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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed April 2022)

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ACKNOWLEDGEMENTS

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

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Levels of Evidence for Primary Research Question[a]

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

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

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

SUMMARY

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Original Article

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ORIGINAL ARTICLE

HAND SURGERY AND RECONSTRUCTIVE MICROSURGERY

EFFECT OF HYPERBARIC OXYGEN THERAPY ON NERVE REGENERATION IN RATS

EFEITO DA TERAPIA HIPERBÁRICA DE OXIGÊNIO NA REGENERAÇÃO NERVOSA EM RATOS

Thiago Felipe dos Santos Barros[1], Renata Gregorio Paulos[1], Fernanda do Carmo Iwase[1], Gustavo Bispo dos Santos[1], Marcelo Rosa de Rezende[1], Rames Mattar Júnior[1]

1. Universidade de São Paulo, Medical School, Hospital das Clínicas, Institute of Orthopedics and Traumatology, Hand Surgery and Reconstructive Microsurgery Group, São Paulo, SP, Brazil.

ABSTRACT

Objective: To evaluate histological changes in peripheral nerves of rats after sciatic nerve neurorrhaphy, according to the time of exposure to hyperbaric oxygen chamber treatment. Methods: Twenty-five Wistar rats were divided into 5 groups according to the amount of exposure to hyperbaric oxygen chamber treatment. Group 1 was the control and there was no use of hyperbaric oxygen chamber; group 2 received one week of therapy; group 3, two weeks; group 4, three weeks; and group 5, four weeks. After the fourth postoperative week, the animals were submitted to euthanasia and a sciatic nerve sample sent for histological analysis. Axons proximal and distal to the neurorrhaphy were counted with axonal regeneration index measurement. Results: We observed that the number of axons distal to neurorrhaphy increases with the amount of hyperbaric oxygen chamber exposure, the results were more expressive from the third week of treatment. However, the statistical analysis found no significant difference between the groups. Conclusion: The descriptive analysis suggests benefit of using hyperbaric oxygen chamber directly proportional to the time of therapy. The study, however, did not present statistically relevant results, probably due to the reduced sample size. Subsequent studies with more significant sampling would be of great value. ***Level of Evidence II, Prospective Comparative Study.***

Keywords: Peripheral Nerves. Hyperbaric Oxygenation. Nerve Regeneration. Rats.

RESUMO

Objetivo: Avaliar as alterações histológicas nos nervos periféricos após neurorrafia do nervo ciático de ratos, de acordo com o tempo de exposição ao tratamento com câmara hiperbárica de oxigênio. Métodos: Vinte e cinco ratos da raça Wistar foram divididos em cinco grupos conforme o tempo de exposição ao tratamento com câmara hiperbárica de oxigênio. O grupo 1 não recebeu o tratamento; o grupo 2 recebeu uma semana de terapia; o grupo 3, duas semanas; o grupo 4, três semanas; e o grupo 5, quatro semanas. Após quatro semanas de pós-operatório, os animais foram submetidos à eutanásia e uma amostra do nervo ciático foi enviada para análise histológica. Foram feitas contagens do número de axônios proximalmente e distalmente à neurorrafia, com medição do índice de regeneração axonal. Resultados: Observamos que o aumento do número de axônios distais à neurorrafia foi diretamente proporcional ao tempo de exposição à câmara hiperbárica de oxigênio, sendo mais expressivo a partir da terceira semana de tratamento. Entretanto, a análise estatística não encontrou diferença significativa entre os grupos. Conclusão: A análise descritiva sugere benefício do uso da câmara hiperbárica de oxigênio. Porém, devido à amostra reduzida, o estudo não apresentou resultados estatisticamente relevantes, sendo necessária a realização de estudos subsequentes com amostragem mais significativa. ***Nível de Evidência II, Estudo Prospectivo Comparativo.***

Descritores: *Nervos Periféricos. Oxigenação Hiperbárica. Regeneração Nervosa. Ratos.*

Citation: Barros TFS, Paulos RG, Iwase FC, Santos GB, Rezende MR, Mattar R Jr. Effect of hyperbaric oxygen therapy on nerve regeneration in rats. Acta Ortop Bras. [online]. 2022;30(2): Page 1 of 4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Peripheral nerves are important for the maintenance of sensory and motor function in living beings; an injury to it results in partial or complete elimination of these functions. Despite several technological advances, including the use of a surgical microscope and epineural and perineural suture without tension of nerve endings, complete sensory and functional recovery of the nerve cannot yet be guaranteed.[1-5]

Innovative methods have been tested in an attempt to obtain better results in the treatment of nerve lesions. Among them, the treatment with hyperbaric oxygen chamber (HOC), which aims to increase oxygenation of peripheral tissues, deserves particular attention. The main objective being the elimination of hypoxia, avoiding the accumulation of substances with toxic effect that promote the process of ischemia and inflammation.

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

The study was conducted at Universidade de São Paulo, Medical School, Hospital das Clínicas, Institute of Orthopedics and Traumatology, Hand Surgery and Reconstructive Microsurgery Group.

Correspondence: Thiago Felipe dos Santos Barros. Rua Dr. Ovídio Pires de Campos, 333, São Paulo, SP, Brasil, 05403010. thiago.medicina@gmail.com

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The proper functioning of aerobic mechanisms must be ensured while maintaining the vitality of the region.[6,7]

Treatments with HOC has been reported to reduce ischemic lesions in various tissues.[8-11] In the peripheral nervous system, HOC treatment rescued nerve fibers in test subjects with experimentally impaired microcirculation.[12,13] In peripheral nerve injury, it has been shown that oxygen at high pressures has favorable effects on the recovery of mechanically damaged nerves, either by nerve sectioning, crushing, or both, in animal models and in humans.[14-22]

On the other hand, there were unsatisfactory functional results in nerve recovery after adjuvant treatment with HOC in rats with transfixing lesion or with crushed peripheral nerves.[22,23] Thus, we observed that there is still no consensus on the benefits obtained with the use of HOC for nerve lesions.

In this study, we evaluated the histological alterations presented in the regenerating nerve according to the duration of HOC treatment. Something not yet established in the studies found.

MATERIALS AND METHODS

This is an experimental study in rats, approved by the Ethics Committee of the Department of Orthopedics and Traumatology of HC/FMUSP, under protocol no. 15026. In total, 25 rats were used and the following inclusion criteria were adopted: Wistar rats; young adult males (120 to 140 days of life); weight between 250 and 330 grams; normal general condition (coat and clinical status) and motricity. Regarding exclusion criteria: females, death after injury; autophagy, and impossibility of reversing infection. We defined as criteria of interruption (suspension) and closure: weight loss greater than 10% during the postoperative period in a significant number of animals (greater than 10%), death of animals during the postoperative period in more than 10% of the total, and adverse reactions to the hyperbaric chamber (including changes in animal behavior and convulsion).

Anesthesia protocol

The animals received preanesthetic tramadol hydrochloride medication at a 5 mg/kg dose associated with meloxicam 2 mg/kg subcutaneously and, after 15 minutes, were anesthetized with xylazine 10 mg/kg + ketamine 100 mg/kg intraperitoneally. The deep anesthetic state was confirmed by the lack of corneal reflexes and lack of reaction to compression of the tail and hind legs. An anesthetic reinforcement was performed with one third of the initial dose in the specimen that still presented reflexes during the procedure.

Surgical procedure

Following the anesthesia, the rat was positioned in ventral decubitus on a wooden board, immobilizing the thoracic and pelvic limbs. Subsequently, trichotomy of the right hind paw was performed, followed by degermation with alcoholic chlorhexidine solution. Through an incision in the posterior facet of the right paw, the musculature was removed until the sciatic nerve was exposed from its middle portion to the distal portion of its branches: fibular, sural, and tibial nerve. The nerve was cross-sectioned with microscissors, five millimeters proximal to the trifurcation of the sciatic nerve. Nerve repair was performed immediately after the injury, always by the same surgeon. The end-to-end external epineural neurorrhaphy technique was used with two stitches using mononylon thread size 10.0. The skin was subsequently sutured with mononylon thread size 5.0, in simple stitches.

Postoperative

After cleaning the surgical scar, a layer of healing ointment was applied, composed of fibrinolysin, deoxyribonuclease, and chloramphenicol (Fibrase ®). After surgery, meloxicam 2 mg/kg was administered for seven days and tramadol hydrochloride 5 mg/kg, for five days; both with a daily subcutaneous dosage. Feed and water were offered as soon as the animal was fully awake and was freely available throughout the treatment period. The rats were submitted to the hypothermia prevention protocol through the use of controlled temperature chambers of 25 to 28°C for 30 minutes in the immediate postoperative period.

Hyperbaric chamber

HOC treatment was initiated after 24 hours of surgery. The test subjects were divided into groups of five. The therapy adopted was the permanence in HOC for 30 minutes daily, at 2.5 ATA, according to the duration protocol per group of animals. The groups were separated as follows:

1) Control (no therapy in HOC)
2) Treatment with HOC for one week
3) Treatment with HOC for two weeks
4) Treatment with HOC for three weeks
5) Treatment with HOC for four weeks

At the end of the fourth week, the rats were sacrificed following the ethical principles in animal experimentation established by the Brazilian College of Animal Experimentation, Federal Law No. 6,638, of 1979. After euthanasia, a piece of the operated sciatic nerve was collected and sent, in a 10% formaldehyde solution, to the Pathology department, where they were examined by an evaluator who was not aware of the procedure to which the animal was submitted or of the previous division of the groups.

After receiving the pieces in 10% formaldehyde solution they were embedded in blocks of paraffin, followed by routine tissue processing. Slices sized five micrometers were performed with the microtome device and were stained with hematoxylin and eosin, toluidine blue, Masson and actin (immunohistochemistry) for microscopic evaluation. Specimens were examined under a light microscope.

After the process of fixation and staining of the pieces, the number of axons proximal and distal to the neurorrhaphy was checked. With these data we estimated the axonal regeneration index (RI), which consists of the ratio between the number of axons distal to the neurorrhaphy and the ones proximal to it.

Statistical procedures

First, the distribution of the data was tested with Shapiro-Wilk test, after which the means of the axonal regeneration index (RI) of the groups in their respective hyperbaric chambers were analyzed by the ANOVA test, with its variances homogeneity tested by the Levene test and Tukey's *post-hoc* test. The data were analyzed with the software SPSS version 24.0, considering as significant a $p \leq 0.05$.

RESULTS

We observed a higher number of axons distal to neurorrhaphy and a higher axonal regeneration rate in all groups submitted to HOC when compared to the control. The increase occurred according to the therapy exposure time, so that group 5 presented the best results.

Table 1 shows the results of the axon count proximal and distal to the neurorrhaphy, as well as the RI of each specimen in groups 1 to 5.

After the ANOVA test we obtained the following result: $F(4, 20) = 2.797$, $p = 0.054$, $\eta^2 p = 0.35$ leading to the conclusion that no significant differences were observed between the groups. (in which F is the function of the result obtained by ANOVA test).

Table 2 shows the RI mean and the standard deviations for each group.
Although the results were not statistically significant, probably due to the small sampling, we noticed that between the second and third week of therapy the increase was more expressive, as shown in Figures 1 and 2.

Table 1. Axons count proximal and distal to the neurorrhaphy of the sciatic nerve of the test subjects after 4 weeks of follow-up in the 5 different groups, n = 25.

	Group 1			Group 2			Group 3		
Nº of specimen	Nº of Axons			Nº of Axons			Nº of Axons		
	P	D	RI	P	D	RI	P	D	RI
1	345	115	0.333	412	189	0.459	368	110	0.299
2	344	224	0.651	321	144	0.449	400	299	0.748
3	396	203	0.513	374	214	0.572	362	205	0.566
4	325	189	0.582	398	328	0.824	398	421	1.058
5	412	330	0.801	347	247	0.712	347	125	0.360
Mean	364	212	0.576	370	224	0.603	375	232	0.606
SD	37	78	0.173	37	69	0.163	23	130	0.308

	Group 4			Group 5		
Nº of specimen	Nº of Axons			Nº of Axons		
	P	D	RI	P	D	RI
1	287	247	0.861	325	298	0.917
2	408	399	0.978	353	288	0.816
3	362	278	0.768	348	315	0.905
4	484	360	0.744	410	297	0.724
5	352	272	0.773	344	330	0.959
Mean	379	311	0.825	356	306	0.864
SD	73	65	0.096	32	17	0.094

P: proximal; D: distal; RI: axonal regeneration index; SD: standard deviation.

Table 2. Mean comparison of the axonal regeneration index (RI) in the sciatic nerve between groups with different durations of HOC treatment and the control group, n = 25.

Groups	Mean RI	SD
Group 1	0.576	0.173
Group 2	0.603	0.163
Group 3	0.606	0.308
Group 4	0.825	0.096
Group 5	0.864	0.094

SD: standard deviation.

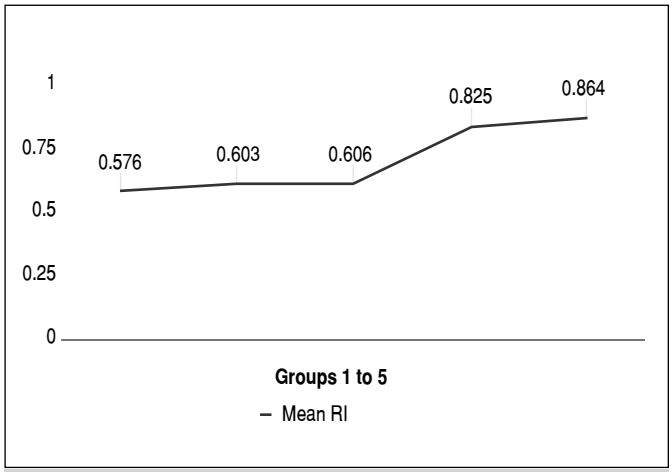

Figure 1. Mean axonal regeneration index per study group.

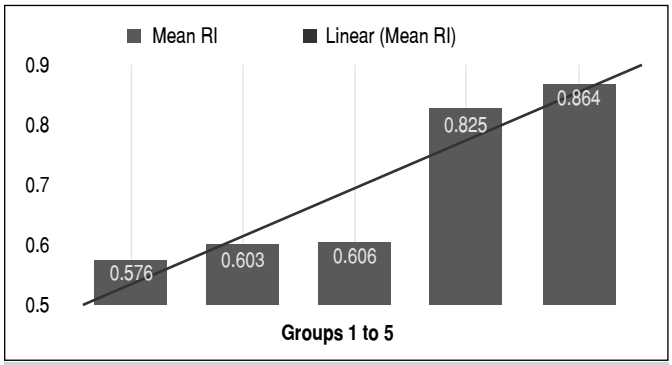

Figure 2. Trend of the mean axonal regeneration index form the data of the 5 groups studied.

DISCUSSION

Several studies have sought a correlation between HOC therapy and axonal regeneration in traumatized nerves. This study sought to understand if there is real evidence of increased and/or improved regeneration in traumatized nerves.[14,16,18,23-26]
During the study, each group was submitted to a different period of treatment, except for the control group, which was only medicated for pain according to the protocol adopted. It was possible to identify that the specimens submitted to HOC had an increase in RI compared to the control group and greater expression in groups 4 with 43% and 5 with 50% increase when compared to the control group. In relation to groups 2 and 3, the increase was not significant (4% in group 2 and 5% in group 3).
Despite these differences, there was no statistically relevant evidence between the control groups and those submitted to HOC. Therefore, there was no evidence of a dose-dependent effect of HOC treatment on the early regeneration of axons using the adopted protocol.
Eguiluz-Ordoñez et al.[7] also evaluated sciatic nerves of rats, in which the animals were sacrificed after seven postoperative weeks (control group and HOC group) or after 14 weeks (another control group and another HOC). In their study, HOC therapy was performed twice a day for ten days, with 100% oxygen, using 2 ATA. As for the animals evaluated at seven weeks, there was an increase in the number of axons in rats treated with HOC compared to the control group. Differently from our study, Eguiluz-Ordoñez et al. observed statistically significant difference, but only in the absolute number of axons, the RI was not considered. After 14 postoperative weeks, the groups showed only a slight difference in the number of axons.
Bradshaw et al.[24] conducted a study in which rabbits were exposed to different oxygen concentrations and to different atmospheric pressures in oxygen therapy. In this study, he noticed that the animals treated with compressed oxygen at 202, 242, and 303 kPa and 100% oxygen presented nerve recovery, with organized fibers similar to uninjured nerves. Animals submitted to 100% oxygen therapy at ambient pressure, compressed air and ambient air did not present a morphology similar to uninjured nerves.
Ince et al.[25] conducted a study to determine the effect of different durations of hyperbaric oxygen treatment application on nerve regeneration in rats. They found that rats submitted to HOC in the first hour after neurorrhaphy (group 2) had better functional gait results when compared to the other study groups (group without HOC therapy – group 1; HOC starting in the first week after neurorrhaphy – group 3; HOC started in the second week after neurorrhaphy – group 4), when evaluated in the eighth postoperative week. In the gait evaluation in the sixteenth postoperative week, group 2 continued with the best gait score

and group 3 presented better results when compared to groups 1 and 4. In conclusion, the benefit of early initiation of HOC after neurorrhaphy has been suggested.

The real cause of the difference in the number of distal axons in groups 4 and 5 is unknown. They may be related, however, to the known physiological effects of HOC, such as increased partial oxygen pressure not only in the blood, but in interstitial fluids and tissues; which causes increased oxygen tension, even in sites with low perfusion, such as the region distal to nerve damage.[27,28] Moreover, HOC is known to improve local perfusion of ischemic tissues, as it decreases the formation of local edema. Although we know the result, the mechanism itself for preventing edema is still poorly understood, but may be associated with the fact that HOC causes temporary vasoconstriction and reduced post-ischemic vascular permeability.[29-34]

There are no conclusive studies on the efficacy of HOC use for the treatment of peripheral neural regeneration. However, some studies, ours included, have provided intriguing results that allow for further study.

Our study suggests that with three weeks or more of HOC, the axonal regeneration index increases in the sciatic nerve of rats, but no statistically relevant HOC effect was demonstrated, probably due to our reduced sample, something that may be proven by conducting a study with a larger sample.

CONCLUSION

Our study did not present statistically relevant results on the use of HOC in sciatic nerve regeneration in rats. Although groups 4 and 5 showed an important improvement in the axonal regeneration index, the limited number of samples (5 rats per group) may have precluded a statistically significant result. Therefore, a greater number of experimental studies with more significant samples would be of great value, mainly aiming to understand HOC's mechanism of action in regions related to nerve damage with a higher incidence of ischemia.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. TFSB: writing of the article, statistical analysis, analysis of the slides; RGP: surgeries, data analysis, and writing of the article; FCI: surgeries, data analysis, and writing of the article; GBS: anesthesia, data analysis, slides analysis, article writing, hyperbaric chamber, and animal care; MRR: review of the article and of all intellectual concept of the article; RMJ: review of the article and also of all intellectual concept of the article.

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THE EFFECT OF THE USE OF ALCOHOL AND DRUGS ON MOTORCYCLICAL TRAUMAS WITH SURGICAL TREATMENT FRACTURES: EPIDEMIOLOGY

O EFEITO DO USO DE ÁLCOOL E DROGAS EM TRAUMAS MOTOCICLÍSTICOS COM FRATURAS DE TRATAMENTO CIRÚRGICO: EPIDEMIOLOGIA

Fernando Araujo Pires[1], *João Baptista Gomes dos Santos*[1], *Renato Hiroshi Salvioni Ueta*[1], *Flávio Faloppa*[1], *Vinicius Ynoe de Moraes*[1], *Marcel Jun Sugawara Tamaoki*[1]

1. Universidade Federal de São Paulo, Escola Paulista de Medicina (EPM-Unifesp), Orthopedics and Traumatology Department, São Paulo, SP, Brazil.

ABSTRACT

Objective: To verify the prevalence of patients who were victims of motorcycle trauma who were under the influence of alcohol and drugs. Methods: The study was observational and prospective, with patients hospitalized to the Orthopedics and Traumatology Ward of Hospital São Paulo (UNIFESP), from March 2015 to March 2016. The study included patients of all genders, over 18 years old, hospitalized due to motorcycle trauma and who needed orthopedic surgical treatment. Results: During the research, 282 patients were hospitalized, of which 23.8% were victims of motorcycle trauma. Of these, 49.3% motorcyclists reported the use of alcohol and drugs before the accident, while 50.7% denied their consumption. In the analysis of alcohol and drug consumption in patients with motorcycle injuries, the results showed that: 65% used only alcohol; 16% used both alcohol and drugs; and 19% used only illicit drugs. Conclusion: The incidence of patients who suffered motorcycle accidents under the influence of alcohol and drugs was 49.3%. ***Level of Evidence IV, Prospective Case Series.***

Keywords: Epidemiology. Traffic Accidents. Alcoholism. Motorcycles.

RESUMO

Objetivo: Verificar a prevalência de pacientes vítimas de trauma motociclístico que estavam sob efeito de álcool e drogas. Métodos: Estudo observacional e prospectivo, com pacientes internados na Enfermaria de Ortopedia e Traumatologia do Hospital São Paulo (Unifesp), de março de 2015 a março de 2016. Foram incluídos pacientes de ambos os sexos, idade superior a 18 anos, internados por trauma motociclístico e que necessitavam de tratamento cirúrgico ortopédico. Resultados: Durante a pesquisa, foram internados 282 pacientes, dos quais 23,8% eram vítimas de trauma motociclístico. Desses, 49,3% motociclistas referiram o uso de álcool e drogas previamente ao sinistro, enquanto 50,7% negaram o consumo. Na análise do consumo de álcool e drogas nos pacientes de traumas motociclísticos, foi observado que 65% estavam sob efeito apenas de álcool, 16% estavam sob efeito de álcool e drogas, e 19% sob efeito de drogas ilícitas. Conclusão: A incidência de pacientes que sofreram acidentes motociclísticos sob efeito de álcool e drogas foi de 49,3%. ***Nível de Evidência IV, Série de Casos Prospectivos.***

Descritores: *Epidemiologia. Acidentes de Trânsito. Alcoolismo. Motocicletas.*

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INTRODUCTION

Traffic accident is any unintentional and avoidable event that involves a vehicle on public road. In the International Classification of Diseases (ICD), traffic accident is included in the division of External Causes, which involve the pedestrian, cyclist, motorcyclist, occupant of automobile, truck, and heavy transport vehicle.[1]

Traffic accidents are among the main causes of trauma, representing an important public health problem worldwide that impact both economic and social espheres.[2] Annually, traffic accidents injure 50 million people and cause 1.3 million deaths worldwide, and these numbers are more concentrated in middle- and low-income countries.[3]

Studies indicate that, in 2020, traffic accidents will be the second cause of premature death. Mortality from land traffic accidents varies by gender, age group and geographic distribution.[4] Traffic accidents affect mainly people between five and 49 years old, with higher prevalence in productive age group, causing emotional, physical, and social changes in the individual and in the family nucleus.[4,5]

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

The study was conducted at The Orthopedics and Traumatology Ward of Hospital São Paulo – Unifesp.
Correspondence: Fernando Araujo Pires. Borges Lagoa Street, 778, São Paulo, SP, Brazil, 04038030. drfernandoapires@gmail.com

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The 1998 Brazilian Traffic Code improved vehicle safety and increased electronic surveillance. However, the changes could not reduce mortality from traffic accidents significantly.[6]
In this scenario, motorcyclists stand out as vulnerable groups.[6-9] If compared to car drivers, motorcyclists have 9.3 times higher risk of death, injury, and involvement in accidents. When compared with pedestrians, motorcyclists have 8.4 times higher possibility of death,[9] more than 50% of these deaths occurring in the traffic. Traffic accidents are responsible for causing physical disabilities and sequalae in this group, especially affecting young males.[10]
Alcohol consumption associated with land transport accidents is responsible for deaths of more than one million people per year worldwide.[11] In 2007, Brazil registered 37,407 deaths caused by land accidents associated with alcohol consumption, and 82% of these deaths were men and young people, aged between 20 and 29 years old.[11]
This is an important subject in Brazil, although data related to motorcyclists driving under influence of alcohol and illicit drugs are scarce. Thus, our study aims to evaluate the frequency of motorcycling accidents, and to verify the incidence of the effect of alcohol or illicit drugs on motorcyclists involved in accidents hospitalized in a quartile hospital.

