**Objective:** To assess patient satisfaction with and preference for naratriptan hydrochloride therapy over previous “nontriptan” therapy for migraines.

**Design and Setting:** Open-label study conducted at 15 primary care clinics.

**Patients:** One hundred forty-three adults meeting International Headache Society diagnostic criteria for migraine who were not using triptans as first-line therapy for migraines were enrolled; 115 completed the study.

**Intervention and Outcome Assessments:** At baseline, satisfaction with current migraine therapy was assessed. Patients were provided with naratriptan hydrochloride, 2.5 mg, to treat 3 migraines and diaries to record headache symptoms and response to treatment. After treating 3 migraines, satisfaction with naratriptan therapy and preference for either previous or naratriptan therapy were assessed.

**Results:** Eighty-nine (62%) of 143 patients had previous exposure to triptans, with lack of prescribing (55%) as the primary reason for not continuing their use as first-line therapy. Medications used for first-line therapy included simple analgesics (59%), combination products (46%), and narcotics (13%). After treating 3 migraines with naratriptan, satisfaction with migraine therapy increased from 47% to 75%. Sixty-three percent of patients preferred naratriptan therapy over their previous nontriptan therapy, 27% preferred their previous therapy, and 10% had no preference. The main reasons for preference for naratriptan therapy were “relieves pain effectively” (86%) and “restores ability to function/perform task” (81%).

**Conclusion:** Naratriptan for first-line migraine therapy was preferred by most patients over previous nontriptan therapy.

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**MIGRAINE is a common problem in primary care practice. It is estimated that 1 in 6 women experience migraine. Yet, despite its prevalence, migraine remains an underdiagnosed and undertreated medical condition.**

The introduction of “triptans” as abortive agents has revolutionized migraine therapy. However, to date, few of the migraine population use these products, and little is known about their optimal positioning in the migraine treatment armamentarium.

The ideal first-line therapy for an acute migraine headache would be delivered before the onset of significant migraine-related disability and abort the process quickly, with a single dose and without adverse effects. Many agents are proposed as first-line therapies, including a variety of nonsteroidal anti-inflammatory drugs and combination analgesics. To date, triptans have, for the most part, been reserved as second-line therapies when initial interventions have failed or the migraine has progressed to more advanced stages, as illustrated in a recent survey suggesting that the average migraineur fails 4.6 treatments before receiving a triptan (data collected by National Family Opinion Research for Glaxo Wellcome Inc, March 1999). This
PATIENTS AND METHODS

STUDY DESIGN

This open-label study, approved by a central institutional review board, was conducted at 15 primary care clinics geographically distributed across the United States. Patients using nontriptans and nonergotamines as first-line migraine therapy were given naratriptan hydrochloride, 2.5 mg, to use as initial treatment for 3 consecutive migraine headaches. Diaries were used to record migraine symptoms and response to treatment. Patients completed a questionnaire assessing satisfaction with nontriptan therapy at baseline and after treating 3 headaches with naratriptan and a questionnaire assessing preference for previous nontriptan therapy or naratriptan after treating 3 headaches.

PATIENT SELECTION

Enrollment was limited to men and women aged 18 years and older who typically initiated migraine therapy with nontriptan, nonergotamine products, either prescription or over the counter. Patients were identified from each investigator’s practice. Patients were not recruited through advertisements. Inclusion in the study required an International Headache Society diagnosis of migraine with or without aura (1.1 or 1.2) or migrainous headache (1.7) and a frequency of 2 to 6 headaches per month during the past 3 months, the standard frequency of headaches in migraine studies. Any prophylactic headache medication use could be continued providing that the dosage had been stabilized for at least 1 month before enrollment. Absence of (1) significant medical and cardiac disease; (2) a history of ergotamine, triptan, or analgesic use; and (3) substance abuse for the previous 3 months were required. All patients understood the requirements and signed informed consent forms.

Excluded from enrollment were women who were pregnant or breastfeeding, patients with known hypersensitivity or intolerance to any of the triptan medications, and those who were involved in another investigative drug study within the past 30 days. No more than 10 tension-type headaches per month were allowed to avoid patients with the potential of chronic daily headache. Excluded medications included monoamine oxidase inhibitors, lithium carbonate, methylergonovine, methysergide maleate, ergotamines, and other triptan medications.

METHOD OF STUDY

Two clinic visits were required for inclusion in the study. A baseline visit evaluated the patient’s headache symptoms and response to treatment. Patients completed a questionnaire assessing satisfaction with nontriptan therapy at baseline and after treating 3 headaches with naratriptan and a questionnaire assessing preference for previous nontriptan therapy or naratriptan after treating 3 headaches.

RESULTS

The study enrolled 143 adults, 24 men and 119 women, with a mean age of 48 years (range, 19-76 years). All patients had at least a 6-month history of headache that fulfilled International Headache Society criteria for diagnosis of migraine with or without aura (1.1 and 1.2) or migrainous headache (1.7). The average number of migraines and tension-type headaches per month was 3.7 (range, 2-6) and 3.7 (range, 0-10), respectively. Of 143 patients enrolled at baseline, 89 (62%) had previous exposure to triptans or ergotamines, but none were using them as first-line therapy for migraines. The primary reasons for not using triptans were lack of efficacy (13%), presence of adverse effects with past use (6%), and exclusion from formulary (1%). At baseline, medications being used for first-line migraine therapy included simple analgesics (aspirin, acetaminophen, and nonsteroidal anti-inflammatory drugs) by 59% of patients, combination products (butalbital combinations and a combination medication containing isometheptene mucate, dichloralphenazone, and acetaminophen) by 46%, and narcotics (codeine phosphate and hydrocodone bitrate combinations) by 13%.

