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Bone-anchored annular closure following lumbar discectomy reduces the risk of complications and reoperations within 90 days of discharge

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Abstract

Purpose: The purpose of this study was to evaluate perioperative complications of lumbar discectomy with or without bone-anchored annular closure device (ACD) implant in patients at high risk of recurrent disc herniation.

Methods: This was a post hoc analysis of a randomized controlled trial that compared outcomes of lumbar discectomy with or without additional placement of an ACD. Patients presented with imaging evidence of lumbar disc herniation and radicular pain that was unresponsive to conservative care. Randomization occurred intraoperatively following discectomy completion and confirmation of annular defect width ≥6 mm. Main outcomes included serious adverse events (SAEs) from any cause, device- or procedure-related SAEs, and reoperations at the index level. The perioperative period included all outcomes occurring between the day of surgery and 90 days following hospital discharge.

Results: Analyses were performed on a modified intention-to-treat population consisting of 272 patients treated with ACD and 278 patients treated with lumbar discectomy only (controls). Mean patient age was 44 years, 59% were men, and mean body mass index was 26 kg/m2. Baseline patient characteristics and operative outcomes were comparable between groups. The risks of all-cause SAE (9.7% vs 16.3%, p=0.056), device- or procedure-related SAE (4.5% vs 10.2%, p=0.02), and index-level reoperation (1.9% vs 5.4%, p=0.03) were lower with ACD vs controls. In multivariable logistic regression, control group assignment and female gender were independently associated with higher risk of device- or procedure-related SAE and index-level reoperation, respectively.

Conclusions: Analyses were performed on a modified intention-to-treat population consisting of 272 patients treated with ACD and 278 patients treated with lumbar discectomy only (controls). Mean patient age was 44 years, 59% were men, and mean body mass index was 26 kg/m2. Baseline patient characteristics and operative outcomes were comparable between groups. The risks of all-cause SAE (9.7% vs 16.3%, p=0.056), device- or procedure-related SAE (4.5% vs 10.2%, p=0.02), and index-level reoperation (1.9% vs 5.4%, p=0.03) were lower with ACD vs controls. In multivariable logistic regression, control group assignment and female gender were independently associated with higher risk of device- or procedure-related SAE and index-level reoperation, respectively.

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Reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large anular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

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