MATERIALS AND METHODS

This is an observational and prospective study conducted with patients hospitalized from March 1, 2015, to March 1, 2016 in the orthopedics and traumatology ward of a quaternary hospital with reference in orthopedics and traumatology, located in the municipality of São Paulo. The research was approved by the Research Ethics Committee and used the recommendations of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).[12]
Patients of all genders, over 18 years old, hospitalized for trauma and requiring orthopedic surgical treatment were included in this study. Patients who had a non-traumatic diagnosis and electively hospitalized were excluded.
All these hospitalized trauma victims were evaluated, and the following data were collected in an attached form: name, age, gender, fractures suffered, and occurrence of associated open fracture.
To minimize the risks of leaking information from medical records, patients were identified only with their initials. Age was placed numerically in years. After the patient's hospitalization, the researcher conducted the alcohol and drug consumption investigation. Fractures were classified according to topography in the upper limb, lower limb, and trunk. Only patients who presented trauma due to motorcycle accidents were directly questioned about the use of licit (alcohol) or illicit drugs (marijuana, cocaine, and crack) immediately before the start of motorcycle driving. The questions were asked with the patients in bed, without the presence of companions or hospital staff, and the patients were informed that their answers would be confidential and would not be used for judicial purposes.

Sample estimation

The 50% value was used as reference since this value allows obtaining the largest possible sample size for the study of proportions, with a 5% significance.
All data collected were placed in a spreadsheet for subsequent analysis of mean age, gender prevalence, mechanism of trauma and prevalence of open fractures. Initially, all variables were analyzed descriptively. For the quantitative variables, the minimum and maximum values were observed, as well as the estimates of means. For the comparison of group means, the analysis of variance to one factor was used, while for the rejection of the hypothesis normality of data, Kruskal-Wallis nonparametric test was used.
To evaluate homogeneity between proportions, the Chi-square test or Fisher's exact test was performed. Pearson's correlation coefficient or Spearman correlation coefficient (when the assumption of data normality is rejected) was used to study correlations betweenvariables. For static analyses, the GraphPad Prism 5.0 program (Software Inc. USA) was used, considering a 5% significance level as statistically significant. In this statistical analysis, the programs SPSS V20, Minitab 16 and Excel Office 2010 were used (Figure 1).

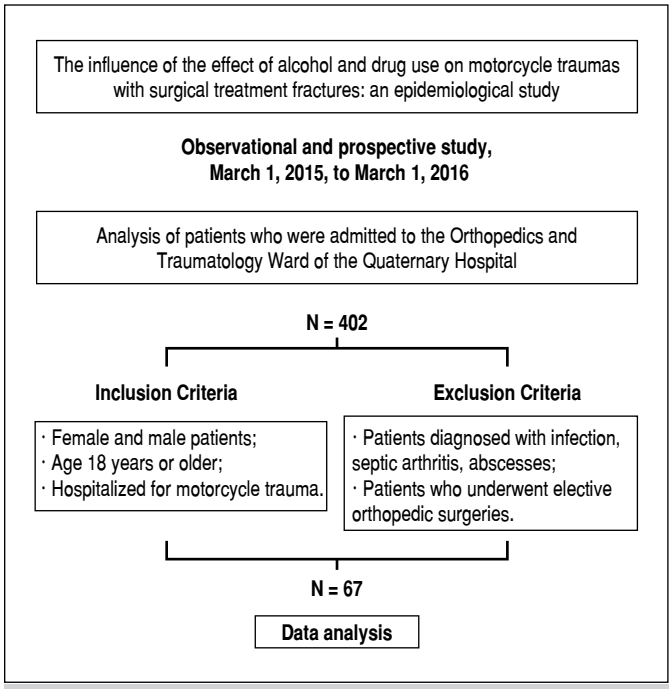

Figure 1. Flowchart of the methodology adopted.

RESULTS

This study analyzed 402 hospitalized patients, of which 282 (76.2%) were victims of trauma, from March 1, 2015, to March 1, 2016. Of these, 67 (23.8%) patients were victims of motorcycle accident, showing a statistically significant difference (Table 1).
Regarding age, the mean of 32 years old was observed, with a minimum of 18 and a maximum of 56 years old. Regarding gender, we can observe that males were more prevalent with 66 (98.5%) patients, obtaining a statistical difference.
In the motorcycle trauma group, we observed that 33 (49.3%) patients were in the alcohol and drug use group (ADG) and 34 patients (50.7%) were in the no alcohol and drug use group (WADG), and this difference was not statistically significant, since the distribution was homogeneous.
In the analysis of alcohol and drug consumption in motorcycle trauma patients (n = 33), it was observed that 22 (66.7%) were only under the effect of alcohol, five (15.2%) were under the influence of alcohol and drugs, and six (18.2%) were only under the effect of illicit drugs (Table 2).
Closed fractures were more frequent in patients with motorcycle trauma; however, no significant difference was observed between the groups with and without alcohol and drug use (Table 3).
According to the topography of the fractures, 46 (68.7%) patients showed fractures only in the lower limb, seven (10.4%) in the upper and lower limb and 14 (20.9%) in the upper limb. Fractures in the trunk were not found. No statistical difference was observed in the groups alcohol and drug use (ADG) and no alcohol and drug use (NADG).

Comparing motorcycle accidents and other causes of trauma, the rate of open fracture in the group other traumas was 17.2%. This index was lower than in the group of motorcyclists using alcohol and drugs (39.4%), and in the group without alcohol and drug use, which showed 41.2% of open fractures. Statistical differences were observed between the other trauma group and the ADG and NADG groups; however, no statistical differences were observed between the ADG and NADG groups, as previously reported (Table 4).

Regarding the topography of fractures, we found no statistical difference when we compared the groups (Table 5).

Table 1. Prevalence of trauma mechanism.

Trauma	N	%	P
Motorcycles	67	23.8%	<0.001
Other	215	76.2%	
Total	282		

Table 2. Prevalence of alcohol and drug use in the motorcycle trauma group.

Motorcycles ADG	N	%
Only Alcohol	22	66.7%
Alcohol and drugs	5	15.2%
Only drugs	6	18.2%
Total	33	

ADG: Alcohol and Drug Use Group.

Table 3. Prevalence of open fractures according to the group in motorcycle trauma.

	Open		Closed		P
	N	%	N	%	
WADG	14	41.2%	20	58.8%	0.146
ADG	13	39.4%	20	60.6%	0.085
Total	27	40.3%	40	59.7%	0.025

NADG: No Alcohol and Drug Use Group; ADG: Alcohol and Drug Use Group.

Table 4. Distribution of groups according to fracture characteristics.

	Open		Closed	
	N	%	N	%
ADG	13	39.4%	20	60.6%
WADG	14	41.2%	20	58.8%
OT	37	17.2%	178	82.8%

NADG: No Alcohol and Drug Use Group; ADG: Alcohol and Drug Use Group; OT: Other Traumas.

Table 5. Distribution of fracture topographies according to groups.

	Lower limb		Upper limb		Upper and Lower Limb	
	N	%	N	%	N	%
MOTORCYCLE ADG	23	69.7%	7	21.2%	3	9.1%
MOTORCYCLE NADG	23	67.6%	7	20.6%	4	11.8%
OT	156	72.6%	54	25.1%	5	2.3%

NADG: No Alcohol and Drug Use Group; ADG: Alcohol and Drug Use Group; OT: Other Traumas.

DISCUSSION

Anjos et al.[13] concluded that the motorcycle accident causes a change in the individual's behavior, disabling him temporarily or permanently. These events change family dynamics, cause psychological and affective traumas, compromise leisure, besides negatively affecting the family economic situation.

Data from the Traffic Engineering Company of São Paulo show that, in 2012, the rates of motorcycle accident deaths increased over the weekend and that 67% were at night. In 2016, 5,727 deaths occurred in São Paulo. Of these, motorcycling accidents led the number of deaths, corresponding to 30% of fatalities (1,718 deaths), followed by pedestrians and car drivers representing 26% and 25% of fatalities, respectively.[14]

Alcohol in the bloodstream causes several neuropsychomotor changes, such as false perception of speed, reduction of attention and peripheral vision, as well as increased euphoria and drowsiness.[5,15,16]

Moura et al.[17] published that alcoholism is relevant in the occurrence of trauma. The authors verified a direct correlation between alcohol and the number of traffic accidents.

In our study, we verified 23.8% of hospitalizations for motorcycle trauma. This rate is much lower than the results found by Modelli, Pratesi and Tauil[18], and Jaña et al.[19], with rates of 70% and 57%, respectively. This difference can be related to distinct locations and hospital characteristics, leading to a higher or lower prevalence of this type of trauma.

The results showed that almost half of our patients were under use of alcohol and/or drugs. In our study, alcohol and drug use were self-reported. Therefore, our data may have been underestimated, and we believe that this rate may be higher. A better method of measurement, such as toxicological tests, would demonstrate the prevalence of drivers using alcohol and drugs more accurately.

In 2008, the law popularly known as "Dry Law" was promulgated, introducing legal provisions that inhibit the consumption of alcoholic beverages by the driver of a motor vehicle. Thus, the identification of any concentration of alcohol in the blood imposes penalties on the driver, such as fine, suspension of the drive's license and seizure of the vehicle.[20]

Paixão et al.[21] showed that 55% of deaths by traffic accident from 2008 to 2010 had positive toxicological tests. The non-reduction in the number of victims of traffic accidents in the period after "Dry Law" was also mentioned by Oliveira et al.,[22] who stress, however, the importance of the law on a permanent character, since it is a strong tool to prevent traffic accidents in the country. Despite these data, few studies have shown the association of alcohol consumption and the use of illicit drugs with motorcycle accidents.[23]

In the U.S., Brady and Li in 2012 reported that more than half of drivers who died in a traffic accident were under the influence of alcohol or drugs, and 20% of them were under the influence of more than one drug.[24]

In Brazil, Albuquerque et al.[25] reported that, in Recife, 60.8% of the motorcyclists, who were victims of trauma, were under the influence of alcohol, and 16.8% of illicit drugs.

Our result differs from the Brazilian study of Malta et al.,[11] who reported a reduction in the frequency of adults who drive drunk in Brazilian capitals after the approval of the "Dry Law". Moreover, our prevalence is higher than the study by Andrade et al.,[10] who reported alcohol consumption in 39.2% in trauma patients. Methodological, geographical, and socioeconomic differences[9,26,27] can justify the divergent results.

Considering that 7,207 compensations to Personal Injuries Caused by Land-based Automotive Vehicles (DPVAT) for motorcycle accidents were registered in 2015 and 2016[14] in São Paulo and, in our study, 50% of the patients used alcohol or drugs, we can estimate that 3,603 motorcyclists could be under the influence of alcohol and illicit drugs. Maybe these accidents could have been prevented with a greater combat against the use of narcotics targeted at motorcycle drivers.

This study demonstrates the high prevalence of alcohol use in motorcyclists and that more than one third of them were

under the effect of illicit drugs during driving, data few reported in the literature. The association between licit/illicit drugs and the driving of cars and motorcycles is a severe problem in Brazil and worldwide, leading us to believe that additional actions to "Dry Law," such as advertising measures and toxicological detectors, should be introduced to combat drug driving.

Studies show that males are 22 times more likely to be involved in traffic accidents[5] and that the incidence of fractures in orthopedic services is extremely higher in males than in females.[28]

The predominance of males may be associated with the greater number of male drivers, characteristics related to age, immaturity, overestimation of capacity and limits, lack of experience and ability to drive reduced by alcohol and other drugs consumption.[5,28]

Thus, the measures against motorcycle accidents should reach mainly this population at risk – young males.

The risk of an exposed fracture is associated with the protection that the vehicle offers, since the lack of protection causes grave bodily injury and, sometimes, severe multiple injuries and death. Our study showed similarity in these data, however, although we did not find statistical difference in relation to the groups of motorcyclists with the variable use of alcohol and drugs.

Despite the differences in incidences in these populations studied, the data indicate a higher incidence of fractures in the lower limbs, a fact easily explained by the lack of protection and, consequently, greater vulnerability of this anatomical region to direct trauma in the event of an accident.

Our study has limitations, which include the absence of sociodemographic information, follow-up, and outcome of victims in the hospital environment, such as death, time of hospital discharge and the need for the rehabilitation service for the victims.

Our main point was the high prevalence of patients who suffered motorcycling accidents under alcohol and drug use, a question few analyzed in the literature. We also show the higher incidence of injuries in the lower limbs, as well as the prevalence of males and young adults, although the use of alcohol and/or drugs was not related to the higher incidence of open fractures.

Thus, the results contribute to increase the knowledge of the prevalence of alcohol and drug use by motorcyclists, which should provide prevention policies to reduce trauma caused by motorcycle accidents and draw attention of emergency care services to the possible toxicological changes of the injured person.

CONCLUSIONS

Our study showed a close association (49%) between motorcycle trauma and the use of alcohol and/or drugs. Among the patients who admitted the use of these substances, 67% used only alcohol, 15% used other illicit drugs and 18% used both alcohol and drugs. Most patients hospitalized due to motorcycle trauma were male, with a mean age of 32 years and had lower limb fractures and closed fractures.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. FAP: interview of patients; JBGS: interview of patients; RHSU: introduction and daily recruitment of cases; FF: analysis of results; VYM: analysis of results; MJST: advisor and reviewer.

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FABREX: A NEW CLINICAL TEST FOR DIAGNOSIS GLUTEAL TENDINOPATHY

FABREX: UM NOVO TESTE CLÍNICO PARA DIAGNÓSTICO DE TENDINOPATIAS GLÚTEAS

ANDERSON FREITAS[1], TATIANE MORELATI ROSA[2], SILVIO LEITE DE MACEDO NETO[1], VANESSA DE CARVALHO BANDEIRA[1], DIOGO RANIER DE MACEDO SOUTO[1], FABRÍCIO REICHERT BARIN[1]

1. Hospital Ortopédico e Medicina Especializada, Brasília, DF, Brazil.
2. Centro Universitário de Brasília, DF, Brazil.

ABSTRACT

Objective: This study aims to describe a simple and accurate semiological method executing a specific maneuver with the lower limb to direct the semiological investigation towards the tendinopathies in the gluteus medius and minimus. Methods: Fifty patients participated in the study, with a mean age of 44.1 ± 13 years, with persistent pain on the side of the hip for more than three months. To compare the FABREX (proposed test) and Lequesne semiological tests, in the diagnosis of tendinopathies in the gluteus medius and minimus, Magnetic Resonance Imaging (MRI) was adopted as the gold standard. Results: FABREX presented high sensitivity and moderate specificity for tendinopathy in the gluteus medius and high sensitivity and specificity for tendinopathy in the gluteus minimus. Conclusion: The proposed test, when positive, can be used to determine the diagnosis of gluteal tendinopathies (high specificity). Moreover, it has high sensitivity, excluding the diagnosis when negative. This study represents the initial step for validating the FABREX test, and can therefore be considered a simple and accurate procedure to identify patients with or without gluteal tendinopathies. ***Level of Evidence III, Case Control Study.***

Keywords: Hip. Gluteal Region. Tendinopathy.

RESUMO

Objetivo: Esse estudo propõe descrever um método semiológico simples e acurado, por meio de uma manobra específica com o membro inferior, a fim de direcionar a investigação semiológica para as tendinopatias dos glúteos médio e mínimo. Métodos: Participaram do estudo 50 pacientes, com média de idade de 44,1 ± 13,0 anos, apresentando dor persistente na face lateral do quadril há mais de 3 meses. A RM foi adotada como padrão ouro, para fins de comparação entre as duas manobras semiológicas (FABREX (teste proposto) e teste de Lequesne) no diagnóstico das tendinopatias do glúteo médio e mínimo. Resultados: O FABREX apresentou alta sensibilidade e moderada especificidade para tendinopatia de glúteo médio e alta sensibilidade e especificidade para tendinopatia do glúteo mínimo. Conclusão: A manobra proposta, quando positiva, pode ser utilizada para determinar o diagnóstico de tendinopatias glútea (alta especificidade). Além disso, possui alta sensibilidade, descartando o diagnóstico quando negativa. O presente trabalho constitui o passo inicial para validação do teste de FABREX, podendo assim, ser considerado um procedimento simples e acurado para identificar pacientes com ou sem tendinopatias glúteas. ***Nível de Evidência III, Estudo de Caso Controle.***

Descritores: *Quadril. Região Glútea. Tendinopatia.*

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INTRODUCTION

Physical examination of patients with hip pain is not simple.[1-3] The process is quite complex due to a wide range of differential diagnoses that include intra-articular and extra articular pathologies, besides pains in other regions, such as pelvic and vertebral.[2]

The Greater Trochanteric Pain Syndrome (GTPS) is a common problem found in clinical practice and its main characteristic is chronic pain on the lateral region of the affected hip, exacerbated when lying on the affected side and in activities such as ascending and descending stairs and long periods of standing.[4] Originally defined as "tenderness to palpation over the greater trochanter," this syndrome includes trochanteric bursitis, tendinopathies of the gluteus medius and minimus and the external snapping hip, being more prevalent in women[1,2] and affecting up to 25% of the general population.[2,5,6] The pathogenesis of this syndrome is uncertain and multifactorial, but the tendinopathy of the muscles gluteus medius and minimus, with or without reactive bursitis, is the main cause of pain in the lateral region of the hip.[2-4,6]

Regarding the diagnostic process, anamnesis and physical examination are preponderant at the clinical level, complemented with magnetic resonance imaging (MRI), when possible, which is

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The study was conducted at Hospital Ortopédico e Medicina Especializada (Home).
Correspondence: Fabrício Reichert Barin. Setor de Grandes Áreas Sul, Quadra 613, Conjunto C, Brasília, DF, Brazil, 70200730. fabriciobarin@gmail.com

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considered the gold standard for investigation, since it provides precious details of the relevant soft tissue structures.[7] Lequesne et al.[8] described the main semiological maneuvers used to aid in the diagnosis of gluteus medius and minimus tendinopathies. In the evaluation, the hip and knee are flexed at 90°, with subsequent external rotation of the hip and request of force generation towards internal rotation by the patient.[8]

The anatomical descriptions of the insertions of the mean and minimum glutes and their functions are important information for the functional evaluation and for the development of semiological tests.[9,10] Thus, the lack of an abduction movement during hip flexion in the Lequesne test does not allow the relaxation of the iliotibial complex, and may produce painful sensations related to other reasons that are not associated to the disorders of the gluteus medius and minimus.[11,12] Moreover, at the time of muscle contraction, the patient may not understand the correct movement of the maneuver, directly influencing its outcome. Given the context, finding a more effective and easy-to-implement approach becomes mandatory. Thus, our study proposes a simple and accurate test that can contribute to clinical decision-making. It presents two details which are different from the test proposed by Lequesne: the abduction of the hip in flexion, which is a maneuver that will make the iliotibial complex relax, and the fact that it is a strictly passive test, with no influence on the patient's poor execution on the outcome of the maneuver.

Therefore, this study aimed to describe a semiological method, by means of a specific maneuver, with the lower limb that can direct the semiological investigation to the most common painful cause in GTPS, such as tendinopathies of the gluteus medius and minimus, accurately and with easy execution.

METHODS

Study design and participants

This is a cross-sectional study, conducted between 2018 and 2019, involving 50 patients, 42 women and 8 men, with a mean age of 44.1 ± 13 years, diagnosed with Greater Trochanteric Pain Syndrome (GTPS) by experienced specialists in hip disorders. The participants had persistent pain in the lateral face of the hip for more than three months and were treated at the Orthopedics offices of the Orthopedic Hospital and Specialized Medicine (HOME) and Santa Luzia, in the municipality of Brasília, Federal District, Brazil. Among the patients, 26 had tendinopathy in the gluteus minimus, 14 tendinopathy in the gluteus medius and 17 trochanteric bursitis (trochanteric bursitis and tendinopathy in the gluteus minimus: three; trochanteric bursitis, tendinopathy in the gluteus medius, and tendinopathy in the gluteus minimus: 13 and isolated trochanteric bursitis: one), according to the MRI assessment performed (Table 1).

The inclusion criteria were the presence of pain in the anterior, lateral, or posterior region of the trochanter major, pain to the external rotation of the flexed hip at 90° with the remainder of joint mobility without alterations. Participants with the presence of joint pathologies such as coxarthrosis, avascular osteonecrosis of the femoral head, pain from spinal disorders or any arthropathy detected on radiographic examination, as well as undergoing hip surgery or who presented rupture of the tendons were excluded.

All patients were evaluated at the Orthopedic Hospital and Sports Medicine (HOME) or Hospital Santa Luzia. Before participation, the objectives, procedures, and risks of the study were explained to each participant. This study was approved by the Ethics Committee of the University Center of Brasília (UniCEUB) with protocol number 1,800,385. All participants signed an Informed Consent Form before the study.

Table 1. Sample characterization. Age (in years) was expressed by mean, standard deviation (SD), minimum and maximum, and categorical data by frequency (n) and percentage (%).

Age (years)		
Average ± SD (minimum - maximum)	44.1 ± 13 (19 – 67)	
Gender (n)		
Male	8	16%
Female	42	84%
Injured Hip Side (n)		
Right	25	50%
Left	25	50%
Lequesne Test (n)		
Positive Lequesne	20	40%
Difficulty in achieving the Lequesne	27	54%
FABREX test (n)		
Positive proposal	23	46%
Difficulty in conducting the proposed	2	4%
Pathologies of Great Trochanter Painful Syndrome (n)		
Tendinopathy in the gluteus medius	14	28%
Tendinopathy in the gluteus minimus	26	52%
Trochanteric bursitis	17	34%
Trochanteric bursitis and tendinopathy in the gluteus minimus	3	6%
Trochanteric Bursitis and Tendinopathy in the gluteus medius and minimus	13	26%
Trochanteric bursitis	1	2%

Instruments

Anthropometric data and clinical variables were initially collected via questionnaire.

MRI was used in the evaluation of the affected hip in all patients who presented the inclusion criteria, seeking to clarify the presence of tendinopathy and specifying the affected tendon.

In the physical evaluation, Lequesne test was applied to each participant of the research, considering itself as positive when the patient reported pain in the lateral region of the hip during the maneuver.[8]

The FABREX test (flexion, abduction, and external rotation), semiological evaluation proposed by our study, was then applied and documented in a simple questionnaire to evaluate the phases of the test.

Procedures

Initially, the participants were evaluated using a questionnaire containing the following analysis variables: name, age, gender, clinical complaint, and time of clinical complaint.

The MRI examination was evaluated by a specialist in musculoskeletal radiology, which was blinded to the results of clinical examinations. The two parts of the tendon of the middle gluteus, the tendon of the gluteus minimus, the trochanteric and subgluteal bursas were systematically analyzed on the images. Tendinopathy was defined as a thickening or signal increase in the tendon area seen on T2-weighted images, without discontinuity of the tendon. Bursitis was defined as a fluid collection in T2-weighted image located in a place containing bursa. MRI was adopted as the gold standard for comparison between the two semiological maneuvers (FABREX (proposed test) and Lequesne test) in the diagnosis of tendinopathies of the gluteus medius and minimus.

The physical evaluation was made by an orthopedist with long-standing experience in semiology, blinded to the results of the imaging examination. Lequesne test was applied leading the hip and knee to a flexion of 90°, with external hip rotation, requesting the patient to perform strength in the direction of internal rotation. The test result was considered positive when the patient reported pain in the lateral region of the hip during the maneuver.

