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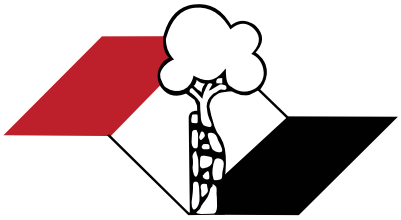

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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed January 2016)

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ACKNOWLEDGEMENTS
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Levels of Evidence for Primary Research Question[a]

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

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

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

SUMMARY

VOLUME 28–Nº 3 – 2020

Original Articles

ELBOW

GENERAL

HAND

HIP

KNEE

PEDIATRIC ORTHOPEDICS

TRAUMA

DOI: http://dx.doi.org/10.1590/1413-785220202803228291
ORIGINAL ARTICLE

PROSPECTIVE EVALUATION OF PERIARTICULAR HYALURONIC ACID INFILTRATION FOR THE TREATMENT OF LATERAL EPICONDYLITIS

AVALIAÇÃO PROSPECTIVA DA INFILTRAÇÃO PERIARTICULAR DE ÁCIDO HIALURÔNICO PARA O TRATAMENTO DA EPICONDILITE LATERAL

Guilherme Augusto Stirma[1], *Deginaldo Holanda Chaves*[1], *Simone Tortato*[1], *Paulo Santoro Belangero*[1], *Paulo Henrique Schmidt Lara*[1], *Benno Ejnisman*[1]

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ABSTRACT

Objective: To prospectively, clinically and functionally follow-up patients previously diagnosed with lateral epicondylitis after periarticular application of hyaluronic acid and analyze the results. Methods: All patients were previously treated conservatively and had no clinical improvement. Data such as age, positivity for specific tests (Cozen and Mill), visual analogue pain scale (VAS) before and during dorsiflexion of the wrist with resistance, diagnosis time, Mayo Elbow Performance Score was collected. Patients were reevaluated 30 and 90 days after application. Results: The positivity rates for Cozen and Mill tests were identical, starting at 100%, dropping to 50% after one month, and ending at 41.7% after 3 months. The initial Mayo Elbow Score average was 61.3 points; 85.8 in the first month, remaining at 85 in the third month. VAS in active force situations had the initial average of 8.1; after one month it dropped to 3.8, and 3.6 after three months. At rest, the initial average was 5.9; after one month it decreased to 3 and ended at 2.1 in three months. Conclusion: Patients showed improvement in pain parameters, in the Mayo Elbow Performance Score standard, but with 25% of failure in satisfaction. ***Level of evidence IV, Case series.***

Keywords: Hyaluronic Acid. Tennis Elbow. Mayo Elbow Performance Score.

RESUMO

Objetivo: Acompanhar de maneira prospectiva, clínica e funcionalmente, os pacientes previamente diagnosticados com epicondilite lateral após a aplicação periarticular de ácido hialurônico e analisar os resultados. Métodos: Todos pacientes foram tratados previamente de maneira conservadora e não obtiveram melhora clínica. Foram coletados idade, positividade nos testes específicos (Cozen e Mill), escala visual analógica da dor (EVA) antes e durante a dorsoflexão contrarresistência do punho, tempo de diagnóstico, Mayo Elbow Performance Score. Os pacientes foram reavaliados após 30 e 90 dias das aplicações. Resultados: Os índices de positividade para os testes de Cozen e Milll foram idênticos, começaram em 100%, caíram para 50% após 1 mês, e terminaram em 41,7% em 3 meses. A média inicial do Mayo Elbow Score foi 61,3 pontos; 85,8 no primeiro mês e manteve-se em 85 no terceiro mês. A EVA em situações de força ativa teve a média inicial de 8,1; após 1 mês caiu para 3,8, e 3,6 em 3 meses. Em repouso, a média inicial foi 5,9; após 1 mês diminui para 3, e terminou com 2,1 em 3 meses. Conclusão: Os pacientes apresentaram melhora nos parâmetros de dor, no padrão Mayo Elbow Performance Score, mas com 25% de falha na satisfação. ***Nível de evidência IV, Série de casos.***

Descritores: *Ácido Hialurônico. Epicondilite Lateral. Mayo Elbow Performance Score*

Citation: Stirma GA, Chaves DH, Tortato S, Belangero PS, Lara PHS, Ejnisman B. Prospective evaluation of periarticular hyaluronic acid infiltration for the treatment of lateral epicondylitis. Acta Ortop Bras. [online]. 2020;28(3):107-10. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Lateral epicondylitis is one of the main causes of pain and functional incapacity of the elbow, affecting 1% to 3% of the adult population annually.[1] Despite the classic relationship to the practice of tennis (tennis elbow), only 5% to 10% of total cases of this disease affect practitioners of this sport.[2]

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

The study was conducted at the Universidade Federal de São Paulo (UNIFESP), Department of Orthopedics and Traumatology, Sports Traumatology Center (CETE).
Correspondence: Guilherme Augusto Stirma. Rua Arruda Alvim, 297, apartment 205, São Paulo, SP, Brazil, 05410020. drstirma@outlook.com

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Although the terms epicondylitis and tendinitis are both descriptive of the "tennis elbow" condition, and that the existence of inflammatory process in the early stages is recognized, histopathological studies characterize it not only as an inflammatory condition, but also as a fibroblastic and vascular response, known as angiofibroblastic degeneration. The tissue changes are characterized by microruptures of collagen fibers, accompanied by the invasion of fibroblasts, creation of abnormal vascular tissue and granulation tissue (although the cicatricial tissue created is grayish, friable and susceptible to new lesions).[1,3,4]

The pharmacological and non-pharmacological treatments are the recommended methods for this condition; however, there is no consensus or specific protocols for the conservative treatment of lateral epicondylitis.[1]

The application of periarticular hyaluronic acid (HA) is an alternative with clinical effects that have been positive for lateral epicondylitis and periarticular disorders. Testing in models *in vitro* has suggested that HA might increase tenocyte viability, as well as production and deposition of type I collagen. Its viscoelastic properties reduce surface friction in the tendons, increasing sliding. Thus, it provides pain reduction, decreased joint stiffness, patient satisfaction as well as the recently-confirmed clinical safety of the application in torsional ligament lesions in the ankle.[5-10]

Due to the lack of prospective analyses on the application of periarticular hyaluronic acid on the treatment of lateral epicondylitis, the failure of non-surgical treatments associated with its collateral effects may be due to the absence of protocols for the conservative treatment. The objective of this study is to follow patients previously diagnosed with lateral epicondylitis in a prospective, clinically pragmatic fashion, after the periarticular application of hyaluronic acid, with following result analysis after the treatment.

METHODS

Study approved by the ethics and research committee of the institution under the number 04798918.0.0000.5505 with opinion 3,318,006. All 52 patients diagnosed with lateral epicondylitis for one year (2018) were analyzed and all those previously subjected to the conservative treatment (physiotherapy with a minimum of three months, in conjunction or not with corticosteroid infiltration and oral analgesia) who did not obtain clinical improvement. The patients signed the free and informed consent form before participation. Data on age, laterality and test-positivity (Cozen and Mill, for the specific case of lateral epicondylitis) was collected, as well as results on the visual analog pain scale (VAS) before and during wrist dorsiflexion with resistance scoring from 0 to 10, in which 0 was absence of pain and 10 was unbearable pain. In addition, the following variables were analyzed: diagnosis time, Mayo Elbow Performance Score and time since the previously conservative treatment within an accepted minimum of three months.

The Mayo Elbow Performance Score (MEPS) is a performance index widely used to evaluate clinical outcomes for a variety of elbow-related conditions. It consists in the evaluation of pain, motion arc, stability and patient-stablished classification of daily function. Pain is classified into four variables. The score ranges from 0 to 100 with higher values indicating better result.[11]

The diagnosis of lateral epicondylitis was confirmed via ultrasound in conjunction with clinical examination. Both the Cozen and the Mill tests were performed, and the possibility of differential diagnoses such as plica syndrome, radial nerve compression, and posterolateral instability was rejected. Radiographic imaging was performed to exclude fractures.

Infiltrations of periarticular hyaluronic acid were ultrasound-guided, with directions in the lateral epicondyle and the extensor carpi radialis brevis. The procedures were performed by a radiologist specialized in the musculoskeletal system and by an orthopedist specialized in shoulders and elbows. Two doses within an interval of one week were applied. The applied dose of sodium hyaluronate was 12 mg/1.2 mL according to the manufacturer's guidance. The medication was donated by the manufacturer (Sportvis™ Injectable 12 mg/1.2 mL with 1 filled syringe).

Patients were reevaluated after 30 and 90 days since the applications. Data from the specific tests for lateral epicondylitis (Cozen and Mill) were collected, as well as results from the visual analog pain scale (VAS) before and during wrist dorsiflexion, the Mayo Elbow Performance Score and patient satisfaction after each treatment.

All cases with fracture sequelae were excluded, as well as cases of patients regularly receiving corticosteroids for any medical reason, cervical radiculopathy and peripheral nerve diseases.

There is no conflict of interest with the applied medication.

Infiltration technique

The performed technique consists in local antisepsis with chlorhexidine or topical iodine. A 27 mm gauge needle is directed to the lateral epicondyle with the elbow flexed at 90° (Figure 1). The medication is injected through the "fan" technique with up to 1 cm in radius. After application, five active movements of flexion/extension of the elbow and pronation/supination of the forearm are performed, and the patient is instructed to avoid physical activities or repetitive work with the upper limb in question for 24 hours.

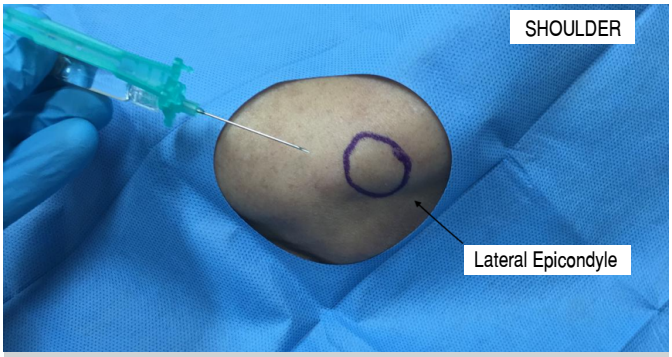

Figure 1. Infiltration of periarticular hyaluronic acid.

After application, the patients were instructed to use simple analgesic medications (dipyrone and acetaminophen), in conjunction to rehabilitation exercises (standard home procedures of stretching and strengthening)[12] guided by a physical therapist of the institution and application of cold compresses at the site according to necessity.

RESULTS

Twelve patients met the inclusion criteria and were subject to the local infiltrations. Eight, 75%, were women and four, 25%, were men. In eight cases (75%) laterality was on the right and in four cases (25%) on the left. The mean age was 51.4 ± 6.2 years and mean diagnosis time was 8.4 ± 3.1 months.

Previous treatment involved physical therapy and analgesia in 66.7% of cases. Four patients (25%) were previously subjected to corticoid

infiltration and at least one, 8.3%, to acupuncture. The Cozen and Mill tests were positive in all patients after the first evaluation. After application of the medication, the positivity rates for both tests were identical; started at 100% (all 12 patients), dropped to 50% (six patients) after one month and ended at 41.7% (four patients) in three months (Tables 1 and 2, Figure 2).

Table 1. Compares moments for the Cozen test distribution.

Cozen Test	Initial		1 month		3 months	
	N	%	N	%	N	%
Negative	0	0%	6	50%	7	58.3%
Positive	12	100%	6	50%	5	41.7%

Table 2. Compares moments for the Mill test distribution.

Mill Test	Initial		1 month		3 months	
	N	%	N	%	N	%
Negative	0	0%	6	50%	7	58.3%
Positive	12	100%	6	50%	5	41.6%

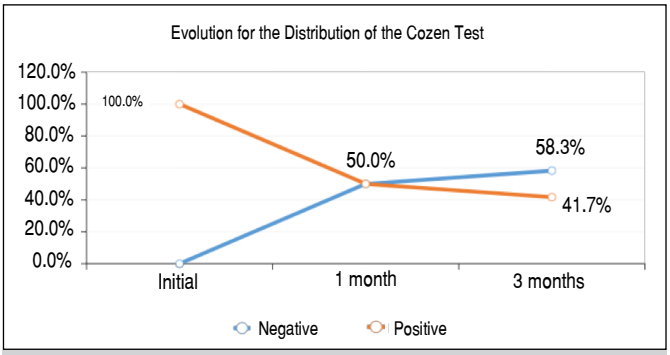

Figure 2. Evolution for the distribution of the Cozen test.

In relation to the application of the Mayo Elbow Score, the initial mean was 61.3 points, while in the first month after the infiltration of sodium hyaluronate it went up to 85.8 and kept still in 85 after the third month (p = 0.009, Table 3).

Table 3. Compares moments of the Mayo Elbow Score.

Mayo Elbow	Mean	Median	Standard Deviation	CV	Min	Max	N	CI	*p*-value
Initial	61.3	55	15.5	25%	35	85	12	8.8	0.009
1 month	85.8	85	15.5	18%	55	100	12	8.8	
3 months	85	100	21.2	25%	40	100	12	12	

There was a significant reduction in both VAS scores analyzed. VAS in situations of active force (during wrist dorsiflexion with resistance) had an initial mean of 8.1 and after 1 month it went down to 3.8, ending with 3.6 in 3 months (p = 0.005, Figure 3). Resting VAS had a mean of 5.9 and after 1 month it decreased to 3, ending at 2.1 in 3 months (p = 0.015, Table 4).

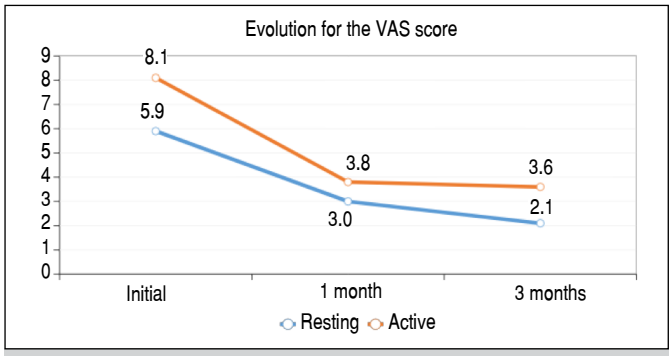

Figure 3. Evolution for the VAS score.

Table 4. Compares moments for VAS score.

VAS		Mean	Median	Standard Deviation	CV	Min	Max	N	CI	*p*-value
Resting	Initial	5.9	6	2.6	45%	2	10	12	1.5	0.015
	1 month	3	2.5	2.9	96%	0	7	12	1.6	
	3 months	2.1	0	3.3	156%	0	9	12	1.8	
Active	Initial	8.1	8	1.6	20%	5	10	12	0.9	0.005
	1 month	3.8	3.5	3.4	87%	0	9	12	1.9	
	3 months	3.6	1	4	113%	0	10	12	2.3	

When questioned about satisfaction with the treatment conducted, 66.7% of patients (a total of 8) in a month were satisfied (p = 0.102), and after three months 75% (a total of 9) were satisfied (p = 0.014). There were no complications or adverse effects with the medications applied.

DISCUSSION

Our study presented the analysis of 12 patients, with previous clinical treatment showing resistance to pain improvement both in rest and in active movement, in one month (p = 0.005) up until three months (p = 0.015), as well as initial increase in the Mayo Elbow Score index of 61.3 points to 85.8 points in the first month and 85 in the third month (p = 0.009) and high patient satisfaction after three months of treatment, in 75% of the cases (p = 0.014). Petrella et al. [5] examined 331 competitive tennis athletes (unlike our study, with lack of previous treatment) diagnosed with lateral epicondylitis through a randomized prospective clinical trial (165 AH × 166 placebos). Two injections of HA within a seven-day interval were applied, and the results were compared with the placebo group that received saline solution during a 1-year follow-up. They concluded, like our patients, that the cases in which injections of HA were applied proceeded with significant improvement in pain, high satisfaction rate and earlier return to sporting activities in relation to the control group, even after 1-year follow-up. There was no description of serious adverse effects. Fogli et al.[13] analyzed 28 patients with lateral epicondylitis for 56 days. After the application of the medication, they discovered through the use of ultrasound equipment a decrease in tendon thickness, reduction in local vascularization and improvement in the visual analog pain scale. Kumai et al.[14] applied HA in only one dose for enthesopathies (plantar fasciitis, achilles tendinopathy and lateral

epicondylitis) and studied the results after one week. In 16 cases, patients had elbow-related complaints and even with the short period after periarticular injections, improvement could already be visualized in the visual analog pain scale at -2.55 ± 2.43.

A recently published meta-analysis compared the efficacy of several local application therapies for lateral epicondylitis. Dong et al. reported that hyaluronic acid injection may be more effective in the medium-term than other therapies like autologous blood injection, platelet-rich plasma, botulinum toxin and placebo. However, more studies and evidence are needed to prove its superiority.[15]

Hyaluronic acid (HA), also known as hyaluronan or hyaluronate, is a glycosaminoglycan composed of disaccharidic units of N-acetyl-glucosamine and glucuronic acid. The average molecular weight of HA in the synovial fluid is 5 to 7×10^6 Da.[16] Hyaluronic acid is present in various types of tissues, including synovial fluid, connective tissues and periarticular soft tissues. Under normal conditions, it is the main constituent of the extracellular matrix and the synovial fluid. It presents properties for joint lubrication, cartilage protection, joint pressure distribution, mechanics for shock absorption and maintenance of structural and functional viscoelastic characteristics in periarticular tissues.[17,18]

HA injections are used in viscosupplementation for the treatment of osteoarthritis. However, there is a recent interest in the use of HA in periarticular and soft tissue disorders, such as tendinopathies, ankle sprain, lateral epicondylitis, subacromial bursitis and partial ruptures of the rotator cuff, particularly in the younger athletic population.[9] Some believe the medication can be identified by the body as biocompatible, similar to endogenous HA, making it active in the soft tissue healing process.[10] It stimulates mitosis and immigration of epithelial cells and fibroblasts during the proliferative phase, contributes to the transformation of immature tenoblasts into tenocytes, and creates a better environment for cell growth with protein matrix accumulation and cell differentiation factors.[1,10,19]

There was no adverse event associated with the infiltrations. One of the most important limitations of this study is the lack of comparison with the control group; however, the small sample size is due to the selection patients with refractory periods to conservative treatment. It is a series of cases with a short follow-up period; however, the results of previous studies highlight the efficacy of the application up to 3 months of follow-up, without improvement after this period and with decline in results.

The Mayo Elbow Performance Score, as an analytical tool, was not specially developed for lateral epicondylitis. It is however a widely used index of performance for the evaluation of clinical outcomes for a variety of elbow-related conditions.[20]

CONCLUSION

Periarticular HA proved to be safe for patients resistant to treatments classically used in lateral epicondylitis within three months of follow-up. The individuals showed improvement in pain parameters (VAS), Mayo Elbow Performance Score (MEPS); however, regarding patient satisfaction, it offered 75% in symptom resolution, that is, a 25% failure rate.

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ORIGINAL ARTICLE

RELATIONSHIP OF FORCE PLATFORM WITH THE CLINICAL BALANCE EVALUATION SYSTEMS TEST IN OLDER ADULTS

RELAÇÃO DA PLATAFORMA DE FORÇA COM O TESTE CLÍNICO DE AVALIAÇÃO DE EQUILÍBRIO (BESTEST) EM IDOSOS

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ABSTRACT

The aging process can alter the organization of postural control causing instability; literature shows several equipment and clinical tests whose purpose is to measure postural balance, involving different protocols and methodologies. Objective: To evaluate postural balance during the task to walk over the force platform (turn and return) and its relationship with clinic balance test (BESTest) in older adults. Methods: 60 older people of both sexes, aged 60 to 79 years, were tested in the force platform (NeuroCom Balance) and BESTest to evaluate postural balance. Results: negative correlations were found when comparing domains of the clinical test with stabilometric parameters in time and velocity variables of the tests Step/Quick turn. The highest correlations were in the total score (time spent to perform the task – 0.41, and in the velocity left side – 0.33/right side – 0.43), as well as in the stability limit (time spent to perform the task left side – 0.34/right side – 0.37, and the equilibrium velocity left side – 0.37/right side – 0.43). Conclusion: There are slim correlations between the clinical test and force platform variables, showing that each test measures different parameters. ***Level of evidence II, Diagnostic study – investigating a diagnostic test.***

Keywords: Postural Balance. Gait. Aged.

RESUMO

O processo de envelhecimento pode alterar a organização do controle postural causando instabilidade. Na literatura há vários equipamentos e testes, envolvendo protocolos e metodologias diversas, com a finalidade de mensurar o equilíbrio corporal. Objetivo: Avaliar o equilíbrio postural e analisar a correlação entre os dados da plataforma de equilíbrio e do teste clínico (BESTest) em idosos. Métodos: Foram avaliados 60 idosos de ambos os sexos, com idade de 60 a 79 anos. Para avaliação do equilíbrio postural foi utilizada a plataforma de força (NeuroCom Balance) e o BESTest. Resultados: Correlações negativas foram encontradas quando comparados os domínios do teste clínico (BESTest) com parâmetros estabiliométricos nas variáveis tempo, velocidade e impacto dos testes Step/Quick turn. As maiores correlações foram no score total (tempo gasto para realizar a tarefa LE – 0,41, e na velocidade do equilíbrio LE – 0,33/LD – 0,43), assim como no limite de estabilidade (tempo gasto para realizar a tarefa LE – 0,34/LD – 0,37, e a velocidade do equilíbrio LE – 0,37/LD – 0,43). Conclusão: Há poucas e fracas correlações entre o teste clínico e as variáveis do teste Step/Quick turn da plataforma de força, mostrando que cada teste mede parâmetros diferentes. ***Nível de Evidência II, Estudos diagnósticos – investigação de exames para diagnóstico.***

Descritores: *Equilíbrio Postural. Marcha. Idoso.*

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INTRODUCTION

Postural balance is the maintenance of the center of gravity within the base support of the body.[1] The aging process leads to changes in the sensory systems involving postural balance and consequently an increase in number of falls.[2]

There are several equipment, clinical tests and scales, developed to evaluate postural balance. Health professionals are frequently looking for clinical tests that could have the same results as gold standard instruments that assess postural balance, such as the force platform, to become useful in clinical practice. However, the biomechanics industry creates more high cost sensitive equipments.[3] The NeuroCom Balance Master® provides objective assessment of the sensory and voluntary motor control of balance with visual biofeedback, which enables objective assessment of performance in essential activities of daily living. Previous studies measuring the stabilometric parameters demonstrated that the equipment is reliable[4] and provides accurate measurements of the postural balance in different groups.[5-6] The Balance Evaluation Systems Test (BESTest) is

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

The study was conducted at Universidade São Judas Tadeu and developed in partnership with the Laboratory of Movement Studies of the Institute of Orthopedics and Traumatology at the Clinic Hospital of the Universidade de São Paulo School of Medicine (HCFMUSP).
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used by clinicians to categorize balance into six underlying systems that may constrain balance, being the first test to include a clinical method for assessing postural responses to external disturbances, whose purpose is to evaluate the postural balance.[7-8]

Both systems have their advantages and disadvantages: the Balance System platform is a more accurate, but costly equipment that requires a trained professional to perform data acquisition; on the other hand, the BESTest is low cost and provides reliable measures related to postural balance, and it can be applied anywhere with a clinical or scientific purpose. These tests are indicated to guide clinical treatment strategies for fall prevention protocols. As such, an analysis of the relationship between the force platform and this clinical test is justified, in view of the prognosis of the postural balance responses resulting from this comparison, whether or not the professionals involved use them with more precision and specificity, and consequently to design more efficient rehabilitation programs.

Thus, the aim of this study was to evaluate postural balance during the task to walk over the force platform (turn and return) and its relationship with clinic balance test (BESTest) in older adults.

METHODS

This was a cross-sectional study approved by the Ethics Committee of the Universidade São Judas Tadeu (registration number: 60952116.4.0000.0089) and developed in partnership with the Laboratory of Movement Studies of the Universidade de São Paulo School of Medicine and the Universidade São Judas Tadeu. All participants provided a written informed consent.

Subjects

Sixty older adults of both sexes between 60 and 79 years old were evaluated. The subjects were recruited from the Integrated Health Center (CIS), endocrinology department of the Universidade Anhembi Morumbi. The inclusion criteria were absence of foot ulcers and/or partial and total lower limb amputations; disease or functional impairment of any system: auditory, vestibular, proprioceptive, neurological, musculoskeletal; no use of medications that could affect the postural balance; and present normative parameters in the cognitive test (MoCA). Exclusion criteria: if for any reason, subjects could not perform any of the proposed tests.

Measurements

The following data were initially collected during the interviews: age, MoCA, education (years of education), weight, height, and body mass index (BMI).

