

Abstract [1682]

Title:

Foraminotomy or anterior cervical discectomy: 1-year randomized trial results (FACET)

Background:

In patients with cervical radiculopathy due to foraminal nerve root compression, the choice of surgical treatment is controversial.

Research question:

Is posterior cervical foraminotomy (PCF) noninferior to anterior cervical discectomy with fusion (ACDF) after 1-year of follow-up?

Design:

This multicenter, noninferiority, randomized trial compared PCF to ACDF in patients with one-sided, single-level cervical foraminal radiculopathy, from 9 hospitals in the Netherlands.

Methods:

The primary outcome was the proportion of successful outcome on the modified Odom criteria, with a noninferiority margin of 10%. Secondary outcomes were change in arm and neck pain, disability, workability, quality of life, satisfaction with surgery, complications, and reoperation within 1 year. Intention-to-treat and per-protocol analyses were performed with a two-proportion z-test at a one-sided 0.05 significance level.

Results:

In total, 265 patients were randomly assigned to either PCF (n=132) or ACDF (n=133) surgery. At 1-year follow-up, the proportion of successful patients was 0.88 in PCF and 0.76 in ACDF (difference, -0.11 percentage points; one-sided 95% confidence interval [CI], -0.02). As the point estimate and CI of the difference were 21% and 12% lower, respectively, than the noninferiority margin; PCF was deemed noninferior to ACDF. Sensitivity analyses confirmed this result. All secondary outcomes had two-sided 90% CIs clustered around zero with small between-group differences.

Conclusion:

In patients with cervical radiculopathy due to foraminal nerve root compression, PCF was noninferior to ACDF regarding the clinical effectiveness at 1-year follow-up.