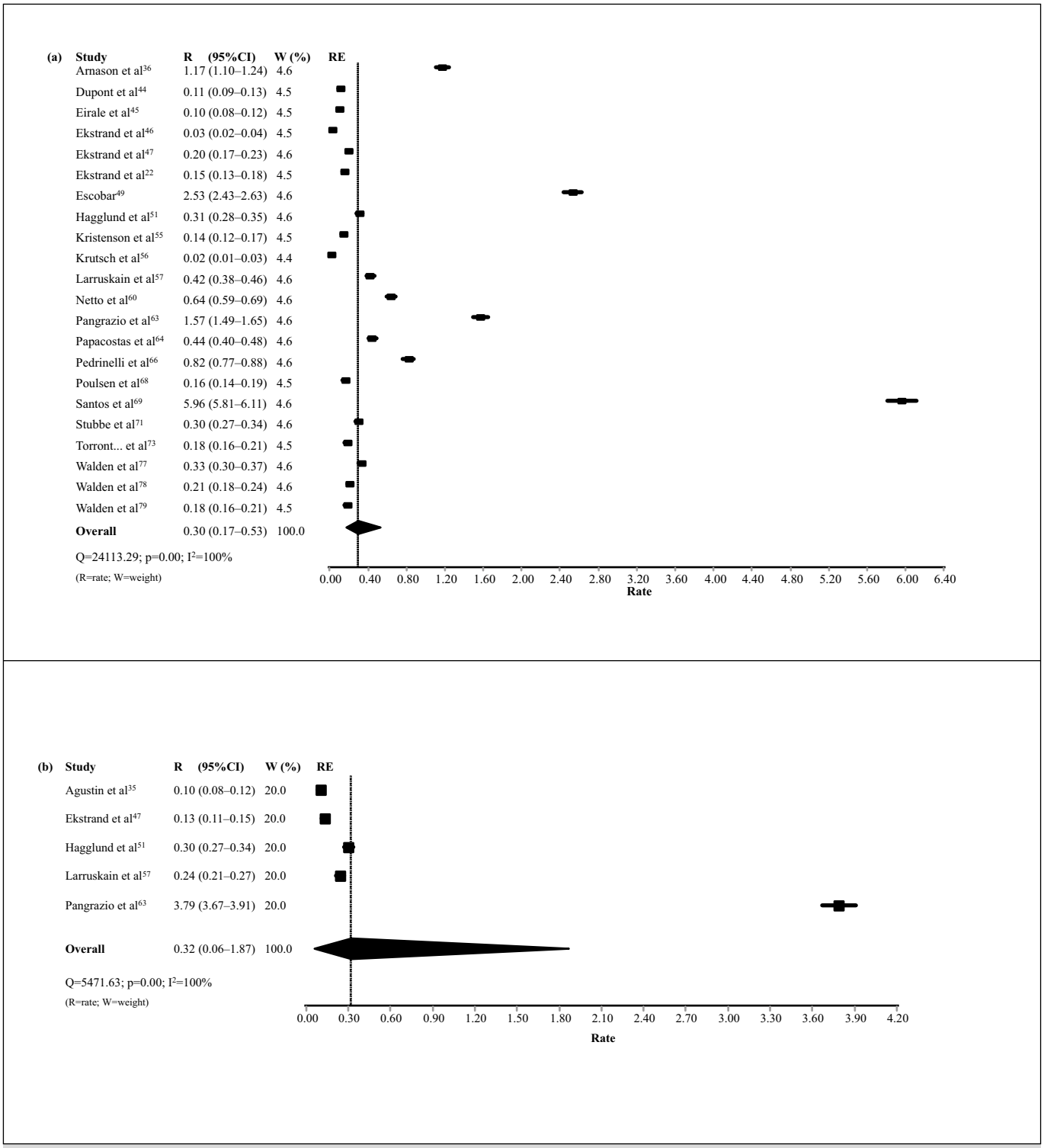

Figure 6. Meta-analyses with pooled incidence rates of low back pain in professional soccer players, according to 1,000 player-hours of exposure, reported in each included study (k = 23).

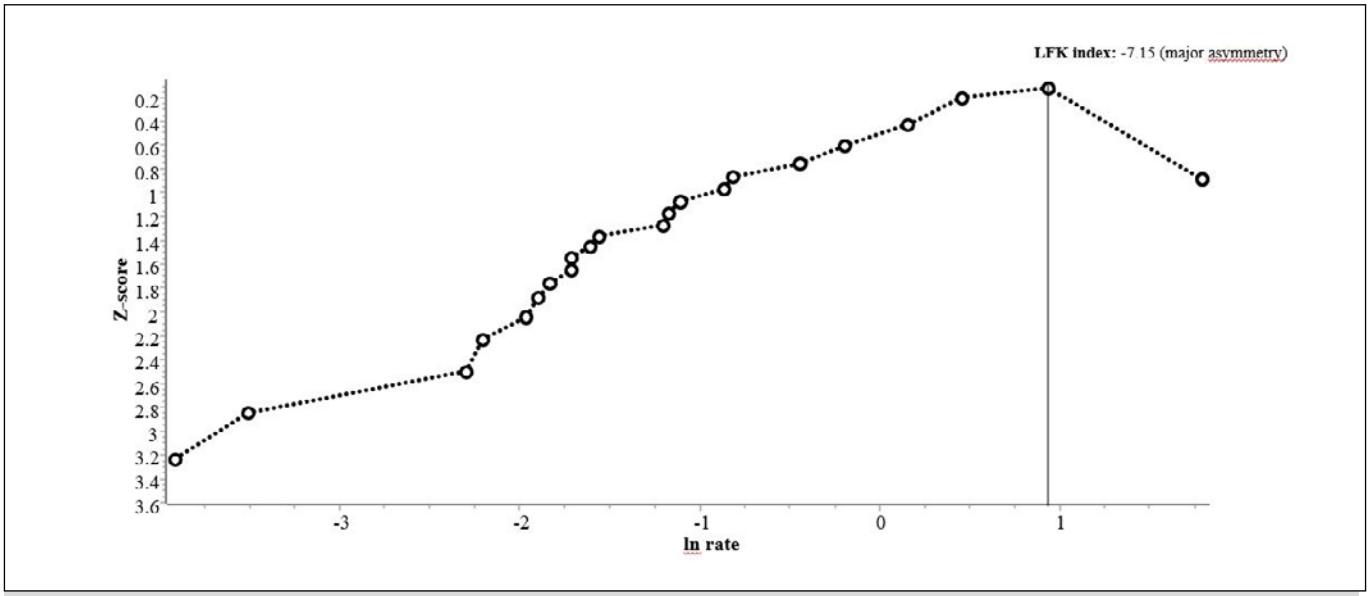

Figure 7. Doi plot of Z-score by rate (k = 23).

Recurrence, intensity, and severity

Three studies[36,46,48] provided the recurrence rate of LBP (only in men), which ranged from 3% to 63%. Five studies[40,41,50,53,62] provided the intensity of LBP, which ranged from 1.68 (2.39) to 4.87 (2.14) points on a 0–10 scale. Three of these studies[40,41,50] reported a minimum of 0 and a maximum of 8 points. Five studies[22,45,46,48,57] provided the days a player is absent from professional activities due to pain, which ranged from 2 (0) to 10 (19) days. Four of these studies[45,46,48,57] reported a minimum of one and a maximum of 28 days absent.

DISCUSSION

General findings

This review included 44 original studies with epidemiological (prevalence and incidence) and clinical (recurrence and severity) data on LBP in professional soccer players. Most studies scored "low risk" in the assessment of bias. Meta-analyses of the prevalence, frequency (according to the total number of injuries), and incidence of LBP provided pooled estimates with quality of evidence ranging from high to low according to the GRADE system. Few studies reported data on the recurrence, intensity, and severity of LBP, with considerable variation between results.

Prevalence findings

The prevalence of LBP in men showed a consistent increase as the exposure/assessment time of the original studies increased. The estimate (1%) was lower when pooling studies that evaluated LBP during ≤ 1 season (e.g., tournaments and championships), but higher (34%) when pooling studies that assessed LBP in the past year. In fact, longer exposure/assessment periods are more sensitive in capturing positive cases, especially for conditions that may present short-term signs/symptoms, such as an acute episode of LBP.[18] Other reviews on the epidemiology of LBP in professional sports also show this same pattern of prevalence estimates.[4,5,80] On the other hand, for women, the inconsistency between prevalence estimates was greater, since only one study provided estimates during ≤ 1 season (29%) and in the past year (57%). Despite this, point prevalence was consistently lower (28%) compared with lifetime prevalence (50%).