Balance Evaluation Systems Test (BESTest) containing 27 items, with a total of 36 tasks organized in six sections (biomechanical constraints, stability limits, postural responses, anticipatory postural adjustments, sensory orientation, dynamic balance during gait, and cognitive), was used to evaluate postural balance. All domains followed the protocol established by the translation and adaptation to Brazilian portuguese.[9]

The postural balance assessment (posturography) was performed on the NeuroCom Balance Master® force platform system (NeuroCom International, Inc., Clackamas, OR, USA). The system uses a fixed 18 in. Å ~ 60 in. dual force plate to measure the vertical forces exerted by the patient's feet.[9-12]

The test is a functional balance evaluation, where older adults were advised to walk on the platform, rotate 180 degrees, and return to the starting place ("Step/Quick Turn" task),first to the left and then to the right, repeating three times in a 30 second interval on each side. This assessment quantifies two movement characteristics as the patient takes two steps forward, quickly turns 180° , and steps back to the starting point. The measured parameters are turn-time (Time spend for the task) expressed in sec; and turn-sway velocity (Balance velocity) expressed in °/s.

Statistical analysis

Data were stored in the SPSS 24.0 program and presented by means and standard deviation. The Kolmogorov-Smirnov test was performed to verify if the variables adjusted to normality. The Spearman correlation test was used to assess the bivariate correlation between measures, and a 5% level of significance was adopted throughout the analysis.

RESULTS

Sample characterization regarding age and anthropometric data, education level and cognitive conditions are presented in Table 1.

Table 1. Baseline characteristics.

	Mean (SD)	Minimum	Maximum
Age (years)	7.03 (5.51)	60	79
MoCA	23.35 (3.15)	16	26
Education (years)	11.5 (4.73)	1	15
Anthropometry			
Body weight (kg)	72.37 (13.16)	46.80	66.30
Height (m)	1.62 (0.09)	1.43	1.69
BMI (kg/m^2)	27.66 (3.78)	18.70	34.70

SD: standard deviation; BMI: body mass index; MoCA: Montreal Cognitive Assessment.

When compared, the clinical test data (BESTest) and the stabilometric parameters, the total BESTest score (the sum of its six domains) and the stability limit, showed a negative correlation between the time spent to perform the "Step/Quick Turn" task and the speed on both sides (right and left) (Table 2).

The Biomechanical Restrictions domain showed negative correlation with the time spent to perform the task on the left side, while "anticipatory transition" showed negative correlation with the time spent to perform the task on both sides.

The reactive test showed a negative correlation only in the time spent to perform the task on the right side, presenting no significant differences in the other data. Sensory orientation showed negative correlation in balance velocity on the right side, while "gait stability" showed negative correlation in the time spent to perform the "Step/Quick Turn" task on the right side (Table 2).

Table 2. Correlation between clinical test (BESTest) and stabilometric parameters in the force platform.

Step/Quick turn	BESTest total	Biomechanical Restrictions	Stability Limits	Anticipatory Transition	Reactive	Sensory Orientation	Gait Stability
Time spend for the task LS (sec)	– 0.36(0.00)**	– 0.24(0.05)*	– 0.34(0.00)**	– 0.25(0.05)*	– 0.17(0.19)	– 0.11(0.37)	– 0.23(0.07)
Time spend for the task RS (sec)	– 0.41(0.00)**	– 0.21(0.10)	– 0.37(0.00)**	– 0.24(0.06)	– 0.26(0.04)*	– 0.21(0.10)	– 0.30(0.01)*
Balance velocity – LS (°/s)	– 0.33(0.10)	– 0.16(0.22)	– 0.37(0.00)**	– 0.15(0.24)	– 0.15(0.25)	– 0.19(0.13)	– 0.17(0.18)
Balance velocity – RS (°/s)	– 0.43(0.00)**	– 0.15(0.22)	– 0.43(0.00)**	– 0.22(0.08)	0.24(0.06)	– 0.30(0.01)*	– 0.31(0.01)*

LS: left side; RS: right side; sec: seconds; BESTest: Balance Evaluation Systems Test; *p ≤ 0.05; **p ≤ 0.01

DISCUSSION

This study found that the tests results (clinical and force platform) had low to moderate association among them, possibly because the stabilometric parameters captured differences in functional performance abilities, whereas the BESTest (clinical method) evaluated postural responses to external disturbances. Both are multifaceted, and the nature of each task demonstrates the results of this study. The BESTest focuses on the variety of disability dimensions[8] and guides treatment decision; while the force platform (Balance Master) provides quantification of the postural balance index[13] with a better precision to demonstrate small disturbances and postural adjustments based on the total oscillation of the platform.[11-4]

One of the most common tasks of the activities of daily living (ADL) and used throughout all the domains of BESTest, "Step/Quick Turn" is a challenging test because stepping must be tightly coordinated, and head rotation changes visual and vestibular inputs. To turn around, the patient must anticipate the action, decelerate the forward progression of the COG, alter the stepping pattern, then re-initiate gait in the opposite direction. The change in direction must be anticipated so that forward COG progression can be sufficiently decelerated to allow the change in direction, but not stopped, or else momentum that can assist with the turn will be lost. A change in step pattern is also required: the most efficient one is pivot on the toes of the lead foot, while the trailing foot does not advance, as it would in taking a step forward, but pivots in place and is immediately ready to accept the body weight as it begins to travel in the opposite direction.[10]

We found several studies comparing functional and physical performance measures with ones based on stabilometric parameters, as well as between clinical tests, scales with force platform parameters, and kinetic and posturographic measurements,[7,11,14-17] but these results must be carefully analyzed, considering methodological differences and application in different groups.

The time (s) and oscillation velocity (°/s) variables obtained by the "Step/Quick Turn" test on the force platform, used to measure stability in a 180° turn, are negatively correlated (low to moderate) to almost all domains of BESTest. Thus, clinical balance tests can discriminate subjects with large differences in posture maintenance,[7-17] but not identify small postural adjustments, which can be done with equipment such as the force platform.[14] If we are able to identify typical movements that demonstrate a poor postural balance (risk of fall) involving walking and a 180° turn, the maneuver becomes challenging to older people compared to walking straight, because the body remains outside the base of support in most of the support phase of the gait.[18-19]

During the test, the patients were instructed to complete it as quickly as possible, where low scores (faster turns) are good, while higher scores (slower turns) are worse. Patients may not be able to safely turn quickly if they cannot control the moving COG over the small base of support (pivot foot) and must instead resort to the slower strategy of taking multiple steps to turn around. This compensatory strategy allows for double support time, sacrificing speed for stability. Patients may not be able to pivot due to ankle weakness, non-coordination, or sensory abnormalities (visual/vestibular). Thus, the negative correlations found between the test and the clinical evaluations of postural balance demonstrate that the higher the score (higher score = better balance) the shorter were the time and speed (shorter time and lower velocity = better balance) spent on the task.

Although our findings are limited and need further studies that include methodological investigations on postural balance measures within the parameters analyzed, this study indicates that, while the clinical test and the force platform provided different data about balance, they complement each other and should be used together to provide more relevant information to the understanding of postural balance. Thus, this study contributed to helping health professionals detect mechanisms essential for the field of gerontology.

CONCLUSION

Clinical tests (BESTest) are poorly to moderate correlated with the Step Quick/Turn test on the Balance Master force platform.

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ORIGINAL ARTICLE

PHALEN TEST POSITIVATION TIME AND ITS CORRELATION WITH ELECTRONEUROMYOGRAPHY

O TEMPO DE POSITIVAÇÃO NO TESTE DE PHALEN E A CORRELAÇÃO COM A ELETRONEUROMIOGRAFIA

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ABSTRACT

Objective: To compare the classification of CTS by the Phalen test with electromyography. Methods: Cross-sectional observational study. Patients at orthopedic outpatient clinic with carpal tunnel syndrome were evaluated by the Phalen test and compared with the result of the electroneuromyography. Results: Sample of 33 patients, mostly women (87.9%). Most patients were already diagnosed with severe CTS by ENMG. The results of the Phalen test and the electromyography were equal in 26 of the 33 patients (78.8%). Conclusion: The Phalen test showed its applicability, since it had results similar to those of ENMG in most cases, especially in the most severe ones. The exam studied is a possible tool for the classification and recommendation of surgical treatment. ***Level of evidence IV, Retrospective observational study***.

Keywords: Carpal Tunnel Syndrome. Median Nerve. Wrist.

RESUMO

Objetivo: Comparar a classificação pelo teste de Phalen com a eletroneuromiografia (STC) na STC. Métodos: Estudo descritivo transversal. Pacientes do ambulatório de ortopedia com STC são avaliados pelo teste de Phalen, cujo resultado é comparado ao resultado da eletroneuromiografia (ENMG). Resultados: Amostra de 33 pacientes, em sua maioria mulheres (87,9%). Maioria dos pacientes com STC grave pela ENMG. Os resultados do teste de Phalen e da ENMG foram iguais em 26 dentre os 33 pacientes avaliados (78,8%). Conclusão: O teste de Phalen mostrou ter sua aplicabilidade, pois teve resultados semelhantes aos da ENMG na maioria dos casos, principalmente nos mais graves. O exame em estudo se mostra uma possível ferramenta de classificação e indicação do tratamento cirúrgico. ***Nível de evidência IV, Estudo retrospectivo de observação***.

Descritores: *Síndrome do Túnel Carpal. Nervo Mediano. Punho.*

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INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common neuropathy in the upper limbs. The incidence of the disease is estimated between 0.1% and 1% per year and the prevalence ranges between 5% and 15%, depending on the criteria used for diagnosis. More than 80% of patients are over 40 years of age, with women being more affected (5:1). Although bilateral involvement is common (> 50% of cases), the dominant hand is usually the first and most severely involved.[1] This syndrome is often considered a sensory disorder, since sensory fibers of the median nerve are more affected than motor fibers.[2]

One million adults from the United States are estimated (annually) to have CTS, requiring high-cost medical treatment for the health system. In 1995, Palmer et al. estimated that between 400,000 and 500,000 cases of CTS require surgical treatment annually in the United States, with an economic cost of more than $2 billion per year. Surgical decompression rates for the UK are between 43 and 74 per 100,000/year.[3]

This is one of the most widely recognized occupational condition, particularly in industries in which work involves high strength/pressure and repetitive use of vibratory tools. Einhorn and Leddy[4] estimated an incidence of 1% on the general population and 5% on workers in industries that require repetitive use of hands and wrists. CTS exact pathogenesis is still unclear. Several theories have tried to explain the symptoms. The most popular ones are mechanical compression, microvascular insufficiency and vibration theories.[5] CTS has the compression of the median nerve as pathophysiological basis, when it passes through the carpal tunnel. This compression can occur due to any tenosynovial proliferation, abnormality of the

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wrist joint, tumor or muscle abnormality, producing a clinical picture of pain, paresthesias and hypoesthesias in the hand. In advanced stages, it can cause thumb paralysis and loss of sensitivity.[6]
Several provocative tests are used for diagnosis with different sensitivity and specificity such as the Phalen and Tinel test.[1] The diagnosis is eminently clinical, based on symptoms and distribution of sensory changes of the hand; and neurophysiological, evaluating the median nerve conduction velocity. Electroneuromyography, besides being the main test for the diagnosis of this neuropathy, is essential to make the differential diagnosis among other neuromuscular pathologies and determine the severity of CTS.[7]
The high prevalence of focal neuropathies (mononeuritis and compressive syndromes) is also noteworthy. Carpal tunnel syndrome is frequent in diabetic patients not only due to alteration of synovial tissue surrounding the nerve, but also because the nerve presents alterations secondary to high blood glucose.[8]
Our study seeks to compare the results of electroneuromyography with a modification we proposed in the Phalen test. Thus, it aims to promote a new way of classifying and recommending a surgical procedure through the Phalen test.

METHODS

This is a cross-sectional observational study. Data were collected between September and December 2018.
The study population is composed of patients with carpal tunnel syndrome that were referred and spontaneously went to the outpatient clinic.
The sample comprises patients that met the following criteria: clinical picture consistent with carpal tunnel syndrome, who underwent electroneuromyography and who agreed to undergo physical examination. All participants signed the informed consent form. The patient to be included in the study had to have at least the Phalen test positive among the physical examination tests, since it was the test to be evaluated in our study.
Those patients that already had electroneuromyography at the time of appointment with CTS diagnosis were included in the study.
Patients that have previously undergone surgical treatment for neuropathy; those who did not have the Phalen test positive for the examination, and those who did not perform electroneuromyography were excluded.
Data were collected through outpatient appointment in the orthopedic service by preceptors and residents of orthopedics and traumatology after training with the specialist in hand surgery of the service. Data on the appointment were recorded in an evaluation form we made, which guided the data collection. In the evaluation, we surveyed epidemiological data from the study population seeking for the presence of comorbidities; the tests of Tinel, Durkan and Phalen were performed during physical examination, and the result of electroneuromyography was noted.
The Phalen test was performed when each patient was included in the study, classifying the involvement into different degrees according to the time required for test positivation. Usually, the patient is actively examined (the patient himself performs movement) for 60 seconds, subjecting the wrist to forced palmar flexion against each other, so that the pressure inside the carpal tunnel increases and CTS paresthesia symptoms are exhausted, showing positive or negative results. In our study, we gauged the result according to the time it takes to make the test positive. If positive before 10 seconds, it will be considered as severe involvement; between 10 and 30 seconds, moderate; and 30 or more seconds will be classified as mild.
R software was used to estimate the sample size in the universe. The total sample was estimated by the simple Random Sampling technique (more details in Bolfarine and Bussab).[9] A 95% confidence interval and a robust, maximum variance were adopted in estimates. With a 5% error in the parameters, the sample size was composed of 33 patients.
Data were organized and analyzed in the SPSS software version 20.0. The qualitative variables were described in a table. For quantitative variables, statistics were used: minimum, maximum, arithmetic mean and standard deviation. The Chi-Square Test was used to compare the proportions of patients with comorbidities.
The procedures described followed the ethical principles in research in force in the country ensuring confidentiality, anonymity and the non-use of the information to the detriment of others, and the data obtained were used only for purposes provided for in this study. Research Protocol No. 2,878,873, Ethics Committee of Federal University of Piauí.

RESULTS

The analysis of the 33 evaluation forms of the patients included in the study showed a mostly female attendance, representing 87.9% of the total. On average, the patients were 44.6 years old.
Regarding the profession, we also observed that most patients with carpal tunnel syndrome were housewives/husbands, 24.2%, followed by those who performed cooking work. Regarding race, 57.6% of people declared themselves brown, 24.2% white, and 18.2% black.
All patients had a positive Phalen test, since it was a criterion to be included in our study. In total, 87.9% patients had the Durkan test and 72.7% had the positive Tinel test during physical examination. Only in 21.2% of the patients, atrophy of the thenar region was verified.
Of the 33 electroneuromyography tests evaluated, 54.5% were classified as severe. All obtained the same classification in the modified Phalen test (positive results in less than 10 seconds), thus, similar results in 100% of cases. Electroneuromyography tests classified as moderate involvement corresponded to 39.4%, of which 46.2% had the same result in the Phalen test, 53.8% were classified as mild and none as severe. The rest of the electroneuromyography, 6.1% had mild involvement as a result, also obtaining the same classification in the Phalen test, generating equal results in 100% of the cases, as shown in Table 1. Therefore, 26 out of 33 patients had similar results in both modified Phalen test and electroneuromyography (78.8%).

Table 1. Percentage of similar results of the modified Phalen Test compared with electroneuromyography.

ENMG	N	%	Modified Phalen test	N	% agreement between exams
Mild			Mild	2	100
	2	6.1	Moderate	-	
			Severe	-	
Moderate			Mild	7	
	13	39.4	Moderate	6	46.2
			Severe	-	
Severe			Mild	-	
	18	54.5	Moderate	-	
			Severe	1	100

ENMG: electromyoneurography.

DISCUSSION

More than 80% of patients with CTS are women and over 40 years of age,[2] agreeing with the findings of Jesus Filho et al.[1] In our study, however, the involvement in women is higher, reaching 87.9%. This

fact may have sociocultural influence in our state, and even in Brazil itself, where there is a greater concern and search for medical appointments among women, which can be confirmed by a study conducted by the Brazilian Institute of Geography and Statistics (IBGE).[10] It also exemplifies the fact that all male patients in the study were classified as severe by both ENMG and Phalen's test.

In addition to the Phalen test, the semiology of carpal tunnel syndrome includes Durkan and Tinel tests, with 87% sensitivity and 90% specificity for the Durkan test. Tinel test is less sensitive, with only 56% positivity in patients in whom CTS was confirmed by electrophysiological investigation and 80% specificity.[1] Our study confirms this trend, since the Durkan test was positive in 87.9% and Tinel in 72.7% of cases.

Electroneuromyography, besides being the main test for the diagnosis of this neuropathy, is essential to make the differential diagnosis among other neuromuscular pathologies and determine the severity of CTS. Recently, with the appearance of high resolution ultrasound, scholars have been trying to demonstrate the usefulness of this method as an aid tool in the diagnosis of carpal tunnel syndrome, especially in cases in which patients showed symptoms compatible with the disease and normal physical and electroneuromyography results. A 9 mm^2 area of the upper median nerve in the distal carpal tunnel at the level of the pisiform bone, measured by ultrasound, is considered a CTS diagnosis.[7] According to Carvalho et al.,[7] this is an examination with high sensitivity and specificity in diagnosis. However, it has not become a very reproducible examination to use it in our study.

Electroneuromyography has a 92.3% sensitivity and a 81.8% specificity.[11] It is effective in detecting CTS, but not in ruling out the diagnosis. In this study, 54.5% of the patients had ENMG classified as severe, 39.4% as moderate and 6.1% as mild. All patients considered severe by complementary examination also had the same classification in the Phalen test, showing that the two tests have similar results in more advanced cases, which are more likely to require surgical treatment. It is also noteworthy that 21.2% of patients already had atrophy of the thenar region. In these cases, the involvement had already exceeded the sensory portion and reached the motor portion of the median nerve. They were classified as severe in both the examination and the test, since atrophy is a sign of an advanced disease.

The cases in which Electroneuromyography showed mild and severe results, it obtained the same results in Phalen test. However, when the electroneuromyography result was moderate, the divergence between the results was very large, with only 46.2% agreement.

The main objective of our study was to compare the results of the Phalen test with those of ENMG. Initially, all patients included in the study had the positive test, since this was one of the inclusion criteria. The results showed that 26 out of 33 patient had the same result in both tests (78.8%).

We observed that most patients were already at an advanced stage of the disease. It possibly happened due to the study being carried out in a specialized tertiary service, to which most are referred when the primary care physician sees the need for surgical treatment, or also due to a delayed diagnosis of mild cases, when the evaluation is not carried out by a specialist. We observed there was a great agreement between the results of the test under study and the examination at the extremes of involvement degrees, that is, in mild and severe cases, reaching 100% of similar results. However, the results were quite divergent in those with moderate involvement.

All patients classified as severe with the Phalen test were recommended for surgical treatment and waited for the procedure at the hospital, which shows that, in addition to other studies, this examination may be an important tool for direct indication of surgical treatment for CTS.

CONCLUSION

The Phalen test showed results similar to those of ENMG, especially in the most severe and mild cases, but with large differences in moderate cases. The test showed its value in cases that require surgical treatment, and it may serve as a suggestive recommendation tool.

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ORIGINAL ARTICLE

PROFILE OF PATIENTS WITH CARPAL TUNNEL SYNDROME TREATED AT A REFERRAL SERVICE

PERFIL DE PACIENTES COM SÍNDROME DO TÚNEL DO CARPO ATENDIDOS EM UM SERVIÇO DE REFERÊNCIA

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ABSTRACT

Objective: To describe the clinical and epidemiological characteristics of people diagnosed with carpal tunnel syndrome (CTS) treated at a hand surgery outpatient clinic of a regional referral service. Methods: Interview and specific medical examination of 150 people diagnosed with CTS underwent, and statistical analysis of the results obtained. Results: Women smokers, in the fifth decade of life, married, overweight and educated until the elementary level prevailed in our study. Arterial hypertension and diabetes were the most reported comorbidities, and Durkan's test was the most prevalent. Conclusion: CTS is prevalent in women in their fifth decade of life, with bilateral involvement and high school. The hypertension and diabetes are the most common diseases in people with CTS. ***Level of evidence IV, Case series.***

Keywords: Carpal Tunnel Syndrome. Median Neuropathy. Epidemiology.

RESUMO

Objetivo: descrever as características clínicas e epidemiológicas das pessoas diagnosticadas com síndrome do túnel carpal (STC) atendidas em um ambulatório de cirurgia da mão de um serviço de referência regional. Métodos: Entrevista e exame médico específico de 150 pessoas diagnosticadas com STC e análise estatística dos resultados obtidos. Resultados: Houve prevalência de mulheres tabagistas, na quinta década de vida, casadas, com nível de instrução até o nível fundamental. Hipertensão arterial sistêmica e diabetes foram as comorbidades mais relatadas e o teste de Durkan foi o mais prevalente. Conclusão: A STC é prevalente em mulheres na quinta década de vida, com acometimento bilateral e nível de escolaridade até o ensino médio. Hipertensão e diabetes são as comorbidades mais frequentes em pessoas com STC. ***Nível de evidência IV, Série de casos.***

Descritores: *Síndrome do Túnel Carpal. Neuropatia Mediana. Epidemiologia.*

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INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common peripheral neuropathy associated with the compression of the median nerve at the level of the carpal tunnel. This syndrome is characterized by numbness, tingling, and, in advanced cases, weakness of the thumb and thenar atrophy.[1]

The median nerve is located below the transverse carpal ligament, and it provides motor and sensory function for the hand. Its delicate positioning makes it susceptible to compression and, in prolonged cases, can lead to compression neuropathy.[2]

The subjects with CTS may describe symptoms in the area of median nerve innervation (thumb, index finger, middle finger and radial side of the ring finger), as well as pain in thenar eminence and, with advanced compression, weakness and atrophy of the abductor pollicis brevis and opponens pollicis muscles.[3]

The overall prevalence ranges between 2.1% and 3% of the population.[4] Risk factors for this condition include pregnancy, fractures, hypothyroidism, rheumatoid arthritis, diabetes, and obesity.[5]

In most cases, CTS is considered idiopathic. Even with the large number of original research on the subject, its etiology and the contribution of work on daily routine as a causal agent of this condition are still controversial. Moreover, its pathophysiology has not been fully clarified. Nerve ischemia by increased pressure within the carpal tunnel, vascular alteration and chronic focal compression deformation are conflicting opinions described in the literature.[6]

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

The study was conducted at the Hospital de Clínicas of Universidade Federal do Triângulo Mineiro.
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This study is justified by the lack of publications in the literature presenting the characteristics of people with CTS attended at a regional referral service of the Brazilian Unified Health System. Our aim is to describe the clinical and epidemiological characteristics of people diagnosed with CTS attended in a hand surgery outpatient clinic of a university hospital.

METHODS

A cross-sectional observational study of quali-quantitative nature was conducted, presenting as design the assessment of patients admitted consecutively in the period of six months in the hand surgery outpatient clinic of a university hospital. All procedures were performed in accordance with the ethical standards determined both by the Research Ethics Committee for Research in Human Beings (CAAE 17608319.9.0000.8667 and Opinion No. 3,578,491 of 09/16/2019) and by the 1964 Declaration of Helsinki. The Free and Informed Consent Form was obtained from all study participants, upon signature of a specific term.

The inclusion criteria were people of both sexes, over 18 years old, in an initial appointment at the hand surgery outpatient clinic, who presented the clinical diagnosis of CTS written in the medical referral of Primary Health Care. People who presented cognitive or mental alterations that made the interview impossible were excluded, as well as those who did not provide consent to this research.

A total of 150 people met the said criteria and were submitted to interview and specific medical exam, according to the routine of the hand surgery outpatient clinic. To characterize the sample and present the results of data collection, qualitative variables (sex, smoking, marital status, dominance, affected limb, schooling level, and presence of comorbidities) were assessed using absolute and relative frequencies, while quantitative (age and body mass index — BMI) were assessed using average, standard deviation, median, minimum and maximum.

The CTS prevalence was described according to each qualitative characteristic, and the association with the use of chi-square or exact tests (Fisher's exact test or likelihood ratio test) was verified. Quantitative characteristics were described according to CTS and compared with the use of the Student's t-test or Mann-Whitney test.

The IBM-SPSS for Windows version 22.0 was used for the analyses, and the software Microsoft Excel 2003 was used for data tabulation. The tests were performed with 5% significance level.