Subsequently, the examiner applied the maneuver proposed by our study (FABREX). In phase one of the maneuver, the patient was positioned in supine position, with the lower limbs in full extension and the examiner positioned next to the hip to be evaluated (Figure 1). In phase 2 of the evaluation, the examiner holds the ankle with one hand and supports the patient's knee with the other, passively performing a 90° flexion of the hip and knee on the side to be examined. Upon completing hip and knee flexion, the examiner performed a hip abduction at 50° (Figure 2). In phase 3 of the proposed examination, the examiner stabilizes the knee and performs a passive external rotation smoothly (Figure 3).

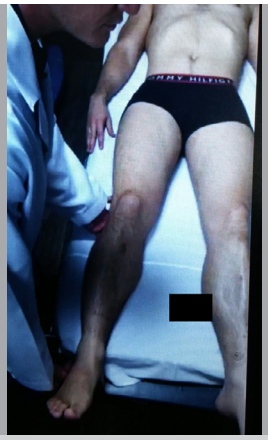

Figure 1. FABREX test phase 1. Patient positioned in supine position, with the lower limbs in full extension and the examiner positioned next to the hip to be examined.

Figure 2. FABREX test phase 2. The examiner holds the ankle with one hand and supports the patient's knee with the other, passively performing a 90° flexion of the hip and knee on the side to be examined. Upon completing hip and knee flexion, the hip was passively abducted at 50°.

Figure 3. FABREX test phase 3. Examiner stabilizes the knee and smoothly performs a passive external rotation.

The evaluation was considered positive when the patient referred to pain in the topography of the large trochanter, suggesting tendinopathy of the glutes medius and minimus. The participants were evaluated again by the same evaluator after 30 days.

Statistics

The normality of data distribution was determined by the Shapiro-Wilk test. Descriptive statistics (mean and standard deviation) was used to describe anthropometric and clinical characteristics. The first step of the analysis was to evaluate the accuracy of the FABREX and Lequesne test. Subsequently, the two semiological evaluations were compared regarding the difficulty of performance, analyzed by the Fisher's exact test.
The significance determination criterion adopted was the level of 5%. Statistical analysis was performed by SPSS software v. 22.0.

RESULTS

Table 1 shows the anthropometric and clinical characteristics of the 50 patients used in the accuracy analysis of the FABREX test. FABREX was positive in 12 out of 14 patients (sensitivity of 85.7%, specificity of 69.4% and agreement of 74%) for tendinopathy in the gluteus medius (Table 2) and 21 out of 26 (sensitivity of 80.8% specificity of 91.7% and agreement of 86%) for tendinopathy in the gluteus minimus (Table 3).

Table 2. Reliability analysis of the Lequesne and FABREX tests for the diagnosis of middle gluteus tendinopathy. Accuracy measures and coefficient Kappa.

Test/Result		Tendinopathy gluteus medius		Sens. (%)	Spec. (%)	PPV+ (%)	NPV- (%)	Accuracy (%)	Kappa	
		present	absent						value	*p-value*
LEQUESNE	pos	11	9	78.6	75	55	90	76	**0.47**	**0.0005**
	neg	3	27							
Proposed PHASE 3	pos	12	11	85.7	69.4	52.2	92.6	74	**0.46**	**0.0004**
	neg	2	25							

Sens: sensitivity; Spec: specificity; PPV+: positive predictive value; NPV–: negative predictive value; Accuracy: percentage of positive and negative concordances.

Table 3. Reliability analysis of the Lequesne and FABREX tests for the diagnosis of middle gluteus tendinopathy. Accuracy measures and coefficient Kappa.

Test/Result		Tendinopathy gluteus minimus		Sens. (%)	Spec. (%)	PPV+ (%)	NPV- (%)	Accuracy (%)	Kappa	
		present	absent						value	*p-value*
LEQUESNE	pos	17	3	65.4	87.5	85	70	76	**0.52**	**0.0001**
	neg	9	21							
Proposed PHASE 3	pos	21	2	80.8	91.7	91.3	81.5	86.0	**0.72**	**<0.0001**
	neg	5	22							

Sens: sensitivity; Spec: specificity; PPV+: positive predictive value; NPV–: negative predictive value; Accuracy: percentage of positive and negative concordances.

Regarding Lequesne test, the positive diagnosis was found in 11 out of 14 patients (sensitivity of 78.6%, specificity of 75%, with the percentage of agreement of 76%) for tendinopathy in the gluteus medius (Table 2) and 17 out of 26 (sensitivity of 65.4%, specificity of 87.5% and agreement of 76%) for tendinopathy in the gluteus minimus (Table 3).
Finally, FABREX showed 4% of difficulty in performing, while Lequesne test showed 54% ($p < 0.0001$) (Table 4). This analysis indicates that FABREX test presented less difficulty in execution, according to the hypothesis raised by our study.

Table 4. Comparison between the difficulty of the FABREX and Lequesne test. It provides the frequency (n) and the percentage (%) of the difficulty of performing the Proposed test according to the difficulty of performing Lequesne test (with difficulty and without difficulty). The inferential analysis was composed by Fisher's exact test.

PROPOSED	LEQUESNE				Total
	with difficulty		without difficulty		
	n	%	n	%	
with difficulty	2	7.4	0	0	2
without difficulty	25	92.6	23	100	48
Total	27		23		50

DISCUSSION

Semiological maneuvers have significant importance in orthopedic clinical practice, since they contribute to the diagnosis of lesions, confirming or eliminating specific musculoskeletal problems.[13]
Lequesne et al.,[8] described the main semiological methods used to direct the diagnostic investigation of tendinopathies in the gluteus medius and minimus,[8] most common painful cause in GTPS[14-16]. However, the movement of the lower limbs in the resistance internal rotation maneuver described by the author does not allow the relaxation of the iliotibial complex and may generate symptomatology for other reasons not related to the gluteus medius and minimus.[11-13]Thus, this study aimed to describe a simple and accurate test to assist in clinical decision-making and compare it with the resistance internal rotation maneuver described by Lequesne and with MRI findings.
The anthropometric and clinical characteristics of the population in our study were like those found in previous investigations,[6,8,13-15] presenting female as the predominant gender and the presence of tendinopathies of the gluteus medius and minimus as the greatest cause of pain in the Greater Trochanteric Pain Syndrome (GTPS). Trochanteric bursitis was indicated in 17 hips, but this pathology was identified in association with gluteal pathology in 16 hips, like the study conducted by Bird et al.,[13] in which trochanteric bursitis was a common and unidentified finding in the absence of gluteal pathology.[13]
FABREX showed high sensitivity and moderate specificity for tendinopathy in the gluteus medius and high sensitivity and specificity for tendinopathy gluteus minimus. As previously mentioned, the relaxation of the iliotibial complex, in association with the strictly passive performance of the test which exclude the patient's poor execution on the outcome of the maneuver, seem to be the main factors to the accurate results obtained.[11,12]
Lequesne et al.,[8] in their study involving 17 patients, evaluated the tests of unipodal support for 30 seconds and resisted internal rotation.[8] The evaluations showed high sensitivity and specificity (100%/97.3% and 88%/97.3%). However, the author indicates that these accuracy values can be associated to the presence of severe gluteal pathology (tendon rupture), present in 15 of the 17 patients evaluated. According to the study by Ganderton et al.,[6] maneuvers used for the diagnosis of gluteal tendinopathies, which involve muscle contraction against resistance of the therapist, demonstrate little sensitivity for pain reproduction. Bird et al.[13] reported that the resistance hip abduction test showed sensitivity of 72.7% and specificity of 46.2%; and the resistance internal rotation showed sensitivity of 54.5% and specificity of 69.2% for the diagnosis of gluteal tendinopathies.[13]
Based on the results of this study, the FABREX test, when positive, can be used to determine the diagnosis of gluteal tendinopathy (high specificity). Besides, it has high sensitivity, discarding the diagnosis when negative. Moreover, our analyses show that the proposed test presented less difficulty in execution, according to the hypothesis raised by this study. Since it is a passive maneuver, we believe that there is no influence of poor execution or non-understanding of the patient, thus generating less difficulty compared to the resistance internal rotation test described by Lequesne.
The limitations of this study may serve as guidance to determine future studies. Intra-examiner and inter-examiner reproducibility should be evaluated to consolidate the accuracy of FABREX. Although blinded to the MRI results, the evaluator knew that the patient had a diagnosis of GTPS, and this fact can be considered a bias. Future studies should be conducted with a homogeneous number of men and women.

CONCLUSION

This study constitutes the initial step to validate the proposed test. The FABREX test showed high sensitivity and moderate specificity for tendinopathy in the gluteus medius and high sensitivity and specificity for tendinopathy in the minimus gluteus, thus being considered a simple and accurate procedure to identify patients with or without gluteal tendinopathies.
However, further studies will be needed to evaluate its reproducibility to contribute to greater precision in the semiological evaluation of gluteal tendinopathy.

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UNDENATURED COLLAGEN TYPE II FOR THE TREATMENT OF OSTEOARTHRITIS OF THE KNEE

COLÁGENO NÃO HIDROLISADO TIPO II PARA TRATAMENTO DA OSTEOARTRITE DO JOELHO

David Sadigursky[1,2], *Victor Filardi Stolze Magnavita*[2], *Cloud Kennedy Couto de Sá*[2,3], *Henrique de Sousa Monteiro*[2], *Oddone Freitas Melro Braghiroli*[4], *Marcos Antônio Almeida Matos*[1]

1. Escola Bahiana de Medicina e Saúde Pública, Salvador, BA, Brazil.
2. Centro Universitário UniFTC, Salvador, BA, Brazil.
3. Hospital Geral Ernesto Simões Filho, Salvador, BA, Brazil.
4. Universidade de São Paulo, São Paulo, SP, Brazil.

ABSTRACT

Objective: To test the hypothesis that undenatured type II collagen (UC-II) relieves pain, quality of life, and joint function in women aged from 60 to 80 years with knee osteoarthritis. Methods: 53 patients in the UC-II treatment group (for 90 days) and 52 in the control group (without UC-II) were evaluated at 1, 30, and 90 days regarding health-related quality of life, pain, and function with questionnaires, anthropometric data, alignment, range of motion, and radiographic analysis. Results: Quality of life increased significantly in the Physical domain in the treatment *vs* control group. Also, there was a difference between the first and the last evaluation on the pain visual analog scale (−3.8 ± 1.8 versus −1.3 ± 2.0) and on the WOMAC score (−9.5 ± 11.9 versus −1.3 ± 11.1). No variation in the temporal evolution of the Mental domain was found. Conclusion: Pain, joint stiffness, and quality of life (Physical domain) improved with the inclusion of UC-II for 90 days to the therapeutic toolbox for knee osteoarthritis in individuals aged 60 to 80 years. ***Level of evidence II, Comparative Prospective Study.***

Keywords: Osteoarthritis. Collagen Type II. Quality of Life. Pain. Drug Therapy.

RESUMO

Objetivo: Testar a hipótese de que o colágeno não hidrolisado tipo II (UC-II) melhora a dor, qualidade de vida e função articular de indivíduos entre 60 e 80 anos com osteoartrite (OA) de joelho. Métodos: Cinquenta e três pacientes do grupo tratamento com UC-II (por 90 dias) e 52 do grupo controle (GC – sem UC-II) foram avaliados no tempo 0, 30 e 90 dias quanto à qualidade de vida em saúde, dor e função com os questionários, além de dados antropométricos, alinhamento, amplitude de movimento e análise radiográfica. Resultados: A qualidade de vida aumentou significantemente no domínio PCS no grupo tratamento versus controle. Houve ainda diferença entre a primeira e última avaliação na dor pela escala visual analógica (−3.8 ± 1.8 versus −1.3 ± 2.0) e no escore WOMAC (−9.5 ± 11.9 versus −1.3 ± 11.1). Não houve variação na evolução temporal do domínio MCS. Conclusão: Dor, rigidez articular e qualidade de vida (domínio físico) melhoram com a inclusão do UC-II por 90 dias ao arsenal terapêutico na OA do joelho em indivíduos de 60 a 80 anos. ***Nível de Evidência II, Estudo Prospectivo Comparativo.***

Descritores: *Osteoartrite. Colágeno Tipo II. Qualidade de Vida. Dor. Terapia Medicamentosa.*

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INTRODUCTION

Osteoarthritis (OA) is a joint disease common in adults of developed countries, causing musculoskeletal pain and disability resulting in limitation of daily activities,[1] depressed mood, and decrease on health-related quality of life.[2] Among the characteristics of this disease are bone remodeling, formation of osteophytes, wear of the articular cartilage, and varied degrees of synovitis that can affect any joint, especially hips and knees.[3,4]

Currently, clinical guidelines of health services value quality of life as a priority, particularly as part of the management of chronic disease.[5] Thus, the treatment of osteoarthritis prioritize pain relief and functional improvement of affected joints.[6] Therefore, the clinical treatment conducted in either a non-pharmacological or pharmacological manner is prioritized and surgical procedures are only recommended when traditional therapy fails.[7]

Some of the non-pharmacological strategies used for the treatment of osteoarthritis to reduce its negative effects on the osteoarticular

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The study was conducted at Centro Universitário UniFTC.
Correspondence: David Sadigursky. Centro Empresarial Thomé de Souza. Av. Antônio Carlos Magalhães, 3244, sala 616, Salvador, BA, Brazil, 418200000. davidsad@gmail.com

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system are based on physical exercise, high-protein diet, and weight loss. Such approaches have successfully improved quality of life, emotional well-being, and functional capacity.[3]

The most commonly used drug therapy includes anti-inflammatory drugs, analgesics, weak opioids, and corticosteroids. Although significant for symptom relief, the use of these elements does not predict changes to the evolution of osteoarthritis, and may also present restrictions due to the undesirable side effects.[8] Consequently, drugs currently referred to as disease-modifying antirheumatic drugs (DMARDs) or symptomatic slow-acting drugs for OA (SYSADOAs) – such as glucosamine, chondroitin, diacerein, and more recently type 1 and 2 collagens – have been gaining ground in the pharmacological therapeutic toolbox.[9]

It is believed that oral administration of undenatured type II collagen (UC-II) may improve the chronic inflammatory process by possibly regulating humoral immunity through the oral tolerance mechanism.[8] Small oral doses of antigen favor the suppression of cells mediated by immune responses, while high doses may produce peripheral tolerance. Several animal models have promoted satisfactory effects for autoimmune diseases.[10] These experimental models of arthritis have allowed us to conjecture the occurrence of an induction and migration pathway of Regulatory T cells (Tregs) to inflammatory areas and of cartilaginous damage. In vitro, Tregs produce anti-inflammatory cytokines, stimulating chondrocytes and synthesizing cartilage components.[11]

Although some studies indicate pain relief and improvement in the quality of life with the treatment of osteoarthritis using UC-II,[8,11] evidence on the clinical importance of this drug still requires further clinical studies.[12] Thus, this study aims to test the hypothesis that UC-II relieves pain, improves health-related quality of life, and joint function of individuals aged from 60 to 80 years with OA of the knee.

MATERIALS AND METHODS

This is a prospective and comparative clinical study with randomized block design.

Sample size

Sample size was calculated based on a decrease of 15.4% in the evaluation of the pain visual scale,[8] using a 10% margin of error and adopting 95% as significance level. With these parameters, a sample size of 60 individuals was adopted.

Inclusion and exclusion criteria

A total of 106 patients with knee osteoarthritis were selected and divided equally into two groups (with UC-II and control group without UC-II).

All participants were aged from 60 to 80 years, with clinical suspicion and radiological diagnosis of knee osteoarthritis, who accepted conservative/traditional treatment for the study period, and who agreed not to start another treatment.

Patient were excluded from the study if they had history of allergic reaction to any of the prescribed drugs, patients diagnosed with secondary inflammatory arthritis, previous knee infection, marked angular deformities, or if they discontinued the treatment stipulated for the study.

Procedures

Patients were randomly distributed into two groups. The experimental group used UC-II (40 mg daily) for 90 days, whereas the comparative group did not use the supplement. Both groups were submitted to standard physical therapy treatment (kinesiotherapy with closed chain exercises, twice a week) and received simple analgesic and weak opioid for pain relief, when necessary; participants also were followed by the institution's nutritionist for nutritional guidance and weight control.

Evaluations were performed on day 1 and after the intervention (30 and 90 days). In the initial evaluation, demographic and social data of the patient were collected, along with the level of physical activity, nutritional history, and use of medication and dietary supplements. During physical evaluation, data were collected on range of motion (degrees), alignment of the lower limb (degrees), joint effusion, and measurement of the thigh (cm), and abdominal perimeter (cm). Health-related quality of life assessments were performed with the SF-12 questionnaire (12-item Health Survey)[13]; pain levels, with the Visual Analog Scale (VAS); and function, with the Western Ontario an McMaster Universities Osteoarthritis Index (WOMAC) questionnaire.[14] Finally, all patients underwent radiographic evaluation (front, profile, monopodalic, and axial patellar support) for analysis of knee osteoarthritis degree, the Kellgren-Lawrence classification was used.[15]

In the final evaluation, in addition to the procedures common to the other moments of the evaluation, data were also recorded on the presence of UC-II side effects, the regular or non-use of the medication, and the effective follow-up of the recommended physical therapy treatment.

Instruments used

The SF-12—developed by Ware, Kosinski, and Keller[16] in 1994—is used to evaluate the different domains that determine health-related quality of life, considering the individual's perception of aspects of their physical and mental health in the last four weeks. The authors consider this questionnaire as more appropriate for evaluating individuals that are affected by diseases involving the musculoskeletal system.[13]

The WOMAC questionnaire was used to identify and to classify pain and joint stiffness and function[14]. The Visual Analog Scale (VAS) was used to measure pain.[17]

Statistics

The primary analysis was performed according to treatment intention and, therefore, included all patients. The baseline characteristics of the groups were reported using frequency and percentage for categorical variables and measures of central tendency and dispersion for continuous variables. Data normality was evaluated by graphical analysis and the Shapiro-Wilk test.

A mixed 2-way analysis of variance (ANOVA) evaluated the combined effect of time and intervention. The sample presented few outliers (maximum of four for mental domain of the SF-12 score), which were reviewed to confirm the values. After the end of the analyses, standardized residues were evaluated, confirming the outliers, which were then excluded to avoid influence on the results. When normality of residues was obtained, no relevant difference in the results was identified. Thus, after a joint critical analysis by the researchers and statistical consultants, it was chosen to maintain the results of the complete sample. Levene's test ($p < 0.05$) confirmed the homogeneity of variances, but WOMAC, VAS, and mental domain scores of the SF-12 did not present covariance homogeneity, which was evaluated by the Box's M test. Researchers chose to proceed with the analysis. In cases in which the Mauchly test indicated that the premise of scouting was not reached (WOMAC, EVA, and Mental domain of the SF-12), the Greenhouse-Geisser correction was adopted. All analyses were performed in the software Statistical Package for Social Sciences (SPSS, Chicago, IL, USA) 21.0 version.

<< SUMÁRIO

Ethical aspects

The participants were informed about the procedures performed and objectives of the study, being free to abandon the research at any time.

As benefits of participating in this research, adequate treatment and follow-up of patients with osteoarthritis of the knee were provided, while presenting the options available in the treatment of the disease.

The study followed the standards of ethical conduct for research contained in National Commission for Research Ethics – CONEP Resolution 466/12, and the project was approved by the FTC/IMES Research Ethics Committee.

All medications and treatments instituted were provided to the patient, as part of the list of medications used as a routine for all patients with osteoarthritis of the knee. The UC-II provided at a dose of 40 mg daily for a period of 90 days is considered as a nutraceutical, and is authorized for commercialization by the Brazilian Health Regulatory Agency – ANVISA, being part of the therapeutic toolbox demonstrated in the literature.

RESULTS

Data from one member of the control group were excluded for non-attendance at the last evaluation. Thus, 53 patients from the UC-II treatment group and 52 of the control group completed the study. As shown in Table 1, the groups were equivalent at the first moment.

There was no significant interaction between time and intervention in the mental domain of the SF-12 score, F (1.497, 154,232) = 0.007, p = 0.978, partial $\eta 2 < 0.001$, $\varepsilon = 0.749$. The analysis of the main effects of time did not indicate statistically significant difference during the temporal evaluation, F (1.497, 154,232) = 0.147, p = 0.801, partial $\eta 2 < 0.001$. The analysis of the intervention showed a statistically significant difference between the groups, F (1.103) = 9.424, p = 0.003, partial $\eta 2 < 0.084$.

In the other scores (WOMAC, VAS, and Physical domain of the SF-12) a statistically significant interaction between time and intervention was identified. Table 2 shows the results of simple main effects analyses.

DISCUSSION

The main results of our study indicate that pain, joint stiffness, and quality of life (Physical domain) improved with the inclusion of UC-II —to the therapeutic toolbox—for 90 days for knee osteoarthritis in individuals aged 60 to 80 years. However, the evaluation of the quality of life revealed that only the physical health component was significantly altered, and no difference was found in the intergroup mental health domain.

Osteoarthritis is the most prevalent form of arthritis in individuals older than 60 years,[15] with great repercussion on pain, functional capacity, and quality of life.[3,4] The current absence of a cure for this condition justifies the investment in resources to control and/or to mitigate its negative effects on individuals.[8,9]

Although further studies are necessary to determine the mechanism of UC-II on osteoarthritis cases, it is believed that UC-II activates immune cells in the Peyer's patch, with consequent induction of T cells in regulatory T cells (Treg) for type II collagen. When Treg cells migrate, they recognize type II collagen in the articular cartilage and secrete anti-inflammatory mediators and inducers of cartilage matrix repair.[18] Moreover, when compared to the other types of collagen, UC-II has active epitopes—smaller part of antigen with the potential to generate the immune response.[19]

Table 1. Baseline characteristics.

	Total (n = 105)	Control (n = 52)	UC2 (n = 53)	P-value
Sex				0.944
Female	69 (65.7)	34 (65.4)	35 (66.0)	
Male	36 (34.3)	18 (34.6)	18 (34.0)	
Age				
Mean ± Standard Deviation	68.6 ± 5.6	68.6 ± 6.0	68.7 ± 5.3	0.954
Affected side				0.285
Right	58 (55.2)	26 (50.0)	32 (60.4)	
Left	47 (44.8)	26 (50.0)	21 (39.6)	
LL Alignment				0.965
Valgus	18 (17.1)	9 (17.3)	9 (17.0)	
Varus	87 (82.9)	43 (82.7)	44 (83.0)	
Kellgren-Lawrence				0.750
2	42 (40.0)	20 (38.5)	22 (41.5)	
3	63 (60.0)	32 (61.5)	31 (58.5)	
Comorbidities				
Hypertension	33 (31.4)	16 (30.8)	17 (32.1)	0.885
Diabetes	6 (5.7)	2 (3.8)	4 (7.5)	0.678
Dyslipidemia	8 (7.6)	5 (9.6)	3 (5.7)	0.488
Hypothyroidism	4 (3.8)	1 (1.9)	3 (5.7)	0.618
BMI				
Mean ± Standard Deviation	27.9 ± 2.0	27.9 ± 1.5	27.9 ± 2.4	0.995

LL: lower limbs; BMI: body mass index. All data is showed as n (%) unless specified.

Table 2. Scores of function, pain, and quality of life in follow-ups of 1 and 3 months, with intergroup and temporal comparison.

