

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: <http://www.elsevier.com/locate/pjnns>

Review article

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



Dariusz Latka^{a,*}, Grzegorz Miekisiak^b, Pawel Jarmuzek^c,
Marcin Lachowski^d, Jacek Kaczmarczyk^e

^aDepartment of Neurosurgery, Regional Medical Center, Opole, Poland

^bDepartment of Neurosurgery, Specialist Medical Center, Polanica-Zdrój, Poland

^cDepartment of Neurosurgery, Regional Neurosurgery and Neurotrauma Center, Zielona Góra, Poland

^dMedical University of Warsaw, Poland

^eDepartment of Orthopedics and Traumatology, Poznan University of Medical Sciences, Poland

ARTICLE INFO

Article history:

Received 19 November 2015

Accepted 2 December 2015

Available online 15 December 2015

Keywords:

Cervical spondylosis

Radiculopathy

Spinal surgery

Guidelines

Cervical disc herniation

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.

© 2015 Polish Neurological Society. Published by Elsevier Sp. z o.o. All rights reserved.

* Corresponding author at: al. W. Witosa 26, 45-418 Opole, Poland. Tel.: +48 601853513.

E-mail address: dlatka@mp.pl (D. Latka).

<http://dx.doi.org/10.1016/j.pjnns.2015.12.002>

0028-3843/© 2015 Polish Neurological Society. Published by Elsevier Sp. z o.o. All rights reserved.

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.

Acknowledgement and financial support

No financial support was received for this study.

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.