Injury frequency findings

The frequency of LBP according to the total number of injuries showed 1,165 events/48,577 injuries (2%) in men and 31 events/886 injuries (4%) in women. Recent longitudinal studies using a similar definition of soccer-related injury (time-loss injury) also show estimates of LBP from 2% to 2.5% in men[48,56,73] and from 2.7% to 3.8% in women,[35,57,63] while older studies report estimates above 5%.[51,81] Over the past few years, new preventive approaches implemented within professional soccer, such as the identification of potential risk factors, the improvement of specialized medical practices, and individualized care, may have contributed to the reduction in the estimates of LBP.[6,80,81] Moreover, other aspects related to soccer itself such as the player's position on the field, can have a significant effect on back complaints. For example, Onaka et al.[82] found a wide variation in the occurrence of LBP according to field position compared with other conditions (e.g., groin pain). Forwards (4.1%) and defensive midfielders (5.2%) had lower estimates, while goalkeepers (28.6) and attacking midfielders (43.1%) had higher estimates. Differences in the biomechanical demands of the musculoskeletal system depending on field position may explain this variation in estimates.[82]

Incidence findings

The incidence of LBP per 1,000 player-hours of exposure showed similar rates in men (0.30) and women (0.32). However, the pooled rate in women shows a wide CI range compared with the pooled rate in men, which may be attributed to the small number of included studies evaluating the incidence of LBP in female soccer players (k = 5). These rates corroborate the high epidemiological burden of LBP among soccer-related injuries worldwide.[4,6] A recent systematic review on the epidemiology of injuries in professional soccer settings showed that the rate of injuries affecting the trunk region (e.g., spine) was 0.40 per 1,000 player-hours of exposure, making it the second most affected anatomical site after lower limb injuries.[32] LBP contributes to most injuries that affect the trunk in professional soccer players, as evidenced by several primary

studies.[35,44,47,57,66,69,71,79] Compared with other elite sports, the incidence rate of LBP is higher in basketball (0.40/1,000 hours of exposure),[83] mainly due to a combination of factors, such as overload and trauma to the lumbar region,[6] and in rowing (1.67/1,000 hours of exposure),[84] mainly due to the exacerbated increase in tension in the lumbar paraspinal muscles.[5]

Recurrence, intensity, and severity findings

A very small number of studies reported the recurrence of LBP ($k = 3$). Two of these studies evaluated large samples over long follow-up periods (Ekstrand, Hägglund, and Waldén,[46] $n \cong 2,299$, 1–9 seasons; and Ekstrand et al.,[48] $n \cong 12,350$, 1–16 seasons) and provided recurrence rates of 3 and 18.8%, respectively. Although previous guidelines presented recommendations for assessing injury recurrence in soccer (e.g., definition and use),[20,23] this measure has not been used in most epidemiological studies, thus failing to show the burden of injury recurrence in professional players. Four original studies reported the intensity of LBP (0–10), which ranged from mild (0–3) to moderate (4–7). Maintaining adequate physical condition, flexibility, and muscle strength of the trunk and lower limbs can be a protective factor against severe injuries that manifest with higher pain intensity.[9,50] Hides et al.[53] found that additional muscle training programs (e.g., strengthening) performed by players during the pre-season to prevent injuries was associated with a significant increase in the cross-sectional area of the multifidus muscle and a clinically important decrease in pain intensity in players suffering from LBP at baseline. Five original studies reported the severity of LBP (days absent from professional activities due to pain), which ranged from one to 28 days (average of 2 [0] to 10 [19] days). This finding highlights that most players with LBP had a severity ranging from minimal (≤ 3 days) to moderate (8–28 days),[20] which suggests the presence of an acute condition (≤ 6 weeks).[15]

Practical implications

Although the included studies provided good data on the occurrence of LBP, this condition is still poorly studied as a primary outcome in professional soccer. Much of the literature specifically on back pain in soccer includes male, young, and non-elite athletes.[6,7,85] The results of this review showed that the epidemiological burden of LBP in professional players may be significant in men (prevalence of 1% to 34%), but consistently higher in women (prevalence of 28% to 57%). Considering both sexes, at least one in four players is likely to suffer from LBP at any given time. With an ever-increasing level of physical demand, health professionals who treat professional players should be alert to the causal mechanisms of lumbar injuries, including acute/traumatic (e.g., muscle strains, trunk hyperextension/hyperflexion, direct contusions, and sitting falls) and chronic/overuse (e.g., repetitive stress, microtraumas, overload, and degenerative changes).[6,9] Particularly in women, a U-shaped perspective should also be considered, since low or (conversely) strenuous levels of sport activities are associated with LBP.[86] Moreover, other aspects, such as less pre-season physical conditioning, the large number of matches played as a starter, and field position can significantly increase estimates of LBP.[41,53,74,82] All these factors are relevant for preventive efforts in clinical practice.

Potential limitations

This was a large-scale literature review, with extensive search, inclusion, and analysis of data on the epidemiology of LBP in professional soccer players. The potential limitations of the review add to the limitations of the existing literature on this topic: (a) the different definitions of LBP as an injury in soccer settings (e.g., pain with or without restriction of sports practice; need or not for medical care; and time-loss injury) are a potential source of important heterogeneity, which may have contributed to inconsistencies in some meta-analyses; (b) most of the included studies did not assess LBP as a primary outcome, which limited the acquisition of additional data and secondary analyses (e.g., age group and field position); (c) we did not estimate the prevalence during ≤ 1 season and in the past year in women, and the recurrence, intensity, and severity of LBP due to the insufficient number of included studies ($k = 1$) and/or the very wide variation between results. Future studies assessing back pain in soccer settings should address these limitations.

CONCLUSION

To the best of our knowledge, this is the first review to evaluate the epidemiology of LBP in professional soccer players. For men, high-quality evidence corresponds to a lifetime prevalence of 32%; moderate-quality evidence corresponds to a prevalence during ≤ 1 season of 1%; and low-quality evidence corresponds to a point prevalence of 25%, a prevalence in the past year of 34%, a frequency (according to the total number of injuries) of 2%; and an incidence rate of 0.30 per 1,000 player-hours of exposure. For women, high-quality evidence refers to a frequency (according to the total number of injuries) of 4%; and moderate-quality evidence refers to a point prevalence of 28%, a lifetime prevalence of 50%, and an incidence rate of 0.32 per 1,000 player-hours of exposure. These results can be used by sports clubs, medical teams, and/or athletes to develop preventive and management strategies aimed at reducing the occurrence of LBP in elite soccer.

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SUPPLEMENTARY MATERIAL

Table 1. Search strategies performed on April 6, 2021.

Embase
(((backache:ti,ab,kw OR 'low back pain':ti,ab,kw) AND sport:ti,ab,kw OR injury:ti,ab,kw OR 'sport injury':ti,ab,kw) AND football:ti,ab,kw OR soccer:ti,ab,kw) AND athlete:ti,ab,kw
LILACS
("back pain") OR ("low back pain") OR (backache) OR (lumbago) OR (spine) AND (injury) OR ("sport injury") OR ("sports injuries") AND (football) OR (soccer) OR (athletes) OR (players)
PubMed/MEDLINE
(((((("Epidemiology"[Mesh] OR "epidemiology" [Subheading]) OR ("Prevalence"[Mesh] OR "Cross-Sectional Studies"[Mesh])) OR ("Incidence"[Mesh] OR "Cohort Studies"[Mesh])) AND "Back Pain"[Mesh]) OR "Low Back Pain"[Mesh]) OR "Back Injuries"[Mesh]) AND ("Football/injuries"[Mesh] OR "Football/statistics and numerical data"[Mesh])) OR ("Soccer/injuries"[Mesh] OR "Soccer/statistics and numerical data"[Mesh])
SciELO
("back pain") OR ("low back pain") OR (backache) OR (lumbago) OR (spine) OR (injury) OR ("sport injury") OR ("sports injuries") AND (football) OR (soccer) OR (athletes) OR (players)
Scopus
TITLE-ABS-KEY ("back pain" OR "low back pain" OR "back injury" OR "lumbar pain" OR backache OR lumbago OR "spinal pain" AND sport AND football OR soccer OR athletes OR players OR professionals OR elite)
SPORTDiscus
(back pain or low back pain or lumbar pain or spinal pain or backache or lumbago or back injury) AND (players or athletes or professionals or elite) AND (sport or football or soccer or ball)
Web of Science
#1 TS = (back pain OR low back pain OR back injury OR lumbar pain OR backache OR lumbago OR spinal pain) #2 TS = (players OR athletes OR professionals OR elite) #3 TS = (sports OR football OR soccer) #4 #3 AND #2 AND #1

Table 2. Definitions of soccer-related injury used in the included studies (k = 44).

Study	Definition	Reference
Arnason et al.[36]	Unable to participate in a match or training session because of an injury incurred in soccer (time-loss injury).	Lewin[87]
Bjørneboe et al.[37]	Unable to take full part in football activity or match play at least 1 day beyond the day of injury (time-loss injury).	Fuller et al.[20]
Brynhildsen et al.[38]	Woman's subjective feeling of back pain.	NA
Brynhildsen et al.[39]	Experience of back pain during the last active soccer playing season but did not have to prevent the woman from her daily activities or from taking part in practice sessions or games.	NA
Cabral[40]	Pain, ache, or discomfort in the lower back with or without radiation to one or both legs.	Kuorinka et al.[88]
Çali et al.[41]	NA	NA
Cesca et al.[42]	NA	NA
Coelho[43]	NA	NA
Dupont et al.[44]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Eirale et al.[45]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Ekstrand et al.[46]	Traumatic distraction or overuse injury to the muscle, leading to a player being unable to fully participate in training or match play (time-loss injury).	Ekstrand et al.[46]
Ekstrand et al.[47]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Ekstrand et al.[22]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Ekstrand et al.[48]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Escobar[49]	NA	NA
Grosdent et al.[50]	Any physical complaint that is the result of participating in football training or a football match, leading to a player being unable to fully participate in future football training or match play (time-loss injury).	NA
Hägglund et al.[51]	Physical complaint resulting from football training or match play, leading to the player being unable to participate fully in at least one training session or match (time-loss injury).	Hägglund et al.[23]

Table 2. Definitions of soccer-related injury used in the included studies (k = 44).

