PUBLICATION ABSTRACT

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Three-year results from a randomized trial of lumbar discectomy with annulus fibrosus occlusion in patients at high risk for reherniation

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Abstract

Background: A larger defect in the annulus fibrosus following lumbar discectomy is a well-known risk factor for reherniation. Procedures intended to prevent reherniation by sealing or occluding the annular defect warrant study in high-risk patients. This study sought to determine 3-year results of lumbar discectomy with a bone-anchored annular closure device (ACD) or lumbar discectomy only (controls) in patients at high risk for reherniation.

Methods: This multicenter randomized trial enrolled patients with sciatica due to lumbar intervertebral disc herniation who failed conservative treatment. Patients with large annular defects after lumbar limited microdiscectomy were intraoperatively randomly assigned to receive ACD or control. Clinical and imaging follow-up was performed at routine intervals over 3 years. Main outcomes included rate of reherniations, reoperations, and endplate changes; leg and back pain scores on a visual analogue scale; Oswestry Disability Index (ODI); Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36; and adverse events adjudicated by a data safety monitoring board.

Results: Among 554 randomized patients, the modified intent-to-treat population consisted of 272 patients in which ACD implantation was attempted and 278 receiving control; device implantation was not attempted in 4 patients assigned to ACD. Outcomes at 3 years favored ACD for symptomatic reherniation (14.8% vs. 29.5%; $P < 0.001$), reoperation (11.0% vs. 19.3%; $P = 0.007$), leg pain (21 vs. 30; $P < 0.01$), back pain (23 vs. 30; $P = 0.01$), ODI (18 vs. 23; $P = 0.02$), PCS (47 vs. 44; $P < 0.01$), and MCS (52 vs. 49; $P < 0.01$). The frequency of all-cause serious adverse events was comparable between groups (42.3% vs. 44.5%; $P = 0.61$).

Conclusions: The addition of a bone-anchored ACD in patients with large annular defects following lumbar discectomy reduces the risk of reherniation and reoperation, and has a similar safety profile over 3-year follow-up compared with lumbar limited discectomy only.

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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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