Comparative effectiveness of surgical approaches for cervical myelopathy: 4-year quality of life assessments from the CSM-S RCT

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Introduction: The Cervical Spondylotic Myelopathy-Surgical study is a randomized prospective study conducted to compare the effectiveness of ventral versus dorsal (fusion or laminoplasty) surgery for patients with multi-level CSM. We have previously published 2 year results. Outcomes were compared 3 and 4 years after surgery.

Materials/Methods: A multi-center prospective, randomized clinical trial was conducted on patients aged 45-80 years with multi-level CSM. Patients were screened and enrolled over a 4 year period (2014-2018) from 15 sites. Patients were randomized to ventral or dorsal surgery (2:3 randomization). Dorsal surgical approach (dorsal fusion or laminoplasty) was at the discretion of surgeon and patient. Outcome assessments (SF-36, NDI, mJOA, and EQ-5D) along with patient work status were obtained pre-operatively, 3 months, 6 months, and at 1, 2, 3 and 4 years post-operatively. Complications were assessed by an independent study coordinator at 1 month and 1 year post-operatively.

Results: A total of 15 sites randomized 163 patients. 63 (38.7%) were randomized to ventral surgery and 100 (61.3%) to dorsal. Average age was 62.2 years and 49% were male. Baseline characteristics were comparable between ventral fusion, dorsal fusion, and laminoplasty groups. We conducted a planned analysis of patients as treated. 66 patients ultimately underwent ventral fusion (VF) and 97 (69 dorsal fusion (DF) and 28 dorsal laminoplasty (DL)) underwent dorsal surgery. Patients, regardless of strategy, demonstrated significant improvements in NDI and mJOA over a four year period post-operatively. DL was associated with the lowest complication rate 10.7% vs. 29.0% (DF) vs. 47.0% (VF) (P=0.002). As randomized, there were no significant differences in SF36-PCS at 2 years between ventral and dorsal surgery. At three years (similar to what was reported previously from 2 year data), DL has superior outcomes in primary outcome SF-36 PCS (9.1) when compared with VF (3.9; P<0.001) and DF (5.0; P=0.004). Moreover at 4 years, DL had superior outcomes in primary outcome SF-36 PCS (10.8) when compared with VF (3.3; P=0.001) and DF (5.4; P=0.001). At both 3 and 4 years, DL also had superior EQ-5D scores [0.21 (3 years), 0.22 (4 years)] when compared with VF [0.10; P=0.001 (3 years), 0.10; P=0.01 (4 years)] and DL had superior EQ-5D scores compared with DF [0.12; P=0.001 (3 years), 0.12; P=0.001 (4 years)].

Conclusion: Patients undergoing surgery for CSM demonstrate improved overall quality of life. In this trial where equipoise was verified, the superior improvement observed at 1 and 2 years in health-related quality of life following dorsal laminoplasty (as selected by surgeon) for CSM was maintained over 4 years.

Figures

Figure 1. Trajectory of change in SF-36 PCS score from 3 months through 4 years for patients by treatment strategy. Dorsal laminoplasty shows sustained improvement over 4 years compared to ventral fusion and dorsal fusion.