peak flows, and nocturnal awakenings also showed a statistically significant difference in favor of beclomethasone.

Recommendations for clinical practice **Inhaled beclomethasone is a significantly more efficacious (and cheaper) maintenance medication for mild to moderate asthma than oral montelukast. Side effect profiles for the 2 drugs are comparable. The average healthy asthmatic patient should be given a steroid inhaler as the preferred asthma controller medication. Though not addressed in this study, montelukast may play a role in patients who have trouble using an inhaler or in addition to an inhaled steroid in severe asthmatics.**

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Treatment of *Helicobacter pylori* Infection in Functional Dyspepsia

Talley NJ, Janssens J, Lauritsen K, Racz I, Bolling-Sternevald E, and the ORCHID investigators. Eradication of *Helicobacter pylori* in functional dyspepsia: randomised double-blind placebo-controlled trial with 12-months' follow-up. BMJ 1999; 318:833-7.

Clinical question **Is *Helicobacter pylori* eradication an effective treatment for patients with functional or nonulcer dyspepsia?**

Background Dyspepsia in the absence of peptic ulcer disease is a very common condition in primary care patients. Approximately 50% of these patients have a coexistent *H pylori* infection, a rate similar to that found in the general population. Although it is known that treatment of *H pylori* is effective for patients with peptic ulcer disease, it is not clear whether this is useful in patients with functional dyspepsia alone.

Population studied Patients with upper abdominal pain for at least 3 months and normal upper endoscopy were enrolled from 40 centers in Australia, New Zealand, and Europe. Almost 90% of them were from subspecialty practices. Patients with gastroesophageal reflux disease, gastric or duodenal erosions or ulcers, malignancy, or Barrett's esophagus were excluded.

Study design and validity This is a prospective randomized double-blinded placebo-controlled trial. The 370 study patients were randomized to placebo (n = 188) or treatment with omeprazole 20 mg twice daily, amoxicillin 100 mg twice daily, and clarithromycin 500 mg twice daily (n = 182) for 1 week. *H pylori* status was determined, and 45 patients from the placebo group and 47 from the treatment group were then excluded from the analysis because they were not infected. Identical placebos were used, allowing for true double blinding. All patients entered into the study were accounted for, but the discontinuation rate was not ideal (21% of treatment group and 26% of the placebo group).

Although the study was generally well designed, there were several potential threats to validity. First, no information was given to allow comparison of patient characteristics between the 2 study groups. Second, although an intention-to-treat analysis was done, 92 patients were excluded from the analysis after randomization because they were found to be *H pylori* negative. Finally, the fact that most of the patients were from a subspecialty setting raises the question of generalizabilty to primary care. However, if any difference exists, these patients would likely have been more symptomatic than those seen in a primary care setting and perhaps more likely to improve with treatment.

Outcomes measured The primary patient-oriented outcome was "treatment success" (no or minimal dyspeptic symptoms) measured by the patient on a validated Likert scale for 1 week before the 12-month follow-up visit.

Results After 1 year, 85% of the patients in the treatment group were cured of *H pylori* infection by breath test and gastric biopsy compared with 4% in the placebo group. However, there was no difference in the rates of treatment success for dyspeptic symptoms between the 2 study groups (32% of the treatment group vs 31% of the placebo group, $P = .70$) The power of the study to detect a two-fold increase in treatment success (40% vs 20% at 1 year) was 94%. The authors also found no difference in symptoms between patients who were cured of *H pylori* infection and those with persistent infection after treatment.

Recommendations for clinical practice **Although this study found a decrease in histologically graded gastritis 1 year after treatment for *H pylori* infection, there was no difference in symptoms perceived by the patient. In patients with dyspepsia and proven *H pylori* infection, antibiotic therapy is ineffective. However, eradication of *H pylori* in patients with ulcer has been shown to prevent recurrence. Since we do not usually know which dyspeptic patients have ulcers, the following approaches are reasonable: (1) assume that none have ulcers and treat them symptomatically with H_2 blockers or proton pump inhibitors and only evaluate the nonresponders or those with recurrent symptoms; or (2) give a trial of *H pylori* therapy and assume**

those who do not respond simply have dyspepsia and treat them symptomatically.

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Acupuncture in the Treatment of Fibromyalgia

Berman BM, Ezzo J, Hadhazy V, Swyers JP. Is acupuncture effective in the treatment of fibromyalgia? J Fam Pract 1999; 48:213-8.

Clinical question **Is acupuncture effective in the treatment of fibromyalgia?**

Background Fibromyalgia is a common cause of chronic diffuse pain. The syndrome is most common in women aged 20 to 60 years, with a prevalence of between 2% and 5%. At least two thirds of patients with fibromyalgia use at least 1 complementary modality of treatment, such as herbal supplements or acupuncture. Tricyclic antidepressants have been shown to have limited benefit in fibromyalgia; most complimentary modalities, however, have not been subjected to rigorous clinical testing. The authors performed a systematic review to evaluate the benefit of acupuncture for patients with fibromyalgia.

Population studied Seven studies were identified and summarized. The average patient age ranged from 39 to 51 years, with women comprising the majority of patients. Most patients had previous treatment with tricyclic antidepressants. The mean disease duration varied from 6 and 12 years.

Study design and validity This was a well-executed systematic review of the literature, with an emphasis on randomized controlled trials and prospective cohort studies. The authors used a wide variety of conventional, specialized, and alternative medical databases to identify studies reporting the effect of acupuncture on fibromyalgia. The methodologic quality of the randomized and cohort studies was evaluated by using a predefined validated scoring system. The authors identified 7 studies, 3 of which were randomized controlled trials. One of the randomized controlled trials received a high-quality score; those investigators had performed sham acupuncture in the control group to reduce bias. The other 2 lower-quality randomized controlled trials did not adequately blind patients or report their randomization process. None of the 3 prospective cohort studies controlled for potential confounding factors. The retrospective cohort study was considered the least suitable because of its nonblinded survey format.

Outcomes measured In the one high-quality study, pain threshold, number of analgesic tablets taken during the previous week, regional pain score, visual analog pain scale, sleep quality, morning stiffness, and patients' and physicians' global subjective ratings were all used as end points. Outcomes in the 6 other studies included pain relief, range of motion, anxiety, depression, and even serum substance P.

Results In the one high-quality study, Deluze and colleagues[1] randomized patients with fibromyalgia to either real or sham electroacupuncture. Exclusion criteria covered severe concomitant disease, opioid use, or past acupuncture treatments. Six sessions of electroacupuncture were scheduled during which patients had needles inserted along common anatomic points. In control patients, researchers placed needles approximately 20 mm away from the predesignated sites and used a lower electrical current. This study found significant differences in pain relief, pain threshold, morning stiffness, and global subjective ratings of both patients and physicians. An intention-to-treat analysis showed that 42% of patients had no benefit; 39% had satisfactory benefit; and 19% had an unexpectedly large benefit. Only 3% of the sham group reported such an unexpectedly large benefit. This study evaluated patients immediately after the 3-week course of therapy and lacked longer-term follow-up. It was noted that 8% of the withdrawals from the trial were because of an exacerbation of fibromyalgia brought on by the acupuncture. The other trials and cohort studies, while limited, were consistent with these findings.

Recommendations for clinical practice **This systematic clinical review summarized all the studies that attempted to assess the use of acupuncture in fibromyalgia. They identified one high-quality study that found short-term clinical benefit to acupuncture, but there is no information on outcomes after 3 weeks. The other studies, while consistently reporting a benefit to acupuncture, were inadequate for drawing meaningful clinical conclusions. Additional well-designed studies are needed to confirm these results.**

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