BARRICAID®

Annular closure device lowers reoperation risk 4 years after lumbar discectomy

Medical Devices: Evidence and Research 2019: 12 327-335
https://doi.org/10.2147/MDER.S220151
D Nanda, MP Arts, LE Miller, H-P Köhler, JM Perrin, C Flüh, P Vajkoczy

Abstract

Objective: To determine whether implanting an annular closure device (ACD) following a lumbar discectomy procedure in patients with large defects in the annulus fibrosus lowers the risk of reoperation after 4 years.

Methods: In a multicenter randomized trial, patients with large annular defects following single-level lumbar discectomy were intraoperatively randomized to additionally receive an ACD or no treatment (Controls). Clinical and imaging follow-up were performed at routine intervals over 4 years of follow-up. Main outcomes included reoperations at the treated lumbar level, leg pain scores on a visual analog scale, Oswestry Disability Index (ODI), and Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36 questionnaire.

Results: Among 550 patients (ACD 272, Control 278), the risk of reoperation over 4 years was 14.4% with ACD and 21.1% with Controls (P=0.03). The reduction in reoperation risk with ACD was not significantly influenced by patient age (P=0.51), sex (P=0.34), body mass index (P=0.21), smoking status (P=0.85), level of herniation (P=0.26), leg pain severity at baseline (P=0.90), or ODI at baseline (P=0.54). All patient-reported outcomes improved in each group from baseline to 4 years (all P<0.001). The percentage of patients who achieved the minimal clinically important difference without a reoperation was proportionally higher in the ACD group compared to Controls for leg pain (P=0.07), ODI (P=0.10), PCS (P=0.02), and MCS (P=0.06).

Conclusions: The addition of a bone-anchored ACD following lumbar discectomy in patients with large post-surgical annular defects reduces the risk of reoperation and provides better long-term pain and disability relief over 4 years compared to lumbar discectomy only.

This article contains off-label use information. Please use medical discretion when reviewing this article.
Barricaid is approved for the following indications for use:
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.

Financial disclosure:
One or more authors have received financial compensation from Intrinsic Therapeutics.
Full financial disclosures can be found in the respective manuscript.

WARNING: This product has labeling limitations. See package insert for additional warnings, precautions and possible adverse effects. **CAUTION:** USA law restricts this device to sale by or on the order of physician. All medical devices have associated risks. Please refer to the package insert and other labeling for a complete list of indications, contraindications,