

Efficacy and safety of dynamic stabilization for patients with degenerative disc, spinal stenosis and low back pain: a systematic review of randomized controlled clinical trials

Eficácia e segurança dos sistemas de estabilização dinâmica em pacientes com doença discal degenerativa, estenose de canal e lombalgia: revisão sistemática de estudos clínicos randomizados

Eficacia y seguridad de los sistemas de estabilización dinámica en pacientes con enfermedad discal degenerativa, estenosis de canal y lumbalgia: revisión sistemática de estudios clínicos randomizados

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ABSTRACT

Study Design: Systematic review of the literature. **Objective:** To perform a systematic review of the literature to organize, critical appraisal and select the best evidence available about the efficacy and safety of non-fusion fixation and its potential use for patients with degenerative disc, spinal stenosis and low back pain. **Summary of background data:** Recent reports have increased debate about the role of dynamic stabilization in the treatment of chronic back pain associated with lumbar disc degeneration and spinal stenosis. We conducted a systematic review of randomized trials through a more sensitivity search strategy and rigorous criteria applied for the type of studies. **Methods:** An electronic search was made in the databases of the Cochrane Central Register of Controlled Trials, Medline, Embase, and Latin Ameri-

RESUMO

Desenho de estudo: Revisão sistemática da literatura. **Objetivo:** Realizar revisão sistemática da literatura para organizar, avaliar e selecionar evidências a respeito do uso dos sistemas de estabilização dinâmica, sua eficácia e segurança no tratamento da doença degenerativa discal, estenose do canal lombar e dor lombar. **Revisão de literatura:** Publicações recentes têm aumentado o debate acerca do papel dos sistemas de estabilização dinâmica no tratamento de dor lombar crônica associada à degeneração discal lombar e estenose de canal lombar. Conduzimos a revisão sistemática de ensaios randomizados por meio de estratégia de busca apurada e seleção criteriosa aplicadas para cada tipo de estudo. **Métodos:** Revisão da literatura pro meio das seguintes fontes: Cochrane Central Register of

RESUMEN

Diseño del estudio: revisión sistemática de la literatura. **Objetivo:** realizar una revisión sistemática de la literatura para organizar, evaluar y seleccionar las mejores evidencias al respecto del uso de los sistemas de estabilización dinámica, su eficacia y seguridad en el tratamiento de la enfermedad degenerativa discal, estenosis del canal lumbar y dolor lumbar a través de estrategias de búsqueda apurada y selección con criterios aplicados para cada tipo de estudio. **Revisión de literatura:** publicaciones recientes han aumentado el debate acerca del papel de los sistemas de estabilización dinámica en el tratamiento del dolor lumbar crónico asociado a la degeneración discal lumbar y estenosis de canal lumbar. Fue conducida una revisión sistemática de ensayos randomizados a través de la estrategia de búsqueda apurada y selección con

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can and Caribbean Health Sciences (Lilacs) extended to November 31, 2008, with no linguistic restrictions. **Results:** One randomized controlled trial that fulfilled the inclusion criteria described above was included in this review. **Conclusion:** The data included in this review show that the use of non-fusion stabilization could be a suitable alternative to another therapies in well selected patients with spinal stenosis and degenerative disc disease. This review highlighted the need for continued research into the use of non-fusion stabilization in the treatment of spinal disorders. There is an urgency need to conduct randomized clinical trials. Long-term efficacy should be evaluated.

Controlled Trials, Medline, Excerpta Medica database (EMBASE) e Literatura Latino-Americana e do Caribe em Ciências da Saúde (Lilacs) identificando os estudos clínicos randomizados ou não. Não houve restrição de idioma e a data limite de busca foi novembro de 2008. Resultados: Um ensaio controlado randomizado que preencheu os critérios de inclusão descritos acima foi incluído neste estudo. **Conclusão:** Os dados incluídos nesta revisão mostram que o uso dos sistemas de estabilização sem fusão é alternativa aceitável para tratamento de pacientes com estenose de canal lombar e doença degenerativa discal, em pacientes bem selecionados. Esta revisão destacou a necessidade de pesquisa continuada sobre o uso dos sistemas de estabilização dinâmica para tratamento das patologias da coluna vertebral. Existe uma necessidade urgente para condução de ensaios clínicos randomizados. Eficácia em longo prazo deve ser avaliada.

