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100. Intraocular Pressure in Lumbar Spine Fusion Patients – A Randomized, Prospective Study

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Introduction: Ischemic optic neuropathy (ION) resulting in visual loss is a rare but devastating complication in spine surgery. Procedure time, blood loss, prone position and systemic factors may contribute to the risk of perioperative blindness. Elevated intraocular pressure (IOP) results in decreased perfusion and possibly ION. We evaluated the effect of head positioning on IOP in lumbar spine fusion patients.

Methods: Surgeries were performed on 52 patients at one institution. Inclusion criteria were lumbar spine fusion in patients 18-80 years old. Exclusion criteria included eye disease or injury, history of cervical stenosis, neck pain, trauma or current neoplasm. The control group had the head in neutral position with the face parallel to the level operating room table and the experimental group had the neck extended so the face had an angle of inclination of 10° with the table. All patients were managed with Gardner-Wells tongs and ten pounds of traction on a Jackson table. Using an applanation tonometer, one author made all IOP measurements in pre-operative holding, supine after anesthetic induction, prone after positioning on the table and at regular intervals throughout the case. IOP measurements were recorded with respective time points and corresponding blood pressure and CO2 values. Independent variables included age, duration of procedure, blood loss, type/amount of fluid replacement, blood pressure, PCO2, gender and head position.

Results: Data were analyzed using ANOVA for categorical risk factors and with regression analysis for continuous risk factors. Mean values for IOP measurements in the prone position were statistically significantly lower in the 10° elevated group versus the head-neutral group (p=0.0014). No patient sustained visual loss or any cervical spine related complications.

Conclusion: Ten degree elevation of the head in the prone position for adult lumbar spine fusion patients resulted in statistically significantly lower IOP measurements compared to controls. As lower IOP correlates with increased optic nerve perfusion, this positioning intervention could mitigate the risk of perioperative blindness in spine surgery patients in the prone position.

101. Costs of Cervical Disc Replacement versus Anterior Cervical Discectomy and Fusion for Treatment of Single-Level Cervical Disc Disease: An Analysis of the Blue Health Intelligence Database for Acute and Long-Term Costs and Complications

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Introduction: The purpose of this study was to determine the reoperation rate, adverse event rate, as well as the direct and follow-on costs of cervical disc arthroplasty (CDA) compared to anterior cervical discectomy and fusion (ACDF) in a "real world" population of patients with single-level symptomatic cervical disc disease.

Methods: This was a retrospective, case-controlled study of a prospectively collected database of actual insurance industry allowed amounts (costs) and outcomes for patients age 18-60, who were continuously enrolled in one of 18 BlueCross BlueShield Association plans contributing data to the Blue Health Intelligence (BHI) claims database. Inclusion criteria were all patients who were treated surgically with either CDA or ACDF between January 2008 and December 2009 for single-level cervical pathology, who had pre-surgery claims reflecting at least six weeks of conservative care, without claims history of prior surgery.

Results: There were 6,962 patients who met inclusion criteria, including 6,635 ACDF patients and 327 CDA patients. There were no statistically significant differences in the incidence of comorbidity between groups (ACDF 24.99% versus CDA 20.8%, p=0.0884 Fisher's Exact test). Patient data was assessed for continuously enrolled patients, with post-operative claims data available as long-term as 48 months for approximately 23% of ACDF patients, and 24% of CDA patients. The mean follow-up was 25 months in both groups (p=0.7).

In the acute term, there was no statistically significant difference in pain events (p=0.17) or readmission rates at 7, 30, or 90 days between groups (p>0.05). However, the mean total costs for the index operation and 90-day post-operative window were significantly reduced in the CDA patients ($22,761 versus $25,029, p=0.0086)

By 24 months post-operative, there was a statistically significant increase in mechanical complications (0.17% versus 0%) in the ACDF patients versus CDA patients. During the same follow-up period, there was a statistically significant increase in all costs for ACDF patients (CDA $34,979.28 versus ACDF $39,820.24, p=0.0008). By 36 months post-operative, the long-term relative rate of occurrence of cervical re-surgery events following ACDF surgery (10.5%) was approximately twice that of the CDA group (5.7%) (Hazard ratio, p=0.0214).

Conclusion: Patients who undergo cervical disc arthroplasty for single-level degenerative disease have lower readmission rates, fewer mechanical complications, less index surgery and total future costs, and lower reoperation rates compared to those treated with ACDF. Excluding the cost of the index procedure, CDA is effective in reducing the monthly cost of care compared to ACDF, over an average of 2 years post-surgery. Patients with medical comorbidities in both groups had increased rates of readmission and increased costs compared to patients without comorbidities.

102. Laminoplasty vs Laminectomy and Fusion to Treat Cervical Spondylotic Myelopathy: Outcomes of the Prospective Multicenter AOSpine International CSM Study

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Introduction: Recent studies conducted in North America have demonstrated benefits of surgical treatment for symptomatic CSM. However, differences in pathology, comorbidities, treatment approaches and cultural response to treatment may affect the generalizability of these findings at the global level.

Methods: Patients receiving surgery for clinically symptomatic CSM were enrolled in a prospective multicenter, cohort study which is continuing to accrue subjects at 16 sites in Europe, Asia, North and South America. Subjects included were a part of a larger ongoing prospective observational study that has enrolled 492 subjects with CSM involving 16 clinical sites in Europe, Asia, North and South America. Of those, 108 received laminectomy and fusion; 66 received laminoplasty. The choice of surgical approach was at the discretion of the surgeon. Outcome measures were mJOA, the Nurick scale, NDI and the SF36 PCS and MCS Component Scores.