RESULTS

Table 1 describes the personal characteristics and associated diseases in our sample. A total of 150 people with CTS were attended, 120 women (80%) and 30 men (20%), with a mean age of 54.1 ± 10.9 years. The mean BMI was 27.3 kg/m^2. In total, 105 people (70%) did not smoke, 25 (16.7%) reported being former smokers and 20 (13.3%) claimed to be smokers. Most people declared to be married, corresponding to 96 cases (64%), followed by 23 singles (15.3%), 22 divorced (14.7%) and 9 widow/widowers (6%). Right hand dominance was reported in 146 people (97.3%), and left hand dominance in 4 (2.7%). The occurrence of symptoms in both hands (bilaterally) was reported by 92 people (61.3%), while 58 (38.7%) reported having symptoms unilaterally. In relation to schooling, 30 people (20%) reported being literate, 79 (52.7%) had elementary school, 33 (22%) high school, and 8 (5.3%) college.

Table 1. Description of the personal characteristics and comorbidities of the patients assessed.

Variable	Description (N = 150)
Sex, n (%)	
Women	120 (80)
Men	30 (20)
Age (years)	
mean SD	54.1 10.9
median (min.; max.)	53.5 (24; 79)
Body mass index (kg/m^2)	
mean SD	27.3 4.5
median (min.; max.)	26.2 (18.6; 44.5)
Smoking, n (%)	
No	105 (70)
Yes	20 (13.3)
Former smoker	25 (16.7)
Marital status, n (%)	
Single	23 (15.3)
Married	96 (64)
Divorced	22 (14.7)
Widow/Widower	9 (6)
Dominance, n (%)	
Right hand	146 (97.3)
Left hand	4 (2.7)
Occurrence, n (%)	
Unilateral	58 (38.7)
Bilateral	92 (61.3)
Schooling, n (%)	
Literate	30 (20)
Elementary school	79 (52.7)
High School	33 (22)
College	8 (5.3%)
Number of comorbidities	
mean SD	2.3 1.7
median (min.; max.)	2 (0; 7)
Systemic Arterial Hypertension n (%)	
No	78 (52)
Yes	72 (48)
Diabetes, n (%)	
No	121 (80.7)
Yes	29 (19.3)
Fibromyalgia, n (%)	
No	107 (71.3)
Yes	43 (28.7)

The mean value of comorbidities presented was 2.3 per person. Out of these, systemic arterial hypertension (SAH) was observed in 72 cases (48%), while 78 (52%) did not present this condition. The presence of diabetes was reported by 29 people (19.3%), while 121 (80.7%) did not report the disease. A total of 43 people (28.7%) reported treatment for fibromyalgia, while 107 (71.3%) did not report the treatment.

Table 2 shows the characteristics of the symptoms mentioned and diagnostic tests applied in our sample.

Table 2. Description of symptoms and diagnostic tests performed.

Variable	Description (N = 150)
Pain, n (%)	
No	21 (14)
Yes	129 (86)
Sensitivity alteration, n (%)	
No	56 (37.3%)
Yes	94 (62.7)
Loss of strength, n (%)	
No	53 (35.3)
Yes	97 (64.7)
Numbness, n (%)	
No	14 (9.3)
Yes	136 (90.7)
Tinel's sign, n (%)	
Negative	69 (46)
Positive	81 (54)
Phalen's maneuver, n (%)	
Negative	85 (56.7)
Positive	65 (43.3)
Durkan's test, n (%)	
Negative	66 (44)
Positive	84 (56)
Flick sign, n (%)	
Negative	52 (34.7)
Positive	98 (65.3)
Time since diagnosis (years)	
mean SD	4.6 3.6
median (min.; max.)	4 (0; 18)

Pain was reported in 129 people (86%), while 21 (14%) did not report symptoms with pain. Sensitivity alteration was reported by 94 people (62.7%) while 56 (37.3%) did not show this alteration. Regarding loss of strength, 97 people (64.7%) reported this symptom and 53 (35.3%) denied it. Numbness was reported by 136 people (90.7%), while 14 (9.3%) did not report this symptom. Tinel's test was positive in 81 people (54%) and negative in 69 (46%). Phalen's test was positive in 65 people (43.3%) and negative in 85 (56.7%). Finally, the Durkan's test was considered positive in 84 people (56%) and negative in 66 (44%). The Flick's sign maneuver was reported by 98 people (65.3%), while 52 (34.7%) did not report it. When asked about the time between the onset of symptoms and the search for medical care for CTS diagnosis, the mean value found was 4.6 years.

Table 3 shows the result of the adjusted model to explain the presence of CTS in people according to age and presence of fibromyalgia.

Table 3. Result of the model adjusted to explain the presence of carpal tunnel syndrome in patients according to the characteristics assessed.

Variable	OR	(95%CI)		p
		Inferior	Higher Education	
Age (years)	1.05	1.01	1.08	0.017
Fibromyalgia	0.34	0.16	0.73	0.006

Multiple logistic regression with Stepwise backward selection method with input and output criterion of 5%.

DISCUSSION

The carpal tunnel is the channel in which the floor is formed by the carpal bones, and the ceiling is the thick and inelastic transverse carpal ligament. In this tunnel, the median nerve is on the surface of the superficial flexor tendons of the fingers, and any factor that increases the contents within the tunnel can compress the median nerve, leading to symptoms of paresthesia in its innervation area.[7] CTS is more frequent in women between the fourth and sixth decades of life, although this syndrome can be found in men and in all age groups, including it has been described in children and young people.[8] Our studies met the literature, with a prevalence of women in 80% of cases and mean age of 54.1 years.

Shiri et al.,[9] in a meta-analysis, found that overweight and obese people had an increased risk of CTS. Our study also showed a significant number of people with BMI above normal values. Although no statistical significance was observed, our results can be used to promote healthy habits and activities for the population and prevent worsening.

In some cross-sectional studies, smoking is recognized as a risk factor for CTS;[10-12] however, studies on its pathophysiology are scarce. In our study, 30% of people reported smoking or were former smokers. We believe that further investigations can help verify correlations between smoking and the development or worsening of CTS.

Studies by Mattioli et al.[13] show that marital status may be associated with CTS; however, its results do not clearly justify this correlation, suggesting that individual and labor factors should be investigated to better elucidate this trend. Our study showed prevalence of married people, corresponding to almost twice of those divorced and single combined.

Dominance was also investigated in our study, showing prevalence of right-handed people, but bilateral symptomatology was reported in more than half of the cases.

According to Pourmemari et al.[14], the prevalence of CTS in people with low education was 60% higher than in those with a high and higher level of education. For these authors, people with a higher level of education are less at risk of being submitted to decompression surgery of the median nerve at the level of the carpal tunnel compared with low educational level. In our study, more than half of the people also had a lower education level than high school, and none of them had undergone prior surgical procedure.

One of the most common complications of diabetes is peripheral neuropathy, and among focal neuropathies (mononeuritis and compression syndromes), CTS is frequent in diabetic people due to some alteration in the synovial tissue surrounding the nerve and because the nerve presents secondary alteration to high blood glucose.[15] In our study, there was a prevalence of systemic comorbidities, arterial hypertension and diabetes in more than half of the cases.

The literature indicates the Tinel's (50% sensitivity and 67% specificity) and Phalen's tests (75% sensitivity and 47% specificity) as the most used in clinical practice for the diagnostic aid of CTS.[16] Nowak and Noszczyk[17] also report Durkan's and Phalen's tests as the most positive clinical trials in people with CTS. In our results, we found the Durkan's test as the most prevalent, followed by Tinel's and Phalen's, respectively. The Flick's sign maneuver, which consists of shaking hands to relieve symptoms of numbness especially at night, was the most reported, being present in almost two-thirds of people affected by CTS in our sample.

Fibromyalgia is a chronic pain syndrome characterized by generalized involvement and pain to muscle palpation, in addition to fatigue, morning stiffness, non-restorative sleep and cognitive symptoms.[18] Some studies show that CTS is more common in people with fibromyalgia,[19] and paresthesia in the extremities is related to abnormal sensory perception due to central sensitization, and this may interfere with the interpretation of paresthetic symptoms in CTS.[20] In our study, only age and the presence of fibromyalgia influenced the diagnosis of CTS, so that every year of age the chance of CTS increased 5%, regardless of the other characteristics

assessed. We observed in our study that people with CTS and fibromyalgia presented a statistically higher mean age than those with CTS without fibromyalgia ($p = 0.010$). The frequency of CTS in patients with fibromyalgia was statistically lower than in patients without fibromyalgia ($p = 0.003$).

The positive finding of our study was the high number of cases, which included most patients treated at secondary level with the diagnosis of CTS in the stipulated period. On the other hand, because our hand surgery service is a regional reference for several surrounding cities, our results may not present the reality of Primary Health Care services. We suggest studies on different levels of health care to better evaluate the profile of the person with CTS.

CONCLUSION

CTS is prevalent in women in the fifth decade of life, with bilateral occurrence and lower level of education. Systemic hypertension and diabetes are the most frequent comorbidities in people with CTS.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article: HRPF: performed bibliographic research and data collection and participated in the discussion of the results; VGNP: idealized the study, checked the results of statistical analysis and the final writing of the manuscript; EFO: assessed the data from statistical analysis; MAR: reviewed the statistical analysis and the final writing of the text.

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ORIGINAL ARTICLE

THE DESIGN OF THE ARTERIOVENOUS VASCULAR LOOP DOES NOT AFFECT ITS PATENCY: EXPERIMENTAL STUDY

O FORMATO DA ALÇA VASCULAR NÃO AFETA A PATÊNCIA ARTERIOVENOSA: ESTUDO EXPERIMENTAL

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ABSTRACT

Objective: To evaluate the effect of the design of a femoral vascular loop with anastomosis in the femoral artery of rabbits on the presence of flow (patency) after seven days. Methods: A total of 39 rabbits underwent arteriovenous microanastomosis using the microsurgical technique. Two loop designs were used: one circular and the other angled. The parameters evaluated were presence or absence of flow, signs of hemolysis and hemodynamic changes. Results: After seven days, flow was present in 68% of the angled loops and 75% of the circular loops ($p > 0.05$). There was a significant intragroup decrease in pCO_2 and a significant increase in pH. For the other parameters evaluated, no significant differences between the two loop models were found. Conclusions: A reproducible vascular loop model was shown. There was no significant difference between the two vascular loop models about the presence of flow after seven days. ***Level of Evidence V, Animal experimental study.***

Keywords: Arteriovenous Anastomosis. Vascular Grafting. Femoral Vein.

RESUMO

Objetivo: Avaliar, em coelhos, qual é a influência do desenho da alça de veia femoral com anastomose na artéria femoral, na presença de fluxo (patência) após sete dias. Método: 39 coelhos foram submetidos à microanastomose arteriovenosa com técnica microcirúrgica. As alças foram acomodadas em dois desenhos, um circular e outro, o mais alongado possível sem dobras na alça. Os parâmetros avaliados foram: presença ou não de fluxo, sinais de hemólise, alterações hemodinâmicas. Resultados: após sete dias, o fluxo estava presente em 68% das alças anguladas e em 75% das alças circulares ($p > 0,05$). Houve, intragrupo, diminuição estatisticamente significante da pCO_2 e aumento estatisticamente significante do pH. Não houve diferença estatística no restante dos parâmetros avaliados entre os dois modelos de alça. Conclusões: apresentamos um modelo reprodutível de alça vascular. Não houve diferença estatística quanto à presença de fluxo após sete dias nos dois modelos de alça vascular. ***Nível de Evidência V, Estudo experimental em animais.***

Descritores*: Anastomose Arteriovenosa. Enxerto Vascular. Veia Femoral.*

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INTRODUCTION

Vascular loops enable the insertion of microsurgical flaps in areas where local recipient vessels are damaged.[1,2] These loops have been used in head and neck, as well as trunk and limb, reconstruction.[3-9] While they can be done during anesthesia for flap transposition, loops can also be prepared days earlier, thereby dividing a long and exhausting procedure into two shorter, more manageable surgeries.[10]

Despite speculation regarding the factors that can lead to its failure, the literature lacks controlled models that demonstrate which of them actually affect the patency of a loop.

The primary objective of this study was to standardize and maintain a vascular loop model in rabbits, thereby determining whether there is a difference in blood flow patency between two different loop designs, “circular” and “angled” (Figure 1).

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

The study was conducted at Universidade de São Paulo, Medical School, Institute of Orthopedics and Traumatology.
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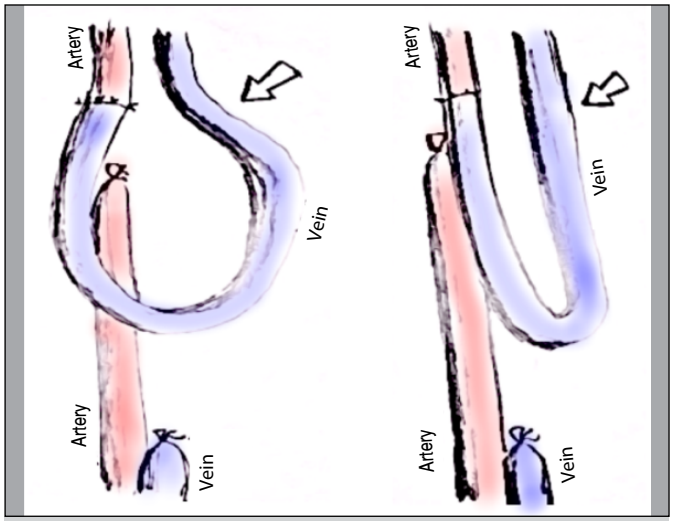

Figure 1. Design of loop models. On the left, CIRCULAR model, on the right, ANGLED model.

The secondary objective was to determine the effects of the different loop designs on heart rate, respiratory rate, blood gas analysis and presence of hemolysis.

MATERIALS AND METHODS

The animals were treated following the "Guide for the Care and Use of Laboratory Animals"[10] and the ARRIVE Protocol (Animal Research: Reporting of *In Vivo* Experiments).[11]

Surgical and Anesthetic Protocol

Our research involved New Zealand rabbits that were provided by the Central Animal Laboratory of the Medical School, Universidade de São Paulo. Male and female adult rabbits were used based on availability.

The weight of the animals ranged from 2,350 g to 6,081 g.

The animals were anesthetized with ketamine (40 $mg.kg^{-1}$) and midazolam (2 $mg.kg^{-1}$), propofol at a 5 mg/kg dosage and isoflurane diluted in 100% oxygen by means of the Mapleson D anesthetic circuit.

The animals were prepared for surgery under aseptic conditions; a surgical microscope was used.

Solutions were prepared with 1 ml of 2% lidocaine to allow vasodilation; a 5000 IU heparin in 10 ml of normal saline was used to prevent thrombus formation in the vessel lumen.

Blood gas, electrolyte, bilirubin and liver enzyme tests were collected from a portion of the femoral artery distal where the anastomosis was performed. An insulin needle was used (0.45 mm x 13 mm).

A medial incision was made in the right thigh, from the inguinal ligament to the knee. The femoral artery and vein were identified from the inguinal ligament to the emergence of the genicular branches (Figure 2). The branches of the femoral vein were ligated, and the vein was detached from its bed. The vein was attached just above the origin of the genicular branches. The distance between the ligature and the point where the vessel crossed the inguinal ligament was measured and noted as the length of the vessel (Figure 3).

An end-to-end anastomosis was performed in the femoral artery immediately after the emergence of the deep femoral artery. A 10-0 mononylon yarn was used with a 75-micrometer needle.

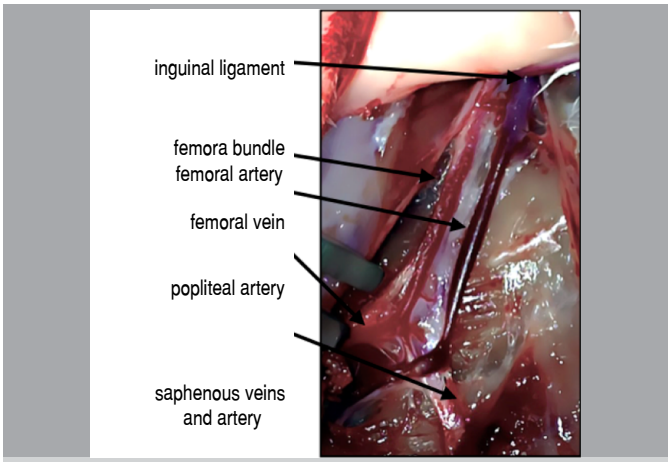

Figure 2. Vascular anatomy of the medial surface of the rabbit's posterior paw.

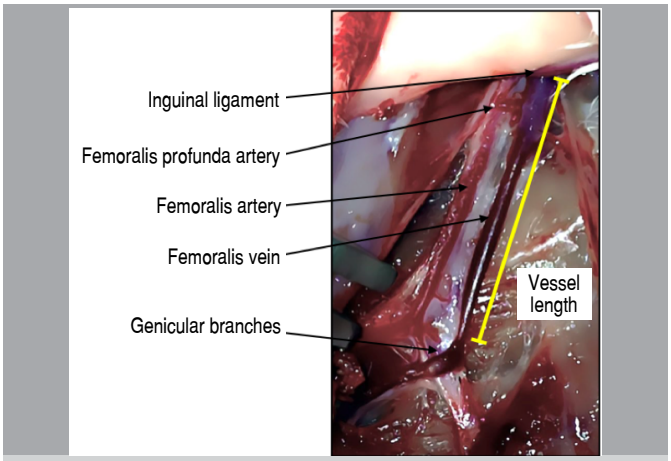

Figure 3. Dissected femoral vessels. Measurement of vessel length, which is used for making the vascular loop.

After completion of the anastomosis (when the loop was positioned), an external collaborator, without direct contact with the procedure, told the surgeon what type of loop to make. This information was generated by a randomization table created on the website www.randomization.com and grouped into permutation blocks ranging from 2, 4 or 6 positions (Figure 4).

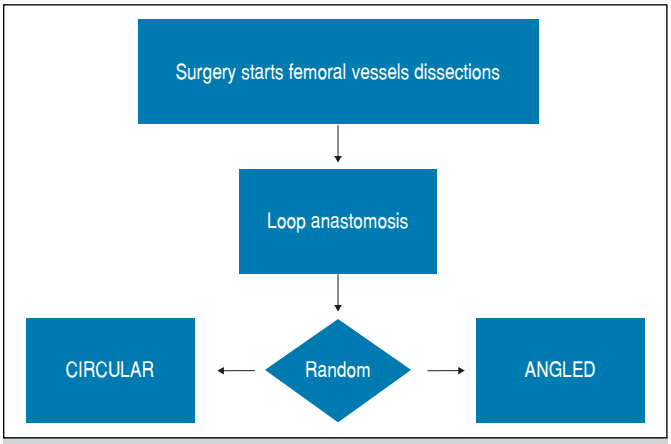

Figure 4. Study design.

The formed loop was then introduced into one of two possible positions, drawn by lot at the end of the anastomosis, to avoid influencing the surgeon's preference:

a) "ANGLED," folded over itself at the midpoint of its length. The vein was inserted so there would be contact between the descending and ascending sections of the loop, but without constriction of its walls. This shape reaches a more distal region of the foot (Figure 5).
b) "CIRCULAR," introduced to be closer to a circular shape. With a balance between length and width, this loop design reaches a more proximal region of the foot when compared with the "ANGLED" loop positioning (Figure 6).

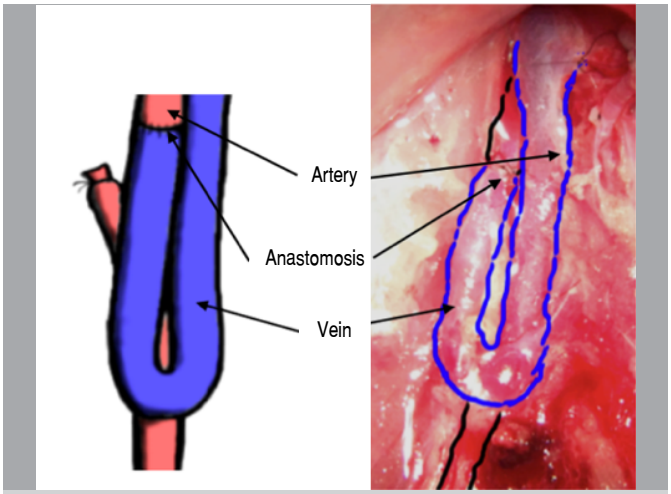

Figure 5. ANGLED loop.

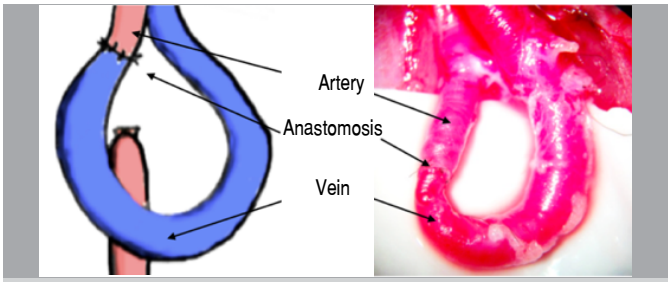

Figure 6. CIRCULAR loop.

The loops were introduced on Bioclusive® sterile plastic film (Johnson & Johnson, USA), prepared in a rectangular shape, folded back on itself to prevent contact between the adhesive and the tissue, and fixed to the bed with sutures. On this structure, strips made of the same material were attached to the base to keep the loop in the shape required for evaluation.

The loop was measured for length, which was defined as the largest distance from the point where the artery crosses the inguinal ligament, and the largest width perpendicular to the length line. If the loop was "circular," it was measured for its inner diameter, also perpendicular to the length, in the space between the ascending and descending segments of the loop (Figure 7).

After the measurements were taken, another plastic film layer was gently placed on the loop to isolate its environment from the rest of the musculature and prevent the adherence of adjacent tissue. Closure was performed in a plane by plane fashion, attaching the musculature distal to the loop with 4-0 nylon. The subcutaneous plane was closed with inverted sutures and 4-0 nylon.

The skin was closed with 4-0 nylon with separate stitching and a continuous running suture to ensure wound closure.

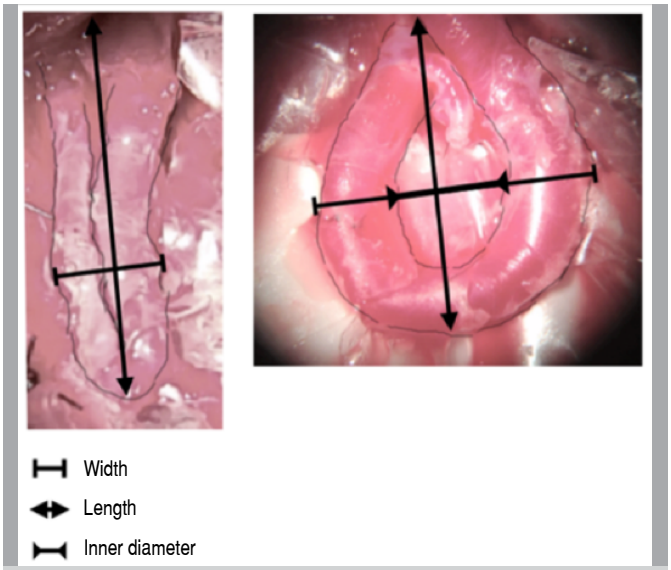

Figure 7. Measurement of the loop dimensions.

The wound was cleaned and coated with antiseptic and repellent spray to discourage licking. A collar was attached to block neck movement but did not disturb the animal's feeding.

The animals were kept in individual cages with food and water available *ad libitum*; their environment was clean and air-conditioned with a light and dark cycle.

Postoperative

Following the same protocol, after seven days the animals underwent an additional round of anesthesia for evaluation and subsequent euthanasia.

The loop was identified, the plastic film cut with microsurgery instruments (Figures 8 and 9), then measured, with blood samples taken from a portion of the distal loop for analysis (Table 1). The loop was then sectioned in its distal third, and the flow was evaluated as "present" , when a continuous flow filled the cavity, or "absent", if it was a simple drip . Finally, a dose of 1.0 to 2.0 mEq/kg potassium chloride was administered.

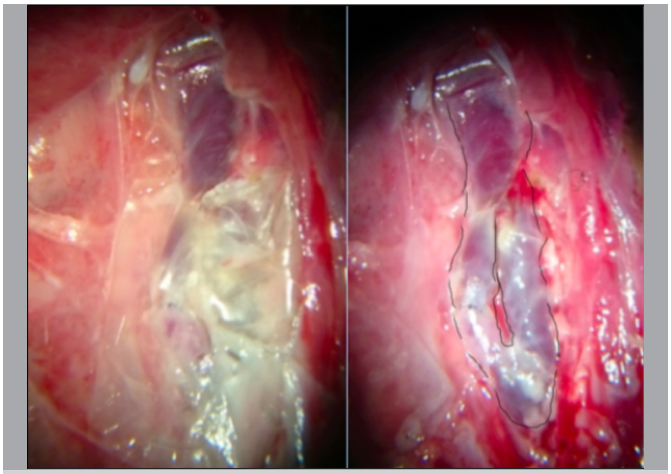

Figure 8. ANGLED vascular loop on the seventh postoperative day (left, still covered in plastic film, right after its removal).

