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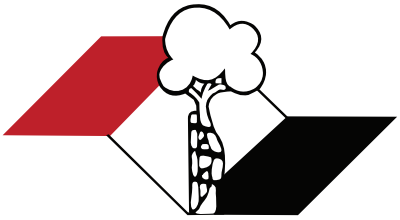

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OSTEOBAN
ibandronato de sódio

PREÇO ACESSÍVEL E COMODIDADE POSOLÓGICA
na prevenção* e tratamento da osteoporose[1,2,3]

1x POSOLOGIA AO MÊS[2]

PREVENÇÃO

34,4% DE REDUÇÃO do risco de **FRATURAS NÃO VERTEBRAIS.**[4]

62% DE REDUÇÃO do risco de **FRATURAS VERTEBRAIS.**[5]

MELHORA DA DENSIDADE mineral óssea em mulheres com Osteopenia e Osteoporose.[6]

Risco **5X MAIOR** da segunda fratura vertebral, após a primeira.[7]

*Estudo mostra aumento da densidade mineral óssea demonstrando prevenção da osteoporose na pós menopausa.

Referência bibliográfica: 1. Kairos Web Brasil. Disponível em: <http://brasil.kairosweb.com>. Acesso em: Maio/2017. **2.** Bula do produto OSTEOBAN: comprimidos revestidos. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **3.** BUMBASIREVIC, M. et al. Prospective clinical study of monthly ibandronate in the treatmetn of osteoporosis and prevention of fractures in postmenopausal women: ORPHEUM study. Srp Arh Celok Lek, v. 139, n. 11-12, p. 790-7694, 2011. **4.** HARRIS, S. T. et al. Ibandronate and the risk of nonvertebral and clinical fractures in women with postmenopausal osteoporosis: results of a metaanalysis of phase III studies. Curr Med Res Opin, v. 24, n. 1, p. 237-245, 2008. **5.** MILLER, P. D. et al. Efficacy of monthly oral ibandronate is sustained over 5 years: the MOBILE long-term extension study. Osteoporos Int, v. 23, n. 6, 2012. **6.** BOCK, O. et al. Impact of oral ibandronate 150 mg once monthly on bone structure and density in post-menopausal osteoporosis or osteopenia derived from in vivo µCT. Bone, v. 50, p. 317-324, 2012. **7.** STOLNICKI, B; OLIVEIRA, L.G. Para que a primeira fratura seja a última. Rev bras ortop, v. 51, n. 2, p. 121-126, 2016.

Interação Medicamentosa: Os pacientes devem esperar 60 minutos após ingerir OSTEOBAN, antes de tomarem outros medicamentos orais.
Contraindicação: OSTEOBAN é contraindicado a pacientes que não conseguem ficar em pé ou sentados durante, pelo menos, 60 minutos.

Osteoban. ibandrônato de sódio 150mg comprimido revestido. USO ORAL USO ADULTO. Indicações: OSTEOBAN é indicado para o tratamento da osteoporose pós-menopausa, com a finalidade de reduzir o risco de fraturas vertebrais. Em um subgrupo de pacientes de risco, com escore T < -3,0 DP no colo do fêmur, ibandronato de sódio também demonstrou reduzir o risco de fraturas não vertebrais. **Contraindicações**: **OSTEOBAN é contraindicado a pacientes com hipersensibilidade ao ibandronato de sódio ou aos demais componentes da fórmula e a pacientes com hipocalcemia não corrigida; pacientes com anormalidades do esôfago, como demora no esvaziamento esofágico, estenose ou acalasia; pacientes que não conseguem ficar em pé ou sentados durante, pelo menos, 60 minutos. Precauções e advertências: OSTEOBAN é contraindicado a pacientes com hipocalcemia não corrigida. Bisfosfonatos administrados por via oral podem causar irritação local da mucosa gastrintestinal superior. O risco de experiências adversas esofágicas graves parece ser maior para pacientes que não seguem as instruções de uso e/ou que continuaram a tomar bisfosfonatos por via oral após desenvolver sintomas sugestivos de irritação esofágica. Os pacientes devem prestar especial atenção e serem capazes de cumprir as instruções de administração. Considerando-se que anti-inflamatórios não esteróides e bisfosfonatos associam-se, ambos, à irritação gastrintestinal, recomenda-se cautela durante a administração concomitante de anti-inflamatórios não esteroides e ibandronato de sódio. Osteonecrose de mandibula foi relatada em pacientes tratados com bisfosfonatos. A maioria dos casos em pacientes oncológicos submetidos a procedimentos dentários, mas alguns casos ocorreram em pacientes em tratamento para osteoporose pós-menopausa e outros diagnósticos. Fatores de risco conhecidos para osteonecrose de mandibula: câncer, terapias concomitantes (ex: quimioterapia, radioterapia e corticosteroides) e distúrbios concomitantes (ex: anemia, coagulopatia, infecção e doença dentária pré-existente). A maioria dos casos foi relatada em pacientes tratados com bisfosfonatos de administração intravenosa, mas também em alguns pacientes tratados com bisfosfonatos orais.Relatos na literatura médica indicam que os bisfosfonatos podem estar associados à inflamação ocular, como uveíte e esclerite. Não foram realizados estudos sobre os efeitos de ibandronato de sódio sobre a capacidade de dirigir veículos e operar máquinas. Gestação e lactação: Categoria de risco na gravidez: B. Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista.** Não há experiência sobre o uso clínico de ibandronato de sódio em mulheres durante a gestação. OSTEOBAN não deve ser utilizado por mulheres que estejam amamentando sem orientação médica ou do cirurgião dentista. **Atenção diabéticos: contém açúcar (lactose). Interações medicamentosas:** é provável que suplementos à base de cálcio, antiácidos e alguns medicamentos orais que contenham cátions multivalentes (tais como alumínio, magnésio e ferro) interfiram na absorção de ibandronato de sódio. Os pacientes devem esperar 60 min após ingerir OSTEOBAN, antes de tomarem outros medicamentos orais. Foi demonstrada, em estudo de interação farmacocinética em mulheres na pós-menopausa, a ausência de qualquer interação potencial com tamoxifeno ou tratamentos de reposição hormonal (estrogênio). Não se observou interferência quando ibandronato de sódio foi administrado concomitantemente com melfalano / prednisolona em pacientes com mieloma múltiplo. **Interações com alimentos:** a ingestão de alimentos deve ser postergada em 60 min após a administração oral de ibandronato de sódio. **Reações adversas: reações adversas comuns (> 1/100 e ≤ 1/10): doença do refluxo gastroesofágico, diarreia, dor abdominal, dispepsia, náusea, flatulência, cefaleia, síndrome influenza–like, fadiga, artralgia, mialgia, exantema. Reação incomum (>1/1.000 e <1/100):** distúrbios gastrintestinais (gastrite, esofagite, incluindo ulcerações esofágicas ou estenose, vômitos e disfagia), distúrbios do sistema nervoso (tonturas), distúrbios musculoesqueléticos e do tecido conjuntivo (dor nas costas). **Reação rara (>1/10.000 e <1/1.000):** distúrbios gastrintestinais (duodenite), distúrbios do sistema imunológico (reações de hipersensibilidade), distúrbios da pele e do tecido subcutâneo (angioedema, edema facial e urticária). **Posologia** deve ser administrado em jejum, 60 min antes da ingestão do primeiro alimento ou bebida do dia (exceto água) e antes da administração de qualquer outro medicamento ou suplemento, inclusive cálcio. Os comprimidos devem ser deglutidos inteiros, com um copo cheio de água filtrada (180 a 240 mL). O paciente não deverá deitar-se nos 60 min seguintes após tomar o medicamento; A dose recomendada de OSTEOBAN é um comprimido de 150 mg, **uma vez por mês**. **Pacientes idosos:** não é necessário ajuste de dose. **Pacientes com insuficiência renal:** não é necessário ajuste de dose para pacientes com insuficiência renal leve a moderada e com depuração de creatinina ≥ 30 mL/min. Em pacientes com depuração de creatinina < 30 mL/min, a decisão de administrar OSTEOBAN deve ser baseada na avaliação individual da relação risco / benefício. **Pacientes com insuficiência hepática:** não há necessidade de ajuste de dose para pacientes com insuficiência hepática. "SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO." **VENDA SOB PRESCRIÇÃO MÉDICA**. MS - 1.0573.0422. **"Material técnico científico de distribuição exclusiva a profissionais de saúde habilitados à precrição e/ou dispensação de medicamentos"**. 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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed January 2016)

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We ask authors to observe the following instructions for publication.

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NUMBER OF WORDS RECOMMENDED ACCORDING TO THE PUBLICATION TYPE: The criteria specified below should be observed for each type of publication. The electronic counting of words should start at the Introduction and end at the Conclusion.

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Type of Article	Abstract	Number of words	References	Figures	Tables	Maximum number of authors allowed
Original	Structured, up to 200 words	2.500 Excluding abstract, references, tables and figures	20	10	6	6
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*These contributions shall be published at the Editors' criteria, with due replica, when applicable.

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Manuscripts should be sent in .txt or .doc files, double-spaced, with wide margins. Measures should be expressed in the International System (*Système International*, SI), available at http://physics.nist.gov/cuu/Units and standard units, where applicable.

It is recommended that authors do not use abbreviations in the title and limit their use in the abstract and in the text.

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KEYWORDS: The article should include at least three and at most six descriptors in Portuguese and in English, based on the Descriptors of Health Sciences (DeCS) http://decs.bvs.br/ or Medical Subject Headings (MeSH) of the National Library of Medicine, available at http://www.nlm.nih.gov/mesh/meshhome.html

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MATERIALS AND METHODS: This section should describe the experiments (quantitatively and qualitatively) and procedures in sufficient detail to allow other researchers to reproduce the results or provide continuity to the study.

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Authors should precisely identify all drugs and chemicals used, including generic names, dosages and administration. Patients' names, initials, or hospital records should not be included. References regarding statistical procedures should be included.

RESULTS: Results should be present in logical sequence in the text, using tables and illustrations. Do not repeat in the text all the data in the tables and/or illustrations, but emphasize or summarize only the most relevant findings.

DISCUSSION: Emphasize new and important aspects of the study and the conclusions that derive from it, in the context of the best evidence available. Do not repeat in detail data or other information mentioned elsewhere in the manuscript, as in the Introduction or Results. For experimental studies it is recommended to start the discussion by briefly summarizing the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study and explore the implications of these results for future research and for clinical practice.

Link the conclusions with the goals of the study, but avoid statements and conclusions that are not supported by the data, in particular the distinction between clinical and statistical relevance. Avoid making statements on economic benefits and costs, unless the manuscript includes data and appropriate economic analysis. Avoid priority claim ("this is the first study of ...") or refer to work that has not yet been completed.

CONCLUSION: The conclusion should be clear and concise, establishing a link between the conclusion and the study objectives. Avoiding conclusions not based on data from the study in question is recommended, as well as avoiding suggest that studies with larger samples are needed to confirm the results of the work in question.

ACKNOWLEDGEMENTS

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

AUTHORS IDENTIFICATION: The ORCID (Open Researcher and Contributor ID, http://orcid.org/) of each author should be informed in the authors' statement of contribution, according to the model below.

STATEMENT OF AUTHORS' CONTRIBUTION: The declaration of authors' contribution should be included at the end of the article, using minimum criteria for authorship, including:

- Substantial contribution in the work conception or design, or acquisition, analysis or interpretation of data to the study;
- Writing the article or critically reviewing its intellectual content;
- Approval of the final version of the manuscript to be submitted for publication;
- Agree to be responsible for all aspects of the work, to ensure that any matters regarding the completeness or accuracy of any of its parts are properly investigated and resolved;

All articles should include a description of the authors' contribution, as follows:

"Each individual author contributed individually and significantly to the development of this work. MJ (0000-0000-0000-0000)*: wrote and reviewed the and performed the surgeries; CPV (0000-0002-3904-2836)*: performed the surgeries, analyzed the data analysis and wrote the articles; JVC (0000-0003-3910-714x (0000-0000-0000-0000)*: performed statistical analysis, participated at the surgeries and reviewed the article; OMA (0000-0000-0000-0000)*: analyzed the slides and reviewed the article; MASP (0000-0000-0000-0000)*: drafted and reviewed the article and contributed to the intellectual concept of the study; ACA (0000-0001-6891-5935)*: performed the surgeries, wrote the article, performed statistical analysis and contributed to the intellectual concept of the study and the entire research project. *ORCID (Open Researcher and Contributor ID)."

REFERENCES: Original articles may include up to about 20 references, restricted to the essential bibliography to the article's content. Number the references consecutively in the order in which they are first mentioned in the text, using superscript Arabic numerals in the following format: (e.g., Reduction of terminal plate functions.[1]).

Authors should make sure that all references are cited in the text. Several citations within a single set of parentheses should be separated by commas without space ([1,5,7]). Where there are 3 or more sequential citations, use a numeric range ([4-9]). Include the first six authors followed by et al.

The titles of journals should be abbreviated according to *Index Medicus*.

a) Article: Author (s). Article title. Journal title. Year; volume: initial page –final page.

Ex.: Campbell CJ. The healing of cartilage defects. Clin Orthop Relat Res. 1969;64:45-63.

b) Book: Author(s) or editor (s). Book title. Edition, if it is not the first. Translator (s), if it applies. Publication place: publisher; year.

Ex.: Diener HC, Wilkinson M, editors. Drug-induced headache. 2nd ed. New York: Spriger-Verlag; 1996.

c) Book chapter: Chapter author (s). Chapter title. Book Editor (s) and supplementary data, likewise the previous item.

Ex.: Chapman MW, Olson SA. Open fractures. In: Rockwood CA, Green DP. Fractures in adults. 4th ed. Philadelphia: Lippincott-Raven; 1996. p.305-52.

d) Abstract: Author(s). Title, followed by [abstract]. Journal. Year; volume (supplement and its number, if it applies): page (s).

Ex.: Enzensberger W, Fisher PA. Metronome in Parkinson's disease [abstract]. Lancet. 1996;34:1337.

e) Personal communications: should only be mentioned in the text, between parentheses.

f) Thesis: Author, title, level (Master, PhD, etc.), city: institution; year.

Ex.: Kaplan SJ. Post-hospital home health care: the elderly's access and utilization [dissertation]. St. Louis: Washington Univ.; 1995.

g) Electronic material: Author (s). Article title. Abbreviated Journal title [medium]. Publication date [access date followed by the expression "accessed on"]; volume (number):initial page-final page or [approximate number of pages]. URL followed by the expression "Available from:"

Ex.: Pavezi N, Flores D, Perez CB. Proposição de um conjunto de metadados para descrição de arquivos fotográficos considerando a Nobrade e a Sepiades. Transinf. [Internet]. 2009 [acesso em 2010 nov 8];21(3):197-205. Available from: http://periodicos.puc-campinas.edu.br/seer/index.php/transinfo/article/view/501

TABLES: Tables should be numbered in order of appearance in the text with Arabic numerals. Each table should have a title and, when necessary, an explanatory caption. Charts and tables should be sent in editable source files (Word, Excel) and not as images. Tables and charts covering more than one page should be avoided. Do not use image elements, text boxes, or tabs.

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Levels of Evidence for Primary Research Question[a]

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

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

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

SUMMARY

VOLUME 25–Nº 4–2017

Original Articles

Oxotron
loxoprofeno

A NOVA OPÇÃO NO TRATAMENTO ANTI-INFLAMATÓRIO.[1,2]

RÁPIDO INÍCIO DE AÇÃO

Início de ação em aproximadamente 15 minutos[2]

- **Atividade preferencial sobre a COX-2[3,4]**
- **Fármaco seguro[3,5]**
- **Boa tolerabilidade[3]**
- **Tão eficaz quanto celecoxibe, ibuprofeno e naproxeno na redução da dor e inflamação em pacientes com dor pós-operatória, osteoartrite e ombro congelado[6]**

Referências Bibliográficas: 1) BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Consulta de produtos. Disponível em: <http://www7.anvisa.gov.br/datavisa/Consulta_Produto/consulta_produto_detalhe.asp>. Acesso em: Out. 2016. 2) Bula do produto OXOTRON: comprimidos. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP: Aché Laboratórios Farmacêuticos S.A. 3) DUTRA, F.G.; ENGELKE, F. O uso do loxoprofeno sódico nos processos inflamatórios comuns em reumatologia e ortopedia: Estudo colaborativo. RBM, v. 58, n. 1/2, p. 39-48, 2001. 4) MARONE, S.; ENGELKE, F. Loxoprofeno sódico no tratamento complementar das infecções agudas das vias aéreas superiores: Estudo colaborativo. RBM, v. 58, n. 3, p. 171-178, 2001. 5) LEDERMAN, R.; GUIMARÃES, S.; VERZTMAN, J.F. Eficácia clínica e segurança do loxoprofeno sódico (Loxonin®) no tratamento da gonartrose. RMB, v. 58, v. 4, p. 263-271, 2001. 6) GREIG, S.L.; GARNOCK-JONES, K.P. Loxoprofen: A review in pain and inflammation. Clin Drug Investig, v. 36, n. 9, p. 771-81, 2016.

Oxotron é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas

Oxotron está contraindicado em: Crianças e jovens menores de 18 anos de idade, gestantes no último trimestre da gravidez e durante o período de lactação; pessoas que apresentaram reações de hipersensibilidade ao loxoprofeno ou a qualquer um dos componentes da fórmula; portadores de úlcera péptica, graves distúrbios hematológicos, hepáticos ou renais.INTERAÇÕES MEDICAMENTOSAS: Coadministração cautelosa: Anticoagulantes cumarínicos, hipoglicemiantes sulfonilureicos, antibacteriano fluoroquinolona, metotrexate, sais de lítio, diuréticos benzotiazídicos, anti-hipertensivos.

Oxotron. Loxoprofeno sódico. MEDICAMENTO SIMILAR EQUIVALENTE AO MEDICAMENTO DE REFERÊNCIA. 60 mg. Comprimido. USO ORAL. USO ADULTO. Oxotron. Loxoprofeno sódico. APRESENTAÇÕES. Comprimidos 60 mg: embalagens com 8, 15 ou 30 comprimidos. USO ORAL. USO ADULTO. **COMPOSIÇÃO:** Cada comprimido de Oxotron contém: Loxoprofeno sódico anidro (como loxoprofeno sódico di-hidratado) 60 mg. Excipientes: lactose monoidratada, estearato de magnésio, hipromelose de baixa substituição, óxido férrico vermelho. **INFORMAÇÕES TÉCNICAS AOS PROFISSIONAIS DE SAÚDE. INDICAÇÕES.** Oxotron está indicado como anti-inflamatório e analgésico no tratamento de artrite reumatóide, osteoartrite, periartrite escapulo-umeral, processos inflamatórios osteomusculares do pescoço, ombro, braço e lombalgias; como analgésico e anti-inflamatório em pós-cirurgia, pós-traumatismo e pós-exodontia, como analgésico anti-inflamatório e antitérmico em processos inflamatórios agudos do trato respiratório superior (acompanhados ou não de bronquite aguda). **CONTRAINDICAÇÕES.** Oxotron está contraindicado em: Crianças e jovens menores de 18 anos de idade, gestantes no último trimestre da gravidez e durante o período de lactação; pessoas que apresentaram reações de hipersensibilidade ao loxoprofeno ou a qualquer um dos componentes da fórmula; portadores de úlcera péptica, graves distúrbios hematológicos, hepáticos ou renais; portadores de disfunções cardíacas graves; indivíduos com asma induzida por AINE. Este medicamento é contraindicado para menores de 18 anos. Categoria de risco na gravidez: D (terceiro trimestre): este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica. Informe imediatamente seu médico em caso de suspeita de gravidez. **ADVERTÊNCIAS E PRECAUÇÕES:** Oxotron deve ser administrado com cautela em: Pessoas com histórico de úlcera péptica; pessoas portadoras ou com histórico de distúrbios hematológicos; pessoas portadoras ou com histórico de disfunção hepática; pessoas portadoras ou com histórico de disfunção renal; pessoas com úlcera associada ao tratamento prolongado com anti-inflamatórios não esteroides, ainda que estejam em uso de misoprostol como medida profilática; pessoas com asma brônquica de qualquer causa; pessoas com disfunção cardíaca; pessoas com história de hipersensibilidade; pessoas com colite ulcerativa; pessoas com doença de Crohn; pessoas idosas. Durante tratamento prolongado com Oxotron, exames laboratoriais, tais como urina tipo I, hemograma completo e enzimas hepáticas devem ser realizados periodicamente. Se forem observadas alterações, recomenda-se redução da dose ou interrupção do tratamento. O uso de Oxotron, bem como de outros anti-inflamatórios, pode provocar alteração do controle da pressão arterial em indivíduos hipertensos sob tratamento. Alguns efeitos indesejáveis como tontura e sonolência têm sido relatados durante o uso de Oxotron. Para segurança do paciente, solicitar cuidado ao dirigir e ao operar máquinas. A segurança do uso de loxoprofeno sódico na gestação não foi estabelecida, portanto, Oxotron somente deverá ser administrado a gestantes se os benefícios terapêuticos justificarem os riscos potenciais para o feto (particularmente no terceiro trimestre) bem como durante a lactação. Categoria de risco na gravidez: B (primeiro e segundo trimestres): Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. **INTERAÇÕES MEDICAMENTOSAS:** Coadministração cautelosa: Anticoagulantes cumarínicos, hipoglicemiantes sulfonilureicos, antibacteriano fluoroquinolona, metotrexate, sais de lítio, diuréticos benzotiazídicos, anti-hipertensivos. **REAÇÕES ADVERSAS.** Oxotron pode causar os seguintes efeitos indesejados: rash cutâneo, urticária, sonolência, edema, dor abdominal, desconforto gástrico, anorexia, náusea e vômito, diarreia e aumento das transaminases hepáticas, prurido, úlcera péptica, constipação intestinal, pirose, estomatite, urticária, dispepsia, cefaleia, anemia, leucopenia, eosinofilia, aumento da fosfatase alcalina, palpitação, fogachos, febre, sede, distensão abdominal, úlcera no intestino delgado e/ou grosso, aumento da pressão arterial, entorpecimento, tontura, trombocitopenia, hematúria, proteinúria, disúria, dor no peito e mal estar. Outras reações adversas clinicamente significantes: choque, sintomas anafilactóides, crise asmática, Stevens-Johnson, síndrome de Lyell (necrose epidérmica tóxica), agranulocitose, anemia hemolítica, leucopenia, trombocitopenia, insuficiência renal aguda, síndrome nefrótica, nefrite intersticial, insuficiência cardíaca congestiva, pneumonia intersticial, sangramento gastrintestinal, estenose e/ou obstrução do intestino delgado e/ou grosso, perfuração gastrintestinal, disfunção hepática, icterícia, meningite asséptica e rabdomiólise. Estes casos devem ser observados cuidadosamente. A terapia com Oxotron deve ser descontinuada imediatamente e adotadas medidas de tratamento apropriadas. Foi reportado que anemia aplástica pode ocorrer com o uso de drogas anti-inflamatórias não esteroides. Em caso de eventos adversos, notifique ao Sistema de Notificações em Vigilância Sanitária – NOTIVISA, disponível em www.anvisa.gov.br/hotsite/notivisa/index.htm, ou para a Vigilância Sanitária Estadual ou Municipal. **POSOLOGIA E MODO DE USAR.** Em geral recomenda-se para o adulto a posologia de um comprimido (60 mg de Loxoprofeno sódico), três vezes ao dia, por via oral. Em casos agudos poderá ser realizada uma única administração de um a dois comprimidos (60-120 mg de Loxoprofeno sódico), por via oral, ajustando-se a dose de acordo com a idade e os sintomas. Não ultrapassar a dose diária de 180 mg, bem como evitar a administração em jejum. A segurança em pacientes pediátricos não foi estabelecida. VENDA SOB PRESCRIÇÃO MÉDICA. MS - 1.0573.0496. Código EDG 321635 00 "Material técnico científico de distribuição exclusiva à classe médica".

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MOTORE
Curcuma longa 250 mg

O ANTI-INFLAMATÓRIO
COMPROVADAMENTE[3] EFICAZ E SEGURO
A LONGO PRAZO[1]

EXTRATO DE CURCUMINA COMPLEXADO
TECNOLOGIA **EXCLUSIVA**[3,4]

Exclusivo complexo curcumina-fosfatidilcolina (fitossomo):
18X mais biodisponível
em comparação à curcumina não complexada.[3]

Cientificamente comprovado
Curcumina principal fração (curcuminoide) com ação anti-inflamatória amplamente estudada.[3]

Referências Bibliográficas: 1) BELCARO, G et al: Efficacy and Safety of Meriva®, a Curcumin-phosphatidylcholine Complex,during Extended Administration in Osteoarthritis Patients. Alternative Medicine Review 15(4):337-344,2010. 2) BOSI,PL: saúde baseada em evidências. disponível em: http://disciplinas.nucleoead.com.br/pdf/Livro_SaudeBaseadaemEvidencias.pdf. Acesso em 11/2015. 3) JURENKA, S. J. Anti-inflammatory properties of Curcumin, a major constituent of Curcuma longa: a review of preclinical and clinical research. Alternative Medicine Review, v.14, n.2, p. 141-153, 2009. 4) CUOMO, J. et al. Comparative absorption of a standardized curcuminoid mixture and its lecithin formulation. J Nat Prod, v.74, p.664-669, 2011. 5) Bula do produto MOTORE: cápsulas. Responsável Técnico: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A.

Contraindicações: contraindicado em caso de alergia à curcumina, açafrão *(Curcuma longa)* ou a qualquer outro componente da fórmula. É contraindicado em pacientes que estejam em tratamento com medicações que alterem as características de coagulação como antiagregantes plaquetários, anticoagulantes, heparina de baixo peso molecular e agentes trombolíticos. É também contraindicado em casos onde haja risco de obstrução de vias biliares ou casos de cálculos biliares, úlceras estomacais e hiperacidez do estômago.

MOTORE curcuma longa Extrato seco. **Cápsulas 250 mg. USO ORAL. USO ADULTO. Indicações**: medicamento fitoterápico destinado ao tratamento da osteoartrite e artrite reumatóide, e tem ação antiinflamatória e antioxidante. **Cuidados e advertências: a curcumina é muito bem tolerada em seu uso por via oral pela grande maioria dos pacientes, sendo raros os relatos de efeitos prejudiciais. Raramente podem ocorrer queixas como desconforto gástrico leve e movimentos intestinais mais frequentes. Precauções e advertências: o uso da curcumina por via oral mostrou ser bem tolerada pela maioria dos pacientes. Em casos esporádicos foram relatados episódios de menor gravidade como desconforto gastrointestinal. Não há relatos de overdose ou efeito tóxico grave. Em caso de ocorrência de reação de hipersensibilidade, a medicação deve ser imediatamente descontinuada e os sintomas avaliados pelo médico. Motore deve ser tomado apenas por via oral. Os riscos do uso por via de administração não recomendada são a não obtenção do efeito desejado e a ocorrência de reações adversas indesejadas. Não há dados de segurança relativo ao uso da curcumina em portadores de insuficiência hepática e/ou renal, não sendo recomendável o uso da medicação em pacientes nessas condições. As doses de tratamento recomendadas não devem ser excedidas. Informe ao seu médico ou cirurgião-dentista se você está fazendo uso de algum outro medicamento. Não use medicamento sem o conhecimento do seu médico. Pode ser perigoso para a sua saúde. Gravidez e lactação:** apesar de não haver estudos conclusivos em humanos que mostrem efeito negativo na fertilidade humana, alguns estudos realizados em animais sinalizaram efeito negativo na implantação de embriões após uso injetável de altas doses de extrato etanol da curcuma. Desta maneira sugere-se evitar o uso da curcumina em pacientes com intenção de engravidar ou em gestantes. Mulheres em fase de lactação também devem evitar o uso desta medicação. Categoria de risco na gravidez C: Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. **Interações medicamentosas: é contraindicado para uso em pacientes que estejam fazendo uso de medicações que alterem as características de coagulação como antiagregantes plaquetários, anticoagulantes, heparina de baixo peso molecular e agentes trombolíticos, pois, pode haver aumento no risco de casos de sangramento. Reações adversas: o uso da curcumina por via oral mostrou ser bem tolerada pela maioria dos pacientes. Em casos esporádicos foram relatados episódios de menor gravidade como desconforto gastrointestinal. Não há relatos de overdose ou efeito tóxico grave.** Em caso de ocorrência de reação de hipersensibilidade, a medicação deve ser imediatamente descontinuada e os sintomas avaliados pelo médico. Motore deve ser tomado apenas por via oral. Os riscos do uso por via de administração não recomendada são a não obtenção do efeito desejado e a ocorrência de reações adversas indesejadas. Não há dados de segurança relativo ao uso da curcumina em portadores de insuficiência hepática e/ou renal, não sendo recomendável o uso da medicação em pacientes nessas condições. As doses de tratamento recomendadas não devem ser excedidas. **Posologia:** Motore deve ser ingerido por via oral, com um pouco de água. A dose habitual para adultos é de 2 cápsulas a cada 12 (doze) horas, ou seja, duas tomadas diárias, totalizando 500mg de medicação a cada tomada. "SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO." **VENDA SOB PRESCRIÇÃO MÉDICA.** MS - 1.0573.0442. **MB 03 SAP 4437701.**

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Referências Bibliográficas: 1) IOLASCON, G. et al. Risendronate's efficacy: from randomized clinical trials to real clinical practice. Clinical Cases in Mineral and Bone Metabolism, v. 7, n. 1, p. 19-22, 2010. **2)** Kairos Web Brasil. Disponível em: http://brasil.kairosweb.com. Acesso em: Abril/2017. **3)** Programa cuidados pela Vida (O Programa Cuidados pela Vida pode alterar ou interromper esta campanha sem aviso prévio. Desconto calculado sobre o Preço Máximo ao Consumidor). **4)** BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Resolução - RE nº 921, de 4 de abril de 2017. Concede Certificação de Boas Práticas de Fabricação ao Aché. Diário Oficial da União, Brasília, DF, p. 37, 10 abril 2017.

CONTRAINDICAÇÕES: OSTEOTRAT está contraindicado em pacientes com hipersensibilidade a qualquer componente da fórmula, com hipocalcemia, durante a gravidez, lactação e para pacientes com insuficiência renal severa ("clearance" de creatinina < 30 mL/min). **INTERAÇÕES MEDICAMENTOSAS:** Não foram realizados estudos formais de interação medicamentosa, entretanto, durante os estudos clínicos não foi observada qualquer interação clinicamente relevante com outros medicamentos.

OSTEOTRAT. risedronato sódico 35 mg. comprimidos revestidos. USO ORAL. USO ADULTO. Indicações: tratamento e prevenção da osteoporose em mulheres no período pós-menopausa para reduzir o risco de fraturas vertebrais e não vertebrais. Tratamento da osteoporose em homens com alto risco de fraturas. **Contraindicações: hipersensibilidade a qualquer componente da fórmula, hipocalcemia, gravidez e lactação e para pacientes com insuficiência renal severa ("clearance" de creatinina <30 mL/min), Precauções e advertências: Alimentos, bebidas (exceto água) e drogas contendo cátions polivalentes (tais como: cálcio, magnésio, ferro e alumínio) podem interferir na absorção dos bisfosfonatos e não devem ser administrados concomitantemente. Em mulheres mais idosas (> 80 anos), a evidência de manutenção da eficácia de risedronato sódico, é limitada. Alguns bisfosfonatos foram relacionados a esofagites e ulcerações esofágicas. Em pacientes que apresentam antecedentes de alteração esofágica que retardam o trânsito ou o esvaziamento esofágico (ex. estenososе ou acalasia), ou que são incapazes de permanecerem em posição ereta por pelo menos 30 minutos após a ingestão do comprimido, o risedronato deve ser utilizado com especial cautela. Os prescritores devem enfatizar a importância das instruções posológicas para pacientes que apresentam antecedentes de alterações esofágicas. A hipocalcemia deve ser tratada antes do início do tratamento com OSTEOTRAT. Outras alterações ósseas e do metabolismo devem ser tratadas quando iniciada a terapia com OSTEOTRAT.** Osteonecrose de mandíbula, geralmente associada com extração dentária e/ou infecção local foi relatada em pacientes com câncer em regimes de tratamento com bisfosfonatos, principalmente, na administração intravenosa. Osteonecrose de mandíbula também foi relatada em pacientes com osteoporose recebendo bisfosfonatos orais. Este medicamento contém lactose. Pacientes com problemas hereditários raros de intolerância à galactose, a deficiência da Lapp lactaseou má absorção da glucose-galactose, não devem tomar esse medicamento. Gravidez e lactação: O risco potencial para humanos é desconhecido. Risedronato sódico só deve ser utilizado durante a gravidez, se o risco benefício justificar o potencial risco para a mãe e o feto. A decisão de descontinuar a amamentação ou o produto deve considerar a importância do medicamento para mãe. Interações medicamentosas: Se considerado apropriado, OSTEOTRAT pode ser utilizado concomitantemente com a terapia de reposição hormonal. A ingestão concomitante de medicamentos contendo cátions polivalentes (ex. cálcio, magnésio, ferro e alumínio) irá interferir na absorção de OSTEOTRAT. O uso concomitante de antiácidos pode reduzir a absorção de risedronato. OSTEOTRAT não é metabolizado sistemicamente, não induz as enzimas do citocromo P450 e apresenta baixa ligação protéica. **Reações adversas: Estão listadas a seguir de acordo com a seguinte convenção: muito comum (>1/10); comum (>1/100; <1/10); incomum (>1/1000; <1/100); raro (>1/10000; <1/1000); muito raro (<1/10000). Comuns: dor de cabeça, constipação, dispepsia, náusea, dor abdominal, diarréia, dor musculoesquelética. Incomuns: gastrite, esofagite, disfagia, duodenite, úlcera esofágica Raros: glossite, estenose esofágica. Muito raramente foram observadas reações como: uveite, irite, osteonecrose de mandíbula, hipersensibilidade e reações cutâneas, incluindo angioedema, rachaduras generalizadas e reações bolhosas de pele, algumas severas. Raramente observaram-se anormalidades nos testes de função hepática. Relatos laboratoriais: foram observados em alguns pacientes discreta diminuição nos níveis de cálcio sérico e fosfato, as quais foram precoces, transitórias e assintomáticas. Posologia:** A dose recomendada nos adultos é de 1 comprimido de 35 mg uma vez por semana, por via oral. Deve ser administrado no mínimo 30 minutos antes da primeira refeição, outra medicação ou bebida (exceto água) do dia. Os comprimidos devem ser engolidos inteiros, sem deixá-los dissolvendo na boca ou mastigá-los. Os pacientes devem utilizar OSTEOTRAT enquanto estiverem na posição vertical, com um copo de água (120 mL) para auxiliar a chegada ao estômago. Os pacientes não devem deitar por 30 minutos após ingestão de OSTEOTRAT. O comprimido de Osteotrat deve ser tomado no mesmo dia de cada semana, não devem ingeridos dois comprimidos no mesmo dia. Nenhum ajuste de dose é necessário para pacientes com insuficiência renal leve a moderada. O uso do risedronato sódico é contraindicado em pacientes com insuficiência renal severa ("clearance" de creatinina menor que 30 mL/min.) "SE PERSISTIREM OS SINTOMAS, O MEDICO DEVERA SER CONSULTADO." VENDA SOB PRESCRIÇAO MEDICA. MS - 1.0573.0418. MB 02_SAP 4389103. Material técnico científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos. Para informações completas, consultar a bula na íntegra através da Central de Atendimento ao Cliente.

