induces labor, but important patient-oriented outcomes regarding the safety and effectiveness of the different routes of administration cannot be determined by this small study. Misoprostol is not yet approved for induction of labor at term in North America, and optimal doses have not been established. Until larger studies of safety, including measurements of cesarean section rate and neonatal asphyxia, are available, the currently approved methods of induction should be used. This pilot study will set the stage for further examination of misoprostol as an induction agent.

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Alternative Therapy for Low Back Pain

Cherkin DC, Deyo RA, Battie M, Street J, Barlow W. A comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain. N Engl J Med 1998; 339:1021-9.

Clinical question **What is the most effective way to manage uncomplicated low back pain: physical therapy, chiropractic manipulation, or the provision of an educational booklet?**

Background Low back pain (LBP) is common, and the costs of treatment and lost productivity are significant. While LBP is most commonly treated with rest, analgesics, or muscle relaxants, there is a lack of comparative data regarding the benefits and costs of chiropractic spinal manipulation and physical therapy.

Population studied This trial was conducted in a large staff-model health maintenance organization (HMO). Eligible subjects included patients 20 to 64 years of age with LBP who were evaluated between November 1993 and September 1995. Patients with sciatica, previous back surgery, osteoporosis, vertebral fractures, spondylolisthesis, or systemic causes of pain were excluded. Additional exclusion criteria were corticosteroid use, pregnancy, involvement in litigation or claims for compensation, or previous use of physical therapy or chiropractic manipulation.

Study design and validity This was an unblinded randomized study comparing chiropractic spinal manipulation and the McKenzie method of physical therapy. A control group only received an educational booklet. The first treatment visit was scheduled within 4 days following randomization, and subjects were allowed up to 8 additional visits at the provider's discretion. All 13 physical therapists were HMO employees trained and certified in the McKenzie method. The 4 participating chiropractors were in private practice. Patients were followed up for 2 years after randomization, and data were analyzed according to the intention-to-treat. The greatest threat to the validity and generalizability of this study was the large dropout rate. Data are only available from 8% of patients initially presenting with LBP. Also, the lack of treatment standardization resulted in a 50% greater number of visits to chiropractors than physical therapists (6.9 vs 4.6, $P < .001$). Adjunctive therapy that is currently part of standard care (ice, heat, and so forth) was discouraged. Finally, the unblinded nature of the study design may have affected the patient's overall satisfaction with treatment.

Outcomes measured Primary outcomes measured were the bothersomeness of symptoms, disability, and level of functioning at 1, 4, and 12 weeks. Patients also rated their satisfaction with treatment from "excellent" to "poor" at 1 and 4 weeks. Secondary outcomes measured included the recurrence of symptoms and the use of other ancillary health care services at 1 and 2 years. The costs of care only included the costs to the HMO and not the patients' out-of-pocket expenses.

Results Of the 3800 patients presenting with LBP, only 714 subjects (19%) met inclusion criteria. A total of 493 of these subjects (69%) were enrolled. One week after the initial physician visit, only 323 (66%) remained eligible. The mean age of the sample population was 40 years, nearly all subjects were employed, and there was equal gender distribution. The groups differed at baseline in days with restricted activity, expectations of care, bothersomeness of symptoms, and previous use of chiropractors. Pairwise comparisons of scores after adjustment revealed less severe symptoms in the chiropractic group than in the booklet group ($P = .02$), but not in the physical therapy group compared with the booklet group ($P = .06$). These differences were no longer significant after statistical adjustment for non-normal distribution. Small differences in disability were again nonexistent after correction ($P = .13$). Medication use decreased from 82% to 18% in the chiropractic group, 84% to 27% in the physical therapy group, and 77% to 32% in the booklet group ($P < .05$). The booklet group members rated their quality of care at 1 and 4 weeks as significantly lower ($P < .001$), but only 18% of them received care during this time and only 25% responded to the question. The costs of care were similar among the chiropractic ($429) and physical therapy ($437) groups, but significantly less in the booklet group ($153).

