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Review

Cervical disc arthroplasty for symptomatic cervical disc disease: Traditional and Bayesian meta-analysis with trial sequential analysis

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HIGHLIGHTS

- Whether cervical disc arthroplasty is superior to ACDF for symptomatic cervical disc disease remains controversial.
- We have compared cervical disc arthroplasty with ACDF in treatment of symptomatic cervical disc disease.
- The trial sequential analysis is applied to test the robustness of our findings and get more conservative estimation.
- According to the results, cervical disc arthroplasty is superior or equivalent to ACDF for cervical disc disease.

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ABSTRACT

Objective: Cervical disc arthroplasty (CDA) has been designed as a substitute for anterior cervical discectomy and fusion (ACDF) in the treatment of symptomatic cervical disc disease (CDD). Several researchers have compared CDA with ACDF for the treatment of symptomatic CDD; however, the findings of these studies are inconclusive. Using recently published evidence, this meta-analysis was conducted to further verify the benefits and harms of using CDA for treatment of symptomatic CDD.

Methods: Relevant trials were identified by searching the PubMed, EMBASE, and Cochrane Library databases. Outcomes were reported as odds ratio or standardized mean difference. Both traditional frequentist and Bayesian approaches were used to synthesize evidence within random-effects models. Trial sequential analysis (TSA) was applied to test the robustness of our findings and obtain more conservative estimates.

Results: Nineteen trials were included. The findings of this meta-analysis demonstrated better overall, neck disability index (NDI), and neurological success; lower NDI and neck and arm pain scores; higher 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) scores; more patient satisfaction; greater range of motion at the operative level; and fewer secondary surgical procedures (all $P < 0.05$) in the CDA group compared with the ACDF group. CDA was not significantly different from ACDF in the rate of adverse events ($P > 0.05$). TSA of overall success suggested that the cumulative z-curve crossed both the conventional boundary and the trial sequential monitoring boundary for benefit, indicating sufficient and conclusive evidence had been ascertained.

Conclusions: For treating symptomatic CDD, CDA was superior to ACDF in terms of overall, NDI, and neurological success; NDI and neck and arm pain scores; SF-36 PCS and MCS scores; patient satisfaction; ROM at the operative level; and secondary surgical procedures rate. Additionally, there was no significant difference between CDA and ACDF in the rate of adverse events. However, as the CDA procedure is a relatively newer operative technique, long-term results and evaluation are necessary before CDA is routinely used in clinical practice.

1. Introduction

Anterior cervical discectomy and fusion (ACDF) has been frequently used and often considered to be the standard surgical

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procedure for treatment of symptomatic cervical disc disease (CDD). Symptoms of CDD include axial and radicular pain, sensory loss and motor weakness associated with neural compression or headache [1–3]. ACDF can effectively relieve pain and facilitate recovery of neurologic function in patients with symptomatic CDD. However, this procedure has invariably been associated with complications, such as loss of range of motion (ROM) at the operative level, accelerated degeneration at the adjacent level, pseudarthrosis, dysphagia, and plate fracture [4–6].

Cervical disc arthroplasty (CDA) has emerged as a substitute for ACDF in the treatment of symptomatic CDD [7] that was designed to preserve normal disk height, maintain functional spinal unit kinematics, and reduce adjacent-level disc degeneration and other drawbacks of fusion [8,9]. However, potential limitations associated with CDA include biocompatibility [10], implant migration or subsidence, and heterotopic ossification.

Several studies have compared CDA with ACDF for the treatment of symptomatic CDD. However, the findings of these studies have been inconclusive. Some studies have found improved lower neck and arm pain [11–16] and Neck Disability Index (NDI) scores [17] to be associated with CDA relative to ACDF. Conversely, other studies have indicated no differences in neck and arm pain [18] or NDI scores [11,13–15,19] between the two treatments. Potentially contributing to these discrepancies are small sample sizes and insufficient analyses. B Using recently published evidence, we performed this meta-analysis to further verify the benefits and harms of CDA for the treatment of symptomatic CDD using both traditional frequentist and Bayesian approaches. Moreover, trial sequential analysis (TSA) was applied to test the robustness of our findings and obtain more conservative estimates.

