

**Carragee EJ, Lincoln T, et al. A Gold Standard Evaluation of the “Discogenic Pain” Diagnosis as Determined by Provocative Discography. Spine 2006;31(18):2113-2123.**

Design: prospective evaluation of the performance of a diagnostic test

Population/sample size/setting:

- 62 patients (32 men, 30 women, mean age 43) undergoing spinal fusion at the orthopedic surgery division of Stanford University
- Two cohorts were defined with different eligibility criteria
- The first cohort qualified for fusion by discography criteria
  - o Inclusion required failed conservative therapy, chronic low back pain without radicular pain, current pain episode between 6 and 24 months duration, a positive discogram at operative level and normal discogram at adjacent levels, working full time prior to onset of new pain episode and no more than 12 months of work loss
  - o Positive discogram had pain of at least 6/10 at a pressure of  $\leq 20$  psi above opening pressure with a demonstrable annular fissure to or through the posterior outer annulus, with adjacent disc having normal morphology and pain level  $\leq 2/10$  on pressurization to 100 psi
  - o Exclusion criteria were disc extrusion/sequestered herniation, symptomatic spinal stenosis, spinal deformity, positive response to a facet or S-I joint block
- Spondylolisthesis cohort qualified for fusion by radiographic criteria
  - o Eligible patients had Grade I or Grade II isthmic spondylolisthesis with or without sciatica in either the L4-L5 or the L5-S1 anatomic segment, with instability defined as  $\geq 4$  mm translation and/or  $\geq 22^\circ$  angulation on standing flexion/extension or upright/recumbent lateral films
  - o Exclusion criteria were disc extrusion or sequestered herniation with positive straight leg raise, L4-S1 motor weakness greater than trace level, or additional spine deformity
- Exclusion criteria common to both groups were workers compensation or other compensation issues, abnormal psychometric exam, additional chronic pain processes, additional occupational disabilities, and other inflammatory, infectious, or neoplastic disease of spine, pelvis, or hip

Main outcome measure

- The gold standard for the accuracy of the diagnostic test (discography vs radiographic spondylolisthesis) was success of fusion

- Both groups had a two-incision 360single-level fusion done in one operative setting, using femoral ring allograft and a buttress screw anteriorly, with pedicle screw and allograft bone posteriorly
- Success was defined in two ways, one more strict and one less strict
  - o The more strict definition of success was defined prior to the study, and required LBP pain VAS <-2, Oswestry disability <=15, with full return to usual occupational duties or equivalent, with no narcotic medication at all and no daily use of any analgesic
  - o The less strict definition was made later during the study and required a final VAS score <4 with Oswestry <30, no narcotic use, and return to at least some occupational function or equivalent
- Each group lost 2 patients to follow-up, which was done at 3, 6, 12, and 24 months; the evaluation on which the main success comparison was made was the 24 month evaluation
- Using the strict definition of success, 72% of the spondylolisthesis group achieved all criteria, compared with 27% of the “discogenic” group
- Using the less strict definition of success, 92% of the spondylolisthesis group was successful, compared with 43% of the “discogenic” group
- One patient in the spondylolisthesis group had a reoperation (for screw repositioning), and three patients in the discogenic group had reoperation (requesting instrumentation removal after fusion was complete)
- Two patients in each group had iliac vein laceration which was repaired intraoperatively without requiring transfusion

Authors’ conclusions:

- Positive discography, which is advocated as a test which identifies patients with discogenic pain, does not effectively identify patients who recover when the alleged pain generator is removed
- Spondylolisthesis, diagnosed by radiographic criteria of translation and angulation, by contrast, does identify patients likely to recover when the anatomic pain generating mechanism is surgically corrected
- It is likely that provocative discography fails to identify effectively the source of chronic low back pain in the affected disc, and that the sources of pain and dysfunction are remote from the disc, in unrecognized structural, neurophysiologic, social, and emotional factors which are the drivers of the pain process
- These remote factors, by way of contrast, are not important drivers of the pain process in patients with radiographically identified spondylolisthesis
- The usefulness of discography remains to be proven

Comments:

- The study does not fit neatly into a category; it identifies itself as a study of diagnostic tests measured against a gold standard of surgical success, but could also be considered as a cohort study in which different “exposures,” positive discography and segmental instability, lead to different outcomes of surgery
- The authors allude to a data supplement in an Appendix at ArticlePlus which is not available at the journal website; the first author has been contacted by e-mail for the supplement
- The section about the positive predictive value of discography, which depends on the data supplement, is uninterpretable until the information is available
- The criteria for a positive discogram are not clearly in a specific category of ISIS levels of probability (pain provocation of  $\geq 6$  rather than  $\geq 7$ , pressure  $\leq 20$  psi above opening rather than  $\leq 15$  psi), but can be interpreted as consistent with definite or highly probable ISIS discogenic pain
- In spite of the ambiguities and analytical difficulties, the study is well conceived and executed as a cohort study
  - o The exposure is clearly defined and measured
  - o The direction of potential confounding, as the authors note, would predict less favorable outcomes of fusion in the spondylolisthesis group, in whom technical difficulties of fusion would be greater than in the group with only a degenerated disc to operate on
  - o The follow-up is nearly complete
  - o The inclusion and exclusion criteria are well specified and would tend to favor the discography group, since many predictors of an unfavorable outcome (compensation claims, psychological distress) are excluded
- The study therefore warrants an assessment as high quality with respect to methodology and execution

Assessment: High quality study supporting a statement that there is good evidence that a positive discogram does not identify patients who benefit from fusion, in contrast to radiographically identified spondylolisthesis, which does identify patients likely to benefit. Only 27% of “discogenic” pain patients had successful outcomes of fusion, even when predictors of a poor outcome were excluded from surgery; 72% of spondylolisthesis patients had success with the same surgery