REFERENCES

- [1] Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S, et al. Grading quality of evidence and strength of recommendations. *BMJ* 2004;328:1490.
- [2] Furlan AD, Pennick V, Bombardier C, van Tulder M. Updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine (Phila Pa 1976)* 2009;34:1929-41.
- [3] Cesaroni A, Nardi PV. Plasma disc decompression for contained cervical disc herniation: a randomized, controlled trial. *Eur Spine J* 2010;19:477-86.
- [4] Nardi PV, Cabezas D, Cesaroni A. Percutaneous cervical nucleoplasty using coblation technology. Clinical results in fifty consecutive cases. *Acta Neurochir Suppl* 2005;92:73-8.
- [5] Heckmann JG, Lang CJ, Zöbelein I, Laumer R, Druschky A, Neundörfer B. Herniated cervical intervertebral discs with radiculopathy: an outcome study of conservatively or surgically treated patients. *J Spinal Disord* 1999;12:396-401.
- [6] Persson LC, Lilja A. Pain, coping, emotional state and physical function in patients with chronic radicular neck pain. A comparison between patients treated with surgery, physiotherapy or neck collar – a blinded, prospective randomized study. *Disabil Rehabil* 2001;23:325-35.
- [7] Oláh M, Molnár L, Dobai J, Oláh C, Fehér J, Bender T. The effects of weightbath traction hydrotherapy as a component of complex physical therapy in disorders of the cervical and lumbar spine: a controlled pilot study with follow-up. *Rheumatol Int* 2008;28:749-56.
- [8] Engquist M, Löfgren H, Öberg B, Holtz A, Peolsson A, Söderlund A, et al. Surgery versus nonsurgical treatment of cervical radiculopathy: a prospective, randomized study comparing surgery plus physiotherapy with physiotherapy alone with a 2-year follow-up. *Spine (Phila Pa 1976)* 2013;38:1715-22.
- [9] Persson LC, Moritz U, Brandt L, Carlsson CA. Cervical radiculopathy: pain, muscle weakness and sensory loss in patients with cervical radiculopathy treated with surgery, physiotherapy or cervical collar. A prospective, controlled study. *Eur Spine J* 1997;6:256-66.
- [10] Sampath P, Bendebba M, Davis JD, Ducker T. Outcome in patients with cervical radiculopathy. Prospective, multicenter study with independent clinical review. *Spine (Phila Pa 1976)* 1999;24:591-7.
- [11] Peolsson A, Söderlund A, Engquist M, Lind B, Löfgren H, Vavruch L, et al. Physical function outcome in cervical radiculopathy patients after physiotherapy alone compared with anterior surgery followed by physiotherapy: a prospective randomized study with a 2-year follow-up. *Spine (Phila Pa 1976)* 2013;38:300-7.
- [12] Phillips FM, Lee JYB, Geisler FH, Cappuccino A, Chaput CD, DeVine JG, et al. A prospective, randomized, controlled clinical investigation comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion. 2-year results from the US FDA IDE clinical trial. *Spine (Phila Pa 1976)* 2013;38:E907-18.
- [13] Carreon LY, Glassman SD, Campbell MJ, Anderson PA. Neck Disability Index, short form-36 physical component summary, and pain scales for neck and arm pain: the minimum clinically important difference and substantial clinical benefit after cervical spine fusion. *Spine J* 2010;10:469-74.
- [14] Nabhan A, Steudel WI, Nabhan A, Pape D, Ishak B. Segmental kinematics and adjacent level degeneration following disc replacement versus fusion: RCT with three years of follow-up. *J Long Term Eff Med Implants* 2007;17:229-36.
- [15] Sasso RC, Anderson PA, Riew KD, Heller JG. Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. *J Bone Joint Surg Am* 2011;93:1684-92.
- [16] Delamarter RB, Murrey D, Janssen ME, Goldstein Ja, Zigler J, Tay BK-B, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients. *SAS J* 2010;4:122-8.
- [17] Burkus JK, Haid RW, Traynelis VC, Mummaneni PV. Long-term clinical and radiographic outcomes of cervical disc replacement with the Prestige disc: results from a prospective randomized controlled clinical trial. *J Neurosurg Spine* 2010;13:308-18.
- [18] Coric D, Kim PK, Clemente JD, Boltes MO, Nussbaum M, James S. Prospective randomized study of cervical arthroplasty and anterior cervical discectomy and fusion with long-term follow-up: results in 74 patients from a single site. *J Neurosurg Spine* 2013;18:36-42.
- [19] Alvin MD, Lubelski D, Abdullah KG, Whitmore RG, Benzel EC, Mroz TE. Cost-utility analysis of anterior cervical discectomy and fusion with plating (ACDFP) versus posterior cervical foraminotomy (PCF) for patients with single-level cervical radiculopathy at 1-year follow-up. *J Spinal Disord Tech* 2014.
- [20] Zoëga B, Kärrholm J, Lind B. One-level cervical spine fusion. A randomized study, with or without plate fixation, using radiostereometry in 27 patients. *Acta Orthop Scand* 1998;69:363-8.
- [21] Oktenoglu T, Cosar M, Ozer AF, Iplikcioglu C, Sasani M, Canbulat N, et al. Anterior cervical microdiscectomy with or without fusion. *J Spinal Disord Tech* 2007;20:361-8.
- [22] Bärlocher CB, Barth A, Krauss JK, Bingeli R, Seiler RW. Comparative evaluation of microdiscectomy only, autograft fusion, polymethylmethacrylate interposition, and threaded titanium cage fusion for treatment of single-level cervical disc disease: a prospective randomized study in 125 patients. *Neurosurg Focus* 2002;12:E4.
- [23] Martins AN. Anterior cervical discectomy with and without interbody bone graft. *J Neurosurg* 1976;44:290-5.
- [24] Rosenørn J, Hansen EB, Rosenørn MA. Anterior cervical discectomy with and without fusion. A prospective study. *J Neurosurg* 1983;59:252-5.
- [25] van den Bent MJ, Oosting J, Wouda EJ, van Acker RE, Ansink BJ, Braakman R. Anterior cervical discectomy with or without fusion with acrylate. A randomized trial. *Spine (Phila Pa 1976)* 1996;21:834-9. discussion 840.
- [26] Xie J, Hurlbert RJ. Discectomy versus discectomy with fusion versus discectomy with fusion and instrumentation: a prospective randomized study. *Neurosurgery* 2007;61:107-16. discussion 116-117.
- [27] Savolainen S, Rinne J, Hernesniemi J. A prospective randomized study of anterior single-level cervical disc operations with long-term follow-up: surgical fusion is unnecessary. *Neurosurgery* 1998;43:51-5.
- [28] Hauerberg J, Kosteljanetz M, Bøge-Rasmussen T, Dons K, Gideon P, Springborg JB, et al. Anterior cervical discectomy with or without fusion with ray titanium cage: a prospective randomized clinical study. *Spine (Phila Pa 1976)* 2008;33:458-64.
- [29] Botelho RV, Dos Santos Buscarioli Y, de Barros Vasconcelos Fernandes Serra MVF, Bellini MNP, Bernardo WM. The choice of the best surgery after single level anterior cervical spine discectomy: a systematic review. *Open Orthop J* 2012;6:121-8.
- [30] McAfee PC, Cappuccino A, Cunningham BW, Devine JG, Phillips FM, Regan JJ, et al. Lower incidence of dysphagia