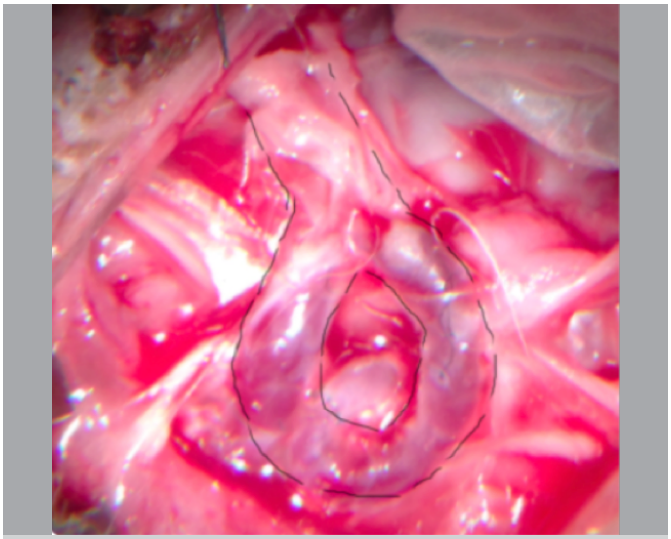

Figure 9. CIRCULAR vascular loop on the seventh postoperative day.

Table 1. Chi-square test, flow x design.

Chi-square tests			
	Value	df	Significance (2-sided)
Pearson's chi-square	0.208	1	0.648
No. of valid cases	39		

Evaluations

Primary evaluation: patency of the vessels

The flow was classified as "present" or "absent."
In the first 12 specimens, the blood flow was measured using a Transonic T106 Doppler flowmeter (Transonic, Ithaca, NY, USA) (Figure 10).

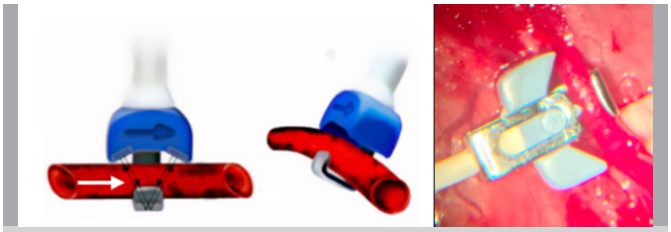

Figure 10. Loop flow evaluation with Doppler flowmeter Transonic T106.

Secondary measures

Heart rate (HR) and respiratory rate (RR) were measured immediately after the two rounds of anesthesia. HR was measured in beats per minute, allowing the hemodynamic effects of the different vessel types to be evaluated. RR was measured in strokes per minute to evaluate, indirectly, the effectiveness of analgesia and the presence of respiratory depression.
HEMOLYSIS MARKERS: hemoglobin (g/dL), hematocrit (%), lactate dehydrogenase (LDH, mg/dl) and direct and indirect bilirubin (DB and IB, mg/dL).
BLOOD GAS ANALYSIS: Arterial blood gas levels were collected to evaluate the quality of oxygen supply that the vascular loop could carry for a hypothetical flap to be performed on the seventh postoperative day. Standard blood gas analyses included pO_2, pCO_2, O_2 saturation, base excess, pH, Na^+, K^+, Cl^- and Ca^{2+}.

RESULTS

Forty-three surgeries were performed in a controlled and randomized manner. Four specimens died: three during induction of anesthesia and the fourth on the first postoperative day. Information for these four specimens was removed from the data analysis. Data were recorded and analyzed for 39 surgeries.
Twenty-nine rabbits were female, and ten male.
The "circular" loop group comprised 20 specimens, and the "angled" loop group 19.
The parameters HR, RR and temperature, measured pre- and post-anesthesia, were similar in both groups.
During sectioning and vessel ligation, the relative percentages of vessel shortening were 26.6% in the "circular" group and 33.5% in the "angled" group.
Presence or absence of flow after seven days regarding the vascular loop design (Figures 11 and 12):

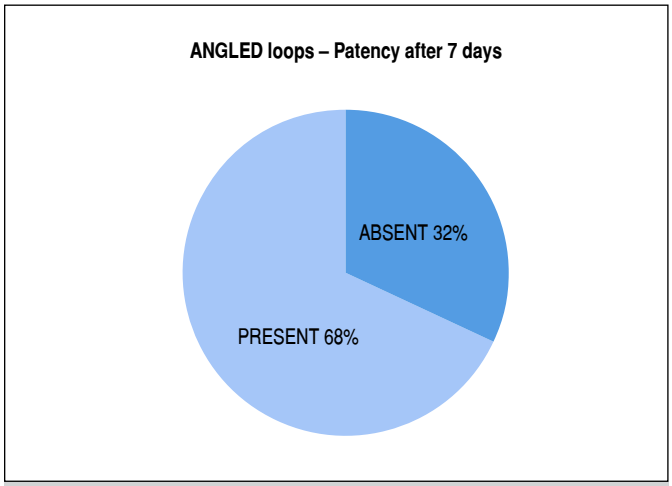

Figure 11. Patency of the "ANGLED" loops.

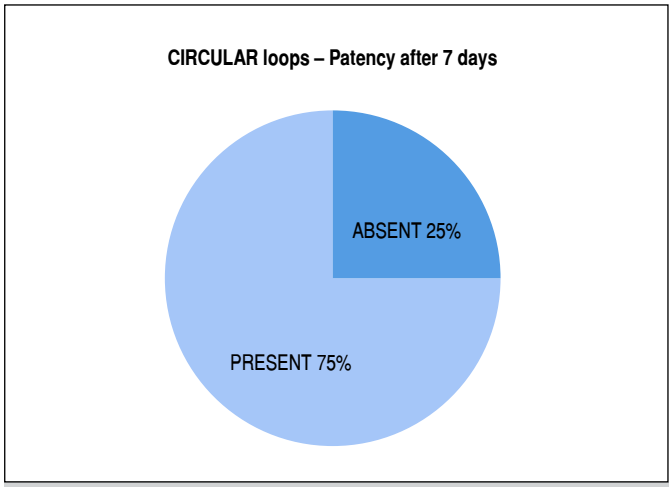

Figure 12. Patency of the "CIRCULAR" loops.

When subjected to statistical analysis using the chi-square test, the comparison between the "angled" and "circular" loop groups showed no significant difference (Table 1).
All blood gas and electrolyte parameters measured showed normal distributions when subjected to the Kolmogorov Smirnov test (Table 2).

Table 2. Electrolytes and blood gases at the start of surgery.

"CIRCULAR" LOOP	Minimum	Maximum	Mean	Standard deviation
Initial pH	7.20	7.42	7.2616	0.07141
Initial pCO_2 (mmHg)	38.70	91.90	68.8273	17.87032
Initial pO_2 (mmHg)	99.60	399.00	213.6909	94.88694
Initial sat O_2 (%)	0.00	100.60	36.3364	50.41730
Initial base excess (mmol/L)	-0.40	9.90	3.4655	3.33866
Initial sodium (mEq/L)	137.00	148.00	140.5455	3.17376
Initial potassium (mEq/L)	3.10	4.60	3.7636	0.48015
Initial calcium (mg/dL)	5.80	6.83	6.3818	0.29144
Initial chloride (mEq/L)	96.00	116.00	104.2727	6.03475
"ANGLED" LOOP	**Minimum**	**Maximum**	**Mean**	**Standard deviation**
Initial pH	7.14	7.40	7.2812	0.07608
Initial pCO_2 (mmHg)	42.40	76.10	59.8182	11.72449
Initial pO_2 (mmHg)	40.40	400.00	236.0727	131.00080
Initial sat O_2 (%)	0.00	99.90	28.9455	41.62591
Initial base excess (mmol/L)	-0.10	6.60	2.3609	2.22143
Initial sodium (mEq/L)	134.00	145.00	137.7273	3.00303
Initial potassium (mEq/L)	3.10	4.10	3.6818	0.38423
Initial calcium (mg/dL)	6.10	6.76	6.4255	0.19831
Initial chloride (mEq/L)	96.00	107.00	101.5455	3.47458

When comparing the initial blood gas and electrolyte values, both the "circular" and "angled" loop groups showed similar baseline values. The laboratory hemolysis markers LDH, total bilirubin (TB), DB and IB measured are listed in Table 3. The concentrations of alanine aminotransferase transaminase (ALT) and aspartate aminotransferase (AST) were measured to rule out hepatopathy concomitant with bilirubin increase, as described in Tables 3 and 4.

A normal distribution of ALT, AST, and LDH was found. The test rejected the hypothesis of normality for TB, DB and IB.

No significant difference was found in any sample in either the intra-group comparison ("circular" or "angled") or the intergroup comparison ("circular" *versus* "angled") regarding hemolysis tests (LDH, TB, DB and IB) and transaminases (ALT and AST) was found. Flow, in $mL.min^{-1}$, was measured in the first 12 specimens (Table 5). The distribution was unusual, with no significant intra- or intergroup differences between initial surgery and euthanasia (Figure 13).

Table 3. Electrolytes and blood gases at euthanasia.

"CIRCULAR" LOOP	Minimum	Maximum	Mean	Standard deviation
Final pH	7.05	7.43	7.3092	0.10133
Final pCO_2 (mmHg)	10.10	66.60	46.4909	15.00989
Final pO_2 (mmHg)	28.40	262.00	135.0818	88.57413
Final sat O_2 (%)	35.10	101.90	80.8875	26.79112
Final base excess (mmol/L)	-6.40	4.70	0.3455	3.81376
Final sodium (mEq/L)	131.00	142.00	137.5455	3.38714
Final potassium (mEq/L)	2.80	4.40	3.6000	0.42661
Final calcium (mg/dL)	5.51	6.74	6.1009	0.36822
Final chloride (mEq/L)	94.00	116.00	103.8182	5.65364
"ANGLED" LOOP	**Minimum**	**Maximum**	**Mean**	**Standard deviation**
Final pH	7.26	7.51	7.3584	0.07149
Final pCO_2 (mmHg)	27.80	55.50	48.5111	8.82715
Final pO_2 (mmHg)	37.70	322.00	154.2222	115.66063
Final sat O_2 (%)	53.70	101.70	86.8000	17.34474
Final base excess (mmol/L)	-2.90	6.40	1.3889	3.06938
Final sodium (mEq/L)	133.00	144.00	138.5556	4.36208
Final potassium (mEq/L)	0.00	4.00	3.1800	1.15065
Final calcium (mg/dL)	0.00	6.52	5.4590	1.92931
Final chloride (mEq/L)	93.00	112.00	103.6667	6.30476

Table 4. Distribution of biochemical hemolysis markers.

Circular design				
	Minimum	**Maximum**	**Mean**	**Standard Deviation**
Initial ALT (IU/L)	20	67	36.75	14.710
Initial AST (IU/L)	11	37	25.25	6.811
Initial TB (mg/dL)	0.0	0.1	0.017	0.0389
Initial DB (mg/dL)	0.0	0.0	0.000	0.0000
Initial IB (mg/dL)	0.0	0.1	0.017	0.0389
Initial LDH (IU/L)	160.7	617.8	333.825	126.8985
Final ALT (IU/L)	12	48	30.36	11.102
Final AST (IU/L)	13	39	22.00	8.450
Final TB (mg/dL)	0.0	0.1	0.018	0.0405
Final DB (mg/dL)	0.0	0.0	0.000	0.0000
Final IB	0.0	0.1	0.018	0.0405
Final LDH (IU/L)	124.2	345.2	232.973	66.7961
Angled design				
	Minimum	**Maximum**	**Mean**	**Standard Deviation**
Initial ALT (IU/L)	17	73	38.42	21.043
Initial AST (IU/L)	18	62	30.17	12.988
Initial TB (mg/dL)	0.0	0.1	0.025	0.0452
Initial DB (mg/dL)	0.0	0.0	0.000	0.0000
Initial IB (mg/dL)	0.0	0.1	0.025	0.0452
Initial LDH (IU/L)	89.8	542.7	274.758	124.3742
Final ALT (IU/L)	11	173	42.09	45.034
Final AST (IU/L)	11	62	27.36	14.603
Final TB (mg/dL)	0.0	0.0	0.000	0.0000
Final DB (mg/dL)	0.0	0.0	0.000	0.0000
Final IB	0.0	0.0	0.000	0.0000
Final LDH (IU/L)	117.9	480.0	237.218	121.2778

Table 5. Flow measured in $mL.min^{-1}$.

Design		Minimum	Maximum	Mean	Standard Deviation
"ANGLED"	Flow at start of surgery	34	156	85.33	40.215
	Flow at euthanasia ($mL.min^{-1}$)	0	101	42.71	39.037
"CIRCULAR"	Flow at start of surgery	23	170	72.46	39.928
	Flow at euthanasia ($mL.min^{-1}$)	0	160	44.33	50.060

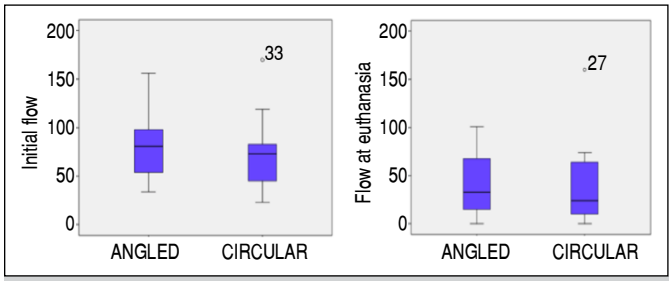

Figure 13. Distribution of initial and final flow in mL min -1 in the two loop designs.

Because of the costly equipment and the absence of additional data for the study, the measurement of flow by Doppler was discontinued.

DISCUSSION

Arteriovenous vascular loops have been widely used for both reconstruction of limbs and tissue revascularization.[12] Despite the technique having been described since 1982,[1] some questions remain unanswered. The purpose of this study is to propose an evaluation model to answer the following question: "What is the effect of the loop design on the presence or absence of flow after seven days?"

The anesthesia protocol was sufficient to allow the animals to survive procedures of up to four hours. There were four deaths in this series, with undefined cause for the three deaths that occurred during induction. The death on the first postoperative day resulted from heavy intraoperative bleeding.

The saphenous vessels were not used, as the arrangement in humans is different, with two veins and one artery composing the same bundle, since this pattern would make the measurement of flow in a single vessel nonviable.

We chose to use the femoral vein, from the confluence of the genicular veins to the confluence of the deep femoral vein. It was necessary to ligate the muscular branches along the entire path of this vessel. The absence of necrosis in the foot shows that the deep femoral artery is sufficient to supply the limb with blood in the absence of the femoral artery.

Concerning the mold that keeps the loop in position, three questions were answered: the biocompatibility of the material; the minimum vessel compression; and the stability of the material when used in the rabbit's thigh (a site of substantial movement).

Hard molds were tested and discarded for causing vessel compression. Instead, we chose to use flaps of Bioclusive® sterile plastic film (Johnson & Johnson, USA).

The period of seven days between loop construction and the evaluation of patency was chosen in accordance with several clinical trials that waited the same period to evaluate loop maturation and the patient's clinical stabilization.[13-15]

A sample power statistical study was conducted and showed significantly similar numbers of patent vessels in the "circular" and "angular" loops. The proportions of patent vessels in the "angled" and "circular" loop populations were 55% and 64%, respectively, thus the sample size calculation, allowing for an alpha error of 5% and a statistical power of 80%, indicated that 466 specimens would be required for each group, for a total of 932. This sample size would make the project nonviable from ethical, logistical and economic perspectives.

Upon the study completion, the patency rates for the "angled" and "circular" loops were 68% and 75%, respectively, which are similar to the success rate of a large clinical series, where flaps made after the loop showed a success rate of 66%.[16] However, the values are slightly below the success rate for vascular loops in rats, estimated at 77%.[17]

The flow measurement results did not reflect differences between the two groups. Perhaps a greater number of studies, such as performed by Asano et al.,[18] can provide different results.

Regarding blood gas analysis, there was a decrease in the pCO_2 rate from 68.8 mmHg to 46.5 mmHg in the specimens receiving the "circular" loop. This difference was significant and could be explained by an increase in cardiac output, resulting from decreased peripheral vascular resistance, generating an increased respiratory rate and a decreased CO_2 level. However, no significant increases in HR and RR were found. This may be explained by an increase in alveolar permeability, which was not measured using this method.

In specimens subjected to the "angled" loop construction, a minimal increase in pH and a slight decrease in pCO_2 were observed. These differences were clinically insignificant.

Other electrolyte and blood gas parameters showed no significant differences.

Transaminases, DB, IB and LDH did not change before and after the construction of the loop in either group. Bilirubin may increase in cases of hemolysis or hepatopathy. The lack of increased transaminases reveals the absence of hepatopathy.

The vein's responses about dilation and increased blood flow has been demonstrated in diabetic patients[19] and experimental studies,[20] although the responses have not been correlated with the vessel shape.

Much of what is known about clinical and histological changes of arteriovenous anastomoses comes from studies with arteriovenous fistulas.[20] However, such research cannot be used to study vascular loops as the evaluations are usually performed on repeatedly punctured vessels. Regarding evaluating the effect of fistula design on the presence of flow, our study is the first in the literature to consider the vein.

In studies of the vessels' response to increased pressure regimes, from venous to arterial, the shapes that the vessels assume were not compared. Efforts have been made to keep the vessels in the same conformation and to evaluate the results of other factors, such as drugs inhibiting neointimal proliferation.[19]

Moreover, the saphenous vessels were discarded because the conformation of one artery with two veins full of communications would turn the study of isolated response of one saphenous vein impossible.

This study was conducted on small animals. The direct application of these results in clinical practice should be approached carefully for the vessel diameter is much smaller than in humans. Performing the technique on medium-sized animals is a step that may be taken to confirm the current results.

The presented thrombosis rate does not preclude comparison between the loop shapes. The same anastomosis procedure was performed on all animals, and the surgeon was advised of the loop only after the anastomosis was completed, requiring only the positioning of the same in its bed, in the "angled" or "circular " shape.

The anesthesia and surgery protocols, as well as the surgical technique for creation of the loop, were simplified to facilitate their reproducibility and use in exploring other gaps in scientific knowledge (such as providing blood flow to flaps or preparation of vascularized composite grafts in reconstructive microsurgery).

A major contribution of this study is to start breaking the paradigm that an angled loop has a greater chance of thrombosis than a circular one.

In reconstructive microsurgery this may be the difference between a loop reaching a distal point or less in the limb that needs a microsurgical flap, covering the poorer areas in covering tissue, such as the distal third of the leg and ankle.

CONCLUSION

In this study, whether the design of the vascular loop was "angled" or "circular" did not affect the presence of flow in the vessel after seven days. The blood gas analysis was minimally affected. This is a suitable and reproductible model of vascular loops.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article: MS: design, intellectual and scientific content, technical procedures, acquisition and interpretation of manuscript writing, critical review and approval of the final version of the manuscript; MRR: orientation, discussion of the study design and manuscript review; GBS: developing the anesthesia protocol; MCN: developing wound isolation techniques and preventing the animal from mobilizing the wound; TB: assisting surgeries, collaborating to the flow monitoring, RMJ: design discussions, manuscript review and institutional support.

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ORIGINAL ARTICLE

ACUTE KIDNEY INJURY FOLLOWING SURGERY FOR HIP FRACTURE

LESÃO RENAL AGUDA APÓS CIRURGIA DE FRATURA DE QUADRIL

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ABSTRACT

Objective: An observational study was carried out to determine the rate of acute kidney injury (AKI) following surgery for hip fracture at our institution and to look for factors associated with AKI. Methods: Preoperative creatinine values were compared to post-operative results for all patients who underwent surgery for hip fracture at our institution between 1st January 2015 and 30th September 2016. AKI was defined as an increase in postoperative creatinine, greater than or equal to 1.5 times the preoperative value within 7 days. Chi-squared test and Student's t-test were used to look for factors associated with AKI. Results: Out of 500 patients, 96 developed an AKI (19.2%). Patients with chronic kidney disease (CKD) were more likely to develop AKI (30.8%) that those without it (17.2%, p = 0.018). Similarly, patients with 2 or more comorbidities were more likely to develop AKI (22.0%) than those without it (12.4%, p = 0.009). No statistically significant association was observed between type of surgery and AKI. Conclusion: A large proportion of patients following surgery for hip fracture developed AKI. Patients with CKD and the presence of 2 or more comorbidities had significantly higher rates of AKI. ***Level III evidence, Retrospective comparative study.***

Keywords: Hip Fractures. Acute Kidney Injury. Hip. Hemiarthroplasty. Fracture Fixation. Arthroplasty, Replacement.

RESUMO

Objetivo: Estudo observacional realizado no Altnagelvin Hospital para determinar a taxa de lesão renal aguda (LRA) após a cirurgia de fratura de quadril e procurar fatores associados à LRA. Métodos: Os valores de creatinina pré-operatória foram comparados aos resultados pós-operatórios em todos os pacientes submetidos à cirurgia de fratura de quadril entre 1º de janeiro de 2015 e 30 de setembro de 2016. A LRA foi definida como aumento da creatinina pós-operatória maior ou igual a 1,5 vezes ao valor pré-operatório dentro de 7 dias. Os testes qui-quadrado e t-Student foram usados para procurar fatores associados à LRA. Resultados: Dos 500 pacientes, 96 desenvolveram LRA (19,2%). Pacientes com doença renal crônica (DRC) foram mais propensos a desenvolver LRA (30,8%) do que os pacientes sem a doença (17,2%, p = 0,018). Da mesma forma, pacientes com duas ou mais comorbidades foram mais propensos a desenvolver LRA (22,0%) do que os pacientes sem comorbidades (12,4%, p = 0,009). Não houve associação estatisticamente significativa entre tipo de cirurgia e LRA. Conclusão: Após a cirurgia de fratura de quadril uma grande proporção de pacientes desenvolveu LRA. Pacientes com DRC e duas ou mais comorbidades tiveram taxas significativamente maiores de LRA. ***Nível de evidência III, Estudo comparativo retrospectivo.***

Descritores: *Fraturas do Quadril. Lesão Renal Aguda. Quadril. Hemiartroplastia. Fixação de Fratura. Artroplastia de Substituição.*

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INTRODUCTION

Hip fracture is a rising epidemic associated with prolonged stay in hospital and reduction in quality of life.[1] Acute kidney injury (AKI) following surgery for hip fracture is common.[2] Long- and short-term mortality rates are higher for patients who develop AKI following surgery for hip fracture compared to those who do not.[3,4] This group of patients is aging with more comorbidities.[5] Recent studies have shown that increasing age and number of comorbidities are associated with significantly more patients developing AKI following surgery for hip fracture.[6] Observational studies have shown that up to 21% of patients following surgery for hip fracture can develop AKI; however, results vary among studies.[6,7] The purpose of this study was to determine how many patients developed AKI following hip fracture in our institution and if previously suggested risk factors for postoperative AKI are true for this patient sample.

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

The study was conducted at Altnagelvin Area Hospital.
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METHODS

All patients aged over 65 years who underwent surgery for hip fracture at Altnagelvin Area Hospital between 01/01/2015 and 09/21/2016 were identified using our hip fracture database.
Baseline serum creatinine concentration (day of hospital admission) and postoperative serum creatinine concentration (day 1 and 4) were recorded at the Northern Ireland Electronic Care Record. Recorded information also included age, sex, type of fracture and surgery, date and duration of surgery, length of stay in hospital and medical comorbidities.
AKI was defined as an increase in postoperative serum creatinine concentration greater than or equal to 1.5 times the baseline value within 7 days.

Statistics

Results are presented as mean and standard deviation (SD) for continuous variables. Binary and categorical variables are summarized by frequency. Chi-squared test and Student's t-test were used to investigate risk factors associated with post-surgical AKI (increasing age, male sex, chronic kidney disease—CKD and 2 or more comorbidities). All analyses were performed with IBM SPSS Statistics version 20 (IBM Corporation, New York, US).

RESULTS

Baseline patient characteristics are summarized in Table 1. The mean age was 81.4 years and most patients were women. Frequent comorbidity included ischaemic heart disease (13%), chronic obstructive pulmonary disease (11.2%) and 14.2% of patients had a history of diabetes mellitus. The most common type of operation performed was hip hemiarthroplasty (46.8%), followed by dynamic hip screw insertion (29.8%) and long intramedullary nail insertion (16.2%). The least common operation performed was total hip replacement (7.2% of patients). The mean preoperative serum creatinine was 90 micromoles per liter.
Out of 500 patients aged over 65 years who underwent surgery for hip fracture, 96 developed AKI (19.2%).