Study	Definition	Reference
Hides et al.[53]	Pain localized between T12 and the gluteal fold.	Hides et al.[89]
Junge et al.[54]	NA	NA
Kristenson et al.[55]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Krutsch et al.[56]	Absence from official football matches of at least 28 days (severe injury).	Fuller et al.[20]
Larruskain et al.[57]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Lu et al.[58]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Martín-San Agustín et al.[35]	Any physical complaint sustained by a player that results from a soccer match or training, irrespective of the need for medical attention.	Fuller et al.[20]
Nascimento et al.[59]	NA	NA
Netto et al.[60]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Noormohammadpour et al.[62]	Pain between the last rib and the lower gluteal fold, which is bad enough to limit or change athletes' daily routine or sports activities for more than 1 day (time-loss injury).	Noormohammadpour90
Pangrazio et al.[63]	NA	NA
Papacostas et al.[64]	Any mishap occurring during scheduled games or practices that causes a player to miss a subsequent game or practice session (time-loss injury).	Nicholas and Hershman[91]
Paus et al.[65]	An injury occurring during soccer practice, which caused the athlete to miss training and games, followed by the need for anatomical diagnosis of the injured tissue and corresponding treatment (time-loss injury)".	Dvorak and Junge[92]
Pedrinelli et al.[66]	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 activities.	Fuller et al.[20]
Peterson et al.[67]	Any tissue damage caused by football regardless of the consequences with respect to absence from training or match.	Junge and Dvorak[93]
Poulsen et al.[68]	Any injury occurring during scheduled games or practices which caused the player to miss the next game or practice session (time-loss injury).	Ekstrand[94]
Santos et al.[69]	Absence of the athletes from their professional activities for at least 48 hours (time-loss injury).	NA
Silva et al.[70]	Any event that occurs during games or training of the club, with a reduction or complete absence from the participation of athletes in their sports activities (time-loss injury).	Schmidt-Olsen et al.[95]
Stubbe et al.[71]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Todeschini et al.[72]	NA	NA
Torrontegui-Duarte et al.[73]	Musculoskeletal complaint (pain and/or discomfort) reported by players to the medical staff and receiving medical attention (medical-attention injury), and injuries resulting in a player being unable to fully participate in future training or match play (time-loss injury).	Fuller et al.[20]
Tunås et al.[74]	Pain, ache, or discomfort in the lower back with or without radiation to one or both legs.	Kuorinka et al.[88]
van Beijsterveldt et al.[75]	According to Fuller et al.[20] (time-loss injury).	Fuller et al.[20]
Vasconcelos Jr. et al.[76]	NA	NA
Waldén et al.[77]	According to Ekstrand[94] (time-loss injury).	Ekstrand[94]
Waldén et al.[78]	According to Hägglund et al.[23] (time-loss injury).	Hägglund et al.[23]
Waldén et al.[79]	According to Hägglund et al.[23] (time-loss injury).	Hägglund et al.[23]

NA = not available

Table 3. Prevalence estimates of low back pain in professional soccer players, according to the total number of players, reported in each included study (k = 19).

Study	Prevalence					
Author	Men			Women		
	n	%	95%CI	n	%	95%CI
a) During ≤ 1 season/≤ 12 months (k = 10)						
Arnason et al.[36]	3	3.6	0.8–10.4	–	–	–
Brynhildsen et al.[39]	–		–	76	29.1	23.9–34.9
Cesca et al.[42]	3	15.0	5.2–36.0	–	–	–
Eirale et al.[45]	1	2.8	0.5–14.2	–	–	–
Escobar[49]	1	3.6	0.6–17.7	–	–	–
Netto et al.[60]	5	0.6	0.2–1.4	–	–	–
Noormohammadpour et al.[62]	7	18.9	9.5–34.2	–	–	–
Poulsen et al.[68]	1	1.8	⁻0.6–10.5	–	–	–
Vasconcelos Jr. et al.[76]	1	5.3	0.9–24.6	–	–	–
Waldén et al.[78]	1	0.3	⁻0.1–1.7	–	–	–
b) Point prevalence (k = 4)						
Brynhildsen et al.[38]	–	–	–	116	32.1	27.5–37.1
Grosdent et al.[50]	10	23.3	13.0–37.9	–	–	–
Hides et al.[53]	7	28.0	14.3–47.6	–	–	–
Tunås et al.[74]	–	–	–	66	24.1	19.5–29.7
c) Past-year prevalence (k = 5)						
Cabral[40]	16	33.3	21.6–47.5	–	–	–
Çali et al.[41]	32	31.4	23.8–40.2	–	–	–
Grosdent et al.[50]	20	43.5	32.5–61.1	–	–	–
Peterson et al.[67]	21	41.2	28.7–54.9	–	–	–
Tunås et al.[74]	–	–	–	158	56.9	51.1–62.7
d) Lifetime prevalence (k = 5)						
Brynhildsen et al.[38]	–	–	–	153	42.4	37.4–47.5
Junge et al.[54]	28	34.6	25.1–45.4	–	–	–
Noormohammadpour et al.[62]	13	35.1	21.8–51.2	–	–	–
Todeschini et al.[72]	9	23.1	12.7–38.3	–	–	–
Tunås et al.[74]	–	–	–	168	60.6	54.7–66.2

n = absolute number of players with low back pain; % = prevalence; 95% CI = 95% confidence interval

Table 4. Frequency estimates of low back pain in professional soccer players, according to the total number of injuries, reported in each included study (k = 34).

Study	Frequency					
Author	Men			Women		
	n	%	95%CI	n	%	95%CI
Arnason et al.[36]	8	9.4	4.6–17.7	–	–	–
Bjørneboe et al.[37]	8	4.6	2.2–9.0	–	–	–
Cabral[40]	16	33.3	21.6–47.1	–	–	–
Cesca et al.[42]	3	5.2	1.2–14.7	–	–	–
Coelho[43]	2	3.0	0.2–11.0	–	–	–
Dupont et al.[44]	2	1.2	0.1–4.6	–	–	–
Eirale et al.[45]	1	1.3	-0.5–7.6	–	–	–
Ekstrand et al.[46]	32	1.1	0.8–1.6	–	–	–
Ekstrand et al.[47]	39	2.2	1.6–3.0	6	1.9	0.8–4.2
Ekstrand et al.[22]	163	2.0	1.7–2.4	–	–	–
Ekstrand et al.[48]	405	2.0	1.9–2.2	–	–	–
Escobar[49]	1	4.0	0.7–19.5	–	–	–
Hägglund et al.[51]	22	4.0	2.6–6.0	16	5.4	3.3–8.6
Kristenson et al.[55]	33	1.5	1.0–2.1	–	–	–
Krutsch et al.[56]	13	2.4	1.3–4.0	–	–	–

<< SUMÁRIO

Table 4. Frequency estimates of low back pain in professional soccer players, according to the total number of injuries, reported in each included study (k = 34).

Study	Frequency					
Author	Men			Women		
	n	%	95%CI	n	%	95%CI
Larruskain et al.[57]	12	3.7	2.1–6.5	6	3.8	1.6–8.1
Lu et al.[58]	31	3.4	2.4–4.8	–	–	–
Martín-San Agustín et al.[35]	–	–	–	3	2.7	0.6–7.9
Nascimento et al.[59]	2	18.2	5.1–47.7	–	–	–
Netto et al.[60]	8	2.6	1.2–5.1	–	–	–
Pangrazio et al.[63]	3	2.6	0.6–7.2	6	3.4	1.7–8.6
Papacostas et al.[64]	5	9.8	3.8–21.4	–	–	–
Paus et al.[65]	140	5.8	4.9–6.7	–	–	–
Pedrinelli et al.[66]	2	3.2	0.2–11.5	–	–	–
Peterson et al.[67]	21	41.2	28.7–54.9	–	–	–
Poulsen et al.[68]	1	1.8	¯0.6–10.2	–	–	–
Santos et al.[69]	6	12.2	5.4–24.6	–	–	–
Silva et al.[70]	2	4.1	0.4–14.5	–	–	–
Stubbe et al.[71*]	14	4.9	2.9–8.1	–	–	–
Torrontegui-Duarte et al.[73]	9	2.5	1.3–4.8	–	–	–
Vasconcelos Jr. et al.[76]	1	5.0	0.9–23.6	–	–	–
Waldén et al.[77]	23	3.5	2.3–5.2	–	–	–
Waldén et al.[78]	1	2.2	¯0.7–12.6	–	–	–
Waldén et al.[79]	136	2.3	1.9–2.7	–	–	–

n = absolute number of players with low back pain; % = frequency; 95% CI = 95% confidence interval
*This study used data from the same sample as the study by van Beijsterveldt et al.[75]

Table 5. Incidence rates of low back pain in professional soccer players, according to 1,000 player-hours of exposure, reported in each included study (k = 24).

Study	Incidence			
Author	Men		Women	
	R	95%CI	R	95%CI
Arnason et al.[36]	1.17	0.50–2.30	–	–
Dupont et al.[44]	0.11	0.01–0.39	–	–
Eirale et al.[45]	0.10	0.00–0.56	–	–
Ekstrand et al.[46]	0.03	0.02–0.04	–	–
Ekstrand et al.[47]	0.20	0.14–0.27	0.13	0.05–0.27
Ekstrand et al.[22]	0.15	0.13–0.18	–	–
Escobar[49]	2.53	0.06–14.07	–	–
Hägglund et al.[51]	0.31	0.19–0.47	0.30	0.17–0.48
Kristenson et al.[55]	0.14	0.10–0.20	–	–
Krutsch et al.[56]	0.02	0.01–0.03	–	–
Larruskain et al.[57]	0.42	0.21–0.73	0.24	0.09–0.51
Martín-San Agustín et al.[35]	–	–	0.10	0.02–0.26
Netto et al.[60]	0.64	0.28–1.26	–	–
Pangrazio et al.[63]	1.57	0.32–4.57	3.79	1.39–8.23
Papacostas et al.[64]	0.44	0.14–1.02	–	–
Paus et al.[65]	43.25	36.50–50.84	–	–
Pedrinelli et al.[66]	0.82	0.10–2.97	–	–
Poulsen et al.[68]	0.16	0.00–0.86	–	–
Santos et al.[69]	5.96	2.19–12.92	–	–
Stubbe et al.[71*]	0.30	0.17–0.51	–	–
Torrontegui-Duarte et al.[73]	0.18	0.08–0.34	–	–
Waldén et al.[77]	0.33	0.21–0.50	–	–
Waldén et al.[78]	0.21	0.00–1.17	–	–
Waldén et al.[79]	0.18	0.15–0.21	–	–

R = rate; 95% CI = 95% confidence interval
*This study used data from the same sample as the study by van Beijstervel+dt et al.[75]

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MESENCHYMAL CELLS IN ROTATOR CUFF REPAIR – TECHNIQUE DESCRIPTION AND CASE REPORTS

CÉLULAS MESENQUIMAIS NO REPARO DA ROTURA DO MANGUITO ROTADOR – DESCRIÇÃO DE TÉCNICA E RELATO DE CASOS

Eduardo Angeli Malavolta[1,2], Vinicius Lamboglia Miceli[1], Jorge Henrique Assunção[1], Fernando Brandao Andrade-Silva[1], Mauro Emilio Conforto Gracitelli[1], Nelson Hidekazu Tatsui[1,3], Luiz César Espirandelli[3], Arnaldo Amado Ferreira Neto[1]

1. Universidade de Sao Paulo, Faculdade de Medicina, Hospital das Clinicas HC-FMUSP, São Paulo, SP, Brazil.
2. Hcor, São Paulo, SP, Brazil.
3. Criogenesis Biotecnologia Ltda, São Paulo, SP, Brazil.