Referências Bibliográficas: 1) Bula do produto NISULID: comprimidos dispersíveis. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 2) HELSINN. The original nimesulide. 2013. Disponível em: <http://www.nimesulide.net/Default.aspx?Pagina=home&SM=home&Lingua=EN>. Acesso em: Mar. 2017. 3) Kairos Web Brasil. Disponível em: <http://brasil.kairosweb.com>. Acesso em: Maio 2017.4) BIANCHI, M; BROGGINI, M. A randomised, double-blind, clinical trial comparing the efficacy of nimesulide, celecoxib and rofecoxib in osteoarthritis of the knee. Drugs, v.63, suppl.1, p. 37-46, 2003. 5) Banco de dados da Anvisa: http://consultas.anvisa.gov.br/#/medicame.

Contraindicação: crianças menores de 12 anos. **Interação medicamentosa:** Não se aconselha usar medicamentos que provoquem irritação no estômago durante o tratamento com NISULID® (nimesulida).

NISULID. nimesulida. 100 mg comprimidos. 100 mg comprimidos dispersíveis. 100 mg / envelope granulado. 50 mg/ml gotas. 10 mg/ml suspensão oral. uso oral. 100 mg supositórios. uso retal. uso adulto e pediátrico. MS – 1.0573.0301. INDICAÇÕES: Indicado em condições clínicas que requeiram atividade anti-inflamatória, analgésica e antipirética. CONTRAINDICAÇÕES: **Hipersensibilidade à nimesulida ou a qualquer outro componente do medicamento; história de hipersensibilidade ao ácido acetilsalicílico ou a outros AINES. Pacientes com úlcera péptica em fase ativa, ulcerações recorrentes ou com hemorragia gastrintestinal; paciente com distúrbios de coagulação grave; pacientes com insuficiência cardíaca grave; pacientes com disfunção renal grave; pacientes com disfunção hepática; crianças menores de 12 anos. A nimesulida não deve ser administrada durante a gravidez ou em mulheres que estejam amamentando.** CUIDADOS E ADVERTÊNCIAS: Raramente nimesulida foi relatada estar associada com reações hepáticas sérias, incluindo casos fatais. Pacientes que apresentaram sintomas compatíveis com dano hepático durante o tratamento com nimesulida (por exemplo, anorexia, náusea, vômitos, dor abdominal, fadiga, urina escura ou icterícia) devem ser cuidadosamente monitorados. A administração concomitante com drogas hepatotóxicas conhecidas e abuso de álcool, devem ser evitados durante o tratamento com nimesulida. Pacientes que apresentaram testes de função hepática anormais devem descontinuar o tratamento e não devem reiniciar o tratamento com a nimesulida. Em raras situações, onde ulcerações ou sangramentos gastrintestinais ocorrem em pacientes tratados com nimesulida, o medicamento deve ser suspenso. Em pacientes com insuficiência renal ou cardíaca, cuidado é requerido, pois o uso de AINES pode resultar em deterioração da função renal. Pacientes idosos são particularmente sensíveis às reações adversas dos AINES, incluindo hemorragia e perfuração gastrintestinal, dano das funções renal, cardíaca e hepática. O uso prolongado de AINES em idosos não é recomendado. A nimesulida deve ser usada com atenção em pacientes com história de ulceração péptica ou inflamações intestinais. Como os AINES podem interferir na função plaquetária, eles devem ser usados com cuidado em pacientes com hemorragia intracraniana e alterações da coagulação, como por exemplo, hemofilia e predisposição a sangramento. As drogas antiinflamatórias não-esteroidais podem mascarar a febre relacionada a uma infecção bacteriana subjacente. Com relação ao uso da nimesulida em crianças, foram relatadas algumas reações graves, incluindo raros casos compatíveis com síndrome de Reye. O uso concomitante de outros anti-inflamatórios não-esteroidais durante a terapia com nimesulida não é recomendado. Como os outros anti-inflamatórios não-esteroidais, a nimesulida deve ser usada com cuidado em pacientes com insuficiência cardíaca congestiva, hipertensão, prejuízo da função renal ou depleção do volume extracelular, que são altamente suscetíveis a uma redução no fluxo sangüíneo renal. Por ser a eliminação do fármaco predominantemente renal, o produto deve ser administrado com cuidado a pacientes com prejuízo da função hepática ou renal. Em pacientes com clearance de creatinina de 30-80 ml/min, não há necessidade de ajuste de dose. Em caso de disfunção renal grave o medicamento é contra-indicado. Em pacientes com história de perturbações oculares devido a outros AINES, o tratamento deve ser suspenso e realizado exames oftalmológicos caso ocorram distúrbios visuais durante o uso da nimesulida. Pacientes com asma toleram bem a nimesulida, mas a possibilidade de precipitação de broncoespasmo não pode ser inteiramente excluída. Os riscos de uso por via de administração não-recomendada são: a não-obtenção do efeito desejado e ocorrência de reações adversas. Atenção diabéticos: contém açúcar (nas apresentações da suspensão oral (300 mg/ml), granulado (1,774 g por envelope) e gotas (300 mg/ml)). GRAVIDEZ E LACTAÇÃO: Categoria de risco de gravidez C: este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. INTERAÇÕES MEDICAMENTOSAS: A potencial interação com glibenclamida, teofilina, varfarina, digoxina, cimetidina e uma preparação antiácida (ou seja, uma combinação de hidróxido de magnésio e alumínio) foram estudadas in vivo. Nenhuma interação clínica significante foi observada. A nimesulida pode antagonizar os efeitos dos diuréticos e em particular bloquear o aumento da atividade da renina plasmática induzida pela furosemida. O uso concomitante de furosemida e nimesulida requer cautela em pacientes renais ou cardíacos suscetíveis. A administração concomitante de nimesulida com anticoagulantes (varfarina) ou ácido acetilsalicílico pode causar efeitos aditivos (aumento do risco de complicações de sangramento). Portanto, esta combinação não é recomendada e é contra-indicada em pacientes com distúrbios de coagulação graves. Se a combinação não puder ser evitada, a atividade anticoagulante deve ser cuidadosamente monitorada. Se nimesulida for prescrita para um paciente sob terapia com lítio, os níveis de lítio devem ser monitorados cuidadosamente. Deve-se ter cuidado com pacientes que apresentem anormalidades hepáticas, particularmente se houver intenção de administrar nimesulida em combinação com outras drogas potencialmente hepatotóxicas. Não há evidência de que a nimesulida afete a glicemia em jejum ou a tolerância à glicose em pacientes diabéticos tratados com sulfoniluréias. Pode haver potencialização da ação da fenitoína. Embora não tenham sido relatados especificamente com a nimesulida, foram documentadas interações entre antiinflamatórios não-esteroidais e lítio, metotrexato, probenecida e nimesulida. Portanto, recomenda-se cuidado na administração concomitante de nimesulida com qualquer uma destas drogas, devido ao aumento do risco de hemorragias gastrintestinais. Devido ao seu efeito sobre as prostaglandinas renais, os inibidores da prostaglandina-sintetase como a nimesulida podem aumentar a nefrotoxicidade das ciclosporinas. Recomenda-se tomar NISULID após as refeições. Não se aconselha a ingestão de bebidas alcoólicas durante o tratamento. REAÇÕES ADVERSAS: **Pele e tecidos subcutâneos: prurido, rash e sudorese aumentada. Gastrintestinais: diarréia, náusea e vômito. Hepatobiliar: alterações dos parâmetros hepáticos (transaminases), geralmente transitórias e reversíveis. Casos isolados de hepatite aguda, falência hepática fulminante (algumas fatalidades foram relatadas), icterícia e colestase. Sistema nervoso: tonturas e vertigens. Sistemas visual e auditivo: raramente visão borrada. Sistema cardiovascular: hipertensão. Renais: raramente: disúria, hematúria e retenção urinária. Sistema sangüíneo e linfático: raramente: anemia e eosinofilia. Sistema imunológico: raramente hipersensibilidade. Sistema endócrino: raramente hipercalemia. Respiratórios: casos isolados de reações anafiláticas como dispnéia, asma e broncoespasmo, principalmente em pacientes com histórico de alergia ao ácido acetilsalicílico e a outros AINES. Distúrbios gerais: edema**. POSOLOGIA: USO PARA ADULTOS E CRIANÇAS ACIMA DE 12 ANOS. Comprimidos: 50 - 100mg (1/2 a 1 comprimido tomado com 1/2 copo de água) duas vezes ao dia, podendo alcançar até 200 mg duas vezes ao dia. A administração é por via oral. Comprimidos dispersíveis: 100mg (1 comprimido) duas vezes ao dia, podendo alcançar até 200 mg duas vezes ao dia. Dissolver o comprimido em 1/2 copo de água (100 mL) ou, se preferir, o comprimido poderá ser deglutido inteiro, sem a necessidade de dissolução prévia. A administração é por via oral. Granulado: 50 a 100mg (1/2 a 1 envelope dissolvido em um pouco de água ou suco) duas vezes ao dia, podendo alcançar até 200mg duas vezes ao dia. A administração é por via oral. Supositórios: 1 supositório de 100mg duas vezes ao dia, podendo alcançar até 200mg (2 supositórios de 100mg) duas vezes ao dia. Aplicar o supositório por via retal. Gotas: administrar 1 gota (2,5mg) por kg de peso, duas vezes ao dia, diretamente na boca da criança ou se preferir diluída em um pouco de água açucarada. Lembramos que cada gota contém 2,5mg de nimesulida e cada mL de NISULID contém 50mg de nimesulida. Cada mL do produto contém 20 gotas. Suspensão: a posologia recomendada é de 5mg/kg/dia - fracionada a critério médico em duas administrações. Agitar antes de usar. Colocar a dose recomendada no copo-medida que acompanha o produto e pedir para a criança tomar pela boca (1mL da suspensão contém 10mg de nimesulida). Pacientes com insuficiência da função renal: não há necessidade de ajuste de dose em pacientes com insuficiência renal moderada. Em casos de insuficiência renal grave o medicamento é contra-indicado. Pacientes com insuficiência hepática: contra-indicado em pacientes com insuficiência hepática. VENDA SOB PRESCRIÇÃO MÉDICA. SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. Material técnico científico de distribuição exclusiva à classe médica - Documentação Científica e informações adicionais estão à disposição da classe médica, mediante solicitação. MB_ 05 SAP4094207(A)09/09.

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ORIGINAL ARTICLE

COMPARISON BETWEEN TWO TYPES OF ABDUCTION ORTHOTICS IN TREATING CONGENITAL CLUBFOOT

COMPARAÇÃO ENTRE DUAS ÓRTESES DE ABDUÇÃO NO TRATAMENTO DO PÉ TORTO CONGÊNITO

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ABSTRACT

Objective: The objective of this study was to analyze and compare the effectiveness of two types of abduction orthotics used for the feet, the Denis-Browne type (traditional) and the Dobbs type (dynamic), with regard to maintenance of deformity correction and prevention of recurrence. Method: In this comparative retrospective case study, information was collected from the medical records of children with idiopathic congenital clubfoot (CCF). We evaluated a total of 43 feet in 28 patients, which were divided into two groups. Group 1 was comprised of 16 patients with a total of 24 CCFs treated with the traditional orthotic device. Group 2 consisted of 12 patients with a total of 19 CCFs treated with the dynamic orthotic device. The statistical analysis used the ANOVA test to compare the categorical variables between the groups. A significance level of 5% was adopted (p-value≤0.05). Results: In Group 1, recurrence was observed in 2 feet (8.33%), and in 1 foot in Group 2 (5.26%). No significant difference in effectiveness was seen between the two types of orthotic devices. Conclusion: Both abduction devices were seen to be effective in maintaining correction of congenital clubfoot deformities. There was no statistical significance between type of orthotic device and recurrence. ***Level of Evidence III, Retrospective Comparative Study.***

Keywords: Congenital abnormalities. Foot deformities. Clubfoot. Foot orthoses.

RESUMO

Objetivo: Analisar e comparar a eficácia entre dois tipos de órtese de abdução para o pé, tipo Denis-Browne (tradicional) e a proposta por Dobbs (dinâmica), quanto à manutenção da correção das deformidades e da prevenção das recidivas. Método: Estudo de casos, retrospectivo e comparativo, com levantamento de prontuários de crianças com PTCI. Foram avaliados 28 pacientes, totalizando 43 pés, divididos em dois grupos: Grupo 1 – tratados com aparelho tradicional, 16 pacientes, 24 PTCI. Grupo 2 – tratados com aparelho dinâmico, 12 pacientes, totalizando 19 PTCI. A análise estatística comparou as variáveis categóricas entre os grupos com o teste ANOVA. Foi adotado nível de significância de 5% (p ≤ 0,05). Resultados: No grupo 1, a recidiva ocorreu em dois pés (8,33%) e no grupo 2 em um pé (5,26%). Na comparação das duas órteses, a eficácia não apresentou diferença significante. Conclusão: Ambos os aparelhos de abdução mostraram-se eficazes na manutenção da correção das deformidades do pé torto congênito. Não ocorreu significância estatística em relação às órteses e a ocorrência de recidivas. ***Nível de Evidência III, Estudo Retrospectivo Comparativo.***

Descritores: *Anormalidades congênitas. Deformidades do pé. Pé torto. Órtoses do pé.*

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INTRODUCTION

Idiopathic congenital clubfoot (CCF) is the principal malformation of the musculoskeletal system, affecting one to two infants per 1000 live births.[1-5] Affected children are born with feet with the following deformities: equinus, varus, adduct, cavus, and supinus.[1-3,6-9]
Today the conservative method described by Ponseti is used in almost all the services that treat this disease around the world.[10] This method involves manipulations and the placement of a series of plaster casts on the feet and legs, which are changed weekly. At the same time that the casts are replaced, the need for tenotomy of the calcaneal tendon is assessed; this usually occurs around the sixth cast replacement, and is intended to definitively correct the equinus deformity. After the correction is achieved, the foot is kept in position using an abduction device with a fixed bar for 23 hours a day for three months and for 14 to 16 hours per day for another three or four years, usually corresponding to nighttime sleep in addition to daytime naps.[11]
This method is more effective when initiated in children under one year of age,[6,10-14] but is also effective in patients aged between one and three years.[14]

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

Work conducted at Hospital Universitário de Taubaté (HUT), Ambulatório de Ortopedia e Traumatologia do Pé e Tornozelo and at Instituto de Ortopedia de Taubaté (IOT), São Paulo, SP, Brazil. Correspondence: Avenida Itália, 1551, Rua 1, nº 666, Jardim das Nações, Taubaté, SP, Brazil. 12030-212. luizrlara@hotmail.com

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Proper use of the appliance is fundamental to maintaining the correction of the deformity. Failure to adhere to its use has a significant correlation with recurrence.[3,4,9,12,15-18]

The traditional orthesis is basically comprised of open-toe high-top boots which are connected with a bar. The angle of the boot and the length of the bar can be adjustable or fixed, depending on the variation.[11] (Figure 1) Recently, Dobbs et al.[9] developed a dynamic orthotic device which is individualized for leg movements, permitting greater comfort and tolerance for children and parents. (Figure 2)

The objective of this study was to analyze and compare the effectiveness of these two types of abduction orthotics, traditional and dynamic, which are used to maintain the correction and prevent recurrence of idiopathic CCF.

MATERIALS AND METHODS

The medical records of patients with idiopathic CCF treated at the outpatient foot and ankle clinic at the Hospital Universitário de Taubaté and in a private clinic of one of the authors were retrospectively analyzed.

All the cases of idiopathic CCF were classified according to the simplified Dimeglio method[1,2] before the beginning of treatment. (Tables 1 and 2, Figure 3)

We evaluated 28 patients with idiopathic CCF (total of 43 feet) and divided them into two groups: Group 1 was treated with traditional abduction equipment as described by Denis-Browne. This type of abduction orthotic device maintains the correction of the CCF

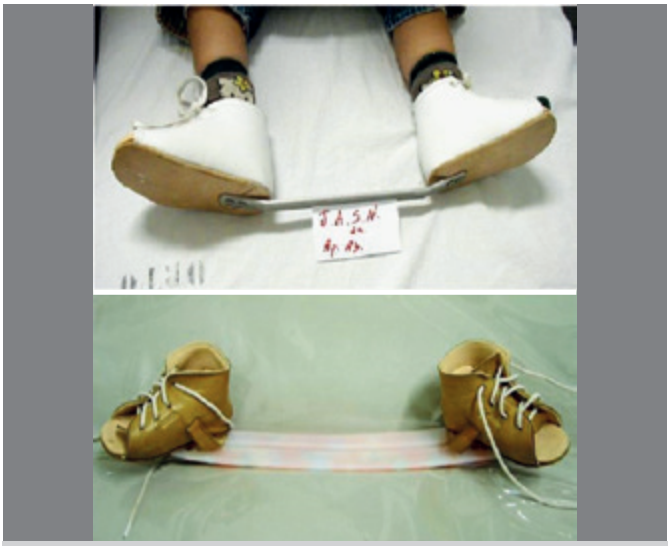

Figure 1. Denis Browne type device.

Figure 2. Dobbs type device.

Table 1. Traditional orthotic device (Group 1).

Patients	Laterality	Side	Sex	Dimeglio	Time of Use	Recurrence
1	Unilateral	L	Male	IV	3y5m	--
2	Bilateral	R	Male	III	5y	--
3	Bilateral	L	Male	III	5y	--
4	Unilateral	R	Male	IV	3y	Yes
5	Unilateral	R	Fem	III	5y	--
6	Bilateral	R	Male	III	2y6m	--
7	Bilateral	L	Male	IV	2y6m	--
8	Unilateral	L	Male	III	3y	--
9	Bilateral	R	Male	III	3y	--
10	Bilateral	L	Male	III	3y	--
11	Bilateral	R	Fem	III	3y	--
12	Bilateral	L	Fem	III	3y	--
13	Unilateral	R	Male	IV	5y	--
14	Unilateral	R	Male	II	2y2m	--
15	Bilateral	R	Male	I	5y	--
16	Bilateral	L	Male	III	5y	--
17	Bilateral	R	Male	I	5y	--
18	Bilateral	L	Male	IV	5y	--
19	Unilateral	R	Fem	III	4y	--
20	Bilateral	R	Male	III	2y	--
21	Bilateral	L	Male	III	2y	--
22	Bilateral	R	Fem	III	2y	Yes
23	Bilateral	L	Fem	III	2y	--
24	Unilateral	R	Male	IV	4y	--

R: right; L: left; Fem: female; y: years; m: months; --: no recurrence.

Table 2. Dynamic orthotic device (Group 2).

Patients	Laterality	Side	Sex	Dimeglio	Time of Use	Recurrence
1	Bilateral	R	Male	III	2y	--
2	Bilateral	L	Male	I	2y	--
3	Bilateral	R	Male	III	2y	--
4	Bilateral	L	Male	IV	2y	--
5	Bilateral	R	Male	III	3y	--
6	Bilateral	L	Male	IV	3y	--
7	Bilateral	R	Male	III	4y	--
8	Bilateral	L	Male	II	4y	--
9	Unilateral	L	Male	III	2y6m	--
10	Unilateral	R	Male	I	2y	--
11	Bilateral	R	Male	IV	2y2m	--
12	Bilateral	L	Male	IV	2y2m	--
13	Unilateral	L	Fem	III	3y	--
14	Bilateral	R	Male	III	2y6m	Yes
15	Bilateral	L	Male	III	2y6m	--
16	Unilateral	L	Male	III	3y	--
17	Unilateral	L	Male	III	2y	--
18	Bilateral	R	Fem	I	3y	--
19	Bilateral	L	Fem	IV	3y	--

R: right; L: left; Fem: female; y: years; m: months; --: no recurrence.

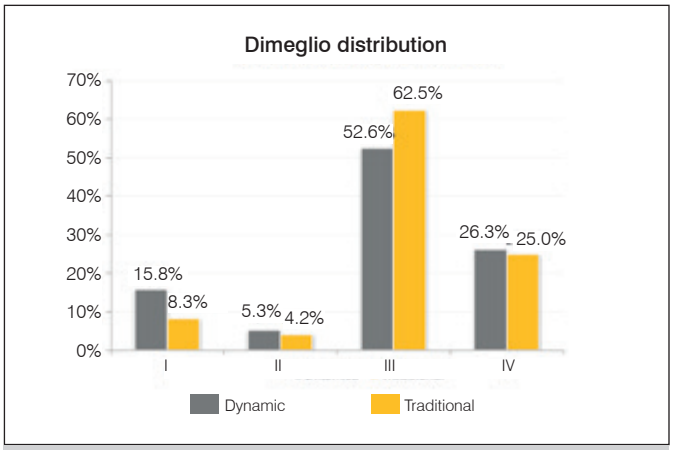

Figure 3. Distribution of groups by Dimeglio classification.

and consists of two shoes connected horizontally by a bar. The unaffected foot is maintained with external rotation of 30°–40° and affected foot is maintained at 60°–70°, with dorsiflexion of 10 to 15°. The distance between the feet should be the same as the distance between the child's shoulders.[1,3,7,13,19] This group was composed of 16 patients totaling 24 idiopathic congenital clubfeet; 12 patients were male and four were female. As for laterality and affected side, eight feet were unilateral and eight were bilateral, 11 left feet and 13 right feet. According to the Dimeglio assessment, two feet were classified as grade I, one as grade II, 15 as grade III, and 6 as grade IV. (Tables 1 and 3)

Group 2 was treated with a dynamic device which independently provides flexion-extension to each leg with movement in a single plane, preserving muscle strength and restricting the child less. The bar has a central release mechanism, which ensures easy handling in daily activities. The affected foot uses the same degrees of external rotation and dorsiflexion as the traditional device. (Figure 2) This group consisted of 12 patients with a total of 19 CCFs; nine were male and three were female. As for laterality and affected side, five feet were unilateral and seven were bilateral, 11 left feet and eight right feet. According to the Dimeglio assessment, three feet were classified as grade I, one as grade II, 10 as grade III, and 5 as grade IV. (Tables 2 and 3)

The study included patients who used abduction orthotics for a minimum period of two years.

The average time the orthotics were used was 3.52 years for Group 1 and 2.62 years for Group 2. The minimum time the device was used was two years for both groups, and the maximum time was 5.0 years for Group 1 and 4.0 years for Group 2. (Figure 4)

Patients who did not adhere to device use or who dropped out of treatment (did not return for outpatient follow-up) were excluded.

The adults responsible for the patients were advised about the need to return periodically for appointments and particularly about the importance of using the abduction device for the treatment to be successful. In addition, weekly lectures explaining the method were given to the family before appointments.[1]

The Ponseti method consists of weekly manipulations and replacements of plaster casts. The goal is to achieve the simultaneous correction of the cavus, varus, and adduct deformities of the foot. When gains are not obtained from correction and the deformity remains strong in equinus, percutaneous tenotomy of the calcaneal tendon is performed and is followed by plaster casting at the surgical center. The immobilizing cast should remain in place for three weeks. After the casts are removed, the abduction device is kept on the corrected foot for a period of 23 hours per day for the first four months, followed by 12 hours at night for three or four years.[11,12]

Table 3. Comparison of orthotic groups for Dimeglio distribution.

Dimeglio	Dynamic		Traditional		P-value
	N	%	N	%	
I	3	15.8%	2	8.3%	0.449
II	1	5.3%	1	4.2%	0.865
III	10	52.6%	15	62.5%	0.515
IV	5	26.3%	6	25.0%	0.922

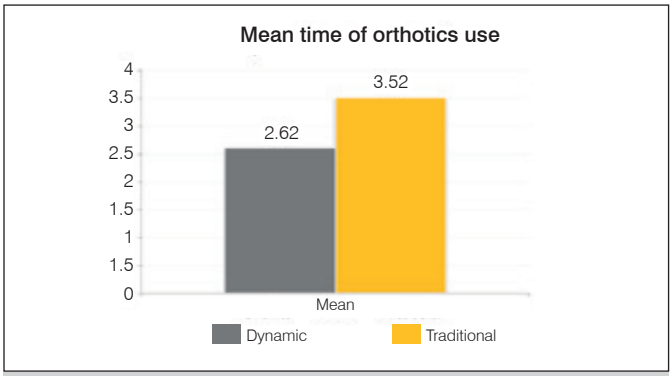

Figure 4. Mean time orthotics were used between groups.

If the deformity recurs while the abduction device is being used, treatment is reinitiated and a new series of plaster casts is placed until the deformity is completely corrected. If necessary, tenotomy of the calcaneal tendon can be performed again. The corrected foot then returns to the abduction brace. We consider recurrence to be all cases in which the initial CCF deformities returned after the treatment described above.

This study was approved by the institutional review board.

The statistical analysis compared the categorical variables between the groups using the ANOVA test. A significance level of 5% was adopted (p-value≤0.05).

Through this analysis, we evaluated the effectiveness of the orthotics and whether one type was more effective.

RESULTS

The results were considered satisfactory for feet in which all components of the deformity were corrected, and unsatisfactory when these components recurred.

In Group 1 recurrence was observed in two feet (8.33%), and in Group 2 in one foot (5.26%); in both groups the recurrences were equinus, cavus, and adduct in a much less acute form than the initial deformity. These feet again underwent serial plaster casting of the feet and legs until the deformities were completely corrected, and then returned to the use of the abduction brace device. (Figure 5)

There was no statistically significant difference in efficacy between the groups. The groups were homogeneous for the variables Dimeglio classification, sex, side, laterality, and recurrence (p=0.695), with no statistical difference between the groups. (Tables 1–4)

No complications related to the method (casting and tenotomy) or prostheses used were seen in either group.

DISCUSSION

The Ponseti method for treating idiopathic CCF has proven consistently successful in correcting deformities. Studies of this method emphasize that the period during which the abduction appliance is used is a very important step for maintaining the correction of the deformities.[1,10,13,19] Correction of the sagittal plane in CCF can be maintained by connecting the feet horizontally with a metal bar and positioning them at the desired angles in fixed bases.[11]

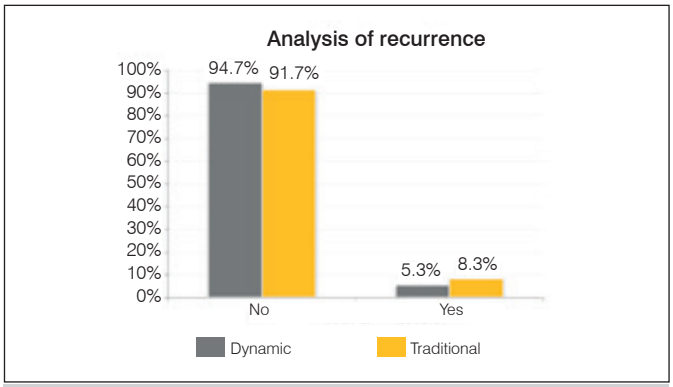

Figure 5. Analysis of recurrence between groups.

Table 4. Comparison of orthotic groups for distribution of recurrence.

Recurrence	Dynamic		Traditional		P-value
	N	%	N	%	
No	18	94.7%	22	91.7%	0.695
Yes	1	5.3%	2	8.3%	

A study by Ponseti[13] on recurrence of CCF deformities showed in patients who do not adhere to the use of orthotics, the recurrence rate is 78%, compared with only 7% in those who correctly use the devices. Based on these principles, in this study we only included patients whose family members were committed to the treatment and complied with outpatient follow-up, and consequently we were able to compare and evaluate the effectiveness of these two types of prostheses.

The incidence of deformity was in line with the literature with respect to sex;[3] males were affected more often than females, at a ratio of three to one in Group 1 and five to one in Group 2. (Figure 3)

In their 1963 work, Ponseti and Smoley[6] achieved success in 80% of their cases. After refining their method, in 2002 these same authors published a study with only 7% recurrence.[13] In this present study, the recurrence rate in Group 1 was 8.33% of the feet, very close to findings of other studies.[7,10,13] Verma et al.[14] reported that in treating older children with idiopathic CCF aged from one to three years, recurrence was higher, around 11%. In Group 2, which used the dynamic orthotic device, the recurrence rate was 5.26%, less than in Group 1 but more than the rate found by Dobbs et al.[9] using the same orthotics, 3.6%.

We agree with Zhao et al.[10] on the importance of developing new orthotics in order to provide comfort and tolerance for both children and parents, thus increasing adherence to the proposed protocol of use as well as the efficacy of treatment, thus reducing the rate of recurrence. The family members of these children often complain that the traditional abduction device is more uncomfortable, keeping the feet in a fixed position with little mobility and in many cases encouraging non-adherence to treatment.[3,5,12,17,18] Dobbs et al.[9] used more dynamic orthotics and noted greater satisfaction in both parents and children.

This study found that both the classic and the dynamic orthotic devices were effective in maintaining the correction of idiopathic CCF deformities, and consequently allow more participation by the parents in selecting the type of device (dynamic or static); the family was more involved and cooperated significantly to achieve better results in treating this important disease.

CONCLUSIONS

Both the classic and dynamic abduction orthotic devices proved effective for maintaining correction of congenital clubfoot deformities. There was no statistical significance in relation to type of orthotics used and recurrence.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. LCATF (0000-0002-0778-2506)* and LCRL (0000-0003-1158-2643)* were the main contributors in drafting the manuscript. BLG (0000-0001-9133-0176)* and TPSS (0000-0001-5606-4896)* collected the clinical data through retrospective analysis of the patient records. TPSS (0000-0001-5606-4896)* evaluated the statistical analysis and compared the categorical variables between the groups using ANOVA. TPSS (0000-0001-5606-4896)* and LCATF (0000-0002-0778-2506) reviewed the literature. LCRL (0000-0003-1158-2643)* revised and approved the final version of the manuscript. *ORCID (Open Researcher and Contributor ID).

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MORTALITY AND FUNCTION AFTER SURGICALLY-TREATED HIP FRACTURE IN ADULTS YOUNGER THAN AGE 60

MORTALIDADE E FUNÇÃO DEPOIS DE TRATAMENTO CIRÚRGICO DE FRATURA DE QUADRIL EM ADULTOS COM MENOS DE 60 ANOS

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ABSTRACT

Objective: Hip fractures in young adults can cause poor functional capacity throughout life because of several complications. The purpose of this study was to prospectively evaluate 1-year mortality and functional outcomes for patients aged 60 years or younger with hip fracture. Methods: We prospectively obtained data for all consecutive patients aged 60 or younger with any type of hip fracture who were treated operatively between 2008 and 2014. After one year, patient outcomes were evaluated according to changes in pain severity, functional status (modified Barthel index), and mortality rate. Results: Of the total of 201 patients, 132 (65.7%) were men (mean age: 41.8 years) and 69 (34.3%) were women (mean age: 50.2 years) ($p<0.001$). Reduced pain severity was reported in 91.5% of the patients. The mean modified Barthel index was 22.3 in men and 18.6 in women ($p<0.001$). At the one-year follow-up, 39 cases (19.4%) were dependent on walking aids while only 17 patients (8.5%) used walking aids preoperatively ($p<0.001$). Seven patients (4 men and 3 women) died during the one-year follow-up period; 2 died in the hospital after surgery. Conclusion: Hip fractures in young adults have a low mortality rate, reduction in pain severity, and acceptable functional outcomes one year after surgery. ***Level of Evidence II, Prospective Comparative Study.***

Keywords: Hip fractures. Morbidity. Mortality. Femoral neck fractures.

RESUMO

Objetivo: As fraturas de quadril em adultos jovens podem ocasionar capacidade funcional insatisfatória durante toda a vida, devido a várias complicações. A finalidade deste estudo foi avaliar prospectivamente a mortalidade e os desfechos funcionais em um ano, em pacientes com 60 anos de idade ou menos com fratura de quadril. Métodos: Coletamos prospectivamente dados de todos os pacientes consecutivos com idade de 60 anos ou menos, com qualquer tipo de fratura de quadril, que foram tratadas por cirurgia entre 2008 e 2014. Depois de um ano, os desfechos dos pacientes foram avaliados de acordo com as mudanças da intensidade da dor, estado funcional (índice de Barthel modificado) e taxa de mortalidade. Resultados: Do total de 201 pacientes, 132 (65,7%) eram homens (média de idade: 41,8 anos) e 69 (34,3%) eram mulheres (média de idade: 50,2 anos) ($p < 0,001$). A menor intensidade de dor foi relatada em 91,5% dos pacientes. A média do índice de Barthel modificado foi 22,3 em homens e 18,6 em mulheres ($p < 0,001$). No acompanhamento de um ano, 39 pacientes (19,4%) dependiam de dispositivos auxiliares da marcha, enquanto apenas 17 pacientes (8,5%) usavam esses dispositivos no pré-operatório ($p < 0,001$). Sete pacientes (4 homens e 3 mulheres) morreram durante o período de acompanhamento de um ano; dois morreram no hospital, depois da cirurgia. Conclusão: As fraturas de quadril em adultos jovens têm baixa taxa de mortalidade, redução da intensidade da dor e desfechos funcionais aceitáveis um ano depois da cirurgia. ***Nível de Evidência II, Estudo Prospectivo Comparativo.***

Descritores: *Fraturas do quadril. Morbidade. Mortalidade. Fraturas do colo femoral.*

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INTRODUCTION

Hip fracture is a major public health problem that has a significant financial impact on patients and health care systems.[1,2] The incidence of hip fracture varies by age and sex; it is more common in older people. Hip fracture in elderly osteoporotic patients most often results from low-energy trauma such as falling down. On the other hand, high-energy trauma is the main mechanism of hip fracture in the young adult population.[3-5]

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

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Although several studies have dealt with the consequences and mortality of hip fractures in older people, only a few studies have reported the outcomes of hip fracture in the younger adult population.[3,4,6-12] Several complications of hip fracture such as osteonecrosis, nonunion, implant failure, and shortening can cause life-long poor functional capacity and impede the adult population from returning to pre-fracture levels of activity.[4,6,10-14] Moreover, the 1-year mortality rate for hip fracture is less than 10% in young patients, but it is approximately 20–30% in older patients.[6,15]
This prospective study presents epidemiologic data for young adults who were treated for hip fractures at our center and evaluates their 1-year mortality and functional outcomes.