Results: Average age was 60.2 years (SD 10.8), 29.8% were female. Subjects threated with laminectomy and fusion had more levels operated (5.0 vs. 4.4, P<.01), shorter length of stay (7.7 vs. 15.7 days, P < .01) and, less severe neurologic impairment measured by mJOA (12.6 vs. 11.2, P < .01). There were no differences in age, and baseline NDI, SF36v2 PCS and SF36v2 MCS. At 12 month follow-up, there were no differences in neurologic and functional outcomes for laminoplasty compared to laminectomy and fusion; mJOA (3.0 and 2.3, respectively, P=0.15). Moreover, there were no differences in NDI (13.3 and 12.0, respectively, P=0.71), SF-36v2 PCS (8.5 and 7.7, respectively, P=0.66) and SF-36v2 MCS (7.9 and 6.9, respectively, P=0.56).

Conclusions: Patients undergoing laminectomy and fusion and laminoplasty surgery for CSM show similar improvements in generic and disease specific outcome measures allowing for baseline differences in clinical presentation between the two groups of patients. Longer term follow-up will be required to determine whether any differences in outcome between the two forms of treatment emerge.

103. A Prospective, Multi-Center Assessment of the Best Versus Worst Clinical Outcomes for Adult Spinal Deformity (ASD) Surgery

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Introduction: Average clinical outcomes are improved with surgery for selected ASD patients, but these outcomes span a broad range. Our objective was to compare ASD patients with best vs worst clinical outcomes to identify distinguishing factors.

Methods: Multicenter, prospective study of consecutive ASD patients treated operatively. Inclusion criteria included: age>18yr, ASD and min 2yr follow-up. Best vs worst outcomes patients were compared separately based on SRS-22 and ODI. Only those with BL SRS-22<3.5 or ODI>30 were included to minimize floor effect. Best and worst outcomes were defined for SRS-22 (>4.5 and <2.5) and ODI (<15 and >50).

Results: Of 227 patients, 187 had SRS-22<3.5 (25 best and 27 worst outcomes) and 162 had ODI>30 (43 best and 51 worst outcomes). Based on SRS-22, compared with best outcomes patients, those with worst outcomes had greater BL SRS-22 (p<0.0001), higher prevalence of BL depression (p<0.001), greater comorbidities (p=0.012), greater prevalence of prior surgery (p=0.007), higher complication rate (p=0.012) and worse BL deformity (SVA [p=0.045], PI-LL mismatch [p=0.034]). The best-fit multivariate model for SRS-22 included BL SRS-22 (p=0.033), BL depression (p=0.012) and complications (p=0.030). Based on ODI, compared with best outcomes patients, those with worst outcomes had greater BL ODI (p<0.001), greater BL BMI (p=0.002), higher prevalence of BL depression (p<0.028), greater BL SVA (p=0.016), higher complication rate (p=0.02) and greater 2yr SVA (p<0.001) and PI-LL mismatch (p=0.042). The best-fit multivariate model for ODI included BL ODI (p<0.001), 2yr SVA (p=0.014) and BL BMI (p=0.037). Age did not distinguish best vs worst outcomes for SRS-22 or ODI (p>0.1).

Conclusions: Factors distinguishing best vs worst outcomes for ASD surgery included several patient factors (BL depression, BMI, comorbidities and disability), as well as residual deformity (2yr SVA) and complications. These findings suggest factors that may warrant further attention in order to achieve optimal surgical outcomes for ASD.

Mayfield Basic Science Award

104. Dual-gene Engineered Human Neural Stem Cells for the Targeted Treatment of Experimental Spinal Cord Gliomas

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Introduction: There is no satisfactory treatment for malignant spinal cord gliomas (SCG). We used human neural stem cells (hNSCs), which possess the ability to track tumor cells, and engineered them to express enzymes for conversion of non-toxic, systemically administered pro-drugs into active local chemotherapeutic agents.

Methods: F3-hNSCs were designed to express two metabolic genes (F3.CD-TK: cytosine deaminase and thymidine kinase) that convert benign 5-fluorocytosine(5-FC) and ganciclovir (GCV) into oncolytic 5-FU and GCV-triphosphate. Immunodeficient RNU rats received injection of 10,000 G55 human glioblastoma cells at the C6 level, followed 7 days later by administration of F3.CD-TK or control cells (F3.CD or F3 debris) at 1mm rostral and caudal to the tumor. 5-FC and GCV were administered by serial intraperitoneal injection. The primary endpoint was survival, and secondary endpoints included tumor growth and autonomic function.

Results: Rats (n=6) treated with F3.CD-TK plus 5-FC and GCV demonstrated increased survival (mean: 35.6 ± 12.1 days; p less than 0.05) relative to controls receiving either F3.CD (20.8 ± 3.4 days) or cell debris (19.8 ± 4.0 days). The speed of tumor growth was slower in the F3.CD-TK group (0.573 ± 0.11 mm3/day) compared to cell debris controls (0.941± 0.02 mm3/day; p less than 0.05). Pathological examination confirmed that F3-hNSCs migrated into the tumor mass and were in contact with glioma cells.

Conclusions: A novel approach of dual gene-altered hNSCs slowed the growth of SCG and increased survival, relative to control treatments. Our approach may offer a new therapy for spinal cord gliomas that can be used synergistically with other modalities.