Table 1. Baseline patient characteristics and type of surgery.

	All Patients N = 500
Mean age, years (SD)	81.4 (8.6)
Sex, n (%)	
Male	133 (26.6)
Female	367 (73.4)
Past Medical History, n (%)	
Ischaemic heart disease	65 (13.0)
Chronic obstructive pulmonary disease	56 (11.2)
Cerebrovascular accident	49 (9.8)
Diabetes mellitus	71 (14.2)
Myocardial infarction	31 (6.2)
Type of Surgery, n (%)	
Dynamic hip screw	149 (29.8)
Hip hemiarthroplasty	234 (46.8)
Long intramedullary nail	81 (16.2)
Total hip replacement	36 (7.2)
Mean preoperative creatinine concentration, micromoles/l (SD)	90 (50.0)

Table 2 shows the risk factors known to be associated with AKI following surgery for hip fracture. Patients with chronic kidney disease and the presence of 2 or more comorbidities had significantly higher rates of AKI (p-value = 0.018 and 0.009 respectively).
A significant difference was identified between mean preoperative serum creatinine concentration and development of AKI (p = < 0.001). No significant difference was found regarding sex (p = 0.200), mean age or type of surgery performed (p = 0.282) and development of AKI (p = 0.459).

Table 2. Possible factors associated with acute kidney injury following hip fracture.

	Patients with AKI	Patients without AKI	p value
Mean age, years (SD)	82.5 (9.1)	81.1 (8.4)	0.459 Student's t-test
Sex, n (%)			
Male	30 (6.0)	103 (20.6)	0.200 Chi-squared test
Female	66 (13.2)	301 (60.2)	
Type of Surgery, n (%)			
Dynamic hip screw	25 (5.0)	124 (24.8)	0.282 Chi-squared test
Hip hemiarthroplasty	44 (8.8)	190 (38.0)	
Long intramedullary nail	22 (4.4)	59 (11.8)	
Total hip replacement	6 (1.2)	30 (6.0)	
Comorbidities, n (%)*			
≥ 2 comorbidities	78 (15.6)	277 (55.4)	0.009 Chi-squared test
< 2 comorbidities	18 (3.6)	127 (25.4)	
Chronic kidney disease, n (%)	20 (4.0)	45 (9.0)	0.018 Chi-squared test
No chronic kidney disease, n (%)	75 (15.0)	360 (72.0)	
Mean preop creatinine concentration, micromoles/l (SD)	109.0 (80.0)	85.0 (39.0)	< 0.001 Student's t-test

*Cerebrovascular accident, transient ischaemic attack, cardiovascular disease, chronic obstructive pulmonary disease.

DISCUSSION

Recent studies have shown that between 12.7% and 24.0% of patients develop AKI following surgery for hip fracture.[2-4,6,7] In this study, 19.2% of patients developed AKI within 7 days of surgery for hip fracture. This is comparable to the findings from other recent studies. Variability exists in relation to how AKI is defined, and this may contribute to the differences presented in numbers of patients developing AKI.
In one of the largest studies investigating AKI following surgery for hip fracture, 12.7% of 13,529 patients from hospitals in Denmark developed AKI.[8] Baseline serum creatinine was estimated using an electronic database of blood results.[8] The highest serum creatinine value in the first 5 postoperative days was compared to baseline.[8] AKI was defined according to the criteria in The Kidney Disease Improving Global Outcome (KIDGO) classification.[9]
A similar study included 2,959 patients from UK hospitals.[10] Baseline serum creatinine was estimated using the Modification of Diet and Renal Disease (MDRD) equation.[10] Then this result was compared to the highest postoperative value for the length of hospital stay.[10] AKI was defined again according to the KIDGO classification. A total of 24% of patients developed a post-surgical AKI.[10]
One modifiable factor that may affect the development of postoperative AKI is the antibiotic choice for surgical prophylaxis. In this study, all patients received flucloxacillin and gentamicin. Higher rates of AKI among patients receiving flucloxacillin and gentamicin have been seen compared to cephalosporins for elective hip and knee surgery.[11]

Intraoperative measures also play an important role in preventing postoperative AKI. Hypovolaemia due to intraoperative blood loss will lead to reduced renal perfusion.[12,13] Even short periods of low mean arterial pressure are poorly tolerated and associated with increased risk of postoperative AKI.[12,13] This fact highlights the importance of accurate measurement of intraoperative blood loss, recording of blood pressure while the patient is anesthetize and careful assessment of fluid balance in the perioperative period.[12,13] Another important modifiable risk factor for the development of postoperative AKI is the administration of nephrotoxic or potentially nephrotoxic medications.[14] Drugs associated with an increased risk of AKI in general are non-steroidal anti-inflammatory drugs, angiotensin converting enzyme inhibitors and angiotensin receptor blockers, and mineralocorticoid receptor antagonists.[14,15] If possible, these drugs should be discontinued preoperatively and held in the perioperative period.[14,15]

In this study, the proportion of patients developing AKI was significantly higher in those patients with a past history of CKD or the presence of 2 or more comorbidities when compared to those without. This is in keeping with findings from other studies.[2-5,8] Porter et al., [10] in a recent observational study, found a significant number of patients who developed AKI following surgery for hip fracture with a history of CKD or the presence of 2 or more comorbidities. Additional factors known to increase the risk of AKI following surgery for fractured neck of femur include increased age and being men.[8] In this study, the proportion of patients developing AKI was not significantly different for patients with these risk factors compared to those without. The reason for this is not clear, but one possible explanation is that the study size was insufficient to present a significant difference.

This study has a number of limitations. Firstly, data collection was retrospective, introducing an element of recall bias. Secondly, no information was recorded about patient medication being potentially nephrotoxic, which could have affected the results. Finally, although the proportion of patients developing AKI in this study is in keeping with other recent studies, the sample size is still relatively small. Further studies are required to analyze the type of operation performed for hip fracture and the subsequent development of AKI.

CONCLUSION

In this single-center observational study involving 500 patients, 19.2% developed acute kidney injury within 7 days following surgery for hip fracture. Patients with a medical history of CKD and 2 or more comorbidities were more likely to develop AKI than those without it.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article: PM: concept/design, data analysis/interpretation, drafting of the article; AS: data analysis/interpretation, critical revision of the article; BH: concept/design, data analysis/interpretation, critical revision of the article.

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ORIGINAL ARTICLE

AUTOLOGOUS CHONDROCYTE IMPLANTATION IN BRAZIL

IMPLEMENTAÇÃO DO TRANSPLANTE AUTÓLOGO DE CONDRÓCITOS NO BRASIL

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ABSTRACT

Objective: To describe the first series of cases of autologous chondrocyte implantation (ACI) in collagen membrane performed in Brazil. Methods: ACI was performed in 12 knees of 11 patients, aged 32.1 ± 10.9 years, with 5.3 ± 2.6 cm^2 full-thickness knee cartilage lesions, with a six-month minimum follow-up. Two surgical procedures were performed: arthroscopic cartilage biopsy for isolation and expansion of chondrocytes, which were seeded onto collagen membrane and implanted in the lesion site; the characterization of cultured cells and implant was performed using immunofluorescence for type II collagen (COL2) for cell viability and electron microscopy of the implant. Clinical safety, KOOS and IKDC scores and magnetic resonance imaging were evaluated. We used repeated-measures ANOVA and post-hoc comparisons at $\alpha = 5\%$. Results: COL2 was identified in the cellular cytoplasm, cell viability was higher than 95% and adequate distribution and cell adhesion were found in the membrane. The median follow-up was 10.9 months (7 to 19). We had two cases of arthrofibrosis, one of graft hypertrophy and one of superficial infection as complications, but none compromising clinical improvement. KOOS and IKDC ranged from 71.2 ± 11.44 and 50.72 ± 14.10, in preoperative period, to 85.0 ± 4.4 and 70.5 ± 8.0, at 6 months ($p = 0.007$ and 0.005). MRI showed regenerated tissue compatible with hyaline cartilage. Conclusion: ACI in collagen membrane was feasible and safe in a short-term follow-up, presenting regenerated formation visualized by magnetic resonance imaging and improved clinical function. ***Level of evidence IV, Case series.***

Keywords: Cartilage. Cell- and Tissue-Based Therapy. Transplantation, Autologous. Chondrocytes.

RESUMO

Objetivo: Descrever a primeira série de casos de transplante autólogo de condrócitos (TAC) em membrana de colágeno realizada no Brasil. Métodos: Doze joelhos de onze pacientes, com idade de 32,1 ± 10,9 anos, com lesões de cartilagem de espessura total do joelho de tamanho de 5,3 ± 2,6 cm^2 foram submetidos ao TAC, com seguimento mínimo de seis meses. Realizamos dois procedimentos cirúrgicos: biópsia artroscópica de cartilagem para isolamento e expansão de condrócitos, que foram semeados em uma membrana de colágeno implantada no leito da lesão. Foi realizada caracterização com imunofluorescência para colágeno tipo II (COL2) de células cultivadas e implantes, viabilidade celular e microscopia eletrônica no implante. Foram avaliados a segurança clínica, os escores funcionais KOOS e IKDC e a ressonância magnética. Utilizamos teste ANOVA para medidas repetidas, com comparações post-hoc, $\alpha = 5\%$. Resultados: COL2 foi identificado no citoplasma da célula, viabilidade celular foi superior a 95% e houve distribuição adequada e adesão celular na membrana. O seguimento mediano foi de 10,9 meses (7 a 19). Como complicações, ocorreram dois casos de artrofibrose, um de hipertrofia do enxerto e um de infecção superficial, nenhum deles havendo comprometimento da melhora clínica. Escalas KOOS e IKDC passaram de 71,2 ± 11,44 e 50,72 ± 14,10, no pré-operatório, para 85,0 ± 4,4 e 70,5 ± 8,0, aos 6 meses ($p = 0,007$ e 0,005). Ressonância magnética mostrou tecido regenerado compatível com cartilagem hialina. Conclusão: TAC em membrana de colágeno foi viável e seguro em seguimento de curto prazo, apresentando formação de regenerado visualizado através de imagens de ressonância magnética e melhora de função clínica. ***Nível de evidência IV, Série de casos.***

Descritores*: Cartilagem. Terapia Baseada em Transplante de Células e Tecidos. Transplante Autólogo. Condrócitos.*

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Authors declare as conflict of interest that MKD is a medical education consultant for Geistlich Pharma of Brazil.

The study was conducted at Institute of Orthopedics and Traumatology of Hospital das Clínicas of the Medical School of Universidade de São Paulo, at the Genetics and Molecular Hematology Laboratory of Hospital das Clínicas of the Medical School of Universidade de São Paulo, at Centro de Criogenia Brasil.
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INTRODUCTION

Articular cartilage defects can impose limiting symptoms, loss of function and predisposition for osteoarthritis. Furthermore, it is a challenging clinical problem, as cartilage damage has limited biological capacity for regeneration.[1] Nowadays, there are several techniques for treating these injuries with proven medium and long-term clinical results, including bone marrow stimulation (subchondral perforations and microfracture), autologous osteochondral transfer, fresh allogeneic osteochondral transplantation and autologous chondrocyte implantation (ACI).[1,2] Each of these techniques has advantages and limitations, but ACI is currently considered first-line surgical treatment for large defects with intact subchondral bone.[3-5]

ACI was introduced in 1994 by Brittberg et al.[6] The procedure is performed in two surgical procedures: arthroscopic biopsy of normal cartilage from a non-weightbearing area, in which chondrocytes are isolated and expanded in a cell culture laboratory; implant of the cultured chondrocytes onto defect site. ACI first-generation techniqueused a periosteum patch harvested from the tibia and sutured to the surrounding of the defect, containing the solution with suspended cells and delimiting the area for cartilage formation.[6] Second-generation technique used a collagen membrane to replace the periosteum patch.[7] Third-generation used previously chondrocytes-seeded membranes, and last days of cell culture are performed directly on the membrane scaffold.[8]

In Brazil, experiences with ACI and other cellular therapies for cartilage regeneration are incipient. After the initial application of first-generation technique,[9,10] there was a period in which other techniques were not available.

The aim of this study was to establish an ACI clinical routine for knee cartilage injuries and report the experience with a six-month minimum follow-up, focusing on feasibility, patient safety and evaluation of adverse events and functional outcome.

METHODS

From January 2017 to December 2018, eleven patients were consecutively recruited to attend an outpatient clinic in a tertiary health service. Inclusion criteria were: aged between 14 and 55 years; and symptomatic chondral knee lesions larger than 2 cm^2, visualized on magnetic resonance imaging, classified as III or IV grade by the International Cartilage Regeneration & Joint Preservation Society (ICRS) score with previous conservative treatment failure. Non-inclusion criteria were: patients with BMI > 30 kg/m^2 and ligamentous instability or limb malalignment greater than 5° which were not correctable during surgery. Meniscal deficiency was not an exclusion criterion.

All patients were informed about their voluntary participation in the research by the application of the Informed Consent Form. The study was approved by the Institutional Research Ethics Committee (protocol 1123) and registered in the National Clinical Trials database.

Cartilage biopsy

In the first surgical stage, cartilage biopsy was performed on the superolateral aspect of the intercondylar notch, outside the loading area. A specific arthroscopic gouge was used to remove a 5 mm by 10 to 15 mm full-thickness fragment (Figure 1). The fragment was immediately placed in a 50 ml conical tube containing DMEM / F12 transport culture medium (GIBCO) supplemented with 50 μM gentamicin (Hypofarma). The samples were promptly transported to the cell culture laboratory, with facilities approved by the Brazilian national sanitary authority (ANVISA) for cell therapy clinical trials (Center for Cellular Technology II – CTC II), where they were kept refrigerated at 4°C for a maximum of 48 hours.

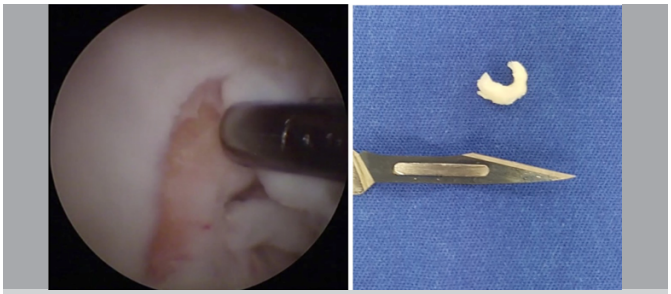

Figure 1. Arthroscopic cartilage biopsy of lateral intercondylar area. Fragment Chondrocyte.

Isolation and culture

Biopsy specimen was washed three times using phosphorus-buffered saline (PBS) supplemented with 50 μM gentamicin and fragmented to obtain small cartilaginous tissue explants. These were placed in 25 cm^2 culture bottles, with 5 ml of DMEM/F12 mixture (GIBCO), supplemented with 10% fetal bovine serum (GIBCO) and 50 uM gentamicin. The bottles were kept in an incubator at 37°C, with relative humidity close to 100% and atmosphere of 5% CO2. After 72 hours, culture medium was changed, and non-adherent fragments were discarded. New culture medium consisted of DMEM/F12 mixture supplemented with 5% fetal bovine serum and 50 μM gentamicin until cells migrated from the explant and formed the first colonies. When maximum confluence (70-90%) was reached, cell suspension was performed. About 1×10^4 cells per cm^2 were placed in culture bottles in DMEM / F12 culture medium supplemented with 5% fetal bovine serum and 50 μM gentamicin until chondrocyte implantation in collagen membrane. Chondrocytes were removed from the culture bottles by TRYPLE enzyme (5 min at 37°C) and transferred to 15 ml conical tubes with culture medium supplemented with fetal bovine serum. Then, they were centrifuged at 800 rpm for 5 minutes. Supernatant was discarded and chondrocytes were resuspended in 5 ml DMEM / F12 culture medium supplemented with 50 μM gentamicin and distributed evenly over the surface of the double-layer type I/III (Chondro-gide® – Geistlich Pharma).[11] Cultures were kept for 3 to 4 days in an incubator at 37°C, with relative humidity close to 100% and atmosphere of 5% CO2 until the second surgical procedure.[12,13]

All samples were subjected to quality control. For microbiological control, approximately 2 ml of culture medium was extracted from the chondrocyte culture flasks and added to the microbiological growth flask (BD Bactec Peds Plus™), to detect the growth of aerobic and anaerobic microorganisms in culture medium samples. Fungal culture tests were also performed on culture medium. Immunofluorescence evaluation with human monoclonal antibody anti-collagen was used in cell cultures to assess the presence of type II collagen as a biological marker of chondrocytes. The final implantation of chondrocyte-seeded collagen membrane was subjected to scanning electron microscopy to assess the presence of adhered cells. Cell viability was assessed by DNA-intercalanting assays using hoechst 33342 (0.1 μg/ml) and iodide propidium (50 μg/ml).

Second surgical stage

Through a parapatellar knee arthrotomy, the chondral lesion was identified and debrided to remove all injured tissue,

calcified cartilage layer and any intralesional osteophytes. The objective was to obtain perpendicular edges of healthy cartilage at the edge of the lesion. Then chondrocyte-seeded collagen membrane was implanted with the porous part facing the bed and fixed with absorbable points on the adjacent cartilage and fibrin glue at the lesion bottom and edges.[8] Additional clinically indicated procedures were performed, as shown in Table 1. Intraoperative clinical images are exemplified in Figures 2 to 4.

Table 1. Patients undergoing autologous chondrocyte implantation.

Patient	Age	Defect location	Etiology	Total defect size (cm^2)	Associated procedures
1	31	LFC	ligament injury	2.2	revision ACL reconstruction
2	21	MFC	ligament injury	3.9	high tibial osteotomy, ACL reconstruction
3	38	patella MFC	patellar instability	5.4	MPFL reconstruction, tibial tuberosity osteotomy
4 (right knee)	36	MFC, LFC, trochlea	ligament injury	8.2	revision ACL reconstruction, anterolateral ligament reconstruction, medial meniscectomy
left	36	MFC, LFC, trochlea	ligament injury	6.7	revision ACL reconstruction, anterolateral ligament reconstruction
5	27	patella, trochlea	fracture sequela	7.6	-
6	34	MFC	Osteochondritis dissecans	3.9	-
7	55	MFC	ligament injury	8.4	-
8	14	trochlear	Osteochondritis dissecans	2.4	bone grafting
9	25	patella	patellar instability	4.7	MPFL reconstruction, tibial tuberosity osteotomy
10	19	trochlear	ligament injury	2.1	ACL reconstruction
11	40	MFC, trochlear	ligament injury	10.1	valgus tibial osteotomy, ACL reconstruction

LFC: lateral femoral condyle; ACL: anterior cruciate ligament; MFC: medial femoral condyle; MPFL: medial patellofemoral ligament; SD: standard deviation.

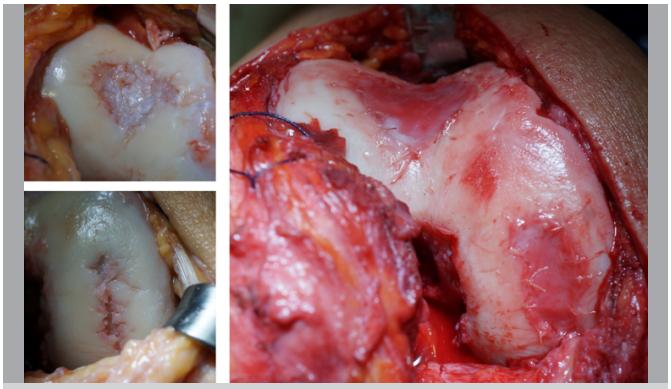

Figure 2. Trochlea and medial femoral condyle injury before and after treatment.

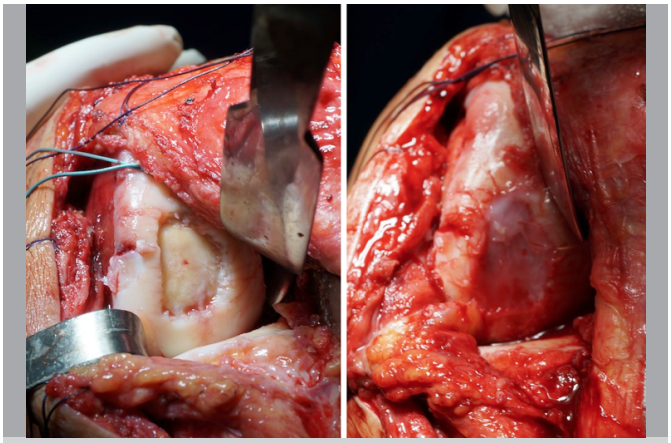

Figure 3. Defect in lateral femoral condyle after debridement and membrane implantation.

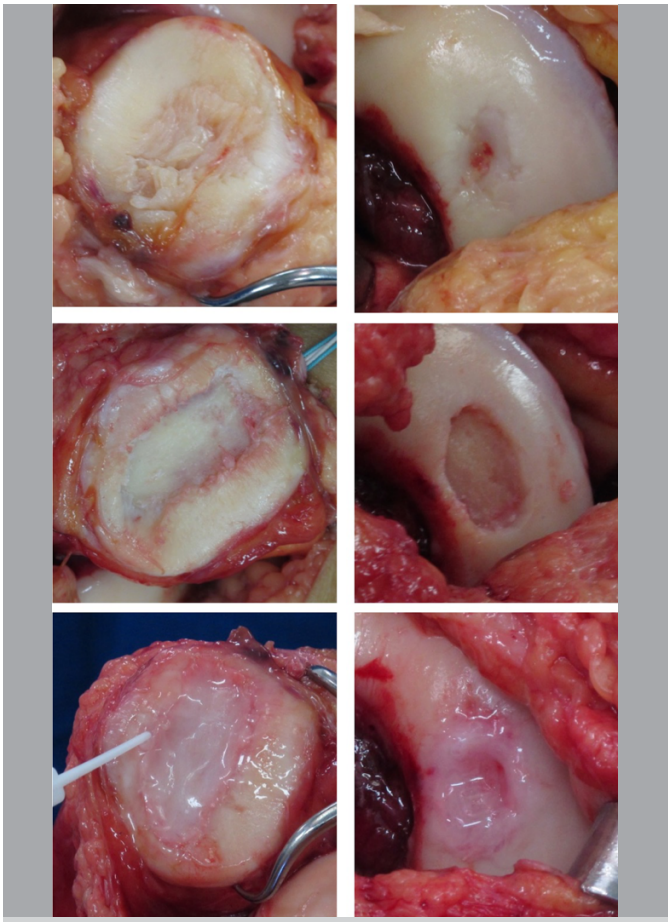

Figure 4. Defects in patella and medial femoral condyle before debridement, after debridement, and after fibrin glue implant.

Postoperative follow-up

All patients received initial rehabilitation with assisted gait training with crutches and continuous *passive motion* (CPM) device at the hospital, for at least three days. For tibiofemoral lesions, immediate partial weightbearing was allowed, progressing to total weightbearing at six weeks. Range of motion (ROM) progression was: 0-30° in the hospital, 0-90° up to three weeks, 0-120° at six weeks, and full ROM after that. For patellofemoral lesions, immediate partial weightbearing with extension immobilizer and crutches was used, progressing to full weightbearing at three weeks and immobilizer removal at six weeks. ROM progression was: 0-20° at admission, 0-60° at three weeks and 0-120° up to six weeks. Running started between 9 and 12 months, and normal sports activities after 12 to 18 months.

KOOS (Knee injury and Osteoarthritis Outcome Score) and IKDC (International Knee Documentation Committee Score) functional outcomes questionnaires were used.[14] T2-mapping magnetic resonance images were performed after six months for all patients.

Preoperative and postoperative patient's functional scores were compared. Repeated-measures ANOVA and Bonferroni method for multiple comparisons were performed using the SPSS 22 statistical package (IBM, New York) to verify statistically significant differences. Results were expressed as mean ± standard deviation for normal distribution variables, considering a statistically significant P value < 0.05.

RESULTS

Twelve knees of eleven patients aged 32.1 ± 10.9 years underwent treatment. Average size of lesions was 5.3 ± 2.6 cm^2. Location and associated lesions treated are summarized in Table 1. Patient's median follow-up was 10.9 months (7 to 19). Two patients followed up for less than two months by our group were not included in this series. We were successful in isolating and culturing all biopsy specimens performed. Average cell culture period was 35 days. There was no microbiological contamination in any of the samples. Immunofluorescence images of cultured chondrocytes showed the presence of type II collagen distributed throughout the cell cytoplasm, demonstrating chondrogenic profile (Figure 5). Membrane scanning electron microscopy at the time of implantation showed the presence of chondrocytes uniformly adhered to the membrane matrix through thin cytoplasmic extensions (Figure 6). There was good cell distribution in the membrane, and cell viability tests showed at least 95% of viable cells (Figure 7).