MATERIALS AND METHODS

After the study was approved by the institutional review board (Ortho-shiraz.Med.Rec.1390.2), we selected all patients 60 years or younger referred to our hospital with hip fracture between March 2008 and February 2014. Patients who died within the first day of admission, patients with pathologic fractures or hip fracture dislocations, and non-surgically treated cases were excluded. After the patients signed the terms of informed consent, a trained researcher interviewed each patient and extracted data from the medical records, surgical log, and discharge orders using a data-gathering form. We followed the patients by telephone for one year after discharge and asked about their functional status and potential mortalities.
Demographic data included age, sex, locomotion history of the patients prior to the fracture, and fracture risk factors such as body mass index (BMI), history of previous fracture, cigarette smoking, and comorbidities were recorded. Mechanism and type of fracture, surgical method, number of days from admission to surgery, and days from surgery to discharge were also recorded.
The main items used to measure patient outcome were pain severity and pain changes over time, functional status, and mortality rate. The functional status of the patients was measured using the modified Barthel index for activities of daily living, level of walking ability, sphincter control (bladder, bowel), and locomotion (walking with or without a walking aid or bedridden).[16] Activities of daily living were measured with five items for feeding, bathing, dressing, toilet use, and transfer. Each was scored as follows: 0=patient unable to perform, 1=patient required help to perform, 2=patient could perform independently. Total possible scores for these five items ranged from 0 to 10. Level of walking ability was measured with seven items including meal preparation, shopping, housework, watering the garden, washing clothes, taking medication, and transportation. The total possible score range was 0–14.
Descriptive statistics were analyzed using SPSS software version 18.0 for Windows (SPSS Inc, Chicago, IL, USA). Continuous variables are presented as mean values ± standard deviation (SD). Categorical variables are presented as absolute numbers and percentages. The differences were considered statistically significant when P was less than 0.05 for all analyses.

RESULT

Over the six-year study period, a total of 230 patients aged 60 years or less were treated surgically for hip fracture. Only 201 patients (87.3%) completed the survey with a one-year follow-up interview. Of these, 132 (65.7%) were men with a mean age (±SD) of 41.8±13.1 years and 69 (34.3%) were women with a mean age of 50.2±11.9 years ($p<0.001$). The mean length of hospital stay was 7.3±3.3 days (injury to surgery interval: 3.4±2.9 days, surgery to discharge interval: 3.8±1.5 days). Other data are reported in Table 1.
As shown in Table 2, right and left hip fractures are equal in frequency. Intertrochanteric fractures were most common, followed by femoral neck fractures and subtrochanteric fractures. Reduction and internal fixation was the most commonly used surgical management for hip fractures in our sample (96.5%). High-energy trauma including traffic accidents and falls from height caused 128 cases (63.7%). Most fractures occurred in the fall and winter seasons.
One-year mortality and functional outcome for patients are displayed in Table 3. Reduction in pain severity was reported in 91.5% of all participants. The mean modified Barthel index was 22.3±3.9 in men and 18.6±7.3 in women ($p<0.001$). More than 90% of patients had bladder and bowel control after surgery. At the one-year follow-up, 39 patients (19.4%) were dependent on walking aids while only 17 (8.5%) had used walking aids prior to surgery ($p<0.001$).
Of the total, 7 patients (4 men and 3 women) died during the one-year follow-up period. The mean age of the dead patients was 51.4±10.3 years. Fracture was the result of high-energy trauma in 5 patients. Intertrochanteric, subtrochanteric, and femoral neck fractures were seen in 4, 2, and 1 cases, respectively. The mean hospital stay was 10.5±5.7 days. Two patients (28.5%) died in the hospital after surgery; 1 (14.2%) died within the first three months after hip fracture surgery and 4 patients (57.1%) died between 3 and 12 months after surgery.

Table 1. Baseline characteristics of patients with hip fracture.

General characteristic	No. (%) of men	No. (%) of women	Total
Age (Mean SD)	41.8 ± 13.1	50.2 ± 11.9	44.7 ± 13.3
Smoking	73 (55.3)	12 (17.4)	85 (42.3)
Body Mass Index (Mean SD)	22.5 ± 3.2	22.8 ± 3.8	22.6 ± 3.4
Length of hospital stay (Mean SD)			
Injury-surgery interval	3.5 ± 2.9	3.3 ± 2.9	3.4 ± 2.9
Surgery-discharge interval	3.9 ± 1.5	3.7 ± 1.4	3.8 ± 1.5
Previous fracture			
Hip fracture	4 (3.0)	2 (2.9)	6 (3.0)
Wrist fracture	3 (2.3)	1 (1.4)	4 (2.0)
Vertebra fracture	3 (2.3)	1 (1.4)	4 (2.0)
Other fracture	32 (24.2)	6 (8.7)	38 (18.9)
Locomotion			
Without walking aids	123 (93.2)	61 (88.4)	184 (91.5)
With walking aids	9 (6.8)	8 (11.4)	17 (8.5)
Comorbidity			
Hypertension	2 (1.5)	1 (1.4)	3 (1.5)
Diabetes mellitus	5 (3.8)	7 (10.1)	12 (6.0)
Heart disease	3 (2.3)	4 (5.8)	7 (3.5)
Cerebrovascular disease	0 (0.0)	2 (2.9)	2 (1.0)
Others	24 (18.2)	24 (34.8)	48 (23.9)

Table 2. Fracture characteristics among young adults.

Characteristics	No. (%) of men 132	No. (%) of women 69	Total
Side of fracture			
Left	69 (52.3)	30 (43.5)	99 (49.3)
Right	62 (47.0)	39 (56.5)	101 (50.2)
Bilateral	1 (0.8)	0 (0.0)	1 (0.5)
Type of fracture			
Intertrochanteric	78 (59.1)	27 (39.1)	105 (52.2)
Subtrochanteric	16 (12.1)	3 (4.3)	19 (9.5)
Femoral neck	38 (28.8)	39 (56.5)	77 (38.3)
Mechanism of fracture			
High-energy trauma	98 (74.2)	30 (43.6)	128 (63.7)
Low-energy trauma	34 (25.8)	39 (56.5)	73 (36.3)
Method of fixation			
Internal fixation	131 (99.2)	63 (91.3)	194 (96.5)
Arthroplasty	1 (0.8)	6 (8.7)	7 (3.5)
Season of fracture			
Spring	30 (22.7)	15 (21.7)	45 (22.4)
Summer	30 (22.7)	11 (15.9)	41 (20.4)
Fall	36 (27.3)	23 (33.3)	59 (29.4)
Winter	36 (27.3)	20 (29.0)	56 (27.9)

Table 3. One-year mortality and functional outcome for patients with hip fractures.

	No. (%) of men	No. (%) of women	Total
Pain			
Decreased	126 (95.5)	58 (84.1)	184 (91.5)
Unchanged	1 (0.8)	5 (7.2)	6 (3.0)
Increased	1 (0.8)	3 (4.3)	4 (2.0)
Modified Barthel index of activity (Mean SD)	22.3 ± 3.9	18.6 ± 7.3	21.0 ± 5.5
Bladder control	125 (94.7)	61 (88.4)	186 (92.5)
Bowel control	126 (95.5)	62 (89.9)	188 (93.5)
Locomotion			
Without walking aids	111 (84.1)	44 (63.8)	155 (77.1)
With walking aids	17 (12.9)	22 (31.9)	39 (19.4)
Mortality			
Alive	128 (97.0)	66 (95.7)	194 (96.5)
Dead	4 (3.0)	3 (4.3)	7 (3.5)

DISCUSSION

Morbidity and mortality among elderly patients after hip fracture have been well described in the literature.[17,18] In young adults, prolonged morbidity after hip fracture as a major public health concern requires significant attention to reduce the economic burden on society. The morbidities are the result of complications such as nonunion, malunion, implant failure, femoral shortening, osteonecrosis, arthritis, and stiffness of joint motions.[7,19,20] To the best of our knowledge, many studies in the literature describe complications of surgically-treated hip fractures (especially femoral neck type) in young adults, but limited research has been carried out on functional outcomes.[11] In this study we showed that pain levels were reduced, activities of daily living increased, and patients were able to move about unaided after one year in most cases.

The survival rate for hip fracture among young adults exceeds 90%. Duckworth et al.[21] reported a mortality rate of 2.6% and complications of about 32% in adults <60 years with surgically-treated hip fracture. Additionally, in a study of mortality and complication-free rates following hip fractures in patients aged 20–40 years, Lin et al.[6] reported 10-year survival rates of 93.3%, 91.8%, and 94.5% for all hip fracture cases, patients with trochanteric fracture, and patients with femoral neck fracture, respectively. The complication-free rate after one year was 86.8%. Overall, these results were similar to our findings. In our study, all dead patients had important comorbidities (e.g. renal failure). This result is in line with recent reports showing a higher risk of mortality and complications in young adults with a higher number of comorbidities.[6] Intertrochanteric fracture was the most prevalent fracture type, not only among all the hip fractures but also in the dead patients. This result is consistent with studies that reported a higher mortality rate for trochanteric fractures in both young and elderly patients.[6,22]

In this present study, hip fractures occurred more frequently in men than women. The mean age of hip fracture in men was about 42 years, significantly lower than the mean age in women who underwent surgery for hip fractures. High-energy trauma was seen to be the main cause of hip fracture in young men, but low-energy trauma (like simple falls) were more common in older women due to osteoporosis. These results are in line with other studies evaluating the incidence and rate of hip fractures in young adult patients.[6,20] We found a higher mortality rate and increased morbidity measures such as pain and quality of life after surgically-treated hip fractures in women in comparison to men. We hypothesize that the higher mean age of the women included in this study could explain this finding.

This survey has several limitations, principally the small sample size. Furthermore, subjects with hip fracture were followed by telephone for one year. It is obvious that some morbidity measures require patient visits and radiographic evaluations for longer follow-up periods. Consequently, caution should be used in extrapolating our results.

CONCLUSION

Hip fractures in young adults have a low mortality rate, reduction in pain severity, and acceptable functional outcomes one year after surgery.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. BP (0000-0002-6118-8938)*, MJE (0000-0001-6598-0968)*, and ARV (0000-0002-6118-8938)* designed the study and directed the research. ARV and ZK (0000-0003-0431-179X)* followed patients and gathered clinical data. BP and HM (0000-0002-8998-1209)* evaluated the data for the statistical analysis. MJE, ARV, and HM performed the literature search, reviewed the manuscript, and contributed to the intellectual concept of the study. All authors participated in drafting the article, critically reviewed the manuscript, and approved the final manuscript as submitted. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

SURVIVAL OF NONAGENARIAN PATIENTS WITH HIP FRACTURES: A COHORT STUDY

SOBREVIDA DE PACIENTES NONAGENÁRIOS COM FRATURAS DE QUADRIL: ESTUDO DE COORTE

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ABSTRACT

Objective: The objective of this study was to assess survival and factors that may influence survival in nonagenarians with hip fracture. Methods: We retrospectively analyzed 134 nonagenarian patients admitted for hip fractures over a period of 9 years, and reviewed medical records and survival data from the National Population Register. The analysis included demographic data, ASA score, surgical delay, type of treatment, and mortality. Results: Mean patient age was 92.53 years (range 90–103 years). Of the total, 35.8% of the fractures involved the femoral neck and 64.2% were in the trochanteric region. Overall mortality was 18.7% at 30 days, and 9% at one year. Mean survival for the entire sample was 683±78.1 days, with a median of 339 days; survival in men and women was 595±136.8 days and 734±94.6 days, respectively. We found that type of fracture (p=0.026) and ASA score (p=0.004) were the main factors influencing survival. Kaplan-Meier survival analysis indicated that patients with extracapsular fractures treated by internal fixation had a better survival rate (p=0.047). There was no significant differences between sexes (p = 0.102) or diagnosis (p = 0.537). Conclusion: Although nonagenarian patients have numerous comorbidities, surgical treatment using internal fixation seems superior to a conservative approach. ***Level of Evidence III, Retrospective Comparative Study.***

Keywords: Hip fractures. Femoral neck fractures. Aged, 80 and over. Survival analysis.

RESUMO

Objetivo: O objetivo deste estudo foi avaliar os fatores que podem influenciar a sobrevida de nonagenários com fratura do quadril. Métodos: Foram analisados retrospectivamente 134 pacientes nonagenários internados por fraturas de quadril e seus prontuários, em um período de nove anos. Efetuou-se a revisão de prontuários médicos e os dados sobre a taxa de sobrevida do Registro Nacional de População. A análise incluiu dados demográficos, classificação ASA, atrasos na cirurgia, tipo de tratamento e mortalidade. Resultados: A média de idade dos pacientes foi 92,53 anos (de 90 a 103 anos). Do total, 35,8% das fraturas localizaram-se no colo do fêmur e 64,2% na região trocantérica. A mortalidade geral foi 18,7% aos 30 dias seguintes e 9% em um ano. A média de sobrevida de toda a amostra foi de 683 ± 78,1 dias, com mediana de 339 dias. A sobrevida em homens e mulheres foi, respectivamente, 595 ± 136,8 dias e 734 ± 94,6 dias. Constatamos que o tipo de fratura (p = 0,026) e a classificação ASA (p = 0,004) foram os principais fatores que influenciaram a sobrevida. A análise de sobrevida pelo método Kaplan-Meier indicou que os pacientes com fraturas extracapsulares tratados com fixação interna tiveram taxa de sobrevida melhor (p = 0,047). Não houve diferença significativa entre sexos (p = 0,102) ou no diagnóstico (p = 0,537). Conclusão: Apesar das numerosas comorbidades em pacientes nonagenários, o tratamento cirúrgico com fixação interna parece ser superior à abordagem conservadora. ***Nível de Evidência III, Estudo Retrospectivo Comparativo.***

Descritores: *Fraturas do quadril. Fraturas do colo femoral. Idoso de 80 anos ou mais. Análise de sobrevida.*

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INTRODUCTION

Hip fractures represent a major public health problem because of their substantial impact on health and healthcare costs. It is estimated that approximately 6.5 million hip fractures will occur around the world in 2050. The majority of hip fractures (80%) occur in persons aged 65 years and older.[1,2]

Recent demographic data confirm that industrialized countries are experiencing longer life expectancies and that the fastest-evolving population segment is people aged 90 and older. Considering that 35% of people over age 65 will suffer at least one trauma from same-level falls, it is clear why hip fracture among the elderly is the most frequent cause of hospitalization associated with severe disability.[3]

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

Study conducted at Grigore T. Popa University of Medicine and Pharmacy, General Medicine Faculty, Department of Orthopedics and Traumatology, Iasi, Romania.
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The traumatic pathology of hip fracture prevails in women; the main cause is osteoporosis, and the proximal femur is one of the main areas affected. In the 1970s, specialized journals indicated that 2% of women over age 85 fracture a hip each year, while the percentage for males is around 0.6%.[4] The risk of hip fracture among people above age 85 is 10 to 15 times higher than in the population between 60 and 65 years old. Increased life expectancy means that women are now more likely to fracture a hip than develop breast cancer.[5]
Over 90% of hip fractures in elderly patients result from low-energy trauma, namely same-level falls, and most of these fractures occur in the home. In comparison with other patients, the elderly are more exposed to this kind of trauma at night because they often use diuretics or medications that include benzodiazepines.[6,7]
The age of patients with hip fracture is known to be associated with a significant increase in postoperative complications, high immediate and long-term mortality, and poor functional prognosis. The maximum vulnerability is specific to the first 3–6 months, and death in the first 12 months must be perceived as an effect of trauma or surgical intervention. If post-fracture status involves limits on activity, this must be considered a component of long-term mortality because it favors the intensification of comorbidities.[8]
Our retrospective study analyzed patients older than 90 years who fractured a hip in order to evaluate if the patient survival period is influenced by operative treatment. We hypothesized that surgical treatment provided better survival rates in the nonagenarian population with hip fractures.

MATERIAL AND METHODS

This retrospective study assessed all nonagenarian patients admitted to our university hospital between 1 January 2007 and 31 December 2015 according to demographic data (gender, age, background) and medical information (intra- or extracapsular fracture type, surgical or non-surgical treatment, type of surgical intervention [internal fixation or arthroplasty], ASA score, status at hospital discharge). We only considered those comorbidities which were described as significant to the prognosis of patients with hip fracture according to Aharonoff et al.[9]
We also collected data about the time between the occurrence of the fracture and the date of surgery, hospitalization period, and complications and deaths during hospitalization.
The data were obtained through the Hospital Manager Program, hospital charts, and surgical protocols.
The inclusion criteria were: single level I trauma center, age >90 years, patients with intracapsular and extracapsular fractures (ICD-10-AM codes S72.0 and S72.1), and unintentional fall (ICD-10-AM codes W00 to W19).
The exclusion criteria were: open fracture, subtrochanteric fracture, polytrauma, pathological fracture, and patients transferred to other hospitals (3 cases, at the patient's request).
Because the program does not provide information about the date the hip fracture occurred, the hospital admission date was considered as the date the fracture occurred, since hip fracture leads to total functional incapacity and patients are normally brought to the hospital by ambulance that same day. Many authors[10,11] correlate the date of admission into hospital with the date of hip fracture.
After approval was obtained from the institutional review board (1/13.01.2016; no formal written approval was required, because of the retrospective design of the study), the names and social security numbers of the patients were sent to the National Population Register in order obtain mortality and survival data.
All patients included in the study were treated by the medical staff at the Orthopedic and Traumatology Clinic. Fractures were evaluated using X-rays of the pelvis or hip. The type of osteosynthesis was decided by the treating physician. A preoperative medical evaluation was conducted by the clinic's anesthesiologist to establish operative risk and improve biological status. After surgery, all patients were included in a medical rehabilitation program under the supervision of a physical therapist.
The results obtained were overlapped with the patient database, and consequently the survival period post-fracture was obtained for the patients included in the study.
Statistical analysis was performed using IBM SPSS Version 20 software (SPSS Inc, Chicago, IL, USA). We assessed the data according to the continuous or non-parametric nature of the variable using the Fischer contingency test and the unpaired Student's t test. Continuous data were expressed as mean±standard error and median. In order to evaluate survival and possible influential factors, we utilized Kaplan-Meier analysis.

RESULTS

Of the 138 nonagenarian patients presenting with hip fracture, 137 were eligible for inclusion and we recruited 134. Three patients were transferred to other hospitals at the request of the patient or family. One patient with bilateral hip fracture occurring two years after the first fracture on the opposite site was excluded from the study.
The group was homogeneous by sex, age, origin, and age of disease ($p>0.05$). There were more females than males, with a ratio of 1.7:1. (Table 1)
There was an increasing trend in the prevalence of fractures in nonagenarian patients ($y = 6.83 + 0.85x$); the prognosis for 2019 is approximately 17% prevalence. (Figure 1)
Mean patient age was 92.53 years and median age was 92 years (range 90–103 years); 85 patients (63.5%) were women and 49 patients (36.5%) were men.

Table 1. Demographic characteristics of the study group.

Characteristics	All patients (n=134)	Male (n=49)	Female (n=85)	p value two-tailed probability
Age mean SD (y)	92.53 2.57	92.61 2.44	92.48 2.65	0.779
Urban area, n (%)	91 (67.9%)	32 (65.3%)	59 (69.4%)	0.766
ASA score SD	3.31 1.20	2.92 0.93	3.53 1.28	0.004
Type of fracture				
femoral neck	48 (35.8%)	24 (49.0%)	24 (28.2%)	0.026
Intertrochanteric	86 (64.2%)	25 (51.0%)	61 (71.8%)	
Surgery				
internal fixation	62 (46.3%)	22 (44.9%)	40 (47.0%)	0.047
prothesis	32 (23.9%)	17 (34.7%)	15 (17.6%)	

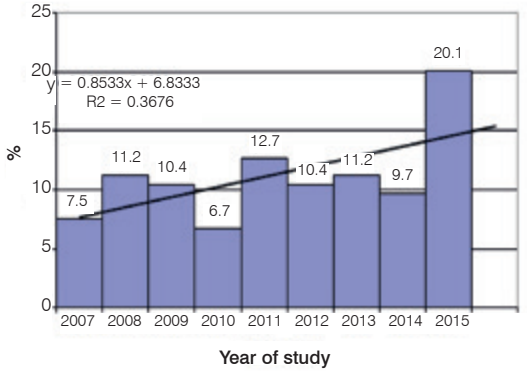

Figure 1. Annual prevalence of fracture in the nonagenarians.

Patient sex distribution according to ASA score was bimodal in women (23.5% ASA 2 and 36.5% ASA 3), while in males peak frequency occurred in ASA 3 (51%). The average ASA score was significantly higher in women, 3.53 vs 2.92. (p=0.004). (Figure 2)
In our sample, the frequency distribution for prevalence of intertrochanteric fracture (64.2%) was significantly higher in women than men, 71.8% vs 51%. (p=0.026).
In 40 (29.9%) cases, a conservative non-surgical approach was chosen because of the high ASA score, the recommendation of the anesthesiologist, or in cases where the patient refused surgical treatment. Among the patients that were treated surgically, 62 (46.3%) were treated with internal fixation and 20 (23.9%) with arthroplasty. Arthroplasty was performed in only 34.7% of men and 17.6% of women, while internal fixation was conducted in 44.9% of the men and 47% of the women. (p=0.047). (Table 1)
The preoperative interval varied from 0 to 15 days, with a mean of 4.34±3.33 days; no significant differences were seen for sex (p=0.521), diagnosis (p=0.487), or type of surgery (p=0.518). (Table 2, Figures 3 and 4)
Hospitalization ranged from 1 to 56 days, with an average of about 13 days without significant differences according to sex (p=0.102) or diagnosis (p=0.537).
Depending on the type of surgery, patients with internal fixation were hospitalized between 2 and 56 days (15 days on average), and patients who received prosthetics were hospitalized between 5 and 27 days (14 days on average), especially women (p=0.001). (Table 3, Figure 5)
The probability of survival in nonagenarian male patients with femoral neck fracture drops to about 60% in the first year, and 30% of men and 65% of women survive this type of fracture. (Figure 6)

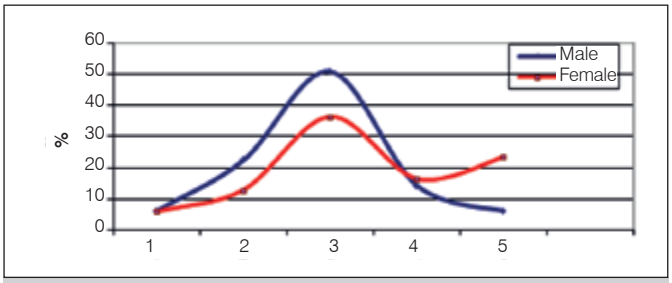

Figure 2. Distribution of ASA score according to patient sex.

Table 2. Descriptive data for preoperative interval.

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Limit	Upper Limit		
Total	94	4.34	3.33	0.343	3.66	5.02	0	15
Sex								
Female	55	4.53	3.87	0.522	3.48	5.57	0	15
Male	39	4.08	2.38	0.381	3.31	4.85	1	11
Diagnosis								
femoral neck fracture	35	4.03	2.71	0.457	3.10	4.96	1	13
Intertrochanteric fracture	59	4.53	3.66	0.476	3.57	5.48	0	15
Surgery								
Internal fixation	53	4.19	3.74	0.513	3.16	5.22	0	15
Internal fixation, 3 screws	9	5.56	2.70	0.899	3.48	7.63	2	11
Prothesis	32	4.25	2.72	0.482	3.27	5.23	2	13

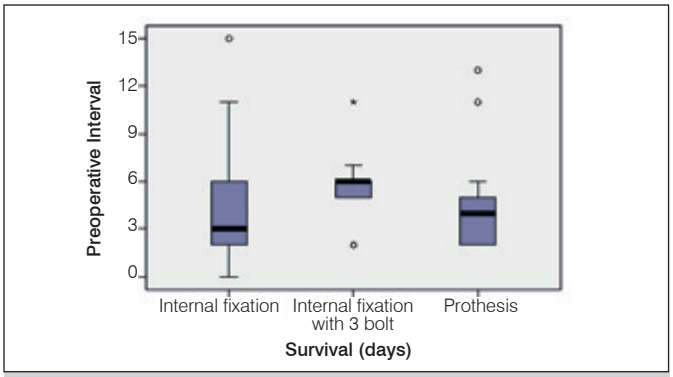

Figure 3. Average values for preoperative interval.

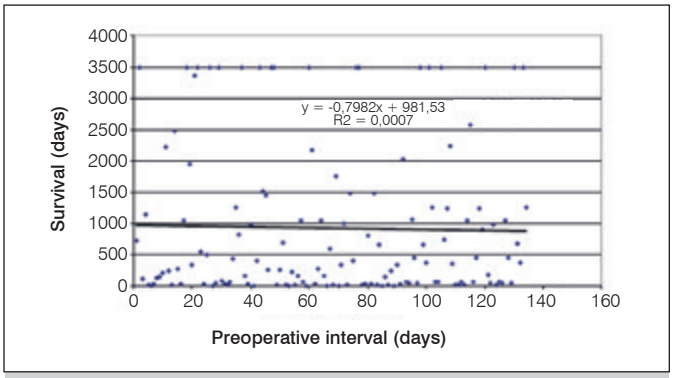

Figure 4. Correlation of survival with preoperative interval.

Table 3. Descriptive data for days of hospitalization.

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Limit	Upper Limit		
Total	134	12.68	10.34	0.893	10.91	14.45	1	56
Sex								
Female	85	13.79	11.98	1.299	11.20	16.37	1	56
Male	49	10.76	6.243	0.892	8.96	12.55	2	27
Diagnosis								
femoral neck fracture	48	11.94	6.62	0.955	10.02	13.86	2	27
Intertrochanteric fracture	86	13.09	11.94	1.287	10.53	15.65	1	56
Surgery								
Internal fixation	53	15.08	13.16	1.808	11.45	18.70	2	56
Internal fixation 3 screws	9	15.44	7.96	2.652	9.33	21.56	6	29
Prothesis	32	14.72	5.44	0.961	12.76	16.68	5	27
None	40	7.25	7.33	1.160	4.90	9.60	1	30

The likelihood of survival of both genres, in the first 3 years for the patients with trochanteric fracture, is reduced to 50-60%, after that, is reduced to 20% in men and by 40% in women. (Figure 7)
Patients with functional treatment had the lowest probability of survival; about 60% of cases survived the first year, with the probability of survival at 2 years at approximately 30%.
Patients with internal fixation have a slightly higher probability of survival, but this drops below 40% 3 years after surgery. Patients with internal fixation using 3 screws survived almost 3 years; in patients who received arthroplasty the probability of survival decreases to about 50% in the first 2 years after surgery. (Table 4, Figure 8)

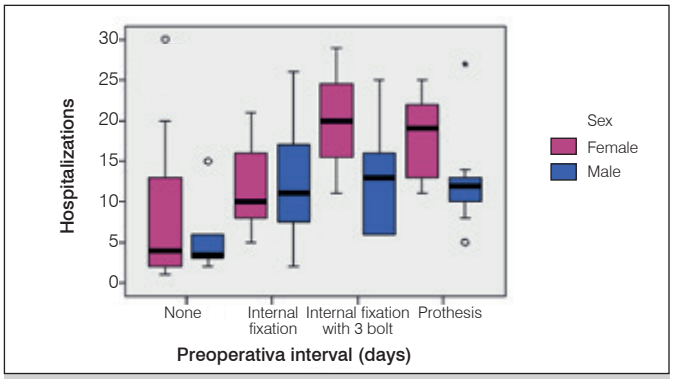

Figure 5. Average values for days of hospitalization according to surgery.

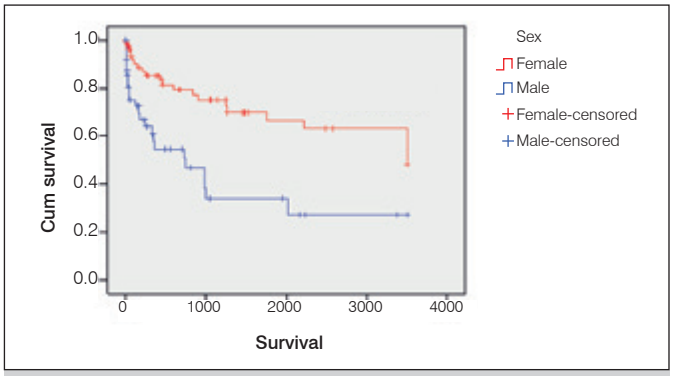

Figure 6. Survival of nonagenarian patients with femoral neck fracture.

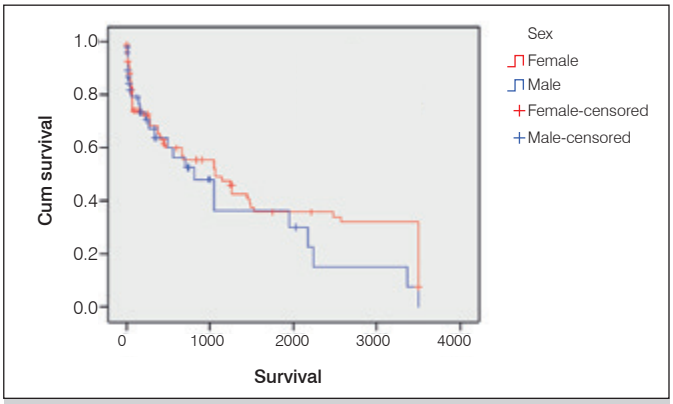

Figure 7. Survival of nonagenarian patients with trochanteric fracture.

DISCUSSION

Although this is not the first study of its kind, our investigation provides new information on postoperative survival time, the association between preoperative interval, type of treatment, and postoperative survival.

Hip fractures are a formidable pathology in elderly patients which may be associated with significant morbidity and high mortality. Despite progress in surgical techniques and postoperative care, mortality remains high: 14–30% one year after surgery, according to recent data.[12] Numerous studies have tried to identify the main factors responsible for high morbidity and mortality after a hip fracture. Most authors consider advanced age to be correlated with other factors, such as patient sex, comorbidities, ASA score, time between fracture occurrence and surgical intervention, and type of fracture.

Table 4. Survival according to demographic characteristics.

Survival Characteristics	30 days (%)	90 days (%)	180 days (%)	1 year (%)	2 year (%)	≥ 3 year (%)	p values Chi-square
All patients (n=134)	18.7	17.2	6.0	9.0	11.9	37.3	
Male (n=49)	32.7	8.2	10.2	14.3	8.2	26.5	0.001
Female (n=85)	10.6	22.4	3.5	5.9	14.1	43.5	
Extracapsular (n=48)	25.0	12.5	10.4	12.5	8.3	31.3	0.177
Intracapsular (n=86)	15.1	19.8	3.5	7.0	14.0	40.7	
Time to surgery: 1–3 days (n=48)	10.4	14.6	6.3	8.3	16.7	43.8	0.204
Time to surgery: >3 days (n=46)	23.9	19.6	2.2	6.5	4.3	43.5	
ASA 1–3 (n=86)	19.8	15.1	8.1	9.3	8.1	39.5	0.317
ASA >3 (n=48)	16.7	20.8	2.1	8.3	18.8	33.3	
Operated (n=94)	17.0	17.0	4.3	7.4	10.6	43.6	0.252
Nonoperated (n=40)	22.5	17.5	10.0	12.5	15.0	22.5	
2007–2010 (n=48)	14.6	18.8	6.3	10.4	16.7	33.3	0.749
2011–2015 (n=86)	20.9	16.3	5.8	7.1	9.3	39.5	

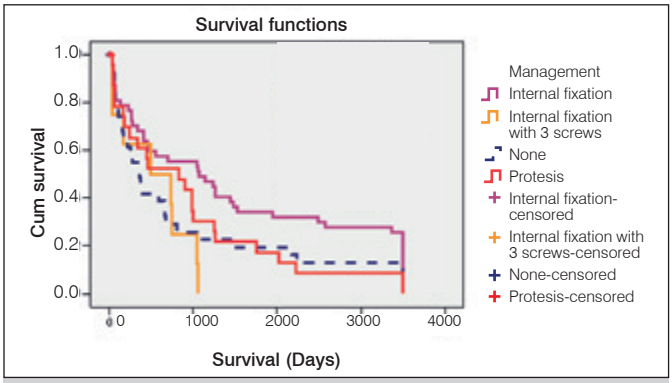

Figure 8. Survival of nonagenarian patients according to surgical intervention.

As the global population ages, an increase in the frequency of hip fractures is inevitable. Our data are in line with the rising tendency toward hip fracture in nonagenarians.[6,13-17]

In our study we obtained lower mortality values at one year than in the literature: 14.3–31.0% in men and 5.9–59.0% in women (p=0.001).[18,19] The higher mortality rate in men was consistent with other previous studies. In the study by Ooi[10] on 84 nonagenarian patients with hip fracture treated both surgically and non-surgically, 2-year mortality was 49%, but the study suggested that surgery significantly increases the ability to move about independently. Our study did not focus on patient mobility and independence after fracture, although we believe this is an important outcome.

In our study, 2-year overall mortality was lower (11.9%) and the group with the longest survival period also was the one that received surgical treatment with internal fixation (14%, p=0.177).

The likelihood of survival for both sexes in the first 3 years for patients with trochanteric fracture is reduced to 50-60%, and after that period is reduced to 20% in men and 40% in women.

Preoperative timeframe is another parameter which influences prognostics for elderly patients with hip fracture. Delaying the surgical intervention is necessary in the context of measures which seek to correct any possible imbalances and optimize the patient's biological status. In a 2011 study, Carretta[3] found that mortality is influenced by the preoperative period, with a rate of about 3.5% for patients operated within the first 48 hours that doubles after this period. Most

current guides confirm that delaying surgical intervention leads to a rise in immediate mortality and mortality during hospitalization. In our group, the preoperative interval varied from 0 to 15 days with a mean of 4.34±3.33 days, and no significant differences were seen for sex (p=0.521), diagnosis (p=0.487) or type of surgery (p=0.518). The correlation between survival time and preoperative interval was indirect and low intensity; a short preoperative interval is associated with increased survival period in only 10.9% of nonagenarian subjects, and the results cannot be extrapolated to the general population (r= - 0.109, R2=0.0119, p=0.297).