ABSTRACT

Objective: To describe a protocol of obtention of mesenchymal stem cells and to report their use as a biological adjuvant in three patients undergoing arthroscopic rotator cuff repair. Methods: Case series of patients who underwent arthroscopic repair of isolated full-thickness supraspinatus tear using mesenchymal stem cells obtained from the bone marrow as a biological adjuvant. All patients were operated on at the same institution, by a surgeon with 13 years of experience. The cells were applied at the end of the procedure, at the tendon-bone interface, at an approximate concentration of 2,000,000 mesenchymal cells/mm^3 and a total volume of 5 ml. Results: All patients improved with the procedure, with one excellent and two good results. All cases overcame the minimally important clinical difference. All cases reached tendon healing, without partial or complete re-tears. We observed no complications. Conclusion: Arthroscopic rotator cuff repair with added mesenchymal cells obtained from bone marrow and submitted to a cell expansion process led to good functional results and healing in all cases in the sample, with no complications. ***Level of Evidence IV, Case Series.***

Keywords: Rotator Cuff. Arthroscopy. Mesenchymal Stem Cell Transplantation.

RESUMO

Objetivo: Descrever o protocolo de obtenção de células mesenquimais e relatar seu uso como adjuvante biológico em três pacientes submetidos ao reparo artroscópico do manguito rotador. Métodos: Série de casos de pacientes submetidos ao reparo artroscópico de rotura transfixante do músculo supraespinal utilizando como adjuvante biológico células mesenquimais obtidas da medula óssea. Todos os pacientes foram operados na mesma instituição por um cirurgião com 13 anos de experiência. As células foram aplicadas ao final do procedimento, na interface do tendão com o osso, na concentração aproximada de 2 milhões de células mesenquimais/mm^3 e volume total de 5 ml. Resultados: Todos os pacientes melhoraram após o procedimento, havendo um resultado excelente e dois bons. Todos superaram a diferença clínica minimamente importante. Em todos os casos ocorreu cicatrização tendínea, sem a presença de rerroturas parciais ou completas. Não observamos complicações. Conclusão: O reparo do manguito rotador artroscópico com adição de células mesenquimais obtidas da medula óssea e submetidas a processo de expansão celular levou a bons resultados funcionais e cicatrização, sem complicações, em todos os casos da amostra. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Manguito Rotador. Artroscopia. Transplante de Células-Tronco Mesenquimais.*

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INTRODUCTION

Rotator cuff tear is present in 20% of the population,[1] and problems related to these tendons represent 64% of consultations with a shoulder and elbow surgeon.[2] The increasing number of surgical repairs of these lesions[3] is costly to the health system.[4]

Despite several advances in the technique and in the development of fixation methods, the rate of re-tear after the procedure remains high.[5]

The main cause of failure after rotator cuff repair concerns tissue deficiency and the healing process between the tendon and

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The study was conducted at Instituto de Ortopedia e Traumatologia HC-FMUSP.
Correspondence: Eduardo Angeli Malavolta. Rua Dr. Ovidio Pires de Campos, 333, 3rd floor, Sao Paulo, SP, Brazil, 05403010. eduardomalavolta@gmail.com

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bone.[6,7] After the intervention, the rotator cuff does not restore its original histological characteristics and its fixation occurs by scar tissue[8] with lower biomechanical resistance.[9] Trying to improve structural outcomes after rotator cuff repair, biological adjuvants are studied, such as platelet-rich plasma,[10] bone marrow stimulation,[11] grafts,[12] and mesenchymal cells,[13-19] still without a consensus in the literature on their effectiveness.
This study aims to describe the protocol for obtaining mesenchymal cells and to report their use as a biological adjuvant in 3 patients undergoing arthroscopic rotator cuff repair, in addition to evaluating their safety and possible complications.

METHODS

We treated a series of cases of patients submitted to arthroscopic repair of full-thickness tear of the supraspinatus, using mesenchymal cells obtained from the bone marrow as a biological adjuvant. All patients were operated in the same institution, by a surgeon with 13 years of experience, in 2019. The research protocol was approved with number 77866417.8.0000.0068 and the participants filled out the informed consent form.
Inclusion criteria were: full-thickness tear of the supraspinatus tendon, with retraction of less than 30 mm; pain and/or decreased shoulder strength for at least 3 months, with no improvement with nonsurgical treatment; fatty degeneration of the rotator cuff muscles of grade 1 or 2 according to the classification of Fuchs et al.,[20] absence of tear of the subscapularis or infraspinatus, and skeletal maturity. We did not include pregnant patients nor those with shoulder arthrosis, previous shoulder surgeries or fractures, psychiatric diseases, fibromyalgia, painful pathologies of the cervical spine, rheumatic diseases, chronic use of corticosteroids, active or recent infection, coagulopathies, vascular or neurological lesions, thrombocytopenia, coagulopathies, chronic use of anticoagulants, or comorbidities not clinically compensated.

Intervention

The patients underwent to general anesthesia associated with interscalene block of the brachial plexus and positioned in beach chair position. Asepsis was performed with 4% chlorhexidine solution, followed by antisepsis with alcoholic solution of the same product. Antibiotic prophylaxis was performed with cefazolin 2 g every 8 hours for a period of 24 hours. The conventional, posterior, anterior, and lateral portals were performed. For placing the anchors, accessory portals were made, in a position that allowed their introduction with an appropriate angle of attack. The procedure was performed without cannulas, except for the moment of the knots.
Bursectomy was performed in all cases. The tendon of the long head of the biceps was approached when it presented instability or partial injury greater than 50%, with tenotomy or tenodesis with anchors in the bicipital groove. The greater tuberosity was debrided until it was free of tendon stumps and bursal tissue, presenting a good site for tendon reinsertion (Figure 1A). No patient underwent distal resection of the clavicle. The rotator cuff was repaired next to the greater tubercle using anchors of 5 mm in diameter. The rotator cuff was repaired using double loaded 5mm anchors, in single-row and with simple stitches (Figure 1B). After suturing the tendon, a Jelco© 14 catheter was positioned at the tendon-bone interface (Figure 1C), then the excess saline solution was aspirated from the subacromial space (Figure 1D) and the arthroscopic portals were sutured with simple stitches, using nylon threads number 4-0.

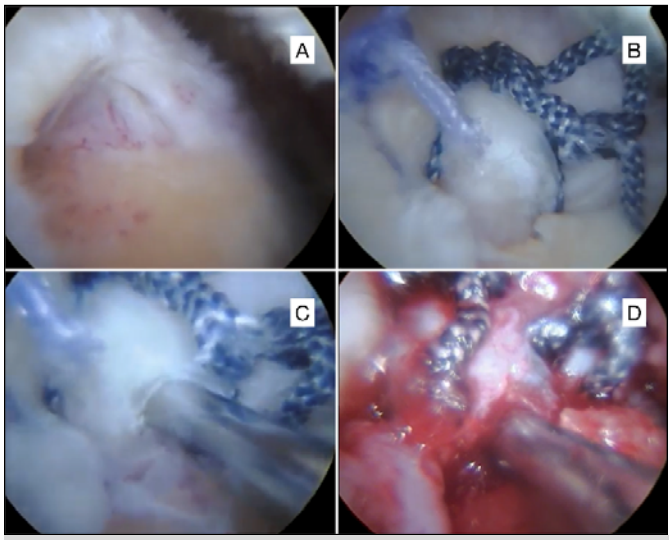

Figure 1. A: Rotator cuff tear before repair; B: Rotator cuff repair; C: Catheter positioning at the tendon-bone interface; D: Joint after aspiration of excess saline.

Mesenchymal cells

Mesenchymal cells collection

The cells were collected by puncture of the sternum medullary region, under local anesthesia and sterile conditions, obtaining around 30 ml of bone marrow. This amount was divided into 3 to 4 syringes containing 1,000 units of heparin each. The material was immediately sent to the cell therapy laboratory to begin the culture.

Culture medium preparation

Autologous Platelet-Rich Plasma (PRP) was used as culture medium, replacing the generally used Fetal Bovine Serum. The PRP was obtained by the apheresis method, using the Haemonetics MCS plus cell separator and the disposable kit for collection of single-donor platelet concentrate 994CF-E (Haemonetics Corp, USA). Initially, the apheresis material was mounted on the cell separator and the apparatus circuit was filled with sodium citrate (anticoagulant solution). The proportion of sodium citrate used was 1 ml for every 9 ml of blood. After preparation, information on the number of cycles to be performed, sex, weight, and height of the donor were provided to the device program to calculate the volume of blood and the number of platelets to be collected. After the peripheral venipuncture, 1 ml of the volunteer's blood was withdrawn for the complete blood count. After receiving the control of hematimetric levels, 400 to 450 ml of blood were drained into the separation device, under continuous centrifugation, at 4,500 rpm for approximately 10 minutes. In the device, the blood was separated into several phases by centrifugation. An optical analyzer located at the apex of the device detected, by refraction, first the platelet-poor plasma (PPP) layer then, upon detecting the platelet layer, the device commanded the collection of this desired component for our therapeutic procedure to a specific bag for blood component, sterile and under a biologically closed system. Around 2 to 4 cycles were performed. At the end, the rest of the blood components returned to the patient through the same venous access. Blood count was performed on the patient and the product collected after the procedure. To the platelet product, 400 micrograms of 10% calcium chloride was added for every 10 ml of platelet concentrate. After 60 minutes, with the formation of the clot and its physiological retraction, the remaining fluid and yellowish

color supernatant was extracted. After filtration, with a 0.22 micra barrier, 1 ml of the product was collected for each culture bottle of the Bact-Alert system. The remainder was preserved at −80° Celsius.