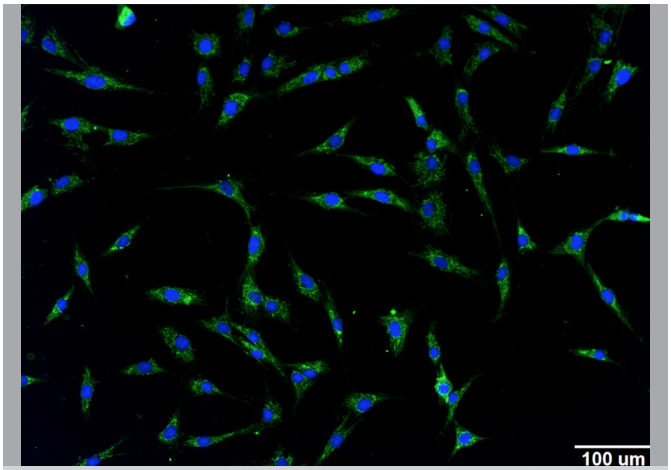

Figure 5. Immunofluorescence showing type II collagen in the cytoplasm of cultured chondrocytes.

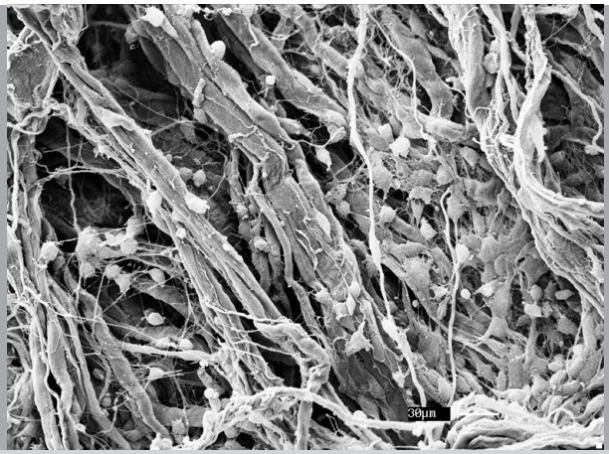

Figure 6. Scanning electron microscopy image showing chondrocytes adhered to the membrane collagen fibers.

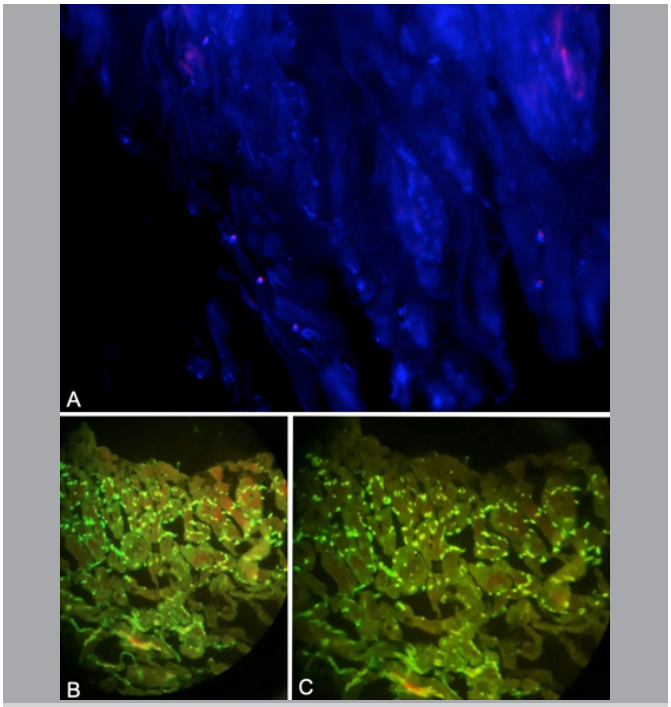

Figure 7. (A) DNA-intercalanting assay showing cell viability greater than 95%. (B, C) Immunofluorescence with human anti-collagen II monoclonal antibody in the final implant, showing presence and cellular distribution in membranes.

Functional results are summarized in Table 2 and Figure 8. KOOS and IKDC scales were 71.2 ± 11.44 and 50.72 ± 14.10 preoperatively; at three months 77.7 ± 16.2 and 62.3 ± 19.2; and six months 85.0 ± 4.4 and 70.5 ± 8.0. KOSS ($p = 0.031$) and IKDC ($p = 0.009$) scores were significantly differentbetween preoperative and 6-month scores ($p = 0.007$ for KOOS and $p = 0.005$ for IKDC).

Table 2. Preoperative clinical scores at three and six months of follow-up.

	Preoperative	three months	six months	p*	p (preop vs 6 months) †
KOOS	71.2 11.44	77.7 16.2	85.0 4.4	p = 0.031 ‡	p = 0.007 ‡
IKDC	50.72 14.10	62.3 19.2	70.5 8.0	p = 0.009 ‡	p = 0.005 ‡

KOOS: Knee Injury and Osteoarthritis Outcome Score; IKDC: International Knee Documentation Committee Score. *Repeated-measures ANOVA with Greenhouse-Geisser correction; † Bonferroni correction t-test; ‡ statistically significant.

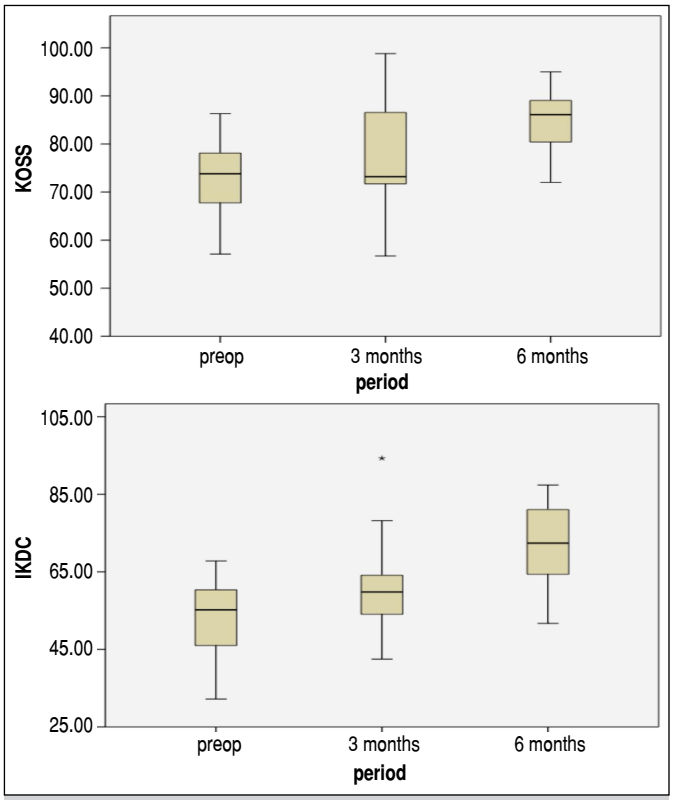

Figure 8. Box charts for the evolution of preoperative KOOS and IKDC scores at six weeks, three months and six months.

Magnetic resonance imaging at six-month follow-up showed regenerated tissue at lesion site, good filling and signs of compatibility with hyaline cartilage (Figures 9 and 10).

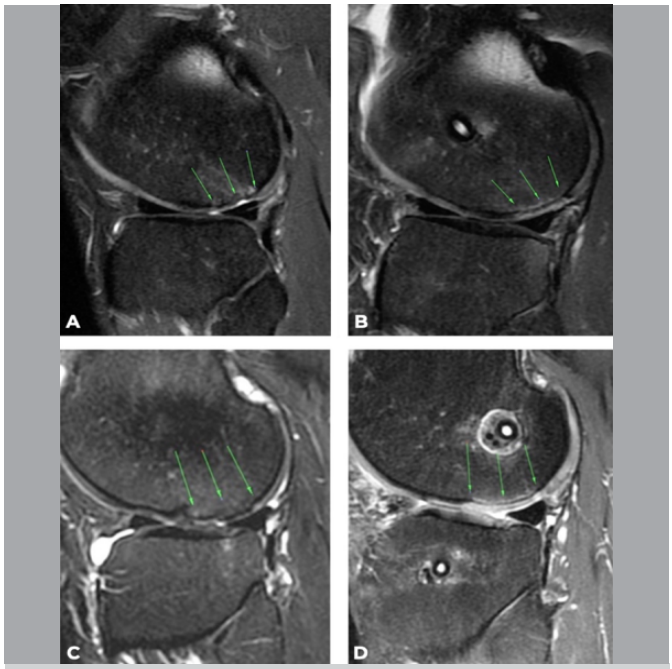

Figure 9. Images demonstrating lateral femoral condyle lesions of two patients. Images A and C are preoperative, showing chondral lesion, bone edema and intra-lesional osteophytes; images B and D show the evolution at 6 months, good filling regeneration and signs of compatibility with hyaline cartilage.

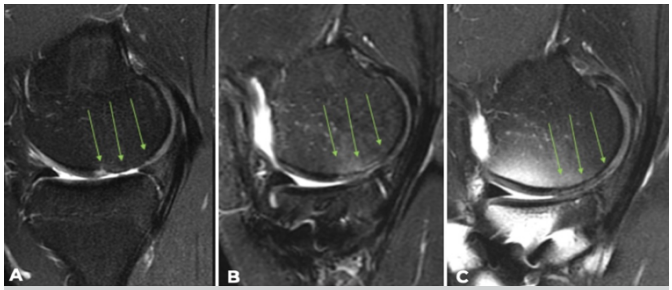

Figure 10. Preoperative magnetic resonance images (A), six months (B) and one year (C) patient follow-up. 1. Increased lesion filling and regeneration, similar to adjacent cartilage on the one-year image.

There were four cases of complication. Two patients presented stiffness and difficulty in ROM progression, with flexion less than 120 degrees at the tenth week. After arthroscopic release and joint manipulation, full ROM was achieved. One patient presented dehiscence and superficial infection in a pelvic surgical wound for iliac graft removal, used for a high tibial osteotomy. He was treated with wound debridement and antibiotic therapy until complete resolution. There was only one complication due to the chondrocyte implantation itself: a graft hypertrophy observed through magnetic resonance imaging but asymptomatic.

DISCUSSION

This study reported the first cases of third-generation ACI using collagen membrane in Brazil.

Isolation and cell cultivation of samples from all patients were successful on chondrocyte growth and positive expression of collagen type II. The quality control of the implants demonstrated good distribution, viable cells adhering to the extracellular matrix of the collagen membrane and no microbiological contamination.

The primary outcome assessed in this short-term follow-up was safety. All surgeries were performed successfully. Although there were four cases of treatment complications, all were successfully treated, without functional outcome impairment. Three cases were due to complex reconstructive knee surgery: post-operative stiffness and wound complication. Only one was related to the implantation itself, with graft hypertrophy observed through magnetic resonance imaging, but not presenting symptoms. This complication has been reported in ACI international literature as occurring in up to 27% of cases,[15] and unrelated to clinical outcomes or cartilage quality.[15,16]

The functional result obtained was adequate until the sixth month, with KOOS and IKDC scores improvement in relation to the preoperative, consistent with previous literature. Gommol et al.[17] reported an increase in IKDC from 45.6 to 68, and KOOS from 45.86 to 70.14 in 2.46 years. Saris et al.[18] reported an increase in IKDC 32.9 to 65.7, and KOOS from 32.5 to 74.1 in 24 months.

As in other literature series, we expect function to improve further with longer follow-ups, as returning to sports activities takes long after ACI application, fully allowed after 12 to 18 months.[13,19]

Our study has limitations. This is a case series with no control group and short-term follow-up. To evaluate the effectiveness of cartilage treatments, a minimum two-year follow-up is desirable. However, the work was fully adequate to its main objective: to report the development of a clinical routine for ACI with feasibility and safety evaluation as a secondary outcome for the initial efficacy. At this follow-up, it was possible to observe the regeneration in imaging exams, initial clinical improvement in all patients and no serious complications.

Patients recruited for this study represent the reality of cartilage treatment defects in Brazil: large chondral lesions requiring additional procedures to treat associated lesions. Using patients with isolated

chondral lesion would result in less varied outcomes. However, for the evaluation of safety and effectiveness, we preferred to include the patient profile in which the technique is most likely to be applied in our country, including associated injuries and previous surgeries. We expect ACI to be frequently used as a combined procedure, and even as a salvage one, after several previous surgeries. Therefore, this choice increases the external validity of our study.[20]

ACI is considered a first-line method in the international literature for the treatment of large unipolar chondral knee injuries in active patients.[4,5] With third-generation technique, chondrocyte adhesion in scaffold occurred *in vitro,* needless of cell manipulation in the operating room.[4,21]

Cell therapy as a treatment for cartilage injury has generated widespread clinical and research interest worldwide.[22] ACI was the first cell therapy for cartilage defects developed and routinely used worldwide and is a first-line therapy for large chondral lesions. Gaining national experience allows us to glimpse the possibility of having this technique available for routine clinical use in near future. It is also the first necessary step towards the future of cell and orthobiologic therapy in Brazil.

CONCLUSION

ACI in collagen membrane was feasible and safe in short-term follow-up for the treatment of cartilage defects larger than 2 cm^2, presenting regenerated formation, visualized through magnetic resonance imaging, and improvement of clinical function.

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ORIGINAL ARTICLE

RESULTS OF ORTHOSES USED ON AMBULATORY PATIENTS WITH BILATERAL CEREBRAL PALSY

RESULTADOS DO USO DE ÓRTESES EM PACIENTES DEAMBULADORES COM PARALISIA CEREBRAL

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ABSTRACT

Objective: To investigate the impact of ankle-foot orthoses (AFO) on subjects diagnosed with bilateral cerebral palsy (CP) using the gait index and temporal data parameters. Methods: Twenty-four subjects, 14 male and 10 female, with a mean age of 11 (5-17 years old), underwent a comprehensive gait analysis under both barefoot (BF) and braced walking conditions. All children had been wearing the orthoses for at least 2 months before the gait analysis. Results: The overall values for the left and right Gait Profile Scores (GPS) did not show statistically significant variations when comparing the same individuals with and without orthoses. Gait velocity increased by 19.5% ($p < 0.001$), while the cadence decreased by 4% with use of orthosis, although it was not statistically significant ($p > 0.05$). The stride and the step lengths on both the right and left sides, however, resulted in statistically significant increases, when wearing AFO. Conclusion: AFO, prescribed for assistance by professionals without using gait data, did not significantly affect the gait index (GPS), but improved temporal data. The determination of quantitative clinical parameters for the prescription of orthotics in patients with bilateral CP, as well as orthotics that meet the specific requirements are points to be addressed in the future to obtain more significant effects. ***Level of evidence III, Case control study.***

Keywords: Cerebral Palsy. Foot Orthoses. Gait.

RESUMO

Objetivo: Investigar o impacto das órteses suropodálicas (AFOs) utilizando índices da análise computadorizada da marcha (ACM) e dados de tempo e espaço, em indivíduos com diagnóstico de paralisia cerebral (PC) bilateral. Métodos: 24 indivíduos, 14 do sexo masculino e 10 do sexo feminino, com média de idade de 11 anos (5-17 anos), foram submetidos a uma análise da marcha, tanto na condição de andar descalço (AD) quanto com uso das órteses. Todas as crianças usavam as órteses há no mínimo 2 meses antes da ACM. Resultados: Os valores do perfil global da marcha (GPS) dos lados direito e esquerdo não apresentaram variações estatisticamente significativas quando os mesmos indivíduos foram comparados, com e sem órteses. Com o uso de órtese a velocidade da marcha aumentou 19,5% ($p < 0,001$), enquanto a cadência diminuiu 4%, embora não tenha sido estatisticamente significativa ($p > 0,05$). No entanto, com o uso da órtese, a passada e o comprimento do passo dos lados direito e esquerdo tiveram aumentos estatisticamente significativos. Conclusão: As AFOs, quando prescritas por profissionais sem o uso de dados da ACM, não alteraram significativamente o índice da marcha (GPS), mas melhoraram os dados de tempo e espaço. A determinação de parâmetros clínicos quantitativos para a prescrição de órteses em pacientes com PC bilateral, bem como órteses que atendam a requisitos específicos, são pontos a serem abordados no futuro, a fim de obter efeitos mais significativos. ***Nível de evidência III, Estudo de caso e controle.***

Descritores: *Paralisia Cerebral. Órteses do Pé. Marcha.*

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INTRODUCTION

Cerebral Palsy (CP) is the most common cause of physical disability affecting children in developed countries, with an incidence rate between 2.0 and 3.5 per every 1,000 live births,[1-3] while in developing countries this index may reach 7 for every 1,000.[4] The explanation for the difference between these two groups of countries is attributed to poor conditions of antenatal care and primary care for pregnant women. Functionally, approximately 60% of patients with CP can walk independently, approximately 10% use a mobility device, and approximately 30% have limited or no walking ability.[5]

Efficient walking is an important treatment goal for children with CP.[6] Orthotic management is a significant and useful treatment

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option for a number of conditions that affect gait and posture, and usually forms part of an overall rehabilitation program established for patients with CP.[6]

Orthoses are commonly prescribed to address both structural and functional deficiencies.[7] Eighty-five percent of children with CP have had at least one orthotic device.[8] The most commonly used lower-limb orthoses in CP are AFO that provide direct control of the ankle and foot to improve gait.[9] Orthoses influence the ankle and foot by providing a control moment opposing ankle motion, and also stabilize the motions of the mid and forefoot joints.[10]

In children with CP, the aim of orthotic management in the form of ankle-foot orthoses (AFO) is to produce a more natural gait pattern. AFO may be used to protect the outcome of a surgical procedure during the healing and rehabilitation phases, to prevent the development or worsening of musculoskeletal deformities with growth and to improve gait.[11]

The prescription of rehabilitation treatments and recommendation of orthoses is generally performed after a clinical evaluation. The use of three-dimensional gait analysis (3DGA) contributes to defining strategies for the treatment of patients with cerebral palsy.[12-14] However, even with the assistance of gait analysis, the degree to which a patient's gait improves after an intervention remains difficult to assess. Considering not only how each feature of the gait pattern has changed, but also how the relationship between the features changed is important to accurately assess the changes in gait resulting from a specific treatment.[15] For such, the gait profile score (GPS) will be used, in order to produce an overview of the gait.[16] The gait index summarizes the kinematic data, helping the clinician to understand the general changes in gait pathology after a specific treatment.[17]

Our study seeks to verify the outcome of the use of orthoses by patients with cerebral palsy that were prescribed through clinical criteria due to the unavailability of gait laboratories in most cities around the world. We must question if we are really improving the gait of patients with cerebral palsy by prescribing orthoses without using 3DGA. It was hypothesized that gait index and spatial-temporal data parameters could improve with the use of orthoses.

METHODS

This retrospective cross-sectional study was conducted using the database of the gait laboratory at the Rehabilitation Center of Paraná in Curitiba, Paraná, Brazil. All participants and parents/guardians signed an informed consent form before the study. The approval of the local research ethics committee (number: 2.447.001) to conduct the study had been previously obtained. A search was conducted for all children with spastic CP who had underwent 3DGA, both barefoot (BF) and for those who were using orthoses during a single visit to the gait analysis laboratory between 2011 and 2017.

Participants

The inclusion criteria were: children with a clinical diagnosis of spastic CP, with bilateral involvement of the lower limbs, using rigid or articulated AFO (the same design worn bilaterally), who had undergone 3DGA with and without orthoses.

Previous treatments such as single event multilevel surgery or botulinum toxin type A injections were allowed, as well as the use of walkers and crutches. All children had been wearing the orthoses for at least 2 months before the gait analysis. The walking motion trials were conducted on those wearing orthoses during the same visit as the barefoot trials.

Measurements

The Gross Motor Classification System (GMFCS) and Functional Mobility Scale (FMS) were assigned by a senior clinical physical therapist and a pediatric orthopedist in appointment with the child and their parents.[18,19]

The kinematic data was collected using reflective markers strategically placed on specific anatomical points on the participants, as described by Kadaba et al.,[20] and recommended by the software user's manual (Cortex Version 1.1.4.368 – User's Manual; Motion Analysis Corporation, Santa Rosa, CA, USA). Three-dimensional kinematic gait data was collected bilaterally using 6 infrared cameras and a motion capture system (infrared digital Hawk; Motion Analysis Corporation, Santa Rosa, CA) sampling at 60 Hz.

Three-dimensional gait kinematics data was used to estimate the GPS and temporal data was used to quantify the overall deviation of an individual's gait from normal gait.

GPS represents the root mean square (RMS) difference between particular gait trials and averaged data from people with no gait pathology. The overall GPS is based upon 15 clinically important kinematic variables including, gait variable score (GVS): Pelvic Tilt (Ant/Post), Pelvic Obliquity (Up/Dn) and the rotation of the left side and hip flexion, abduction, internal rotation, knee flexion, ankle dorsiflexion and foot progression for the left and right sides, as shown in Table 2. In this analysis, a GPS score for each side was used based on all nine GVS for each side. As the GPS uses all the gait features representing the root mean square difference between the patient's data and the average from the reference dataset obtained from all of the relevant kinematic variables for the entire gait cycle, the higher the GPS value the less physiological the gait pattern.[21]

Temporal data, GPS and GVS were used to quantify the changes of the gait with and without orthoses.

Three different analyses were conducted. First, all 24 participants were analyzed while walking barefoot using orthoses. Second, the participants were divided according to the use of rigid or articulate orthoses. Third, they were divided by functional status (GMFCS), classified into levels I, II, III and IV.

Statistical analysis

Data was presented as median and interquartile range, according to the Shapiro-Wilk test for normality. For intragroup analyses (with or without orthoses) the paired t-test or Wilcoxon test was performed, and for the analyses between groups (GMFCS classification and type of orthosis), the t-test for independent samples or Mann-Whitney test was used, according to the normality distribution of the data. Statistical analyses were conducted using SPSS 22 for Windows (SPSS Inc., Chicago, IL), adopting a 5% significance level.

RESULTS

The sample consisted of 24 subjects, 14 male and 10 female, with a median age of 11 [5-17 years old] and with GMFCS as follow: 1 participant at level I, 13 at level II, 9 at level III and 1 at level IV. Regarding orthosis characteristics, 10 patients used rigid AFO and 14 articulated AFO.

No significant differences were found for outcomes considering GPS overall, GPS right and GPS left side when comparing the walking tests with the individuals using or not using the orthoses (Table 1).

Table 1. Median [quartile range] of gait profile scores overall, left and right sides for bilateral cerebral palsy group when walking barefoot and with ankle-foot orthoses.

Variable	Barefoot	AFO	*P*
GPS overall	14.96 [13.11-18.18]	15.54 [14.05-16.40]	0.25
GPS right	13.06 [11.50-16.13]	14.15 [11.77-15.62]	0.73
GPS left	14.80 [13.00-16.85]	14.62 [12.70-16.30]	0.87

Considering GVS variables such as pelvic tilt, pelvic rotation, pelvis obliquity, hip flexion, hip rotation, hip abduction, knee flexion, ankle dorsiflexion, and foot angle of advancement, no statistically significant differences were observed between BF and with use of orthoses, except for one parameter: GVS Hip Abduction-Adduction left- barefoot = 5.76 [4.42-8.85] and with AFO = 6.44 [5.31-8.97] – $p = 0.01$. All results are shown in Table 2.

Table 2. Median [quartile range] of gait variable scores for the bilateral cerebral palsy group when walking barefoot and with ankle-foot orthoses.

Parameter	Barefoot	AFO	*P*
GVS Pelvic Tilt (°)	5.76 [4.24-8.77]	6.77 [4.49-9.79]	0.19
GVS Pelvic Rotation (°)	10.16 [8.52-12.84]	9.87 [7.11-13.60]	0.19
GVS Pelvic Obliquity (°)	4.45 [3.07-5.53]	4.66 [3.24-5.67]	0.39
GVS Hip Flex-Extension right (°)	11.96 [8.24-19.91]	12.06 [10.02-17.61]	0.64
GVS Hip Flex-Extension left (°)	13.26 [6.65-20.16]	12.41 [7.41-15.25]	0.08
GVS Hip Ab-Adduction right (°)	6.60 [5.26-7.45]	6.14 [5.13-8.53]	0.84
GVS Hip Ab-Adduction left (°)	5.76 [4.42-8.85]	6.44 [5.31-8.97]	0.01
GVS Hip Rotation right (°)	9.52 [7.92-14.73]	10.52 [7.92-15.16]	0.27
GVS Hip Rotation left (°)	13.84 [8.12-20.51]	11.67 [8.00-15.83]	0.66
GVS Knee Flex-Extension right (°)	21.48 [15.28-27.93]	20.87 [18.51-27.94]	0.62
GVS Knee Flex-Extension left (°)	22.53 [19.17-29.34]	22.12 [19.72-29.72]	0.58
GVS Ankle Dorsi-Plantarflexion right (°)	10.83 [7.80-14.80]	10.98 [8.74-14.34]	0.97
GVS Ankle Dorsi-Plantarflexion left (°)	11.31 [7.88-15.82]	9.42 [7.07-12.89]	0.24
GVS Foot Progression right (°)	11.88 [9.19-20.71]	15.98 [9.59-24.47]	0.06
GVS Foot Progression left (°)	15.05 [8.28-26.05]	12.85 [8.13-26.98]	0.36

When considering the spatio-temporal parameters of gait, there was a 19.5% increase in Gait velocity with the use of orthosis ($p < 0.001$). The Stride length and the step length of the right and left sides showed a statistically significant increase. No difference were observed in cadence. The values are shown in Table 3.