Outcomes	Baseline	30 days	90 days	P-value	Difference 90 days - baseline
VAS					
Control	7.3 ± 0.7	6.2 ± 1.2	6.0 ± 1.8	< 0.001	–1.3 ± 2.0
UC-II	7.1 ± 0.9	5.1 ± 1.3	3.4 ± 1.6	< 0.001	–3.8 ± 1.8
p-value[1]	0.268	< 0.001	< 0.001		< 0.001
SF-12 Physical					
Control	31.5 ± 6.3	34.2 ± 7.8	33.0 ± 8.2	0.046	1.5 ± 7.2
UC-II	29.5 ± 7.1	36.5 ± 9.6	45.6 ± 8.0	< 0.001	16.0 ± 7.9
p-value[1]	0.145	0.180	< 0.001		< 0.001
SF-12 Mental					
Control	50.3 ± 10.0	50.7 ± 9.8	50.1 ± 11.0	*0.801	–0.2 ± 7.4
UC-II	44.8 ± 11.2	45.1 ± 10.3	44.8 ± 10.8	**0.003	0.0 ± 13.4
p-value[1]	-	-	-		0.924
WOMAC					
Control	58.6 ± 14.3	56.7 ± 13.5	57.3 ± 16.5	0.370	–1.3 ± 11.1
UC-II	54.0 ± 16.6	50.8 ± 14.6	44.6 ± 12.0	< 0.001	–9.5 ± 11.9
p-value[1]	0.140	0.034	< 0.001		< 0.001
WOMAC - Pain					
Control	11.9 ± 3.6	10.9 ± 4.0	11.0 ± 4.7	-	–1.0 ± 3.8
UC-II	12.0 ± 4.2	9.5 ± 4.0	5.4 ± 3.5	-	–6.6 ± 4.8
p-value[1]	0.901	0.073	< 0.001		< 0.001
WOMAC - Stiffness					
Control	3.6 ± 1.2	3.6 ± 1.3	3.7 ± 1.3	-	0.1 ± 1.1
UC-II	3.7 ± 1.4	3.5 ± 1.6	3.2 ± 1.3	-	–0.5 ± 0.9
p-value[1]	0.685	0.661	0.034		0.001
WOMAC - Function					
Control	40.7 ± 10.4	39.7 ± 9.6	40.3 ± 11.2	-	–0.4 ± 7.6
UC-II	37.3 ± 11.6	35.2 ± 11.5	34.2 ± 9.8	-	–3.0 ± 6.2
p-value[1]	0.114	0.029	0.004		0.056

P-value[1]: comparison between groups (at different times or temporal difference); p-value[2]: temporal comparison – ANOVA of repeated measures for each group separately (simple main effects) when non-significant interaction in 2-way ANOVA with repeated measures or for main effects; *Time; **Group.

Table 3. Differences in the scores of function, pain, and quality of life of baseline measurements, 1 and 3 months with comparison between groups and 95 % CI.

	(3 months - baseline)	(1 month - baseline)	(3 months - 1 month)
VAS	–2.4 (–3.2 - –1.7) < 0.001	–0.9 (–1.5 - –0.4) 0.002	–1.5 (–2.3 - –0.7) < 0.001
Control	–1.3 2.0	–1.1 1.4	–0.2 2.3
UC-II	–3.8 1.8	–2.0 1.5	–1.7 1.7
SF-12 Physical	14.5 (11.6 - 17.5) < 0.001	4.2 (1.6 - 6.9) 0.002	10.3 (7 - 13.5) < 0.001
Control	1.5 7.2	2.7 6.2	–1.2 8.9
UC-II	16.0 7.9	6.9 7.5	9.1 7.8
SF-12 Mental	0.2 (–4 - 4.4) 0.924	0 (–2.3 - 2.4) 0.981	0.2 (–3.6 - 4) 0.928
Control	–0.2 7.4	0.3 4.6	–0.6 5.8
UC-II	0.0 13.4	0.4 7.2	–0.4 12.6
WOMAC	–8.2 (–12.6 - –3.7) < 0.001	–1.4 (–4.7 - 1.9) 0.411	–6.8 (–10.5 - –3.1) < 0.001
Control	–1.3 11.1	–1.9 6.7	0.6 11.4
UC-II	–9.5 11.9	–3.3 10.2	–6.2 7.3
WOMAC Pain	–5.7 (–7.3 - –4) < 0.001	–1.5 (–2.8 - –0.2) 0.024	–4.2 (–5.4 - –2.9) < 0.001
Control	–1.0 3.8	–1.0 2.9	0.0 3.3
UC-II	–6.6 4.8	–2.5 3.8	–4.1 3.4
WOMAC Stiffness	–0.6 (–1 - –0.3) 0.001	–0.2 (–0.6 - 0.1) 0.195	–0.4 (–0.8 - 0) 0.033
Control	0.1 1.1	0.0 0.8	0.1 0.9
UC-II	–0.5 0.9	–0.2 1.0	–0.3 1.1
WOMAC Function	–2.6 (–5.3 - 0,1) 0.056	–1.1 (–3.7 - 1,4) 0.381	–1.5 (–4 - 1) 0.244
Control	–0.4 7.6	–1.0 4.9	0.6 7.2
UC-II	–3.0 6.2	–2.1 7.8	–0.9 5.9

All data is showed as ± standard deviation unless specified.

Crowley et al.[8] evaluated the safety and efficacy of UC-II in the treatment of knee osteoarthritis compared to a combination of other nutraceuticals. For this purpose, they performed the 90-day protocol and found that UC-II was better than the combination of glycosamine and condroitin on physical capacity (indicated, for example, by the improvement in walking on a flat surface and in performing heavy household tasks), functionality, and several aspects of pain. Notably, unlike our study, Crowley et al.,[8] included young adults and their sample could not represent the population with a greater intensity of pain.

More recently Bakilan et al.[20] not only evaluated the effect of UC-II associated with acetaminophen on symptomatology in knee osteoarthritis, but also pioneered its effect on biological markers of cartilage degradation. In this study, the follow-up period was also 90 days and patients aged 45 to 70 years were included. Despite finding improvement in indicators of pain, function, and health-related quality of life, no improvement in biochemical markers of cartilage degradation was identified. The authors highlight the sample size and the short follow-up time as main limitations of the study.

In an experimental study with longer follow-up period (180 days) and analyses of cartilage regeneration markers, Lugo et al.[11] evaluated the efficacy and tolerability of UC-II in osteoarthritis. Significant improvement in pain, stiffness, and functionality was observed, but no intra- and intergroup distinction was found for cartilage regeneration and inflammatory markers and synovial fluid biomarkers.

Although pain, functioning, and quality of life are variables that are related to each other, in our study the use of UC-II showed a significant change in pain perception, but no statistically significant differences were detected between the groups in the Mental domain of the SF-12 quality of life score and functioning by WOMAC in the evaluated period. Also, in previous studies,[8,11] no relationship was found for the modification of functioning, quality of life, and pain scores with markers of morphofunctional cartilage health.

The greatest limitation of our study was the non-inclusion of placebo element in the control group. Although the subjects were randomized into the groups and their equivalence was demonstrated by comparing several variables before the beginning of the protocols, it is known that placebo can play an important role and, consequently, become a confounding factor. In a previous study with nutraceuticals, a high response rate to placebo was found.[21]

Another important factor concerns information bias. Firstly, the evaluators were not blind. Secondly, although validated instruments have been used and have been employed by previously trained evaluators, the use of questionnaires presents potential information bias due to possible distortions in the interpretation of questions and answers, besides presenting possible cultural bias in the measurements, justified by differences in national and cultural contexts.[22]

Finally, we emphasize the need for further studies with longer periods using the UC-II, with inclusion of objective measures, with a sample of sufficient size to stratify groups regarding the severity of pain and involvement of knee osteoarthritis. We also suggest the inclusion of long-term UC-II tolerability assessment.

CONCLUSION

The main results of our study indicate that pain, joint stiffness, and quality of life (Physical domain) improved with the inclusion of UC-II to the therapeutic toolbox for 90 days for knee osteoarthritis in individuals aged 60 to 80 years.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. DS: intellectual concept of the article, preparation of the research project, writing of the article, review, and patients' follow-up; VFSM: data collection, data analysis, and writing of articles; CKCS, HSM, and OFMB: statistical analysis and review of the article; MAAM: review of the article and of any intellectual concept of the article.

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FUNCTIONAL EVALUATION OF THE RESULTS OF REPAIR OF PARTIAL AND COMPLETE ROTATOR CUFF TEARS

AVALIAÇÃO FUNCIONAL DOS RESULTADOS DO REPARO DAS LESÕES PARCIAIS E COMPLETAS DO MANGUITO ROTADOR

THIAGO STORTI[1,2], ANNA BEATRIZ SALLES RAMOS[3], RAFAEL SALOMON SILVA FARIA[1], GUILHERME BARBIERI LEME DA COSTA[4], ALEXANDRE FIRMINO PANIAGO[1]

1. Instituto do Ombro de Brasília, Brasília, DF, Brazil.
2. Hospital Ortopédico e Medicina Especializada, Instituto de Pesquisa e Ensino, Brasília, DF, Brazil.
3. Centro Universitário de Brasília, Brasília, DF, Brazil.
4. Clínica Médica Barbieri e Vitaliano, Orlândia, SP, Brazil.

ABSTRACT

Objective: To perform a comparative analysis of the results of arthroscopic surgical treatment of partial and complete rotator cuff (RC) injuries. Methods: Eighty-four shoulders with partial or complete RC tear that underwent arthroscopic repair were retrospectively evaluated using UCLA and Constant scores, assessment of strength, and range of motion. Fifty-seven shoulders with complete injuries and 27 with partial injuries were identified. Results: Age (p = 0.007) was higher in those with complete lesions (mean 61.4 ± 7.9 years), compared to those with partial lesions (mean 56.5 ± 7.1 years). The complete injuries group showed a higher elevation difference in relation to the contralateral shoulder compared to the partial injuries group (partial injuries: −1.1% vs complete injuries: −16.5%), statistically significant difference (p = 0.0004). In addition, complete lesions presented 96.5% of excellent and good results and a median of 35 in the UCLA score and partial lesions presented 84.6% of good/excellent results and a median of 34. The Constant score showed 91.2% of satisfactory results in complete lesions and 77% in partial ones. Conclusion: Arthroscopic repair shows satisfactory functional results for both partial and complete rotator cuff injuries, with similar outcomes between groups. ***Level of Evidence III, Retrospective Comparative Study.***

Keywords: Rotator Cuff. Arthroscopy. Injury.

RESUMO

Objetivo: Realizar análise comparativa dos resultados do tratamento cirúrgico artroscópico das lesões parciais e completas do manguito rotador (MR). Métodos: Foram avaliados retrospectivamente 84 ombros com ruptura parcial ou completa do MR submetidos ao reparo artroscópico, por meio dos escores UCLA e Constant, avaliação de força e amplitude de movimento. Foram identificados 57 ombros com lesão completa e 27 com lesão parcial. Resultados: A idade (p = 0,007) foi maior naqueles com lesões completas (média 61,4 ± 7,9 anos), em relação às lesões parciais (média 56,5 ± 7,1 anos). O grupo lesões completas demonstrou diferença de elevação em relação ao ombro contralateral maior comparado ao grupo de lesões parciais (lesões parciais: −1,1% vs lesões completas: −16,5%), diferença estatisticamente significativa (p = 0,0004). Além disso, foi demonstrado 96,5% de resultados excelentes e bons e mediana de 35 no escore UCLA em lesões completas e 84,6% de resultados bons/excelentes e mediana de 34 nas lesões parciais. O escore Constant mostrou 91,2% de resultados satisfatórios nas lesões completas e 77% nas parciais. Conclusão: O reparo artroscópico mostra resultados funcionais satisfatórios tanto nas lesões parciais quanto nas completas do manguito rotador, com desfechos semelhantes entre os grupos. ***Nível de Evidência III, Estudo Retrospectivo Comparativo.***

Descritores: *Manguito Rotador. Artroscopia. Lesão.*

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INTRODUCTION

Rotator cuff (RC) injury is more frequent in the age group above 40-60 years and is considered the main cause of pain and dysfunction in the shoulder.[1]

RC lesions can be classified in several ways: according to their thickness (partial and complete), the size of the lesion when complete (small < 1 cm; mean of 1-3 cm; large 3-5 cm; and massive > 5 cm),[2,3] chronology (acute, chronic, and acute-on-chronic), and etiology (degenerative, associated with instabilities, traumatic, and microtraumatic).[3] Additionally, partial lesions can also be classified according to their location (intratendinous, articular or bursal) and according to their thickness and size (grade I ≤ 25% or up to 3 mm; grade II = 50% or 3 to 6 mm; and grade III > 6 mm).[3,4]

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

The study was conducted at Instituto Ortopédico Camanho.
Correspondence: Thiago Medeiros Storti. Quadra 102 norte, Lote 5, Apt. 202 A, Brasília, DF, Brazil, 71907000. thiago_storti@hotmail.com

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Partial lesions are approximately twice as common as complete lesions.[5] They are generally symptomatic and there is a consensus that lesions affecting more than 50% of the tendon thickness should be treated surgically.[6]

Most authors argue that the repair of RC lesions leads to more definitive and satisfactory results.[7] The repair of minor lesions is more likely to heal completely when compared to repair of larger lesions.[8-10] However, even partial, or complete lesions, small and medium, have a rate of up to 20% of healing failure, which is often associated with poor clinical results.[11]

According to the pathology natural history, partial RC lesions tend to evolve to complete lesions with time, if left untreated without definitive surgical repair.[12] In the study by Huberty et al.,[13] in which they evaluated 489 consecutive arthroscopies for rotator cuff repair, a higher stiffness index was obtained in patients subjected to partial lesion repair (13.5%) and it was concluded that this type of lesion is one of the risk factors for stiffness.

Thus, our study aims to evaluate and compare the results of arthroscopic surgical treatment of partial and complete RC lesions. Our hypothesis is that the functional results will not be different between the two groups studied.

METHODOLOGY

Study design and participants

This is a retrospective cross-sectional study. During the period from 2011 to 2018, 465 patients underwent arthroscopic RC repair. Patients older than 18 years of age, with a minimum of 6 months of follow-up, and that agreed to participate were included in the study. Those who underwent other procedures during surgery, such as labrum repair, acromioplasty, biceps tenotomy and tenodesis, and cases of large or extensive complete lesions were excluded. After applying the criteria (inclusion and exclusion), 82 patients agreed to participate in the study and to attend the hospital to be reevaluated, totaling 84 shoulders.

Ethical approvals

All participants signed the informed consent form. This study was submitted to the evaluation and approval of the Human Research Ethics Committee, with opinion number 2,444,726, CAAE: 80401317.3.0000.0023.

Surgical procedure

The surgeries were performed by three specialists surgeons, with extensive experience in the field. The technique used was the single-row fixation, as described by Burkhart, in which the tendon is tied to anchors arranged in a single row.[14] In the case of partial ruptures, the lesions were completed and fixed.

Postoperative rehabilitation

All patients followed the same standardized protocol. The movement of the elbow, wrist, and hand were stimulated from the immediate postoperative period. The patients remained immobilized with an arm sling for six weeks; after this period, they gradually began gaining the range of motion of the shoulder. Muscle strengthening began only after the 12th week.

Analysis outcomes

Data collection was performed in two moments. The following were evaluated: A) demographic, surgical, and RC lesion characteristics; B) functional variables, muscle strength, and pain.

The demographic and characterization data of the RC lesions were obtained through analysis of electronic medical records. The variables collected were age, gender, dominance and laterality, follow-up time, smoking habits, diabetes mellitus, pain at follow-up, type of injury (total or partial), classification of the lesion (small or medium, for complete lesions and bursal, joint or intratendinous, for partial lesions), number of tendons addressed, and number of anchors. The size and classification of the lesions were obtained from preoperative magnetic resonance imaging (MRI) and/or surgical descriptions. When there was divergence between the MRI report and the surgical description, the intraoperative description was considered.

The second moment of evaluation was performed in person, where strength (kg) and amplitude (°) of the elevation, lateral rotation, and medial rotation of the shoulder were measured. Strength was measured by a digital dynamometer in Kg, while amplitude was measured by goniometry in degrees. Furthermore, during this evaluation, the functional capacity scores were applied according to the University of California at Los Angeles Shoulder Rating Scale (UCLA)[12] and the Constant-Murley Score (CONSTANT).[15] The aforementioned scales (UCLA and CONSTANT) were translated into Portuguese and culturally adapted to the Brazilian population[16] and are frequently used to assess upper limbs function in patients with rotator cuff injuries.[17,18]

After tabulation of the data, the individuals were divided into two groups, based on the preoperative classification of the lesion: partial or complete (small and medium).

Statistics

The descriptive analysis presented the observed data in the form of tables, expressed by the measures of central tendency and of dispersion appropriate for numerical data and of frequency and percentage for categorical data.

The comparison between the two subgroups of lesion size (partial and complete), regarding clinical variables, surgery, amplitude and strength measurements, and the UCLA and Constant scores, were performed using the following tests: the Student's *t*-test was applied for independent samples; the Mann-Whitney test, for numerical variables; and the chi-square (χ^2) or Fisher's exact test, for categorical variables.

A nonparametric method was applied, since all variables, except age, presented non-Gaussian distribution, according to the rejection of the normality hypothesis by the Shapiro-Wilk test. The significance determination criterion adopted was of 5%. Statistical analysis was processed by statistical software SAS® System, version 6.11 (SAS Institute, Inc., Cary, North Carolina).

RESULTS

Demographic and surgical characteristics among the groups

The sample consisted of 84 shoulders (82 patients). Of these, 57 (67.86%) correspond to cases of complete lesions and 27 (32.14%) to partial lesions. When the demographic characteristics and the surgical profile were compared between the groups, a statistically significant difference was observed for age (partial lesions: 56.5 ± 7.1 *vs* complete injuries: 61.4 ± 7.9), higher in the group of complete lesions ($p = 0.007$); and for the number of anchors used (partial lesions:2 *vs* complete lesions: 3), superior in the group of complete lesions ($p = 0.002$). Table 1 shows other variables, which were statistically similar.

Characteristics of rotator cuff lesions between groups

Among the partial ruptures, most were bursal-sided (77.7%). Regarding the size of the complete lesions, there was a slight predominance of the medium lesions (54.3%). The lesions were of traumatic etiology in 33.3% of partial lesions cases and in 30.9% of complete lesions (Table 1).

Table 1. Clinical and surgical variables.

Variable	total	partial	complete	p-value
Age (years)				
Mean ± Standard Deviation	59.8 ± 7.9	**56.5 ± 7.1**	**61.4 ± 7.9**	**0.007**
Operated shoulder				
Right	47 (56.0%)	14 (51.9%)	33 (57.9%)	0.60
Left	37 (44.0%)	13 (48.1%)	24 (42.1%)	
Dominant limb				
Right	76 (90.5%)	25 (92.6%)	51 (89.5%)	0.49
Left	8 (9.5%)	2 (7.4%)	6 (10.5%)	
Surgical position				
beach chair	47 (56.0%)	18 (66.7%)	29 (50.9%)	0.17
lateral decubitus	37 (44.0%)	9 (33.3%)	28 (49.15%)	
Type of injury				
degenerative	56 (68.3%)	18 (66.7%)	38 (69.1%)	0.82
traumatic	26 (31.7%)	9 (33.3%)	17 (30.9%)	
Number of anchors				
median (Q1-Q3)	3 | 2 | - | 4	**2** | 2 | - | 4	**3** | 3 | - | 4	**0.002**

Age (years) was expressed by mean and standard deviation and compared by Student's *t*-test for independent samples and number of anchors by median and interquartile range (Q1-Q3) and compared by Mann-Whitney test, since it did not present normal distribution. On the other hand, categorical data were expressed by frequency (n) and percentage (%) and compared by the chi-square (χ^2) or Fisher's exact test.

Comparison between the group's variables for motion range, muscle strength, and functional scores

A statistically significant difference was observed in the anterior elevation measure compared to the contralateral shoulder between the groups (p = 0.0004). The group of complete lesions showed a difference in elevation in relation to the greater contralateral shoulder compared to the group of partial lesions (partial lesions: −1.1% *vs.* complete lesions: −16.5%). The other variables of muscle strength and function (range of motion – ROM) were similar (p > 0.05) (Table 2). Regarding functional scores, it was observed that there was no significant difference, at the level of 5%, between the groups. In the UCLA score, the subgroup of complete lesions presented a median of 35, while the subgroup of partial lesions had a median of 34 (p = 0.085), with complete lesions showing 96.5% of good and excellent results, while partial lesions showed 84.6% of good/excellent results (p = 0.13). Regarding the Constant score, the complete lesions showed 91.2% of satisfactory results and a median of 87, while partial lesions showed 77% of satisfactory results (p = 0.12) and a median of 84 (p = 0.67) (Table 3).

DISCUSSION

It is widely accepted that arthroscopic surgical treatment of partial and complete RC lesions – smaller than 3 cm – brings excellent functional results with high healing index.[19] However, some current studies have shown an inadequately high rates of a new rupture, even for minor lesions. Chung et al.[20] reported 27.3% of healing failure in patients with small rotator cuff lesions, partial and complete. Kamath et al.[21] reported 12% of complete reruptures in the postoperative evaluation of patients with partial lesions subjected to arthroscopic repair, after evaluation with ultrasound.

In our study, we obtained 92.8% of good/excellent in the UCLA score and 86.7% of satisfactory results by constant score. Patients recovered 90.4% of the lifting force and 96.4% of the lateral rotation force in relation to the contralateral limb.

Moreover, we evaluated and compared the results of arthroscopic surgical treatment of partial and complete RC ruptures, which few studies in the literature have done, especially in the national literature, since there are no studies on the topic.

Table 2. Measurements of range of motion and strength in the total sample and according to the size of the lesion.

Variable	Total		Partial		Complete		p-value
Operated shoulder							
Elevation – ROM	**170**	146 - 180	**165**	130 - 180	**170**	151 - 180	0.46
External rotation – ROM	**60**	42 - 71	**54**	40 - 70	**62**	45 - 72	0.58
Internal rotation – ROM	**68**	45 - 80	**70**	45 - 80	**65**	48 - 80	0.66
Elevation – force	**5**	3 - 8	**5**	3 - 9	**5**	4 - 8	0.95
External rotation – force	**5**	3 - 7	**4**	3 - 7	**5**	4 - 7	0.50
Internal rotation – force	**6**	4 - 10	**6**	4 - 10	**7**	5 - 9	0.43
Contralateral shoulder							
Elevation – ROM	**170**	154 - 180	**168**	149 - 180	**170**	159 - 180	0.58
External rotation – ROM	**70**	50 - 80	**70**	49 - 80	**70**	51 - 80	0.74
Internal rotation – ROM	**70**	54 - 80	**70**	58 - 80	**70**	53 - 80	0.59
Elevation – force	**6**	4 - 8	**6**	4 - 9	**6**	4 - 8	0.86
External rotation – force	**5**	3 - 7	**6**	3 - 7	**5**	4 - 7	0.98
Internal rotation – force	**7**	4 - 9	**6**	4 - 10	**7**	4 - 9	0.84
Relative delta (%)*							
Elevation – ROM	**–15.5**	–21 - –2	**–1.1**	–16 - 0	**–16.5**	–21 - –11	0.0004
External rotation – ROM	**–8.1**	–25 - 0	**–11.9**	–27 - 0	**–6.3**	–18 - 0	0.45
Internal rotation – ROM	**–4.5**	–14 - 0	**–4.0**	–20 - 0	**–4.9**	–14 - 0	0.41
Elevation – force	**–9.6**	–24 - 11	**–14.3**	–20 - 0	**–9.1**	–27 - 11	0.73
External rotation – force	**–3.6**	–22 - 0	**–11.1**	–33 - 29	**0**	–21 - 0	0.76
Internal rotation – force	**0**	–12 - 16	**0**	–20 - 17	**0**	–9 - 16	0.27

Data were expressed by median and interquartile range (Q1-Q3) and compared by the Mann-Whitney test.
*Relative delta (%) expresses the variation between the operated and contralateral shoulder relative to the contralateral one: (operated-contralateral) / contralateral ×100
ROM: range of movement in °.
Unit of force (kg).

Table 3. UCLA and Constant questionnaire in the total sample and according to the size of the lesion.