Patient sex is another parameter that must be taken into consideration when evaluating mortality. Data published in the specialized literature confirms the predisposition of females to hip fractures. In 2008 Van de Kerkhove et al.[17] published a retrospective study covering a 20-year period and including 155 nonagenarian patients (83% women, 17% men). These authors concluded that extracapsular fractures are much more frequent in women (62%) and that this is associated with a high mortality rate. In our sample, 71.8% of women and 51% of men had an intertrochanteric fracture (p=0.026). We were able to establish a correlation between type of fixation and days of hospitalization. Patients with internal fixation were hospitalized between 2 and 56 days, on average 15 days, and patients who received prosthetics stayed in the hospital between 5 and 27 days, an average of 14 days, especially women (p=0.001). As for type of fracture, Kang et al.[8] indicated that extracapsular fracture of the proximal femur generates higher mortality compared to intracapsular fracture. In our study, survival at 30, 90, and 180 days and 1 year post-fracture was better in extracapsular fracture patients: 25%, 12.5%, 10.4%, and 12.5%, as opposed to 15.1%, 19.8%, 3.5%, and 7.0% in patients with intracapsular fractures.

Associated pathology influences the evolution of patients with hip fracture. An ASA score of 1-2 increases the risk of death in the first year after surgery from 0.36 to 1.33, and for patients with an ASA score of 3-4, the risk of death goes up to 2.33.[4] Our data were not conclusive on this matter, probably because the number of comorbidities often influences the type of treatment selected (conservative or surgical). Our data, like that of other studies,[15] suggest that surgical treatment remains the best option, even for nonagenarian patients. Even though mortality is high, the hospitalization period long and the functional prognosis is limited, the rate of surgical complications is acceptable. The probability of survival in nonagenarian male patients with femoral neck fracture drops to about 60% in the first year, and 30% of men and 65% women can survive this type of fracture.

Patients receiving functional treatment had the lowest probability of survival, with about 60% of cases surviving the first year; the probability of survival at 2 years is approximately 30%.

Patients with internal fixation have a slightly higher probability of survival, although this number drops below 40% 3 years after surgery. Patients with internal fixation using 3 screws survived almost 3 years. In patients receiving arthroplasty, the probability of survival decreases to about 50% in the first 2 years after surgery.

As the global population ages, an increase in the frequency of hip fractures is inevitable. The medical system will face increasingly older patients with significant associated pathologies and a predisposition to postoperative complications. Although nonagenarian patients have numerous comorbidities, surgery utilizing internal fixation seems to be superior to a conservative approach.

The main limitations of this study are the number of patients included. To detect a statistical difference in mortality, a larger study should be conducted, probably involving several thousand patients.

CONCLUSION

In conclusion, we found that mortality after hip fracture was high in nonagenarians, especially men. ASA score has a high influence in determining the type of treatment and patient survival. Although we found a low statistical significance, survival was better in patients who were surgically treated with internal fixation.

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STRUTHERS' LIGAMENT AND SUPRACONDYLAR HUMERAL PROCESS: AN ANATOMICAL STUDY AND CLINICAL IMPLICATIONS

LIGAMENTO DE STRUTHERS E PROCESSO SUPRACONDILAR DO ÚMERO: ESTUDO ANATÔMICO E IMPLICAÇÕES CLÍNICAS

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ABSTRACT

Objective: The objective of this study was to determine the frequency and anatomical characteristics of Struthers' ligament and the supracondylar humeral process and evaluate the clinical implications in compressive neuropathy of the median nerve. Method: We dissected 60 arms from 30 cadavers (26 males and 4 females): 15 were previously preserved in formalin and glycerin and 15 were dissected fresh in the Anatomy Laboratory for this paper. The relationships between Struthers' ligament and the median nerve and brachial artery and veins were documented with drawings and photos. Results: The supracondylar humeral process was not found in any of the 60 dissected arms. Struthers' ligament was identified in six arms (two bilateral); in all cases high insertion of the pronator teres muscle was observed. Conclusion: Struthers' ligament is an aponeurotic structure that may or may not be associated with the supracondylar humeral process, and is an important potential site of median nerve compression in the lower third of the arm. ***Level of Evidence IV, Case Series.***

Keywords: Ligaments. Nerve compression syndromes. Median nerve. Humerus.

RESUMO

Objetivo: Determinar a frequência e as características anatômicas do ligamento de Struthers e do processo supracondilar do úmero e avaliar sua implicação clínica na neuropatia compressiva do nervo mediano. Método: Foram dissecados 60 membros superiores de 30 cadáveres de adultos, 26 do sexo masculino e quatro do sexo feminino, 15 previamente preservados em formol e glicerina e 15 dissecados a fresco no Laboratório de Anatomia. A relação do ligamento de Struthers com o nervo mediano e a artéria e veias braquiais, foi documentada com desenhos e fotografias. Resultados: O processo supracondilar do úmero não foi encontrado em nenhum dos 60 braços dissecados. O ligamento de Struthers foi identificado em seis membros (dois bilaterais); em todos havia inserção alta do músculo pronador redondo. Conclusão: O ligamento de Struthers é uma estrutura aponeurótica que pode estar ou não associada ao processo supracondilar do úmero e representa local de possível compressão do nervo mediano no terço inferior do braço. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Ligamentos. Síndromes de compressão nervosa. Nervo mediano. Úmero.*

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INTRODUCTION

Struthers' ligament was described by the anatomist John Struthers[1] in 1848; this fibrous band extends from a bone spike located on the anteromedial face of the lower third of the humerus known as the supracondylar process and is part of the medial epicondyle of the humerus. Struthers' ligament passes over the median nerve and the brachial artery, and can cause compression of these structures. This ligament may be present even when the supracondylar process is absent, and even when it is present may not cause the compression of these structures. The supracondylar process of the humerus has been described by anatomists and anthropologists and is phylogenetically considered to be a remnant of the supracondylar foramen found in reptiles, marsupials, and some mammals.[2,3] Kessel and Rang[4] consider that from the embryonic point of view, Struthers' ligament is a remaining vestige of the tendon of the latissimus-condyloid muscle tendon, which is found in some climbing animals and serves as an anchor for the pronator teres muscle. In the lower mammals, the tunnel of osteo-fibrous tissue formed by the humerus, the supracondylar process and Struthers' ligament protects the nerves and blood vessels that extend to the forearm.[4] Its occurrence in humans is very rare, in only 0.7–2.5% of the population.[4-6] It is more frequent in women and Europeans and

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is extremely rare in Black individuals.[7] Some authors have reported familial occurrence of this bone spike.[5,6]

Struthers' ligament and the arcade of Struthers are two different anatomical structures which are often confused. The arcade of Struthers was first described in 1973 by Kane et al.[8] and has sometimes been defined as a thickening of the brachial fascia, and at other times as an aponeurotic or musculoaponeurotic structure which extends from the medial intermuscular septum to the medial head of the triceps brachii muscle at a variable distance above the medial epicondyle of the humerus. The arcade of Struthers can cause compression of the ulnar nerve.

Compression of the median nerve in the elbow is usually caused by the presence of fibrous bands, which may be seen in four different anatomic locations in the following order of frequency:[9] between the superficial and deep heads of the pronator teres muscle, in the arcade formed by the proximal insertions of the superficial flexor muscle, in the bicipital aponeurosis (lacertus fibrosus), and in Struthers' ligament which may or may not be associated with the supracondylar process of the humerus. Clinically, it is not easy to identify the exact location of compression. The most common cause of median nerve compression syndrome in this region occurs between the humeral and ulnar heads of the pronator teres muscle. However, the decreased muscle strength of the pronator teres suggests compression above the elbow. Some provocative tests can be used to differentiate the location of the nerve compression:[9,10] 1. Pronation of the forearm against resistance with the elbow flexed and then gradually extended indicates compression between the two heads of the pronator teres muscle. To test the pronator teres muscle alone, the elbow must be extended and supported on a flat surface, with the patient prone and the forearm against resistance with the arm in neutral rotation and the wrist flexed (to relax the superficial muscular flexor of the fingers). Pain and paresthesia show the involvement of the pronator teres muscle in compression of the median nerve. 2. Independent flexion of the middle finger against resistance reproduces the paresthetic symptoms in the area where the median nerve innervates indicates compression in the arch formed between the proximal insertions of the superficial flexor muscle. 3. Elbow flexion and supination of the forearm against resistance reproduces the symptoms and indicates compression by the bicipital aponeurosis (lacertus fibrosus). 4. Compression by Struthers' ligament is usually associated with pain in the forearm that is accentuated during extension of the wrist. The elbow is flexed against resistance and simultaneously palpating the area 5 to 10 cm above the medial epicondyle in an attempt to palpate the supracondylar process of the humerus. Radiological examination rules out the presence of the supracondylar process. Tinel's sign can be useful to find the location of the compression. The results of electrophysiological examinations are consistent with a nerve compression at the elbow, suggesting but not confirming the exact location of the compression.[9] Only surgical exploration of the nerve can identify the structure responsible for nerve compression.[9,10]

The objective of this study was to analyze 60 limbs from 30 cadavers in order to identify the presence of Struthers' ligament and the supracondylar process of the humerus, along with the possibility that these anatomical variations may be responsible for compression of the median nerve.

MATERIALS AND METHODS

We dissected 60 forearms of 30 adult cadavers belonging to the Anatomy Department Laboratory to conduct this study; 26 corpses were male and four were female, 15 had previously been preserved in formaldehyde and glycerin and 15 were fresh cadavers. Ages ranged from 28 to 77 years, 17 were white and 13 were non-white. Forearms deformed by trauma, congenital malformations, and scars were excluded. The dissection was performed through a midline incision in the arm and forearm, and two flaps including the skin and subcutaneous tissue were folded back to the radial and ulnar sides, respectively. This same process was repeated for the fascia of the arm and forearm, exposing all the musculature. The median nerve was identified in the proximal third of the arm in the medial margin of the brachial biceps muscle and dissected distally, analyzing the presence of any fibrous bands, Struthers' ligament, and the supracondylar process of the humerus that could narrow its passage. The dissection continued distally on the forearm where we analyzed the presence of nerve compression from the bicipital aponeurosis, between the humeral and ulnar heads of the pronator teres muscle and through the archway formed between the radial and ulnar humerus inserts of the superficial flexor muscle, and also identified the Gantzer muscle, the Martin-Gruber anastomosis, and possible anatomical variations. These are part of studies that have already been published or are forthcoming. The anatomical variations were identified, recorded, and photographed. We used a Keeler 2.5x magnifying glass. The study was approved by the institutional review board under process number 1,611,295.

RESULTS

In all 60 dissected arms we recorded that in the middle third of the arm, the median nerve crossed in front of the brachial artery in a lateral-to-medial direction and proceeded toward the cubital fossa, where it was positioned medially to the brachial artery and the tendon of the biceps brachii muscle. The supracondylar process of the humerus was not found in any of the 60 dissected arms. Struthers' ligament was identified in 6 arms (two bilateral) and in all cases the pronator teres muscle had a high insertion. In the right arm of one cadaver we identified high insertion of the pronator teres muscle where it came from a cord-shaped ligament positioned on the median nerve and brachial artery, inserting into the diaphysis of the humerus. (Figure 1A) On the left side the ligament originated from the same place and was inserted proximally, but had no relation with the median nerve and brachial artery. (Figure 1B) Unlike Struthers' ligament, the arcade of Struthers is an aponeurotic or musculoaponeurotic structure which extends from the medial intermuscular septum to the medial head of the triceps brachii muscle. (Figure 2A) A case similar to the situation in Figure 1B was recorded in the left arm of another cadaver. (Figure 2B) In two arms from one cadaver, we identified an anatomical variation consisting of high insertion of the humeral head of the pronator teres muscle which was inserted through a short ligament in the diaphysis of the humerus causing pressure on the median nerve and brachial artery, but there was no bone spike. (Figures 3A and 3B) We identified two similar cases on the right arm of a recently-deceased cadaver and in the left arm of another cadaver preserved in formaldehyde and glycerin; Struthers' ligament was composed of a fibrous lamina originating in the medial epicondyle and adjacent brachial fascia, moving upwards and passing over the median nerve and brachial artery to insert itself into the fascia of the brachial muscle and the humeral shaft. (Figures 4A and 4B)

DISCUSSION

Nerve compression in the elbow region is generally called pronator teres syndrome because compression most frequently occurs between the two heads of this muscle.[9] Tubbs et al.[11] considered this nomenclature to be incorrect when compression occurs

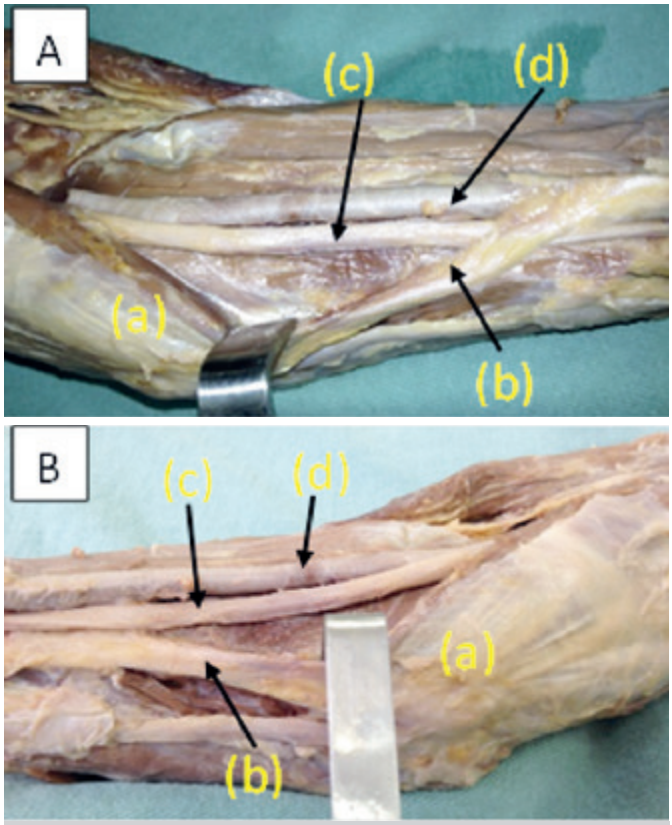

Figure 1. A) In the right arm of one corpse, we identified high insertion of the pronator teres muscle (a) from which a cord-shaped ligament originated (b) and was positioned on the median nerve (c) and the brachial artery (d) inserting into the diaphysis of the humerus. B) On the left side, the ligament originated in the same place and was inserted proximally but had no relation to the median nerve or brachial artery. The pronator teres muscle (a); Struthers' ligament (b); median nerve (c); brachial artery (d).

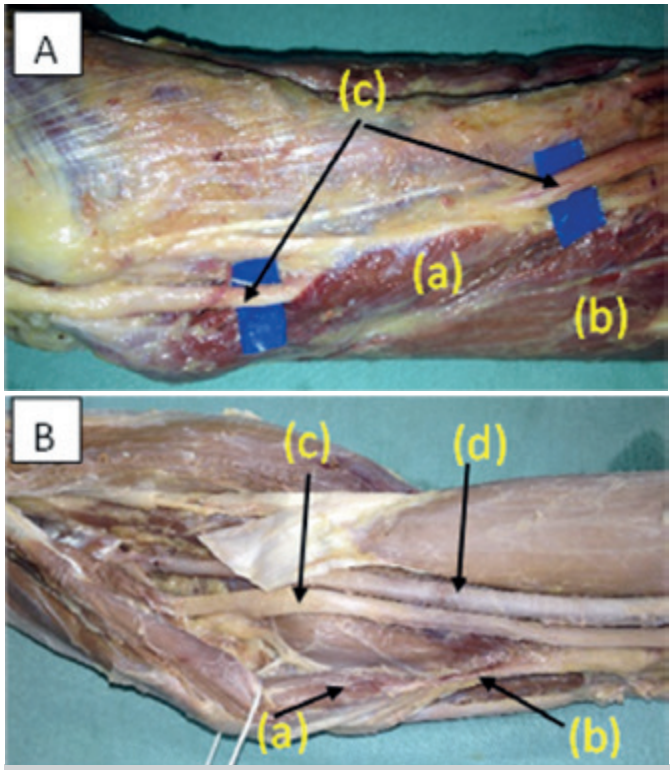

Figure 2. A) The arcade of Struthers (a) is a musculoaponeurotic structure which extends from the medial intermuscular septum to the medial head of the triceps brachii muscle (b). It is positioned anterior to the ulnar nerve (c) and may compress this structure. B) A case similar to the situation in Figure 1B was recorded in the left arm of another cadaver. Pronator teres muscle (a). Struthers' ligament (b). Median nerve (c). Brachial artery (d).

through Struthers' ligament, bicipital aponeurosis, or through the archway of the superficial flexor, and suggested that the correct name would be compressive neuropathies proximal to the median nerve and not pronator teres syndrome. Struthers' ligament and supracondylar process of the humerus can be asymptomatic and differ from the osteocartilagenous exostosis because they do not have a cartilaginous cap and histologically are normal bone in continuity with the humeral cortex.[6] The cartilaginous cap can be visualized using magnetic resonance imaging.[6,12] Clinical abnormalities caused by the supracondylar process of the humerus were first described by Soliere,[13] who described sensory and motor changes in the median nerve which was compressed by the supracondylar process of the humerus in a 19-year-old man. Suranyi[14] reported the case of a 60-year-old patient exhibiting progressive weakness, pain, and numbness in the left forearm and hand. Clinical examination showed that these changes occurred in the area of distribution of the median nerve. Electrophysiological examination showed impairment of the nerve in the segment immediately proximal to the elbow. Surgery revealed that Struthers' ligament was the cause of the compression of the median nerve. The bone spike was not found via palpation or x-ray examination. Sectioning of the Struthers' ligament relieved the symptoms. Caetano and Brandi[15] reported the case of a 26-year-old patient with pain in the shoulder, forearm, and hand as well as numbness of the hand for six months; he was unable to fully extend his left or right elbows. During palpation the presence of a hard and painful tumor was noted on the antero-medial surface of the lower third of the left and right arms; it was more extensive on the right side with positive Tinel's sign at the level of the tumor. On this side there was a limitation of 35 degrees extension and 30 degrees supination. Pain was exacerbated with passive supination and active pronation with simultaneous extension of the elbow. There were no signs of vascular compression. The left arm had a limitation of 15 degrees of extension and 20 of supination, and negative Tinel's sign with no symptoms of neurovascular compression. Radiological examination showed the presence of a 3-cm bone spike in the right arm and a 1.5-cm bone spike in the left arm. Surgery showed that the pronator teres muscle was inserted abnormally via a short ligament in the supracondylar process of the humerus. (Figure 5A) Disinsertion of the muscle and resection of the bone spike resulted in decompression of the median nerve. (Figure 5B) Clinical improvement was already evident in the second month after surgery. After 18 months, the patient was completely asymptomatic. The pronator teres muscle was reinserted in the medial epicondyle of the humerus. In our dissections we identified in both arms from a single cadaver an anatomical variation identical to that registered in the clinical case described above. The pronator teres muscle was inserted the same way via a short ligament in the diaphysis of the humerus, but there was no bone spike. (Figures 4A and B) We do not know the medical history of this individual, but the narrowing of the space where the nerve passed was evident. Aydinlioglu et al.[16] described the rare case of a 21-year-old woman who complained of pain, sensory disturbances, and loss of motor function in the area where the median nerve innervated in both arms. Clinical examination identified the presence of a painful bone spur in the distal third of the humerus. Radiological and electrophysiological

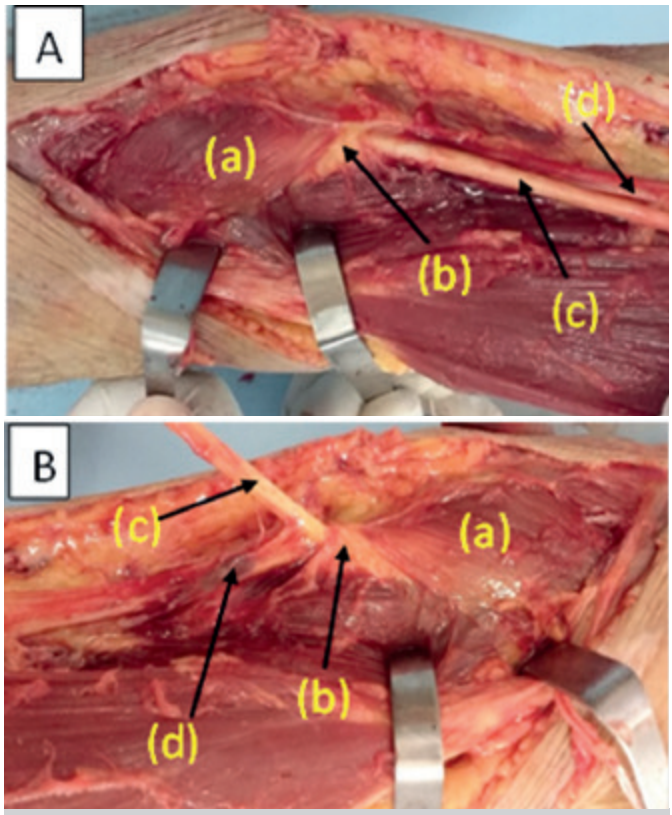

Figure 3. A-B) In one cadaver, we identified a bilateral anatomical variation consisting of high insertion of the humeral head of the pronator teres muscle (a) which was inserted through a short ligament (b) in the diaphysis of the humerus causing pressure on the median nerve (c) and brachial artery (d), but no bone spike was seen.

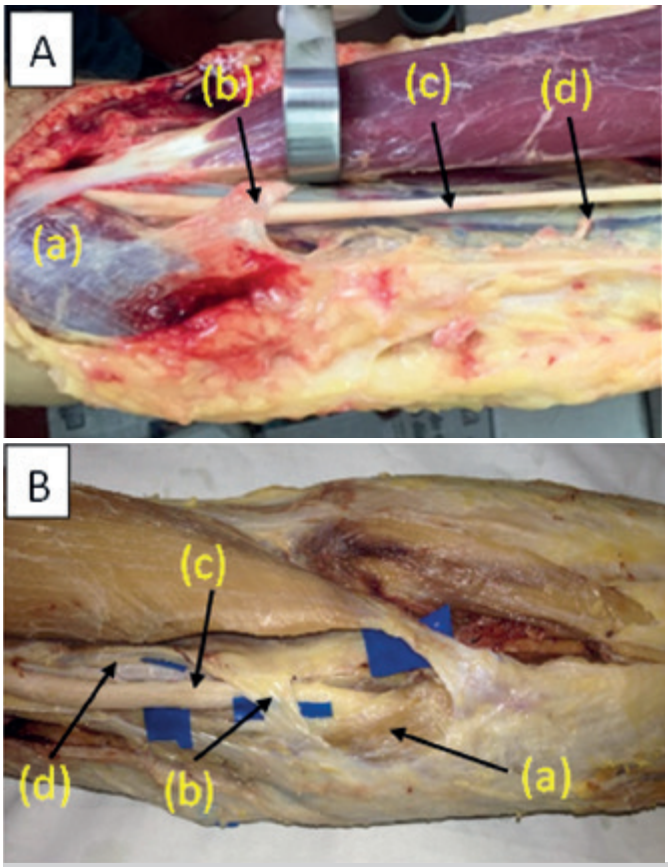

Figure 4. We identified two similar cases (A) in the right arm of a recently-deceased cadaver and (B) in the left arm of another cadaver preserved in formaldehyde and glycerin; the Struthers' ligament was composed of a fibrous lamina (b) originating in the medial epicondyle and adjacent brachial fascia, moving upwards and passing over the median nerve (c) and brachial artery (d) to insert itself into the fascia of the brachial muscle and the humeral shaft. Pronator teres (a).

examination confirmed the diagnosis of bilateral compression of the median nerve caused by Struthers' ligament. These authors stated that this was the first reported case of bilateral compression of the median nerve caused by this ligament. The patient underwent surgical decompression of the nerve on both sides and symptoms were relieved after two weeks. These authors described the importance of removing the adjacent periosteum to avoid regrowth in the supracondylar process. Lordan et al.[17] reported the case of a 13-year-old boy with a history of 4 weeks of vague pain in the left forearm after hitting his elbow during sports activity. Palpation identified a hard mass along the distal humerus. X-ray revealed a bone spike 5 cm proximal to the elbow. The clinical history showed the boy had paresthesia in the ipsilateral thumb, index finger, middle and radial half of the ring finger, as well as pain in the forearm during pronossupination. Physical examination revealed mild weakness in grip strength, but no atrophy of the thenar muscles or sensory deficits of the hand. Because the neurological symptoms were persistent, the patient underwent surgery. Struthers' ligament and supracondylar process were identified as responsible for the symptoms. The ligament was sectioned and the supracondylar process removed, and the symptoms consequently disappeared. These authors also stated that compression of the median nerve by Struthers' ligament and the supracondylar process should be considered in cases where symptoms persist after decompression of the median nerve in the carpal tunnel. Petret et al.[18] presented the case of a professional tennis player with a stress fracture in the supracondylar process of the humerus who underwent surgery to avoid possible displacements and neurovascular complications. These authors state that this was the first report of a stress fracture in the supracondylar process, and believed that the excessive traction of the pronator teres caused the fracture, which was seen in both X-ray and MR imaging. Jelev et al.[19] reported noticing an unusually high insertion for the pronator teres muscle during routine anatomic dissection of the right arm of a 53-year-old female cadaver; this insertion had two bone origins, one in the medial epicondyle and a smaller insertion in the supracondylar process of the humerus, with tendinous arch (Struthers' ligament) extending between them with the median nerve and brachial vessels passing through this arch. They noticed that the musculocutaneous nerve was absent and that the coracobrachialis, brachialis, and biceps brachialis muscles received innervation from the median nerve.

The anatomical relationships between the supracondylar spur and Struthers' ligament and the neighboring neurovascular structures have been clearly demonstrated in MR imaging by some authors.[20,21] Other associated anatomical variations may occur: high insertion of the pronator teres, high division of the brachial artery, low insertion of the coracobrachialis muscle, or high origin of the anterior interosseous nerve.[22] In the left arm of a cadaver with a high origin for the pronator teres muscle, we noted low insertion of the coracobrachialis muscle and high origin of the anterior interosseous nerve, (Figure 6A) but did not identify Struthers' ligament, the supracondylar process,

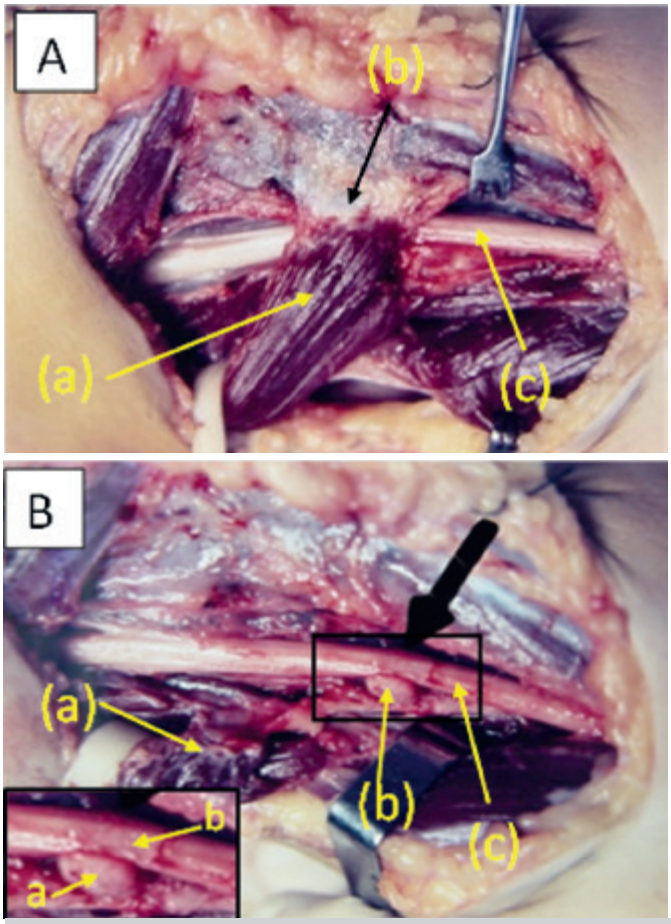

Figure 5. A) Clinical case. In one cadaver, we identified a bilateral anatomical variation consisting of high insertion of the humeral head of the pronator teres muscle (a) which inserted via a short ligament (b) in the supracondylar process of the humerus, compressing the median nerve (c). B) Surgery showing the pronator teres muscle disinserted (a) from the supracondylar process of the humerus (b) and compressing the median nerve (c). Detail: supracondylar process (a) and median nerve (b).

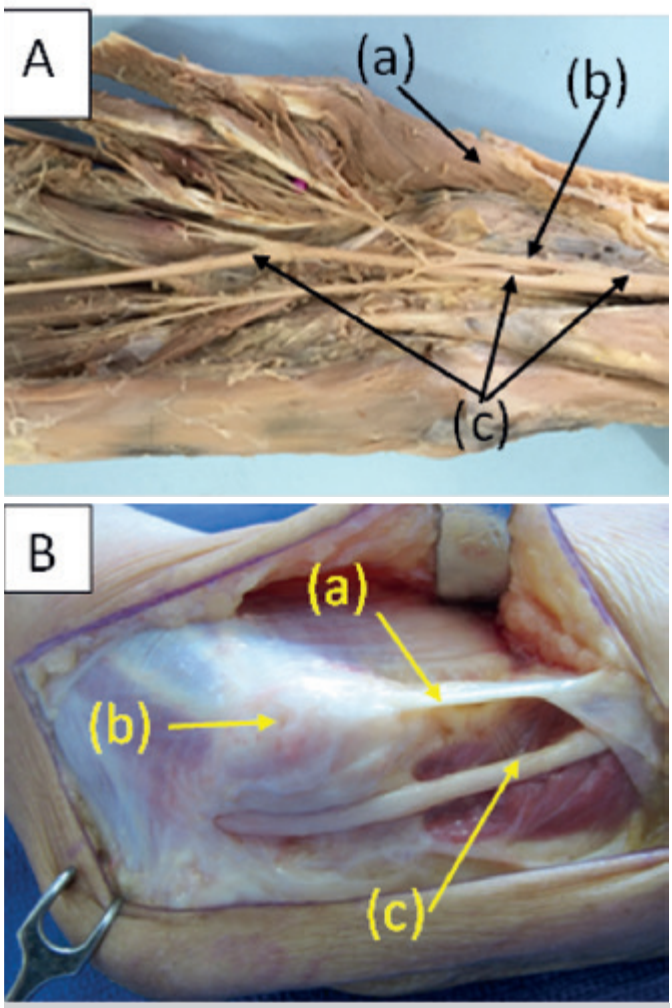

Figure 6. A) High insertion of the pronator teres muscle (a) associated with high origin of the anterior interosseous nerve (above the elbow joint) (b). Median nerve (c). B) The Struthers' ligament (a) originated in the medial epicondyle (b) and moved proximally, fanning out and inserting into the brachial fascia and the internal brachial ligament and passing over the ulnar nerve (c) in precisely the place where the nerve passed from the anterior compartment to the posterior of the arm.

or high division of the brachial artery in this cadaver. The proximity of the ligament and the supracondylar process to the brachial artery and veins can cause symptoms resulting from the compression of these structures, with ischemic episodes of pain and changes in the arterial pulses which have been previously described.[4,6] Some authors[4,23] have indicated that Struthers' ligament can compress the ulnar nevus, but consider this phenomenon to be very rare. We did identify a case not belonging to this series (but rather in a demonstration of access routes to the elbow) in which Struthers' ligament originated in the medial epicondyle and moved proximally, fanning out and inserting into the brachial fascia and the internal brachial ligament and passing over the ulnar nerve in precisely the place where the nerve passed from the anterior compartment to the posterior of the arm. (Figure 6B) Gessini et al.[24] considered compression of the median nerve by Struthers' ligament to be very rare, and reported that in a series of 228 patients with compressive syndromes of the median nerve, only three cases occurred above the elbow: one case involving Struthers' ligament and two involving the bicipital aponeurosis, 201 cases of carpal tunnel syndrome, 21 cases involving the pronator teres muscle, and three involving the anterior interosseous nerve.

CONCLUSION

Struthers' ligament is a rare aponeurotic structure that may or may not be associated with the supracondylar process of the humerus and may compress the median nerve against the deeper structures, changing the normal course of the nerve; it is consequently one of the rare potential sites for nerve compression which narrow the space where nerves pass and consequently can cause motor and sensory symptoms.

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ANALYSIS OF FUNCTIONAL CAPACITY IN INDIVIDUALS WITH AND WITHOUT CHRONIC LOWER BACK PAIN

ANÁLISE DA CAPACIDADE FUNCIONAL EM INDIVÍDUOS COM E SEM DOR LOMBAR CRÔNICA

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ABSTRACT

Objective: The objective of this study was to analyze the functional status of adult and older adult individuals with lower back pain. Methods: Eighty-three individuals were recruited, 42 older adults (20 with lower back pain and 22 control group) and 41 younger adults (21 with lower back pain and 20 control group). Functional capacity was assessed using the following tests: Timed Up and Go (TUG), Five Times Sit-to-Stand (FTSTS), six-minute walking test (SMWT), and sitting-rising test (SRT). Results: In the younger adults, there was no difference in functional capacity between the groups ($p>0.05$). On the other hand, when statistical analysis was adjusted using body mass index (BMI) as a covariate, the lower back pain group performed more poorly on the SRT ($p<0.004$). Furthermore, poorer physical capacity was seen in the older adults with back pain via the SRT test ($p=0.001$), and when the BMI was adjusted, a statistical difference was seen in the SRT as well as the SMWT ($p<0.05$). Conclusion: Older individuals with lower back pain have poorer physical performance, and the sitting-rising test is the most discerning for assessment of functional status in individuals with lower back pain. ***Level of Evidence III, Retrospective Comparative Study.***

Keywords: Low back pain. Aged. Reproducibility of results.