Table 3. Median [quartile range] of velocity and cadence. Mean (standard deviation) of stride length and step length of right and left sides for the bilateral cerebral palsy group when walking barefoot and with ankle-foot orthoses.

Parameters	Barefoot	AFO	*P*
Velocity (cm/sec)	68.85 [25.95-80.50]	82.31 [36.70-89.25]	0.01
Cadence (steps/min)	112.25 [68.15-123.15]	107.50 [61.42-118.87]	0.46
Stride Length (cm)	68.62 (4.15)	77.65 (4.58)	< 0.01
Right Step Length (cm)	35.15 (2.16)	40.28 (2.28)	< 0.01
Left Step Length (cm)	33.42 (2.20)	37.82 (2.49)	< 0.01

When performing the detailed gait analysis with and without orthoses according to the functional classification – GMFCS 1-2 and GMFCS 3-4, as well as between subjects using rigid and articulated orthoses, we found the same results reported for the general sample. That is, no significant difference was found between the groups related to overall, right, left GPS and GVS. However, the significant increase in velocity and stride length was maintained.

DISCUSSION

The most typical use of an AFO is to optimize the normal dynamics of walking by applying a mechanical constraint (control moment) to the ankle to control motion and, at the same time, to produce a more efficient gait.[22]

Different types of orthoses may be prescribed for children with CP, such as AFO, which can help with alignment and in improving gait quality. AFO in fact, reduce, plantarflexion of the ankle, leading to greater stability in the support phase of gait.[22]

The values for general, left and right GPS did not present statistically significant differences when comparing the same individuals with and without the use of orthoses. These results are in concordance with a previous study by Danino et al.,[23] that did not find any changes in GPS in subjects with cerebral palsy when walking BF and using AFO. The explanation for the non-improvement in GPS was postulated because the index mainly examined the general kinematics of gait as measured from normal, and despite some changes in distal parameters, the overall gait pattern did not change significantly.

Our study analyzed GVS variables and significant changes were not found when analyzing the subjects walking BF or with orthoses, except for, hip adduction/abduction at the left side, the only parameter that changed. However, this had no clinical significance. In contrast with our results, Galli et al.[22] reported improvement in GVS of the ankle and pelvic tilt with a small sample of 10 subjects diagnosed with bilateral cerebral palsy, walking barefoot and with AFO. It is important to remember that the GVS evaluates the area of the kinematic curve as a whole. However, the orthosis positions the ankle in such a way that it avoids extreme positions of plantar flexion and/or dorsiflexion, without necessarily making the ankle movements look close to normal.

On the other hand, the temporal parameters showed changes that included gait velocity increasing by 19.5% with the use of the orthoses, while the cadence decreased by 4%, although the latter is not statistically significant. The lengths of the stride and step of the right and left sides had a statistically significant increase.

With the concept of minimal clinically important difference (MCID), which means a limit to determine when significant changes occur, there is an increasing emphasis in clinical research into establishing whether outcomes are clinically meaningful, as well as statistically significant.[24,25] Oeffinger et al.,[26] reported that changes in gait velocity, cadence and stride length, respectively 9.1%, 8.1% and 5.8% from normal were MCID. The mean subject's velocity, cadence and stride length in our study changed 19.5%, – 4.2% and 13%, respectively. When comparing these changes with normal values, we noted that the velocity and the stride lengths were MCID. The reported changes that reach statistical significance were also clinically meaningful (gait velocity and stride length). As walking velocity is often used as a surrogate measure for overall gait quality, we can say that orthoses in our sample produced functional benefits, agreeing with a systematic review and meta-analysis published by Lintanf et al.,[27] despite avoiding the appearance of musculoskeletal deformities. Furthermore, we can observe the results above point to an improvement in function, since the increase in velocity relates to an increase in the stride length, rather than an increase in cadence, as shown in Table 3.

The authors also performed the subdivision of the sample considering greater and lesser motor impairment (GMFCS 1-2 and GMFCS 3-4), and by the type of orthosis used (articulated or rigid). The results reported for the general sample were the same when the sample was divided using the level of motor impairment and type of orthosis. Therefore, the heterogeneity in the sample was not responsible for the changes.

For children with CP, Davids et al.,[11] argued that analogous with multilevel surgery decision making, optimal orthotic management

requires the physician to clearly identify the gait deviation and functional deficits to be addressed using the orthosis.
Recommendations for orthoses must meet specific requirements in physical exams and in gait performance. Adequate range of motion for typical alignment while walking is necessary to properly fit the orthosis and to expect good functionality. This requires at least a neutral ankle dorsiflexion with the knee extended and no knee flexion contractures. Femoral anteversion and tibial torsion decrease the effectiveness of a well-made orthosis and should be identified and corrected to maximize effectiveness.[7] Rodda and Graham,[28] proposed the use of articulated AFO in true equinus gait and jump gait as well as the use of rigid AFO for apparent equinus and crouch gait. This recommendation reveals the concern with keeping the ankle in a more neutral position during the stance phase of gait.
Careful clinical evaluation of the patient by the professional is essential to avoid prescribing an orthosis under suboptimal conditions for use. Clinical gait analysis may aid in orthosis recommendations. In our study, the fact that prescriptions for orthoses were issued without the aid of quantitative data (gait analysis), may have been a contributing factor for non-significant changes in some parameters such as ankle GVS.
The lack of evidence is also observed due to the scarcity of prescription guidelines.[29] In clinical practice, this lack of consensus observed due to differences in treatment paradigms regarding both the recommendations and the mechanical construction of AFO.[9] A systematic review on the quality of AFO studies in children with CP concluded that substantial variability in the quality or reporting was present in currently published studies.[30]
The prevention of the occurrence of skeletal muscle dysfunction is one of the reasons to prescribe orthoses in this population. Studies such as these do not evaluate this important effect of the use of orthoses in patients diagnosed with CP.
The limitations of our study relate to the small study cohort sample, collected out of convenience and for the efficacy of orthoses, who were evaluated in a laboratory, and not in an environment where children participated in normal daily activities.

Clinical implications

The attending professional needs to carefully assess the recommendations and effects of orthoses on ambulatory patients with CP. This is because some predicted effects of orthoses recommendations may not be achieved, as occurred in the sample studied in which no changes were observed in the overall gait characteristics.
The determination of quantitative parameters for the prescription of orthotics in patients with bilateral CP, as well as orthotics that meet specific requirements are points to be addressed in the future to obtain more significant effects.

CONCLUSION

In this study, the AFO, prescribed for assistance by professionals without using gait data, did not significantly affect the gait index (GPS), but improved temporal data. Answering the question: are we improving the gait of patients with cerebral palsy by prescribing orthoses without using 3DGA? In the evaluated sample the patients using orthoses became more functional with increased velocity, step and stride length. However, the movements of the lower limbs were no closer to normality.

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ORIGINAL ARTICLE

INDICATORS OF MORBIDITY AND MORTALITY BY FEMUR FRACTURES IN OLDER PEOPLE: A DECADE-LONG STUDY IN BRAZILIAN HOSPITALS

INDICADORES DE MORBIDADE E MORTALIDADE POR FRATURAS DE FÊMUR EM IDOSOS: ANÁLISE DE UMA DÉCADA EM HOSPITAIS BRASILEIROS

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ABSTRACT

Objective: To evaluate the profile of femur fractures in older adults in Brazil between 2008 and 2018. Methods: Population-based time series study with data from the Department of Informatics of the Unified Health System (Datasus), including 480,652 hospitalizations, of adults from 60 years and over, with hip fracture (ICD10-S72). Results: There was an increase of 76.9% in the hospitalization register (mean 5.87%/year) and an average incidence rate of 19.46 fractures for every 10,000 older adults. In total, 68% of hospitalizations were female, 28% from São Paulo. The average length of stay was 8.9 days, being higher in the Northern Region (11.8) and in the Federal District (18.7). Average mortality rate was 5%, being higher in men (5.45%) and over 80 years old. Northeast Region had the lowest mortality rate (3.54%). Southeast Region had the highest rate (5.53%). Total cost of hospitalizations was R$ 1.1 billion, with an average of R$ 100 million/year. Average cost per hospitalization was higher in the Southern Region (R$ 2,491.00). Conclusion: Femoral fracture is an important cause of mortality among older adults, with a higher incidence in women but higher mortality in men, with high cost to the system and regional differences. ***Level of Evidence II, Economic and decision analyses – developing an economic or decision model.***

Keywords: Femur. Aged/Mortality. Risk Factors. Health Systems. Osteoporosis.

RESUMO

Objetivo: Avaliar o perfil das fraturas de fêmur em idosos no Brasil no período de 2008 a 2018. Métodos: Estudo de série temporal baseado em dados do Departamento de Informática do Sistema Único de Saúde (Datasus), incluindo 480.652 internações de pessoas com idade a partir de 60 anos e com fratura de quadril (ICD10-S72). Resultados: Houve aumento de 76,9% no registro de hospitalização (média de 5,87% por ano) e taxa de incidência média de 19,46 fraturas para cada 10 mil idosos. O estado de São Paulo respondeu por 28% do total de registros, e as internações de pacientes do sexo feminino corresponderam a 68% do total. O tempo médio de permanência foi de 8,9 dias, com maiores índices na Região Norte (11,8) e no Distrito Federal (18,7). A taxa média de mortalidade foi de 5% e atingiu os maiores valores entre os homens (5,45%) e os pacientes com mais de 80 anos. A região Nordeste apresentou a menor taxa de mortalidade (3,54%) e a região Sudeste teve a maior (5,53%). O custo total das internações foi de R$ 1,1 bilhão, com média de R$ 100 milhões ao ano. O custo médio por hospitalização foi maior na região Sul (R$ 2.491,00). Conclusão: A fratura do fêmur é importante causa de mortalidade em idosos, com maior incidência em mulheres e maior mortalidade em homens, alto custo para o sistema e diferenças regionais. ***Nível de Evidência II, Análises econômicas e de decisão – desenvolvimento de modelo econômico ou de decisão.***

Descritores: *Fêmur. Idoso/Mortalidade. Fatores de Risco. Sistemas de Saúde. Osteoporose.*

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INTRODUCTION

Although the aging process is more advanced in Europe and North America, where one in five people were 60 or older in 2017, populations in other regions are also aging. By 2050, older adults are expected to account for 35% of the population in Europe, 28% in North America, 25% in Latin America and the Caribbean, 24% in Asia, 23% in Oceania and 9% in Africa.[1]

The Brazilian Institute of Geography and Statistics (IBGE), based on projection models, estimated that 13% of the population was 60 or older in 2018, which corresponds to 19.2 million. However, by 2060, the country will have more older than younger people.[2]

The association between longevity and the prevalence of chronic diseases is described in the literature.[3] In the United States, about half (50.9%) of adults have at least one chronic condition and 26% have two or more conditions.[4] A study with data from the National Health Survey (PNS), held in 2013 in Brazil, revealed that the prevalence of three simultaneous diseases in the age group 60 and older was 3.7 times the prevalence in the 35-59 age group, and almost 20 times the prevalence of those between 18 and 34 years old.[5]

Insufficient muscle function and poor physical performance are also strong predictors of clinically relevant adverse events in older adults.[6] These factors corroborate the falls, which, may predict future fractures when frequent, in addition to the likelihood of associated risk factors.[7] Regarding hip fractures, they are a useful substitute to determine the burden of osteoporosis. Although they may account for less than 20% of all osteoporotic fractures, hip fractures account for most fracture-related health care due to high morbidity, mortality, and hospitalization costs.[8,9]

Determination of the individual hip fracture incidences in several countries and even in many locations within the same country has shown great variability in rates, leading to the suspicion of several factors that explain such differences, mainly the genetic, climatic, ethnic-cultural, anthropometric and geographic ones. Tools like FRAX®, specific to each country and based on national epidemiological studies, from clinical risk factors (CRF), with or without bone mineral density (BMD), may provide the likelihood of fracture of the femur and other bones over the next 10 years.[10]

Based on the perspective of population aging as a consequence of the individual aging process, our study sought to analyze the panorama of health services utilization through the registration of femur fracture in Brazilian older adults between 2008 and 2018. Our study seeks to identify sociodemographic characteristics and the profile of assistance to users, represented by the differences between the hospitalizations of the analyzed localities to collaborate to guide regional policies for prevention and to promote the best allocation of services offer.

METHODS

This is a descriptive study, population-based, in time series, from public domain data and provided by the Hospital Information System of the Unified Health System (SIH/SUS), through health information (Tabnet). It was enabled by the Health Surveillance Secretariat of the Ministry of Health, through the electronic portal of the Department of Informatics of the Unified Health System (Datasus), extracted between June 9th and June 11th, 2019 (http://www.datasus.gov.br). The system database is generated through hospital units (public and private publicly funded) that send the information of hospitalizations made through the Authorization of Hospital Admission (AIH) for Municipal and State management. Such information is processed by the Datasus and form an extensive database with hospital information from all over the Brazilian territory.

The filters referring to hospital morbidity data related to femur fracture were applied, without distinction of anatomical location, referring to the 10th International Classification of Diseases review (ICD-10 S72), in patients aged 60 years or older, between 2008 and 2018 in Brazil. The variables analyzed were: number of hospitalizations, age groups, sex, total and average cost per hospitalization, average number of days of hospital stay, deaths and mortality rate. Variables such as race, type of care and funding were not considered for analysis due to the considerable percentage of ignored records. Data were presented descriptively, proportionally and analyzed as coefficients and rate when possible.

The hospital mortality coefficient for femur fracture was obtained by the ratio between the number of deaths from femur fracture by the total number of hospitalizations for this diagnosis in the same age group as the patients.

Hospitalization rate in older adults due to femur fracture was obtained by the ratio between the number of hospitalizations due to femur fracture in people aged 60 years or older, by place of residence and total population aged 60 and over, in the same period and place considered in the numerator, using the database of the Brazilian Institute of Geography and Statistics (IBGE) referring to population projections.

The cost projection was performed using triple time series exponential smoothing analysis, Holt-Winters. Projections were made until the year 2028.

Our study supports a regional study conducted with secondary data on the subject and was approved by the Research Ethics Committee under number CAAE: 89658718.8.0000.5553

RESULTS

Between January 2008 and December 2018, 480,652 hospitalizations for femur fracture were recorded in the population over 60 years old in Brazil, accounting for 2.5% of all hospitalizations for this age group, in both sexes. In the same period, hospitalizations record increased by 76.9%, an average increase of 5.87% per year, as shown in Figure 1. Considering the IBGE annual projections for the population, the average hospitalization rate in the age group over 60 years old due to femur fracture over 10 years, for both sexes, was 19.46 for every 10,000 older adults in Brazil.

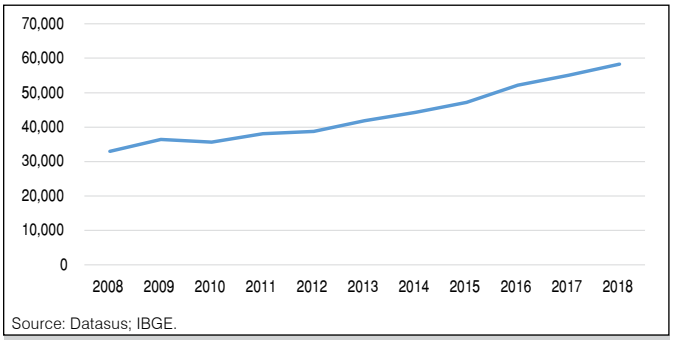


Figure 1. Number of hospitalizations for femur fracture in Brazil, older adults over 60 years old, between 2008 and 2018.

The number of femoral fracture records was higher among women, who represent 68% of total hospitalizations. The result is a female/male hospitalization ratio of 2.1/1. Regarding the age groups over 60 years old, the analysis shows a sustained increase of hospitalization due to femur fracture with age progression for both sexes, and the population from 80 years old and over accounts for 47.5% of the patients, increasing the hospitalization ratio between women/men in this age group to 2.9/1.

The average length of hospital stay for femur fracture in Brazil was 8.9 days for both sexes. However, there was a slight predominance of more days of hospitalization in the male population for all age groups. Between 2008 and 2018, considering the ICD S72 in the population over 60 years old, for both sexes, 24,027 deaths were recorded in Brazil, representing an average mortality rate of 5%, estimated by the ratio between the number of deaths and the number of hospitalizations in this population over 60 years old due to femur fracture.

We observed a predominance of the male population in the average mortality rate (5.45%), in all age groups above 60 years old, which represents a male/female death ratio of 1.13/1, and an ascending pattern. Mortality rate among men above 80 years old was 4.6 higher than among the age group of 60 to 64 years, representing a variation of 38.9%. In women, the variation in mortality between these age groups is smaller (31.4%), with a rate 3.81 times greater when 80 years, as shown in Table 1.

The total cost of hospitalizations from 2008 to 2018 in Brazil was R$ 1.1 billion, with an average of R$ 100 million/year. The cost analysis reveals an increase of 158% in the period from 2008 to 2018, which represents 9.14% per year. The average value of each hospitalization was R$ 2,290.80 (R$ 1,781.62 – R$ 2,602.18), and 80% of the total cost focused on the age group of 70 years old, regardless of sex, as shown in Table 2.

The estimated cost projection analysis for the next decade (2019-2028) is R$ 2.16 billion, 107.0% over than the period studied, as shown in Figure 2.

Table 1. Number of hospitalizations, average length of stay, deaths and mortality rate, total by age group and by sex, between 2008 and 2018.

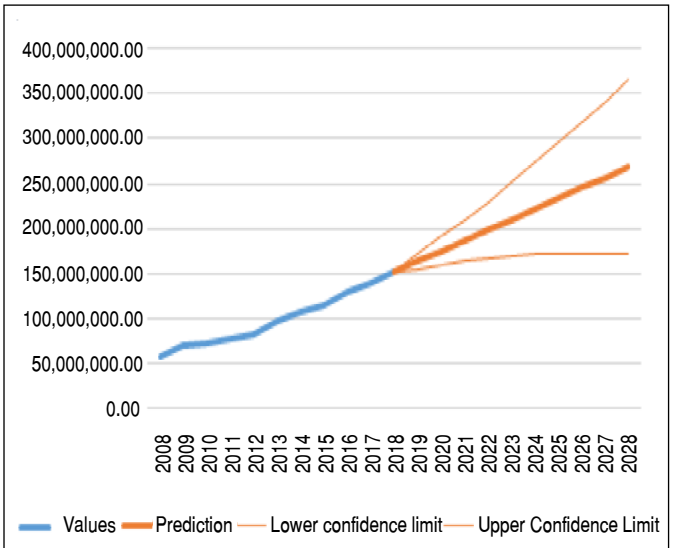
Sex	Age Group	Number of Hospitalizations	Average length of stay (days)	Deaths	Mortality Rate (%)
Total	**Total**	**480,652**	**8.9**	**24,027**	**5.00**
	60 to 64	43,834	8.9	804	1.83
	65 to 69	52,587	8.9	1,269	2.41
	70 to 74	68,129	8.8	2,027	2.98
	75 to 79	87,761	8.8	3,405	3.88
	80 and over	228,341	8.9	16,522	7.24
Male	**Total**	**153,608**	**9.0**	**8,368**	**5.45**
	60 to 64	22,662	9.1	435	1.92
	65 to 69	22,325	9.1	596	2.67
	70 to 74	23,758	9.0	846	3.56
	75 to 79	26,224	9.0	1,239	4.72
	80 and over	58,639	9.0	5,252	8.96
Female	**Total**	**327,044**	**8.8**	**15,659**	**4.79**
	60 to 64	21,172	8.7	369	1.74
	65 to 69	30,262	8.8	673	2.22
	70 to 74	44,371	8.7	1,181	2.66
	75 to 79	61,537	8.8	2,166	3.52
	80 and over	169,702	8.8	11,270	6.64

Source: Datasus.

Table 2. Number of hospitalizations, cost of hospitalization and average value per total hospitalization between 2008 and 2018 and per year of processing.

Year Processing	Hospitalizations (n)	Cost (R$)	Average Value Hospitalization (R$)
Total (2008-2018)	**480,652**	**1,101,072,872.24**	**2,290.79**
2008	32,950	58,704,215.87	1,781.62
2009	36,435	69,269,677.41	1,901.19
2010	35,620	72,767,862.66	2,042.89
2011	38,119	78,749,699.25	2,065.89
2012	38,755	82,170,390.49	2,120.25
2013	41,874	97,259,762.36	2,322.68
2014	44,316	107,536,595.16	2,426.59
2015	47,138	114,839,321.03	2,436.24
2016	52,130	129,496,301.52	2,484.10
2017	55,034	138,627,352.66	2,518.94
2018	58,281	151,651,693.83	2,602.08

Source: Datasus.



Source: Datasus; IBGE.

Figure 2. Cost projection for femur fracture in Brazil, over 60 years old, between 2008 and 2018.

Regarding demographic analysis, Table 3 shows an overview of the Brazilian scenario between 2008 and 2018. Considering the five regions of the country, the number of hospitalizations records for femur fractures in the same period and age groups over 60 years old, in both sexes, predominated in the southeast region (53.1%).

The state of São Paulo stands out with 136,402 hospitalizations, which represents 28% of the records for femur fracture in Brazil. Roraima (RR) was the state with the lowest hospitalization for femur fracture, with 495 records in 10 years, as shown in Figure 3. Almost half of the Brazilian states (Rondônia, Amazonas, Amapá, Tocantins, Maranhão, Ceará, Paraíba, Sergipe, Bahia, Espírito Santo, Rio de Janeiro and the Federal District) has twice the average national hospitalization time, especially Amapá (19.5 days), Rondônia (19.2 days) and Federal District (18.7 days), reaching twice the national average (8.9 days).

The Northeast Region had the lowest mortality rate due to femur fracture in Brazil, between 2008 and 2018, with 3.54% of deaths, considering all age groups of 60 years old and over. Ceará had the lowest proportion between the number of deaths and the number of hospitalizations, with a 2.37% rate in the study period. It was followed by the state of Alagoas (2.53%), which also had the lowest average hospital stay in Brazil (6.5 days), and the state of Paraíba with 2.99% of deaths, regardless of age group or sex, representing almost half of the national average of 5%. In the overall average for the period, the Southeast Region had the highest mortality rate (5.53%) in Brazil, featured for the state of Rio de Janeiro (6.08%), as shown in Table 4.

Table 3. Number of hospitalizations, cost, average length of stay, deaths and mortality rate, total by region, between 2008 and 2018.

Region	Hospitalizations (n)	Total Cost (R$)	Average hospitalization cost (R$)	Average length of stay (days)	Deaths (n)	Mortality Rate (%)
Total	**480,652**	**1,101,072,872.24**	**2,290.79**	**8.9**	**24,027**	**5**
North Region	17,870	39,110,174.72	2,188.59	11.8	692	3.87
Northeast Region	88,452	188,705,323.81	2,133.42	9.6	3,130	3.54
Southeast Region	255,097	587,449,632.96	2,302.85	8.8	14,082	5.52
South Region	90,512	225,474,745.18	2,491.10	7.8	4,816	5.32
Midwest Region	28,721	60,332,995.57	2,100.66	9.1	1,307	4.55

Source: Datasus.

