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Review article

Treatment of lumbar disc herniation with radiculopathy. Clinical practice guidelines endorsed by The Polish Society of Spinal Surgery

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ABSTRACT

Introduction: Herniated lumbar disc (HLD) is arguably the most common spinal disorder requiring surgical intervention. Although the term is fairly straightforward, the exact pathology and thus the clinical picture and natural history may vary. Therefore, it is immensely difficult to formulate universal guidelines for surgical treatment.

Aim: The aim of this paper is to organize the terminology and clear the inconsistencies in phraseology, review treatment options and gather available published evidence to address the clinical questions to create a set of clinical guidelines in relevant to the topic.

Methods and results: Twelve queries, addressing optimal surgical treatment of the HLD have been formulated. The results, based on the literature review are described in the present work. The final product of the analysis was a set of guidelines for the surgical treatment of symptomatic HLD. Categorized into four tiers based on the level of evidence (I–III and X), they have been designed to assist in the selection of optimal, effective treatment leading to the successful outcome.

Conclusions: The evidence based medicine (EBM) is becoming ever more popular among spinal surgeons. Unfortunately this is not always feasible. Lack of uniform guidelines and numerous conflicts of interest introduce flaws in the decision making process. The key role of experts and professional societies is to provide high value recommendation based on the most current literature. Present work contains a set of guidelines for the surgical treatment of HLD officially endorsed by the Polish Spine Surgery Society.

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Introduction

Herniated lumbar disc (HLD) is the most common spine disorder requiring surgical intervention. It is a problem in daily practice of spine specialists. Although HLD is quite consistent in clinical presentation, it is due to the variable pathology and natural history that indications for surgical intervention are not precise. The necessity of choosing the right surgical technique makes the situation even more complex. New methods and technologies are constantly being adapted in treatment of spine disorders. Currently, not only do we have means of intraoperative visualization (naked eye, microscope, endoscope), but also various methods of tissue dissection (classic and tubular retractors, percutaneous techniques) and a range of systems for supplementation and internal instrumentation. Variety of therapeutic options imposes making decisions based on trustworthy and up-to-date articles (EBM). Unfortunately, there are still no clear therapeutic guidelines. Spine surgeons are often subjects of external, nonobjective influence, also from the medical industry. In these circumstances, the main role of expert groups and scientific societies is to create recommendations based on up-to-date articles to be used in medical practice. Such recommendations provide help in choosing the optimally effective procedure for a functional cure.

Definition and classification of HLD

In order to create a systematic review of literature on lumbar discopathy patients with radiculopathy the authors used the definition of HLD based on the consensus of North American Spine Society published in 2001 [1]. According to the consensus:

> HLD is a localized displacement of the disc material outside the anatomic borders of intervertebral space that causes pain, weakness or numbness in myotomal or dermatomal distribution.
> HLD is not a homogenous disorder. Equally important in indications for surgical treatment and choosing the right method and surgical approach is the degree of lumbar disc herniation, being the basis for pathologic classification [2] and the spatial relationship on which the topographic classification of the disease is based [3].

Methods

Twelve queries connected with optimal surgical treatment of HLD were designed. The results, based on the review of literature are presented in this article. The guidelines for a surgical treatment of symptomatic disc herniation with radiculopathy in adult population were created, classified into four grades using the four levels of quality specified by GRADE [4], according to the Cochrane Back Review Groups [5] (Table 1).

Table 1 – Assessment criteria for scientific evidence and grading of recommendations.

Initial quality levels of scientific evidence

Type of study	Quality level of a scientific study	Grade
RCT	High	4
–	Medium	3
Observational study	Low	2
Different studies	Very low	1

Modification of grade/points

Score reducing factors:
- Serious (−1) or very serious (−2) limitation to study quality
- Important inconsistency (−1)
- Some (−1) or major (−2) uncertainty about directness
- Data not precise or lacking (−1)
- High probability of selective reporting (−1)

Score increasing factors:
- Strong evidence of association – significant relative risk >2 ($p < 0.5$) based on consistent results of two or more observational studies, with no plausible confounders (+1)
- Very strong evidence of association – significant relative risk >5 ($p < 0.2$) based on direct evidence, without concerns about credibility with no major threats to validity (+2)
- Evidence of a dose response gradient (+1)
- All plausible confounders have reduced the effect (+1)

Final recommendation classes in relations to the strength of scientific evidence

Score (pts)	Recommendation class
4	I
3	II
2	III
No evidence	X

Based on Atkins et al. [4] with modifications.