RESUMO

Objetivo: Avaliar a funcionalidade de indivíduos idosos e jovens com dor lombar crônica. Método: Foram avaliados 83 indivíduos, sendo 42 idosos (Grupo controle: 22 e Grupo dor lombar: 20) e 41 jovens (Grupo controle: 20 e Grupo dor lombar: 21). Para avaliação da capacidade funcional, foram utilizados os testes Timed Up and Go (TUG), sentar e levantar de uma cadeira 5 vezes (Five Times Sit-to-Stand - FTSTS), o teste da caminhada dos seis minutos (TC6min) e sentar e levantar do solo (TSL). Resultados: Não houve diferença na capacidade funcional dos jovens entre os grupos ($p > 0,05$). Contudo, quando a análise é ajustada para a covariável "IMC", o Grupo dor lombar apresentou pior desempenho no teste TSL ($p = 0,004$). No grupo de idosos, foi observado pior desempenho no Grupo dor lombar no teste TSL ($p = 0,001$). Após o ajuste pela variável "IMC", observou-se diferença estatística nas condições do teste TSL, assim como no TC6min ($p < 0,05$). Conclusão: Idosos com dor lombar crônica apresentaram pior desempenho funcional e o teste TSL foi o mais discriminativo para avaliação funcional de indivíduos com dor lombar crônica. ***Nível de Evidência III, Estudo Retrospectivo Comparativo.***

Descritores: *Lombalgia. Idoso. Reprodutibilidade dos testes.*

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INTRODUCTION

Like a number of other developing countries, Brazil is undergoing a demographic shift, which is more evident in recent decades; the Brazilian population has been aging quickly since the early 1960s. According to data from the Brazilian Institute of Geography and Statistics (IBGE),[1] an increase in the population aged 65 years or over has been observed in this country, and it is estimated that by 2025 the elderly population could comprise 15% of the entire population. This fact is attributed to the chronic nature of diseases that lead to an increase in physical disabilities such as decline in health, decreased strength, reduced muscle endurance, flexibility, and mobility, as well as deterioration in motor control, causing postural instability in a variety of situations in daily life.[2]

The incidence of chronic degenerative diseases, namely chronic musculoskeletal pain, particularly in the lumbar region, is one of the most common complaints in individuals over age 60, and leads to functional limitation and greater physical dependence.[3]

Some of the tests used to evaluate functional capacity include the sitting-rising test (SRT),[3] the Timed Up and Go (TUG) test,[4] the six-minute walking test (SMWT)[5] and the Five Times Sit-to-Stand

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test (FTSTS).[6] These tests are notable because they are practical to implement and apply in clinical practice, have a low level of complexity, and do not require costly equipment.

The assessment of functional capacity is described in the literature in various populations. Puhan et al.[7] assessed functional capacity in individuals with COPD using the SMWT and the FTSTS and concluded that these tests are able to assess functional capacity and would be responsive in pulmonary rehabilitation programs. Homann et al.[8] reported the efficiency of the SMWT to determine the functionality of women with fibromyalgia by reducing the distance traveled during the test in the diseased group. Champagne et al.[9] assessed balance and functional capacity in women with chronic lumbar pain in relation to several factors such as stiffness in the lumbar region, pain radiating to the buttocks, and pain in the lumbar region, and found that pain affects these individuals in relation to the risk of falls, mainly in elderly women.

Although different studies have applied functional tests, few address the population of individuals with chronic lumbar pain.

Considering the high prevalence and functional disability in different age groups resulting from chronic lumbar pain, new proposals to assess functional capacity are expected to help health professionals develop preventive programs and intervention, thus promoting an improvement in life expectancy and quality of life during the aging process. Functional capacity assessments can provide important information on the population with lumbar pain; this requires the use of instruments that assess motor function, muscle strength and aerobic resistance, flexibility, coordination, agility, and dynamic balance. These activities aim to ensure muscular and skeletal integrity in individuals, particularly in the elderly population, helping to reduce the risk of falls and functional disability, and in individuals recovering from chronic conditions.

Therefore, the objective of this study was to evaluate the functionality of elderly and younger individuals with chronic lower back pain, and to identify which tests are most discerning in analyzing the functional status of these individuals.

MATERIALS AND METHODS

This study is part of a multicenter research project (UNOPAR/UNIC), which was approved by the UNIC institutional review board (CEP n° 273,376). All participants signed a document indicating free and informed consent before tests were performed.

This study was observational, cross-sectional, descriptive, and used a quantitative approach.

The Bioestat 5.0 program was used to calculate the sample, using the data obtained from the study of Champagne et al.[9] as parameters. The confidence interval was set at 95%, alpha level at 5% and test power at 80%, and consequently a minimum sample of 16 individuals per group was required to test the null hypothesis that there is no difference between the sensory-motor properties of individuals with and without chronic lumbar pain. Considering possible losses, we recruited a 20% larger sample (20 subjects in each group).

We evaluated 83 individuals of both sexes in the local community of Londrina, Paraná, Brazil: 41 younger adults and 42 older adults. The participants were divided into four groups for analysis: 1) healthy young adults (G1 n=20); 2) young adults with chronic lumbar pain (G2, n=21); 3) healthy older adults (G3 n=22); 4) older adults with chronic lumbar pain (G4, n=20). Chronic lumbar pain determined via self-report and was defined as being of unknown mechanical origin and persisting for more than 3 months. We used data on the pressure pain threshold to confirm the presence of low back pain.

The eligibility criteria for the groups with pain were: presence of lumbar pain with or without irradiation limited to the knees, measured by assessing the pressure pain threshold using a EGM Systems brand device; presence of chronic pain, defined as pain every day or nearly every day over the previous three months; lower back pain of unknown mechanical origin (muscle or passive structures); non-participation in rehabilitation programs, such as conventional physiotherapy, Pilates, or global postural re-education.

Inclusion criteria for the control group were lack of any lumbago or lower back pain radiating to the lower limbs; non-participation in physical activity programs more than three days per week in accordance with the recommendations of the American College of Sports Medicine,[10] good overall health; be physically independent and voluntarily opt to participate in the study. The young adult participants were between 18 and 50 years of age and the older participants were 60 years or over.

Exclusion criteria for all groups were presence of any kind of neurological, respiratory, metabolic, and/or orthopedic disorder, rheumatic disease with bone or muscular impairment; vestibular disease or acute attacks of labyrinthitis; mental problems, attention and speech disorders; having undergone any type of surgery of the locomotor system; non-volunteer.

This study was conducted at the Universidade Norte do Paraná (UNOPAR) from August to December 2014. The assessments were conducted in just one day, always in the afternoon. Initially we collected sociodemographic and anthropometric data such as weight and height, and calculated body mass index (BMI).

Evaluation of pain to pressure threshold (PPT)

An EGM Systems brand device was used to measure PPT. The device measures pressure in kgf and has a rod at one end with a 1 cm^2 flat circular end surface which applies constant and increasing pressure perpendicular to anatomic pressure points.[11]

The sitting-rising test

The sitting-rising test evaluates the functional mobility of older adults. In this test, the individual rises from the floor using as little support as possible, without concern for speed. Total score ranges from zero to 10, with five points attributed to sitting and five points to rising from the floor. One point is subtracted for each support used; these can be the hands, knee, or the side of the leg, and half a point is deducted for loss of balance.

Five Times Sit-to-Stand Test (FTSTS)

This test is easy to administer and assesses leg strength, balance, and risk of falls. The patient is directed to cross his arms over his chest and sit with his back against the chair (43 cm high, 47.5 cm deep). The examiner gives the following instructions according to the standard protocol: "I want you to stand up and sit down five times, as fast as you can, when I say 'Go.'" Timing begins when the examiner says "Go" and ends when the buttocks touch the chair after the fifth repetition.

Timed Up and Go Test (TUG)

This test assesses fall risk. Transfer from a seated position to standing is evaluated along with stability and gait changes without using compensatory strategies. The assessor asks the individual to get up from a chair where she/he was fully supported, walk three meters, turn around, return by the same route, and sit back down in the chair with his or her back supported; performance is measured as the time (in seconds) required to perform the test.

Six-Minute Walk Test (SMWT)

According to the recommendations of the American Thoracic Society (ATS),[12] this self-paced test assesses the sub-maximal level of functional capacity on a 30-meter course marked by two cones at each end. This test measures the distance an individual can walk as quickly as possible without running on a flat, firm, covered surface

for a period of six minutes. The individual is allowed to pause or rest during the test if necessary, but the timer does not stop.
The assessments were performed on the same day, always in the afternoon. The better score for each test was considered, except for the SMWT, which according to the ATS uses a 30-minute rest interval. All tests were applied twice, with a rest period of 1 minute between tests. The tests were applied in the following order: sitting-rising test, then Five Times Sit-to-Stand test, then the Timed Up and Go test, and last the six-minute walk test.

Statistical analysis

The data were analyzed descriptively and analytically using Statistical Package for Social Sciences software (SPSS) version 18.0. A confidence interval of 95% was established, along with a 5% significance level ($P<0.05$) for all tests.
The Shapiro-Wilk test was used to test the normality of the data. To compare the four groups we used the t test for independent samples, considering normal distribution in the comparable subgroups.
Finally, the ANCOVA test was used to compare the groups in order to reduce the variance of the error and adjust the means of the covariate "body mass index" (BMI) for all subjects to a fixed value.

RESULTS

Eighty-three individuals participated in the study. The anthropometric characteristics were similar between the groups with regard to age, weight, height, BMI, and pain pressure threshold. (Table 1)
As for the presence of multiple morbidities and medication use in the population studied, the older adults exhibited a higher prevalence for these variables than the younger adults. (Table 2)

Table 1. Characteristics of the study population.

Young adults			
Variable	**Control Mean ± SD**	**Lower back pain Mean ± SD**	**Independent t test (P)***
Age (years)	30.75 ± 10.86	31.38 ± 8.52	0.837
Weight (kg)	70.32 ± 18.82	75.76 ± 11.26	0.265
Height (m)	1.67 ± 0.73	1.66 ± 0.85	0.679
BMI (kg/m^2) Pressure pain threshold (kgf)	24.73 ± 5.14 7.31 ± 0.45	27.23 ± 3.55 5.31 ± 0.49	0.076 0.002*
Older adults			
Age (years)	71.23 ± 5.06	69.42 ± 5.67	0.283
Weight (kg)	66.41 ± 8.48	70.48 ± 10.53	0.176
Height (m)	1.56 ± 0.57	1.56 ± 0.75	0.732
BMI (kg/m^2) Pressure pain threshold (kgf)	27.40 ± 3.90 7.48 ± 0.32	28.83 ± 4.90 6.05 ± 0.29	0.303 0.002*

$P>0.05$; SD = standard deviation; kg= kilogram; m= meters; BMI = body mass index; kgf= kilogram force.

No statistically significant difference in the functional performance of the younger adults was observed between the groups ($p>0.05$). But when the analysis was adjusted for the covariate BMI in this same population, the group with chronic lower back pain showed higher scores in the SRT ($p>0.004$), indicating functional limitation in mobility when rising from the ground. (Table 3)
In the older adults with and without chronic lower back pain, differences in functional performance were only observed in the SRT ($p=0.00$). The group of older adults with pain demonstrated functional limitation in rising from the floor, which highlights the sensitivity of this test in describing functionality in relation to other tests used in the study.
When adjusted by the covariate BMI, the group of older adults with chronic lower back pain also showed differences in relation to the control group for both sitting and rising in the SRT and in the SMWT (ANCOVA, $p<0.05$); the older adults with pain showed reduced functional performance, as shown in Table 4.

DISCUSSION

In this present study no difference was seen between the control and pain groups in younger adults in terms of the relationship between functional capacity and lower back pain. However, the older adults with chronic lower back pain performed more poorly on functional tests than the older adults without lower back pain.

Table 3. Functional capacity results in young individuals.

Variable	Control Mean ± SD	Lower back pain Mean ± SD	Independent t test (P)*	ANCOVA (P)*
SRT (sitting)	4.30 ± 0.85	4.42 ± 0.50	0.55	0.169
SRT (rising)	3.4 ± 0.81	4.0 ± 1.11	0.87	0.004*
FTSTS	10.29 ± 2.05	9.00 ± 1.57	0.50	0.825
TUG	5.79 ± 0.84	5.70 ± 0.70	0.70	0.967
SMWT	646.0 ± 53.84	630.95 ± 55.88	0.38	0.238

SRT= sitting-rising test (from ground); FTSTS= Five Times Sit-to-Stand Test; TUG: Timed Up and Go; SMWT= six-minute walk test. *P*<0.05*.

Table 4. Functional capacity results in older individuals.

Variable	Control Mean ± SD	Lower back pain Mean ± SD	Independent t test (P)*	ANCOVA (P)*
SRT (sitting)	3.04 ± 0.92	2.16 ± 1.23	0.12	0.000*
SRT (rising)	2.69 ± 1.03	1.42 ± 1.12	0.00*	0.000*
FTSTS	13.07 ± 2.80	14.97 ± 3.35	0.53	0.229
TUG	7.17 ± 1.31	7.97 ± 1.26	0.52	0.16
SMWT	523.09 ± 85.91	468.66 ± 82.53	0.43	0.001*

SRT= sitting-rising test (from ground); FTSTS= Five Times Sit-to-Stand Test; TUG: Timed Up and Go; SMWT= six-minute walk test. *P*<0.05*.

Table 2. Characteristics of medication use and presence of multiple morbidities in the study population.

Young adults						
	Control			Lower back pain		
Variable	**Category**	**Frequency absolute (n)**	**Frequency relative (%)**	**Category**	**Frequency absolute (n)**	**Frequency relative (%)**
Sex	Female	14	46.67%	Female	16	53.33%
	Male	6	54.54%	Male	5	45.46%
Medication use		0	0		2	9.5%
Multiple morbidities		0	0		0	0
Older adults						
	Control			Lower back pain		
Variable	**Category**	**Frequency absolute (n)**	**Frequency relative (%)**	**Category**	**Frequency absolute (n)**	**Frequency relative (%)**
Sex	Female	18	48.65%	Female	19	51.35%
	Male	4	80%	Male	1	20%
Medication use		3	14.3%		13	61.9%
Multiple morbidities		9	42.9%		15	71.4%

Studies on aging have emphasized the search for strategies that can mitigate the deleterious consequences of the aging process on quality of life; aging is a physiological process and functional capacity in the elderly may be affected by several factors, since these individuals have more chronic health problems than younger people.

Although elderly patients with lumbar pain can use medications that act centrally or peripherally for pain control, we found that the vast majority of this sample did not use medication for pain on a continuous basis. These data agree with the study by Figueiredo et al.,[13] who reported that elderly individuals with lumbar pain only used medication when pain was acute. When we assessed the physical function and capacity of individuals with lower back pain, we found that lumbar pain in young people has no significant clinical repercussions, except in cases where the participant was also overweight or obese.

Lira et al.[14] evaluated the acute effect of increased body weight on performance in the sitting-rising test among young, active adults and found that overweight status had a negative impact on test performance, and concluded that active overweight individuals performed worse in the activities performed (sitting down and standing up), in agreement with our findings.

This present study demonstrated that older adults with chronic lumbar pain performed more poorly on functional tests than the older adults without lower back pain. It can be assumed that the aging process, associated with incorrect posture and excess burden on the spine, are significant factors in triggering serious injury to the discs of the vertebra and mechanical or degenerative changes. The presence of pain has been described by some authors as a limiting factor in elderly individuals during performance of daily activities.[15] In assessing functional capacity, we highlight the use of some functional evaluations such as the sitting-rising test (SRT), the six-minute walk test (SMWT), the Five Times Sit-to-Stand test (FTSTS), and the Timed Up and Go test.

In terms of performance in the SRT and SMWT, older individuals in both groups had much poorer performance compared to the younger adults, which is consistent with a study conducted by Lee et al.,[16] who found that individuals with chronic lower back pain tend to walk more slowly in the SMWT. Mascarenhas and Santos[17] assessed the perception and intensity of pain and functional capacity in young and elderly people with chronic low back pain and found that pain in the lumbar region was not seen as a limiting factor in relation to daily activities, especially in younger individuals, which was also found by Bento et al.[18] This latter finding explains that it is unusual for chronic lumbar pain to completely incapacitate an individual in terms of performing everyday activities, but this pain can partially and temporarily affect individuals, at times on a recurring basis, when individuals are economically active.

Camara et al.[19] stated that the ability to rise from a chair or bed, even though it may be considered a simple task, is considered a complex action which may be related to musculoskeletal and neuromotor disorders which make significant demands of elderly individuals. For Silva et al.[20] this is because of the exposure of the body when there is an extra load that the musculoskeletal system must support, and consequently may cause alterations to the biomechanical balance of the body.

CONCLUSION

The findings of this study provide evidence about the best strategy to evaluate the function of older adults with chronic lower back pain in order to reproduce the functional tests in daily clinical practice, being the SRT the most discerning for this population.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. CPR (0000-0001-7711-1217)*, RASJ (0000-0001-6879-436X)* ENN (0000-0002-2085-6717)*, RACA (0000-0002-3849-0872)*, MTPF (0000-0003-4494-0187)* e KBPF (0000-0002-1276-4900)* were the main contributors in drafting the manuscript. CPR, ENN e MTPF, performed the data collection, followed the individuals and collected the clinical data. RASJ e KBPF evaluated the data from the statistical analysis.RASJ, RACA e KBPF and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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POSTURAL CONTROL ASSESSMENT IN PHYSICALLY ACTIVE AND SEDENTARY INDIVIDUALS WITH PARAPLEGIA

AVALIAÇÃO DO CONTROLE POSTURAL EM INDIVÍDUOS COM PARAPLEGIA FISICAMENTE ATIVOS E SEDENTÁRIOS

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ABSTRACT

Objective: The aim of this study was to evaluate functional independence and trunk control during maximum-range tasks in individuals with spinal cord injuries, who were divided into sedentary (SSI, n=10) and physically active (PASI, n=10) groups. Methods: Anamnesis was conducted and level and type of injury were identified (according to the American Spinal Injury Association protocol, ASIA) and the Functional Independence Measure (FIM) questionnaire was applied. For the forward and lateral reach task, the subjects were instructed to reach as far as possible. Mean data were compared using the unpaired t test and Mann-Whitney test and differences were considered significant when $p<0.05$. Results: The PASI group performed better in self-care activities (PASI: 40.8±0.42 points, SSI: 38.0±3.58 points, p=0.01), sphincter control (PASI: 10.5±1.84 points, SSI: 8.2±3.04 points, p=0.02), transfers (PASI: 20.7±0.48 points, SSI: 16.9±4.27 points, p=0.04), and total FIM score (PASI: 104.0±2.30 points, SSI 105.1±8.56 points, p=0.01). On the maximum reach task, the PASI group had a greater average range in all directions evaluated ($p<0.05$). Conclusion: The continuous practice of exercise increased motor function independence and trunk control in individuals with complete spinal cord injury. ***Level of Evidence II, Prospective Comparative Study.***

Keywords: Motor activity. Sedentary lifestyle. Recovery of function. Spinal cord injuries. Cross-sectional studies. Postural balance.

RESUMO

Objetivo: O objetivo deste estudo foi avaliar a independência funcional e o controle de tronco durante tarefas de alcance máximo em indivíduos com lesão medular, que foram divididos em grupo sedentário (SSI, n = 10) e grupo fisicamente ativo (PASI, n=10). Métodos: Foi realizada anamnese, identificação do nível e tipo de lesão (de acordo com o protocolo da ASIA - American Spinal Injury Association), e aplicou-se o questionário de Medida de Independência Funcional (MIF). Para a tarefa de alcance anterior e lateral os indivíduos foram instruídos a fazer o alcance máximo. Para comparação das médias dos dados foram aplicados o teste t não pareado e teste de Mann-Whitney, e as diferenças foram consideradas significativas quando $p < 0,05$. Resultados: O grupo PASI teve melhor desempenho na realização de atividades de autocuidado (PASI: 40,8 ± 0,42 pontos, SSI 38,0 ± 3,58 pontos, p = 0,01), controle de esfíncter (PASI: 10,5 ± 1,84 pontos, SSI 8,2 ± 3,04 pontos, p = 0,02), transferências (PASI: 20,7 ± 0,48 pontos, SSI 16,9 ± 4,27 pontos, p = 0,04) e MIF total (PASI: 104,0 ± 2,30 pontos, SSI 105,1 ± 8,56 pontos, p = 0,01). No alcance máximo, o grupo PASI teve maior alcance médio em todas as direções avaliadas ($p < 0,05$). Conclusão: A prática de exercício físico contínuo aumentou a independência funcional motora e o controle de tronco em indivíduos com lesão medular completa. ***Nível de Evidência II, Estudo Prospectivo Comparativo.***

Descritores: Atividade física. Estilo de vida sedentário. Recuperação de função fisiológica. Traumatismos da medula espinal. Estudos transversais. Equilíbrio postural.

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INTRODUCTION

Spinal injury is due to trauma or to a disease that, depending on the spinal level affected, can generate a disabling condition that alters motor, sensory and autonomic function in affected individuals, leading to adaptations and changes of habits in order to adapt to the new reality.[1] These changes may severely affect the functional independence of persons with spinal injury.

The stability of the pelvic girdle and of the lumbar spine is very important for body balance and trunk control in persons with spinal injuries. In order to perform routine activities such as driving a wheelchair,[2,3] getting dressed, bathing, and transferring positions, these individuals need lumbar-pelvic stability, which is mainly provided by the action of spinal and abdominal erector muscles[4] This stability permits the subject to keep his balance and to be

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Study conducted at Laboratório de Biomecânica e Reabilitação do Aparelho Locomotor do Hospital Universitário da UNICAMP e da Faculdade de Educação Física da UNICAMP, Campinas, SP, Brazil.
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able to perform movements of the trunk and upper limbs during the tasks proposed.

There is evidence that regular physical activity is associated with increased functional activity, independence, reduction of events with adverse effects on health[5] and improved quality of life of persons with traumatic spinal injury. The cited authors emphasize that the regular practice of physical activity promotes control of joint mobility and increased aerobic resistance, muscle strength and bone mineral density. In addition to promoting physical benefits, physical activity promotes psychosocial benefits such as increased self-esteem, stress relief and wellbeing, as well as maintenance of autonomy and reduction of depression.[6]

However, the practice of sports adapted for persons with paraplegia does not seem to change the pattern of activation of trunk muscles during the task of forward and lateral reach, although the pattern of muscle activation of persons with spinal injury differs from that of persons with no such injury.[7]

In view of the physiological benefits that adapted sports can have for persons with spinal cord injury, there is a need to compare trunk control and performance during the execution of daily activities between individuals with paraplegia who practice or not adapted exercise.

A more in-depth understanding of the benefits of adapted sports for balance and functionality is important in order to provide a scientific basis for the encouragement of the participation in sports of persons with paraplegia and to elaborate a complementary strategy in order to help improve the independence and quality of life of these individuals.

Our hypothesis is that individuals who practice adapted sports may have better control of the trunk and consequently a better performance in the execution of functional activities.

Thus, the objective of the present study was to assess and compare postural control and functionality between paraplegic subjects who regularly practice physical exercise and those who do not.

METHODS

This was a cross-sectional study. For sample calculation we considered the total value of the Functional Independence Measure (FIM), considered to be one of the major outcomes. Mean values and standard deviations were obtained in a pilot study of 5 volunteers per group. This resulted in a total sample size of 20 individuals who were divided into two groups. The GPower 3.1 software was used for this calculation, considering a sample power = 0.92, α=0.05 and effect size = 0.43.

We selected 20 subjects with complete traumatic spinal injury at a neurological level between T1 and T12 according to the classification of the American Spinal Injury Association (ASIA).[8] The participants were divided into two groups: sedentary subjects with spinal injury (SSI, n=10) and physically active subjects with spinal injury (PASI, n=10).

Subjects who engaged in some sport or physical activity of one hour duration at least 3 times a week and for at least 6 consecutive months were considered to be physically active. The sports activities included in the study were basketball, handball and badminton. The physically active participants were recruited at the Laboratory of Biomechanics and Rehabilitation of the Locomotor Apparatus of the University Hospital, UNICAMP, and at the Faculty of Physical Education, UNICAMP.

The sedentary group consisted of subjects who had not practiced any physical activity or adapted sport during the last year.

Exclusion criteria were: presence of neurological diseases associated with spinal injury or involvement of inferior motor neuron, or any other clinical entity causing comorbidities such as cardiac or orthopedic dysfunction, uncontrolled diabetes, distal degenerative disease, cognitive deficits, or psychiatric problems.

The study was approved by the local Ethics Committee (Protocol no. 12515/2013) and all subjects gave written informed consent to participate.

Application of clinical questionnaires

Subjects were first submitted to anthropometric measurements (height and body mass) and provided personal information such as age and duration of the injury for both groups and information about the pracice of physical activity for the physically active group.

Functionality was assessed using the Functional Independence Measure (FIM), which assesses the ability of patients with functional limitations of varied origin.[6,7] The FIM measures task execution performance regarding 18 items divided into the 6 following domains: personal care, sphincter control, mobility and transfers, locomotion, communication, and social cognition. The score for each question may range from 1 to 7.

The total score for the FMI questionnaire ranges from 18 to 126 points, with 18 points meaning full subject dependency (need for total assistance), 19-60 points meaning modified dependency (need for assistance in up to 50% of a task), 61-103 points meaning modified dependency (need for assistance in up to 25% of a task), and 104-126 points meaning modified full independence.[9]

Assessment of Balance

Postural balance was assessed using the anterior and lateral functional reach test.

Functional forward reach test

The participant was instructed to adopt the following position: sitting in his wheelchair, without support for the upper limbs, positioned lateral to the wall without touching it and keeping his shoulder flexed 90° at a distance of 10 cm from the wall. A measuring tape positioned at the height of the acromion was fixed parallel to the floor. The subject was then instructed to bend forward as much as possible without losing balance or shift the position of the wheelchair. (Figure 1)

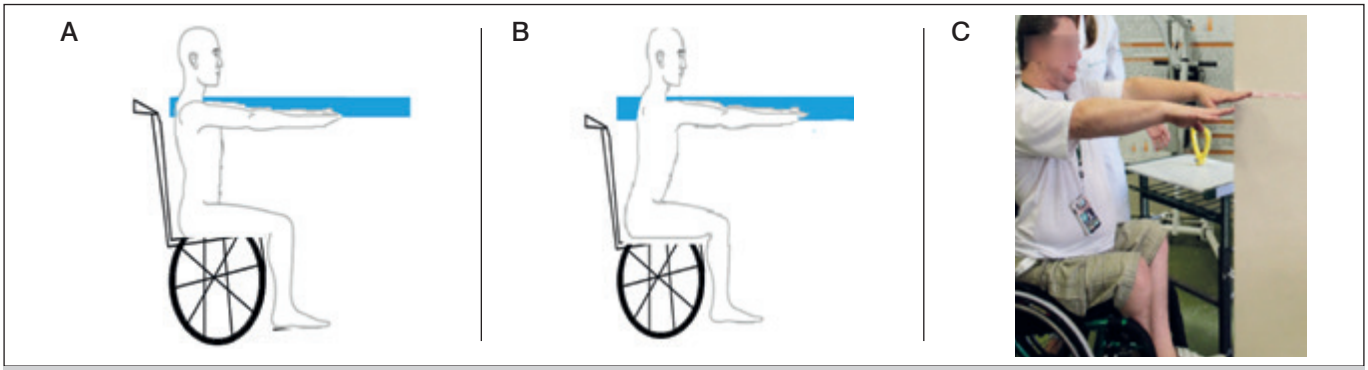

Figure 1. Figure illustrating the maximum forward reach test. A) Initial test position, with the blue band corresponding to the measuring tape; B) final test position; C) Volunteer performing the test.

Lateral reach test

The participant keeps his arms extended by the side of the chair as close as possible to his body so that the distance between his hand and the floor can be measured at rest (measure 1). Next, he is asked to perform lateral bending of the trunk as much as possible and the maximum distance of his hand from the floor is measured (measure 2). Lateral reach was defined as the difference between these two measures (Lateral reach = measure 1- measure 2). (Figure 2)

The types of reach were measured in three attempts and the mean of the three attempts was calculated. The subject was allowed to familiarize himself with the movement before the beginning of the tests.

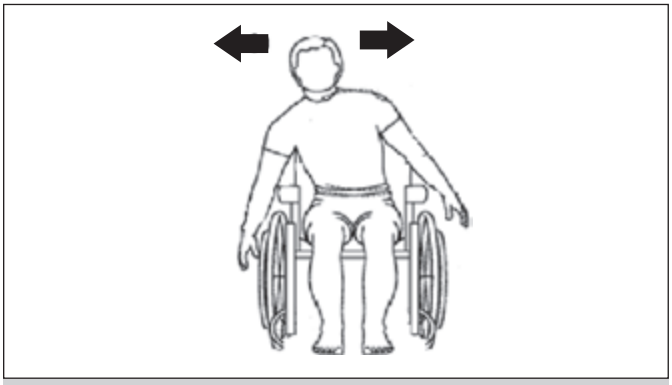

Figure 2. Illustration of the lateral reach test.

Statistical analysis

Descriptive statistics (mean ± SD) were calculated for the anthropometric measurements [height and body mass index (BMI)] and for age and duration of the injury. The Shapiro-Wilk test was used to determine data normality. For data with normal distribution, the Student t-test was used to determine differences between groups regarding anamnesis data, functional reach tests and FIM domains (sphincter control, locomotion, communication, social cognition, and total score). Data with non-normal distribution were analyzed by the Kruskal-Wallis test followed by the Mann-Whitney post-hoc test in order to determine differences between active and sedentary subjects. Data are reported as mean ± SD, with the level of significance set at $p < 0.05$.

RESULTS

Table 1 presents the characterization of the study sample. All participants had complete spinal cord injury (ASIA A).

There was no significant difference between groups regarding the anthropometric measurements performed ($p > 0.05$).

The physical activities practiced by the PASI group were: basketball (30%), handball (60%) and badminton (10%). Mean time of physical activity was 7.5±3.24 hours per week, practiced on average for 4.5 ±4.67 consecutive years.

The results obtained for the self-care, sphincter control, transfer, locomotion, communication and social cognition subscales of the FIM questionnaires are presented in Figure 3.

The score varies for each domain due to the number of questions present. The score ranges from 6 to 42 points for Self-care, from 2 to 14 points for Sphincter control, from 3 to 21 points for Transfer, from 2 to 14 points for Locomotion and for Communication, and from 3 to 21 points for Social cognition.

Figure 4 illustrates the total mean FIM values for the two groups studied.

The mean ± SD values obtained for the functional forward reach test and for the lateral right and left reach tests are illustrated in Figure 5.

Table 1. Sample characterization including anthropometric data and information about the duration and level of injury for the physically active and sedentary groups. Data are reported as mean and standard deviation.

	Age (years)	Weight (kg)	Height (meters)	BMI (kg/m²)	Duration of injury (years)	Level of injury
Physically Active Group	35.2± 6.28	75.37± 14.14	1.76± 0.08	25.14± 4.39	13.2± 6.89	T3A – T9A
Sedentary Group	37.3± 11.09	78.76± 16.82	1.73± 0.09	26.08± 3.62	8.9± 5.46	T3A – T8A

BMI = body mass index.

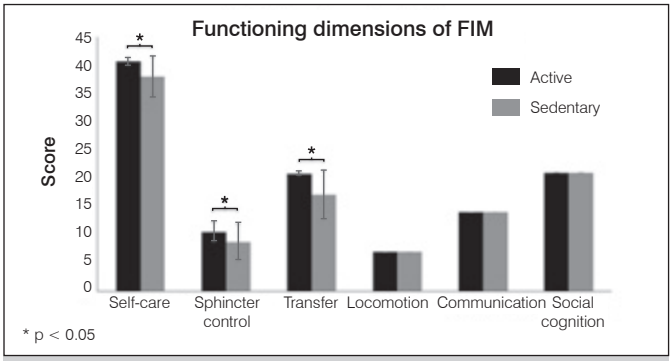

Figure 3. Values reported as mean + SD regarding the subscale of the FIM questionnaire.

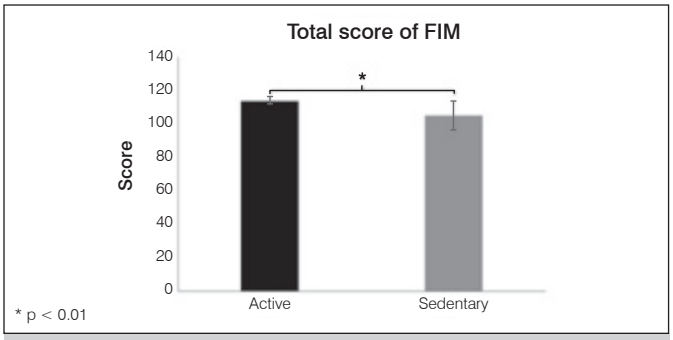

Figure 4. Mean + SD values of the total score for the FIM questionnaire.

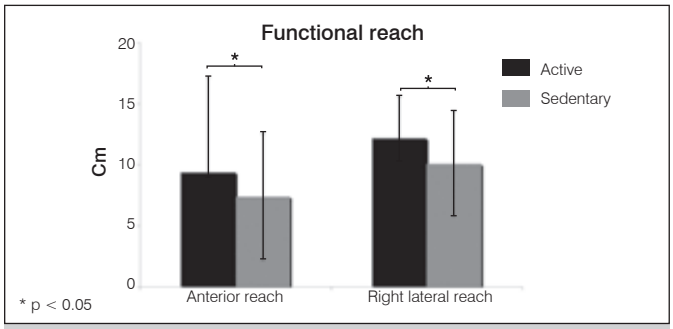

Figure 5. Mean + SD values of forward, right and left lateral reach for the groups of physically active and sedentary groups with spinal injury.

DISCUSSION

The present anamnesis data agree with those reported in several other studies of individuals with spinal cord injury. The age range of the participants at the time of spinal injury was 20-60 years and the mean age was 30-40 years, in agreement with the literature, which points out that the occurrence of spinal cord trauma is highest between 15 and 40 years of age and among men.[10-12] In the present

study we only included males since they corresponded to more than 80% of the volunteers recruited.

The best score for the active group was obtained for the subitems related to self-care, sphincter control and transfer, as well as for the final FIM score. These results suggest that individuals who regularly practice adapted physical exercise such as basketball, handball and badminton are more independent, mainly regarding motor aspects. Our results support those reported by Silva et al.,[6] who observed that physical exercise, swimming in their case, improved patient performance regarding transfers, motor aspects in general and the total score obtained with the FIM questionnaire.[6]

Since all subjects studied here have complete spinal cord injury, they have no motor or sensory control of the perineal region. However, the question of the FIM regarding sphincter control also assesses the number of urinary and fecal losses (daily, monthly or weekly), the use of some instrument for aid, or dependency on a person during bladder or intestinal emptying, among other things.. On this basis, the best result observed for the PASI group was a lower frequency of urinary or fecal losses, with no subject depending on another person's help for these activities. Thus, physically active subjects with spinal injury were found to be more cautious and disciplined at the times scheduled for bladder emptying and all reported a lower loss, a fact that resulted in a better FIM score.

In the present study we did not detect any cognitive change among the subjects with spinal injury evaluated. All showed the same score (7 points) for the locomotion domain (2-24 points) which assesses locomotion on flat or slightly inclined surfaces and stair climbing, since they all reported the same difficulties.

According to Vall et al.,[13] persons with spinal cord injury suffer an important reduction of quality of life mainly regarding social aspects. For this reason, in the present study we applied the complete FIM questionnaire since the impact of physical exercise also on social aspects represents relevant information for this population. However, we did not observe an impact of physical activity on the social life of the subjects.

