
Design. Randomized Controlled Trial

Population/sample size/setting:
- 323 patients (48% women, mean age 41) with low back pain (LBP) with LBP persisting 7 days after an initial physician visit, treated at the Group Health Cooperative of Puget Sound in Seattle
- Exclusion criteria were sciatica, systemic cause of pain, osteoporosis, fracture, history of back surgery, spondylolisthesis, coagulopathy, concurrent illness, pregnancy, compensation/litigation claim, or current use of chiropractic or physical therapy

Main outcome measures:
- Randomized to PT (McKenzie exercises but no modalities provided, n=133), chiropractic (DC, n=122), or back pain booklet (n=66); all PT/DC visits to be completed within 1 month
  - McKenzie practitioners were credentialed by the McKenzie Institute, and were permitted to schedule up to 8 visits in the month following the first visit for clinical evaluation; other modalities (TENS, heat, ice, etc) were not permitted
  - Chiropractic visits entailed short-lever, high-velocity thrusts, supplemented with stretching and strengthening exercises, but not with extension exercises such as are used in the McKenzie method; as with the McKenzie practitioners, they were permitted to schedule up to 8 visits in the month following the initial evaluation
  - The booklet group was the minimal care control group; the booklet discussed causes of back pain, its prognosis, and activities for promoting recovery and avoiding recurrences
- “Bothersomeness of symptoms” score and modified Roland-Morris Disability score at baseline and at 1, 4, 12 weeks, 1 year, and 2 years were main outcomes
- These outcomes compared by analysis of covariance (ANCOVA) after square root transformation adjusted for age, age^2, SF-36 general/mental health
- Bothersomeness symptom & Roland-Morris scores were equal at baseline and 12 weeks after statistical adjustment for potential confounders
  - The bothersomeness scores before statistical adjustment were lower at 4 weeks for the McKenzie group (2.3 points) and the chiropractic group (1.9 points) than for the booklet group (3.1 points), but after adjustment, the differences between groups remained statistically significant (p=0.02) but small in size (less than the 1.5 points specified as clinically important at baseline)
- No significant difference in symptom or disability scores were reported at 1 and 2 years of follow-up
- Number of days of back-related disability similar among groups in year after treatment
- Total HMO costs nearly equal over 2 year period for DC and PT ($429 and $437 respectively), both almost 3 times booklet group costs ($153)
- In the booklet group, 18% of patients visited a health care provider for back pain during the study month, compared to 8% of the chiropractic group and 9% of the McKenzie group seeking care from providers other than those assigned

Authors’ conclusions:
- McKenzie PT and DC manipulation produce small marginal outcome advantages over booklet alone, with greatly increased costs
- It seems unwise to refer all patients with acute LBP for chiropractic care of McKenzie therapy
  - It would be ideal to identify subgroups of patients with LBP for chiropractic or McKenzie care, but such characteristics were not identified in this study

Comments:
- As with Machado 2010, the acute LBP population (especially after exclusion of patients with litigation or compensation claims) has such a favorable prognosis that it would be surprising if clinically important differences in outcome could be demonstrated
- As with Machado 2010, there are potential difficulties with floor effects in the outcomes, which at the end of treatment are close to the minimum scores on the 0-10 point scale
  - Although it is not clear that the complex analytical methods of Twisk 2009 would have produced a different analysis (given that it was published 11 years later), there remains the difficulty that when ceiling and floor effects are present, the numerical distribution of outcomes close to the floor depart from the normal distribution assumed by analysis of covariance that was used by the authors (see references in Machado critique)
- However, in contrast to Machado 2010, the cost comparisons are less affected by ceiling or floor effects, and the additional costs of chiropractic and McKenzie therapy are appreciable in a population for which spontaneous recovery is expected
- In the acute care setting of patients with uncomplicated LPB, the authors appear to have supported their conclusion that referral of all patients for chiropractic or McKenzie therapy does not produce benefits commensurate with costs

Assessment: Adequate for evidence that referral of patients in the first weeks of uncomplicated low back pain adds little to the favorable prognosis of acute LBP, but does incur considerable additional short term costs of care