

Boselie TFM, Willems PC, et al. Arthroplasty Versus Fusion in Single-Level Cervical Degenerative Disc Disease. Spine 2013;38(17):E1096-E1107.

Design: Meta-analysis of randomized clinical trials

PICOS:

- Patient population: Skeletally mature patients with symptomatic cervical degenerative disc disease (radicular pain and/or myelopathy) who had arthroplasty or fusion at that level
 - o Patients with previous surgery at the index level or at adjacent levels were excluded
- Intervention: Cervical disc arthroplasty at one level
- Comparison: Anterior cervical discectomy and fusion (ACDF) at one level
- Outcomes: Arm and neck pain on a visual analog or numerical rating scale, neck-related functional status (NDI), patient satisfaction, neurological outcome, and global health status
 - o Radiological fusion at the operated segment (yes or no) and neurological status (unchanged/improved versus worsened) were entered as dichotomous outcomes with treatment effects reported in terms of relative risk (RR)
 - o A minimum of one year of follow-up was required for outcome estimation
 - o Some secondary outcomes were also considered: revision surgery at the operated segments, and segmental range of motion (ROM)
- Study types: Randomized controlled trials only

Study selection:

- Databases included MEDLINE, EMBASE, the Cochrane Register of Controlled Trials, the US FDA database on medical devices, and the System for Information on Grey Literature (SIGLE)
- Three authors independently performed the initial selection based on title and abstract
- Two authors independently used a standardized data extraction form to extract relevant data from selected studies
- Quality was based on the Cochrane Back Review guidelines, which estimate the risk of bias on a 12 point scale; studies with an overall score of 6 or more points were classified as having “low risk of bias”
 - o The authors noted that none of the included studies would be blinded for the important patient-reported outcomes of pain, disability, and satisfaction
- Clinical relevance of results was classified according to the pooled effect sizes
 - o Small effect meant that the differences in group means was <10% of the scale, or that the RR was >0.8 when a low RR meant that a low RR (preventing an undesirable outcome) was favorable

- Medium effect meant that the mean difference was between 10% and 20% of the scale, or that the RR for preventing an undesirable outcome was between 0.5 and 0.8
- Large effect meant that the mean difference was more than 20% of the scale, or that the RR was <0.5 (an undesirable outcome was less than half as likely to occur)
- Most of the data did not go beyond two years of follow-up
 - To avoid heterogeneity, the authors extracted one-year results when available; if these were not available, they extracted two-year results

Results:

- 9 studies with a total of 2400 patients (1262 with artificial discs, 1138 with ACDF) were included in the analysis
 - 5 studies had a low overall risk of bias; 4 had a high risk of bias, but no study had a fatal flaw in the judgment of the authors
- For arm pain, data was available from 6 studies with data on 1310 patients at 1 to 2 years
 - There was low quality evidence of a significant difference in favor of arthroplasty at 3 months and at 1-2 years; the clinical relevance was small because the effect size was <10% of the scale
- For neck pain, 6 studies with 1309 patients at 1-2 years contributed data
 - There was moderate quality evidence of a small (<10% of the scale) in favor of arthroplasty at 1-2 years
- For the Neck Disability Index, 6 studies had data for 1505 patients at 1-2 years
 - As with neck pain, there was moderate quality evidence of a small difference in favor of arthroplasty at 1-2 years
- For patient satisfaction, 2 studies with 498 patients yielded very low quality evidence that there was no difference between arthroplasty and fusion at 1-2 years
- For neurological status, defined as the percentage of patients with unchanged or improved neurological status, 3 studies with 1147 patients yielded moderate quality evidence of a small effect (RR=1.05 against fusion which equals an RR of 0.95 in favor of arthroplasty) that the artificial disc had better neurological outcomes
- For global health status on the SF-36 physical component summary at 1-2 years, 3 studies yielded moderate quality evidence of a small advantage of arthroplasty
- Sensitivity analyses were done, in which the effect sizes for analyses of all studies were compared with effect sizes for only the studies with low risk of bias; there were no important differences in these sensitivity analyses for arm and neck pain, suggesting that study quality did not greatly influence the effect size estimates from pooling the data

- For arm pain, the exclusion of studies with a high risk of bias (keeping only the studies with low risk of bias) did erase the statistical significance of the small advantage of arthroplasty
 - This is seen in Figure 4, where the horizontal line for all studies does not cross the vertical line where the effect size is 0, but the horizontal line for only the low risk of bias studies barely crosses that line
- Although reported in the discussion section rather than in the results section, the authors reported moderate quality evidence that there was a large reduction in revision surgery at the operated level for arthroplasty compared to fusion (but no evidence of a difference in adjacent level surgery)
 - There was also high quality evidence of large differences in segmental ROM for the arthroplasty groups
- Whether the secondary outcomes of revision surgery and segmental ROM resulted in better clinical or functional outcomes was not determined

Authors' conclusions:

- A clinically relevant difference between arthroplasty and fusion was not seen for any of the primary outcomes
- The overall quality of the evidence was low to moderate, largely due to lack of blinding for the patient-reported primary outcomes
 - Whether lack of blinding gave biased results after 1 to 2 years was considered debatable
- Only studies of patients without prior surgery at the operated level (or the adjacent level) were included, excluding some studies from the analysis
- At this time, neither treatment option is an obvious choice; even though there was a trend towards favorable results with arthroplasty, its use should still be limited to clinical trials

Comments:

- The methods and analyses were of high quality
- The meta-analyses were reported in a single forest plot for the 1 and 2 year data combined as if measured at a single time point
- Because it is thought that adjacent level degeneration events accrue over time, future meta-analyses should consider pooling data using person-time measurements (rates at which events occur rather than the cumulative risk of their occurring)

Assessment: High quality meta-analysis which does not yield evidence of a clinically important difference between arthroplasty and fusion for single level disc disease of the cervical spine for pain or function; there is good evidence of greater segmental range of motion after 1-2 years with arthroplasty, but its relevance to neck disability is not known.