The sitting functional reach test[14] represents a clinical assessment of postural control that measures the maximum reach distance. It is a reliable test that can be used also for subjects with spinal cord injury.[15,16]

According to a battery of tests applied to persons with spinal cord injury in 2014, forward and lateral reach is part of the daily activities for which these individuals have greatest difficulty, a fact showing the importance of the assessment of these movements.[17]

In the present study the active group showed greater forward and bilateral functional reach than the sedentary group, suggesting that continuous physical exercise promotes better trunk control. According to Santos et al., victims of spinal cord trauma who practice basketball in a wheelchair are able to move their trunk anteroposteriorly and laterolaterally more rapidly than sedentary persons with the same injury.[18]

Patients with spinal cord injury, because of the loss of muscle activation below the level of the injury, use new patterns of muscle activation employing intact muscles in order to adapt and to maintain postural control and stability during routine activities.[19] In a recent study (2016) conducted on paraplegic subjects, trunk electromyography results indicated that sports practice did not affect the bilateral activation of the longissimus, iliocostalis and multifidus muscles compared to sedentary individuals. However, a different pattern of muscle activation was observed iin forward reach tasks in the subjects with spinal injury compared to uninjured persons.[7] In the present study we suggest that physical activity can be of help for the improvement of these new motor patterns among subjects with spinal cord injury, thus contributing to a better postural control and to greater functional independence.

The present study had limitations regarding the use of the FIM questionnaire, since the subjects are assessed by means of self-reports and not by examiner's observation of the type of execution and quality of movement of the task in question. In addition, only some sport modalities (basketball, handball and badminton) were included, while it would be interesting to compare trunk control between various modalities.

CONCLUSION

We conclude that subjects with spinal cord injury who perform physical exercise have greater functional independence regarding motor, self-care and transfer functions, as well as better trunk control as determined by the forward and lateral functional reach tests.

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ASSOCIATED POSTERIOR PELVIC INJURY PATTERNS IN TRANSVERSE-ORIENTED ACETABULAR FRACTURE

PADRÕES DE LESÃO PÉLVICA POSTERIOR ASSOCIADA EM FRATURA ACETABULAR COM ORIENTAÇÃO TRANSVERSAL

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ABSTRACT

Objective: Our study analyzed the incidence of posterior pelvic injury patterns and their influence on the surgical treatment of transverse-oriented acetabular fractures. Methods: Fifty-one transverse-oriented acetabular fracture cases admitted between 1999 and 2013 were evaluated retrospectively. Comparative studies were performed for groups organized by acetabular fracture type, degree of sacroiliac separation, and postoperative reduction quality. Results: Associated posterior pelvic injuries were found in 34 (66.7%) of the 51 patients. There were 32 sacroiliac separations in the 34 patients with associated posterior pelvic injury, and ipsilateral sacroiliac separations were more frequent in this subgroup. Measurements guided by computerized tomography showed that 16 sacroiliac separations were ≤0.5 cm (mean=0.43±0.14 cm), 10 were 0.5–1 cm (mean=0.73±0.17 cm), and the remaining 6 were >1 cm (mean=1.55±0.15 cm). In the group of 34 patients with associated posterior pelvic injury, acetabular reduction was anatomic in 19 (55.9%) patients, imperfect in 10 (29.4%) patients, and poor in 5 (14.7%) patients. For isolated acetabular fractures, reduction rates were as follows: 12 (70.6%) anatomic, 3 (17.6%) imperfect, and 2 (11.8%) poor. The rate of anatomic reduction was significantly higher when sacroiliac separation was ≤0.5 cm (p=0.027). Conclusion: Associated posterior pelvic injuries, especially ipsilateral sacroiliac joint separation, accompany most transverse-oriented acetabular fractures and may influence the quality of acetabular reduction. ***Level of Evidence III, Therapeutic Studies Investigating the Results of Treatment.***

Keywords: Acetabulum. Fractures, bone. Pelvic bones. Fracture fixation, internal.

RESUMO

Objetivo: Nosso estudo analisou a incidência de padrões de lesão pélvica posterior e sua influência no tratamento cirúrgico das fraturas do acetábulo com orientação transversal. Métodos: Cinquenta e um casos de fratura acetabular com orientação transversal foram avaliados retrospectivamente entre 1999 e 2013. Foram realizados estudos comparativos para grupos formados de acordo com o tipo de fratura acetabular, grau de separação sacroilíaca e qualidade da redução no pós-operatório. Resultados: Constataram-se lesões pélvicas posteriores associadas em 34 (66,7%) dos 51 pacientes. Havia 32 separações sacroilíacas nos 34 pacientes com lesão pélvica posterior associada, e as separações sacroilíacas ipsilaterais foram mais frequentes nesse subgrupo. De acordo com medições guiadas por tomografia computadorizada, 16 separações sacroilíacas foram ≤ 0,5 cm (média = 0,43 ± 0,14 cm), 10 estavam entre 0,5 e 1 cm (média = 0,73 ± 0,17 cm) e os 6 restantes foram >1 cm (média = 1,55 ± 0,15 cm). No grupo de 34 pacientes com lesão pélvica posterior, a redução acetabular foi anatômica em 19 (55,9%) pacientes, imperfeita em 10 (29,4%) pacientes e deficiente em5 (14,7%) pacientes. Nas fraturas acetabulares, as taxas de redução foram as seguintes: 12 (70,6%) anatômicas, 3 (17,6%) imperfeitas e 2 (11,8%) deficientes. A taxa de redução anatômica foi significativamente maior quando o grau de separação sacroilíaca foi ≤ 0,5 cm (p = 0,027). Conclusão: As lesões pélvicas posteriores associadas, especialmente a separação da articulação sacroilíaca ipsilateral, acompanham a maioria das fraturas do acetábulo com orientação transversal e podem influenciar a qualidade da redução acetabular. ***Nível de Evidência III, Estudos Terapêuticos – Investigação dos Resultados do Tratamento.***

Descritores: *Acetábulo. Fraturas ósseas. Ossos pélvicos. Fixação interna de fraturas.*

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INTRODUCTION

Judet and Letournel[1] classified transversely oriented fracture lines running in the sagittal direction involving both the anterior and posterior column of the acetabulum as transverse, transverse-posterior wall, and T-type fractures.

Acetabular fractures are often present with other equally severe associated injuries which could modify the strategy and timing of treatment.[2] Combined acetabular-pelvic injury has recently gained renewed interest because of the more severe injuries involved and potential involvement of multiple complicating factors, unlike isolated pelvic or acetabular injuries which are less severe.[3-5]

Transversely oriented acetabular fractures were found to be most common in patients with combined pelvic ring disruption and acetabular fracture.[3] The purpose of this present study was to show that the incidence of associated posterior pelvic injuries in transversely oriented acetabular fractures is higher than reported in the previously literature. We also analyzed the influence of associated posterior pelvic injuries on the surgical treatment of transverse-oriented acetabular fractures.

PATIENTS AND METHODS

This retrospective study included records of all patients admitted to our hospital with transverse-oriented acetabular fractures between January 1, 1999 and December 31, 2013. All patients signed an informed consent form and the study design and procedures were approved by the institutional review board (KOU KAEK 2013/191). We identified 66 patients, but 15 were excluded for the following reasons: 9 were followed with conservative treatment, 2 were in the pediatric age group, and the computed tomography (CT) images of 4 patients did not include sacroiliac (SI) joints. The remaining 51 patients who had been operated on by the senior author were included in the study; of these, 34 were male (66.7%). Patient age ranged from 19 to 63 with a mean of 37.6 years. The most common cause of injury was traffic accidents (39 patients) followed by falls from height (10 patients).

A different orthopedic trauma surgeon reviewed and classified preoperative and postoperative plain radiographs and CT images of 51 patients. Transversely oriented acetabular fractures were classified as simple transverse, transverse-posterior wall (PW), and T-type fractures based on the classification by Letournel and Judet.[1] Disruption of the integrity of the pelvic ring at the posterior as well as acetabulum fracture was defined as associated posterior pelvic injury.[6] The largest sacroiliac joint displacement was measured in centimeters using axial CT images.[6] The sacroiliac joint separations were divided into three groups, ≤0.5 cm, 0.5-1 cm, and >1 cm, according to the measured displacement. Postoperative acetabular reduction was assessed according to Matta's classification.[7,8] A displacement of ≤1 mm was considered as anatomic, 2–3 mm as imperfect, and >3 mm as poor.

Comparative studies were performed for groups, which were formed according to acetabular fracture type, degree of SI separation, and postoperative reduction quality.

Statistical analysis

Statistical analysis of the data obtained from 51 patients was performed using the chi-square and Fisher's exact tests. A p value of less than 0.05 was considered statistically significant (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp., USA).

RESULTS

Fourteen (27.5%) out of 51 transversely oriented acetabular fractures were simple transverse, 20 (39.2%) were transverse-posterior wall, and 17 (33.3%) were T-type acetabular fractures. (Table 1) Associated posterior pelvic lesions were present in 34 (66.7%) of the 51 patients; of these, 18 (52.9%) were ipsilateral, 11 (32.4%) were contralateral, 3 (8.8%) were bilateral sacroiliac separations, and 2 were sacrum fractures. (Figure 1a-d) Ipsilateral SI separation was higher in pelvic injuries seen in patients with transversely oriented acetabular fractures, but this difference was not statistically significant (p = 0.14).

Of 14 patients with simple transverse fractures, 12 (85.7%) had associated posterior pelvic injury. 12 (60%) of 20 patients with transverse-PW and 10 (58.8%) of 17 patients with T-type fractures also had associated posterior pelvic injuries. (Table 1) Comparatively, simple transverse patients had more associated pelvic injuries (mainly ipsilateral SI separation) compared to transverse-PW and T-type patients, but this difference was not statistically significant (p = 0.209).

Overall, 32 SI separations were seen in the 34 patients with associated posterior pelvic injury. Of these, 16 SI separations were ≤0.5 cm (mean=0.43±0.14 cm), 10 were 0.5–1 cm (mean=0.73±0.17 cm), and the remaining 6 were >1 cm (mean=1.55±0.15 cm). (Table 2) The mean displacements were 0.66±0.40 cm and 0.94±0.51 cm in the 18 ipsilateral and 11 contralateral SI separations, respectively. None of the patients with <0.5 cm SI separation had internal fixation for SI separation. Of the 16 patients with >0.5 cm separation, only 9 were treated using internal fixation for SI separation. Of these 9 patients, 3 had 0.5–1 cm separation while 6 had >1 cm SI separation. (Table 3) In the remaining 23 patients out of the 32 patients with SI separation, this separation was missed preoperatively.

Acetabular reduction was anatomic in 19 (55.9%) patients, imperfect in 10 (29.4%) patients, and poor in 5 (14.7%) patients among the 34 patients with associated posterior pelvic injury. The reduction rates in isolated acetabular fractures revealed 12 (70.6%) anatomic, 3 (17.6%) imperfect, and 2 (11.8%) poor reductions. (Figure 2) Nevertheless, no statistically significant difference was found (p=0.416).

Table 1. Pelvic injuries associated with transverse-oriented acetabular fractures.

	Simple transverse (n:14)	Transverse-posterior wall (n:20)	T-Type (n: 17)
Associated pelvic injury (n:34)	12	12	10
Ipsilateral SI Sep. (n:18)	6	7	5
Contralateral SI Sep. (n:11)	4	4	3
Bilateral SI Sep. (n:3)	2	1	0
Sacrum fr. (n:2)	0	0	2

SI Sep: sacroiliac joint separation; fr: fracture.

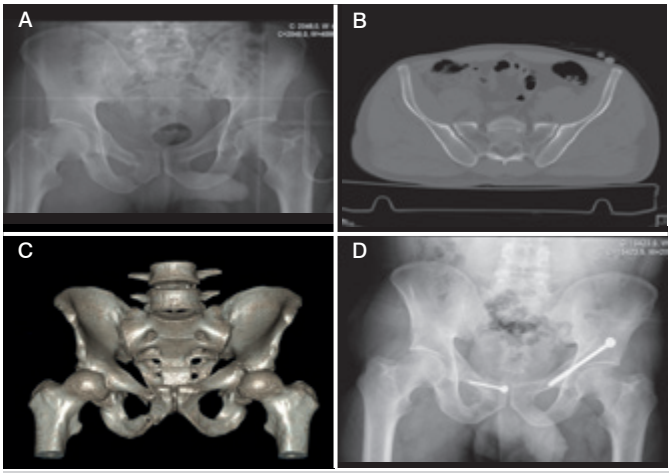

Figure 1. Patient with both transverse acetabular fracture and contralateral sacroiliac joint separation. (A) Preoperative X-ray (B) Preoperative CT scan (C) Preoperative CT scan (3D) (D) Postoperative X-ray.

The difference between ipsilateral or contralateral SI separation according to fracture reduction rate was insignificant (p=0.934). Additionally, fracture reduction rates did not differ in patients who were treated or not treated with internal fixation for SI separation (p=0.49) There were no cases of poor reduction among the patients with SI separations ≤0.5 cm. Four (40%) patients with SI separation 0.5–1 cm and 1 (16.7%) patient with SI separation >1 cm had poor reduction. (Table 4) The anatomic reduction rate was significantly higher when the degree of SI separation was ≤0.5 cm (p=0.027).

Table 2. Degree of sacroiliac separation.

	Simple transverse (n:14)	Transverse-posterior wall (n:20)	T-Type (n: 17)
SI sep. ≤0.5 cm (n:16)	6	5	5
SI sep. 0.5-1 cm (n:10)	4	4	2
SI sep. >1 cm (n:6)	2	3	1
SI sep. Total (n:32)	12	12	8

SI Sep: sacroiliac joint separation.

Table 3. Sacroiliac separation treatment modality.

	SI fixate	SI not fixate
SI sep. ≤0.5 cm (n:16)	0	16
SI sep. 0.5-1 cm (n:10)	3	7
SI sep. >1 cm (n:6)	6	0
SI sep. Total (n:32)	9	23

SI Sep: sacroiliac joint separation.

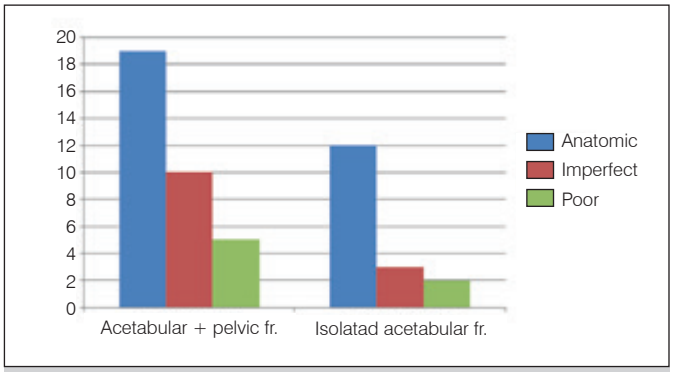

Figure 2. Acetabular reduction rates.

Table 4. Acetabular reduction rates by group.

	Anatomic (n/%)	Imperfect (n/%)	Poor (n/%)
Degree of SI sep.			
≤0.5 cm (n=16)	11(68.7)	5(31.3)	0(0)
0.5-1 cm (n=10)	5(50)	1(10)	4(40)
>1 cm (n=6)	2(33.3)	3(50)	1(16.7)

SI Sep: sacroiliac joint separation.

DISCUSSION

Young and Burgess[9,10] reflected anecdotally that most combined pelvic and acetabular fractures result from a lateral compression mechanism of injury. Transverse fractures are assumed to result from lateral compression force transmitted via the trochanter or proximal femur or axially along the femur if the hip is in a flexed position at the time of impact.[11] With the more recent use of superior image resolution and decreased slide thickness, previously unrecognized instability patterns for various pelvic injuries have been analyzed.[12] It became evident that lateral compression does not completely describe the wide range of injury patterns.[13] In two recent studies, Osgood and Suzuki analyzed the injury mechanism in combined pelvic-acetabular injury.[3,4] Osgood analyzed 40 cases and identified anteroposterior compression (APC) or lateral compression (LC) injury mechanisms.[4] According to Suzuki et al.,[3] 62 posterior pelvic lesions were associated with transverse-type acetabular fractures, and the majority had ipsilateral SI disruption. Unlike previous studies, both of these studies suggested that APC is just as common as LC as the mechanism of injury. Our study supports recent studies indicating complex translational and rotational displacements in patients with combined transverse-oriented fracture and posterior pelvic injury.[3,4]

Letournel and Judet[1] reported a 16.1% incidence of associated pelvic-acetabular injury. Though it was not addressed specifically in the studies by Osgood et al.[4] and Porter et al.,[5] their studies indicated the incidence of pelvic injury in transverse-oriented acetabular fractures as 59% and 20.8%, respectively. Our study reveals a higher incidence (66.7%) of posterior pelvic injury in transverse-oriented acetabular fractures. Twelve of 14 (85.7%) simple transverse fracture patients in our study had pelvic injury, which is a higher percentage than that reported by Osgood and Porter. Twelve out of 14 patients with simple transverse fractures in our study had posterior pelvic disruption, mostly in the form of ipsilateral SI disruption, in accordance with Suzuki's findings.

Previous studies have reported that combined posterior pelvic injuries affect acetabular reduction.[3,4] Excellent outcomes were achieved in cases with associated SI separation of <0.5 cm, and satisfactory-anatomic reduction was readily obtained. Residual displacement of <1 cm in a posterior pelvic lesion has been reported as acceptable, although no previous studies have analyzed the acceptability criteria for posterior pelvic displacement in combined pelvic injury-acetabulum fracture.[14,15] We found that combined transverse-oriented acetabulum fracture with residual SI separation of >0.5 cm is likely to result in unsatisfactory reduction of the acetabular fracture.

Previous research has suggested that reduction can generally be obtained in transverse acetabular fractures by mobilizing the inferior ischiopubic segment.[16] The literature underestimates the value of mobilizing the superior iliac segment in reducing transverse fracture. We believe it may be essential in transverse acetabular fractures with ipsilateral SI separation to internally rotate the fractured iliac segment while reducing both the SI separation and transverse acetabular fracture.

While the greater energy associated with these injuries, patient condition, and surgical timing may also influence outcome, our study supports the decrease in reduction quality with greater SI separation. All patients with transverse-oriented fractures should be thoroughly evaluated to rule out accompanying posterior injuries that may possibly influence outcomes.

The value of this study may be limited by its retrospective design, the lack of a control group, and the relatively small number of patients. We also did not investigate other important factors that may influence the quality of fracture reduction, such as bone quality and preoperative fracture displacement. It may be difficult to blame a single mechanism of injury in the case of combined acetabulum fracture-posterior pelvic injury. For posterior SI separations, the most common associated injury pattern, more than 0.5 cm may be critical, since this could affect acetabular reduction. A much larger sample with greater power may be needed to ascertain the true differences in the incidence of injury mechanisms as well as other factors influencing acetabular reduction in this heterogeneous group.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. OS (0000-0003-0149-2492)* and AYS were the main contributors in drafting the manuscript. TB (0000-0002-7052-4171)*, UG (0000-0003-2659-7952)*, and HC (In memoriam) performed surgery, followed patients, and gathered clinical data. OS and TB evaluated the data for the statistical analysis. OS, UG, HC, and AYS (0000-0003-2659-7952)* performed the literature search, reviewed the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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EPIDEMIOLOGY OF FEMUR FRACTURES IN THE ELDERLY AND COST TO THE STATE OF PARANÁ, BRAZIL

EPIDEMIOLOGIA DAS FRATURAS DE FÊMUR EM IDOSOS E SEU CUSTO PARA O ESTADO DO PARANÁ, BRASIL

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ABSTRACT

Objectives: To evaluate the incidence and economic impact of femur fractures in the state of Paraná, Brazil. Methods: This descriptive study included men and women ≥ 60 years of age with hip fractures which were treated by the Public Health System in emergency care from January 2010 to December 2014. Data were collected from the DATASUS public health database using filters to select patients; results were presented descriptively and as proportions. The standardized incidence of femur fracture was calculated by sex and age for 10,000 inhabitants in Paraná state and in Brazil for the year 2012. Results: During the study period, 11,226 fractures were registered, 66.8% in women and 33.2% in men. There was a preponderance of fractures in Caucasians and in older age groups. Mortality during hospitalization was 5.9%, higher in males, in patients aged ≥80 years, and in Blacks and Asians. The total cost was R$ 29,393,442.78 and the average cost per hospitalization was R$ 2,618.34. The eastern region of the state had the highest rate of fractures, predominantly in the capital, Curitiba. The standardized incidence rate was higher in females and in the population of Paraná. Conclusion: Femur fractures have a high incidence rate in the elderly population of Paraná and a large economic impact. ***Level of Evidence II, Prognostic Studies Investigating the effect of a Patient Characterisctic on the Outcome of Disease.***

Keywords: Incidence. Fractures, bone. Femur. Aged. Costs and cost analysis.

RESUMO

Objetivo: Avaliar a incidência e o impacto econômico das fraturas de fêmur no Estado do Paraná, Brasil. Métodos: Este estudo descritivo incluiu homens e mulheres ≥ 60 anos de idade com fraturas de quadril, tratados no serviço de emergência do Sistema Único de Saúde, de janeiro de 2010 a dezembro de 2014. Os dados foram coletados na base de dados DATASUS, usando-se filtros para selecionar os pacientes; os resultados foram apresentados de forma descritiva e proporcional. A incidência padronizada de fratura femoral foi calculada por sexo e faixa etária em 10 mil habitantes do Estado do Paraná e no Brasil, referente ao ano de 2012. Resultados: Durante o período de estudo, foram registradas 11.226 fraturas, 66,8% em mulheres e 33,2% em homens. Houve predomínio de fraturas em brancos e mais idosos. A taxa de mortalidade durante a internação foi 5,9%, maior nos homens, na faixa etária de 80 anos ou mais, negros e asiáticos. O custo total foi R$29.393.442,78 e o custo médio por internação foi R$2.618,34. A taxa mais alta de fraturas ocorreu na região leste do estado, predominantemente na Capital, Curitiba. A taxa de incidência padronizada foi superior nas mulheres e na população paranaense. Conclusão: As fraturas de fêmur têm alta incidência em idosos no Estado do Paraná, com alto impacto econômico. ***Nível de Evidência II, Estudos Prognósticos – Investigação do Efeito de uma Característica de um Paciente sobre o Desfecho da Doença.***

Descritores: *Incidência. Fraturas ósseas. Fêmur. Idoso. Custos e análise de custo.*

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INTRODUCTION

Population aging is a trend of emerging and developed countries, increasing chronic-degenerative diseases. It is estimated that the percentage of the Brazilian population aged 60 years or more will increase from 11.71% in 2015 to 33.71% in 2060.[1] In this context, osteoporosis represents a public health problem, since it increases the risk of femur fracture in the elderly, a condition with high morbidity and mortality and high costs. Osteoporotic fractures are usually related to falls and have known risk factors such as advanced age, female gender, early menopause, sedentary lifestyle, among others.[2] The incidence of fracture increases with age and maintains a higher proportion in females.[3]

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Study conducted at Universidade Federal do Paraná, Curitiba, PR, Brazil.
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The fracture treatment is surgical in most cases and the longer the patient remains bedbound, the greater the chances of having complications such as infection, deep venous thrombosis, and pulmonary embolism.[4,5]

The mean mortality rates, estimated by a recent review, were 5.5% during hospitalization and ranged from 4.7% in the first month, 10.8% in the 6th month to 24.9% in the second year. Advanced age, number of comorbidities, male gender, and presence of cognitive deficits were identified as the main factors related to higher mortality.[6]

In addition to high mortality, femoral fracture also presents a high morbidity rate and functional impairment, causing a psychosocial impact with the degree of post-fracture dependence, reaching 30%.[7,8]

Total expenditures on hospitalization for femoral fractures in the elderly in Brazil were around 40 million R$ per year in the three-year period of 2006-2008, representing about 2% of all causes of hospitalization among the elderly.[9]

Driven by the absence of data on osteoporotic femoral fractures in the State of Paraná and the need to know the magnitude of the problem and its costs to the public health care system (SUS), the present study aims to assess the incidence and economic impact that this morbidity represented for the state in the period from January 2010 to December 2014.

METHODS

A descriptive study on femoral fractures was carried out in elderly people living in the state of Paraná from January 2010 to December 2014. Elderly is considered to be 60 years of age or older.

The study was approved by the Ethics Committee of the Hospital de Clínicas da Universidade Federal do Paraná, number 19749613.3.0000.0096. Data were collected from the Department of Information Technology of SUS (DATASUS; http://www.datasus.gov.br) on April 25, 2015, accessing the links in the following sequence: health information (TABNET) - epidemiological and general morbidity by place of residence as of 2008 - State of Paraná (on the map). The selection of the outcome of interest was performed based on the main diagnosis "Femur fracture" ICD-10: 72.0 to 72.9. The following filters were then selected: January 2010 to December 2014, ICD 10 morbidity list - femur fracture, emergency care character, age group of 60 years or more, sex, color / race, number of hospitalizations, mean length of stay (days), total and average hospitalization cost, number of deaths, mortality rate, chapter ICD-10 all categories (filter used to compare costs with other comorbidities). These filters correspond to the studied variables.

Inclusion criteria were as follows: men and women of any ethnic group, age 60 years or older, with femoral fracture, urgent care admission, attendance by the SUS, from January 2010 to December 2014, and data present on the basis of DATASUS.

Exclusion criteria did not apply to the present study.

The data were presented in a descriptive and proportional way when pertinent. The incidence rates of femur fracture per 10,000 people, standardized by sex and age group in the state of Paraná and in Brazil for the year 2012, were calculated.

RESULTS

From January 2010 to December 2014, 11,226 elderly people ≥ 60 years old, living in the state of Paraná, were hospitalized for a femoral fracture in SUS hospitals. There was a predominance of females with 7,497 cases (66.8%), while 3,729 (33.2%) cases were males.

The data corresponding to ethnicity are shown in Table 1. Despite the absence of information in 27.5% of the cases, there was a predominance of fractures in Caucasians (64.6%). The number of fractures increased progressively with aging. (Table 2)

Out of the 11,226 elderly patients hospitalized for a femoral fracture, 660 died, corresponding to a mortality rate of 5.9%. Although the higher incidence of fractures occurred in females, the mortality rate was greater in males, 80 or more years old, black and Asian. There was no major difference throughout the years studied. (Table 3)

The total cost of fractures in the period from 2010 to 2014 was R$ 29,393,442.78, and the mean cost for hospitalization was R$ 2618.34, similar between sexes and higher in patients aged 80 years or over (R$ 2831.73). The mean cost per hospitalization to treat a femoral fracture was higher than that calculated for neoplasms, infectious diseases, circulatory system diseases, among others, in the assessed period. (Table 4)

Table 1. Number of femoral fractures according to ethnicity.

Ethnicity	Number of fractures	%
Caucasian	7253	64,61
Mutato	683	6,08
Black	145	1,29
Asiana	55	0,49
Indigenous	1	0,008
Not available	3089	27,52
Total	11226	100

Source: Datasus; (http://www.datasus.gov.br) April 25, 2015.

Table 2. Number of fractures according to age group.

Age	Number of fracturess	%
60 - 69 years	2248	20,02
70 - 79 anos	3920	34,92
≥ 80 years	5058	45,06
Total (≥ 60 years)	11226	100

Source: Datasus; (http://www.datasus.gov.br) April 25, 2015.

Table 3. Deaths and mortality by sex, ethnicity and studied period.

		Number of fractures	Number of deaths	Mortality rate (%)
	Total	11226	660	5,88
Gender	Female	7497	433	5,78
	Male	3729	227	6,09
Age	60 a 69 anos	2248	57	2,54
	70 a 79 anos	3920	162	4,13
	≥ 80 anos	5058	441	8,72
Year	2010	1971	113	5,73
	2011	2114	123	5,82
	2012	2189	126	5,76
	2013	2401	147	6,12
	2014	2551	151	5,92
Ethnicity	Caucasian	7253	427	5,89
	Mulato	683	34	4,98
	Black	145	11	7,59
	Asian	55	4	7,27
	Indigenous	1	0	0
	Not Available	3089	184	5,96

Source: Datasus; (http://www.datasus.gov.br) April 25, 2015.

The average hospitalization period was 6.9 days. No difference was found between sexes, ethnic groups, or years studied. The group of 80 years or older had a longer average stay (7.2 days).
Considering the great regions of the state, the eastern region had the highest number of cases (4,982); in Curitiba and the metropolitan area there were 2,969 hospitalizations, of which 70.1% occurred in the state capital, followed by the city of São José dos Pinhais with 7.9% of the total. In Curitiba, one hospital named Hospital do Trabalhador treated most of the cases (1019).
The incidence rate of femoral fracture per 10,000 inhabitants standardized by gender and age (≥ 60 years) was higher in females compared to males in the state of Paraná (25.14 / 10 thousand, females and 13.12 / 10 thousand, males, respectively) and in the whole country (22.58 / 10 thousand and 13.52 / 10 thousand respectively). The fracture rate in the female population of Paraná (25.14 / 10 thousand) was higher than the national female rate (22.58 / 10 thousand). Considering both sexes, the total standardized rate of fractures in Paraná (19.80 / 10 thousand) exceeded the national rate (18.55 / 10 thousand). (Table 5)
When the population was divided by age (60-69, 70-79, ≥ 80 years), there was a progressive increase in the incidence of fractures with increasing age in all groups (male, female, and total population, in Paraná and Brazil), with a predominance in females and in the population of Paraná. (Table 5)

Table 4. Average hospital cost accoring to International Classification Disease (ICD)-10 code.

CID-10 Code	Average hospitalization cost
Infectious diseases	R$ 1.063,50
Neoplasia (tumors)	R$ 1.582,12
Mental and behavioral disorders	R$ 1.530,93
Nervous System Disease	R$ 1.310,22
Circulatory Disease	R$ 2.485,57
Respiratory Disease	R$ 897,43
Femur Fracture	R$ 2.618,34

Source: Datasus; (http://www.Datasus.Gov.Br) april 25, 2015.

Table 5. Standardized incidence ratio of femoral fractures per 10,000 inhabitants by sex and age.

Rate		60-69 years	70-79 years	≥ 80 years	Total ≥ 60 years
Paraná	Female	6.68	26.31	85.27	25.14
	Male	5.5	15.5	42.78	13.12
	Total	6.13	21.58	68.88	19.8
Brazil	Female	6.65	23.88	73.82	22.58
	Male	7.13	14.63	40.57	13.52
	Total	6.87	19.84	61.01	18.55

DISCUSSION

The present study is pioneer in compiling recent data that allow the evaluation of the behavior of femoral fractures in the elderly in the State of Paraná.
The study presented results consistent with the literature regarding the higher incidence of fractures in females and in the higher age groups.[3,10,11] The male / female ratio observed of 1: 2.01 was similar to that in Sobral, Ceara (1:1.7), and lower than that in Recife, Pernambuco (1:3.02). Women are more likely to develop osteoporosis and, consequently, fractures as observed in the BRAZOS study.[2] Caucasian was the prevalent ethnicity, which was not demonstrated in the national BRAZOS study.[2] We should consider that the population of Paraná is mostly Caucasian, which can cause a bias in the results, the same being observed in Pelotas, Rio Grande do Sul.[12]
Femoral fracture is a condition of high mortality during hospitalization and months and years following the fracture. In this study, the mortality rate was 5.88% during the hospital stay, similar to that observed in a review of 25 studies,[6] which showed an average rate of mortality in the post-fracture period of 11.9%, 19.2%, and 24.9% at 3 months, one year, and two years, respectively.
Although the number of fractures was higher in females, mortality rates were greater in males (6.1%), blacks (6.6%), Asians (7.3%), and people 80 years of age or older(8.7%), consistent with national and international literature.[13-17]
The literature also shows a high morbidity related to femoral fractures, with some degree of physical limitation around 4 months after a fracture.[18] In a prospective study of 68 patients, only 32.56% reacquired the walking capacity and 27.9% of the previously independent patients needed special care.[7]
As a condition of high prevalence among the elderly, whose treatment is essentially surgery[5] and a long hospital stay, femoral fracture entails high costs. In the triennium 2006-2008, femur fracture accounted for 2% of the expenditures of all hospitalizations in the elderly over 60 years in Brazil, and cost approximately R$ 120 million.[9] In the 5 years studied (2010 to 2014), the hospitalization for femoral fracture in the elderly cost the State of Paraná around R$ 29 million, with an average cost for hospitalization of R$ 2,618.34. This cost for hospitalization was higher than that calculated for neoplasms, infectious diseases, including the diseases of the circulatory system, among others.
The mean hospital stay found in this study (6.9 days) is consistent with the national literature. Studies carried out in the cities of Sobral[19] and Brasília[20] showed an average stay of 7.2 and 7.1 days, respectively. An interesting issue pointed out by Bortolon et al.[9] was that the early discharge from the hospital was associated with the lack of guidance regarding the diagnosis of osteoporosis and the need for physical therapy. The BRAZOS study showed that 70% of women and 85% of men with previous history of low-impact fracture were unaware of the diagnosis of osteoporosis.[2]
The most populous eastern region concentrated the majority of the hospitalizations, with the capital, Curitiba, having most of the cases, probably due to better structure and the presence of the Workers' Hospital, which is a reference center for trauma.
The total standardized incidence rate (≥ 60 years) was higher in females and increased progressively with increasing age similar to that in other epidemiological studies.[3,11] The female and total rates in Paraná were superior to the national one, in agreement with the findings of Silveira et al.,[11] who believed that the incidence of femur fracture in the elderly is higher in the southern region due to colder temperatures and lower incidence of sunlight, which favors osteoporosis. Taking this into account, we expected that the rate of fractures in Paraná (24°00'S, 51°00W) would be similar to that calculated for the same age group (≥ 60 years) in the city of Marília, São Paulo (50.03 / 10 thousand female inhabitants and 18.73 / 10 thousand male inhabitants) and to exceed Fortaleza's rates (27.5 / 10 thousand female inhabitants and 13/10 thousand male inhabitants); however, we obtained a rate similar to that of Fortaleza (03° 43' S, 38° 32' W)and well below that of Marília (22° 12'S, 49° 56' W).[10,11]
The fact that we did not capture patients covered by private care insurance could have interfered in the rate of our study. Also, this study was realized many years after Marília's study (1995), when the ratio of osteoporosis treatment was lower, which may have impacted the fracture rate.
The main limitation of this study was the impossibility of confirming the osteoporotic character of the fractures, since in the DATASUS database there is only a general diagnosis of "femur fracture." However, considering that the higher incidence of fractures and osteoporosis occurs in the more advanced age, we inferred that osteoporosis was the main cause of fractures in the population studied.

