Lumbar herniated disc treatment with percutaneous hydrodiscectomy

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Final version: March 17, 2017

http://dx.doi.org/10.1590/1806-9282.64.09.778

The Guidelines Project, an initiative of the Brazilian Medical Association, aims to combine information from the medical field in order to standardize producers to assist the reasoning and decision-making of doctors.

The information provided through this project must be assessed and criticized by the physician responsible for the conduct that will be adopted, depending on the conditions and the clinical status of each patient.

SUMMARY

Lumbar herniated disc are common manifestations of degenerative spine diseases, the main cause of radiated lower back pain. This guideline followed standard of a systematic review with recovery of evidence based on the movement of evidence-based medicine. We used the structured method for formulating the question synthesized by the acronym p.l.C.O., In which the p corresponds to the lumbar herniated disc, i to the treatment intervention with percutaneous hydrodiscectomy, c comparing with other treatment modalities, o the outcome of clinical evolution and complications. From the structured question, we identify the descriptors which constituted the evidence search base in the medline-pubmed databases (636 papers) and therefore, after the eligibility criteria (inclusion and exclusion), eight papers were selected to answer to clinical question. The details of the methodology and the results of this guideline are exposed in annex i.

INTRODUCTION

Lumbar herniated discs are common manifestations of degenerative spine diseases, being the main cause of radiated lower back pain. Conservative treatment with anti-inflammatory and physical therapy provides relief of pain in a significant proportion of patients, and surgery is indicated in nonresponsive patients after at least six weeks of conservative treatment to avoid irreversible structural changes in the nerve roots due to chronic compression¹. Microdiscectomy is the surgical intervention of choice for hernias that cause root symptoms, not relieved by conservative treatment^{2,3}. Surgery provides 85-95% of good and excellent results in the short-term postoperative period, however, the recurrence rate of LHD after mi-

crodiscectomy has been reported to be approximately 26%. The surgical treatment includes a great variety of options: percutaneous, endoscopic, by minimally invasive accesses, open treatments; and segmental arthrodesis may or may not be performed.

Percutaneous hydrodiscectomy was developed as a less invasive alternative for traditional microdiscectomy. The procedure is performed under local anaesthesia with sedation, using an image guided technique and a 3.8 mm cannulated system to dilate the annular fibres in order to access the disc space. The core material of the disc is mechanically removed using a high speed (non-thermal) salt solution which sprays the tissue.

REV ASSOC MED BRAS 2018; 64(9):778-782

OUTCOMES

Author Type of Study	Publication Date	Publication Status	Participants	Study Length	Pre and post-op VAS MI	Pre and post-op lumbar VAS	Mac- Nab Crite- ria	Complica- tions	Comments
Lo WC, et al.5(B) Case series – retrospective	2012	Preliminary Report – pending	97 participants with HDL<6 mm and radiculop- athy confirmed through imaging. Extruded and sequestered discs were excluded.	6 months	8.2±1.1 2.8 ±1.0 (p<0.05)	6.5±1.7 2.9±1.2 (p<0.05)	88% excel- lent and good	n/r	
Han HJ, et al.6(B) Case series – retrospective	2009	Preliminary Report Source - Kor J Spine	12 participants with lower back pain (LBP) and radiculopathy, and 1 with back pain only. Extruded and seques- tered discs were excluded.	6 months	8.5±1.1 2.7±1.0 (p<0.05)	6.2±1.9 3±1.4 (p<0.05)	n/a	n/r	"A long follow-up and additional cases are needed to confirm these initial results."
Hardenbrook MA, et al.7(B) Case series – retrospective	2013	Source - Internet J of Spine Surg	50 participants with lumbar HNP secondary radicu- lopathy confirmed through MRI in 1-2 levels. Exclud- ed: free fragment, central stenosis or bone holding.	Mean of 4.6 months	n/a	n/a	n/a	n/r	94% of patients presented improvement of the symptoms. 6% did not experience improvement of symptoms. Seven participants with initial improvement after the procedure had recurrence of symptoms; of these, three had recurrence of LHD at the same level. Therefore, treatment failure was 20%.
Kowalkows- ki8(B) Case series – retrospective	2013	Abstract Accepted by ASIPP; June, 2013	15 participants with subliga-mentous lumbar HNP secondary radiculopathy in a single level.	4 months	60 32 (p = 0.032)	n/a	n/a	n/r	93% of the patients presented improvement of the symptoms. Five patients who reported improvement of symptoms were treated with subsequent injections of transforaminal epidural steroids.
Jasper, et al.9(B) *Case series – retrospective	2013	Pending - ePlasty	30 participants with herniated disc in levels 1-3 confirmed through imaging. Excluded: sequestrated disc, >50% loss of disc height, severe DDD or osteophytes spinal stenosis and vertebral instability.	12 months	n/a	n/a	73% excel- lent and good		There was a reduction in the pain score in 26 of the 30 participants (87%).
Borshchenko I, et al.10(B) Case series - retrospective	2010	Pending (Abstract - pilot study)	16 participants with confirmed disc bulging (protrusion or small extrusion) in a single level. Large disc extrusion excluded.	6 months	n/a	n/a	88% excel- lent and good	n/r	