Variable	Total		Partial		Complete		p-value
UCLA							
median and (Q1-Q3)	35	33-35	34	31-35	35	33-35	0.085
UCLA class							
Excellent	51 (61.5%)		13 (50.0%)		38 (66.7%)		0.13
Good	26 (31.3%)		9 (34.6%)		17 (29.8%)		
Regular	5 (6.0%)		3 (11.5%)		2 (3.5%)		
Poor	1 (1.2%)		1 (3.9%)		0 (0%)		
Constant							
median and (Q1-Q3)	87	79-93	84	71-95	87	79-92	0.67
Constant class							
Excellent	30 (36.1%)		10 (38.5%)		20 (35.1%)		0.12
Good	26 (31.3%)		6 (23.1%)		20 (35.1%)		
Satisfactory	16 (19.3%)		4 (15.4%)		12 (21.0%)		
Regular	8 (9.7%)		3 (11.5%)		5 (8.8%)		
Poor	3 (3.6%)		3 (11.5%)		0 (0%)		

Data were expressed by median and interquartile range (Q1-Q3) and compared by the Mann-Whitney test. Categorical data were expressed as frequency (n) and percentage (%) and compared using Fisher's exact test.

According to Diebold et al.,[17] the relationship between age and RC lesion is linear in patients between 50 and 69 years of age, with an increase of 5% between decades, and increases substantially after 70 years of age. In this study, age (p = 0.007) was significantly higher in the subgroup with complete lesions, with a mean of 61.4 ± 7.9 years, in relation to partial lesions, which have a mean age of 56.5 ± 7.1. This is due to the natural history of rotator cuff pathology, in which lesions tend to progress with advancing age

<< SUMÁRIO

and chronic involvement, resulting in the progression of partial lesions into complete lesions and a higher rate of complete lesions in the older population.[11]

In our study, the range of motion showed no significant difference between the groups, whether in elevation or in lateral or medial rotation. As an exception, it was observed that the subgroup with complete lesion showed significantly lower comparative elevation of the contralateral shoulder ($p = 0.0004$) when compared with the subgroup with partial lesion. We also observed that in the group of partial lesions, the lifting force, lateral rotation, and medial rotation was of 85.7%, 88.9%, and 100% in relation to the contralateral shoulder, respectively. In the group of complete lesions, the lifting force was of 90.9% and the lateral and medial rotation forces were of 100% in relation to the contralateral shoulder. However, we observed no significant difference between the groups. Peters et al.,[22] did not obtain significant differences between groups in limb elevation. They showed, however, a greater range of abduction and lateral rotation in the group of complete lesions 6 months after the surgical procedure ($p < 0.05$).

In the subgroup with complete lesions, our study presented 96.5% of excellent and good results with the UCLA score. Other studies showed similar results in patients with complete RC lesions, such as the study conducted by Miyazaki et al.[9] that evaluated 163 patients aged 65 years or older who had complete RC lesions subjected to arthroscopic repair, presenting 96.4% of excellent and good results. In addition to these studies, one by Veado et al.,[18] which evaluated 28 patients over 65 years of age, reported 89.28% of excellent and good results. In the group of partial lesions, we observed 84.6% of good and excellent results, showing no statistically significant difference compared to complete lesions (96.5%). In the study by Godinho et al.,[23] the authors obtained 97% of good and excellent results with arthroscopic surgical treatment of partial RC lesions in 64 patients.

Although there was no significant difference, the index of satisfactory functional results was higher in the group of complete lesions, different from what we could assume. By the UCLA score, we obtained 84.6% of good/excellent results in partial lesions, while we obtained a score of 96.5% in the complete lesions. According to the constant score, we obtained 77% of satisfactory results in the group of partial lesions and 91.2% in the group of complete lesions. Surprisingly, some articles have shown a higher rate of healing failure in the repairs of partial lesions, compared to complete lesions < 3 cm. Chung et al.[20] obtained a healing failure rate observed by computed arthrotomography of 35.3% in partial lesions and 14.3% in complete lesions. They believe that this may be due to the higher degree of tendinosis observed in partial lesions in relation to complete lesions.

Among the limitations of our study are the fact that it is a retrospective study, with a relatively low number of evaluated patients, with a disproportional number of patients between the groups, making any type of comparison of their results difficult. Among the strengths, we highlight the postoperative analysis performed with several variables of shoulder functionality

CONCLUSIONS

Arthroscopic repair shows satisfactory results for the treatment of RC ruptures, both for partial and complete lesions, small and medium, without large functional differences between the two groups.

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PECTORALIS MAJOR TENDON INJURY: RECONSTRUCTION USING BONE TUNNEL AND ANCHORS

LESÃO DO TENDÃO DO PEITORAL MAIOR: RECONSTRUÇÃO UTILIZANDO TÚNEL ÓSSEO E ÂNCORAS

José Carlos Garcia Junior[1], *Eduardo Ferreira Cordeiro*[1], *Hilton Vargas Lutfi*[1], *Maurício de Paiva Raffaelli*[1], *Maurício Salomão Fadel*[1], *Márcio Eduardo Kozonara*[1]

1. NAEON Institute, São Paulo, SP, Brazil.

ABSTRACT

Objective: This study aims to assess a new technique used for pectoralis major reconstruction using bone tunnel and fixation with metallic anchors in the contralateral cortical bone. Methods: Patients who had undergone post-surgical reconstruction of the pectoralis major at least 24 months before were assessed by the UCLA Shoulder Score and the Simple Shoulder Test and compared with the contralateral side by manual goniometry. Subgroup analysis was also performed between grafted and non-grafted patients. Results: 13 patients fulfilled the inclusion criteria. The average UCLA score was 34.77 ± 0.12, compared with the standard 27 of good and excellent results $p < 0.0001$. The Simple Shoulder test mean was 11.92 ± 0.08. Grafted and non-grafted subgroups had no statistical differences for UCLA $p = 0.58$ and Simple Shoulder Test $p = 1.00$. Long term losses for elevation or external rotation were lower than 5º. No lesions recurred. All patients returned to their physical activities with no restrictions. Conclusion: The pectoralis major reconstruction technique using a bone tunnel and metallic anchors in the contralateral cortical bone was effective. However, its execution needs special care to avoid complications. ***Level of Evidence IV, Case Series.***

Keywords: Pectoralis Muscles. Suture Anchors. Athletic Injuries.

RESUMO

Objetivo: Avaliar, em uma série de casos, o uso da técnica de reconstrução do músculo peitoral maior através de túnel ósseo na cortical umeral anterior, feito no local de inserção original desse tendão, com fixação tendínea, usando âncoras metálicas na cortical contralateral. Métodos: Foram avaliados pacientes com mais de 24 meses depós-operatório de reconstrução do tendão do peitoral maior através do escore da UCLA, do teste simples de ombro e da goniometria manual comparativa com o lado contralateral. Foram também avaliados e comparados os subgrupos uso de enxerto versus sem enxerto usando os testes de qualidade de vida e goniometria mencionados acima. Resultados: De todos os pacientes operados pelo cirurgião sênior do serviço, 13 alcançaram os critérios de inclusão e foram incluídos nesse trabalho. O escore da UCLA foi de 34,77 ± 0,12, comparado com o padrão 27 de bons e ótimos resultados $p < 0,0001$. A média para o teste simples de ombro foi de 11,92 ± 0,08. Com relação ao uso de enxerto, não houve diferenças entre os subgrupos com e sem enxerto, $p = 0,62$ para o escore da UCLA e $p = 0,35$ para o teste simples de ombro. Não houve perda de elevação ou rotação externa superior a 5º nem relesões. Todos os pacientes retornaram às atividades físicas. Conclusão: A técnica de reconstrução do tendão do peitoral maior com túnel ósseo e fixação na cortical contralateral com âncoras demonstrou-se efetiva, mas sua execução necessita cuidado afim de evitarem-se complicações. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Músculo Peitoral. Âncoras de Sutura. Traumatismos em Atletas.*

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INTRODUCTION

Lesions of the pectoralis major muscle were first described in 1822 by Patissier.[1] Until 2012, medical literature had reported around 200 cases only of this type of injury.[2] Although uncommon, such lesions have been more prevalent in recent decades, mainly in 20 to 40-year-old males. Its main causes are car accidents[3] and an increasing number of sports, including: weightlifting, especially straight supine; rugby; boxing; and some throwing sports.[2,3] The most common rupture mechanism is an excessive eccentric contraction with pectoral extension after resisting a load applied with the arm in abduction and extension position.[1-5]

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The study was conducted at NAEON Institute and at Hospital Moriah.
Correspondence: José Carlos Garcia Junior. Avenida Ibirapuera, 2907, room 1206, São Paulo, SP, Brazil, 04028001. josecarlos@naeon.org.br

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More individuals seem to have suffered total rupture of the pectoral caused by abuse of anabolic steroids for rapid muscle mass gain, possibly because of disproportion in the cross-sectional area of the tendon and the muscle, changes in sensitivity to pain and tendon stiffness, less energy absorption, and fail caused by stretching loss.[6]

The pectoralis major is a muscle with two parts: the clavicular and the sternal, the latter most commonly involved in ruptures.[1] This lesion is diagnosed by clinical diagnosis, i.e., using only anamnesis and physical examination.[7] Imaging such as ultrasound and magnetic resonance are useful in cases of doubt or chronic lesions and to establish the site and extension of the pectoral lesion.[1] Radiographic examination is useful to assess cases with bone avulsion or which need fracture differentiation.[1,5]

During clinical examination, patients usually feel a sudden pain in the medial and cranial face of the arm and/or the thorax associated with a click, with or without ecchymosis. Loss of the axillary fold causes muscle asymmetry,[2,3] which is more visible when patients perform limb abduction by flexing against resistance, especially with the shoulder in external rotation or resisting forced adduction by the examiner.

Compared to conservative treatment, surgery leads to improved function and is usually recommended for young individuals, athletes, and those with aesthetic complaints.[8] Non-surgical treatment is best indicated for patients with partial or muscle mass rupture, patients with low functional demand, and older adults.[1,8]

Surgical options include fixation of the tendon to the humerus with bone tunnels or suture anchors; suture of the tendon of the ruptured sternal head with an intact clavicular head tendon; screws with washers; "endobuttons;" interference screws; and direct repair of lesions in the musculotendinous junction.[4] Auto/allografts may be needed for reconstructions or repair of chronic lesions. The most commonly used grafts are of the patellar tendon with bone fragment, of tensor fascia latae, and of semitendinosus, gracilis, and calcaneal tendons.[9-12]

This study sought to evaluate a technique of pectoralis major muscle reconstruction which uses bone tunnels in the anterior humeral line at the original insertion site of the tendon and metal anchors in the contralateral cortical area for fixation. We also compared chronic patients with semitendinosus tendon graft and those with acute ruptures without graft.

METHODS

Retrospective cohort study of case series type. This study also compared two subgroups: patients with chronic injury or any type of lesion who needed a semitendinosus tendon graft against patients who did not require grafting. The only patient with acute rupture who required grafting had a rare transtendinous injury.

Inclusion criteria: all patients diagnosed with total rupture of the pectoralis major tendon who were subjected to surgery and operated from March 2009 to March 2018 by anchoring in the contralateral cortical using bone tunnel where the tendon is reinserted with or without graft.

Exclusion criteria: patients who were not diagnosed with pectoralis major rupture, patients older than 60 years, patients with muscular lesions, patients subjected to other surgical techniques, vulnerable populations, and those who refused to provide data for the study.

Of the 25 patients with pectoralis major injury who were operated by the senior surgeon of the group, 13 fit the inclusion criteria and were evaluated. The other 12 were excluded for using other fixation methods, of which: three underwent suturing of the sternal head with the clavicular head (technique no longer recommended by the author) and nine had transosseous fixations. We assessed 13 patients subjected to surgery for repair/reconstruction of the pectoralis major muscle tendon performed by a single surgeon from January 2009 to March 2018, with at least 27 months of post-surgery follow-up.

Evaluation scores were:

UCLA Shoulder Score, Simple Shoulder Test, and comparative manual goniometry with contralateral side: all with at least two years of post-surgery.

Intraoperative and postoperative complications were reported.

Surgical technique:

The patient is placed in beach chair position under general anesthesia and Brachial plexus block. A pathway is made similarly to the deltopectoral approach but lower (about 2 cm below the coracoid process and 7 cm towards the armpit). For injuries in which reinsertion is possible, a bone tunnel with three holes in the anterior cortical is prepared using Kirschner 4.0 wires spaced about 5 mm. These holes are joined using rongeur. If needed, one more hole can be made, but three are usually enough. Three more holes as wide as the anchor cylindrical shaft diameter are then made through the tunnel in the contralateral cortical, one in the middle and 90° from the canal, one upper, and another lower, the latter two with about 70° – 45° angulation with the larger axis of the canal in extrinsic directions toward the center. Three 5 mm diameter metal anchors with at least two high strength wires each are inserted into these three holes through the tunnel. A Krackow-type suture is made in the tendon towards the pectoral and back using the high resistance wires of the anchors (Figure 1). The wires are then pulled to the intraosseous and sutured (Figure 2). When necessary, two tendons are usually used for grafting: the gracilis and the semitendinosus tendon, both trespassed through the middle of muscle mass, medial to myotendinous junction. A continuous-anchored suture is also made with a few more high-strength wires in the medial part of the graft and the lateral part of the pectoral, forming a web to dissipate energy to the muscle (Figure 3) and prevent new acute ruptures of this region of the pectoral trespassed with grafted tendons. This "web" must be tested, and all areas of the pectoral should be tensioned by the web distribution of points to avoid vascular strangulation as much as possible. Grafted tendons are then sutured with a tension that keeps adequate tone in the pectoral, with the three anchors in the same way as described above for acute pectoral injury (Figures 4 and 5). At closure, only skin and subcutaneous tissue are closed.

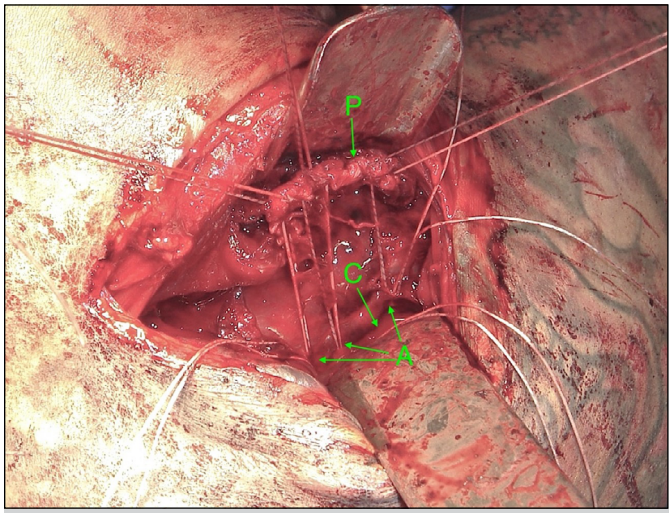

Figure 1. Visualization similar to deltopectoral approach, sutured tendon and view of the osseous canal. P: pectoral; C: bone tunnel; A: anchors.

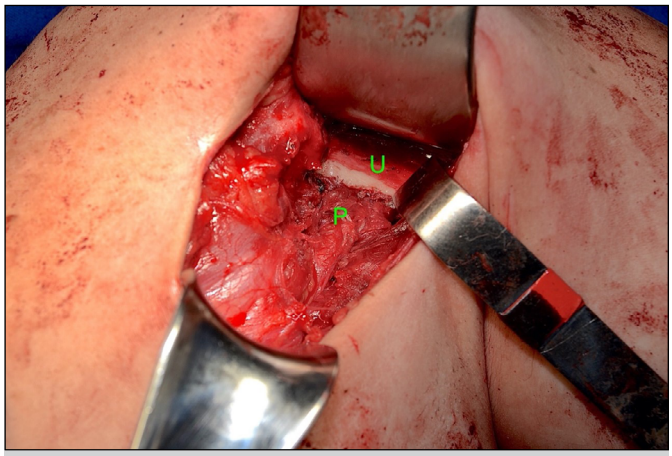

Figure 2. Visualization similar to deltopectoral approach, insertion of the pectoralis major tendon. U: humerus; P: pectoral major.

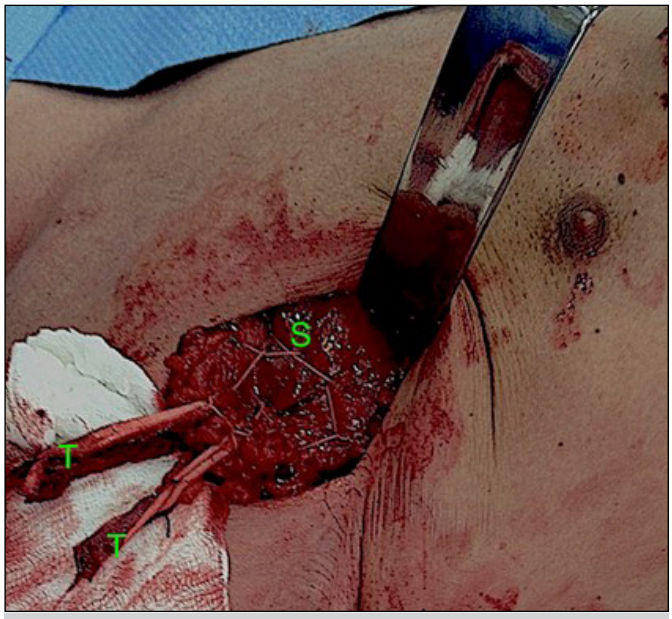

Figure 3. Visualization similar to deltopectoral approach, semitendinosus graft and web suture. S: "web" sutures; T: graft of the semitendinosus tendon.

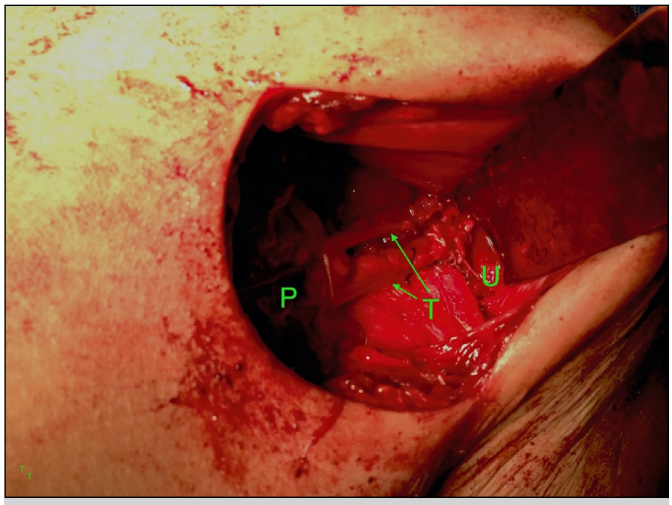

Figure 4. Visualization similar to deltopectoral approach, graft inserted in the osseous canal. P: pectoral; A: inserted anchors; U: humerus.

Figure 5. Radiography of the 3 implanted anchors and the bone tunnel.

After the procedure, the patient has to wear a sling for four weeks and the pendulum exercises begin after 2 weeks of surgery. After four weeks of surgery, passive range of motion exercises begin at the pain limit. The patient usually completes the movement after 12 to 13 months of operation at most. The patient returns to physical activities after 10 weeks of surgery and to activities with normal loads after 20 weeks.

Statistical evaluation respected the nature of the curves and sub-group analysis was performed between patients with and without tendon graft. Data were compared with good and excellent result patterns established by the literature and between subgroups. Established significance was 0.05 in a two-tailed curve.

This study was approved by the Research Ethics Committee under no. 3.734.596.

RESULTS

Of the 13 patients who participated in the study, nine were operated on the right side and four were operated on the left side. Seven patients required a semitendinosus tendon graft: six who had chronic injury and tendon degeneration and one with a transtendinous lesion. The six others did not need grafting because they had acute injury or had all grafts removed from the gracilis and semitendinosus tendons. The mean follow-up time was 76 months (27-135). All patients were male. The overall UCLA Shoulder Score was 34.77 $\pm$ 0.12, compared to the standard 27 of good and optimal results $p < 0.0001$. The mean for the Simple Shoulder Test was 11.92 $\pm$ 0.08. Subgroups with and without graft had $p = 0.62$ for the UCLA score and $p = 0.35$ for the Simple Shoulder Test.

Means, standard errors of UCLA and SST, and mean evolution and injury time between subgroups with and without graft are summarized in Table 1. However, since this lesion is rare, the number of individuals is still low to indicate equality between subgroups.

Table 1. Data and comparison of subgroups with and without grafts.

	Graft	No graft	p
Number of patients	7	6	
UCLA Score	34.57 0.30	34.83 0.17	0.35
Simple Shoulder Test	12 0	12 0	0.62
Injury time	24.71 months	Up to 2 weeks	———
Follow-up Time	56.71	92.17	———

One patient developed quadrilateral space syndrome caused by mispositioning of the synthesis material four years after the procedure and required surgical removal of the extruded extremity of the anchor with a diamond drill through the posterior pathway, without compromising pectoral fixation. This patient returned to activities with no functional losses and all the other patients returned to their physical activities with no restrictions. Elevation and external rotation losses were lower than 5º compared to the contralateral side.

DISCUSSION

Pectoralis major tendon rupture is uncommon and has three fixation methods: suture in the enthesis with anchors,[3] suture in the enthesis with "endobuttons,"[12] transosseous fixation,[13] and others less frequent. Transosseous fixation is one of the most frequently used methods, has greater contact with the bone marrow, and possibly the greatest biological potential.[14]

The method that uses anchors had the lowest pull-out strength.[9] On the other hand, transosseous fixations had no significant differences in pullout strength compared to fixations with "endobuttons."[9] In this biomechanical study, the anchor bone fixation surface is scarified, weakening the cortical where it is inserted; however, the senior author used anchors through a bone tunnel and fixed in the contralateral cortical bone. According to the standard osteosynthesis technique used for cortical screws, an orifice of similar width to that of the cylindrical shaft of the anchor is made from the inside to the outside of the contralateral cortical bone to avoid losing the thread or breaking the cortical. The wedge design of the anchor helps its thread to create a trail in the bone with progressive increase in pressure and decreased fragility points, similarly to tapered compression screws.[15] Moreover, the bone elliptical tunnel of the first cortical favors tendon-bone healing, as seen in transosseous points.[14]

These results were successful for all cases, with safety and excellent functional recovery. However, the anchor should be carefully inserted, so it does not excessively pass through the contralateral cortical. The anchor usually has a strong handle, typical of cortical bone. To avoid the more medial part of the arm and its neurovascular structures, the anchors should be carefully positioned and introduced in the direction of the triceps, with inclination of at least 30º lateral in relation to the sagittal plane in the posterior cortical while the patient's arm is in anatomical position. The senior surgeon believes that, except for transosseous points, this positioning is important regardless of the synthesis material used, since it could avoid possible neurological lesions or complications.

Acute lesions show better results when they are operated within three weeks.[16] However, based on our experience, the surgery for chronic lesion using graft did not influence the functional results, with $p = 0.62$ for the UCLA Score and $p = 0.35$ for the Simple Shoulder Test. The senior surgeon increased only the sling time as a precaution.

The web arrangement created by the author is somewhat similar to another mentioned in the literature and with a similar function.[12] It interweaves the systems of each graft with the entire distal portion of the muscle, creating a unique mechanism of energy dissipation to protect the graft and improve its fixation to the muscle.

The limitation of this study is the lack of biomechanical studies of pull-out strength which use the fixation technique in the contralateral cortical and the small number of participants, since pectoralis major rupture is an uncommon lesion.

CONCLUSION

The technique of pectoralis major tendon reconstruction with bone tunnel and fixation in the contralateral cortical with anchors proved to be effective, but needs to be carefully executed to avoid complications.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. JCGJ: intellectual concept of the article, writing of the article, critical review, and surgeries; EFC: data analysis and critical review; JCGJ, HVL, MPR, MSF, MEK: data acquisition and writing of the manuscript.

