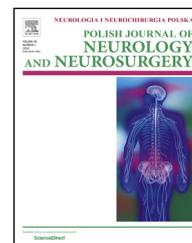


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## Review article

# Treatment of degenerative cervical spondylosis with radiculopathy. Clinical practice guidelines endorsed by The Polish Society of Spinal Surgery

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## ABSTRACT

**Introduction:** Degenerative cervical spondylosis (DCS) with radiculopathy is the most common indication for cervical spine surgery despite favorable natural history. Advances in spinal surgery in conjunction with difficulties in measuring the outcomes caused the paucity of uniform guidelines for the surgical management of DCS.

**Aims:** The aim of this paper is to develop guidelines for surgical treatment of DCS. For this purpose the available up-to-date literature relevant on the topic was critically reviewed.

**Methods and results:** Six questions regarding most important clinical questions encountered in the daily practice were formulated. They were answered based upon the systematic literature review, thus creating a set of guidelines. The guidelines were categorized into four tiers based on the level of evidence (I–III and X). They were designed to assist in the selection of optimal and effective treatment leading to the most successful outcome.

**Conclusions:** The evidence based medicine (EBM) is increasingly popular among spinal surgeons. It allows making unbiased, optimal clinical decisions, eliminating the detrimental effect of numerous conflicts of interest. The key role of opinion leaders as well as professional societies is to provide guidelines for practice based on available clinical evidence. The present work contains a set of guidelines for surgical treatment of DCS officially endorsed by the Polish Spine Surgery Society.

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## 1. Introduction

Despite favorable natural history of the disease, degenerative cervical spondylosis is the most common indication for cervical spine surgery. Although preferred from a historic point of view, there are still no clear indications for a surgical treatment or a specific surgical procedure. The questions that remain unclear are: should anterior or posterior approach be used, should internal instrumentation be used or not, if yes, then should spinal fusion be applied or not. The best way to repel external influence on spinal surgeons' decision making process, especially from the medical industry, is to provide guidelines based on high quality medical evidence. Opinion leaders and professional societies play a major role here. Such recommendations provide help in choosing the optimally effective procedure for a functional cure.

## 2. Methods

Six questions, based on surgical treatment of DCS with radiculopathy, were designed. The results, based on analysis of available literature, provided a basis for recommendations for surgical treatment in adult patients. They were classified into four grades using the four levels of quality specified by GRADE [1], according to the *Cochrane Back Review Groups* [2] (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 D, Best D, Briss PA, et al. (2004) *Grading quality of evidence and strength of recommendations*. *BMJ* 328:1490. DOI: 10.1136/bmj.328.7454.1490 with modifications.

## 3. Results

### 3.1. Natural history of the disease

Among many articles on DCS with radiculopathy only five were identified, the quality of which allowed for a proper analysis [3–7]. Two of them describe results of RCTs, in which cohorts for natural history assessment could be distinguished [3–6]. Low quality of the evidence prevented from forming a recommendation of a class higher than III.

**Class III recommendation:** In a vast majority of cases, worsening of pain in DCS with radiculopathy should significantly decrease without treatment in 4–6 months.

### 3.2. Surgical or conservative treatment? Indications for a surgery

The query returned four articles describing RCTs in which results of surgical treatment were directly compared with conservative treatment [8–11]. Risk of bias in all studies was high. In all of the cited articles, the criterion of inclusion was significant pain of arm/hand and criterion of exclusion was presence of myelopathy. None of the articles described an analysis of outcome modifying factors.

**Class II recommendation:** In a majority of the patients, surgical treatment is effective in the treatment of radicular pain in the course of DCS.

**Class X recommendation:** Evidence for superiority of surgical treatment over conservative treatment two years after operation is lacking. Surgical treatment probably provides a faster recovery and shortens the pain duration.

**Class X recommendation:** No precise recommendations for surgical treatment and favorable predicting factors can be created.

### 3.3. What are the medium- and long-term outcomes of surgical treatment

In eight RCTs [11–18] and two meta-analyses based on RCTs, a medium-term (2–4 years) assessment of outcome of radiculopathy surgical treatment in DCS was performed. In four of them, further assessment was done after min. 4 years after operation [15–18]. Quantitative analysis allowed to create a class II recommendation.

**Class II recommendation:** surgical treatment of radiculopathy in DCS is effective both in medium- and long-term observation.

