Yale University Open Data Access

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The Yale University Open Data Access (YODA) Project's mission is to advocate for the responsible sharing of clinical research data, open science, and research transparency. The Project is committed to supporting research focused on improving the health of patients and informing science and public health. The YODA Project can only improve with your feedback. Please share your comments and ideas.

The YODA Project seeks mutually beneficial partnerships with Data Holders, promoting independence, responsible conduct of research, good stewardship of data, and the generation of knowledge in the best interest of society. To participate, each Data Holder must transfer full jurisdiction over data access to the YODA Project.

The aim of a study was to determine if patients with degenerative disc disease who achieve radiographic fusion after single-level lumbar interbody fusion have better clinical outcomes than patients with radiographic pseudarthrosis at 12 and 24 months postoperative.

Individual patient-level data of 4 randomized controlled trials (RCTs) were obtained from the Yale University Open Data Access Project project and analyzed. Clinical outcomes (Oswestry Disability Index [ODI]; Numeric Rating Scales [NRSs] for back and leg pain) were compared between patients with radiographically confirmed fusion and those with radiographic nonunion 1 and 2 years postoperative. The results of each study were first analyzed separately, and then were pooled by metaanalysis. The GRADE approach was applied to evaluate the level of evidence.

A total of 496 patients with clinical and radiographic data at 1- and 2-year follow-ups were identified. Of these, 5.5% (95% confidence interval: 3.7; 8.3) had radiographic nonunion which did not require reoperation. Patients with fusion had better improvements in ODI ($P<0.001$) and NRS back pain scores ($P<0.001$). The overall percentage of fused patients with ODI and NRS back pain scores that exceeded the criteria for minimal clinically important differences was also significantly higher than that of patients with nonunion (ODI, odds ratio [OR] = 2.7, $P=0.019$; NRS back pain, OR = 3.5, $P=0.033$). The predictive values of fusion for clinical outcomes, however, were poor, with low specificity and low negative predictive values.

The presence of radiographic fusion is clinically significant, as patients with fusion had better clinical outcomes at 1 and 2 years postoperative than those with nonunion; however, patient-centered clinical outcomes should also be taken into consideration as independent, complimentary variables when assessing treatment success [1)].

1)
Noshchenko A, Lindley EM, Burger EL, Cain CM, Patel VV. What Is the Clinical Relevance of Radiographic Nonunion After Single-Level Lumbar Interbody Arthrodesis in Degenerative Disc Disease?: A Meta-Analysis of the YODA Project Database. Spine (Phila Pa 1976). 2016 Jan;41(1):9-17. doi: 10.1097/BRS.0000000000001113. PubMed PMID: 26274529.