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RESULT OF BONE BLOCKING SURGERY IN COMBAT ATHLETES WITH ANTERIOR SHOULDER INSTABILITY: A PROSPECTIVE STUDY

RESULTADO DA CIRURGIA DE BLOQUEIO OSSEO EM ATLETAS DE LUTA COM INSTABILIDADE ANTERIOR DO OMBRO: UM ESTUDO PROSPECTIVO

ARTHUR RODRIGUES BALDAN[1], *VITOR LUIS PEREIRA*[1], *PAULO HENRIQUE SCHMIDT LARA*[1], *BENNO EJNISMAN*[1], *PAULO SANTORO BELANGERO*[1]

1. Universidade Federal de São Paulo (Unifesp), Orthopedics and Traumatology Department, Sports Traumatology Center, São Paulo, SP, Brazil.

ABSTRACT

Objective: This study aims to understand the way fighting athletes respond to bone block surgery in the treatment for shoulder instability. Methods: Prospective clinical study with competitive fighters with shoulder instability who underwent bone block surgery from 2013 to 2016, followed by a postoperative rehabilitation protocol. For the evaluation, eight combat athletes with anterior shoulder instability were treated, with a total of nine shoulders, since one athlete underwent bilateral surgery. All patients signed the Free and Informed Consent Form. The evaluation protocol included medical consultation, radiography of the operated shoulder, degree of active and passive lateral rotation; degree of active and passive elevation; visual analogue scale (VAS) for pain; Athletic Shoulder Outcome Rating Scale (EROE; acronym in Portuguese) scores; Western Ontario Shoulder Instability Index (WOSI), and American Shoulder and Elbow Surgeons (ASES). Results: We observed a decrease in the range of passive and active movement in the recent postoperative period. In later postoperative, values were close to those in the preoperative period at the end of the follow-up. There was improvement in pain, and in all ASES, WOSI and EROE scores no complications were documented. As for returning to sport, two athletes did not return, one of them due to shoulder pain and the other due to retirement. Conclusion: Bone block surgery has shown good functional results in uncomplicated combat athletes. ***Level of Evidence IV, Prospective Case Series.***

Keywords: Shoulder Dislocation. Athletic Injuries. Return to Sport.

RESUMO

Objetivo: Este estudo objetiva entender como atletas de luta respondem ao tratamento para instabilidade do ombro após cirurgia de bloqueio ósseo. Métodos: Estudo clínico prospectivo com pacientes lutadores competitivos que apresentavam instabilidade do ombro submetidos à cirurgia de bloqueio ósseo de 2013 a 2016, seguido por protocolo pós-operatório de reabilitação. Oito atletas de luta com instabilidade anterior do ombro foram tratados, sendo, no total, 9 ombros. Um atleta foi submetido a cirurgia bilateral. Todos os pacientes assinaram o Termo de Consentimento Livre e Esclarecido. O protocolo de avaliação incluía consulta médica, radiografia do ombro operado, grau de rotação lateral ativa e passiva; grau de elevação ativa e passiva; escala visual analógica da dor (EVA); escores EROE; WOSI e ASES. Resultados: Observamos diminuição do arco de movimento passivo e ativo no pós-operatório recente e valores próximos aos do pré-operatório ao final do acompanhamento. Houve melhora da dor e em todos os escores ASES, WOSI e EROE no período pós-operatório, não havendo complicações. Quanto ao retorno ao esporte, dois atletas não retornaram ao esporte, sendo um deles por dor no ombro e outro por aposentadoria. Conclusão: A cirurgia de bloqueio ósseo apresentou bons resultados funcionais em atletas de luta sem complicações. ***Nível de Evidência IV, Série de Casos Prospectivo.***

Descritores: *Luxação do Ombro. Traumatismos em Atletas. Volta ao Esporte.*

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INTRODUCTION

Anterior shoulder instability affects mainly young athletes. The bone block technique (coracoid process transfer) is an option to the retentive process of soft tissue, especially in patients with bone loss in the glenoid and/or humeral head.[1,2]

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

The study was conducted at Universidade Federal de São Paulo (Unifesp), Orthopedics and Traumatology Department, Sports Traumatology Center.
Correspondence: Arthur Rodrigues Baldan. Rua Estado de Israel, 493, apt. 112, São Paulo, SP, Brazil, 04022001. arthur_rbn@hotmail.com

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Combat sports encompass all martial arts modalities involving competition. The rules of each modality vary, as well as the epidemiology of the lesions. However, we can observe shoulder dislocation in all fighting modalities.[3]

The literature indicates that athletes of contact sports such as rugby, hockey and American football have higher rates of relapse and worse prognosis regarding evolution, often requiring bone block surgery, especially with > 20% to 25% bone loss.[4,5] The efficacy of this type of surgery for athletes of contact sports has shown good results in several modalities.[6,7] However, the literature lacks specific data on combat athletes, such as epidemiology, clinical and functional results of open bone block surgery.

This study aims to evaluate the outcome of treatment with bone block in anterior shoulder instability in combat athletes.

MATERIALS AND METHODS

The patients signed the informed consent form before participation. From February 2013 to October 2016, eight combat athletes with anterior shoulder instability were treated, totalizing nine shoulders, since one athlete underwent bilateral surgery. The general characteristics of the sample are shown in Table 1.

Only in one of the athletes the non-dominant limb was affected. The body mass index (BMI) mean of the patients was 24.5 kg/m^2, ranging from 20.8 to 27.1 kg/m^2. The distribution of modalities is found in Table 2. Four athletes were professionals and four amateur competitors, with weekly practice above 10 hours of training. The average practice of the athletes before dislocation was 85.3 months, ranging from 12 to 228 months. The mean follow-up was 21.13 months, ranging from six to 51 months.

The inclusion criteria required patients who had never undergone shoulder surgery and who were followed-up in the postoperative period for at least six months. Exclusion criteria observed patients with previous shoulder surgery and those with postoperative follow-up shorter than six months.

All patients were prospectively evaluated according to a pre-established protocol (Figure 1), in which they were evaluated by physicians and physiotherapists of the Sports Traumatology Center of the Paulista School of Medicine. Besides medical consultation, all patients underwent radiography and computed tomography of the operated shoulder. Patients were evaluated both pre and postoperatively, considering the following: degree of active and passive lateral rotation; degree of active and passive elevation; visual analog scale (VAS) for pain;[8] Athletic Shoulder Outcome Rating Scale (EROE) score;[9] Western Ontario Shoulder Instability Index (WOSI) score[10] and American Shoulder and Elbow Surgeons (ASES) score.[11] The EROE[9] score assesses shoulder stability, range of motion, daily function and pain. In this score, bad results are related to scores ≤ 50 points; regular results to scores between 51 to 74 points; good results to scores between 75 to 89 points; and excellent scores to 90 to 100 points. The WOSI[10] score assesses quality of life in patients with shoulder instability, in which a higher score indicates worse quality of life, being 0 (excellent) and 210 (very poor). The ASES[11,12] score evaluates pain and shoulder function from 0 to 100, with higher values indicating better results. The postoperative evaluation periods followed the protocol (Figure 1). Moreover, it was also evaluated if the patients returned to sports practice, if there were any complications or new episodes of dislocation after surgery.

Table 1. General characteristics of the sample.

Patient sample (N = 8)	
Age (years)	
Average	24.6
Variation	20-35
Gender (N.,%)	
Male	8 (100%)
Affected limb (N.,%)	
Left	5 (55%)
Right	4 (45%)
Dislocation Mechanism (N.,%)	
Traumatic	8 (88%)
Atraumatic	1 (12%)
Category	
Amateur	4 (50%)
Professional	4 (40%)

Table 2. Fighting modalities practiced by the athletes.

Case	Modalities
1	Olympic Wrestling Jiu-Jitsu Judo
2	Jiu-Jitsu Capoeira
3	Kickboxing
4	Muay Thai Jiu-Jitsu
5	Mixed Martial Arts
6	Jiu-Jitsu
7	Chinese Boxing
8	Mixed Martial Arts
9	Boxing

FEDERAL UNIVERSITY OF SÃO PAULO – UNIFESP
Sports Traumatology Center – (CETE)

Shoulder Ambulatory

PROJECT OF BONE BLOCK SURGERY
CHECK LIST

Preoperative
- VAS (Visual Analog Scale for pain)
- ADM of External Rotation (ER) and Bilateral Passive Elevation
- ADM of ER and Bilateral Active Elevation
- ASES
- SQR
- WOSI

1° and 2° WEEK OF POSTOPERATIVE:
- VAS (Visual Analog Scale for pain)

4° WEEK OF POSTOPERATIVE:
- VAS (Visual Analog Scale for pain)
- ADM of ER and Bilateral Passive Elevation
- ADM of ER and Bilateral Active Elevation

8° WEEK OF POSTOPERATIVE:
- VAS (Visual Analog Scale for pain)
- ADM of ER and Bilateral Passive Elevation
- ADM of ER and Bilateral Active Elevation

12° WEEK OF POSTOPERATIVE:
- VAS (Visual Analog Scale for pain)
- ADM of ER and Bilateral Passive Elevation
- ADM of ER and Bilateral Active Elevation

6 MONTHS OF POSTOPERATIVE:
- VAS (Visual Analog Scale for pain)
- ADM of External Rotation (ER) and Bilateral Passive Elevation
- ADM of ER and Bilateral Active Elevation
- ASES
- SQR
- WOSI

<< SUMÁRIO

INITIAL FORMULARY AND INTERVIEW

1 YEAR OF POSTOPERATIVE:
- VAS (Visual Analog Scale for pain)
- ADM of External Rotation (ER) and Bilateral Passive Elevation
- ADM of ER and Bilateral Active Elevation
- ASES
- SQR
- WOSI
- INITIAL FORMULARY AND INTERVIEW

2 YEARS (OR MORE) OF POSTOPERATIVE:
- VAS (Visual Analog Scale for pain)
- ADM of External Rotation (ER) and Bilateral Passive Elevation
- ADM of ER and Bilateral Active Elevation
- ASES
- SQR
- WOSI
- INITIAL FORMULARY AND INTERVIEW

OBS[1]- ADM measures must be bilaterally performed;
OBS[2]- The identification form and the questionnaires should have ALL questions signed without exception;
OBS[3]- If both shoulder of the same patient undergo surgery operation, the register should be record on separated worksheets for each limb. Do not forget to identify the respective limb.

Figure 1. Evaluation protocol of the athletes.

Regarding the referral for surgery, all patients underwent bone block surgery (described by Latarjet) according to the flowchart (Figure 2). Regarding surgical technique, all patients were operated in the beach chair position, and the anterior access was about 5 cm, performed on the coracoid process extending to the deltopectoral interval. The coracoid process was osteotomized at 1.5 to 2 cm from its tip, at the origin of the joint tendon. The graft was prepared according to the Latarjet technique. The subscapularis muscle was opened longitudinally between the upper two-thirds and the lower third and the joint capsule was opened vertically. The graft was fixed at the anterior edge of the glenoid with two screws. Regarding the type of implants, screws with washers for small fragments were used in all cases.

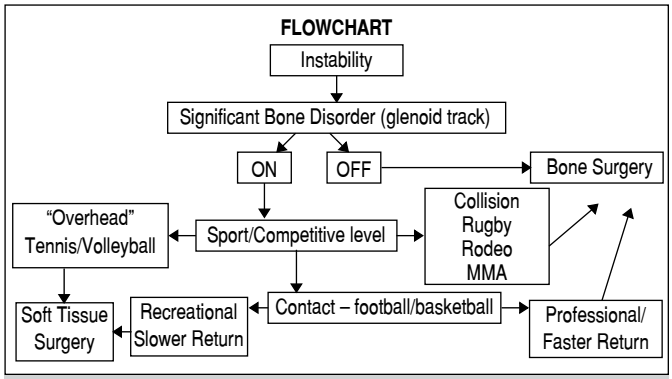

Figure 2. Surgery indication flowchart.

All patients underwent the same postoperative rehabilitation protocol, performed by the team of physical therapists of the Sports Traumatology Center of the Paulista School of Medicine. Immobilization using arm sling for three weeks, followed by progressive increase in the range of active and passive movement and beginning of strengthening exercises at eight weeks.

The Ethics Committee of Paulista School approved this study (1.660.771).

Statistical Analysis

We used statistical parametric evaluations since data are quantitative and continuous. We used the Two-Proportion Equality test to characterize the distribution of the relative frequency of qualitative variables. To verify the correlation between variables, the Pearson correlation coefficient was used. Differences with $p < 0.05$ were considered statistically significant and the analysis was performed using SPSS V20 software.

RESULTS

Regarding shoulder mobility, we observed that passive and active elevations and passive and active lateral rotations show a diminution in the recent postoperative period, reaching values close to those of the preoperative period at the end of the follow-up. Table 3 shows the results.

Regarding the results of the scores in Table 4 and 5, the postoperative period improved in all cases.

Table 3. Description of the functional data of the individuals.

Variables	Active Lateral Rotation	Passive Lateral Rotation	Active Elevation	Passive Elevation	N
Preoperative	62	73.2	163.7	170.4	9
4 weeks	14.6	24.2	107.8	120	9
8 weeks	25.3	30.7	115	123.9	9
12 weeks	36.7	42.8	122	132.6	9
6 months	52	56.6	132.6	140.4	9
1 year	48.8	51	150	154.6	5
2 years old	55.5	63.8	152.5	162.5	4
3 years	75	80	159	165	2
4 years old	75	80	158	160	1

Table 4. Description of the results of the evaluated scores.

Variables	ASES	WOSI	EROE	N
Preoperative	47.8	112.9	47.2	9
6 months	69.2	63.4	70.6	9
1 year	73.2	42.4	73.4	5
2 years old	78.5	59.3	82.3	4
3 years	82	62.5	93	2
4 years old	92	66	88	1

Table 5. Distribution of athletes according to EROE Score.

EROE	Weak		Regular		Good		Excellent	
	N	%	N	%	N	%	N	%
Pre	4	44.4	4	44.4	1	11.1%	0	0%
6 months	2	22.2%	1	11.1%	5	55.5%	1	11.1%
1 years old	1	20%	0	0%	3	60%	1	20%
2 years old	0	0%	1	25%	2	50%	1	25%
3 years	0	0%	0	0%	1	50%	1	50%
4 years old	0	0%	0	0%	1	100%	0	0%

Regarding the Visual Analog Scale (VAS) for pain, we also observed an improvement. Postoperative period indicated an average of 4.22 (0-7) and at six postoperative months indicates an average of 1.33 (0-6). The athletes did not present complications during the follow-up period and new episodes of dislocation did not occur. Regarding the return to the sport, two athletes did not return. One of them due to shoulder pain and the other for having retired from professional wrestling.

DISCUSSION

The practice of fighting has spread out in our country and throughout the world. Thus, the knowledge about the correct procedures for combat athletes presenting anterior shoulder instability will increase. Duazère et al.[13] compared active elevation and active and passive lateral rotation in the postoperative period and in the follow-up of

patients undergoing bone block surgery. Their values were similar to those found in our study, with averages of 167 degrees for active elevation; 50 degrees for active lateral rotation; and 82 degrees for passive lateral rotation at follow-up. The study by da Silva et al.[14] evaluated active lateral elevation and rotation in the postoperative period and also found similar results to our investigation, with an average of 146 degrees of elevation and 59 degrees of lateral rotation.
In the study by Mook et al.,[15] American Shoulder and Elbow Surgeons (ASES) score was compared before and after surgery, with an average of 70.2 (28.3-100) in the preoperative period and 89.2 (56.6-100) in the postoperative period. Our study showed an average of 47.8 (25-75) and 69.2 (55-80). The results showed difference; however, we emphasize that the study conducted by Mook et al.[15] included athletes and nonathletes.
Several studies used the ROWE score to evaluate the outcome of bone block surgery. The main ones are illustrated in Table 6. For this analysis, we used the results of 6 months of follow-up because we have the data of all athletes included in this period. As in previous studies, most patients are in the excellent or good categories of the score, demonstrating satisfactory results in this group of patients.

Table 6. Comparison of the EROE Score in several studies.

Study	Patients	Follow-up (months)	Redislocation rate	Excellent ROWE score	Good ROWE score	Regular ROWE score	Weak ROWE score
Banas et al. 1993	79	103	4%	74%	11%	9%	6%
Singer et al. 1995	14	246	0%	36%	57%	7%	1%
Pap et al. 1997	31	31	3%	45%	39%	6%	10%
Hovelius et al. 2004	118	182	4%	71%	15%	11%	4%
Matthes et al. 2007	29	38	0%	59%	24%	10%	7%
Ruci et al. 2015	42	46	0%	64%	22%	9.5%	4.5%
Current study	8	21	0%	11.1%	55.5%	11.1%	22.2%

In the study by Beranger et al.,[8] 100% of the patients returned to sport after Performing Latarjet surgery. On the other hand, in the study by Neyton et al.[16], who rated only Rugby players, the rate of return was 56%. In our study, the rate of return was 75%.
Griesser et al.[17] reported a complication rate of 30%, which were recurrences, neurovascular lesions, hematomas, infections, graft pseudarthrosis and limitations to the movement arc. We had no complications in our study.
In the work of Stein et al.[18] an evaluation of the results of arthroscopic surgery of retensioning on soft tissue was performed in several types of sports. Martial arts athletes have a worse rehabilitation beginning than in other athletes, but present similar results at the end of rehabilitation. Moreover, 66% of professional martial arts athletes started playing sports recreationally after surgery.
The strengths of our study are: first study to address this theme (result of bone block surgery for anterior shoulder instability in combat athletes) providing epidemiological data of injuries in this specific group of athletes; homogeneous nature of the sample, since it presents young male athletes. All athletes were treated with a surgical procedure studied in the literature for patients who were athletes of contact modalities, associated with bone injury.[15]
One limitation of our study was the small number of cases, besides a short follow-up period for a procedure that presents good functional results, but, at the same time, does not reproduce the original anatomy of the shoulder. Complications such as arthrosis (which has been described as one of the complications of the bone block procedure) require a longer postoperative follow-up period to verify its incidence.

CONCLUSION

Bone block surgery showed good functional results in combat athletes with no complications, being a good option for this group of athletes with anterior shoulder instability.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article: ARB: writing, evaluation of patients and performing surgeries; VLP: writing, evaluation of patients and performing surgeries; PHSL: evaluation of patients, statistical analysis and performance of surgeries; BE: review and advising; PSB: review and advising.

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EXPERIMENTAL MODEL STUDY OF ISCHEMIC NECROSIS INDUCTION OF THE GROWING FEMORAL HEAD

ESTUDO DO MODELO EXPERIMENTAL DE INDUÇÃO DA NECROSE ISQUÊMICA DA CABEÇA FEMORAL EM CRESCIMENTO

Antonio Gorios Filho[1], Gustavo Bispo dos Santos[1], José Roberto Bevilacqua Guarniero[2,3], Luiz Renato Agrizzi de Angeli[1,4], Patricia Moreno Grangeiro[1], Roberto Guarniero[1]

1.Universidade de São Paulo, Medical School, Hospital das Clínicas, Institute of Orthopedics and Traumatology (IOT-HCFMUSP), São Paulo, SP, Brazil.
2. Hospital Municipal Infantil Menino Jesus, São Paulo, SP, Brazil.
3. Instituto de Responsabilidade Social Sírio-Libanês, São Paulo, SP, Brazil.
4. Hospital Israelita Albert Einstein, São Paulo, SP, Brazil.

ABSTRACT

Many experimental models exist to better understand the necrosis of the femoral head etiology, both in terms of the species variety in which necrosis is induced and in the operative techniques used for treatment. Objective: This study has two main objectives, the first is to review the literature concerning experimental models of avascular necrosis of the growing femoral head, the second, to demonstrate the experimental pig model's reproducibility using a pilot study. Methods: This was a bibliographic review to describe the attempts over time to find the best species and technique for induction that would reproduce ischemic necrosis of the growing femoral head in humans. Simultaneously, a pilot study was performed to verify the replication of induction in pigs, the species that has more similarities with the human hip. The pilot's methodological analysis consists of conventional radiology and verification of possible anatomical, pathological changes. Results: In imaging exams; lateral sub-dislocation of the femur head and triangular appearance of the head were observed, characterizing its flattening; in macroscopic examination, the femoral head flattening with femoral neck widening and shortening was identified; in histology, the proliferation of articular cartilage with the presence of vascular granulation regenerative tissue, with osteoclasts and fibrocartilaginous tissue in the metaphyseal femoral neck region was identified. Conclusion: The experimental pig model can be used as a valuable tool for the reproducibility of anatomical, pathological changes in ischemic necrosis of the growing femoral head. The model is reproducible and feasible and can be beneficial for future studies on the anatomical pathology of necrosis of the growing femoral head. ***Level of Evidence III, Literature Review.***

Keywords: Femur Head Necrosis. Legg-Calvè-Perthes Disease. Models, Animal.

RESUMO

Na tentativa de compreender melhor a etiologia da necrose da cabeça femoral, existe uma diversidade de modelos experimentais tanto no que diz respeito à variedade das espécies em que é induzida a necrose quanto nas técnicas operatórias utilizadas para o tratamento. Objetivo: Este trabalho tem fundamentalmente dois objetivos: a revisão da literatura concernente aos modelos experimentais da necrose avascular da cabeça do fêmur em crescimento e demonstrar a reprodutibilidade do modelo experimental do suíno por meio de um estudo piloto. Métodos: Foi realizada uma revisão bibliográfica descrevendo as tentativas ao longo do tempo em buscar qual seria a melhor espécie e técnica para indução que reproduzisse a necrose isquêmica da cabeça do fêmur em crescimento nos humanos. Simultaneamente foi feito um estudo piloto para verificar a replicação da indução na espécie suína, o espécime cujo quadril tem mais similaridades com o humano. A análise metodológica do piloto consiste na radiologia convencional e verificação das possíveis alterações anátomo patológicas. Resultados: Nos exames por imagem, foram observadas sub-luxação lateral da cabeça do fêmur e aparência triangular da cabeça, caracterizando o achatamento da mesma; no exame macroscópico, identificamos o achatamento da cabeça femoral com alargamento e encurtamento do colo; na histologia, identificamos a proliferação da cartilagem articular com presença de tecido regenerativo vascular de granulação, com osteoclastos e tecido fibrocartilaginoso na região metafisária do colo femoral. Conclusão: Podemos inferir que o modelo experimental suíno pode servir como ferramenta valiosa para a reprodutibilidade das alterações anátomo patológicas da necrose isquêmica da cabeça femoral em crescimento. O modelo é reprodutível e factível, servindo para estudos futuros sobre a anátomo patologia da necrose da cabeça do fêmur em crescimento. ***Nível de Evidência III, Revisão da Literatura.***

Descritores: *Necrose da Cabeça do Fêmur. Doença de Legg-Calve-Perthes. Modelos Animais.*

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The study was conducted at Universidade de São Paulo, Medical School, Hospital das Clínicas, Institute of Orthopedics and Traumatology (IOT-HCFMUSP).
Correspondence: Antonio Gorios Filho. Rua Dr. Ovídio Pires de Campos, 333, sala 317, São Paulo, SP, Brazil, 05403010. agorios7@gmail.com

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INTRODUCTION

Avascular necrosis of the femoral head is an orthopedic disease. When it affects the hip of the growing child it is denominated Legg Calvé Perthes disease (LCPD), due to the disease was reported almost simultaneously in 1910 by Legg, Calvé, and Perthes.[1-3]
The authors described an affection in the hip of the child different from joint tuberculosis, which was the disease most found at that time. During all these years, about 2,000 studies have been published on the subject; however, the etiology remains unclear, but certainly occurs a disturbance in the arterial circulation of the growing femoral head.[4-7]
To better understand the etiology of femoral head necrosis, we have a diversity of experimental models discussing both: the variety of species, in which necrosis is induced, and the techniques used for induction.[8]
In this study, we present an analysis of the literature in relation to the models idealized over time, and the description of an experimental model in the swine species in a pilot project, used for the study of ischemic necrosis of the growing femoral head.

MATERIALS AND METHODS

This study was approved by the Ethics Committee on the Use of Animals under protocol number no. 141/15.
To review the literature, the most relevant databases available on the Internet (PubMed, SciELO, LILACS, MEDLINE, Cochrane) from 1933 to the present. were used. The keywords used were the following: osteonecrosis, experimental model, femur head necrosis, Legg Calvè Perthes disease.
Simultaneously, a pilot induction study was conducted in the swine species that was subjected to methodological analysis with conventional radiology and analysis of possible anatomopathological changes.