Results

Natural history of the disease

HLD with radiculopathy is characterized by a favorable natural history. Many articles on correlation of radiological improvement with clinical improvement were identified. In a vast majority of patients there is an improvement after few weeks. No evident radiological correlation with prognosis of spontaneous remission was found [6–21].

Surgical or conservative treatment? Indications for a surgery

Six controlled, randomized or quasi-randomized clinical trials comparing results of surgical treatment (discectomy) with results of conservative treatment were identified [15,22–26], one of which was classified as Class I evidence [15], the others as Class II.

> Class II recommendation: in particular patients, short-term result of surgical treatment is better when compared with conservative treatment. Patients, who improved after

surgical treatment, fit the pattern: pain radiating consistently with the level of HLD-nerve conflict, positive stretch test (straight leg raising test positive at 10–45°), convincing diagnostic imaging (level, side) [26]. Reoperated patients were not included in any of cited studies.
Class X recommendation: based on literature analysis, there is no clear evidence favoring surgical treatment over conservative treatment in longer observation (longer than 1 year).

What is the optimal time from the onset of symptoms to the surgical treatment?

The query returned four prospective controlled trials/studies (Class II) [27–30] and 9 retrospective studies of Class III [31,32,33,34,35,36,37,38]. Analysis of the literature allows to formulate the recommendations:

Class II recommendation: longer delay from the onset of symptoms to surgical treatment is associated with worse outcomes.
Class III recommendation: the threshold period after which the treatment outcome is significantly worse is 6 months.

Which patients have the best outcomes when treated surgically?

Authors of three articles of sufficient quality attempted to identify factors predicting favorable outcome of surgical treatment. Two articles concerned the endoscopic techniques [39,40] and the remainder pertained to the open surgery [41].

Class II recommendation: better outcome can be expected in patients younger than 40, with severe pain radiating to the leg, and when the symptoms are present for less than 3 months.

What is the effectiveness of intradiscal techniques?

Percutaneous discectomy
Among the Randomized Controlled Trials (RCT) analyzed on the effectiveness of percutaneous discectomy [42–45], none met the minimal quality criteria, mainly because of the short follow-up outcomes only. A few prospective studies without control and/or without randomization [46–49] were found.

Class III recommendation: percutaneous discectomy is an effective method of treatment.

No advantage of the method over the open surgery was found (Class X recommendation).

Intradiscal electrotherapy (IDET)

Class X recommendation: there is no clinical evidence [50] proving IDET's effectiveness or lack of thereof in radicular pain treatment.

What is the effectiveness of various surgical techniques (microdiscectomy, open discectomy, tubular techniques) used in the treatment of HLD?

Sixteen articles describing RCTs addressing the effectiveness and comparing treatment outcomes of various techniques were identified [51–66].

Class I recommendation: either microdiscectomy, open discectomy or discectomy with the use of tubular technology are effective treatment methods of the HLD with radiculopathy.
Class X recommendation: because of the lack of sufficient scientific evidence of proper quality, no technique can be called superior.

Sequestrectomy or discectomy?

The query returned one RCT [58,67,68] comparing results of the microdiscectomy with sequestrectomy, and 5 observational, mainly retrospective studies [69–74].

Class X recommendation: because of the lack of scientific evidence of sufficient quality, the superiority of sequestrectomy over discectomy cannot be proven.

Should the means of prevention of epidural adhesions be used?

Ten RCTs on safety and effectiveness of techniques and materials limiting the development of epidural adhesions were identified and analyzed [75–83]. Two studies have shown the advantage of using anti-adhesion gel in comparison with control group [77,84], although little power of these studies does not allow to form firm recommendation. One study has shown no relationship between the outcomes and the presence of adhesions on MRI scans [83].

Class X recommendation: there is no scientific evidence supporting the use of barrier methods in prevention of epidural adhesions.

Is the antibiotic prophylaxis effective?

Among the large number of articles pertaining to this topic, only two describe the results of RCTs on the effectiveness of antibiotic prophylaxis in spinal surgery [85,86]. All analyzed studies are of low value because of many confounders [87–92].

Class II recommendation: the antibiotic prophylaxis applied immediately before the spine surgery decreases the risk of infectious complications.
Class X recommendation: there is not enough evidence, that the prophylactic administration of antibiotics after the surgery decreases the risk of infectious complications.

Can lumbar fusion be an appropriate primary method of treatment of the HLD with radiculopathy?

No RCTs were identified, only a few observational studies [93–100], mainly retrospective of low value. Many confounding

factors and the lack of standardization prevent from performing meta-analyses.

Class X recommendation: available clinical evidence does not allow to create recommendations or contraindications for spondylodesis as a primary method of treatment of the HLD with radiculopathy.

