Study design and validity This is a randomized, double-blind, placebo-controlled trial. The intervention group (n = 160) received omeprazole 20 mg twice daily, amoxicillin 500 mg 3 times daily (with tetracycline 500 mg 3 times daily for patients with penicillin allergies), and metronidazole 400 mg 3 times daily. The control group (n = 158) received only omeprazole 20 mg twice daily and placebos to match the antibiotics. The patients were evaluated 4 weeks after therapy for side effects and *H pylori* status and at 1 year for dyspepsia symptoms, quality of life, and *H pylori* status. The study was appropriately analyzed using an intention-to-treat analysis; 97% of the patients completed the study. While the study was methodologically well done (high internal validity), the results may not be generalizable to a typical family practice in the United States, because patients were British and were referred to a specialty clinic (possible low external validity).

Outcomes measured The primary outcome was resolution of symptoms, defined as a Glasgow Dyspepsia Severity Score of 0 or 1 at 1-year follow-up. Secondary outcomes included *H pylori* status and quality of life.

Results Symptoms resolved in 33 of 154 (21%) patients in the intervention group and 11 of 154 (7%) patients in the omeprazole plus placebo group (95% confidence interval [CI] for the difference, 7 - 22; number needed to treat = 7). In addition, 85% of the intervention group had a negative *H pylori* test result, compared with 12% of the control group. The quality-of-life scores were not statistically different. In a multivariate analysis, having symptoms for less than 5 years predicted a positive response to therapy.

Recommendations for clinical practice **While this study demonstrated a benefit of eradicating *H pylori* on the basis of the Glasgow Dyspepsia Severity Score, this did not translate into a difference in the patients' quality of life. A second study in the same issue of the *New England Journal of Medicine* found no statistical difference in dyspepsia symptoms after treatment to eradicate *H pylori*.[1] However, there were methodologic differences in the second study that could explain the difference in their findings, including 1 week (rather than 2 weeks) of therapy, a multinational population, using a Likert scale to assess symptoms, and excluding patients with reflux disease. On the basis of this study it seems reasonable to eradicate *H pylori* in patients with dyspepsia who are *H pylori*–positive, knowing that this will probably help the 20% to 30% of patients with an ulcer, but may not benefit the remainder. A recent guideline from the American Gastroenterological Association supports testing all patients with dyspepsia for *H pylori*. Then it suggests eradicating the bacteria empirically in those who are *H pylori*–positive, younger than 45 years and without "red flags," and considering endoscopy for the remainder.[2] Because this study is based on a decision analysis, not a randomized trial, more studies are necessary to clarify the causes of NUD and to determine the best way to treat our patients.**

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Gabapentin for Painful Diabetic Neuropathy

Backonja M, Beydoun A, Edwards KR, et al. Gabapentin for the symptomatic treatment of painful neuropathy in patients with diabetes mellitus: a randomized controlled trial. JAMA 1998; 280:1831-6.

Clinical question **How effective is gabapentin in reducing the pain associated with diabetic peripheral neuropathy?**

Background As many as 45% of patients with diabetes develop peripheral neuropathy, and associated pain can be significant and debilitating. Good evidence exists supporting the analgesic effectiveness of tricyclic antidepressants. Carbamazepine, topical aspirin, and lidocaine may also be beneficial.[1] A newer anticonvulsant, gabapentin, has been used for neuropathic pain, but until now there have been no placebo-controlled trials validating its effectiveness.

Population studied A total of 165 patients with a 1- to 5-year history of pain clinically attributed to diabetic neuropathy were recruited from 20 outpatient clinics. Additional criteria for inclusion were a rating of moderate or greater on a visual analog pain scale, reasonable diabetic control (hemoglobin A_{1c} level <0.11), and a creatinine clearance greater than 60 mL per minute. Concurrent use of acetaminophen, once-daily aspirin, and serotonin reuptake inhibitors was allowed, but patients taking other analgesics were excluded.