Experimental model: pilot study

We used the experimental model in the growing swine. An animal with four weeks of life and weighting 8 kg was operated. We used the right coxofemoral joint for the operation, remaining the left coxofemoral joint as an unoperated control.

Anesthesia

The animal received preanesthetic medication with ketamine (3 mg/kg IM) and midazolam (0.4 mg/kg IM). Anesthesia induction was executed with isoflurane (3.5%) with mask aid and anesthesia maintenance was performed with isoflurane (2%) and fentanyl (0.2 μg/kg/h IV). For intubation, 5 mg/kg of propofol was administered. Immediately before the surgery, prophylactic antimicrobial therapy with cefazolin (30 mg/kg IV) was performed and non-steroidal anti-inflammatory drugs (meloxicam 0.4 mg/kg IM) were administered.
At the end of the surgical procedure, analgesia was performed with dipyrone (25 mg/kg IV), morphine (3 mg/kg IV), wound dressing in the surgical region, and a peripheral catheter for the administration of analgesic and anti-inflammatory drugs in the postoperative period.

Surgical procedure

After induction and anesthesia, a longitudinal incision was made in the right hip of the animal under sterile conditions (Figure 1). To access the joint capsule, the middle and superficial gluteus muscles are pulled with the aid of a Farabeuf retractor. Partial joint capsulotomy is executed, and longitudinal traction of the lower limb is performed to dislocate the joint. The round ligament is sectioned to facilitate looping a circumferential double suture in the femoral neck of the animal (Figure 2). Using a curvilinear instrument, type curved Mixter or with a tonsil needle, an absorbable vicryl suture 2 is positioned around the femoral neck and tied with greatest possible pressure to block the arterial circulation of the cervical ascending vessels that supply the proximal femoral epiphysis.

Figure 1. Surgical procedure: Longitudinal and cranial incision to the coxofemoral joint.

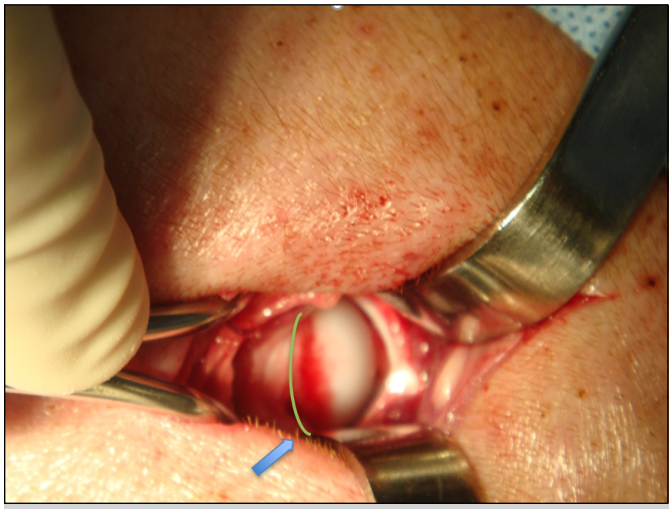

Figure 2. Surgical procedure: exposure and ligation of the femoral neck (the arrow points to ligation site).

Image evaluation

Imaging diagnosis was performed by fluoroscopy at the time of the operation of ischemic necrosis induction and six weeks postoperatively, at the time of euthanasia of the animal. The left hip serving as control.

Macroscopic and histological evaluation

The right and left hip of the animal were carefully dissected. Afterward, macroscopic and microscopic examinations of the samples were performed.
For histology, only the sample of the right hip (operated) of the animal was fixed in formalin at 10%, embedded in paraffin and cut into slices sized 6 μm.
The sections thus obtained were stained by Hematoxylin and eosin (HE) and examined under common optical microscopy. With microscopic evaluation we tried to answer the following questions:

- presence of an increased number of osteoclasts;
- increased bone resorption;
- presence of granulation vascular regenerative tissue;
- joint cartilage proliferation.

RESULTS

Figure 3 shows the result of radiographic evaluation at the time of euthanasia of the animal six weeks after ischemia induction

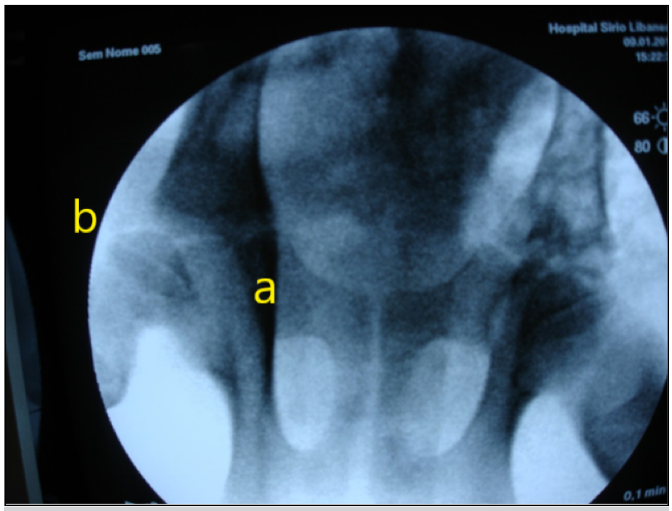

Figure 3. Fluoroscopy image after six weeks postoperatively (EUTHANASIA).

In "a", we observed sub dislocation of the femur head; in "b" triangular appearance of the femur head with flattening on it. The image of the normal left coxofemoral joint (control).

Macroscopy

Macroscopic analysis of the right and left hip samples was performed immediately after euthanasia (Figure 4). Note the flattening of the right femoral head with enlargement and shortening of the femoral neck, when compared with the control hip (left).

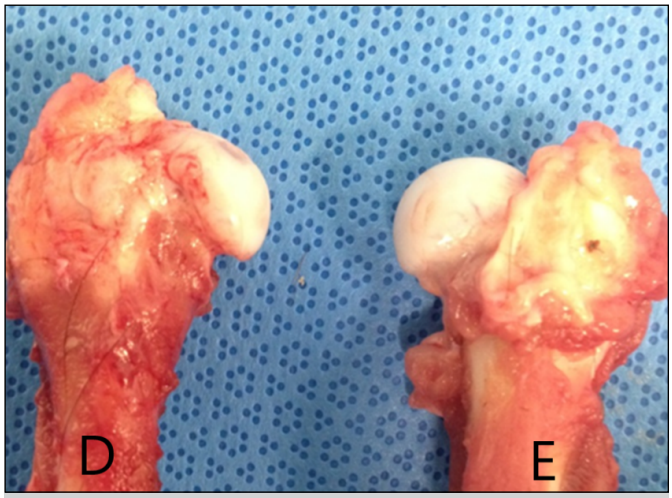

Figure 4. Macroscopic evaluation of the right and left femurs (control). Advisor source, advisor's personal file.

Histological evaluation

Figure 5 shows (a) the proliferation of articular cartilage; (b) presence of granulation vascular regenerative tissue in the metaphyseal region of the femoral neck; and (c) presence of fat cells in granulation tissue. Figure 6 complements our analysis showing (d) the presence of osteoclasts in the fibrocartilaginous tissue; and (e) chondrocytes.

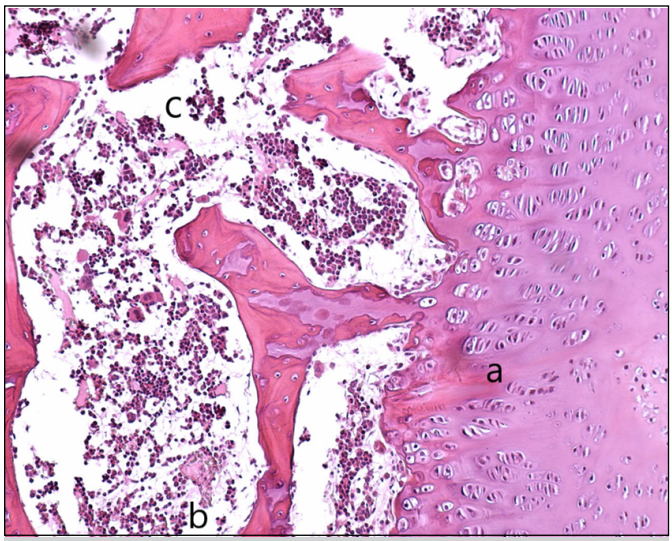

Figure 5. Histological cut of the sample with an increase of 20×, HE staining.

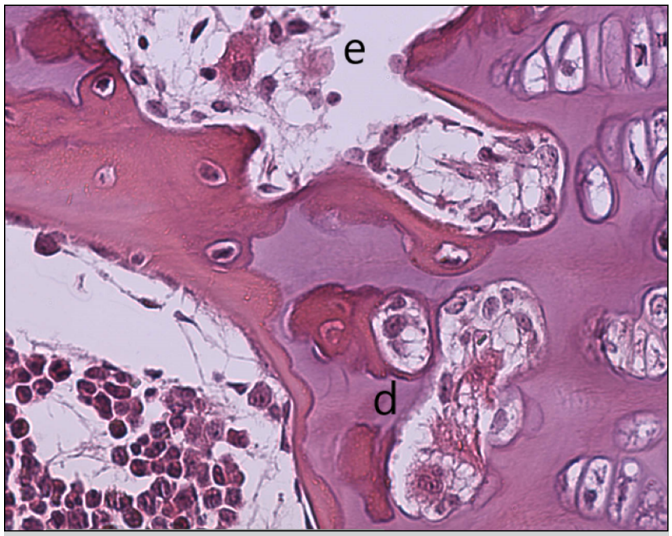

Figure 6. Higher increase 40× – osteoclasts + fibrocartilaginous tissue + chondrocytes (articular cartilage).

DISCUSSION

This study has two objectives: the review of the literature concerning the experimental models of avascular necrosis of the growing femoral head and the demonstration of reproducibility in the experimental swine model by a pilot study.

Most animal models for the study of ischemic necrosis focused on quadrupeds, including pigs, rabbits, dogs, rats, and goats. Biped investigation was limited to chicken and ema. The list of techniques that attempted to induce osteonecrosis of the femoral head is extensive.

Comparing the pig model with other species, we found rabbits' femoral neck to be short, hindering the correct application of the surgical technique of induction of avascular necrosis, causing difficulty for surgical ligation. As Robichon et al. refer, in dogs the collateral circulation allows a faster revascularization when compared to pig.[9]

<< SUMÁRIO

We also note that the cycle of bone remodeling in pigs is more similar to that of humans when compared to the cycles of rats or mice.[10] Thinking about the biomechanics of the human hip, the Ema, for being biped, has a great advantage in the anatomical similarity in relation to quadrupeds, besides being an animal with a joint dimension similar to that of children.[11]

We agree with authors such as Salter[12] and Rang,[13] that induction by surgical ligation of the femoral neck is the most appropriate to reproduce the results observed in humans, being useful to elucidate the development of Legg Calvè Perthes pathogenesis, and also serving for prevention and therapeutic studies for the disease. Compared to noninvasive methods, the advantages of traumatic techniques are due to the femoral necrotic lesions concentrate on the femoral head, unlike non-traumatic techniques (corticosteroid overdose, autoimmune reactions) where the lesion reaches the femoral metaphysis and other bones when induced by a systemic reaction. Another advantage of invasive techniques is that we can determine the exact moment of the ischemic lesion, enabling the control of examinations by image and histology in all stages of the pathophysiological process, from the ischemic phase to the remodeling phase.[8,14]

This study showed similarity between induced osteonecrosis methods by femoral neck ligation described earlier in the literature review; the pilot model executed in our research using swine species was successful in inducing avascular necrosis, confirming that it is feasible in our institution, serving for future studies. Although it is a single piece, we found that the time of six weeks after surgical induction is able to induce osteonecrosis due to the various radiological, anatomical, and cellular alterations that we observed.

The absence of a fully satisfactory therapy for Legg Calvè Perthes disease and the morbidity associated with joint injury justify the maintenance of scientific research on the subject and even with the evolution of computer programs capable of copying pathological events, the maintenance of animal experimentation to study avascular necrosis of the femoral head is necessary. The canine species also develops aseptic necrosis of the femoral head without a treatment that shows complete efficacy, being only possible to perform resection of the femoral head or total prosthesis of the hip, procedures that can cause functional limitation.[15] Therefore, we advocate for the continuation of the experimental study of femoral head ischemia, and the swine species was the one that best reproduced the disease due to its anatomical similarity to humans, a relatively low maintenance cost, a species easy to deal, and a wide literature on the subject available .

CONCLUSION

We can infer that the experimental swine model can serve as a valuable tool for the reproducibility of pathological anatomic alterations of ischemic necrosis of the growing femoral head. The model is reproducible and feasible, serving for future studies on the pathology anatomic of necrosis of the growing femoral head.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. AGF: writing of the article, performing surgeries, bibliographic survey, data collection and analysis, approved the final version of the article; GBS: surgery, data collection and analysis, and approved the final version of the article; JRBG: performing surgeries, data collection and analysis, and approved the final version of the article; LRAA: data collection, analysis, and approved the final version of the article; PMG: intellectual concept of the article, critical revision of the text of the article, and approved the final version of the article; RG: intellectual concept of the article, performing surgeries, critical review of the text of the article, orientation of the study, and approved the final version of the article.

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UPDATE ARTICLE
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ATYPICAL FEMORAL FRACTURES DUE TO THE USE OF BISPHOSPHONATES: EPIDEMIOLOGIC STUDY IN A TERTIARY HOSPITAL

FRATURAS ATÍPICAS DE FÊMUR POR USO DE BIFOSFONATOS: ESTUDO EPIDEMIOLÓGICO EM UM HOSPITAL TERCIÁRIO

FERNANDA DA COSTA GOLFIERI[1], *MAURÍCIO ZANON*[2], *PEDRO PAULO VERONA PERCIO*[1]

1. Fundação Hospitalar São Lucas, Centro Especializado em Ortopedia e Traumatologia, Cascavel, PR, Brazil.
2. Centro Universitário Assis Gurgacz, Cascavel, PR, Brazil.

ABSTRACT

Objective: Show the relationship between atypical femoral fractures and prolonged use of bisphosphonates and analyze the limit of its beneficial use. Methods: Retrospective cohort study (level of evidence 2B). From Atypical fracture cases, patients who used bisphosphonates were selected and the time period of their use was analyzed. Additionally, the variables sex, age, and the side most affected were studied. Results: Nine atypical femur fractures were found, all associated with the use of bisphosphonates. The average period of use of this medication was nine years (minimum of three years; maximum of 14 years). The patients' mean age was of 78 years (69-88 years) and all were women, with the right member being the most affected. Conclusion: The use of bisphosphonates to prevent osteoporotic fractures has been increasingly frequent and, when used for a prolonged period, it has been related to atypical fractures. Further scientific studies on doses, maximum periods of treatment, and risk-benefit in the indication of these medications are needed to assist in therapeutic management for each case. ***Level of Evidence II, Retrospective Study.***

Keywords: Bisphosphonates. Adverse Effects. Insufficiency Fractures. Subtrochanteric Fractures. Femoral Fractures. Osteoporosis.

RESUMO

Objetivo: Demonstrar relação entre as fraturas atípicas de fêmur e o uso prolongado de bifosfonatos, descrever sua incidência e analisar até qual momento o seu uso é benéfico. Métodos: Estudo de coorte retrospectivo (nível de evidência 2B). Análise de 151 prontuários de pacientes com diagnóstico de fratura de fêmur em um hospital terciário, no período de janeiro de 2013 a dezembro de 2018. Foram selecionados os casos de fraturas atípicas e, dentre esses, os que faziam uso de bifosfonatos e o tempo de utilização. Ademais, foram estudadas as variáveis sexo, idade e lado mais acometido. Resultados: Constatadas 9 fraturas atípicas de fêmur, todas associadas ao uso de bifosfonatos. O período médio de uso dessa medicação foi de 9 anos (mínimo – 3 anos; máximo – 14 anos). A idade média dos pacientes foi de 78 anos (69-88 anos) e ocorrência unicamente em mulheres, tendo como membro mais acometido o direito. Conclusão: O uso dos bifosfonatos na prevenção de fraturas osteoporóticas tem sido cada vez mais frequente e relacionado às fraturas atípicas, quando empregado por tempo prolongado. A coleta de mais informações científicas que estudem doses, períodos máximos de tratamento e risco-benefício na indicação dessas medicações é essencial para auxiliar no manejo terapêutico apropriado para cada caso. ***Nível de Evidência II, Estudo Retrospectivo.***

Descritores: *Bifosfonatos. Efeitos Adversos. Fraturas por Insuficiência. Fraturas Subtrocantericas. Fraturas do Fêmur. Osteoporose.*

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INTRODUCTION

Bisphosphonates are a class of drugs prescribed mainly for the treatment of senile and postmenopausal osteoporosis since they reduce the incidence of vertebral and non-vertebral fractures.[1,2] Its mechanism is based on antiresorptive activity in bone, reducing the number of osteoclasts, as well as decreasing its function and increasing apoptosis, preventing bone destruction. The strong and continuous inhibition of resorption unbalances the normal bone remodeling, necessary to maintain bone quality, leading to exaggerated mineralization and increased bone density. This process increases bone stiffness, resulting in the accumulation of microcracks, followed by increased microfractures and possibly

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

The study was conducted at Hospital São Lucas.
Correspondence: Fernanda da Costa Golfieri. Rua Pernambuco, 1561, apt. 22, Cascavel, PR, Brazil, 85810021. fer.golfieri@hotmail.com

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leading to the appearance of fractures, especially when associated with extrinsic factors, such as the action of asymmetric mechanical burden in the femur. Other medications may also be related to the suppression of bone remodeling, such as estrogens, glucocorticoids and/or proton-pump inhibitors.[3-5]

Multiple reports within the literature indicate a probable relationship between the use of bisphosphonates and the increase of non-osteoporotic femur fractures with atypical patterns in patients medicated for six years or more with this class of drug. The first case of this association was reported in 2005.[6] Other similar cases of fractures appeared in the sequence, which had in common, in addition to the use of bisphosphonates, small or no trauma involved and pain in the thigh/groin of the affected leg in approximately 70% of patients.[7,8]

Clinically, atypical fractures of the femur are difficult to be identified due to nonspecific symptoms, such as persistent pain in the thigh, with worsening when supporting the foot on the ground, vague discomfort and/or subjective fatigue. However, in the presence of these symptoms along with the use of bisphosphonates, it is recommended to investigate fractures through pelvis and thigh radiographs in two planes and both limbs to rule out differential diagnoses.[3,5,9]

In 2013, the Brazilian Health Regulatory Agency (Anvisa) issued a report to physicians on the prolonged use of bisphosphonates and its safety, recommending the interruption of treatment after three years to analyze each patient individually to determine the necessity of its use for a longer period.[10]

Based on the aforementioned concepts, it becomes relevant to alert all physicians about the adverse effect of this drug class. This study aimed to show the relationship between atypical fractures of the femur and the prolonged use of bisphosphonates, describe its incidence and analyze to what extent the use of this medication is beneficial.

MATERIALS AND METHODS

From January 2013 to December 2018, 151 cases of femoral fractures from a tertiary hospital in the city of Cascavel, in the state of Parana, were reviewed; those with atypical fractures related to prolonged use of bisphosphonates were selected and analyzed.

To classify the fractures, the criteria established by the American Society for Bone and Mineral Research (ASBMR) were used, considering as atypical fractures those with all major criteria, accompanied or not by any of the minor criteria. Some of the major criteria are: absence of a marked history of local trauma or low-energy trauma; fracture located in any region distal to the lesser trochanter and proximal to the supracondylar area; transverse or short oblique configuration; simple, non-fragmented/comminuted fracture; medial spur in complete fractures and involvement of only lateral cortical in incomplete ones. The minor criteria are: thickening of the periosteum next to the lateral cortical; generalized thickening of femoral corticals; prodromal symptoms; association with symptoms or bilateral fracture; evidence of de-consolidation; presence of comorbidities (rheumatoid arthritis, rickets, osteomalacia, and renal osteoarthritis) or use of some medication (bisphosphonates, glycochoticoids and proton-pump inhibitors). Furthermore, fractures of the femoral neck, intertrochanteric region with extension to the subtrochanteric region, pathological fractures associated with neoplastic lesions, and periprosthetic fractures should be excluded.[5,8]

RESULTS

The epidemiological study included patients aged 50 years or older, with a shaft, subtrochanteric or diaphyseal femoral fracture, hospitalized between January 2013 and December 2018. Patients with changes in bone integrity, high-energy trauma fractures, proven pathological fractures, and periprosthetic fractures were excluded. Radiographs were properly studied and classified, according to ASBMR criteria, into atypical or typical femoral fractures; medical records were analyzed and patients or family members were contacted via telephone was made when necessary to gather further information on the occurrence of the fracture and the duration of the use of bisphosphonates (Figures 1, 2, 3, and 4).

Figure1. Female patient, 73 years old, three years of bisphosphonate use. Radiography of femur evidencing atypical fracture of the right femur, simple traits, medial spur, and cortical thickening.

Figure 2. Female patient, 86 years old, three years of bisphosphonate use. Radiography of femur with evidence of atypical fracture on the right femur, simple trait medial spur.

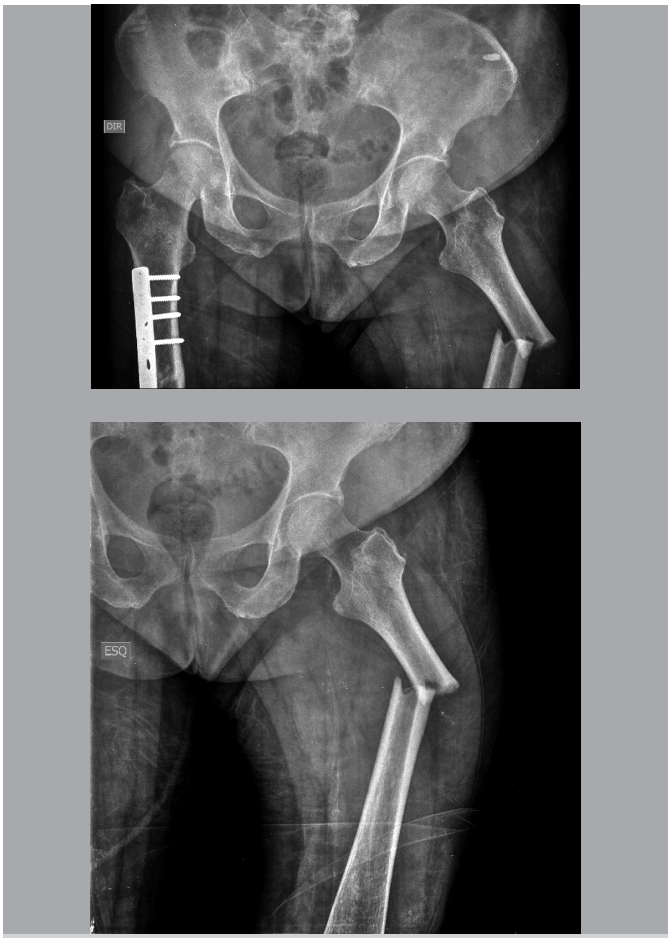

Figure 3. Female patient, 78 years old, atypical fracture of four years on the right, 10 years of bisphosphonate use. Radiography of the hip and femur evidencing synthesis material on the right and new atypical fracture on the left femur; there is an increase in cortical thickness and density.

Figure 4. Female patient, 74 years old, three years of bisphosphonate use. Atypical fracture on the right femur; there is an increase in the cortical thickness and density.

In total, 151 medical records were identified with femoral fractures diagnosis; nine patients presented atypical fractures, of which all made use of bisphosphonates. Thus, the incidence of atypical fractures was approximately of 6% (Figure 5).