- with cervical arthroplasty compared with ACDF in a prospective randomized clinical trial. *J Spinal Disord Tech* 2010;23:1–8.
- [31] Marzluff J, McConnell J, Tomaras C, Peppelman W, Volcan I, Baker K. 2-year multicenter follow-up in a prospective randomized clinical trial: comparison of a cervical artificial disc to an ACDF treatment. *Spine J* 2010;10:S135–6.
- [32] Zigler JE, Delamarter R, Murrey D, Spivak J, Janssen M. ProDisc-C and anterior cervical discectomy and fusion as surgical treatment for single-level cervical symptomatic degenerative disc disease: five-year results of a Food and Drug Administration study. *Spine (Phila Pa 1976)* 2013;38:203–9.
- [33] Nunley PD, Jawahar A, Cavanaugh DA, Gordon CR, Kerr EJ, Utter PA. Symptomatic adjacent segment disease after cervical total disc replacement: re-examining the clinical and radiological evidence with established criteria. *Spine J* 2013;13:5–12.
- [34] Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. *Neurosurg Focus* 2004;17:E6.
- [35] Pettine K a. Clinical and radiographic outcome of the neodisc cervical total disc replacement (TDR) at 2-year follow-up. *Spine J* 2010;10:S44.
- [36] Mummaneni PV, Burkus JK, Haid RW, Traynelis VC, Zdeblick T.A.. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. *J Neurosurg Spine* 2007;6:198–209.
- [37] Howell K, Phillips F, Cappuccino A, Geisler F, Chaput C, DeVine J, et al. A prospective, randomized clinical investigation of the porous coated motion (PCM) artificial cervical disc: two-year results from the US IDE study. *Spine J* 2011;11:S18.
- [38] Heller JG, Sasso RC, Papadopoulos SM, Anderson PA, Fessler RG, Hacker RJ, et al. Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiographic results of a randomized, controlled, clinical trial. *Spine (Phila Pa 1976)* 2009;34:101–7.
- [39] Coric D, Nunley PD, Guyer RD, Musante D, Carmody CN, Gordon CR, et al. Prospective, randomized, multicenter study of cervical arthroplasty: 269 patients from the Kineflex|C artificial disc investigational device exemption study with a minimum 2-year follow-up: clinical article. *J Neurosurg Spine* 2011;15:348–58.
- [40] Grob D, Porchet F, Kleinstück FS, Lattig F, Jeszenszky D, Luca A, et al. A comparison of outcomes of cervical disc arthroplasty and fusion in everyday clinical practice: surgical and methodological aspects. *Eur Spine J* 2010;19:297–306.
- [41] Sullivan MJL, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. *Psychol Assess* 1995;7:432–524.
- [42] Lake WB, Brooks NP, Resnick DK. Comparative effectiveness research in spine surgery. *J Comp Eff Res* 2013;2:45–51.
- [43] Bono CM, Ghiselli G, Gilbert TJ, Kreiner DS, Reitman C, Summers JT, et al. An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders. *Spine J* 2011;11:64–72.
- [44] North American Spine Society. NASS Coverage Recommendations; 2012.