Author Type of Study	Publication Date	Publication Status	Participants	Study Length	Pre and post-op VAS MI	Pre and post-op lumbar VAS	Mac- Nab Crite- ria	Complica- tions	Comments
Wang W, et al.11(B) Case series – prospective	2010	Source: Chinese J Pain Med	69 participants with uncomplicated HDL imaging by MRI or CT and that met the McCulloch criteria. Exclusion: stenosis of the mixed type canal, lumbar spondylolisthesis and sequestered hernia.	9 months	n/a	n/a	98.6% excel- lent and good	One case of infec- tion in the disc space	
Cristante, et al.12(B) *RCT	2013	Pending	40 pts with MRI evidence of small herniated disc or protrusion on a single level were randomized for open lumbar microdiscectomy or percutaneous hydrodiscectomy.	12 months	There was a statistically significant improvement	No sta- tistically significant improve- ment	n/a	One with PO infection. One death related to underlying disease (HIV)	20% of patients had subsequent intervention.
ClinicalTrials. gov Identifier: NCT00384007 **Study 1	Closed Last Up- dated June 4, 2009 ClinicalTri- als.gov ac- cessed on 18/11/2015	No esti- mated date for publica- tion							
ClinicalTrials. gov Identifier: NCT02414698 ***Study 2	Recruiting patients. ClinicalTrials.gov accessed on 18/11/2015								

MI = lower member; PO = postoperative; LHD = lumbar herniated disc; LBP = lower back pain, n/a = not available; n/r none reported; HNP = herniated nucleus pulposus; MRI = magnetic resonance imaging; DDD = disc degenerative disease; McCulloch Criteria = no improvement in symptoms after ≥ 3 months of conservative treatment; RCT = randomized controlled trial. * Data recovered at http://www.washawaybackpain.com/uploads/studies/Clinical%20Evaluation.docx (complete text not available).

CLINICALTRIALS.GOV PROCESSED THIS RECORD ON NOVEMBER 18, 2015

**Study 1:

Title: A Randomized Trial Comparing SpineJet® Hydrodiscectomy to Open Lumbar Microdiscectomy for Treatment of

Lumbar Radiculopathy Due to Disc Herniation

Recruitment: Completed

Study First Received: October 2, 2006

Last Updated: June 4, 2009

Study Results: No Results Available

Conditions: Disc Herniation With Radiculopathy Interventions: Procedure: Hydrodiscectomy with Spinejet URL: https://ClinicalTrials.gov/show/NCT00384007

***Study 2:

Title: Percutaneous HydroDiscectomy Compared to TESI for Radiculopathy

Recruitment: Recruiting

Study Results: No Results Available Conditions: Lumbar Herniated Disc

Interventions: Procedure: Percutaneous Hydrodiscectomy|Drug: TESI

URL: https://ClinicalTrials.gov/show/NCT02414

DISCUSSION

Three characteristics are essential for a good systematic review of the literature: to gather all available evidence until the most recent moment; assess the quality of the studies individually and finally, summarize the results of the studies found. In this review on the use of percutaneous hydrodiscectomy in the treatment of lumbar herniated disc, we did not find any study in the scientific information databases consulted (Medline via PubMed, Central and Lilacs via BVS, Embase and Cinahl via Ebsco). With handsearching accessing the grey literature, of the eight included studies, only three case series present full text, impairing the assessment of studies quality. Therefore, caution is advised in interpreting the results, as they may present distortions of reality. In a search in the Clinical Trials database (https://clinicaltrials.gov/ - accessed on 11/18/2015), which registers protocols of studies to be conducted, we found a randomized controlled trial completed (NCT00384007 - "Last Update June 4, 2009 "- no results available) and one in progress (NCT02414698).

RECOMMENDATION:

The available evidence related to percutaneous hydrodiscectomy in the treatment of lumbar herniated disc is very weak, and its clinical use, generalized and systemic, is not recommended at this time. Its use should be restricted to the clinical research environment, so that data on efficacy and safety are produced consistently and strongly.