### 3.4. Anterior or posterior approach?

Available literature on the outcome of anterior discectomy and posterior foraminotomy in DCS with radiculopathy was analyzed. Four articles directly comparing outcomes were identified. All were based on cohort observational studies.

**Class III recommendation:** Both anterior discectomy and posterior foraminotomy are effective treatment methods in DCS with radiculopathy.

**Class X recommendation:** No scientific evidence on advantage of any method was identified. One article pointed

to significantly lower cost of posterior foraminotomy with similar therapeutic effect [19].

### 3.5. Discectomy or discectomy with fusion? Use of plate fixation.

In available literature, 9 RCTs or quasi-RCTs [20–28] and one meta-analysis based on RCT [29] were identified. These studies compared outcomes of DCS with radiculopathy treatment at one level with various methods and/or implanted materials, and compared discectomy (*anterior cervical discectomy – ACD*) directly with discectomy and fusion (*anterior cervical discectomy and fusion – ACDF*).

**Class II recommendation:** Both single-level ACD and ACDF are effective treatment methods of DCS with radiculopathy.

**Class II recommendation:** Using fixation plate in single-level ACDF reduces kyphotisation with no effect on the outcome.

**Class X recommendation:** No advantage of ACD over ACDF can be proven.

### 3.6. Spondylodesis or arthroplasty?

The query returned 13 articles describing RCTs [15,17,18,30–39]. Three had a low risk of bias [30,31,38]. Five described long-term results, with a follow-up of more than 48 months [15,17,18,32,33], all of these had a moderate or high risk of bias. All studies included single-level surgeries only.

**Class II recommendation:** Either short-term, medium- or long-term outcomes of arthroplasty are subtly better in comparison with ACDF. The difference, while statistically significant, has probably no clinical relevance.

**Class X recommendation:** There is no evidence proving lower incidence of disorders at nearby segments in patients treated with arthroplasty when compared with ACDF.

## 4. Discussion and conclusions

There is still not enough high quality medical evidence in spine surgery – this thesis is proven true also by analysis of literature on cervical spondylosis with radiculopathy.

The basic sources of data for creation of clinical guidelines are the results of RCTs. Unfortunately, they are difficult to perform and are very expensive. There is some hope in growing popularity of spine surgery registries. First results comparing data from RCTs with data from registries show a great convergence [40], with a significantly lower cost of the latter.

In spine surgery such studies prove a real challenge as there are great many confounding traits. 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 [41] should be executed. Often well-designed and well-performed research may lead to completely opposing conclusions proving recommendation formulation impossible [42]. Recommendations of such type have started to be a common requirement, mainly because of multitude of therapeutic options, often with differing costs. In this environment,

taxpayers' pressure tends to rise and imposes a standardization of the treatment. Papers classifying nomenclature and rules of treatment of spine disorders are being created by expert groups working under scientific societies, for example, therapeutic recommendations [43] and refunding recommendations of North American Spine Society that shape funding policies of medical procedures from taxpayers' money (NASS Coverage Recommendations [44]). This publication was greatly influenced by the publications of the latter society. It is endorsed by the Polish Society of Spinal Surgery as it takes into consideration epidemiologic and socio-economic status of Poland.

Performed analysis of literature allows to create recommendations shown below, which have been endorsed by Polish Society of Spinal Surgery.

1. Cervical spondylosis with radiculopathy with concurrent signs of irritation or deficits may be treated surgically.
2. Patients treated surgically should be symptomatic, with correlation between radiological imaging and clinical presentation.
3. Considering the favorable natural history of the disease, advantage of surgical treatment over conservative is caused by faster recovery from pain.
4. In cases of pain with radiculopathy, surgical treatment should be proposed after 6 weeks of ineffective conservative treatment and patients in remission should not be treated surgically.
5. Gold standard in the treatment of cervical discopathy is discectomy via the anterior approach with fusion, but there is no evidence for its clinical superiority over anterior discectomy without fusion or foraminotomy from posterior approach.
6. Use of anterior plate in cervical spondylodesis after discectomy is not required and depends on the preference of the surgeon.
7. Clinical evidence on superiority of cervical arthroplasty after discectomy over spondylodesis is not convincing enough. No recommendation can be stated and using this method should depend on surgeon's preferences.

### 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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