Recommendations for clinical practice **Treatment of low back pain by chiropractic manipulation or the McKenzie method of physical therapy provides few advantages over simple written information, and there is no evidence that physical therapy is better than chiropractic or vice versa. Most of the benefit appears to be related to patient satisfaction and not clinical end points. The costs per patient using these alternative methods are higher. It is reasonable for primary care physicians to treat patients with uncomplicated LBP conservatively and refer them to allied health professionals only if the standard treatment fails.**

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Therapeutic Touch and Osteoarthritis of the Knee

Gordon A, Merenstein JH, D'Amico F, et al. The effects of therapeutic touch on patients with osteoarthritis of the knee. J Fam Pract 1998; 47:271-7.

Clinical question **What effects does therapeutic touch have on pain, functioning, and general well-being in patients with osteoarthritis of the knee?**

Background Osteoarthritis is a common disease and a leading cause of disability, but our treatment options remain limited. Therapeutic touch (TT) is a form of complementary medicine in which a practitioner attempts to heal or improve many medical problems by manual manipulation of an energy field above the patient's skin. This study examines the efficacy of TT for patients with osteoarthritis of the knee.

Population studied Thirty-one patients with osteoarthritis in at least one knee were enrolled at a family practice residency office. Patients with connective tissue disease or knee replacement were excluded. Most of the enrollees were women, and the average age was 64 years to 68 years. An attempt was made to estimate severity of disease with a questionnaire and review of radiographs. The population seems similar to those in the usual family practice, but additional information about physical findings, functional status, current treatment, and comorbidities would have provided a clinical anchor for the study.

Study design and validity This single-blinded randomized controlled trial compared 3 groups: a group receiving TT, a placebo group receiving a mock TT intervention (MTT), and a group receiving no additional treatment. The TT and MTT groups received treatments weekly for 6 weeks, with outcomes measured at weeks 1, 7, and 13. Randomization was stratified by disease severity. The placebo intervention was well designed: a different practitioner, resembling the true TT provider, provided the mock treatment while focusing on a cognitive task. TT and MTT treatments were videotaped and reviewed to ensure that objective observers could not tell the difference. The analysis seems appropriate, with the exceptions that patient drop-out was not addressed and no correction was made for multiple comparisons.

In general, the study design is moderately strong. Its strengths include randomization with stratification by severity, the use of 2 different control groups, the inclusion of a wash-out period, and assessment of outcomes by both quantitative and qualitative techniques. The lack of specific detail about the TT intervention and the TT provider makes it difficult to apply the results to other settings, and the small numbers of the study reduce the statistical power for detecting clinically important confounders.

Outcomes measured Outcome measures were pain and its impact, level of functioning, and general well-being and health status as measured by the Stanford Health Assessment Questionnaire (HAQ), the West Haven-Yale Multidimensional Pain Inventory (MPI), and visual analog scales of pain and well-being. Complementary data was obtained from TT and MTT patients using in-depth qualitative interviews. Useful outcomes that were not measured include physical examination findings; changes in other medications; changes in cost; and patient satisfaction.

Results Randomization with stratification resulted in groups with similar ages, gender distribution, and disease severity; follow-up was 80%. Using the MPI, the treatment group had significantly decreased pain and improved function on 9 of the 13 scales. This improvement was paralleled by improvement in average visual analog scores for pain level and general well-being, and in the qualitative interview data. Changes in medication did not account for these changes. These improvements persisted after cessation of treatment. No improvement, however, was found in visual analog scales completed before and after each treatment or in the HAQ scale, which measures specific functional disability. Side effects were not mentioned.

Recommendations for clinical practice **This study provides fair evidence that TT can improve the pain and level of functioning in patients with osteoarthritis of the knee. The clinical significance of the changes detected by**