(Oxford 2009¹³ - Level of evidence 4 and Degree of Recommendation C; Grade¹⁴ 1D)

RESUMO

Hérnias discais lombares são manifestações comuns das doenças degenerativas da coluna, sendo a principal causa de dor lombar irradiada. Esta diretriz seguiu padrão de uma revisão sistemática com recuperação de evidências com base no movimento da Medicina Baseada em Evidências. Utilizamos a forma estruturada de formular a pergunta sintetizada pelo acrônimo P.I.C.O., em que o P corresponde à Hérnia de disco lombar, I à intervenção Tratamento com hidrodiscectomia percutânea, C comparando com Outras modalidades de tratamento, O de desfecho de Evolução clínica e complicações. A partir da pergunta estruturada, identificamos os descritores que constituíram a base da busca da evidência nas bases de dados Medline-PubMed (636 trabalhos) e, assim, após os critérios de elegibilidade (inclusão e exclusão), oito trabalhos foram selecionados para responder à dúvida clínica. Os detalhes da metodologia e dos resultados desta diretriz estão expostos no Anexo I.

ANNEX I

Structured question

The clinical question is structured through the components of P.I.C.O.

TABLE 1 – PICO COMPONENTS

P	Lumbar herniated disc in one or more levels					
ı	Treatment with percutaneous hydrodiscectomy					
С	Other treatment modalities					
0	Clinical evolution and complications					

(P (Patient); I (Intervention); C (Comparison); O (Outcome).

Evidence search strategy

The bases of scientific information consulted were Medline via PubMed, Central and Lilacs via BVS, Cochrane Library and Embase. Handsearch from references of selected papers was also performed.

PubMed-Medline

TABLE 2 – SEARCH STRATEGY USED IN THE SCIENTIFIC INFORMATION DATABASES

Without methodological filter

Search 1: (lumbar herniated nucleus pulposus OR disc herniation OR disc hernia OR intervertebral disk displacement) AND (percutaneous lumbar discectomy OR percutaneous mechanical disc decompression OR percutaneous discectomy OR diskectomy percutaneous OR hydro discectomy OR hydro surgical decompression OR spinejet OR percutaneous microdiscectomy) – 624 studies RECOVERED.

Search 2: (percutaneous hydrodiscectomy OR hydrodiscectomy OR spinejet) – One study RECOVERED.

Initially selected by the title, sequentially by the abstract, and finally by its full text, the latter being subjected to critical evaluation and extraction of the results related to the outcomes.

TABLE 3 – NUMBER OF PAPERS RECOVERED WITH THE SEARCH STRATEGY USED FOR THE SCIENTIFIC INFORMATION DATABASES

Information base	Number of papers	Number of selected papers
Primary	624	0
Grey literature	12	8

PAPERS RECOVERED (until 11/29/2015)

Inclusion criteria for the papers recovered

The selection of the studies, review of the titles and abstracts obtained with the search strategy in the consulted information bases was conducted by two researchers with skills in the preparing systematized reviews, independently and blindly, strictly following the inclusion and exclusion criteria established, thus selecting the papers with potential relevance.

According to the study designs

Narrative reviews, case reports, case series, papers presenting preliminary results were, at first, excluded from selection. Systematic reviews and meta-analyses were used with the principle of retrieving references that might have been lost at first in the initial search strategy. We included systematic reviews (SRs) of randomized controlled trials (RCTs) and randomized controlled trials not included in the SRs. The controlled clinical trials were evaluated according to the Jadad score and the Grade score.

Papers recovery

The papers recovered were evaluated by title, abstract and full text (when available), allowing the initial selection of studies to be critically evaluated. After the critical evaluation, we obtained the final selection of the studies (8), with or without full text, that provided the data for the overall synthesis. The main reasons for exclusion were: did not respond to PICO, cadaver study and case report.

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Language

Studies in Portuguese, English and Spanish languages were included.

According to the publication

Only papers for which the complete text was available were considered for critical evaluation.

Critical evaluation methods

When, after applying the inclusion and exclusion criteria, the selected evidence was defined as randomized a controlled trial (RCT), it was submitted to an appropriate critical evaluation checklist.

Results exposure

For results with available evidence, population, intervention, outcomes, presence or absence of benefit and/or damage and possible comments will be specifically defined, whenever possible.

Recommendations

The recommendations will be prepared by the authors of the review, with the initial characteristic of evidence synthesis, being submitted to validation by all the authors participating in the preparation of the guideline.

The degree of recommendation to be used comes directly from the available strength of the included studies¹⁵ and the use of the Grade system¹⁴.

Conflict of Interest

No conflict of interest was declares by the participants in the preparation of this guideline.

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