Factors Affecting the Choice of Anterior Procedure (TDR versus ACDF) for Cervical Radiculopathy: Analysis of 3-7 Years Follow-up from 4 Randomized Controlled Trials

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Purpose: Total disc arthroplasty has been shown as equally safe and effective as ACDF for intractable radiculopathy due to cervical disc disease. The purpose of present study was to analyze the long-term outcomes from 3 to 7 years follow-up of patients participating in 4 different prospective randomized controlled trials for cervical total disc arthroplasty devices at one or two consecutive levels of the cervical spine.

Methods: Six surgeons from three different institutions within the United States enrolled 275 patients in 4 different FDA investigational device exemption clinical trials for cervical total disc arthroplasty. Although, the primary requirement for all protocols was to have 2-year follow-up, the patients were followed subsequently with annual clinic visits and radiographic studies. Thus, 255 patients have completed 3-7 years follow-up (median 45 months). The results from these long term annual visits were analyzed in an attempt to determine the factors that statistically affected the clinical outcomes in these patients. Multivariate regression analysis was performed to study the influence of various factors on the primary outcomes and possibly identify demographic characteristics that may help surgeons chose a specific procedure i.e. total disc arthroplasty versus anterior cervical fusion for individual patient.

Results: 255 patients with mean age of 50 years (range 22-68 years) completed 36-84 months follow-up (mean 45 months). There was a marginal female predominance (56.5%), 40% were habitual tobacco users, 18% had osteopenic bone mineral density scores and 30% had documented, actively treated lumbar spine disc disease at the time of cervical procedure. The randomization was 2:1 in favor of total disc arthroplasty (167 TDA versus 88 ACDF). 179 patients (70%) had single level disease and 30% were treated for two levels. The primary outcomes were visual analogue scores (VAS) for neck pain, neck disability index and detailed neurological examination. The data was collected at 6 weeks, 3, 6, 12, 24 months after the surgery and then annually. Both procedures (TDA and ACDF) provided significant reduction in the pain scores and the NDI, however, in the longer term follow-up, NDI proved to be a better outcome indicator (p = 0.01). Although long term outcomes overall were better in younger patients regardless of the index procedure (p = 0.007), nevertheless, TDA provided significantly higher incidence of better long term outcomes in patients older than 50 years (p = 0.03). Habitual tobacco use and osteopenic bone density significantly worsened the outcomes in patients with ACDF (p = 0.02 and 0.04 respectively) but did not affect the outcomes after TDA. However, presence of concurrent documented lumbar disc disease at the time of cervical procedure negatively affects the outcome in patients after TDA (p = 0.03) but does not affect the outcomes of ACDF.

Conclusions: Statistical analysis reveals that ACDF provides longer term symptom relief than TDA in patients with cervical radiculopathy who have concurrent lumbar degenerative disease. However, TDA is superior to ACDF for patients older than 50 years, habitual tobacco users and those with osteopenic bone density. Considering these demographic factors may help clinicians to choose a surgical option that may afford the best chance of longer term symptom relief.