Cell culture

The bone marrow aspirate was handled in a class II biological safety booth, within a class 10,000 laboratory environment and in a clinic approved for the Brazilian Health Regulatory Agency (ANVISA)/group II cell therapy category. The aspirate was mixed with 4 volumetric parts of DPBS (Dulbecco Phosphate-buffered saline; GIBCO, Grand Island, NY) in 3 or 4 Falcon tubes of 50 ml. After centrifugation at 900 g for 10 minutes at 20°C, surface layers were transferred to another container with 25 ml of Percoll at a density of 1,073 g/ml and cell concentration not exceeding 2×10^7 (Sigma, St. Louis, MO). These samples were submitted to 900 g for 10 minutes at 20°C. The mononuclear cells were resuspended in DPBS and centrifuged at 460 g for 10 minutes at 20°C. The cells were again resuspended at a concentration of 1×10^6 nucleated cells per milliliter of DMEM low Glucose (Dulbecco modified Eagle medium, low glucose, Gibco), 10% serum from autologous platelet-rich plasma and 1% non-essential amino acid (NEAA), L-Glutamine proportion of 1% and antibiotic with antimycotic proportion of 1%. Around 30 ml of suspension were plated per bottle of 175 cm^2 or 75 cm^2 (Falcon, Franklin Lakes, NJ). The culture bottles were grown in incubators with a controlled environment at 5% CO_2. Culture media were changed every 24 to 48 hours. When the culture reached around 90% confluence, the adherent cells were detached with 0.05% trypsin (Gibco) and the passage was made respecting the concentration of 1×10^6 per bottle. After 2 passages, they were processed for surgical use.

Flow cytometry

To demonstrate the immunological characteristics and the homogeneous population obtained after the expansion culture of mesenchymal stem cells, a small aliquot containing at least 4×10^4 cells was evaluated for the expression of surface markers, namely: CD 105 FITC clone: 43A3 (BD Pharmigen, San Diego, CA), CD90 PE clone: 5E10 (BD Pharmigen, San Diego, CA), CD34 PE clone: 581 (BD Pharmigen, San Diego, CA), CD45 FITC clone: HI30 (BD Pharmigen, San Diego, CA). The analysis was performed in FACScan (Beckton Dickinson), and the data were analyzed with the CellQuest program (Beckton Dickinson). The immunophenotyping assay for mesenchymal stem cell culture expressed negativity for CD45 and CD34 and positivity for CD90 and CD105. The results were expressed by histogram. The markings with positive expressions had to reach > 90%, otherwise the sample was discarded.

Cell count

Around 0.5 ml of the final product was submitted to cell counting by the manual method using the Neubauer chamber and optical microscopy.

Contamination by bacteriological agents

Before the surgical use of mesenchymal stem cells, an aliquot of 2 ml was evaluated for possible bacterial or fungal contamination. The Bact-Alert automated culture system (bioMérieux, Durham, NC) was used. Samples that showed a possible contaminant were discarded.

Cryopreservation of an aliquot

At least one representative cell sample of the material was cryopreserved with 2 ml of the following cryoprotective solution: DMEM F12 or DMEM low glucose 70%, Hyclone 20% and DMSO 10%. With a pipette, the cryoprotective solution was aspirated and added to the container containing the mesenchymal stem cells. Programmable freezing was performed with the Cryomed 1010 system. After the freezing was finished, the container was placed in nitrogen vapor at a temperature below −160°C.

Surgical use

The cells were transported in a sterile and apyrogenic container. The transport temperature was maintained between 20 and 25°C. The means of transport was the PRP obtained from the patient. After closing the saline flow in arthroscopy and emptying the excess saline from the subacromial space, the material containing mesenchymal cells and PRP, totaling 5 ml and with an approximate concentration of 2,000,000 mesenchymal cells/ml was applied to the tendon-bone interface, through a previously positioned Jelco© catheter following the same protocol of previous studies conducted by our group using platelet-rich plasma.[21,22] During this process, an assistant kept the already sutured portals compressed, to avoid extra leakage of the material (Figure 2).

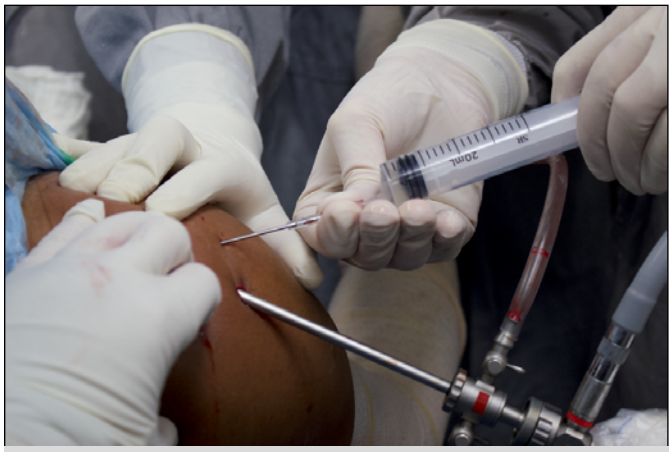

Figure 2. Application of mesenchymal cells, through a catheter positioned at the tendon-bone interface, while the auxiliary occludes the arthroscopic portals.

Postoperative care and rehabilitation

During hospitalization, patients were maintained on intravenous medications, those being an analgesic (Dipyrone 2 g every 6 hours), a non-hormonal anti-inflammatory drug (Ketoprofen 100 mg every 12 hours), and an opioid analgesic (Tramadol 100 mg every 8 hours). After discharge, the medication was administered orally and consisted of Dipyrone 2 g every 6 hours for 10 days and Tramadol 50 mg every 6 hours for 5 days. After this period, the need for medication was individualized. The patients were discharged the day after surgery. The dressing was changed on the 1st day and kept closed until the return, 7 days after surgery.

Velpeau-type immobilization was used for 6 weeks, and no movement was performed with the shoulder in the first 3 weeks. Movements with the elbow, wrist, and fingers were oriented. After the end of the third week, passive exercises started. The assisted active and free active exercises started after the sixth week, alongside stopping the use of the sling. Muscle reinforcement, with active resistance exercises, was performed only after the significant gain of movement, in the twelfth week.

Outcomes

Patients were clinically evaluated using the University of California at Los Angeles (UCLA) scale,[23] 1 week before surgery and at 24 months. The patients underwent magnetic resonance imaging (MRI) before the procedure and 6 months after. The tests were performed on a GE HDxt® 1.5 Tesla device (General Electric Corp, USA). The postoperative aspect of the tendon was described according to the classification of Sugaya et al.,[24] which stratifies the aspect of the tendon after repair into 5 levels: type I (sufficient

thickness with low signal in all sections); type II (sufficient thickness with high focal signal); type III (insufficient thickness without discontinuity); type IV (small size tear); and type V (medium or large size tear).

RESULTS

We performed three rotator cuff repairs adding mesenchymal cells. Table 1 shows the general characteristics of the sample.
All patients improved with the procedure. According to Ellman's classification, we had one excellent result and two good ones, all of which overcame the minimally important clinical difference.[25] In all cases, tendon healing occurred without partial or complete tears. Table 2 and Figure 3 show the data. We observed no complications.

Table 1. General sample characteristic.

	Sex	Age	Comorbidity	Biceps procedure	Anchors	Retraction (mm)	Extension (mm)
Patient 1	F	58	Diabetes	None	2	20	16
Patient 2	M	59	Hypertension	Tenotomy	2	12	11
Patient 3	M	61	None	Tenodesis	1	10	8

Table 2. Postoperative results.

	UCLA pre-op	UCLA 24m	Sugaya
Patient 1	16	31	Type II
Patient 2	11	30	Type I
Patient 3	27	35	Type I

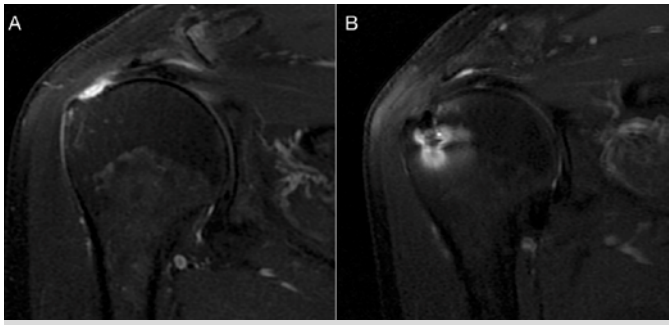

Figure 3. MRI. A: Preoperative oblique coronal image demonstrating full-thickness tear of the supraspinatus; B: Complete repair, with Sugaya type I classification (sufficient thickness with low signal in all cuts).