criterios aplicados para cada tipo de estudio. Métodos: una revisión de la literatura a través de las siguientes fuentes fue realizada: Cochrane Central Register of Controlled Trials, MEDLINE, Excerpta Medica database (EMBASE) y Literatura latino-Americana y del Caribe en Ciencias de la Salud (LILACS). La revisión pudo identificar los estudios clínicos randomizados o no. No hubo restricción de idioma y la fecha límite de búsqueda fue 31 de noviembre de 2008. **Resultados:** un ensayo controlado randomizado, que llenó los criterios de inclusión descritos encima, fue incluido en este estudio. **Conclusión:** los datos incluídos en esta revisión muestran que el uso de los sistemas de estabilización sin fusión son una alternativa aceptable para el tratamiento de pacientes con estenosis de canal lumbar y enfermedad degenerativa discal en pacientes bien seleccionados. Esta revisión destaca la necesidad de investigación continuada sobre el uso de los sistemas de estabilización dinámica para tratamiento de las patologías de la columna vertebral. Existe una necesidad urgente para la conducción de ensayos clínicos randomizados. La eficacia a largo plazo debe de ser evaluada.

KEYWORDS: Spine; Intervertebral disk; Spinal stenosis; Low back pain; Orthopedic procedures/methods; Randomized controlled trials

DESCRITORES: Coluna vertebral; Disco intervertebral; Estenose espinhal; Dor lombar; Procedimentos ortopédicos/métodos; Ensaio clínico controlado aleatório

DESCRIPTORES: Columna vertebral; Disco intervertebral; Estenosis lumbar; Dolor de la región lumbar; Procedimientos ortopédicos/métodos; Ensaio clínico controlado aleatorio

BACKGROUND

The standard treatment for degenerative disc disease, low back pain and spinal stenosis has been the spinal fusion with rigid fixation¹. However, new therapies have been arising to obtain postoperative stability intending to achieve more physiological results, without the loss of motion required by fusion surgery. Soft fixation or dynamic stabilization is procedures that can reduce the compensatory hypermotion stress associated with instability and degenerative disc disease. Dynamic stabilization devices place the posterior structures under tension and create a focal increase in lordosis, altering the mechanical loading of the motion segment by unloading the disc. These

techniques are known as a motion preserving devices to provide stability to restore normal segmental kinematics and also to avoid adjacent segment degeneration².

Techniques such as Dynesys, Bioflex, Graf Ligamentoplasty, Wallis and X Stop can theoretically achieve stabilization without bone grafting³. However, few studies evaluated the clinical efficacy of these interventions, mainly, in long-term follow-up.

Although, there is a review about this topic⁴, we proposed to perform a systematic review of the literature to organize, critical appraisal and select the best evidence available about the efficacy and safety of non-fusion fixation and its potential use for patients with degenerative

disc disease, spinal stenosis and low back pain through a more sensitivity search strategy and rigorous criteria applied for the type of studies.

METHODS

Literature search

There was no language restriction. Trials were obtained from the following sources: Cochrane Central Register of Controlled Trials (Central, The Cochrane Library, issue 3, 2008), Medical Literature Analysis and Retrieval System Online (Medline; 1966-2008), Excerpta Medica database (Embase; 1980-2008) and Literatura Latino-Americana e do Caribe em Ciências da Saúde (Lilacs; 1982-2008) to identify randomized and quasi-randomized controlled clinical trials. The date of the last search was November 2008.

The databases were searched using a comprehensive search strategy for degenerative disc, spinal stenosis, low back pain and non-fusion fixation, along with Mesh and text words, including an exhaustive list of synonyms. The search strategy was adapted for each database in order to achieve more sensitivity. References in the relevant studies identified were also scrutinized for additional citations. The summary of the bibliographic search strategies for type of clinical situation and intervention of interest are showed in Appendix 1.

Data collection

Two reviewers independently screened the trials identified by the literature search, extracted the data, assessed trial quality and analyzed the results. A standard form was initially used to extract the following information: study characteristics (type of design and randomization methods), participants, interventions and outcomes.

Study selection

We included randomized controlled trials that specifically stated that the conditions under investigation were dynamic stabilization devices (Dynesys; BioFlex Graf Ligamentoplasty, X Stop, etc.) and which involved adults and/or children diagnosed with degenerative disc, spinal stenosis and/or low back pain. The diagnostic was based on computed tomography scan, magnetic resonance imaging and/or radiographic signs, physical examination and patients' history. The Control Group could be arthrodesis, total disc arthroplasty, rehabilitation programme, nonoperative therapy, and others. We also considered rigid *versus* semirigid dynamic instrumentation techniques.

We were interested in the following clinical outcome measurements: disability (measured by Oswestry disability index – ODI – or other tests); SF-36 questionnaire; complications (perioperative and postoperative); pain intensity measured by Visual Analogue Scale (VAS); hospitalization data; patient overall assessment; any adverse events reported, cost (as a narrative description) and, others.

