

Brox JI, Sorensen R, Friis A, et al. Randomized Clinical Trial of Lumbar Instrumented Fusion and Cognitive Intervention and Exercises in Patients with Chronic Low Back Pain and Disc Degeneration. Spine 2003;28:1913-1921.

Design: Randomized clinical trial

Population/sample size/setting:

- 64 patients (25 men, 39 women, mean age 43) referred from departments of orthopedics, neurosurgery, and physical medicine from all regions of Norway
- Eligible if age 25-60, at least 1 year of back pain, at least 30 points on Oswestry, degeneration at L4-L5 or L5-S1 on plain x-ray
- Excluded for widespread myofascial pain, spinal stenosis, radiculopathy, generalized degeneration on plain x-ray, previous back surgery, or somatic/psychiatric disorder preventing acceptance of either treatment arm
- Randomized to posterolateral fusion with transpedicular screws and autologous bone (n=37) or cognitive intervention and exercises (n=27)

Main outcome measures:

- Cognitive intervention consisted of a lecture describing pain receptors in discs, facets, muscles, including instruction that ordinary activity cannot harm discs, that pts can use their backs and do not need to be extra cautious
- This advice was repeated each day during exercises, which included co-contraction of abdominal muscles and lumbar multifidus, aerobics, water gymnastics, and individual exercises
- Supervised instruction was 1 week, followed by 2 weeks at home, followed by 2 more weeks of supervised instruction (approximately 25 hours per week)
- Oswestry scores improved in both groups at 1 year follow-up, without significant difference between groups
- Both groups improved equally in most secondary outcomes, including general function scores, back pain, use of medication, emotional distress, life satisfaction, patients' overall rating of success of treatment, and blinded independent observer's assessment of success of treatment
- Fusion group did better than cognitive group in lower limb pain (improved in fusion group, but unchanged in cognitive group)
- Cognitive group did better than fusion group in fear-avoidance of physical activity, fear-avoidance of work, and fingertip-floor distance
- Few patients in either group were working at end of study (22% of fusion and 33% of cognitive/exercise)
- Complication of surgery in 6 patients: 2 wound infections, 2 bleedings, 1 dural tear, 1 venous thrombosis, but no late complications

Authors' conclusions:

- The difference between fusion surgery and cognitive rehabilitation with exercise was not clinically important or significant
- Most cases of chronic LBP can be managed with cognitive intervention and exercise

Comments:

- Even though both groups improved on several scales of symptoms and self-rated function, this did not translate into successful return to work
- Surgery group all received posterolateral fusion; comparison with anterior fusion has not been done
- Some analytical methods remain unclear: Table 2 shows p values for secondary measures and notes that the Bonferroni correction can be obtained by multiplying by 12, but in many cases this would yield p values greater than 1, which is not possible
- Standard deviations in Oswestry scores in Table 2 (11-19.6) were slightly greater than the standard deviations assumed in the planning of the study (10), meaning that power of study is less than sample size anticipated
- The intervention appears to have been predominantly informative about the physiology of back pain rather than psychotherapeutic in nature

Assessment: Adequate for evidence that educational information combined with individualized exercise may be comparable in effectiveness to posterolateral fusion for chronic LBP