CONCLUSION

From these results, we can conclude that femoral fractures in the State of Paraná represent a public health problem due to their high incidence and economic impact. The incidence is higher in females, Caucasian, and older age groups. The male sex, blacks, Asians, and oldest groups presented the highest mortality rates. Considering osteoporosis as the primary cause of fractures in the elderly, the creation of public policies aimed to prevent and treat this disease should be encouraged in the State of Paraná.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. CCO (0000-0002-4863-9394)* and VZCB (0000-0003-0555-0880)* drafted the manuscript and were responsible for collecting and analyzing the data, bibliographical research, review of the manuscript, and the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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INTRA- AND INTER-OBSERVER AGREEMENT IN THE AO AND GARNAVOS SYSTEMS FOR DIAPHYSEAL HUMERUS FRACTURE

CONCORDÂNCIA INTRA E INTEROBSERVADOR DOS SISTEMAS AO E GARNAVOS NA FRATURA DA DIÁFISE DO ÚMERO

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ABSTRACT

Objective: The objective of this study was to compare inter- and intra-observer agreement using the Garnavos and AO/ASIF systems for classifying humeral diaphysis fractures. Methods: Eighty X-ray images taken of humeral diaphysis fractures in adult patients (age≥18 years) between January 2013 and September 2015 in the Radiology Department of Hospital São Paulo were selected for subsequent classification by five orthopedic surgeons with differing levels of experience. The images were examined at two different times and reproducibility analysis was evaluated using Fleiss' kappa to verify intra- and inter-observer agreement. Results: High-level agreement was observed for both classification systems, but particularly for the AO/ASIF classification. Inter-observer evaluation yielded excellent levels of agreement for both classifications, but principally for the Garnavos classification. Conclusions: Good or excellent inter- and intra-observer agreement was seen for both the AO/ASIF and Garnavos classification systems. However, intra-observer agreement was higher for the AO/ASIF system and inter-observer agreement was higher for the Garnavos classification. ***Level of Evidence II, Diagnostic Studies – Investigating a Diagnostic Examination.***

Keywords: Humeral fractures/classification. Adult. Orthopedics.

RESUMO

Objetivo: Averiguar a superioridade da concordância inter e intraobservadores do sistema de classificação Garnavos com relação ao sistema AO/ASIF para as fraturas diafisárias do úmero. Métodos: Foram selecionadas 80 radiografias com fraturas da diáfise do úmero de pacientes adultos (idade ≥ 18 anos) no período de janeiro/2013 a setembro/2015, no Departamento de Radiologia do Hospital São Paulo. Essas radiografias foram classificadas por cinco ortopedistas com diferentes níveis de experiência. Foram examinadas em dois momentos distintos e a análise da reprodutibilidade foi avaliada pelo índice Kappa de Fleiss para verificar a concordância intra e interobservadores. Resultados: Foram obtidas concordâncias intraobservadores de alto nível, tanto para a classificação AO/ASIF quanto para a Garnavos, especialmente para a classificação AO/ASIF. A avaliação interobservadores apresentou níveis de concordância excelentes para ambas as classificações, principalmente para a classificação Garnavos. Conclusões: Observamos concordância intra e interobservadores boa ou excelente tanto para o sistema de classificação AO/ASIF e quanto para o sistema de Garnavos. No entanto, houve maior concordância intraobservador na classificação AO/ASIF e concordância elevada interobservador na classificação de Garnavos. ***Nível de Evidencia II, Estudos Diagnósticos - Investigação de um Exame para Diagnóstico.***

Descritores: *Fraturas do úmero/classificação. Adulto. Ortopedia.*

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INTRODUCTION

Fractures of the humeral diaphysis account for approximately 3% of fractures in adults[1-7] and 20% of humerus fractures.[7] Recent studies have estimated that these fractures are increasing in number, and incidence is expected to double by 2030.[6] Non-surgical treatment is still the gold standard for this type of fracture.[1,5]

Fracture classification is essential to determine epidemiology, guarantee communication between orthopedists, and to define treatment algorithms.[8] Multiple classification systems have been developed based on the location and morphology of injuries to categorize each type of long bone injuries; these must be clinically relevant, simple, reliable, reproducible and valid,[9,10] and ideally should also establish the method of treatment, complications and outcome.[10]

Fractures of the humeral diaphysis are predominantly classified according to the AO/ASIF system.[10-12] This classification has low inter- and intra-observer agreement and low reliability.[13-18]

A new classification proposed by Garnavos et al.[10] was proved to have greater inter- and intra-observer agreement, be easier to remember, and to yield more rapid classification in comparison with the AO/ASIF classification. Furthermore, this new classification

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

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has a predictive value for selecting treatment method, complication rate, and the functional outcome of the injury.[10]
This effectiveness of this new classification system led us to conduct this study to test the inter- and intra-observer agreement of the AO/ASIF classification and the Garnavos system.

MATERIALS AND METHODS

This research project was submitted to and approved by the institutional review boards of Plataforma Brasil, Hospital São Paulo, and UNIFESP (CAAE no.: 58279916.0.0000.5505) and the institution waived the need for an informed consent form for this type of study.
Radiographs were selected consecutively from January 2013 to September 2015 from the Department of Diagnostic Imaging at Hospital São Paulo, SP (quaternary care). We included X-rays from adults aged >18 years who presented humeral diaphyseal fractures. The images were selected by two orthopedic surgeons who did not participate in the fracture classification process to include X-rays with two orthogonal planes and good image quality.
The radiographs were classified by five examiners with different levels of experience. Two examiners were considered expert level (≥4 years of experience as an orthopedist specialized in the shoulder and elbow), one examiner was considered advanced (≥1year experience as an orthopedist specialized in the shoulder and elbow), and two were considered basic level (second- and third-year resident orthopedists).
The examiners received an explanation of the classification systems prior to classification in order to minimize bias from difficulties in interpreting and inexperience with the new classification. Moreover, during the classification process the examiners had access to the brochure fully describing the AO and Garnavos classifications for humerus shaft fractures.
The classifications were done by the five examiners on two different occasions with an interval of 15 days between the first and second assessments. During the first session, the X-rays were arranged in chronological order, and during the second session, the X-rays were randomized. In both cases, closed digital files were organized. Each of the examiners independently evaluated the radiographs. They were given all the time they need for assessment, and were instructed to not discuss the classification systems until the end of the classification stage. They also did not have access to the patient's history or any clinical information.
No correct response was established, but rather we looked for intra- and inter-observer agreement.

Statistical analysis

The statistical analysis was performed by a specialist in medical statistics. Fleiss' kappa was used to evaluate the intra- and inter-observer agreement for each classification. Use of Fleiss' kappa coefficient is considered most appropriate when faced with a situation where multiple examiners or assessments are involved and when the scale under evaluation presents many categories.[19]
The test was interpreted according to Altman[20] as "proportional agreement with correction of chance". Kappa is the coefficient of agreement that has a value ranging from +1 (representing perfect agreement) through 0 (representing agreement the same as chance) up to -1 (representing complete disagreement). There are no definitions for accepted levels of agreement, but some studies suggest that results between 0 and 0.2 show minimal agreement, 0.21–0.40 is poor agreement, 0.41–0.60 is moderate agreement, and 0.61–0.80 is good agreement. A value exceeding 0.80 is considered optimal agreement.[4,7,8,11]
Humeral diaphyseal fractures can be divided, according to the Arbeitsgemeinschaft für Osteosynthesefragen classification (AO), into long bone fracture in bone 1 (humerus) and segment 2 (shaft). Depending on the type of fracture, it can be classified as A (simple), B (wedge), and C (complex). Group A can be further divided into types A1 (spiral), A2 (oblique) and A3 (transverse), respectively. Spiral, flexion, and comminuted wedge fractures are classified as B1, B2, and B3, respectively, and C1 comprises complex spiral fractures, C2 complex segmental fractures, and C3 complex comminuted fractures.[21]
In the Garnavos classification for long bones, the humerus shaft is the bone segment between two parallel lines perpendicular to the long axis of the humerus, which pass through the surgical neck, and the line that passes 1 cm above the apex of the olecranon fossa. First, the fracture is classified according to its location. To do so, the segment is divided into three equal parts which are labeled P (proximal segment), M (middle segment), and D (distal segment); if the fracture line affects more than one segment, it receives more than one letter, so for example a fracture affecting the proximal and medial segments is labeled PM. A fracture can also be labeled J if it extends to the joint. Next, the fractures were classified according to their morphology into three patterns: simple fractures were divided into transverse or oblique (labeled as T) or spiral (S), intermediate fractures (with 1 or 2 significant fragments) were labeled I, and complex fractures (≥3 fragments or large comminution) were labeled C. If a fracture was segmented, each of the fractures was classified independently, with the most proximal segment classified first.[10]

RESULTS

The five examiners evaluated the radiographs separately. Examiners 1 and 3 were basic level, examiner 2 was advanced level, and examiners 4 and 5 were expert level.
A high degree of intra-observer agreement was seen. Optimal agreement was seen between four examiners (kappa >0.8) for the AO classification, and one examiner showed good agreement (0.6<kappa≤0.8). For the Garnavos classification intra-observer agreement was also high, but two examiners showed optimal agreement and three showed good agreement. (Table 1 and Figure 1)
A high degree of inter-observer agreement was also evident; for both AO classification as well as the Garnavos system agreement was optimal. We also observed that agreement increased between the first and second evaluations. The greatest inter-observer agreement was seen for the Garnavos classification. (Table 2 and Figure 2)

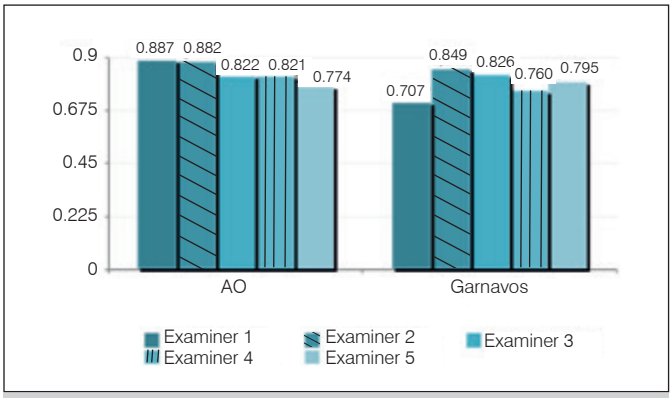

Figure 1. Intra-observer agreement for AO classification and Garnavos system..

Table 1. Intra-observer agreement for AO classification and Garnavos system.

	AO		Garnavos	
	Kappa	P-value	Kappa	P-value
Examiner 1	0.887	<0.001	0.707	<0.001
Examiner 2	0.882	<0.001	0.849	<0.001
Examiner 3	0.822	<0.001	0.826	<0.001
Examiner 4	0.821	<0.001	0.760	<0.001
Examiner 5	0.774	<0.001	0.795	<0.001

Table 2. Inter-observer agreement for AO classification and Garnavos system.

		Kappa	P-value
AO	Series 1	0.836	<0.001
	Series 2	0.844	<0.001
Garnavos	Series 1	0.878	<0.001
	Series 2	0.890	<0.001

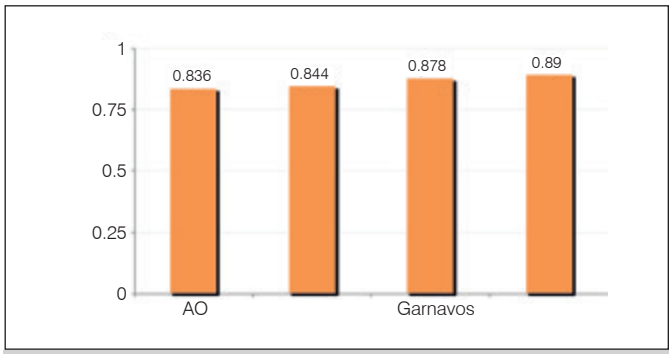

Figure 2. Inter-observer agreement for AO classification and Garnavos system.

DISCUSSION

The AO/ASIF classification is a well-established method, which is most commonly used to describe humeral diaphyseal fractures. A new classification system, the Garnavos system, has recently been introduced for diaphyseal fractures of the long bones. Few studies were seen in the literature addressing this new classification. In his article, Garnavos noted poor agreement (0.2<kappa≤0.4) for the AO classification for both intra- and inter-observer evaluation. For the Garnavos classification, this author observed good inter-observer agreement (0.6<kappa≤0.8) and moderate intra-observer agreement (0.4<kappa≤0.6).[10]

In our study, we observed good to optimal inter- and intra-observer agreement. Furthermore, we also observed that the AO classification system obtained a higher rate of intra-observer agreement than the Garnavos system. This fact was already expected, since we are more accustomed to this system of classification. Nevertheless, in the inter-observer comparison, we observed higher agreement for the Garnavos system. This may be explained by the simplification of the Garnavos classification grouping transverse and oblique fractures. We also observed that inter-observer agreement increased in the second evaluation period, showing that familiarity and practice in classifying fractures increased agreement.

In contrast with the literature, our data showed high agreement, perhaps because we selected only X-rays of the humerus shaft with two orthogonal planes and good image quality.

The difficulties related to the new classification system involved adaptation, because this classification system was unknown to the evaluators until they were involved in this study, and because this system does not make a clear division between the regions of the humerus. For example, fractures can be classified as P, M, or PM, since the classification does not provide parameters to make such a distinction. We also observed that the examiners took slightly longer to classify the fractures under the new system during the first session, but this time was not measured.

The strengths of our study included the use of five examiners with different levels of experience, a reasonable number of radiographs evaluated (80), and selection of radiographs with two good-quality views. Weaknesses included the fact that we did not measure the time needed to classify the fractures and did not compare the classification with each patient's clinical data, which made it impossible to assess any prognosis associated with the established treatment. Interestingly, this study found greater inter-observer agreement for the Garnavos classification, which could facilitate communication between orthopedists and epidemiological studies. Further studies are needed with more institutions to evaluate the prognosis and complications of this new classification, since in our opinion an ideal classification system has not yet been established.

CONCLUSIONS

We observed good or excellent intra- and inter-observer agreement for both the AO/ASIF classification and the Garnavos system. However, there was greater intra-observer agreement for the AO/ASIF classification and high inter-observer reliability for the Garnavos classification.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. RMN (0000-0002-5023-0627)*, RYM (0000-0003-0414-5752)*, and AYU (0000-0002-6320-9659)* were the main contributors to writing the manuscript. RMN and FTM (0000-0001-7328-1446)* were responsible for collecting the imaging tests for evaluation and collecting the clinical data. RMN, RYM, and AYU evaluated the data for the statistical analysis and revised the manuscript. RMN, RYM, AYU, RP (0000-0002-1745-4362)*, FTM, and MJST (0000-0002-9539-4545)* evaluated and classified the X-ray images, conducted the bibliographic research, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

INCIDENCE OF POSTURAL CHANGES AND TEMPOROMANDIBULAR DISORDERS IN STUDENTS

INCIDÊNCIA DAS ALTERAÇÕES POSTURAIS E TRANSTORNOS TEMPOROMANDIBULARES EM ESTUDANTES

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ABSTRACT

Objective: The aim of this study was to identify the incidence of postural changes and temporomandibular disorders (TMD) in children and adolescents. Methods: We selected 117 individuals aged 10–18 years from a state school in the Zona da Mata region of Minas Gerais. The students were evaluated in four stages: assessment of body weight and height and calculation of body mass index; posture evaluation using a questionnaire developed by the researchers; application of a questionnaire recommended by the American Academy of Orofacial Pain to assess TMD; and, finally, application of the Fonseca anamnesis questionnaire. Results: Of our sample, 26.36% had no TMD, 50.9% had mild TMD, 21.8% moderate TMD, and 0.9% severe TMD. Of the participants with moderate or severe TMD (30.8%), about 56% had some kind of change in head positioning. We found that 88% of the children with moderate or severe TMD had changes in the shoulders. Conclusion: The postural changes found in the head and shoulders are related to the biomechanical adaptation of the muscles of mastication and consequent changes in the TMJ. ***Level Of Evidence Iii, Non-Consecutive Patient Study Without Gold Reference Standard Applied Uniformly.***

Keywords: Temporomandibular joint disorders. Physical therapy specialty. Therapy.

RESUMO

Objetivo: O objetivo deste estudo foi identificar a incidência de alterações posturais e transtornos temporomandibulares (TTM) em crianças e adolescentes. Métodos: Foram selecionados 117 indivíduos com idade entre 10 e 18 anos, de uma escola estadual na Zona da Mata de Minas Gerais. A avaliação dos escolares foi feita em quatro etapas: avaliação do peso corporal, da estatura e cálculo do índice de massa corporal; avaliação postural, utilizando um questionário elaborado pelos pesquisadores; aplicação do questionário para avaliação de TTM recomendado pela American Academy of Orofacial Pain; e, por fim, aplicação do questionário anamnésico de Fonseca. Resultados: Em nossa amostra, 26,36% não tinham TTM, 50,9% apresentavam TTM leve, 21,8% TTM moderado e 0,9% TTM severo. Dos participantes com TTM moderado ou severo (30,8%), cerca de 56% apresentaram algum tipo de alteração de posicionamento da cabeça. Constatou-se que 88% das crianças com TTM moderado ou severo tinham alterações nos ombros. Conclusão: As alterações posturais verificadas na cabeça e nos ombros estão relacionadas com a adaptação biomecânica dos músculos da mastigação e a consequente alteração na ATM. ***Nível De Evidência Iii, Estudo De Paciente Não Consecutivo Sem Padrão De Referência Ouro Aplicado Uniformemente.***

Descritores: *Transtornos da articulação temporomandibular. Fisioterapia. Terapia.*

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INTRODUCTION

The temporomandibular joint (TMJ) is a modified ginglimal joint composed of the condylar process, fossa of the mandible and articular tubercle of the temporal bone.[1-18] This joint allows the protrusion, elevation, retraction and lateral sliding movements of the mandible, which are mainly produced by mastication muscles: masseter, temporal and lateral and medial pterygoid.[2-18] There are diseases that compromise TMJ and adjacent structures, constituting temporomandibular disorders (TMD), which are characterized by pain, joint sounds, chewing and speech impairments, irregular jaw function and even changes in global posture.[3]

A ATM is directly related to the biomechanics of the cervical and scapular structures through a common neuromuscular system, being that postural alterations of the spine May entail to disturbances in the TMJ and vice versa. Body realignment may interfere with the function and organization of the joint, Just as it can be consequence of temporomandibular disorder.[4] This relationship of reciprocity between body posture and TMD can establish a form of prevention and rehabilitation for patients.[3]

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

Study conducted at Universidade Federal de São João Del-Rei, Dom Bosco Campus.
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Studies show that about 40% of the world population has some type of TMD and several studies indicate what carriers with such dysfunction can undergo several changes in the positioning of the head and shoulders. In addition, It is verified in the literature there is a greater impairment of TMJ in women than in men, in a ratio of 4 to 1, respectively.[5]

The etiology of TMD is related to muscular hyperactivity and this, in turn, has as its main cause the practice of parafunctional habits that is aggravated by emotional stress. The symptoms of TMD are: pain, headache, joint noise, besides changes in mandibular dynamics, restriction of movements and changes in muscle tone.[4] Individuals with TMD present an overload in the cervical muscles due to increased activity of the masticatory muscles to compensate for joint disorder.[6] Such overloading may result in mandibular and spinal deviations, as well as cervical hyperlordosis, since there is shoulder elevation and head protrusion in patients with TMD. Thus, although the main complaint of TMD is the pain and limitation of the mandibular opening, this may be accompanied by muscle fatigue and alteration in the bone axis of the spine and, therefore, postural problems in the patient.[7] The objective of this article was to identify the incidence of postural changes and TMD in school children and adolescents in a medium-sized city in the forest area of Minas Gerais.

METHODS

Were selected 117 school - aged individuals aged 10 to 18 years old were selected from a state school of Minas Gerais. As inclusion criterion were school children and adolescents between the ages of 10 and 18, of both genders, who signed the term of free and informed consent and accepted to participate in the research. The exclusion criterion was children and adolescents who did not agree to participate in the study and did not sign the free and informed consent form.

All the participants were informed about the questionnaire to be answered, the TMD assessment, the postural evaluation and their responsible signed the consent form and free and informed consent at the time of admission to the research, according to Council Resolution 466/2004 The development of this research project was approved by the Ethics Committee of the Federal University of São João Del Rei / Santo Antônio Campus (protocol 017/2014). The evaluation of the students in the research followed four stages: in the first stage the body weight, height and calculation of Body Mass Index (BMI) were evaluated; In the second stage, a postural evaluation was performed, using a questionnaire prepared by the researchers. In the third stage, the questionnaire for the evaluation of TMD recommended by the American Academy of Orofacial Pain was applied, and in the fourth step the Fonseca anamnestic questionnaire was applied, being that Fonseca anamnestic questionnaire was applied only to the individuals who answered "yes" "On the questionnaire of the American Academy of Orofacial Pain. The postural changes were evaluated through the application of a postural evaluation sheet prepared by the researchers, being that and the same was done in a calm environment where the child or adolescent was evaluated in three positions: anterior, profile and posterior. The postural evaluation was performed with the supervision of a physiotherapist.

The American Academy of Orofacial Pain Questionnaire was used for an initial screening of potential TMD patients. This questionnaire presents ten TMD questions. The questions are simple questions that can be answered by the student, having as answer: yes or no.[10-17] The Fonseca anamnestic questionnaire was applied in the last phase and aims to characterize the severity of TMD,[11-19] and is widely used in epidemiological studies. This questionnaire consists of ten simple questions, where each question has three possible answers (yes, no and sometimes), for which the scores are: 10, 5 and 0, respectively. The final sum of the questionnaire allows to classify the evaluated according to the severity of the symptoms: without TMD (0 to 15 points), mild TMD (20 to 45 points) and moderate TMD (50 to 65) and severe TMD (70 to 100 points).

RESULTS

The results showed that of the 110 individuals evaluated, the mean age was 13.9 years (10-18) and the mean BMI was 19.3 kg / cm. About 18 individuals were not evaluated by the Fonseca (NA) questionnaire because they answered "no" in all questions from the American Academy of Orofacial Pain Questionnaire. Among the total of the sample, about 10% of the individuals (n = 11) had no TMD, 50.9% (n = 57) had mild TMD, 21.8% (n = 24) had moderate TMD and 0.9 % (N = 1) presented severe TMD, as shown in Figure1. Of the 22.7% (n = 25) who had moderate or severe TMD, about 56% (n = 14) presented some type of head alteration and the other 44% (n = 11) presented no head position changes. Among the postural alterations evaluated in the head was observed that 12% presented head protrusion and 44% presented head tilt to the right or left.

Among the patients with moderate or severe TMD, 22.7% (n = 25), 64% presented a shoulder elevation and 24% had a shoulder protrusion. Other postural alterations were observed in the studied population, and 67.27% (n = 74) had pelvic alterations, such as anteversion and pelvic retroversion, and 24.3% (n = 18) of these individuals were classified as having moderate and severe TMD. Other postural alterations were found, such as: cervical hyperlordosis, thoracic hyperkinesis, lumbar hyperlordosis and thoracolumbar scoliosis, with about 24.1 (n = 14) presenting moderate and severe TMD. In the knee, changes were identified as: valgus knee, varus knee and recurvatum knee in 26% (n = 13) of individuals with moderate and severe TMD.

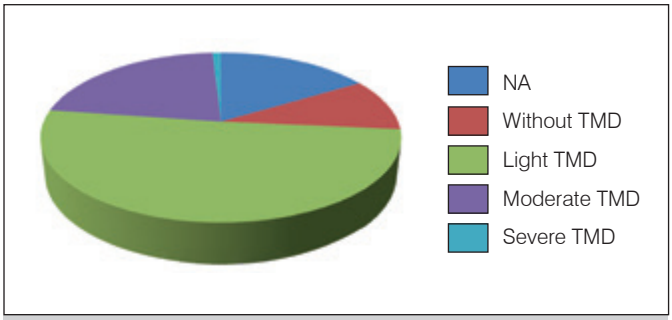

Figure 1. TMD Severity by Fonseca's Anamnestic Questionnaire. The questionnaire presented the following items:no reply (NA), without TMD, mild TMD, moderate TMD and severe TMD.

DISCUSSION

Thus, a high incidence of postural changes and TMD can be observed in the studied population. The higher incidence of alterations in the cervical, head and shoulders region is related to the mechanism of biomechanical adaptation of chewing muscles in this region.[12-20] DTM promotes compensatory mechanisms of the masticatory muscles that fixate in the region of the sternum and the scapula.[13] This biomechanical adaptation pulls the shoulder superiorly or anteriorly, determining changes in the shoulders.[8]

In the present study, no correlation was found between postural changes found in the spine, hip and lower limbs with the presence of TMD, but these alterations could trigger future problems in the study population. These changes may be related to the intrinsic

and extrinsic factors of the child or adolescent.[14] Studies show that there are genetic, ergonomic and lifestyle factors that may trigger these postural changes.[15] With this, it becomes necessary to develop orientation programs And rehabilitation for these children and adolescents with the purpose of preventing future complications.[16]

CONCLUSION

It was concluded that a high incidence of mild TMD and postural alterations occurred in the head, neck and shoulders region among the evaluated children and adolescents. There was no significant relationship between pelvic and knee changes, as well as BMI, and the occurrence of TMD. Thus, a program of prevention and orientation of these students is essential, aiming at reducing the incidence of postural changes and consequently TMD.

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Contraindicação: Hipersensibilidade a qualquer dos componentes da fórmula. Interação Medicamentosa: A administração concomitante de glicocorticóides e outros agentes anti-inflamatórios não-esteróides pode levar ao agravamento de reações adversas gastrintestinais.

TANDRILAX é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

TANDRILAX (cafeína 30 mg / carisoprodol 125 mg / diclofenaco sódico 50 mg / paracetamol 300 mg) Comprimidos. USO ORAL. USO ADULTO. Indicações: Tratamento de reumatismo nas suas formas inflamatório-degenerativas agudas e crônicas; crises agudas de gota, estados inflamatórios agudos, pós-traumáticos e pós-cirúrgicos. Exacerbações agudas de artrite reumatóide e osteo-artrose e estados agudos de reumatismo nos tecidos extra-articulares e como coadjuvante em processos inflamatórios graves decorrentes de quadros infecciosos. **Contraindicações: Nos casos de úlcera péptica em atividade; hipersensibilidade a quaisquer dos componentes de sua fórmula; discrasias sanguíneas; diáteses hemorrágicas (trombocitopenia, distúrbios da coagulação), porfiria; insuficiência cardíaca, hepática ou renal grave; hipertensão grave. É contra-indicado em pacientes asmáticos nos quais são precipitados acessos de asma, urticária ou rinite aguda pelo ácido acetilsalicílico e demais inibidores da via da cicloxigenase da síntese de prostaglandinas. Precauções e Advertências: O uso em pacientes idosos, geralmente mais sensíveis aos medicamentos, deve ser cuidadosamente observado. Desaconselha-se o uso do TANDRILAX durante a gravidez e lactação. A possibilidade de reativação de úlceras pépticas requer anamnese cuidadosa quando houver história pregressa de dispepsia, hemorragia gastrintestinal ou úlcera péptica. Nas indicações do TANDRILAX por períodos superiores a dez dias, deverá ser realizado hemograma e provas de função hepática antes do início do tratamento e, periodicamente, a seguir. A diminuição da contagem de leucócitos e/ou plaquetas, ou do hematócrito requer a suspensão da medicação. Em pacientes portadores de doenças cardiovasculares, a possibilidade de ocorrer retenção de sódio e edema deverá ser considerada. Observando-se reações alérgicas pruriginosas ou eritematosas, febre, icterícia, cianose ou sangue nas fezes, a medicação deverá ser imediatamente suspensa. Não use outro produto que contenha paracetamol. Não é indicado para crianças abaixo de 14 anos, com exceção de casos de artrite juvenil crônica. Interações medicamentosas:** O diclofenaco sódico, constituinte do TANDRILAX, pode elevar a concentração plasmática de lítio ou digoxina, quando administrado concomitantemente com estas preparações. Alguns agentes antiinflamatórios não-esteróides são responsáveis pela inibição da ação de diuréticos da classe da furosemida e pela potenciação de diuréticos poupadores de potássio, sendo necessário o controle periódico dos níveis séricos de potássio. A administração concomitante de glicocorticóides e outros agentes antiinflamatórios não-esteróides pode levar ao agravamento de reações adversas gastrintestinais. A biodisponibilidade do TANDRILAX é alterada pelo ácido acetilsalicílico quando este composto é administrado conjuntamente. Recomenda-se a realização de exames laboratoriais periódicos quando anticoagulantes forem administrados juntamente com TANDRILAX, para aferir se o efeito anticoagulante desejado está sendo mantido. Pacientes em tratamento com metotrexato devem abster-se do uso do TANDRILAX nas 24 horas que antecedem ou que sucedem sua ingestão, uma vez que a concentração sérica pode elevar-se, aumentando a toxicidade deste quimioterápico. **Reações adversas: Distúrbios gastrintestinais como dispepsia, dor epigástrica, recorrência de úlcera péptica, náuseas, vômitos e diarréia. ocasionalmente, podem ocorrer cefaléia, sonolência, confusão mental, tonturas, distúrbios da visão, edema por retenção de eletrólitos, hepatite, pancreatite, nefrite intersticial. Foram relatadas raras reações anafilactóides urticariformes ou asmatiformes bem como síndrome de stevens-johnson e síndrome de lyell, além de leucopenia, trombocitopenia, pancitopenia, agranulocitose e anemia aplástica. o uso prolongado pode provocar necrose papilar renal. TANDRILAX é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas. Posologia:** A dose mínima diária recomendada é de um comprimido a cada 12 horas e a duração do tratamento deve ser a critério médico e não deverá ultrapassar 10 dias. Tratamentos mais prolongados requerem observações especiais (vide "Precauções"). Os comprimidos do TANDRILAX deverão ser ingeridos inteiros (sem mastigar), às refeições, com auxílio de líquido. "SE PERSISTIREM OS SINTOMAS O MÉDICO DEVERÁ SER CONSULTADO." VENDA SOB PRESCRIÇÃO MÉDICA - MS - 1.0573.0055 - MB 08 - SAP 4104203

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osteo muscular

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ALÍVIO COM[1,2]

dorene pregabalina

Rápido, eficaz e seguro no tratamento da fibromialgia.[3]

Redução da dor
a partir da primeira semana de tratamento na fibromialgia[4]

A pregabalina é eficaz
em reduzir a dor dos pacientes com fibromialgia[5]

Melhora da disfunção do sono
relacionada à fibromialgia.[6]
Grande parte desse benefício foi devido:[6]

- Efeito da pregabalina na insônia[6]
- Atividade analgésica do medicamento[6]

Referências Bibliográficas: 1) TOLLE, T. et al. Pregabalin for relief of neuropathic pain associated with diabetic neuropathy: a randomized, double-blind study. European Journal of Pain, v. 12, n. 2, p. 203-213, 2008. 2) OHTA, H. et al. A randomized, double-blind, multicenter, placebo-controlled phase III trial to evaluate the efficacy and safety of pregabalin in Japanese patients with fibromyalgia. Arthritis Research & Therapy, v. 14, N. 217, 2012. 3) BOOMERSHINE, C. S. Pregabalin for the management of fibromyalgia syndrome. Journal of Pain Research, v. 3, p. 81-88, 2010. 4) PAUER, L. et al. An international, randomized, double-blind, placebo-controlled, phase III trial of pregabalin monotherapy in treatment of patients with fibromyalgia. J Rheumatol, v. 38, n. 12, p. 2643-2652, 2011. 5) HEYMANN, R.E. et al. Consenso Brasileiro do tratamento da fibromialgia. Rev Bras Reumatol, v. 50, n.1, p.56-66, 2010. - A pregabalina é eficaz em reduzir a dor dos pacientes com fibromialgia (grau de recomendação A, nível de evidência 1b. Página 60, coluna 1, 5º parágrafo. - Consenso brasileiro do tratamento da fibromialgia, que inclui a pregabalina no tratamento da fibromialgia com grau de recomendação A e nível de evidência 1B. 6) RUSSELL, I.J. et al. The effects of pregabalin on sleep disturbance symptoms among individuals with fibromyalgia syndrome. Sleep Med., v. 10, n. 6, p. 604-610, 2009.