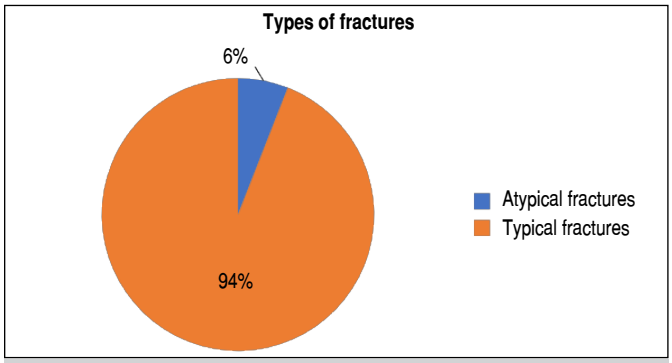

Figure 5. Typical fractures × Atypical fractures.

The approximate mean age of patients with atypical fracture was 78 years (minimum of 69 years of age; maximum of 88 years of age), with an incidence of 45% of people aged 80 years or over, 44% of patients aged 70 to 79 years, and 11% of patients under 70 years of age (Figure 6).

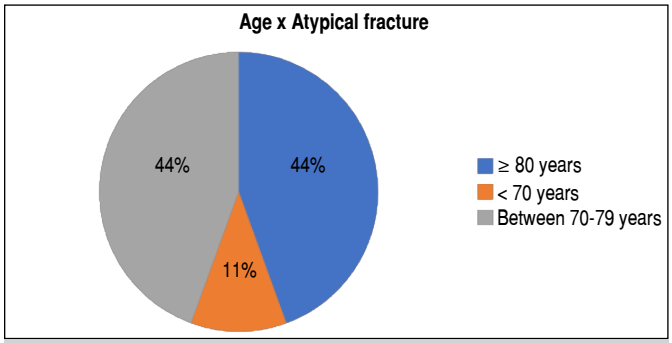

Figure 6. Age × Atypical fracture

The mean period of bisphosphonates use was of nine years (minimum of three years; maximum of 14 years); In view of the analysis of the data and consensus of treatment for osteoporosis, 89% of the patients who had atypical fracture used their medication for more than five years, while 11% used them for less than five years (Figure 7).

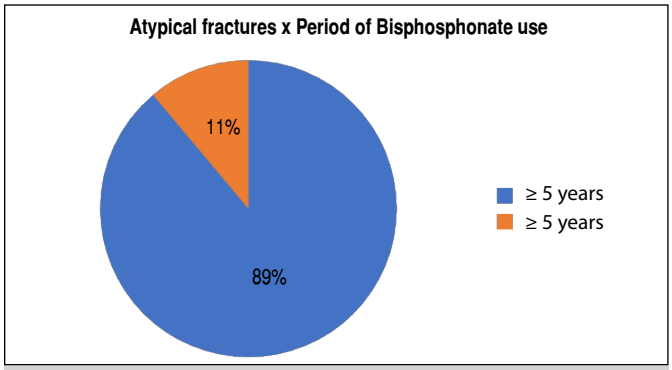

Figure 7. Atypical fractures × period Bisphosphonate of use.

The right limb was the most affected, totaling six exclusive fractures, including 45% diaphyseal and 22% subtrochanteric. The left limb presented only one isolated fracture, located in the diaphysis, representing 11%. In total, two patients had bilateral fractures in the region of the diaphysis, a total of 22% (Figure 8).
In our study, atypical fractures due to the use of the drug occurred only in women.

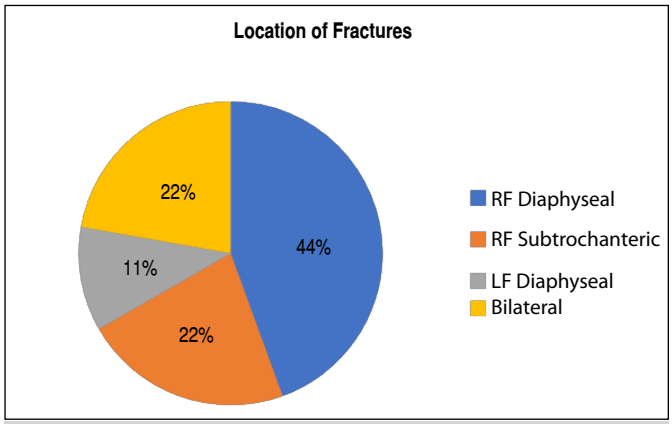

Figure 8. Location of atypical fractures.

DISCUSSION

Regarding the occurrence of atypical fractures among the cases selected in our study, this lesion was still rare (9%), an incidence already manifested within the literature.[8,11] However, our study showed the relationship with the prolonged use of bisphosphonates, reinforcing the association established in the study by Odvina et al. in 2005.[6] On the other hand, in comparison to this and other studies, a lower percentage of atypical fractures in our study (22%) was found in the subtrochanteric region, most of them (78%) in the diaphyseal region.[6,12] There is no definitive relationship between atypical fractures and greater involvement of the right lower limb (RLL), despite the large difference compared to the left lower limb involvement (LLL) in this study (67% RLL; 11% LLL). Bilateral involvement is frequently mentioned, since it may be present in 28 to 44.2% of patients, and it may lead to the consideration of a contralateral prophylactic fixation.[8,13,14] Several authors have reported an increase in atypical femoral fractures in patients older than 65 years and with five or more years of bisphosphonate use. In 2009, Capeci and Tejwani presented seven patients with bilateral atypical subtrochanteric fracture with an average of 8.6 years of use of this medication, a value similar to that found among the studied patients (nine years).[15]

The increased life expectancy of the population and its proven preventative actions will increase the indication of bisphosphonates and, eventually, the period of its use. This shows the importance of establishing an appropriate relationship between the duration of treatment and the risk of fracture. Unfortunately, the best period of use is not yet defined, but it is known that the use of these drugs for up to five years is effective in reducing osteoporotic fractures. From this period on, one should evaluate the need for medication continuity by analyzing bone densitometry (Femoral T-score <= −2.5 – treatment should be continued for up to six to 10 years), concomitant diseases, polypharmacy, and the risk of fall of the patient (frail older adult).[10] Prolonged time os use and predilection for females have often been reported by other authors.[16] The predominance of low-energy subtrochanteric and diaphyseal fractures in females and mean age > 65 years, with all exclusion criteria contained in our study, were also highlighted by Neviaser et al. in a retrospective analysis with 70 patients published in 2008 in New York City, with an average age of 67 years and 84% of occurrence in women.[17]

CONCLUSION

The low incidence of atypical fractures makes the screening to evaluate bone abnormalities in patients using bisphosphonates impossible. However, the prevalence of this type of injury in patients older than 65 years and femoral fractures subsequent to low-energy trauma scans in females show the importance of discriminating the methods of prevention of osteoporotic fractures in these cases, since a prolonged use of bisphosphonates is progressively associated with this complication. Obtaining and disseminating more scientific information is exceptionally relevant to establish doses, maximum treatment periods, and the risk-benefit of the indication of these medications.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. FCG: acquisition, analysis and interpretation of the data, writing of the article, final approval of the manuscript, responsibility for all aspects of the study; MZ: acquisition, analysis and interpretation of the data, writing of the article; PPVP: conception and design of the study, critical review, final approval of the manuscript.

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UPDATE ARTICLE
TRAUMA
DOI: http://dx.doi.org/10.1590/1413-785220223002245479

RADIOLOGICAL RESULTS OF SEVERE SCFE TREATMENT AT IOT-FMUSP FROM 2012 TO 2018

RESULTADOS RADIOLÓGICOS DO TRATAMENTO DE EPIFISIOLISTESE GRAVE NO IOT-FMUSP ENTRE 2012-2018

EDELVAN GABANA[1], *BRUNO SERGIO FERREIRA MASSA*[1], *CARLOS AUGUSTO MALHEIROS LUZO*[1], *PAULO ROBERTO DOS REIS*[1], *JORGE DOS SANTOS SILVA*[1], *KODI EDSON KOJIMA*[1]

1. Universidade de São Paulo, Medical School, Hospital das Clínicas, Institute of Orthopedics and Traumatology (IOT-HCFMUSP), Trauma Group, SP, Brazil.

ABSTRACT

Objective: To assess the complications in patients with severe slipped capital femoral epiphysis treated with the Dunn or modified Dunn procedure from 2012 to 2018 at the Institute of Orthopedics and Traumatology, Medical School, Universidade de São Paulo. Methods: Analysis of medical records, preoperative and postoperative radiographs with at least one year of radiographic follow-up of patients with severe slipped capital femoral epiphysis. Results: We reviewed the complications in 19 operated cases from 2012 to 2018, out of which 36.8% had osteonecrosis of the femoral head, one patient had chondrolysis, and another had postoperative infection. Conclusion: The osteonecrosis rate observed in this series of cases is similar to that described in other orthopedic facilities. We assessed factors that could potentially influence this outcome, including other characteristics of the patient (obesity, endocrine diseases, and history of sports activities) and of the health system. ***Level of Evidence III, Restropective Case Series.***

Keywords: Slipped Capital Femoral Epiphyses. Osteonecrosis. Osteotomy. Dunn Procedure. Modified Dunn Procedure. Southwick Angle.

RESUMO

Objetivo: Avaliar as complicações apresentadas nos pacientes com epifisiolistese grave tratados por meio do procedimento de Dunn ou Dunn Modificado entre 2012 e 2018 no IOT-FMUSP. Métodos: Análise de prontuários, radiografias pré-operatórias e radiografias pós-operatórias com pelo menos 1 ano de seguimento radiográfico dos pacientes com epifisiolistese grave. Resultados: Analisou-se a presença de complicações em 19 casos operados de 2012 a 2018. Desses pacientes, 36,8% apresentaram osteonecrose da cabeça femoral, oi observada condrólise em 1 paciente e infecção pós-operatória em 1 paciente. Conclusão: A taxa de osteonecrose observada nesta série de casos está próxima à descrita em outros serviços. Alguns fatores que potencialmente influenciariam neste desfecho poderiam ter sido avaliados, como outras características do paciente (obesidade, doenças endócrinas e atividade esportiva) e do sistema de saúde. ***Nível de Evidência III, Série Retrospectiva de Casos.***

Descritores: *Epifisiolistese. Osteonecrose. Osteotomia. Procedimento de Dunn. Procedimento de Dunn Modificado. Ângulo de Southwick.*

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INTRODUCTION

Slipped capital femoral epiphysis (SCFE) is the displacement of the femoral head relative to the neck of the femur through the growth plate, commonly with superior anterior deviation of the femoral metaphysis relative to the epiphysis.[1] Despite its unknown etiology in most cases, this condition is associated with the following risk factors: morphology of the proximal femur (femoral anteversion or retroversion), obesity, sports practice, and endocrine disorders.[2] Different classifications can be used. One of them concerns the length of symptoms and displacement: acute (up to three weeks), chronic (after three weeks), acute-chronic (when a previous displacement suffers an acute "slip").[3] However, to define prognosis and conduct, two classifications are crucial: the first is radiographic, which refers to the degree of displacement and is obtained by measuring the Southwick angle in frog-leg or cross-table lateral radiographs. SCFE can be classified as: mild (up to 30° of epiphyseal displacement relative to the healthy side), moderate (30–50°), and severe (over 50°).[4] The second classification is clinical, proposed by Loder in 1993 and used to this day as a predictor of possible complications: stable (patient can walk using crutches or not, despite the pain) or unstable SCFE (patient cannot walk).[5]

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

The study was conducted at the Institute of Orthopedics and Traumatology of the Hospital das Clínicas of USP Medical School (IOT-HCFMUSP).
Correspondence: Edelvan Gabana. Rua Dr. Ovídio Pires de Campos, 333, São Paulo, SP, Brazil, 05403010. edegabana@gmail.com

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Among possible complications, osteonecrosis and its progression to osteoarthrosis is probably the most feared.[1] Other unfavorable outcomes include postoperative infections, chondrolysis, femoroacetabular impingement, loosening of the synthesis material, and changes in limb growth.[1,4]
This study aims to assess complications, especially osteonecrosis of the femoral head, in patients with severe slipped capital femoral epiphysis of the proximal femur treated by a Dunn or modified Dunn surgical procedure from 2012 to 2018 at the Institute of Orthopedics and Traumatology of Hospital das Clínicas of the Universidade de São Paulo (HCFMUSP).

MATERIALS AND METHODS

The medical records of patients with SCFE of the proximal femur submitted to a Dunn or modified Dunn procedure from 2012 to 2018 were collected.
The Southwick angle (on AP and/or profile radiography) of each patient was calculated according to the method published by Southwick in July 1967 (Figure 1).[6]
After the epiphyseal line (black lines) is designed, a line is drawn perpendicular to it (blue lines); then, the angle between the blue line and a line drawn by the long axis of the diaphyseal femur (red lines) is calculated; finally, the value found on the affected side is subtracted from the unaffected side. Figure 1 shows the radiography of Patient 3, 11 years old, preoperative, Southwick angle: 81° (affected side, left) − 13° (unaffected side, right) = 68°.
A period of one year was considered as the minimum radiographic follow-up time. Alterations that are compatible with the various stages of osteonecrosis of the proximal femur on control radiographs (anteroposterior and profile) were analyzed, including: presence of cysts or sclerosis in the femoral head, presence of the crescent sign (subchondral fracture), and flattening or collapse of the femoral head (Figure 2).[7]
Data were presented according to the types of variables. Absolute frequencies and percentages were used for qualitative variables. Quantitative variables were presen ted by the mean, median, standard deviation, and minimum and maximum values. The boxplot Graph shows the distribution of the Southwick angle according to osteonecrosis.
The association between the variables sex and laterality according to the presence of osteonecrosis was assessed by Fisher's exact test. Angle values were compared among patients with and without osteonecrosis by the Mann-Whitney nonparametric test. The significance level adopted for hypothesis tests was 5%. The analyses were performed by the IBM SPSS statistical software for Windows version 25©.

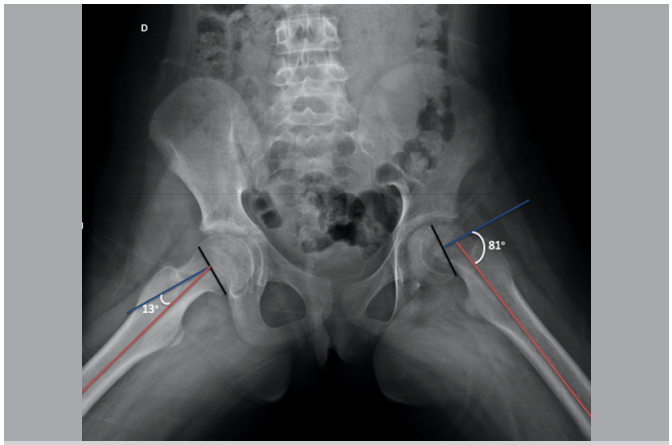

Figure 1. Calculation of the Southwick angle in the "frog leg" incidence.

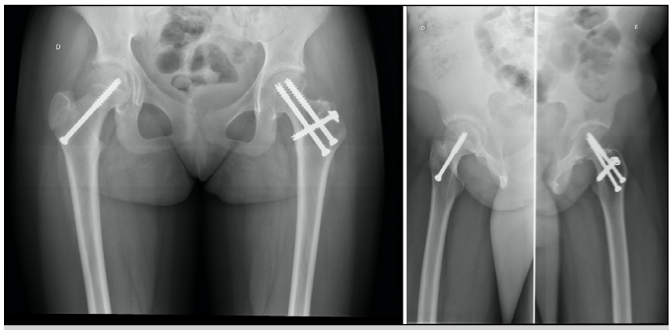
Figure 2. Patient 3 of Figure 1, 12 years old, one year and two months after surgery.

RESULTS

We identified 20 patients with severe slipped capital femoral epiphysis (Southwick angle > 50°)4 submitted to Dunn or modified Dunn procedure from 2012 to 2018. After assessing the minimum radiographic follow-up of one year, 19 cases met our inclusion criteria.
The mean age of the patients was 11.9 years (standard deviation [SD] 1.8 years) and half of the participants were 12 years old (minimum-maximum: 9–17 years old). Most were women (11, 57.9%) and had the right side affected (12, 63.2%) (Table 1).

Table 1. Sociodemographic characteristics of patients with severe slipped capital femoral epiphysis treated by Dunn or modified Dunn procedure, IOT-FMUSP, 2012–2018.

Characteristic			n = 19
			n (%)
Age (years)	Mean (SD)	11.9 (1.8)	
	Median (min-max)	12 (9-17)	
Sex	Female		11 (57.9%)
	Male		8 (42.1%)
Laterality	Right		12 (63.2%)
	Left		7 (36.8%)

SD: standard deviation; min: minimum value; max: maximum value.

Out of all patients, seven (36.8%) had osteonecrosis at the end of the follow-up. Other complications were less frequent, including: chondrolysis, in one case; infection requiring removal of the synthesis material, in one patient (did not progress to femoral osteonecrosis); and a case with loosened fixation of the greater trochanter.

DISCUSSION

The treatment of unstable severe SCFE is a major challenge for orthopedists, especially since its main complication is a frequent evolution of the femoral head to osteonecrosis. Several treatments have been used, including in situ fixation, which may show good clinical results in minor deviations but can lead to femoroacetabular impingement, chondrolysis, early osteoarthrosis of the hip, and high rates of osteonecrosis in cases of severe deviations—up to about 33%.[4,8] The modified Dunn procedure is currently the main technique for moderate and severe deviations,[1,8-11] particularly in unstable cases,[9] aiming at lower complication rates.
Criteria for choosing cases was the classification (degree of deviation or stability) and incidence of osteonecrosis of the femoral head in cases of surgery for severe and/or unstable SCFE, which vary with the surgical method used. In 2013, Zaltz, Baca, and Clohisy[12] reviewed 15 articles (397 cases) on unstable

SCFE and found an overall mean osteonecrosis in 23.9% of patients. However, frequency ranged from 0% to 58%. Lerch et al.[11] described in their series that 5% of cases with severe SCFE submitted to the modified Dunn procedure evolved to osteonecrosis. However, this rate ranged from 0% to 29% in 14 of the articles reviewed by us. Regarding the possible complications of SCFE, Roaten and Spence[1] reported that the incidence of osteonecrosis in patients undergoing Dunn or modified Dunn procedure can range from 8% to over 30%.

In our retrospective analysis of severe cases of SCFE submitted to Dunn or modified Dunn procedure, we found a 36.8% rate (7 out of 19 hips) of osteonecrosis of the femoral head, similar to that observed in other series.

The prevalence of osteonecrosis was 62.5% in boys and 18.2% in girls, with no statistically significant association (p = 0.074). Laterality was also not associated with the presence of osteonecrosis (p = 0.656). The distribution of patients' ages was similar between those with osteonecrosis and those without (p = 0.793). Table 2 describes the aforementioned data.

Table 2. Clinical characteristics of patients with severe slipped capital femoral epiphysis treated with the Dunn or modified Dunn procedure, IOT-FMUSP, 2012-2018.

Characteristic	n = 19	Osteonecrosis		p-value
		Yes	No	
		n = 7 (36.8%)	n = 12 (63.2%)	
Sex	Female	2 (18.2%)	9 (81.8%)	0.074[1]
	Male	5 (62.5%)	3 (37.5%)	
Age	Mean (SD)	11.9 (1.8)	11.9 (1.9)	0.793[2]
	Median (min-max)	12.0 (9-14)	11.5 (10-17)	
Laterality	Right	5 (41.7%)	7 (58.3%)	0.656[1]
	Left	2 (28.6%)	5 (71.4%)	
Affected side	Mean (SD)	92.9 (22.1)	91.6 (31.7)	0.582[2]
	Median (min-max)	81.0 (79-138)	81.5 (64-165)	
Normal side	Mean (SD)	21.3 (24.1)	28.2 (31.3)	0.703[2]
	Median (min-max)	15.0 (1-72)	16.0 (2-99)	
Southwick angle	Mean (SD)	71.6 (15.9)	63.3 (10.7)	0.204[2]
	Median (min-max)	66.0 (57-105)	61.5 (50-80)	

SD: standard deviation; min: minimum value; max: maximum value. [1]Fisher's exact test; [2]Mann-Whitney test for independent samples.

Because of the sample size, we could not statistically state that the increase in the Southwick angle is directly related to the increased incidence of osteonecrosis (p = 0.204) (Table 3). However, Figure 3 shows the distribution of Southwick angle values in patients who developed the complication under analysis or not.

This study has some limitations. The case series was insufficient to statistically determine the relationship between the increase in the Southwick angle and the development of osteonecrosis. We did not arrange a control group to compare the different treatments currently used (in situ fixation and modified Dunn procedure). We also should have questioned the time for SCFE diagnosis considering the limitations of the Brazilian Unified Health System (SUS) to directly affect the degree of deviation and consequent complications. This information and other factors related to the worst outcome of SCFE could not be assessed because of inconsistencies in the data of some medical records, such as the presence of obesity, endocrinopathies, and sports practices.

Table 3. Southwick angles and osteonecrosis of the femoral head.

Patient	Age	Sex	Laterality	Affected Side	Normal Side	Southwick angle	Osteonecrosis
Patient 1	12	male	right	72	19	**53**	no
Patient 2	12	female	left	82	2	**80**	no
Patient 3	11	female	left	81	13	**68**	no
Patient 4	14	female	right	82	19	**63**	no
Patient 5	12	male	right	80	23	**57**	yes
Patient 6	12	male	left	80	15	**65**	yes
Patient 7	11	female	right	86	24	**62**	yes
Patient 8	14	male	right	138*	72*	**66**	yes
Patient 9	11	male	right	78	23	**55**	no
Patient 10	11	female	right	88	32	**56**	no
Patient 11	11	female	left	64	9	**55**	no
Patient 12	11	female	right	79	3	**76**	yes
Patient 13	12	female	left	70	10	**60**	no
Patient 14	12	male	left	149*	99*	**50**	no
Patient 15	10	female	right	92	13	**79**	no
Patient 16	17	female	right	165*	87*	**78**	no
Patient 17	10	female	right	76	13	**63**	no
Patient 18	9	male	right	81	11	**70**	yes
Patient 19	14	male	left	106	1	**105**	yes

*Note: we had to assess the Southwick angle in the anteroposterior incidence in three patients.

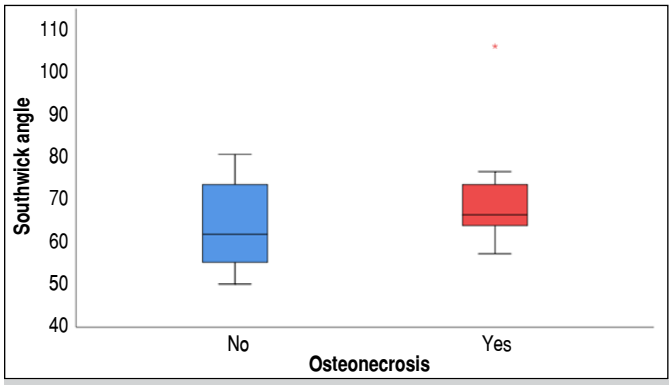

Figure 3. Distribution of the Southwick angle values according to the presence of osteonecrosis (boxplot) in patients with severe slipped capital femoral epiphysis treated by the Dunn or Modified Dunn procedure, IOT-FMUSP, 2012–2018.

CONCLUSION

The analysis of the rate of osteonecrosis of the femoral head (36.8%) in patients operated for severe SCFE from 2012 to 2018 indicates that results obtained were satisfactory and consistent with those found in other services, but still far from ideal. Other variables that could negatively affect this outcome should also be questioned and minimized, including other clinical characteristics of patients and the health system.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. EG: acquisition, analysis, and interpretation of data and writing of the study; BSFM: substantial contribution to the study design, interpretation of data for the study; CAML: substantial contribution to the study conception, interpretation of data for the study; PRR: substantial contribution to the study design, critical review of intellectual content; JSS: critical review of intellectual content, approval of the final version of the manuscript; KEK: critical review of intellectual content, approval of the final version of the manuscript.

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