DISCUSSION

In this study, we describe the clinical and structural results of patients submitted to arthroscopic repair of the rotator cuff with added mesenchymal cells. All patients had significant functional improvement by the UCLA scale, surpassing the minimally important clinical difference.[25] All cases also showed tendon healing.
Few comparative studies to date have evaluated the effect of mesenchymal cells on rotator cuff repair, including three randomized[13,16,19] and two cohorts.[15,18] Šmíd et al.[19] observed significantly greater clinical and structural improvement in the group that received mesenchymal cells during open repair, in a randomized study involving 50 patients. Randelli et al.[13] observed clinical superiority only at 6 months, with no difference in the other follow-up times or in the image analysis, in a randomized study involving 44 patients undergoing arthroscopic repair. In turn, Lamas et al.[16] observed no differences between the groups, when analyzing a sample of only 13 patients submitted to open repair.
Hernigou et al.,[18] in a paired cohort study involving 90 patients, observed a significant reduction in the number of tears in the group submitted to mesenchymal cell application, without evaluating functional outcomes. Kim et al.,[15] on the other hand, despite not noticing functional differences between the groups, also reported better structural results with the use of mesenchymal cells.
Thus, although the literature shows no consensus and no meta-analyses compiling the data, we can observe that most studies demonstrate effectiveness of the use of mesenchymal cells as biological adjuvants to rotator cuff repair.
We observed no complications in our study. These data agree with those reported by Randelli et al.,[13] who did not describe any complications in the 22 patients submitted to the application of mesenchymal cells. Lamas et al.,[16] however, discontinued their study early due to the high number of complications, 23%, against 8% in the control group. They describe the formation of subacromial inflammatory tissue, consisting of intense synovitis and granulomatous tissue.
Mesenchymal cells can be obtained from bone marrow[16,18,19] or from adipose tissue,[13,15] and our protocol used the first option. Note that we obtained the cells by puncture of the sternum, unlike Lamas et al.[16] and Hernigou et al.,[18] who punctured the iliac crest, and Šmíd et al.,[19] who used the humeral head.
Our protocol performed cell culture and expansion to apply a known and high concentration of cells at the time of surgery (10×10^6 cells). This procedure was performed only by Lamas et al.,[16] where about 20×10^6 cells were used. Our culture time, however, was longer (4 vs. 2 weeks) and we cryopreserved an aliquot, allowing future expansion and application. The other studies analyzed did not perform cell expansion, and applied cells obtained at the time of surgery.[13,15,18,19] We believe that high concentrations of mesenchymal cells, made possible by cell culture, as well as cryopreservation, are highly beneficial in procedures involving cell therapy.
Our study has some limitations. In particular, this being a case series with few patients. In addition, the use of metallic anchors impairs the visualization of tendon healing, and we did not perform a new arthroscopy to collect anatomopathological material that confirms tendon regeneration. However, we describe a protocol with cell culture and expansion, which allows to apply a large number of cells in patients with a clinical follow-up of 24 months and structural evaluation by magnetic resonance imaging. Further randomized studies and meta-analyses are needed to determine the effectiveness of the use of mesenchymal cells in rotator cuff repair.

CONCLUSION

Arthroscopic rotator cuff repair with added mesenchymal cells obtained from bone marrow and submitted to a cell expansion process led to good functional results and healing in all cases in the sample, with no complications.

AUTHORS' CONTRIBUTIONS: Cada autor contribuiu individual e significantemente para o desenvolvimento deste artigo/Each author contributed individually and significantly to the development of this article. EAM: substantial contribution in the conception or design of the work, or acquisition, analysis or interpretation of the data for the work and writing of the work or critical review of its intellectual content; VLM: writing the work or critically reviewing its intellectual content; JHA, FBAS, MECG, AAFN: final approval of the version of the manuscript to be published; NHT, LCE: substantial contribution in the conception or design of the work, or acquisition, analysis or interpretation of the data for the work..

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CAN TEMPORARY ARTERY CATHETERIZATION EXTEND LIMITS OF ISCHEMIA TIME FOR MACROREPLANTATION?

CATETERIZAÇÃO TEMPORÁRIA ARTERIAL AMPLIA O LIMITE DE TEMPO DE ISQUEMIA NO MACRORREIMPLANTE?

Raquel Bernardelli Iamaguchi[1], *Guilherme Moreira Dias*[1], *Fernanda do Carmo Iwase*[1], *Marcelo Rosa de Rezende*[1], *Rames Mattar Jr*[1]

1. Universidade de Sao Paulo, Faculdade de Medicina, Hospital das Clinicas, Instituto de Ortopedia e Traumatologia IOT HCFMUSP, Grupo de Cirurgia da Mao e Microcirurgia Reconstrutiva, Sao Paulo, SP, Brazil.

ABSTRACT

We observe delayed referrals to appropriate Microsurgery Unit and definitive treatment of traumatic limb amputations. Cases with wrist proximal amputations have a deadline for surgical replantation as these configure life-threatening injuries. Objective: To analyze patients with traumatic proximal wrist upper limb amputations with prolonged ischemic time who underwent temporary artery catheterization to assess stump viability and results. Methods: A case-series study including all patients with a proximal wrist upper limb amputation and a cold ischemic time equal to or above six hours from 2017 to 2021. Results: In total, two surgeons operated eight patients who had experienced forearm amputation injuries. Median ischemia time totaled eight hours. All patients required additional surgeries, most commonly split-thickness skin graft or fixation revision (three patients). This study obtained five successful macroreimplantations. The mean cold ischemia time was longer in the group with successful macroreimplantations (7.4 hours) than of the unsuccessful group (9 hours). Conclusion: Macroreplantations require immediate referral to microsurgery and, although temporary artery catheterization helps surgical decision making, the technique seems to fail to influence outcomes. ***Level of Evidence IV, Retrospective Case Series.***

Keywords: Amputation. Extremities. Forearm. Microsurgery. Catheterization. Wounds and Injury.

RESUMO

Observa-se um atraso no referenciamento dos casos para o tratamento definitivo das amputações traumáticas de membros no Brasil. Casos com amputações proximais ao punho apresentam um prazo limite para reimplante, sendo lesões que promovem risco de vida ao paciente. Objetivo: Analisar os macrorreimplantes com tempo de isquemia prolongado submetidos à cateterização temporária da artéria, para determinar a viabilidade do coto de amputação, e seus resultados. Métodos: Série de casos de todos os pacientes com amputações traumáticas proximais ao punho, cujo tempo de isquemia fria foi igual ou superior a seis horas, entre 2017 e 2021. Resultados: A amostra foi composta por oito pacientes com amputações traumáticas de antebraço operados por dois cirurgiões. O tempo médio de isquemia foi de oito horas. Todos os pacientes necessitaram de cirurgias adicionais, sendo as mais comuns o enxerto de pele ou a revisão da fixação óssea. Sucesso do macrorreimplante foi observado em cinco pacientes. O tempo médio de isquemia fria foi maior no grupo com sucesso no macrorreimplante (7,4 horas) quando comparado com o grupo sem sucesso (9 horas). Conclusão: Os macrorreimplantes necessitam de transferência imediata para serviços especializados, e, apesar de a cateterização temporária arterial auxiliar no manejo cirúrgico, a técnica parece não interferir nos resultados. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Amputação. Extremidades. Antebraço. Microcirurgia. Cateterismo. Ferimentos e Lesões.*

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INTRODUCTION

Upper limb macroreimplants with wrist proximal amputations represent life-threatening injuries that are associated with high-energy trauma. The decision to reimplant the amputated limb should be based on patients' clinical conditions and amputation stump techniques, according to injury type, amputation level, the conditions of stump soft tissues, and cold or warm ischemic time.

A recurrent problem in health systems refers to the prolonged time between the trauma of the limb and the moment in which the patient is received in the service that will perform such surgical procedure. This referral delay increases the chance of complications in patients undergoing macroreimplantation, such as microanastomosis thrombosis, muscle necrosis with rhabdomyolysis, infections, and others. Although some articles have recommended macroreimplantation up to

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The study was conducted at Hospital das Clinicas da Faculdade de Medicina da Universidade de Sao Paulo.
Correspondence: Raquel Bernardelli Iamaguchi. Rua Dr. Ovidio Pires de Campos, 333, Sao Paulo, SP, Brazil, 05403010. rbiamaguchi@gmail.com

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12 hours of cold ischemia,[1] Sabapathy et al.[2] consider that the critical time of cold ischemia would total eight hours, after which, the authors advise against macroreimplantation. Our referral service for complex orthopedics and traumatology cases often receives wrist proximal amputation cases late, forcing Brazilian microsurgeons to decide to try macroreimplantation in these dramatic cases in young patients.
This study aims to critically analyze macroreimplants with prolonged ischemia times that received temporary artery catheterization to determine the viability of these amputation stumps and related clinical results.

METHODS

Our project was submitted to the Research Ethics Committee under CAAE: 51739221.8.0000.0068. Informed consent forms were obtained from all patients following Resolution 466/12 of the National Research Ethics Commission.
Individuals who were referred for surgical treatment of their traumatic upper limb injuries from 2017 to 2021 were included in this study. Inclusion criteria consisted of:

- Wrist proximal amputations
- Mechanism of injury: avulsion
- Cold ischemia times equal to or greater than six hours
- Patients aged 18 years or above
- The presence of appropriate clinical and technical conditions to macroreimplant limbs

For statistical analysis, SPSS, version 20.0 (SPSS Inc®, Chicago, IL, USA), was used for descriptive statistics and univariate analysis via the Student's *t*-test for quantitative data. In the descriptive analysis, intraoperative technical data (need for venous grafts, vessels used for arterial anastomosis, number of microanastomoses, venous system used for microanastomosis), total ischemic time, complications, and additional surgical procedures were evaluated.
The selected cases were transferred to our service so patients could be evaluated. Limb macroreimplantation was indicated after the adequate stabilization of patients and preparation of the technical conditions for the procedure.
The following sequence was set for surgical reimplantations: patients' admission to the hospital and clinical stabilization, preparation of blood and blood products, radiographs, and transport of the amputated part, correctly packed in a compartment with a saline solution and covered in ice to maintain its cold ischemia.
The total cold ischemic time until the beginning of the surgical procedure was recorded and temporary artery catheterization with revascularization of the amputated part was performed. Regarding venous returns, the vein of the amputated part was freely bled for up to five minutes with adequate hemodynamic stabilization and consent of the anesthesiologist in the room.
A Zeiss OPMI VARIO S88 microscope and 9.0 or 10.0 nylon suture threads (according to vessel diameter) were used.
Prophylactic low-molecular-weight heparin (to prevent postoperative thrombosis in patients who underwent long surgeries), hydration, and analgesia were postoperatively performed at the beginning of recovery together with the intensive care team of the Hospital.

RESULTS

This study included eight wrist proximal amputations due to six work accidents, one automobile accident, and one train hit from 2017 to 2021. The first and third authors performed all surgeries in cases meeting our inclusion factors (Table 1).

Patients' age ranged from 23 to 37 years, averaging 29.4 years. Cold ischemic time ranged from six to 10 hours (standard deviation of 1.5 hours) with a mean of eight hours. The mean time of cold ischemia totaled 7.4 hours (standard deviation = 1.5 hours) for the group with successful macroreimplantations and nine hours (standard deviation = 1.0 hours) for the group with unsuccessful macroreimplantations (no statistically significant difference p = 0.12) (Figure 1).