DORENE (pregabalina) 75 mg e 150 mg. Cápsula. USO ORAL. USO ADULTO E PEDIÁTRICO ACIMA DE 12 ANOS (vide Indicações). Indicações: Dor Neuropática; Epilepsia; Transtorno de Ansiedade Generalizada (TAG); Fibromialgia. Contraindicações: Dorene é contraindicado a pacientes com hipersensibilidade conhecida à pregabalina ou a qualquer componente da fórmula. Precauções e advertências: **Pacientes com problemas hereditários raros de intolerância a galactose, deficiência de lactase ou má- absorção de glicose-galactose não devem utilizar pregabalina cápsulas. Alguns pacientes diabéticos sob tratamento com pregabalina que obtiverem ganho de peso podem necessitar de ajuste da medicação hipoglicêmica. Houve relatos de reações de hipersensibilidade, incluindo casos de angioedema. Pregabalina deve ser descontinuado imediatamente se ocorrerem sintomas de angioedema, tais como edema facial, perioral ou da via aérea superior. O tratamento com pregabalina está associado com tontura e sonolência, que pode aumentar a ocorrência de acidentes (queda) na população idosa. Pacientes devem ser alertados para ter cautela até que os efeitos potenciais de pregabalina sejam familiares. Visão borrada transitória e outras alterações na acuidade visual foram reportadas por pacientes tratados com pregabalina. A descontinuação da pregabalina pode resultar na resolução ou melhora desses sintomas visuais. Foram observados sintomas de retirada em alguns pacientes após a descontinuação do tratamento prolongado e de curto prazo com pregabalina. Os seguintes eventos foram mencionados: insônia, dor de cabeça, náusea, ansiedade, hiperidrose e diarreia (vide item Reações Adversas). Como é o caso com qualquer droga ativa do SNC, deve-se avaliar cuidadosamente o histórico de pacientes quanto ao abuso de drogas e observá-los quanto a sinais de abuso da pregabalina. Foi relatada melhora da função renal após a descontinuação ou redução da dose de pregabalina. Houve relatos pós-comercialização de insuficiência cardíaca congestiva em alguns pacientes recebendo pregabalina. Devido aos dados limitados de pacientes com insuficiência cardíaca congestiva grave, Dorene deve ser administrado com cautela nesses pacientes (vide item 9. Reações Adversas).** Efeitos sobre a Habilidade de Dirigir e Operar Máquinas: Dorene pode produzir tontura e sonolência que, portanto, podem prejudicar a habilidade de dirigir e operar máquinas. Os pacientes devem ser aconselhados a não dirigir, operar máquinas complexas, ou se engajar em outras atividades potencialmente perigosas até que se saiba se este medicamento afeta a sua capacidade de executar tais atividades. Uso em Idosos, Crianças e Outros Grupos de Risco: Vide item Posologia. Gravidez e lactação: Uso durante a Gravidez: Não há dados adequados sobre o uso de pregabalina em mulheres grávidas. Estudos em animais mostraram toxicidade reprodutiva. O risco potencial a humanos é desconhecido. Portanto, Dorene não deve ser utilizado durante a gravidez. Métodos contraceptivos eficazes devem ser utilizados por mulheres com potencial de engravidar. **A pregabalina é um medicamento classificado na categoria C de risco de gravidez. Portanto, este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista.** Uso durante a Lactação: Não se sabe se a pregabalina é excretada no leite materno de humanos. Entretanto, está presente no leite de ratas. Portanto, a amamentação não é recomendada durante o tratamento com Dorene. **Interações medicamentosas:** A pregabalina provavelmente não inibe o metabolismo de fármacos ***in vitro*** e nem se liga a proteínas plasmáticas. A pregabalina pode potencializar os efeitos do etanol e lorazepan. A pregabalina parece ser aditiva no prejuízo da função cognitiva e coordenação motora grosseira causado pela oxicodona. Em experiência pós-comercialização, houve relatos de insuficiência respiratória e coma em pacientes sob tratamento de pregabalina e outros medicamentos antidepressivos do SNC. Há relatos pós-comercialização de eventos relacionados à redução da função do trato gastrintestinal inferior (por ex, obstrução intestinal, íleo paralítico, constipação) quando a pregabalina foi coadministrada com medicamentos que têm o potencial para produzir constipação, tais como analgésicos opioides. Não foram conduzidos estudos de interação farmacodinâmica específica em voluntários idosos. Reações adversas: **As reações adversas mais comuns foram tontura e sonolência, em geral, de intensidade leve a moderada. As reações adversas comuns foram: Aumento de apetite, Confusão, desorientação, irritabilidade, humor eufórico, diminuição da libido, insônia, Ataxia, coordenação anormal, transtorno de equilíbrio, amnésia, distúrbios de atenção, dificuldade de memória, tremores, disartria, parestesia, sedação, letargia, Visão turva, diplopia, Vertigem, Vômitos, distensão abdominal, constipação, boca seca, flatulência, disfunção erétil, edema periférico, edema, marcha anormal, sensação de embriaguez, sensação anormal, fadiga e aumento de peso. As seguintes reações adversas foram relatadas durante a pós-comercialização: Sistema imune: angioedema, reação alérgica, hipersensibilidade. Sistema nervoso: dor de cabeça, perda de consciência, prejuízo mental.** Oftalmológicos: cerátite. Cardíacos: insuficiência cardíaca congestiva. Respiratório e torácico: edema pulmonar. Gastrintestinais: edema de língua, diarreia, náusea. Pele e tecido subcutâneo: inchaço da face, prurido. Renais e urinários: retenção urinária. Reprodutor e mamas: ginecomastia. Geral: mal-estar. Idosos (acima de 65 anos de idade). Num total de 998 pacientes idosos, não foram observadas diferenças quanto a segurança geral, em comparação aos pacientes com menos de 65 anos de idade. Posologia: Dorene deve ser utilizado por via oral, com ou sem alimentos. Cada cápsula de Dorene contêm 75 mg ou 150 mg de pregabalina. Dor Neuropática: A dose inicial recomendada de Dorene é de 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos. Para a maioria dos pacientes, 150 mg duas vezes ao dia é a dose ideal. Com base na resposta individual e na tolerabilidade do paciente, a dose poderá ser aumentada para 150 mg duas vezes ao dia após um intervalo de 3 a 7 dias e, se necessário, até uma dose máxima de 300 mg duas vezes ao dia após mais uma semana. Epilepsia: A dose inicial recomendada de Dorene é de 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos. Com base na resposta e tolerabilidade individuais do paciente, a dose poderá ser aumentada para 150 mg duas vezes ao dia após 1 semana. A dose máxima de 300 mg duas vezes ao dia pode ser atingida após mais 1 semana. Transtorno de Ansiedade Generalizada (TAG): A dose varia de 150 a 600 mg/dia, divididas em duas ou três doses. A necessidade para o tratamento deve ser reavaliada regularmente. Fibromialgia: A dose recomendada de Dorene é de 300 a 450 mg/dia. A dose deve ser iniciada com 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos, e a dose pode ser aumentada para 150 mg duas vezes ao dia (300 mg/dia) em uma semana baseado na eficácia e tolerabilidade individuais. Descontinuação do Tratamento: Se Dorene for descontinuado, recomenda-se que isto seja feito gradualmente durante no mínimo 1 semana. Uso em Pacientes com Insuficiência Renal: A redução da dosagem em pacientes com a função renal comprometida deve ser individualizada de acordo com o clearance de creatinina. Para pacientes submetidos à hemodiálise, a dose diária de Dorene deve ser ajustada com base na função renal. Além da dose diária, uma dose suplementar deve ser administrada imediatamente após cada tratamento de 4 horas de hemodiálise. Uso em Pacientes com Insuficiência Hepática: Nenhum ajuste de dose é necessário para pacientes com insuficiência hepática. Uso em Crianças: A segurança e a eficácia de pregabalina em pacientes pediátricos abaixo de 12 anos de idade ainda não foram estabelecidas. O uso em crianças não é recomendado. Uso em Adolescentes (12 a 17 anos de idade): Pacientes adolescentes com epilepsia podem receber a dose como adultos. A segurança e a eficácia de pregabalina em pacientes abaixo de 18 anos de idade com dor neuropática não foram estabelecidas. Uso em Pacientes Idosos (acima de 65 anos de idade): Pacientes idosos podem necessitar de redução da dose de Dorene devido à diminuição da função renal. Dose Omitida: Caso o paciente esqueça de tomar Dorene no horário estabelecido, deve tomá-lo assim que lembrar. Entretanto, se já estiver perto do horário de tomar a próxima dose, deve desconsiderar a dose esquecida e tomar a próxima. **Este medicamento não pode ser partido, aberto ou mastigado.** SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. **VENDA SOB PRESCRIÇÃO MÉDICA. SÓ PODE SER VENDIDO COM RETENÇÃO DA RECEITA.** MS - 1.0573.0457. MB 02_VP SAP 4475900.

Contraindicações: Dorene não deve ser utilizado se você tem hipersensibilidade (alergia) conhecida à pregabalina ou a qualquer componente da fórmula.
Interações medicamentosas: A pregabalina pode potencializar o efeito da oxicodona (analgésico), bebidas alcoólicas e de lorazepam (tranquilizante).

DORENE é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

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REVISTAS ACTAS DORENE CL.4 2017

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HÁ 13 ANOS CONSTRUINDO

histórias de sucesso[1]

ARTROLIVE

sulfato de glicosamina+sulfato de condroitina

PIONEIRISMO* & LIDERANÇA[1,2]
NO TRATAMENTO DA OSTEOARTRITE[3,4]

Novas evidências

Estudo demonstrou que os participantes **que tomaram sulfato de glucosamina + sulfato de condroitina reduziram a perda de volume de cartilagem após 24 meses**, argumentando para um efeito modificador da doença.[5]

*Pioneirismo refere-se ao lançamento do produto à classe médica.

Referências Bibliográficas: 1. 1. Internal Report. Dados de auditoria IMS Health. Fevereiro/2017. **2.** Internal Report. Dados de auditoria IMS-PMB. Fevereiro/2017. **3.** Bula do produto ARTROLIVE: cápsulas. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **4.** Bula do produto ARTROLIVE: granulado em sachê. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **5.** MARTEL-PELLETIER, J. et al. First-line analysis of the effects of treatment on progression of structural changes in knee osteoarthritis over 24 months: data from the osteoarthritis initiative progression cohort. Ann Rheum Dis, v. 74, n. 3, p. 547-556, 2015.

Contraindicação: Pacientes que apresentem hipersensibilidade a quaisquer dos componentes de sua fórmula. Interação medicamentosa: É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com Artrolive.

ARTROLIVE CAPS. sulfato de glicosamina + sulfato de condroitina. MS – 1.0573.0286. **INDICAÇÕES: ARTROLIVE** é indicado para osteoartrite, osteoartrose ou artrose em todas as suas manifestações. **CONTRAINDICAÇÕES: ARTROLIVE** É CONTRAINDICADO EM PACIENTES QUE APRESENTEM HIPERSENSIBILIDADE A QUAISQUER DOS COMPONENTES DE SUA FÓRMULA, GRAVIDEZ E LACTAÇÃO. **PRECAUÇÕES E ADVERTÊNCIAS:** SÃO NECESSÁRIOS O DIAGNÓSTICO PRECISO E O ACOMPANHAMENTO CUIDADOSO DE PACIENTES COM SINTOMAS INDICATIVOS DE AFECÇÃO GASTRINTESTINAL, HISTÓRIA PREGRESSA DE ÚLCERA GÁSTRICA OU INTESTINAL, DIABETES MELLITUS, OU A CONSTATAÇÃO DE DISTÚRBIOS DO SISTEMA HEMATOPOIÉTICO OU DA COAGULAÇÃO SANGUÍNEA ASSIM COMO PORTADORES DE INSUFICIÊNCIA DAS FUNÇÕES RENAL, HEPÁTICA OU CARDÍACA. SE OCORRER EVENTUALMENTE ULCERAÇÃO PÉPTICA OU SANGRAMENTO GASTRINTESTINAL EM PACIENTES SOB TRATAMENTO, A MEDICAÇÃO DEVERÁ SER SUSPENSA IMEDIATAMENTE. DEVIDO À INEXISTÊNCIA DE INFORMAÇÕES TOXICOLÓGICAS DURANTE O PERÍODO GESTACIONAL, **ARTROLIVE** NÃO ESTÁ INDICADO PARA SER UTILIZADO DURANTE A GRAVIDEZ. NÃO EXISTEM INFORMAÇÕES SOBRE A PASSAGEM DO MEDICAMENTO PARA O LEITE MATERNO SENDO DESACONSELHADO SEU USO NESSAS CONDIÇÕES E AS LACTANTES SOB TRATAMENTO NÃO DEVEM AMAMENTAR. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. FORAM RELATADOS POUCOS CASOS DE PROTEINÚRIA LEVE E AUMENTO DA CREATINO-FOSFOQUINASE (CPK) DURANTE TRATAMENTO COM GLICOSAMINA E CONDROITINA, QUE VOLTARAM AOS NÍVEIS NORMAIS APÓS INTERRUPÇÃO DO TRATAMENTO. **INTERAÇÕES MEDICAMENTOSAS:** O tratamento concomitante com antiinflamatórios não-esteroidais pode incorrer no agravamento de reações adversas do sistema gastrintestinal, sendo recomendado um acompanhamento médico mais rigoroso nesses casos. Alguns autores da literatura médica descrevem que o uso de glicosamina e condroitina pode incorrer em um aumento da resistência à insulina, porém, esses estudos foram realizados com doses muito superiores às indicadas na terapêutica clínica normal e sua validade ainda é discutida por vários outros autores. Estudos recentes demonstraram que a associação condroitina e glicosamina, quando empregada em pacientes portadores de diabetes mellitus tipo II, não levou a alterações no metabolismo da glicose. Os resultados destes estudos não podem ser extrapolados para pacientes com diabetes mellitus descompensado ou não-controlado. É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com **ARTROLIVE**. O uso concomitante de **ARTROLIVE** com os inibidores da topoisomerase II (etoposídeo, teniposídeo e doxorrubicina) deve ser evitado, uma vez que a glicosamina induziu resistência in vitro a estes medicamentos em células humanas cancerosas de cólon e de ovário. O tratamento concomitante de **ARTROLIVE** com anticoagulantes como o acenocoumarol, dicumarol, heparina e varfarina, pode levar ao aumento das chances de sangramento, devido a alterações nos valores de INR (International Normalized Ratio). Há relato de um caso na literatura de potencialização do efeito da varfarina, com consequente aumento dos valores sanguíneos de INR. Portanto, o uso concomitante de **ARTROLIVE** com anticoagulantes orais deve levar em conta avaliações rigorosas do INR. **Reações adversas: SISTEMA CARDIOVASCULAR:** EDEMA PERIFÉRICO E TAQUICARDIA. JÁ FORAM RELATADOS COM O USO DA GLICOSAMINA, PORÉM NÃO FOI ESTABELECIDA UMA RELAÇÃO CAUSAL. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **SISTEMA NERVOSO CENTRAL:** MENOS DE 1% DOS PACIENTES EM ESTUDOS CLÍNICOS APRESENTARAM CEFALEIA, INSÔNIA E SONOLÊNCIA NA VIGÊNCIA DO TRATAMENTO COM A GLICOSAMINA. **ENDÓCRINO-METABÓLICO:** ESTUDOS RECENTES DEMONSTRARAM QUE A ASSOCIAÇÃO CONDROITINA E GLICOSAMINA, QUANDO EMPREGADA EM PACIENTES PORTADORES DE DIABETES MELLITUS TIPO II, NÃO LEVOU A ALTERAÇÕES NO METABOLISMO DA GLICOSE. OS RESULTADOS DESTES ESTUDOS NÃO PODEM SER EXTRAPOLADOS PARA PACIENTES COM DIABETES MELLITUS DESCOMPENSADO OU NÃO-CONTROLADO. É RECOMENDÁVEL QUE PACIENTES DIABÉTICOS MONITOREM SEUS NÍVEIS SANGUÍNEOS DE GLICOSE MAIS FREQUENTEMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **GASTRINTESTINAL:** NÁUSEA, DISPEPSIA, VÔMITO, DOR ABDOMINAL OU EPIGÁSTRICA, CONSTIPAÇÃO, DIARREIA, QUEIMAÇÃO E ANOREXIA TÊM SIDO RARAMENTE DESCRITOS NA LITERATURA NA VIGÊNCIA DE TRATAMENTO COM GLICOSAMINA E CONDROITINA. **PELE:** ERITEMA, PRURIDO, ERUPÇÕES CUTÂNEAS E OUTRAS MANIFESTAÇÕES ALÉRGICAS DE PELE FORAM REPORTADAS EM ENSAIOS CLÍNICOS COM GLICOSAMINA. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. **POSOLOGIA: Adultos:** Recomenda-se iniciar a terapêutica com a prescrição de 1 cápsula via oral 3 vezes ao dia. Como os efeitos do medicamento se iniciam em média após a terceira semana de tratamento deve-se ter em mente que a continuidade e a não-interrupção do tratamento são fundamentais para se alcançar os benefícios analgésicos e de mobilidade articular. **SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA.** MB03a SAP4470700. **ARTROLIVE**. 1,5 g sulfato de glicosamina + 1,2 g sulfato de condroitina. MS – 1.0573.0286. **INDICAÇÕES: ARTROLIVE** é indicado para osteoartrite, osteoartrose ou artrose em todas as suas manifestações. **CONTRAINDICAÇÕES: ARTROLIVE** É CONTRAINDICADO EM PACIENTES QUE APRESENTEM HIPERSENSIBILIDADE A QUAISQUER DOS COMPONENTES DE SUA FÓRMULA, GRAVIDEZ E LACTAÇÃO. **PRECAUÇÕES E ADVERTÊNCIAS:** SÃO NECESSÁRIOS O DIAGNÓSTICO PRECISO E O ACOMPANHAMENTO CUIDADOSO DE PACIENTES COM SINTOMAS INDICATIVOS DE AFECÇÃO GASTRINTESTINAL, HISTÓRIA PREGRESSA DE ÚLCERA GÁSTRICA OU INTESTINAL, DIABETES MELLITUS, OU A CONSTATAÇÃO DE DISTÚRBIOS DO SISTEMA HEMATOPOIÉTICO OU DA COAGULAÇÃO SANGUÍNEA ASSIM COMO PORTADORES DE INSUFICIÊNCIA DAS FUNÇÕES RENAL, HEPÁTICA OU CARDÍACA. SE OCORRER EVENTUALMENTE ULCERAÇÃO PÉPTICA OU SANGRAMENTO GASTRINTESTINAL EM PACIENTES SOB TRATAMENTO, A MEDICAÇÃO DEVERÁ SER SUSPENSA IMEDIATAMENTE. DEVIDO À INEXISTÊNCIA DE INFORMAÇÕES TOXICOLÓGICAS DURANTE O PERÍODO GESTACIONAL, **ARTROLIVE** NÃO ESTÁ INDICADO PARA SER UTILIZADO DURANTE A GRAVIDEZ. NÃO EXISTEM INFORMAÇÕES SOBRE A PASSAGEM DO MEDICAMENTO PARA O LEITE MATERNO SENDO DESACONSELHADO SEU USO NESSAS CONDIÇÕES E AS LACTANTES SOB TRATAMENTO NÃO DEVEM AMAMENTAR. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. FORAM RELATADOS POUCOS CASOS DE PROTEINÚRIA LEVE E AUMENTO DA CREATINO-FOSFOQUINASE (CPK) DURANTE TRATAMENTO COM GLICOSAMINA E CONDROITINA, QUE VOLTARAM AOS NÍVEIS NORMAIS APÓS INTERRUPÇÃO DO TRATAMENTO. **INTERAÇÕES MEDICAMENTOSAS:** O tratamento concomitante com antiinflamatórios não-esteroidais pode incorrer no agravamento de reações adversas do sistema gastrintestinal, sendo recomendado um acompanhamento médico mais rigoroso nesses casos. Alguns autores da literatura médica descrevem que o uso de glicosamina e condroitina pode incorrer em um aumento da resistência à insulina, porém, esses estudos foram realizados com doses muito superiores às indicadas na terapêutica clínica normal e sua validade ainda é discutida por vários outros autores. Estudos recentes demonstraram que a associação condroitina e glicosamina, quando empregada em pacientes portadores de diabetes mellitus tipo II, não levou a alterações no metabolismo da glicose. Os resultados destes estudos não podem ser extrapolados para pacientes com diabetes mellitus descompensado ou não-controlado. É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com **ARTROLIVE**. O uso concomitante de **ARTROLIVE** com os inibidores da topoisomerase II (etoposídeo, teniposídeo e doxorrubicina) deve ser evitado, uma vez que a glicosamina induziu resistência in vitro a estes medicamentos em células humanas cancerosas de cólon e de ovário. O tratamento concomitante de **ARTROLIVE** com anticoagulantes como o acenocoumarol, dicumarol, heparina e varfarina, pode levar ao aumento das chances de sangramento, devido a alterações nos valores de INR (International Normalized Ratio). Há relato de um caso na literatura de potencialização do efeito da varfarina, com consequente aumento dos valores sanguíneos de INR. 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OS RESULTADOS DESTES ESTUDOS NÃO PODEM SER EXTRAPOLADOS PARA PACIENTES COM DIABETES MELLITUS DESCOMPENSADO OU NÃO-CONTROLADO. É RECOMENDÁVEL QUE PACIENTES DIABÉTICOS MONITOREM SEUS NÍVEIS SANGUÍNEOS DE GLICOSE MAIS FREQUENTEMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **GASTRINTESTINAL:** NÁUSEA, DISPEPSIA, VÔMITO, DOR ABDOMINAL OU EPIGÁSTRICA, CONSTIPAÇÃO, DIARREIA, QUEIMAÇÃO E ANOREXIA TÊM SIDO RARAMENTE DESCRITOS NA LITERATURA NA VIGÊNCIA DE TRATAMENTO COM GLICOSAMINA E CONDROITINA. **PELE:** ERITEMA, PRURIDO, ERUPÇÕES CUTÂNEAS E OUTRAS MANIFESTAÇÕES ALÉRGICAS DE PELE FORAM REPORTADAS EM ENSAIOS CLÍNICOS COM GLICOSAMINA. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. **POSOLOGIA: Adultos:** Recomenda-se iniciar a terapêutica com a prescrição de 1 envelope por dia, dissolvido em um copo com água. Como os efeitos do medicamento se iniciam em média após a terceira semana de tratamento deve-se ter em mente que a continuidade e a não-interrupção do tratamento são fundamentais para se alcançar os benefícios analgésicos e de mobilidade articular. **SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA.** MB03a SAP4406702.

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A ação eficaz[1] no tratamento da Osteoartrite.

Glicolive
sulfato de glicosamina

Qualidade Aché e preço acessível para o tratamento da OA.[2-5]

Referências Bibliográficas: 1) MATHESON, A. J; PERRY, C. M. Glucosamine: a review of its use in the management of osteoarthritis. Drugs Aging, v. 20, n. 14, p. 1041-60, 2003. **2)** Kairos Web Brasil. Disponível em: http://brasil.kairosweb.com Acesso em: Agosto/16. **3)** Programa Cuidados pela Vida (" O Programa Cuidados pela Vida pode alterar ou interromper esta campanha sem aviso prévio". Desconto calculado sobre o Preço Máximo ao Consumidor)". **4)** Bula do produto GLICOLIVE: pó para solução oral. Farmacêutica Responsável: Gabriela Mallmann, Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **5)** BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Resolução - RE nº 1.101, de 9 de abril de 2015. Concede Certificação de Boas Práticas de Fabricação ao Aché. Diário Oficial da União, Brasília DF, p. 133, 9 abr 2015. **6)** Internal Report.

Contraindicações: hipersensibilidade a glicosamina ou a qualquer outro componente da fórmula. Interações medicamentosas: o sulfato de glicosamina pode favorecer a absorção gastrintestinal de tetraciclinas e reduzir a de penicilina e cloranfenicol.

GLICOLIVE é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

GLICOLIVE (sulfato de glicosamina) 1500 mg pó para solução oral. USO ORAL. USO ADULTO. **Indicações:** GLICOLIVE é indicado no tratamento deartrose ou osteoartrite primária e secundária e suas manifestações. Contraindicações: **GLICOLIVE é contra-indicado em pacientes com hipersensibilidade a glicosamina ou a qualquer outro componente da fórmula. Não deve ser utilizado durante a gravidez, lactação ou em fenilcetonúricos. Cuidados e advertências: informar ao médico caso esteja utilizando outros medicamentos. Recomenda-se cautela em pacientes com sintomas indicativos de distúrbios gastrintestinais, história de úlcera gástrica ou intestinal, diabetes mellitus, portadores de insuficiência renal, hepática ou cardíaca. Caso ocorra ulceração péptica ou sangramento gastrintestinal a medicação deverá ser suspensa imediatamente. Recomenda-se evitar a ingestão de bebidas alcoólicas, durante o tratamento.** Gravidez e lactação: não há dados com relação ao uso de GLICOLIVE na gravidez e lactação humana, portanto, seu uso não é recomendado nestes casos. Interações medicamentosas: o sulfato de glicosamina pode favorecer a absorção gastrintestinal de tetraciclinas e reduzir a de penicilina e cloranfenicol. Não existe limitação para administração simultânea de analgésicos ou anti-inflamatórios esteroides e não esteroides. **Reações adversas: os efeitos colaterais mais comuns são de origem gastrintestinal, de intensidade leve a moderada, consistindo em desconforto gástrico, diarreia, náusea, prurido e cefaléia. Reações hematológicas: não foram observadas alterações clínicas significativas.Testes laboratoriais: não se observaram diferenças significativas nos valores médios nem nos dados individuais das provas laboratoriais e constantes vitais. Glicolive é um medicamento. "Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas."** Posologia: GLICOLIVE apresenta-se na forma de pó branco a levemente amarelado, com odor e sabor de abacaxi. Dispensar o conteúdo do envelope em um copo com água. Aguardar entre 2 a 5 minutos, mexer a solução com o auxílio de uma colher e consumir. Consumir 1 envelope por dia antes das refeições ou segundo indicação médica. A duração do tratamento fica a critério do médico. Para informações completas, consultar a bula na íntegra através da Central de Atendimento ao Cliente.VENDA SOB PRESCRIÇÃO MÉDICA. MS - 1.0573. 0403. MB05 SAP 4423401. "Material técnico científico de distribuição exclusiva à classe médica." SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO.

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lisinato de cetoprofeno

SMR
SMART MODULATED RELEASE[3]

O ÚNICO lisinato de cetoprofeno[1] com **TECNOLOGIA SMR[2,3]**

SEGURANÇA[2]
- Tolerabilidade gástrica 3 a 4 vezes maior comparado ao cetoprofeno comum.[2]

RÁPIDO INÍCIO DE AÇÃO[2]

EFICÁCIA[2]
- **Potência** anti-inflamatória, analgésica e antipirética superior ao cetoprofeno.[2]
- **Liberação prolongada:** Níveis plasmáticos mantidos por até 24h.[2,4]

Apresentações[4]
Cápsulas de liberação prolongada
de 160 e 320 mg com 10 e 20 cápsulas

Referências Bibliográficas: 1) ANVISA. Consulta de produtos. Disponível em: <http://www7.anvisa.gov.br/datavisa/Consulta_Produto/consulta_medicamento.asp>. Acesso em: Abr/2016. **2)** PELOGGIA, C.C.N.; BRITO NETO, A.J.; CUNHA, J. Avaliação da eficácia terapêuta e da tolerância do antiinflamatório lisinato de cetoprofeno, na forma cápsulas. Estudo multicêntrico aberto e não comparativo. Revista Brasileira de Medicina, v.57, n.6, p.617-624, 2000. **3)** Internal Report. **4)** Bula Do Produto ARTROSIL: Cápsulas. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A.

Contraindicações: Úlcera péptica na fase ativa. Interações medicamentosas: Devido à elevada ligação de cetoprofeno com proteínas plasmáticas, é necessário reduzir a dosagem de anticoagulantes, fenitoínas ou sulfamidas quando administrados concomitantemente.

ARTROSIL (lisinato de cetoprofeno) - 160 mg e 320 mg - Cápsulas de liberação prolongada - Uso oral - Uso Adulto - Indicações: Artrose, coxartrose, espondiloartrose, artrite reumatóide, bursite, flebite e tromboflebite superficial, contusão, entorse, luxação, distensão muscular. **Contraindicações: Úlcera péptica na fase ativa, anamnese positiva de úlcera péptica recorrente, dispepsia crônica, gastrite, insuficiência renal grave, leucopenia e plaquetopenia, grave distúrbio de hemocoagulação.** Hipersensibilidade a quaisquer componentes de sua fórmula. Existe a possibilidade de hipersensibilidade cruzada com ácido acetilsalicílico ou outros fármacos anti-inflamatórios não-esteroidais. Portanto, o cetoprofeno não deve ser administrado a pacientes nos quais o ácido acetilsalicílico ou outros fármacos antiinflamatórios não-esteroidais tenham provocado sintomas de asma, rinite, urticária. O uso de lisinato de cetoprofeno é contra-indicado durante o primeiro e o último trimestre de gestação, pois pode causar hipertensão pulmonar e toxicidade renal no feto, característica comum aos inibidores da síntese de prostaglandinas. Pode também levar ao aumento do tempo de sangramento das gestantes e fetos e conseqüentemente eventuais manifestações hemorrágicas no recém-nascido. Há risco de retardar o trabalho de parto. **Precauções e advertências: O uso de cetoprofeno em pacientes com asma brônquica ou com diáteses alérgicas pode provocar uma crise asmática. Em pacientes com função renal comprometida, a administração de cetoprofeno deve ser efetuada com particular cautela levando-se em consideração a eliminação essencialmente renal do fármaco.** Embora não tenha sido observada experimentalmente toxicidade embriofetal com cetoprofeno nas doses previstas para uso clínico, a administração em mulheres grávidas, durante a amamentação ou na infância não é recomendada. **Interações medicamentosas: Devido à elevada ligação de cetoprofeno com proteínas plasmáticas, é necessário reduzir a dosagem de anticoagulantes, fenitoínas ou sulfamidas quando administrados concomitantemente.** O uso com ácido acetilsalicílico reduz o nível sérico de cetoprofeno e aumenta o risco de distúrbios gastrintestinais. No caso da administração com lítio há aumento de seu nível sérico podendo levar à intoxicação. Foi observado aumento da toxicidade do metotrexato em decorrência da diminuição de seu "clearance" renal. A probenecida reduz as perdas de cetoprofeno e aumenta seu nível sérico. A metoclopramida reduz a biodisponibilidade do cetoprofeno e pode ocorrer uma pequena redução de sua absorção no uso simultâneo com hidróxidos de magnésio ou alumínio. **Reações adversas: Assim como com outros antiinflamatórios não-esteroidais, podem ocorrer distúrbios transitórios, no trato gastrintestinal, tais como gastralgia, náusea, vômito, diarréia e flatulência.** Excepcionalmente foram observadas hemorragia gastrintestinal, discinésia transitória, astenia, cefaléia, sensação de vertigem e exantema cutâneo. O produto pode ser tomado às refeições ou com leite, a fim de evitar possíveis distúrbios gastrintestinais. **Posologia:** ARTROSIL 160 mg: Uma cápsula duas vezes ao dia durante ou após às refeições. A duração do tratamento deve ser a critério médico. ARTROSIL 320 mg: Uma cápsula ao dia durante ou após às refeições. A duração do tratamento deve ser a critério médico. SE PERSISTIREM OS SINTOMAS O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA. MS – 1.0573.0128. MB_08 SAP 4057006.

Material técnico-científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos.

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Referências Bibliográficas: 1) ALFANO, G. et al. Analgesia with paracetamol/tramadol vs. paracetamol/codeine in once DaySurgery: a randomized open study. European Review for Medical and Pharmacological Sciences. v.15,p.205-21, 2011. 2) PERROT, S. et al. Efficacy and Tolerability of Paracetamol/Tramadol (325 mg/37.5 mg) Combination Treatment Compared with Tramadol (50 mg) Monotherapy in Patients with Subacute Low Back Pain: A Multicenter, Randomized, Double-Blind, Parallel-Group, 10-Day Treatment Study. Clin Ther, v. 28, n. 10, p. 1592-1606, 2006. 3) Bula do produto REVANGE: comprimidos revestidos. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 4) MEDVE, R.A.; WANG, J.; KARIM, R. Tramadol and acetaminophen tablets for dental pain. Anesth Prog, v.48, n.3, p.79-81 , 2001.

Contraindicações: hipersensibilidade ao tramadol, paracetamol ou a qualquer componente da fórmula ou aos opioides; intoxicações agudas pelo álcool, hipnóticos, analgésicos de ação central, opioides ou psicotrópicos; pacientes em tratamento com inibidores da monoaminoxidase (MAO) ou tratados com estes agentes nos últimos 14 dias. Interações medicamentosas: REVANGE® comprimido revestido não é recomendado como medicação pré-operatória obstétrica ou na analgesia pós-parto em lactantes, pois a segurança em lactentes e recém-nascidos não foi estudada.

REVANGE® é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

REVANGE®, cloridrato de tramadol e paracetamol 37,5 MG + 325 MG comprimidos revestidos. USO ORAL. USO ADULTO. Indicações: dores moderadas a severas de caráter agudo, subagudo e crônico. **Contraindicações:** hipersensibilidade ao tramadol, paracetamol ou a qualquer componente da fórmula ou aos opioides; intoxicações agudas pelo álcool, hipnóticos, analgésicos de ação central, opioides ou psicotrópicos; pacientes em tratamento com inibidores da monoaminoxidase (MAO) ou tratados com estes agentes nos últimos 14 dias. Cuidados e advertências: convulsões foram relatadas em pacientes recebendo tramadol na dose recomendada. Relatos espontâneos pós-comercialização indicam que o risco de convulsões está aumentado com doses de tramadol acima das recomendadas. A administração de tramadol pode aumentar o risco de convulsão em pacientes tomando inibidores da MAO, neurolépticos ou outros fármacos que reduzem o limiar convulsivo. REVANGE® comprimido revestido não deve ser administrado à pacientes dependentes de opioides. O tramadol reinicia a dependência física em alguns pacientes previamente dependentes de outros opioides. REVANGE® comprimido revestido deve ser usado com cautela e em dose reduzida em pacientes recebendo depressores do SNC como álcool, opioides, agentes anestésicos, tenotiazinas, tranquilizantes ou sedativos hipnóticos. REVANGE® comprimido revestido deve ser usado com bastante cautela em pacientes sob tratamento com inibidores da monoaminoxidase pois os estudos em animais mostraram aumento da incidência de óbito com a administração combinada de inibidores da MAO e tramadol. Precauções e advertências: REVANGE® comprimido revestido não deve ser administrado em conjunto com outros produtos à base de tramadol ou paracetamol. REVANGE® comprimido revestido deve ser administrado com cautela em pacientes sob risco de depressão respiratória. REVANGE® comprimido revestido deve ser usado com cautela em pacientes com pressão intracraniana aumentada ou traumatismo craniano. Alterações da pupila (miose) provocadas pelo tramadol podem mascarar a existência, extensão ou curso da patologia intracraniana. Gravidez e lactação: uso na gravidez e lactação: REVANGE® comprimido revestido somente deverá ser utilizado durante a gravidez se o potencial benefício justificar o potencial risco para o feto. Interações medicamentosas: REVANGE® comprimido revestido não é recomendado como medicação pré-operatória obstétrica ou na analgesia pós-parto em lactantes, pois a segurança em lactentes e recém-nascidos não foi estudada. Reações adversas: efeitos sobre a capacidade de dirigir e operar máquinas: mesmo quando usado de acordo com as instruções, REVANGE® comprimido revestido pode afetar a habilidade mental ou física necessária para a realização de tarefas potencialmente perigosas como dirigir ou operar máquinas, especialmente ao início do tratamento, na mudança de outro produto para REVANGE® comprimido revestido e na administração concomitante de outras drogas de ação central e, em particular, do álcool. REVANGE® é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas. Os eventos adversos relatados com maior freqüência ocorreram no sistema nervoso central e gastrintestinal, sendo que os relatos mais comuns foram vertigem, náusea e sonolência. **Posologia:** a dose diária máxima de REVANGE® comprimido revestido é 1 a 2 comprimidos a cada 4 a 6 horas de acordo com a necessidade para alívio da dor, até o máximo de 8 comprimidos ao dia. A administração dos comprimidos pode ser feita independentemente das refeições. Nas condições dolorosas crônicas, e tratamento deve ser iniciado com 1 comprimido ao dia e aumentado em 1 comprimido a cada 3 dias, conforme a tolerância do paciente, até atingir a dose de 4 comprimidos ao dia. Depois disso, REVANGE® comprimido revestido pode ser administrado na dose de 1-2 comprimidos a cada 4-6 horas, até o máximo de 8 compémidos ao dia. Nas condições dolorosas agudas, o tratamento pode ser iniciado com a dose terapêutica completa (1-2 comprimidos a cada 4-6 horas), até o máximo de 8 comprimidos ao dia. Pacientes com disfunção renal: em pacientes com "clearance" de creatinina inferior a 30 mL/min, recomenda-se aumentar o intervalo entre as administrações de REVANGE® comprimido revestido de forma a não exceder 2 comprimidos a cada 12 horas. VENDA SOB PRESCRIÇÃO MÉDICA. SÓ PODE SER VENDIDO COM RETENÇÃO DA RECEITA. Farmacêutica Responsável: Gabriela Mallmann CRF-SP 30.138. MS - 1.0573.0440. MB02 SAP 4389200.

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