potential harms of patching (loss of binocular vision, inconvenience, and possibly increased pain), patching of uncomplicated corneal abrasions is not recommended. Though patients in this analysis presented primarily to emergency departments, the results should apply to primary care settings as well, since these abrasions would probably be less complicated. This study did not examine the role of antibiotics and cycloplegics in treating corneal abrasions.

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Oral Versus Vaginal Administration of Misoprostol for Labor Induction

Bennett KA, Butt K, Crane JMG, Hutchens D, Young DC. A masked randomized comparison of oral and vaginal administration of misoprostol for labor induction. Obstet Gynecol 1998; 92:4:481-6.

Clinical question **Are oral and vaginal misoprostol equally safe and effective for labor induction?**

Background There is accumulating evidence that misoprostol, a synthetic prostaglandin E_1 analog, given either vaginally or orally can effectively induce labor at a significantly lower cost than other induction agents. Excessive uterine contractions and potentially increased rates of caesarean sections and birth asphyxia remain a safety concern. Optimal dosage and route of misoprostol administration need to be determined before large and costly trials are carried out to address safety concerns.

Population studied Study subjects included pregnant women of at least 37 weeks' gestation with an indication for induction, a single live fetus, intact membranes, and cephalic presentation. Almost all of the patients were white, and all were receiving perinatal care from a Canadian referral center with an induction rate of 20%. Women younger than 18 years, with previous uterine surgery, nonreassuring fetal heart rate tracings, or contraindications to vaginal birth were excluded.

Study design and validity This was a masked randomized trial comparing 2 treatments. Eligible subjects were randomly assigned to receive a 50 µg dose of misoprostol either orally or vaginally every 4 hours until the occurrence of: a contraction frequency of 3 per 10 minutes; a nonreassuring fetal heart rate tracing; spontaneous rupture of membranes; or delivery. While identical doses of misoprostol were used in each group, the authors suggest that the vaginal route results in a threefold higher bioavailability than that of orally administered misoprostol. Both patients and clinicians were blinded to the route of administration of misoprostol through the administration of a placebo by the alternate route. Time to delivery was compared between the groups on an intention-to-treat basis.

Outcomes measured The primary outcome measured was time to vaginal birth. Secondary outcome measures included frequency of tachysystole (contraction frequency of more than 5 in a 10-minute period or 2 consecutive 10-minute periods) and hyperstimulation (exaggerated uterine response with late fetal heart rate decelerations or fetal tachycardia greater than 160 beats per minute) associated with route of administration. Fetal heart rate and uterine activity graph interpretations were done before unmasking the study groups. Maternal gastrointestinal side effects and patient satisfaction were determined through a survey. The authors also measured more significant outcomes, such as cesarean section rates and birth asphyxia, but indicated that 3400 to 5030 patients would be needed to detect a significant difference in these measures.

Results During the study period, 393 patients presented for induction; 308 were eligible. Of these, 17 patients refused enrollment and 85 patients were excluded because their attending physicians preferred alternative induction methods. Of the remaining 206 women, 104 were randomized to the oral group and 102 to the vaginal group. The authors indicate that baseline data from nonvolunteers did not differ significantly from that of the volunteers, but they did not characterize the nature of that baseline data. Follow-up was complete.

Vaginal birth occurred earlier on average in the vaginal group than in the oral group (846 minutes vs 1072 minutes, respectively; $P = .004$). There was an increased incidence of tachysystole ($P < .01$) and hyperstimulation ($P < .04$) in the vaginal group, but these differences did not reach statistical significance by the authors' conservatively preset level for secondary analysis of $P < .001$. There was an increased incidence of cesarean sections in the vaginal misoprostol group, but the study had inadequate power to determine the significance of this finding. There was no difference between groups in maternal gastrointestinal side effects and patient satisfaction.

Recommendations for clinical practice **Misoprostol given orally or vaginally effectively**

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).