Region/State	Hospitalizations
Amazonas	3,346
Pará	8,054
Acre	827
Amapá	773
Tocantins	2,258
Rondônia	2,117
Roraima	495
Ceará	12,923
Alagoas	5,765
Paraíba	8,174
Pernambuco	17,427
Rio Grande do Norte	6,554
Maranhão	5,436
Piauí	6,666
Bahia	21,058
Sergipe	4,449
Minas Gerais	69,801
Espírito Santo	9,071
São Paulo	136,402
Rio de Janeiro	39,823
Rio Grande do Sul	39,164
Paraná	33,324
Santa Catarina	18,024
Federal District	4,576
Mato Grosso	5,301
Goiás	11,230
Mato Grosso do Sul	7,614

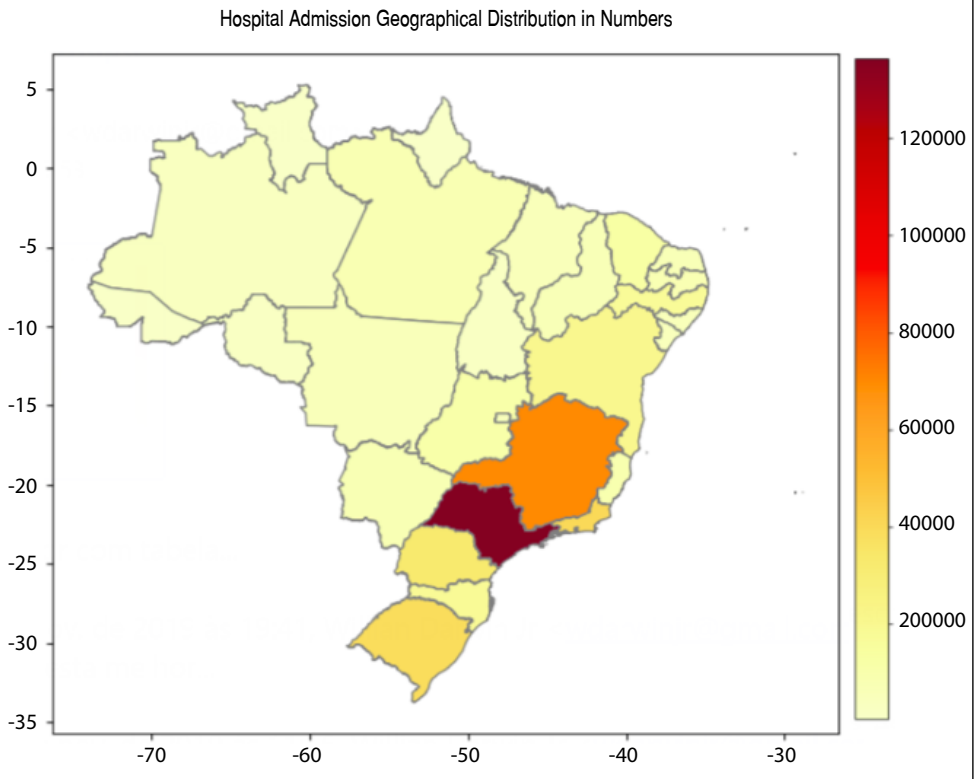


Figure 3. Number of hospitalizations due to femur fractures in patients over 60 years old by Brazilian state between 2008 and 2018.

Table 4. Number of hospitalizations, average length of stay, deaths and mortality rate, total by region/state, between 2008 and 2018.

Region/State	Hospitalizations	Average length of stay (days)	Deaths	Mortality Rate (%)
TOTAL	**480,652**	**8.9**	**24,027**	**5.00**
North Region	**17,870**	**11.8**	**692**	**3.87**
Amazonas	3,346	14.1	111	3.32
Pará	8,054	8.7	277	3.44
Acre	827	8.9	34	4.11
Amapá	773	19.5	35	4.53
Tocantins	2,258	11.4	105	4.65
Rondônia	2,117	19.2	105	4.96
Roraima	495	8.5	25	5.05
Northeast Region	**88,452**	**9.6**	**3,130**	**3.54**
Ceará	12,923	10.3	306	2.37
Alagoas	5,765	6.5	146	2.53
Paraíba	8,174	10.1	244	2.99
Pernambuco	17,427	9.7	548	3.14
Rio Grande do Norte	6,554	8.0	211	3.22
Maranhão	5,436	10.5	190	3.50
Piauí	6,666	7.9	261	3.92
Bahia	21,058	9.9	920	4.37
Sergipe	4,449	11.9	304	6.83
Southeast Region	**255,097**	**8.8**	**14,082**	**5.52**
Minas Gerais	69,801	7.3	3,165	4.53
Espírito Santo	9,071	10.4	482	5.31
São Paulo	136,402	7.8	8,015	5.88
Rio de Janeiro	39,823	14.2	2,420	6.08
South Region	**90,512**	**7.8**	**4,816**	**5.32**
Rio Grande do Sul	39,164	8.7	1,699	4.34
Paraná	33,324	6.8	1,946	5.84
Santa Catarina	18,024	8.0	1,171	6.50
Mideast Region	**28,721**	**9.1**	**1,307**	**4.55**
Federal District	4,576	18.7	191	4.17
Mato Grosso	5,301	8.1	225	4.24
Goiás	11,230	6.8	528	4.70
Mato Grosso do Sul	7,614	7.4	363	4.77

Source: Datasus.

Regarding the states, Sergipe recorded the highest average mortality rate in Brazil (6.83%). When considering age groups individually, 75.3% of deaths occurred in the population aged 80 and over, with a 10.25% mortality rate. Men in this age group had a higher death rate, 12.29%, more twice of the national average under the same conditions (8.96%). Santa Catarina has the highest mortality rate under the same conditions (13.03%). Alagoas and Bahia stand out, despite the lower than average mortality, the mortality rate is higher among women over 80 years old, 4.1% and 4.41%, comparing with other states, as shown in Table 5.

The average cost per hospitalization in the Southern Region (R$ 2,491) was higher than the national average, due to the higher value for hospitalization in the states of Paraná (R$ 2,795.62) and Santa Catarina (R$ 2,725.61). In these, filtering by age groups and sex, the highest cost in hospitalizations over 80 years old occurs among men (R$ 3,018.09 and R$ 2,867.63, respectively). Cost of 21% (Paraná) and 27% (Santa Catarina) higher than the national average for the same sex and age group (R$ 2,376.01), also shown in Table 5.

Table 5. Number of hospitalizations, total and average hospitalization, number of deaths and mortality rate, by sex, in the population aged 80 and over, by region/state, Sul and Northeast from 2008 to 2018.

Sex	Age Group	Hospitalizations (n)	Total Cost (R$)	Hospitalization Average Cost (R$)	Deaths (n)	Mortality Rate (%)
State: Santa Catarina						
	Total	**18,024**	**49,126,435.18**	**2,725.61**	**1,171**	**6.5**
Male	80 years old and over	1,896	5,437,021.32	2,867.63	247	13.03
Female	80 years old and over	6,448	17,892,549.71	2,774.90	572	8.87
State: Paraná						
	Total	**33,324**	**93,161,247.99**	**2,795.62**	**1,946**	**5.84**
Male	80 years old and over	4,159	12,552,222.68	3,018.09	423	10.17
Female	80 years old and over	10,919	32,434,056.18	2,970.42	892	8.17
State: Rio Grande do Sul						
	Total	**39,164**	**83,187,062.01**	**2,124.07**	**1,699**	**4.34**
Male	80 years old and over	3,680	8,121,912.65	2,207.04	335	9.1
Female	80 years old and over	15,415	32,596,898.39	2,114.62	835	5.42
State: Ceará						
	Total	**12,923**	**28,900,973.42**	**2,236.40**	**306**	**2.37**
Male	80 years old and over	1,442	3,237,808.28	2,245.36	61	4.23
Female	80 years old and over	4,788	10,432,863.43	2,178.96	142	2.97
State: Alagoas						
	Total	**5,765**	**10,405,461.29**	**1,804.94**	**146**	**2.53**
Male	80 years old and over	758	1,319,245.37	1,740.43	22	2.9
Female	80 years old and over	1,977	3,686,575.29	1,864.73	81	4.1
State: Sergipe						
	Total	**4,449**	**9,117,137.19**	**2,049.26**	**304**	**6.83**
Male	80 years old and over	586	1,233,046.04	2,104.17	72	12.29
Female	80 years old and over	1,648	3,506,065.87	2,127.47	157	9.53
State: Bahia						
	Total	**21,058**	**45,114,541.03**	**2,142.39**	**920**	**4.37**
Male	80 years old and over	2,895	15,841,507.14	2,148.58	317	4.3
Female	80 years old and over	7,173	29,273,033.89	2,139.06	603	4.41
State: Maranhão						
	Total	**5,436**	**9,463,191.36**	**1,740.84**	**190**	**3.5**
Male	80 years old and over	708	1,150,221.72	1,624.61	44	6.21
Female	80 years old and over	1,629	2,822,523.42	1,732.67	87	5.34
State: Paraíba						
	Total	**8,174**	**9,463,191.36**	**2,191.68**	**244**	**3.51**
Male	80 years old and over	1,120	2,505,247.24	2,236.83	63	5.63
Female	80 years old and over	3,145	6,913,466.57	2,198.24	117	3.72
State: Pernambuco						
	Total	**17,427**	**39,302,298.70**	**2,255.25**	**548**	**3.14**
Male	80 years old and over	2,095	4,550,246.74	2,171.96	122	5.82
Female	80 years old and over	6,220	14,128,881,19	2,271.52	255	4.1
State: Piauí						
	Total	**6,666**	**12,598,755.69**	**1,890.00**	**261**	**3.92**
Male	80 years old and over	832	1,653,334.90	1,987.18	88	6.73
Female	80 years old and over	2,344	4,481,404.60	1,911.86	173	5.38
State: Rio Grande do Norte						
	Total	**6,554**	**15,888,204.17**	**2,424.20**	**211**	**3.22**
Male	80 years old and over	890	2,246,935.87	2,524.65	44	4.94
Female	80 years old and over	2,674	6,770,452.81	2,531.96	105	3.93

Source: Datasus.

DISCUSSION

There are limitations of ecological studies regarding the low applicability at their individual level about the associations between exposure and outcome, and risk for possible confounding variables.[11] Despite the need for proper registration, the information systems of the Unified Health System (SUS) are powerful tools that guide analyses regarding the punctual or time series situational diagnosis. Moreover, it can base hypothesis of association of variables of interest of the subject,

stimulating the elaboration of new studies.[12] In addition, studies estimate that 15% of the Brazilian population does not use the SUS service, which may result in underestimated data for the total population.[13]

The profile is compatible with the epidemiological for osteoporosis fractures.[8,9] A population-based study conducted with 4,332 women in the metropolitan region of São Paulo between 2004 and 2007 showed that advanced age, menopause, previous low impact fracture and current smoking were the main risk factors associated with osteoporosis and fractures. The study also showed a 33% and 11.5% prevalence of osteoporosis and bone fragility fractures, respectively.[14]

The reason of the difference in regionalization about the occurrence of fractures in older adults cannot be confirmed by the methodology of our study. However, there is a possibility of discussion regarding the aspects involved with the multifactoriality of the event, such as ethnic patterns, eating habits, climate and urbanization, related to hypovitaminosis D, mobility conditions, social protection, access to the health system, notifications of the disease and life expectancy.[8,9]

The Northeast Region had the lowest mortality rate due to femur fracture in Brazil, except in the state of Sergipe, especially in older men. A study conducted in Sobral, Ceará, also identified a low incidence rate of hip fractures among a population living in an equatorial area.[15]

Studies show a 20% overall mortality rate within 12 months after hip fracture. Although the overall prevalence of fragility fractures is higher in women, men generally have higher fracture-related mortality rates.[16]

The American literature considers the treatment of hip fracture has improved in the last 20 years. Advanced surgical devices and movement toward replacement arthroplasty, early mobilization, better use of prophylactic antibiotics and aggressive medical management may have contributed to improvements in mortality.[17] These factors impact hospitalization and treatment costs. The southern states presented the highest average costs during the study period, with an increase when selected by sex and age group. Some studies conducted in this location reveal the Caucasian population, with longer life expectancy and risk factors for fracture incidence, as well as the profile of how femur fracture care is performed in older adults. Thus, economic factors may play a significant role in the health of this population. However, the behavior of the three states is shown to be individual when associated with means of permanence and mortality rate.[18,19,20]

CONCLUSION

The analysis performed in our study showed agreement between population aging, assessed by population projections, and fracture incidence. The highest occurrence of the event occurred in older women in the southeastern and southern states, and the lowest incidence was in the north and northeast regions. Longer stay in the Midwest and higher cost in the South. It is an important cause of mortality and functional loss among older adults, presenting a higher incidence in men over 80 years. The evaluation and monitoring of this indicator are important, considering the differences between the regions of Brazil, with consequences for the individual and economic for health systems.

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ORIGINAL ARTICLE

SOCIOECONOMIC IMPACT OF MOTORCYCLE ACCIDENT VICTIMS IN THE EMERGENCY ROOM OF A HOSPITAL (PART 2)

IMPACTO SOCIOECONÔMICO EM VÍTIMAS DE ACIDENTE DE MOTO NA EMERGÊNCIA DE UM HOSPITAL (PARTE 2)

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ABSTRACT

Objective: To evaluate the socioeconomic impact of motorcycle accidents of a metropolis with one million inhabitants treated by a university hospital in 2017. To study hospital cost and time of victims, evaluate definite and incapacitating sequelae, and analyze patient's insertion in the labor market six months after the accident. Methods: Retrospective study of 62 victims of motorcycle accidents treated in the emergency room and referred for surgical procedure in a university hospital. Data were collected from medical records and answers via telephone six months after the trauma. Results: Injuries related to motorcycle accident resulted in high hospital costs. Average loss per patient was R$ 17,555. Of those who answered the functional impact questionnaire, 64% were on paid leave by INSS and 84% presented partial or permanent physical disabilities after the accident. Only 9 people (36%) received any kind of financial benefit from public authorities. Conclusion: High costs are directly related to hospitalization time and surgical needs. Most victims needed financial help and had their social lives aggravated. Investments in motorcyclists' awareness of traffic laws and use of safety equipment are needed, as well as in road infrastructure. ***Level of evidence II, Prognostic studies.***

Keywords: Accidents, Traffic. Socioeconomic Factors. Wounds and Injuries.

RESUMO

Objetivo: Avaliar o impacto socioeconômico de acidentes motociclísticos de uma metrópole com mais de um milhão de habitantes atendidos, no ano de 2017, em um hospital universitário. Estudar custo e tempo de internação hospitalar das vítimas, avaliar sequelas definitivas e incapacitantes e analisar a inserção no mercado de trabalho seis meses depois do acidente. Métodos: Estudo retrospectivo de 62 pacientes vítimas de acidentes motociclísticos, atendidos na urgência e emergência, levados para procedimento cirúrgico de um hospital universitário. Coleta de dados através do levantamento de prontuários e contato telefônico seis meses após o trauma. Resultados: Lesões relacionadas às vítimas implicaram elevados custos hospitalares. Prejuízo médio por paciente foi de R$ 17.555. Dos que responderam ao questionário do impacto funcional, 64% ficaram afastados da atividade laboral pelo INSS e 84% apresentaram incapacidades físicas parciais ou permanentes após o acidente. Apenas 9 (36%) receberam algum tipo de benefício financeiro do governo. Conclusão: Elevados custos estão diretamente relacionados ao tempo de internação e necessidades cirúrgicas. A maioria das vítimas necessitou de auxílio financeiro e teve sua vida social prejudicada. Investimentos em conscientização dos motociclistas, para que conduzissem respeitando as leis de trânsito e utilizando equipamentos de segurança, e na infraestrutura das rodovias são necessários. ***Nível de evidência II, Estudo prognóstico.***

Descritores: *Acidentes de Trânsito. Fatores Socioeconômicos. Ferimentos e lesões.*

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INTRODUCTION

The increase in the number of motorcycles circulating over the years is a consequence of the low cost, ease of locomotion and fuel efficiency of this vehicle. However, this increase has grown proportionally to the number of traffic accidents, making them a major problem for public health worldwide, since they have been considered one of the main causes of morbidity and mortality in the world, according to Martins et al.[1] and Sant'Anna et al.[2]

Martins et al.[1] also mention that the highest rates of traffic accidents occur in low- or medium-development countries, of which Brazil is considered part, according to the World Health Organization (WHO). In Brazil, mortality grew seven times between 1998 and 2008, as well as the number of hospitalizations, which grew by 83% in 2000. Also, the growth of the motorcycle fleet is supported by government policies, given the manufacturing stimulation, the possibility of financing the product and its cost reduction.

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

The study was conducted at Pontifícia Universidade Católica de Campinas, Center for Life Sciences, Medical School, Campus II.
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Owning a motorcycle has some advantages, such as avoiding congested roads, low buying and maintenance cost, and fuel economy, in addition to its increasing use in the labor market (motorcycle taxi and deliveries) when compared with other means of transportation. Therefore, the motorcycle use in Brazil is increasing significantly.[1,3] This is evidenced in the study by Sant'Anna et al.[2] Thus, the need for new public policies to improve public health by reducing the number of accidents is evident.

Our study evaluated the socioeconomic impact of motorcycle accidents that occurred in a metropolis with more than one million inhabitants, in 2017, on the lives of victims treated in a reference university hospital, their definitive and disabling sequelae, their reintegration into the labor market after six months of the event and, finally, the time of hospital stay and its costs.

OBJECTIVE

To evaluate the socioeconomic impact of motorcycle accidents that occurred in a metropolis with more than one million inhabitants, in 2017, on the lives of victims attended in a reference university hospital, through medical records and questionnaires answered via telephone with patients addressing their definitive and disabling sequelae and their reintegration into the labor market after six months of the accident. Moreover, to analyze the influence of cost and hospitalization time for socioeconomic impact.

METHODS

This is a retrospective cross-sectional study conducted at the PUC-Campinas University Hospital, filed by the Research Ethics Committee with registration on *Plataforma Brasil* under the number 88812818.3.0000.5481, in which the medical record analysis of 62 victims of motorcycle accident was performed in Campinas, São Paulo, Brazil, in 2017 (from January to December). The patients were treated primarily in the emergency room of a university hospital of reference and required a surgical procedure.

Data such as sex, age group, cost and hospital stay were evaluated in 62 medical records. However, of this total, only 25 patients answered the phone call after six months of the accident, providing information regarding their expenses after hospital discharge, removal and acquisition of benefit by the National Institute of Social Security (INSS), receipt compulsory insurance that covers personal damages caused by road vehicles (DPVAT), return to motorcycle activities and comparison of physical integrity before the accident and after six months of recovery.

Data regarding patients' hospitalization costs were obtained from the Billing sector of the PUC-Campinas Hospital. The remaining data (age group, sex and location of injuries) were obtained from medical records recorded in the Orthopedics and Traumatology service of the same hospital, and answers were obtained from a questionnaire via telephone, with the interviewee's consent.

RESULTS

The age of the 62 victims involved in motorcycle accidents ranges between 14 and 62 years (mean age of 31 years), in which 11.3% (7) ranged between 14 and 18 years, 43.6% (27) between 19 and 30 years, and 45.1% (28) over 30 years. Out of 62 patients, 77.4% (48) were male and 22.6% (14) female. All patients were from Campinas.

In the evaluation of medical records, we observed the high hospital costs were, on average, R$ 27,781 per patient (ranging from R$ 3,101 to R$ 225,500), and 95% of them (59) caused an average loss of R$ 17,555 and 5% (3) caused an average profit of R$ 203,396, which are directly proportional throughout the hospitalization period, whose mean time was 13 days (1-87 days), as well as the extent and complexity of fractures. Patients who gave financial losses (95%) to the hospital correspond to those treated in the Brazilian Unified Health System (SUS), while those who gave profit were covered by health insurance (5% – 1.6% each), such as Bradesco, Amil and Unimed.

During data analysis, we observed that all were subjected to surgical procedure and that patella lesions had the lowest cost, followed by polyfractured patients with lesions associated with lower limbs (tibia, fibula and femur) and upper limbs (radio and humerus). Traumatic brain injury corresponds to 3% of cases and brachial plexus injury to 1.6%. However, what most contributed to the increased cost were open-book fractures (4.8% of cases) in the case of polytraumatic and polyfractured patients, with other structures such as urethra, ureters and bladder affected or with abdominal trauma. Of the 4.8% of patients who suffered open-book fractures, 1.6% was covered by Bradesco's Health Plan, avoiding major losses to the university hospital, since the amount spent would be R$ 225,550.

Regarding the 25 patients who responded via telephone, 21 (84%) were male and 4 (16%) were female, aged between 17 and 62 years (mean of 28.3 years) and 68% were aged between 15 and 35 years. The average time of stay was 9 days (1-20 days), with hospital costs, on average, of R$ 16,307 per patient, all of which caused financial loss to the hospital, on average, of R$ 10,814 per patient. All patients analyzed had hospitalizations covered by SUS.

Regarding the functional evaluation and socioeconomic impact of the 25 patients after six months of the motorcycle accident, we observed that 16 patients (64%) were on paid leave (INSS), and 8 (50%) were still absent, 6 (24%) presented polyfractures and most lesions (37%) were solely in the left lower limb. Only 9 patients (36%) received some kind of benefit (sickness aid, accident aid, disability retirement, etc.), 11 (44%) used DPVAT insurance and 15 (60%) needed extra financial resources after the accident.

Of the means of transport used for treatment, 16% were buses, 40% owned or borrowed car, 24% ambulance of the municipality, 8% UBER, and 12% did not undergo treatment. Most victims, 21 (84%), underwent follow-up with physical therapists and only 1 (4%) water aerobics after the accident. Regarding the practice of physical activities six months after the accident, 21 patients (84%) presented partial physical disabilities and only 4 patients (16%) did not present transient physical disabilities. In the recovery period after the accident, 20 (80%) patients were helped by the mother and/or father, 3 (12%) by the wife and 2 (8%) by a brother.

Only 4 (16%) patients showed interest in returning to their activities with the motorcycle after the accident.

DISCUSSION

In 2005, the cost of hospitalizations resulting from motorcycle accidents in Brazil reached R$ 31 million. About R$ 10 million of this amount were in the state of São Paulo. It is noteworthy that the costs of SUS with hospitalizations resulting from motorcycle accidents totaled R$ 58 million from 2001 to 2005 only in the Southeast region. The analysis of hospitalizations of 62 patients in a reference hospital in Campinas found that the high costs of hospital admissions were caused by motorcycle accidents in 2017. All victims underwent surgery, contributing to high hospital expenses, and all hospitalizations were made by SUS.

A similar study conducted by Diniz,[3] in the city of Goiânia, with 122 medical records, reported that the hospital costs of the city's reference hospital were, on average, R$ 20,000 per patient. A difference of R$ 7,781 was observed when compared with the expenses of the reference hospital of Campinas. This is justified by the fact that the hospitalization period in Campinas were greater than those in Goiânia (longer period of 25 days). Considering that hospital time is directly proportional to the cost, the expenses of the hospital in Campinas were therefore naturally higher. Moreover, all the victims

assisted in the metropolitan city underwent surgery, and some had several structures simultaneously affected, such as urethra, ureters, bladder, pulmonary contusions and traumatic brain injury, increasing the complexity of trauma. On the other hand, in the city of Goiânia, only 80.3% (98) performed the same type of procedure, with the highest complication being a traumatic brain injury (10.6% of the cases). Studies by Ankarath et al.[4], Zargar et al.[5] and Nwadiaro et al.[6] confirm that traumatic brain and abdominal traumas are responsible for reducing survival rates in these types of accidents. All of these facts also contribute to increased hospital spending.

Regarding functional impact, the study conducted in Goiânia and the study of Chichom-Mefire et al.[7] showed that limb injuries provide a longer recovery period for the victim and, consequently, a major impact on their social life. Our study had similar results, since most victims (84%) could not perform the same physical activities after six months of trauma, 16% were on paid leave by INSS and 60% needed extra financial resources during the treatment period after the accident. Moreover, the time of absence of these patients associated with functional deficit after the accident were responsible for the inability of these patients to return to their work routine, remaining, in many cases, unemployed for a long period.

According to the Brazilian Ministry of Health,[8] to reduce the number of victims, traffic accidents must be treated as a health promotion issue with the development of intersectoral projects to stimulate the participation of the entire population and the adoption of more supportive behaviors, which aim both at traffic education and information on the physical consequences of motorcycle accidents. All this correlates with the purpose of our study, which is to promote preventive guidelines for the epidemiological group most vulnerable to traffic accidents. For such, it is essential to raise society's awareness of traffic laws and, at the same time, use of safety equipment to reduce the extent of fractures and, consequently, hospital time and financial expenses, as already reported by Phillip et al.[9], from de Rome et al.[10], Heldt et al.[11] and Kim et al.[12] In addition, improving the infrastructure of streets and roads is indispensable for a safer and more adequate circulation of motor vehicles.

CONCLUSION

The extent and complexity of fractures and other injuries, associated with prolonged hospitalization time significantly influence the hospital costs of victims of motorcycle accidents, generating a great socioeconomic imbalance in SUS and in health plans, and in victims' expenses with care after hospital discharge. Thus, our study provides preventive guidelines for the epidemiological group most vulnerable to traffic accidents and society awareness traffic laws and, at the same time, use of safety equipment such as helmets and appropriate clothing, which contribute to reducing the extent of fractures, hospital time and financial expenses that victims may have with institutional care, according to Phillip et al.[9], de Rome et al.[10], Heldt et al.[11], and Kim et al.[12].

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