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Challenges in the analysis of longitudinal pain data: Practical lessons from a randomized trial of annular closure in lumbar disc surgery

Pain Research and Treatment Volume 2019, Article ID 3498603, 6 pages
https://doi.org/10.1155/2019/3498603
GJ Bouma, M Barth, LE Miller, S Eustacchio, C Flüh, R Bostelmann, S Jadik

Abstract

Purpose: To analyze leg pain severity data from a randomized controlled trial (RCT) of lumbar disc surgery using integrated approaches that adjust pain scores collected at scheduled follow-up visits for confounding clinical events occurring between visits.

Methods: Data were derived from an RCT of a bone-anchored annular closure device (ACD) following lumbar discectomy versus lumbar discectomy alone (Control) in patients with large postsurgical annular defects. Leg pain was recorded on a 0 to 100 scale at 6 weeks, 3 months, 6 months, 1 year, and 2 years of follow-up. Patients with pain reduction ≥20 points relative to baseline were considered responders. Unadjusted analyses utilized pain scores reported at follow-up visits. Since symptomatic reherniation signifies clinical failure of lumbar discectomy, integrated analyses adjusted pain scores following a symptomatic reherniation by baseline observation carried forward for continuous data or classification as nonresponders for categorical data.

Results: Among 550 patients (272 ACD, 278 Control), symptomatic reherniation occurred in 10.3% of ACD patients and in 21.9% of controls ($p < 0.001$) through 2 years. There was no difference in leg pain scores at the 2-year visit between ACD and controls (12 versus 14; $p = 0.33$) in unadjusted analyses, but statistically significant differences favoring ACD (19 versus 29; $p < 0.001$) in integrated analyses. Unadjusted nonresponder rates were 6.0% with ACD and 6.7% with controls ($p = 0.89$), but 15.7% and 27.8% ($p = 0.001$) in integrated analyses. The probability of nonresponse was 16.4% with ACD and 18.3% with controls ($p = 0.51$) in unadjusted analysis, and 23.7% and 31.2% ($p = 0.04$) in integrated analyses.

Conclusions: In an RCT of lumbar disc surgery, an integrated analysis of pain severity that adjusted for the confounding effects of clinical failures occurring between follow-up visits resulted in different conclusions compared to an unadjusted analysis of pain scores reported at follow-up visits only.

Intrinsic Therapeutics, Inc.
30 Commerce Way, Woburn, MA 01801 USA

info@barricaid.com
www.barricaid.com

t: +1 781 932 0222

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