Table 1. Descriptive epidemiological analysis of cases.

Case	Age	Gender	Injury level	Mechanism	Ischemia (beginning of surgery)	Associated injuries
1	30	F	Proximal radius	Avulsion	8 hours	Extensive muscle injury of the amputated arm and forearm
2	37	M	Middle-third forearm	Avulsion	9 hours	Extensive muscle injury in the biceps and brachii muscles Irreparable damage of the ulnar nerve (over 30 cm)
3	24	F	Proximal radius	Avulsion	9 hours	Ipsilateral humerus fracture
4	23	M	Distal forearm	Avulsion	6 hours	Irreparable damage of the ulnar nerve (over 30 cm)
5	27	M	Arm diaphysis	Avulsion	6 hours	Extensive muscle injury of the arm
6	37	M	Distal forearm	Avulsion	7 hours	Amputation of the second finger + open fractures on the first and third fingers of the contralateral hand
7	23	F	Proximal radius	Avulsion with crushing	10 hours	Degloving up to the proximal third of the humerus
8	34	M	Proximal radius	Crushing followed by avulsion	9 hours	Vascular segmental lesion in the proximal third of the forearm and lesion of the palmar arch in the hand

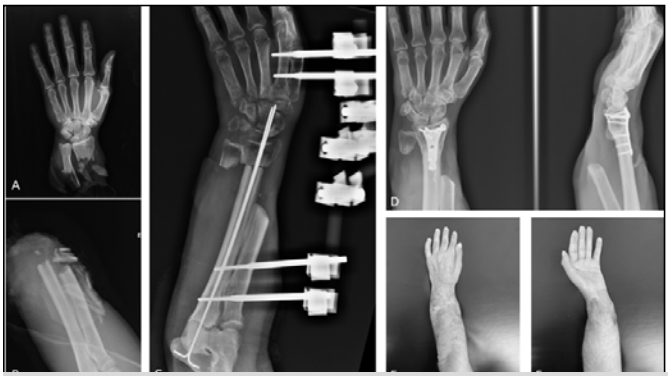

Figure 1. Case 6: (A, B) X-ray of the amputated limb on arrival at the hospital; (C) Radiography after three months of reimplantation showing no bone consolidation; (D) Image after eight years of surgery and a synthesis revision with good consolidation; (E) Clinical image of the limb after eight years.

Cases showed the injury levels and associated injuries in Table 1. The most common associated injury was extensive muscle injury (Figures 2 and 3).

The team prepared stumps on a sterile operating table with adequate debridement, tendons, and nerves for repair (if feasible), and arteries and veins for microanastomoses. Each case underwent bone shortening and bone fixation preparation as needed (Figure 4).

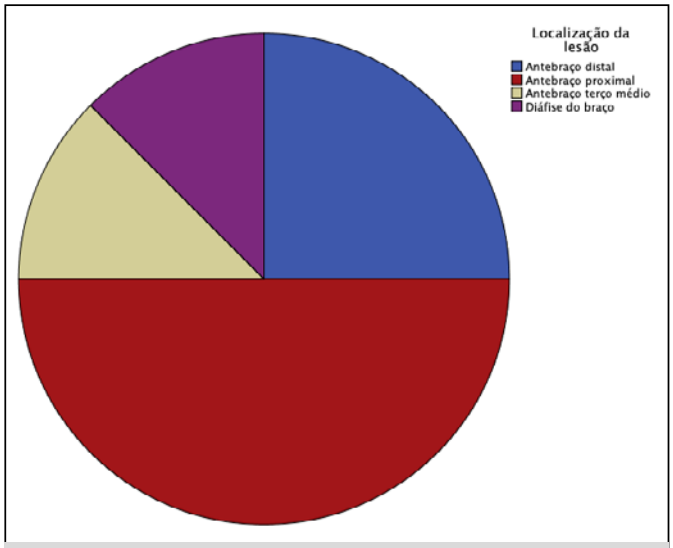

Figure 2. Distribution by amputation level.

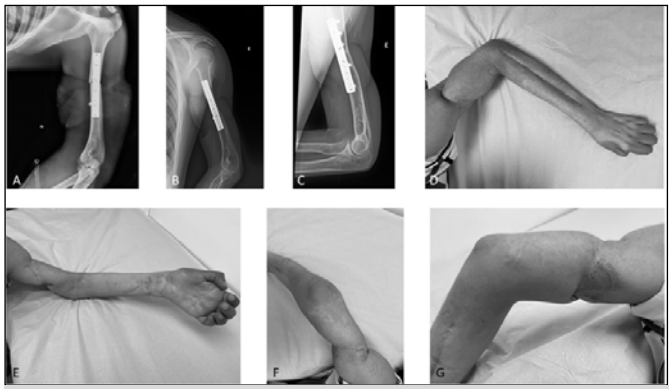

Figure 3. Case 5: (A) Postoperative radiography with synthesis with plate and screws; (B, C) X-ray after nine years of surgery, showing bone healing; (D, E, F, G) Clinical images of the upper limb after nine years.

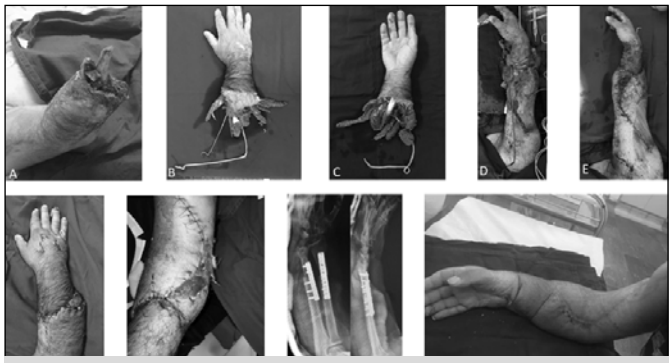

Figure 4. Case 2: (A, B, and C) Upper limb and amputated forearm; (D and E) Intraoperative images; (F and G) Appearance after one week of surgery; (H) Forearm X-ray after conversion for synthesis with a screw plate; (I) Aspect of the upper limb at follow-up.

To reduce the time of additional intraoperative ischemia, all patients received artery catheterization with a silicone catheter before the steps to reimplant the amputated limb to quickly revascularize it. Patients also underwent free vein bleeding for five to 10 minutes to venously drain their stumps, as per the literature.[3] The team adequately performed water support and volume replacement with blood and hydroelectrolytic products to replace volume due to increased bleeding stemming from temporary arterial catheterization.

After revascularizing amputation stumps via temporary catheterization, this study analyzed patients' clinical stability and the viability of amputation stumps (by attesting to the absence of reperfusion ischemia, which could occur due to prolonged ischemia) and indicated macroreimplantation for the eight evaluated patients. After temporary artery catheterization, the team released muscle compartments, inspected the stumps, and debrided the segments without perfusion or bleeding by observing soft tissues (including the muscles) (Figure 5).

Then, reimplantation followed the conventional steps in the literature. The surgical team performed fixation with plate and screws in five cases; with an external fixator in one case; and with Kirschner wires in one case (due to the absence of suitable material for urgent fixation). Moreover, one patient underwent wrist arthrodesis (Table 2).

All patients required additional surgeries (Table 3) (Figure 6).

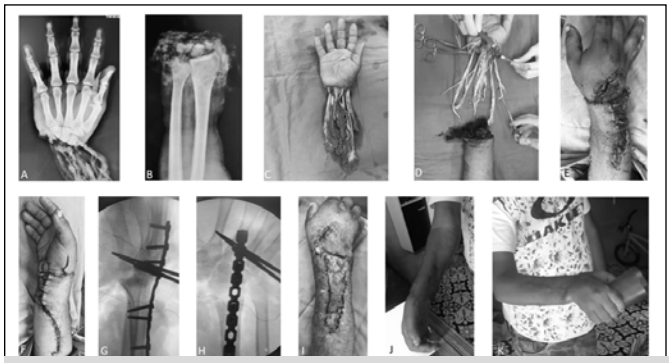

Figure 5. Case 4: (A and B) X-rays of the wrist and amputated hand; (C) Appearance of the hand amputated by avulsion; (D) Debridement of non-viable tissue; (E and F) Final appearance after surgery; (G and H) Radioscopy imaging after wrist arthrodesis; (I) Image after skin graft surgery showing good integration; (J) Clinical image of the upper limb at follow-up; and (K) Patient holding an object.

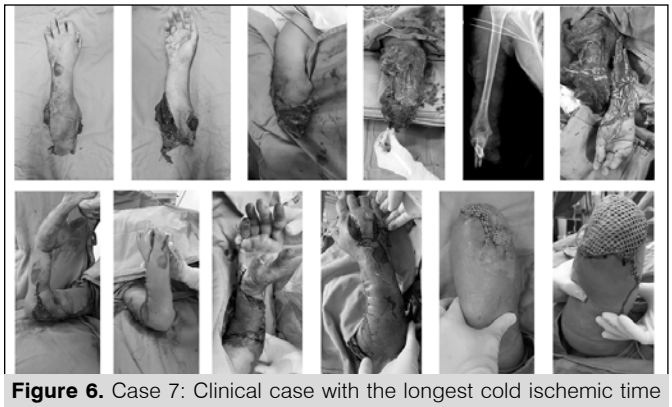

Figure 6. Case 7: Clinical case with the longest cold ischemic time (10 hours). This female patient was hit by a train, which traumatically amputated her right forearm. The case evolved to worsened perfusion four days after macro-reimplantation and the patient chose amputation and regularization of her right upper limb.

Of the successful macroreimplantations, five patients reported using their limb functionally, remaining economically active, and working as administrative staff, porter, informal worker, or household worker (Figure 7).

Table 2. Variables of the operative technique.