2. Materials and methods

2.1. Search strategy and study selection

This study was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines [20]. A literature search of the PubMed, EMBASE, and Cochrane Library databases was conducted independently by two researchers to identify relevant studies comparing CDA and ACDF for the treatment of symptomatic CDD. The literature search was completed on February 9, 2016. Search strategy details are presented in Table A.1. The search was not restricted by languages or date of publication. References of included studies and related meta-analyses were also manually reviewed. After reviewing the titles and abstracts, two reviewers identified potentially eligible studies, and full texts of identified articles were examined for eligibility. Any disagreement was resolved through consensus. There was no registered protocol.

2.2. Eligibility criteria

(1) Participants: Only studies enrolling participants who were adults; had symptomatic CDD (including myelopathy, radiculopathy, or disc herniation); and were unresponsive to nonoperative treatment for 6 weeks or longer were included.
(2) Interventions: The intervention in the experimental group was cervical disc arthroplasty. Prostheses used for CDA included Bryan, Kineflex|C, Mobi-C, Prestige ST, and PCM.
(3) Comparisons: The intervention in the control group was anterior cervical discectomy and fusion.
(4) Outcomes of interest were overall, NDI, and neurological success; NDI, neck and arm pain, and 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) scores; patient satisfaction; range of motion (ROM) at the operative level; secondary surgical procedures; and adverse events.
(5) Study design: Only randomized controlled trials (RCTs) were regarded as eligible for meta-analysis. Multiple publications of the same trial were excluded.

2.3. Data extraction and outcome measures

Data extraction was independently conducted by two assessors. For each included study, information including methodological details, participants, experimental and control interventions, duration of follow-up, and outcomes was extracted. Intention-to-treat data were used in the analysis of dichotomous variables. Per-protocol data were used for continuous variables. Any disagreements were resolved through consensus.

The primary outcome parameter was overall success. The secondary outcome parameters included NDI, neck and arm pain, and SF-36 PCS and SF-36 MCS scores; NDI and neurological success; patient satisfaction; ROM at the operative level; secondary surgical procedures; and adverse events.

2.4. Risk of bias assessment

Two assessors independently appraised the methodological quality of individual trials according to the Cochrane Handbook. Parameters assessed included randomization; allocation sequence concealment; blinding of patients, surgeons and outcome assessors; incomplete outcome data; outcome reported selectively; and other bias (baseline balance and funding). Each trial was scored as “low risk”, “high risk” or “unclear”.

2.5. Quality of evidence assessment

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology [21] was applied to evaluate the strength of evidence for all evaluated outcomes. On the basis of parameters such as risk of bias, inconsistency, indirectness, imprecision and publication bias, each outcome was rated as high, moderate, low, or very low quality. Two investigators conducted the appraisal independently.

2.6. Statistical analysis

Both traditional frequentist and Bayesian meta-analysis were used to synthesize evidence within random-effects models [22]. When the two methods generated different results, the Bayesian method was adopted.

E61For the frequentist method, outcomes were analyzed using Review Manager, version 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, 2014) and Stata, version 12.0 (Stata Corp, College Station, TX). Relative risk (RR) or standardized mean difference (SMD) with 95% confidence interval (CI) were estimated. The I^2 statistic was utilized to assess heterogeneity. I^2 values above 50% were considered significantly heterogeneous.

For the Bayesian approach, we utilized a random-effects hierarchical model. WinBUGS (version 1.4.3, MRC Biostatistics Unit, Cambridge, UK) was used to fit the model using Markov Chain Monte Carlo (MCMC) sampling. Posterior inferences (RR or SMD with 95% credible intervals (CrI)) were calculated by sampling from the posterior distribution of the parameters. Convergence was assessed by visually checking trace plots [23]. Following an initial burn-in of 10,000 iterations, a further 100,000 iterations were utilized to approximate the posterior quantities.