Methodological quality assessment

The methodological quality of the trials included in this review was judged using the Cochrane instrument approach recommended by the Cochrane Handbook⁵, since

scales and checklists are not a reliable method for assessing the validity of a primary study⁶. The randomization methods, allocation concealment, blinded assessment of outcomes, intention-to-treat analysis, sample size calculations were recorded when it was available.

RESULTS AND DISCUSSION

Literature search results

We performed the search up to November 2008. The search strategy in the electronic databases identified 2,347 titles. After screening by title and then abstract, we obtained full paper copies for 58 potential studies that were potentially eligible for inclusion in the review. Of these, we identified 30 studies as case series, retrospective studies and controlled clinical trials that are presented as exclusion studies and their respectively main reasons of exclusion (Appendix 2). Thus, only one randomized controlled trial⁷ that fulfilled the inclusion criteria described above was included in this review.

Description of included studies and methodology quality assessment

Zucherman did not report how the generation of randomization, allocation concealment were, neither if there were a blinded assessment of outcomes measured and an intention-to-treat analysis. Besides that, the drop-outs and withdrawals were also not report. Thus, Zucherman was classified as B (unclear) regarding the internal validity of the study. This study had a follow-up of two years after the procedures⁷.

The description of data in the results sessions found in the included studies meant that it was not possible to combine studies in a meta-analysis. Therefore, we only described the main results reported by the authors and expressed some of them in a representation of meta-analysis found in the Appendix session.

Zucherman evaluated 191 patients with neurogenic intermittent claudication with or without back pain treated with interspinous process decompression system (X Stop) or nonoperative therapies at 9 US centers from May 2000 to July 2001⁷. The patients in the Control Group received at least one epidural steroid injections, nonsteroidal anti-inflammatory medications, analgesics, and physical therapy as necessary. The mean ages in the X Stop group was 70.0 years and in the Control Group was 69.1 years, without a statistically difference between them. The primary outcomes measured was the Zurich Claudication Questionnaire (ZCQ) and complications assessed intraoperatively and postoperatively.

There were more complications in the X Stop group compared with the Control Group. The complications were intraoperatively and included: respiratory distress, ischemic coronary episode, pulmonary edema, wound dehiscence and swelling, hematoma and incisional pain, although there was no statistical significant difference between both groups (Appendix 3).

Regarding the symptom severity domain, 60.2% patients reported a clinically significant improvement at the

2-year follow-up compared with 18.5% in the Control Group, with a statistical significant difference. A total of 57% of the patients in the X Stop group reported clinically improvement in the physical function domain compare with 14.8% in the Control Group, with also a statistical significant difference between both groups studied. Finally, 48.4% in the treatment group satisfied all the three ZCQ criteria (symptom severity, physical function and satisfaction) compared with only 4.9% in the Control Group.

The device (X Stop) was being evaluated as a part of ongoing FDA-approved investigation protocol (IDE) or corresponding national protocol for the X Stop at the time of the study (2005). Corporate/Industry funds were received in support of this work.

We planned to perform sensitivity analysis to explore methodological heterogeneity among the different types of studies (randomized and quasi-randomized clinical trials); however, there were no sufficient number of trials included on this review that allowed us to investigate causes of heterogeneity. Furthermore, we planned to perform subgroup analysis to explore clinical heterogeneity for the following subcategories: different types of clinical situation (degenerative disc, spinal stenosis and low back pain); different types of dynamic stabilization devices (Dynesys; BioFlex, etc.); different types of control groups; age (less than 18 years old versus 19 years or older), and significant medical comorbidity. Future studies should consider analysis of subgroups to better present their results avoiding bias and misunderstands.

Good clinical research aims to reduce uncertainty in order to help to make uniform clinical decisions, however the absence or poor evidence with regards all interventions

proposed to be studied in this review corroborated with the findings of El Dib⁸, 2007 study in which 47.8% from a total of 1,016 Cochrane reviews analyzed are found to have insufficient evidence to answer the questions around therapeutic strategies for treatment and prevention of diseases, and the authors of them did ask for further research. This does not mean that the techniques, interventions or surgical procedures evaluated by these authors are not useful for the clinical practice; contrarily it means that more studies are needed to establish its real clinical efficacy.

Although there are some studies reporting the benefits of non-fusion fixation, there is only one study found in our review with adequate design to evaluate its effectiveness available in the literature. The results of this study showed that non-lumbar fusion techniques is a feasible way to treat some of the spinal disorder, however there were some complications related to the procedure.

