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Survivorship Analysis of Interspinous Spacer for Treatment of Lumbar Spinal Stenosis and Disc Herniation

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Object: Recently, interspinous spacers have been introduced for the surgery of degenerative lumbar disc diseases. Several studies reported clinical or radiological results of interspinous spacers for degenerative lumbar disc diseases. However, to our best knowledge, there has been no study to investigate the survivorship of interspinous spacers. DIAM[®] is a relatively new interspinous spacer designed for surgery of degenerative lumbar disc diseases. The authors, therefore, performed the current study to investigate the survivorship of DIAM[®] implantation for primary lumbar spinal stenosis or disc herniation and to determine risk factors for revision surgery.

Methods: Between February 2005 and May 2009, 150 consecutive patients underwent decompressive surgery (laminectomy or discectomy) and DIAM[®] implantation for primary lumbar spinal stenosis or disc herniation. Characteristics of the 150 patients (84 male, 66 female) included: mean age at the time of surgery, 46.5 years (range, 20 - 73 years); mean duration of follow-up, 24.2 months (range, 1 - 48 months); 96 spinal stenosis and 54 disc herniation; 146 one-level (115 L4-5, 31 L5-S1) and 4 two-levels (L4-5 and L5-S1 levels). Revision surgery due to any reasons of the DIAM[®] implantation level was defined as failure and used as the end point for determining survivorship. Cumulative survival rate of DIAM[®] implantation was determined via Kaplan-Meier analysis, with univariate comparisons between variables through the Log-Rank test. Cox regression model was used for multivariate analysis.

Results: During a 4-year follow-up, 7 (2 male, 5 female) out of 150 patients underwent revision surgery at the DIAM[®] implantation level, giving a revision rate of 4.7%. The mean time between primary and revision surgeries was 13.4 months (range, 2-29 months). In Kaplan-Meier analysis, the cumulative survival rate was predicted to be 92% (8% of revision rate) at 4 years after the operation. The survival rate of DIAM[®] implantation at L4-5 level ($p = 0.002$) and one-level ($p = 0.01$) were statistically higher compared with those of DIAM[®] implantation at L5-S1 level and two-levels, respectively. However, gender ($p = 0.16$), age ($p = 0.41$), and type of disease ($p = 0.67$) did not significantly affect the survival rate of DIAM[®] implantation, respectively. In multivariate Cox regression model, DIAM[®] implantation at L5-S1 level (Hazard ratio [HR] = 10.3; 95% Confidential interval [CI] = 1.7 - 63.0; $p = 0.01$) and two-levels (HR = 10.4; 95% CI = 1.2 - 90.2; $p = 0.04$) were significantly correlated with risk of revision surgery, which were consistent with results of univariate analysis.

Conclusions: The current results suggest that 8% of the patients who has DIAM[®] implantation for primary lumbar spinal stenosis or disc herniation undergo revision surgery at the same operation level within 4 years after the operation. Especially, DIAM[®] implantation at L5-S1 level and two-levels appear to be risk factors for revision surgery.