Study design and validity In this double-blind, 8-week trial, patients were randomly assigned to receive either placebo or gabapentin. They received doses titrat-

ed from 900 mg per day to a maximum of 3600 mg per day during the first 4 weeks and then completed 4 more weeks at their maximum tolerated dose. Patient demographics and rates of withdrawal from the study were similar between the treatment and control groups.

Since patients had their dosage titrated according to side effects there is the potential for bias from unblinding to occur. There were significant differences in the side-effect rates between treatment and control groups, but their magnitude is clearly smaller than the treatment effect. Therefore, it seems unlikely that any bias would substantially change the overall outcome and conclusions of the study. If the authors had presented comparative information about dosages in the 2 groups it would have lessened this concern.

Outcomes measured Subjective daily pain and sleep interference was measured by an 11-point Likert-type scale that was summarized and reported weekly. Other measures using standardized questionnaires included pain scores, patient and clinician impression of change scores, a mood profile, and quality-of-life measures.

Results Daily pain severity (0 = no pain; 10 = worst possible pain) was significantly lower at the study end point in gabapentin-treated patients than in placebo-treated patients (3.9 vs 5.2; P <.001). Approximately 60% of patients receiving gabapentin had at least moderate improvement on change scores compared with 33% of patients receiving placebo (number needed to treat = 3.7). Other outcomes relating to sleep interference (P <.001) and quality of life also favored gabapentin treatment.

Adverse events were more frequent in the gabapentin group, including dizziness (24% vs 5%), somnolence (23% vs 6%), and confusion (8% vs 1.2%). A total of 8% of gabapentin-treated and 6% of placebo-treated patients withdrew because of adverse effects (number needed to harm = 50). A majority of patients (67%) in the treatment group tolerated the maximum 3600-mg per day dose.

Recommendations for clinical practice **This well-designed trial supports the use of gabapentin for painful diabetic neuropathy. Another trial published concurrently in the *Journal of the American Medical Association* used virtually the same treatment and methodology in patients with postherpetic neuralgia.[2] Outcomes were similar, endorsing the utility of gabapentin for this common cause of neuropathic pain as well.**

Neither this 8-week study nor any other study to date has investigated the long-term effectiveness of any drug in peripheral neuropathies.[1] This study also did not address the potential benefits or risks of combining gabapentin with other drugs used for peripheral neuropathy.

Similar results have been obtained when tricyclic antidepressants have been studied for the treatment of both diabetic neuropathy and postherpetic neuralgia. Since they are less expensive, they should still be considered first-line therapy. However, improvement may be slower, contraindications are common, and many patients cannot tolerate the adverse effects. In these patients, or others who do not respond to tricyclic antidepressants, gabapentin is a good alternative.

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Comparing Epidural and Parenteral Opioid Analgesia During Labor

Halpern SH, Leighton BL, Ohlsson A, Barrett JFR, Rice A. Effect of epidural vs parenteral opioid analgesia on the progress of labor: a meta-analysis. JAMA 1998; 280: 2105-10.

Clinical question **Does epidural anesthesia increase the risk of cesarean sections?**

Background The optimal management of labor discomfort remains controversial. In recent years, the use of epidural anesthesia has increased dramatically, and some reports have suggested that epidurals increase the risk of cesarean section. This meta-analysis compared the impact of epidurals with parenteral opioids on the rate of cesarean sections, as well as other maternal and neonatal outcomes.

Population studied The authors' search identified 10 randomized controlled trials enrolling 2369 total patients; all studies were done after 1980, and only 5 took place in the United States. A total of 68% of the subjects were nulliparous. Seven trials used meperidine as the opioid and 6 trials used a combination of bupivacaine and opiates for epidural anesthesia. In 4 studies, an active labor management approach including early amniotomy and oxytocin was employed, but otherwise little information was given about labor and analgesia protocols, delivery settings, or obstetric providers. The