Case	Tenorrhaphy or Myorrhaphy	Microneurorrhaphy	Arterial anastomosis	Venous anastomosis
1	Foream flexor and extensor muscle mass	Median and ulnar nerves	Brachial artery	A vena comitans of the brachial artery and a superficial vein
2	Deep flexor tendons of the fingers, long flexor tendon of the thumb, and finger and wrist extensor muscle mass	Median nerve with graft	Proximal ulnar artery and distal radial artery	A vena comitans of the ulnar artery and a superficial vein
3	Foream flexor and extensor muscle mass	Median nerve	Ulnar artery	A vena comitans of the ulnar artery and a superficial vein
4	Superficial and deep flexor tendons of the fingers and finger extensors	Median nerve	Ulnar artery	A vena comitans of the ulnar artery and a superficial vein
5	Myorrhaphy of anterior and posterior muscle bellies	Median nerve	Brachial artery	A vena comitans of the brachial artery and a superficial vein
6	Tenorrhaphy of flexors and extensors with solidarization	Median and ulnar nerves	Ulnar artery	Arteriovenous fistula of the radial artery with reflux in the cephalic vein with a saphenous vein graft
7	Tenorrhaphy of flexors and extensors with solidarity	Median Nerve	Ulnar artery	Arteriovenous fistula of the radial artery with reflux in the cephalic vein
8	No procedure	No procedure	Ulnar artery with saphenous vein graft	Amputation

Table 3. Complications and additional surgeries.

Case	Ischemia (beginning of surgery)	Complications	Additional surgeries
1	8 hours	Muscle necrosis	Serial debridements (three) and amputation of the reimplantation
2	9 hours	Loosened Kirschner wire fixation	Revision two weeks after fixation for open reduction and internal fixation
3	9 hours	Skin necrosis on anastomoses	Anterolateral microsurgical flap of the thigh
4	6 hours	Failure of muscle area coverage.	Skin graft
5	6 hours	Failure of muscle area coverage.	Skin graft
6	7 hours	Pulmonary thromboembolism; Forearm pseudarthrosis	Skin graft and revision of the fixation with consolidation (4 months after surgery)
7	10 hours	Venous congestion and muscle necrosis	Amputation after 5 days
8	9 hours	Lack of intraoperative perfusion	Intraoperative amputation

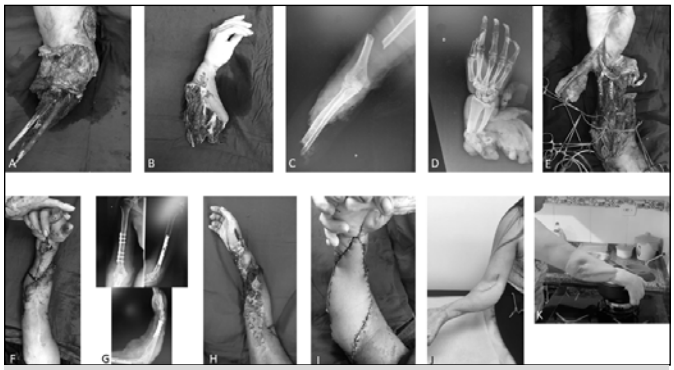

Figure 7. Case 3: (A and B) Upper limb and amputated forearm; (C and D) Radiographs of the upper limb (showing an ipsilateral fracture of the humerus) and amputated forearm; (E) Intraoperative imaging with isolated vessels; (F) Final surgery image; (G) Postoperative X-ray with humerus, radius, and ulna synthesis; (H) Evolution with necrosis of the skin and of the soft portions of the anterior forearm; (I) post-surgery image of the anterolateral flap of the thigh for forearm coverage; (J) Final image of the upper limb; and (K) Evidence of function for activities of daily living.

DISCUSSION

Wrist proximal amputations are rare lesions that require specialized emergency support with clinical patient stabilization and a team specialized in microsurgical surgery. The study of macroreimplantation indications requires the assessment of patients' history and the characterization of lesions (trauma mechanism, level, elapsed time, and associated injuries) and comorbidities (peripheral arterial disease, diabetes, and smoking cause worse outcomes). In cases of segmental lesion, reimplantation should be rethought in the absence of clinical-hemodynamic stability and prolonged cold or warm ischemia.[4]

The adequate preservation of amputation stumps for macroreimplantation is essential for the best prognosis. Stumps should be wrapped with sterile gauze soaked in a physiological solution or immersed in a saline solution (plain water should be avoided) and placed in a closed compartment surrounded with ice to cool them to about 4°C.[1,4] In Brazil, delays in patient and stump referrals raise the cooling temperature around the bag holding the stumps to above 4°C, which makes it impossible to determine the adequacy of stump cold ischemia in some cases. In other cases, although extensively described in the medical literature, amputation stumps are place directly on ice, leading to cooling burns and impairing case prognosis.

An available resource in cases with prolonged cold ischemic time (over six to eight hours) is the temporary catheterization of the artery to rapidly revascularize the amputation stump. Nunley, Koman, and Urbaniak[5] described artery catheterization with or without vein catheterization for venous drainage in 1981, which can be used to evaluate amputation stump viability, especially that of ischemic muscles. However, temporary catheterization is neither a consensus nor should it delay arteriorrhaphies and final venorrhaphies. We recommend its use in cases with prolonged ischemia (over six to eight hours) and vein bleeding from five to 10 minutes with hemodynamic support to eliminate free radicals (including myoglobin, CPK, and potassium) and reduce the risk of acute renal failure or lethal consequences, as per the literature.[3,5] Chin and Hart[6] described a case of traumatic wrist amputation, in which they used temporary artery catheterization due to

<< SUMÁRIO

the critical time of warm ischemia (above six hours), gaining time for adequate fixation and other repairs before definitive microanastomosis.
In cases of wrist-proximal upper limb macroreimplantation, the classic sequence of finger reimplantation in the literature should be changed according to ischemic time and surgeons' preferences. The suggested order for macroreimplantation is:

- Temporary shunt of the artery, according to prolonged ischemic time or surgeon's preferences (with the advantage of evaluating the viability of the muscle to be debrided)
- Preparation of the amputation stump with aggressive debridement and release of compartments
- Bone shortening and fixation
- Arteriorrhaphy with vascular graft as needed
- Venous anastomoses with vascular graft as needed
- Neurorrhaphy
- Tendon or myotendinous sutures
- Tension-free closure with skin grafts, local flaps, or at a distance as needed.

This surgical technique differs from distal reimplants due to the greater amount of muscle mass in proximal amputations, their greater susceptibility to necrosis due to ischemia, and the need for quicker revascularizations. Although digital amputations can withstand 12 hours of warm ischemia and 24 hours of cold ischemia, macroreimplants tolerate from two to three hours of warm ischemia and six to eight hours of cold ischemia, depending on their level. Unlike Sabapathy et al.,[2] we recommend proximal myotendinous or muscular repair before the closure of soft tissues (rather than before the neurorrhaphy) as this muscle repair can aid covering noble structures, including nerves and repaired vessels since the skin for closing the macroreimplant may be compromised.
With the advancement of techniques to prepare amputation stumps with target reinnervation of a muscle proximal to the amputation and techniques to sensitize cutaneous nerves with neurotization of the severed nerves of the stump (median, ulnar, and radial, according to availability and indication); the prognosis of patients without the possibility of reimplantation or with non-functional reimplanted limbs may improve with this evolution and new prostheses.[7] However, studies describe even greater patient satisfaction and functional results, which may promote functional return and amputation stump sensitivity (including cases with unsatisfactory results), when compared to amputees and patients who received prostheses.[8-10]
In Brazil, GM/MS Ordinance 793[11] establishes the care network for people with physical disabilities within the Unified Health System and provides for upper limb prostheses[12] (including myoelectric devices following a multidisciplinary team's analysis according to the steps to prepare and grant orthoses, prostheses, or auxiliary means of locomotion as per the World Health Organization).[13]
However, the adherence of patients with upper limb amputations to the available upper limb prostheses remains low. Reasons for their dissatisfaction include poor prosthesis function, low comfort, high prosthesis weight, and inadequate adjustment.[14-17] Studies have shown[16,18] that patients who receive prosthetics soon after amputation, have more distal amputations, and receive adequate training, have greater long-term adherence to upper limb prosthesis. In our service, patients with traumatic wrist proximal amputations are often unable to undergo early prosthesis preparation following the WHO steps[13] and have low prosthesis use adherence. Moreover, patients' cultural preference for amputation usually configures a reimplantation attempt to the detriment of primary amputation. Studies have described that reimplanted patients suffer fewer psychological impacts, feel less disfigured,[19] and have better function (including return to work) and greater satisfaction than patients who received prostheses regardless of functional outcomes.[15,20] Thus, our service prioritizes macroreimplantations whenever possible.
The Hand Surgery[21] reference book indicates macroreimplantations for cold ischemic times ranging from six to 12 hours but states that from two to three hours of cold ischemia onward, amputation stumps begin to undergo muscle necrosis with risk of rhabdomyolysis and coagulopathy during macroreimplantation. On the other hand, Sabapathy et al.[22] recommend no reimplantations for the middle-third forearm after seven hours of cold ischemia and from the distal third of the arm to the middle third of the forearm after six hours. Most cases in our tertiary referral service for complex cases of orthopedic trauma show that the time elapsed between the trauma and the beginning of the surgical procedure exceeds six hours of cold ischemia, averaging eight hours in our casuistry. Although our comparison between the mean time of ischemia of successful and unsuccessful macroreimplantation cases showed no statistical differences, the mean of the successful group (7.4 hours) was lower than the group with macroreimplantation loss (mean of 9.0 hours). This absence of statistical difference may stem from the number of treated cases. However, due to the rarity of this severe lesion with ischemia times equal to or above six hours, this sample is comparable with the literature.[23] We believe that the ischemic time limit for macroreimplants should consider the severity of the injury; anesthetic and clinical teams' technical and support conditions; and especially the adequate packaging of the amputated part, which arrives in inadequate preservation conditions in some cases.
The limitation of this study refers to its number of cases as this is a serious and rare accident in Brazil, but its strength lies in its consecutive inclusion of all cases with prolonged ischemia time, being one of the largest national series.

CONCLUSION

Macroreimplants require immediate transport to specialized services. Moreover, temporary arterial catheterization to assist surgical management seems to fail to interfere with outcomes.

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