CONCLUSIONS

Implications for practice

The data included in this review showed that the use of non-fusion fixation could be a suitable alternative to other therapies in patients with degenerative disc disease, spinal stenosis and low back pain.

Implications for research

This review highlighted the need for continued research into the use of non-fusion fixation in the treatment of spinal disorders. There is an urgency need to conduct randomized clinical trials, and long-term efficacy should be evaluated.

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APPENDIX 1 - Summary of the bibliographic search strategies for type of clinical situation and intervention of interest

| Search history |
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| ((lumbar discal degenerative disease) or (lumbar discal degenerative diseases) or (degenerative disc disease) or (degenerative disc diseases) or (lumbar spinal disorder) or (lumbar spinal disorders) or (degeneration of the intervertebral disc) or (nonspecific degenerative spinal disorders) or (degenerative disc) or (degenerative joint) or (facet joint) or (herniated intervertebral disc) or hyperlordosis or kyphosis or (lumbar spondylosis) or osteoarthritis or osteophytes or (spinal instability)) and ((dynamic stabilization) or (dynamic stabilization devices) or (dynamic stabilization device) or (lumbar fusion) or (dynamic instrumentation) or (semirigid instrumentation) or (dynesys spinal system) or Dynesis or (cosmic posterior dynamic system) or (Isobar TTL dynamic instrumentation) or BioFlex or (graf ligamentoplasty) or (graf soft stabilization) or (dynamic stabilization system) or DSS-II OR Wallis or (X Stop) |

APPENDIX 2 - Characteristics of exclusion studies

| Study | Reason of exclusion |
|----------------------------------|---|
| Lee ²⁵ 2008 | Case series (Graf device). |
| Schaeren ³² 2008 | Case series (interlaminar decompression and dynamic stabilization with Dynesys). |
| Würgler-Hauri ³⁷ 2008 | Case series (lumbar microsurgical decompression and implantation of Dynesys). |
| Beastall ⁹ 2007 | Case series (Dynesys lumbar spinal stabilization). |
| Benezech ¹⁰ 2007 | Retrospective study (dynamic stabilization without fusion). |
| Kanayama ²¹ 2007 | Retrospective study (posterior dynamic stabilization using Graf artificial ligament). |
| Kim ¹ 2007 | Retrospective study (DIAM implant). |
| Kong ²⁹ 2007 | Controlled clinical trial (interspinous implantation Coflex versus posterior lumbar interbody fusion). |
| Sapkas ³¹ 2007 | Retrospective study (dynamic neutralization system). |
| Sénégas ³⁴ 2007 | Retrospective study (dynamic stabilization system). |
| Kim ²³ 2007 | Retrospective study (nitinol spring rod dynamic stabilization system versus nitinol memory loops). |
| Welch ³⁶ 2007 | Case series (Dynesys system). |
| Cakir ¹² 2006 | Controlled clinical trial (total disk replacement versus posterior dynamic stabilization). |
| Schnake ³³ 2006 | Case series (Dynesys system). |
| Grob ¹⁸ 2005 | Retrospective study (Dynesys semirigid fixation system). |
| Putzier ²⁸ 2005 | Retrospective study (nucleotomy with dynamic stabilization versus nucleotomy alone). |
| Saxler ³⁰ 2005 | Controlled trial (Graf's ligamentoplasty versus instrumental dorsoventral fusion). |
| Putzier ²⁹ 2004 | Case series (Dynesys system). |
| Cakir ¹¹ 2003 | Retrospective study (decompression surgery with dorsoventral fusion versus decompression surgery with posterior dynamic stabilization). |
| Markwalder ²⁷ 2003 | Retrospective study (Graf's ligaments). |
| Gardner ¹⁴ 2002 | Case series (Graf implant). |
| Stoll ⁴² 2002 | Case series (Dynesys system). |
| Hashimoto ²⁰ 2001 | Retrospective study (Graf stabilization system). |
| Hadlow ¹⁹ 1998 | Retrospective study (soft tissue stabilization system according to Graf and instrumented posterolateral fusion). |
| Gertzbein ¹⁵ 1996 | Retrospective study (Circumferential fusion with posterior pedicle screw fixation using a semirigid rod). |
| Katz ²⁷ 1996 | Retrospective study (decompressive laminectomy with or without fusion). |
| Grevitt ¹⁷ 1995 | Case series (Graf stabilization system). |
| Markwalder ²⁶ 1995 | Case series (soft-system-Stabilization according to Graf). |
| Guigui ¹⁶ 1994 | Retrospective study (Graf ligamentoplasty). |
| Frymoyer ¹³ 1979 | Retrospective study (Disc excision and midline spinal fusion and simple disc excision). |

APPENDIX 3

