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Review Article

Cervical arthroplasty: a critical review of the literature

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Abstract

BACKGROUND CONTEXT: Cervical disc arthroplasty (CDA) is a motion-preserving procedure that is an alternative to fusion. Proponents of arthroplasty assert that it will maintain cervical motion and prevent or reduce adjacent segment degeneration. Accordingly, CDA, compared with fusion, would have the potential to improve clinical outcomes. Published studies have varying conclusions on whether CDA reduces complications and/or improves outcomes. As many of these previous studies have been funded by CDA manufacturers, we wanted to ascertain whether there was a greater likelihood for these studies to report positive results.

PURPOSE: To critically assess the available literature on cervical arthroplasty with a focus on the time of publication and conflict of interest (COI).

STUDY DESIGN/SETTING: Review of the literature.

METHODS: All clinical articles about CDA published in English through August 1, 2013 were identified on Medline. Any article that presented CDA clinical results was included. Study design, sample size, type of disc, length of follow-up, use of statistical analysis, quality-of-life (QOL) outcome scores, COI, and complications were recorded. A meta-analysis was conducted stratifying studies by COI and publication date to identify differences in complication rates reported.

RESULTS: Seventy-four studies were included that investigated 8 types of disc prosthesis and 22 met the criteria for a randomized controlled trial (RCT). All Level Ib RCTs reported superior quality-of-life outcomes for CDA versus anterior cervical discectomy and fusion (ACDF) at 24 months. Fifty of the 74 articles (68%) had a disclosure section, including all Level Ib RCTs, which had significant COIs related to the respective studies. Those studies without a COI reported mean weighted average adjacent segment disease rates of 6.3% with CDA and 6.2% with ACDF. In contrast, the reverse was reported by studies with a COI, for which the averages were 2.5% with CDA and 6.3% with ACDF. Those studies with a COI (n=31) had an overall weighted average heterotopic ossification rate of 22%, whereas those studies with no COI (n=43) had a rate of 46%.

CONCLUSIONS: Associated COIs did not influence QOL outcomes. Conflicts of interest were more likely to be present in studies published after 2008, and those with a COI reported greater adjacent segment disease rates for ACDF than CDA. In addition, heterotopic ossification rates were

FDA device/drug status: Approved (Bryan Cervical Disc Prosthesis, Prestige Cervical Disc Prosthesis, Porous Coated Motion Cervical Disc Prosthesis, ProDisc-C Cervical Disc Prosthesis, and Mobi-C Cervical Disc Prosthesis).

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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much lower in studies with COI versus those without COI. Thus, COIs did not affect QOL outcomes but were associated with lower complication rates.

Keywords: Cervical disc arthroplasty; Arthroplasty; Fusion; Outcomes; Adjacent segment disease; Heterotopic ossification

Introduction

A common surgical treatment for symptomatic cervical spondylosis (ie, radiculopathy and/or myelopathy) is anterior cervical discectomy and fusion (ACDF). It has been shown to be safe and clinically efficacious. However, there exists considerable debate about degeneration and development of related disease at adjacent levels after fusion surgery [1–9]. Specifically, it is unclear if such adjacent degeneration is a reflection of the natural history of spondylosis or, alternatively, if it is related to the adjacent fused segment. Whereas some studies have shown an average 3% reoperation rate, others have shown rates exceeding 10% after 2 years to treat complications related to the index surgery [1].

Cervical disc arthroplasty (CDA) is an alternative to fusion after the index decompression procedure (ie, discectomy). Interest in CDA has gained substantial momentum over the past decade [1–9]. Cervical disc arthroplasties are designed to maintain cervical motion, and if segmental fusion is responsible for inducing adjacent-level degeneration and disease, it could diminish the incidence or prevent the occurrence of this problem. Intuitively, maintaining near physiologic motion in the cervical spine, if possible, makes perfect sense. However, recent reports have shown a high incidence of heterotopic ossification (ie, abnormal bone formation around or within the intervertebral disc space) and/or implant migration [1–9]. There have been a multitude of published clinical trials investigating various artificial discs to date (Table 1), with some studies showing better outcomes with CDA versus ACDF and others showing equivalent outcomes [1–9]. Given the conflicting results, one must consider potential biases of the authors or conflicts of interest (COIs) that may have led to underreporting of complications or overreporting of positive results. Bhandari et al. [10] examined 332 randomized trials in 13 leading surgical and medical journals and found significant positive association between industry financial involvement and successful trial outcome. We suspect that some of the heterogeneity of conclusions may be because of the influences of having a COI. The purpose of this study is to critically evaluate the literature on clinical and quality-of-life (QOL) outcomes of CDA versus ACDF with respect to both timeframe (published before or after 2008) and author COI.

Methods

A literature search was performed using the Medline database via the Pubmed search engine with the following search terms: ‘‘cervical arthroplasty,’’ ‘‘cervical disc arthroplasty,’’ ‘‘cervical disc replacement,’’ and ‘‘disc replacement.’’ Inclusion criteria were any articles that presented clinical results associated with the cervical disc replacement using a mechanical artificial disc. Biomechanical, radiographic, and animal studies and case reports were excluded as were articles dealing with nucleus replacement. All articles were reviewed and classified according to level of evidence (LOE) independently by two senior spine surgeons. The criteria put forth by Sackett et al. [11] were used to analyze the data and stratify according to LOE. For the purpose of this study, only levels Ib, IIb, IIIb, and IV were relevant [11]. The reported LOE may be different from the LOE derived using the criteria of Sackett et al. [11] and thus requires downgrade. The reasons for downgrade included lack of adequate follow-up (<85% of original sample size), incomplete reporting of important outcome measures or percent of subjects available at follow-up, complete absence or incomplete reporting of statistical analysis of results, and/or inadequate sample size, which was defined in this study as n less than 50 patients undergoing CDA [12].

All randomized, controlled, retrospective, and prospective studies were presented for completeness. Studies were separated into early versus late studies to evaluate for differences. Anything published after 2008 were considered late studies, and 2008 was chosen as the cutoff point for multiple reasons. First, the Prestige (Medtronic Sofamor Danek, Memphis, TN, USA) and ProDisc (Synthes Spine, Paoli, PA, USA) artificial discs were Food and Drug Administration (FDA) approved in 2007, whereas the others were approved in or after 2009. Second, a trend toward higher complication rates and COIs was observed for articles published during or after 2008, compared with earlier years. Finally, we used the concept of Scott parabola to divide the articles at a point where ‘‘encouraging reports’’ were separated from ‘‘widespread enthusiasm,’’ corresponding to 2008 as most likely that point [13]. Scott parabola describes a common theme in the medical profession of surgeries or medical therapies whereby early studies show great promise for the treatment at the outset, the treatment becomes standard of care, and then falls into disuse as a result of subsequent negative outcome reports [13]. All articles were then evaluated with regard to COI by review of their respective disclosure sections. Any remunerative or nonfinancial activity with the potential of creating bias in the author or author(s) of a published article was considered a COI as per the guidelines published online by the North American Spine Society [14,93]. All included journals had a minimum of certain disclosure