Can lumbar fusion be used as the treatment of recurrent HLD?

The result of the query was one article describing results of a RCT with high risk of bias [101] and a few observational studies. In the literature there is no data on observations longer than 3 years [102–104]. An important confounding factor affecting meta-analyses is heterogeneity of clinical manifestation among various groups.

Class III recommendation: Lumbar fusion is an effective method of treatment for recurrent HLD, especially when the clinical presentation is dominated by axial pain and/or signs of instability.

What are the medium- (1–4 years) and long-term outcomes of the surgical treatment of HLD with radiculopathy in comparison with the conservative treatment?

Five RCTs comparing short- and medium-term (up to 2 years) outcomes from treatment were identified [15,22,26,105,106]. The available long-term results come only from an RCT of poor quality[23] or observational studies, either prospective [7] or retrospective [107]. Although numerous articles pointed to advantage of surgical treatment in any time period, none of these studies was of sufficient quality allowing for the formulation of recommendations.

Class X recommendation: based on the available literature, superiority of surgical treatment over conservative treatment in HLD with radiculopathy cannot be proven, neither in medium- nor long-term assessment.

Discussion and conclusions

Our analysis confirms a long and well-known belief among spine surgeons that there still is not enough high quality medical evidence allowing standardization of diagnostic and therapeutic decisions, even in regards to a very common disorder such as HLD. Currently, the main sources of data used to create of guidelines are the results of RCTs [108]. In spine surgery, conduction of such studies poses a great challenge, not only because of the amount of workload and associated great costs. Many confounders must be considered, some of the very difficult to measure. For example the most frequent indication for surgery is pain and poor quality of life, and these factors are notoriously difficult to assess and further studies on significance of psychosocial factors are required [109]. Very often well designed and well performed studies may lead to completely contradicting conclusions making the formulation of clinical recommendations virtually impossible [110]. There is a certain hope in recent advances in spine surgery registries, such as SpineTango. First analyses comparing results of RCTs with data from registries are promising [111], with similar results but at largely reduced costs.

At the same time, pressure of taxpayers imposes standardization of treatment. There are many attempts to organize the general of treatment of spinal disorder, ranging from establishing the formal nomenclature [1] to detailed indications for performing particular surgical procedures. Most often, they are created by expert groups working under auspices of professional societies, such as North American Spine Society recommendations [112]. Such formal guidelines are required not only for making optimal clinical decisions but also play an important role in socio-economic perspective, shaping payers' policies (NASS Coverage Recommendations) [113]. Formulation of such guidelines should take into account various regional factors, in particular the socioeconomic status.

This publication, influenced to some degree by aforementioned NASS publication [112], is an attempt to create recommendations for the most common surgical spine pathologies encountered in a typical practice. We hope it will undergo further refinement by panels of expert as new evidences become available.

The analysis of literature presented in this paper allowed for the formulation of guidelines shown below. This publication has been endorsed by the Polish Society of Spinal Surgery.

(1) The herniation of nucleus pulposus causing neurological symptoms and signs of irritation or deficits may be treated surgically.
(2) Patients treated surgically should be symptomatic, and there should be a clear correlation between radiological imaging and clinical presentation.
(3) Given the natural history of the disease, surgical treatment is superior over conservative treatment, mainly because of the shorter recovery of symptoms, i.e. the benefit is in short-term.
(4) The indication for immediate surgical treatment is neurological deficit: cauda equina syndrome and/or reduced muscle strength.
(5) In cases with painful radiculopathy, surgical treatment should be offered after 6 weeks of ineffective conservative treatment, but not later than 6 months after the onset of symptoms. Patients in remission should not be treated surgically.
(6) The mainstay of surgical treatment is discectomy without fusion. Effectiveness of discectomy is similar regardless of the method of viewing aids used (endoscopy, microscope, open) or the method of tissue retraction (percutaneous, tubular, classic retractors), therefore the selection of technique can be based on surgeon's preference. In case of recurrent disc herniation, lumbar fusion can be considered, especially in patients with severe axial pain and/or signs of instability.
(7) The choice between full discectomy and sequestrectomy can also be based on surgeon's preference – there is no evidence for superiority of either method.
(8) There is no evidence supporting the use of barrier methods in prevention of epidural adhesions when performing the transcanal discectomy.

(9) The antibiotic prophylaxis applied immediately before the spine surgery decreases the risk of infectious complications.
(10) There is no evidence for effectiveness of IDET and hence it should not be recommended.
(11) The percutaneous discectomy is an effective method of treatment. There is no evidence for its superiority over open discectomy.

Conflict of interest

The authors declare no conflict of interest.

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Ethics

The work described in this article has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

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