Of 143 patients enrolled in the study, 115 (80%) treated 3 migraines with naratriptan and completed the follow-up visit. These patients were offered the opportunity to treat 6 additional headaches and were provided with naratriptan. Of the 28 patients who did not complete the study, 11 withdrew consent for personal reasons, 13 were lost to follow-up, 2 had no headaches, 1 lost the study medication, and 1 began having cluster headaches.

The percentage of patients who were satisfied or very satisfied with migraine therapy increased from 21% at baseline to 61% after treating 3 migraines with naratriptan. When using naratriptan vs baseline therapy, total satisfaction (very satisfied, satisfied, and somewhat satisfied) increased from 47% to 75%. Total dissatisfaction (very dissatisfied, dissatisfied, and somewhat dissatisfied) decreased from 43% at baseline to 20% after treating 3 migraines with naratriptan (Figure 1). Overall, there was a substantial shift in satisfied patients at base-
diagnosis, current medical condition, and acceptance for inclusion in the study. A questionnaire regarding their satisfaction with current migraine therapy was completed. A second visit was required after treating 3 migraines with naratriptan.

At baseline, patients received instructions regarding the medication and diary use and completed a practice diary scenario to ensure their understanding. Patients were given 6 tablets of naratriptan hydrochloride, 2.5 mg, to treat 3 migraine headaches. A 24-hour headache-free period with no use of ergotamines or triptans was required between each migraine. Patients were instructed to initiate treatment at onset of headache pain with naratriptan hydrochloride, 2.5 mg. In the diary, patients recorded pain severity, nausea, vomiting, light and sound sensitivity, and disability immediately before taking the medication and 30, 60, 120, 180, and 240 minutes later. Migraine pain severity was rated on a scale from 0 to 3 (0 indicates none; 1, mild; 2, moderate; and 3, severe). Patients recorded the time they achieved "satisfactory relief," with the measurement based on the individual patient's definition or perception of relief.

If headache relief was inadequate 2 hours after taking naratriptan, then rescue medication, other than triptans or ergotamines, could be taken as designated by the investigator. A second dose of naratriptan hydrochloride, 2.5 mg, was allowed as rescue or to treat recurrence 4 to 24 hours after taking the initial dose of naratriptan. No other rescue medication had been taken. No more than 2 doses of naratriptan were allowed within 24 hours. Use of rescue medications, use of additional doses of naratriptan, and the presence of adverse effects were recorded in the diary.

At baseline and follow-up, patients completed a "Satisfaction With Therapy" questionnaire consisting of 12 questions assessing their satisfaction with the medication used to treat migraines. The questions related to the effectiveness of the medication in relieving headache pain and associated symptoms. Specific attributes of convenience, speed of onset, duration of action, and lack of recurrence of migraine were also addressed. Ability to function with migraine and global satisfaction with treatment were also evaluated. The questionnaire used a 7-point Likert scale ranging from "very dissatisfied" to "very satisfied." All questionnaires were completed independently by the patients.

At the follow-up visit, a "Treatment Preference" questionnaire was completed to assess the patient's preference for previous nontriptan therapy, preference for naratriptan therapy, or lack of preference and the reasons for their preference. Multiple reasons could be selected, including "worked fast, relieved pain effectively, relieved other headache symptoms, worked a long time, didn't cause tiredness, restored ability to function, allowed return to activities quicker, required fewer doses, fewer side effects, and less recurrence."

In many respects, patient preference might be one of the most critical aspects of medication studies. Preference for therapy includes a range of reasons—from the more tangible, such as efficacy and restoration of function, to the more subtle, such as convenience and tolerability. Preference might ultimately be one of the most crucial determinants of a patient's use and compliance with treatment programs.

The present study explores the role of naratriptan as first-line therapy for migraine. Naratriptan was selected for this study because it has an adverse event profile similar to that of placebo, has a longer half-life than other available triptans, and has been shown to be well tolerated in patients receiving naratriptan for up to 6 months. The
study population was using a variety of nontriptan medications as first-line therapy. After treating 3 migraines with naratriptan, the reasons most commonly reported for preferring it over their previous therapy were that it was more efficacious, restored ability to function more quickly, and did not cause tiredness.

Patients in this study were drawn from primary care clinics in an attempt to study the headache population currently presenting to primary care physicians for migraine management. Patients entering this study were not required to be dissatisfied or to have failed with their current therapy. In fact, most patients had been using previous nontriptan therapy for an extended period, and nearly half (47%) reported being at least somewhat satisfied with their nontriptan therapy; of these, 4% were very satisfied. After using naratriptan, 75% of patients reported being at least somewhat satisfied; of these, 35% were very satisfied.

This observation underscores the need for physicians to assist patients in evaluating the effectiveness of therapy. A general question such as “Did your medicine work okay?” might gain an affirmative nod, but it in no way implies that a patient’s needs are being met. Patients might judge a treatment as satisfactory without awareness that other options might be beneficial; therefore, the physician should take time to explore the results of therapy with the patient to determine whether the intervention is in fact beneficial.

Sixty-two percent of patients in this study had previous exposure to triptans or ergotamines, yet none had been prescribed a triptan as first-line therapy. The reason given by the majority of patients was a lack of prescribing triptans by their physician. Possible explanations for this observation include physicians believing that current nontriptan therapy was working adequately, physicians underestimating patient treatment needs, or the conflicted role physicians often play in being “cost managers” for managed care plans. Only 20% of patients stated cost as the reason they were not using these therapies.

Cost of therapy is an important issue for both physicians and patients. However, adequate appraisal of cost must be balanced with the value gained from successful therapy. Recognizing the variability in treatment needs from patient to patient, or even from attack to attack within the same patient, assists these clinical judgments. It is rare that a single therapy will be the optimal therapy for every attack of headache. Therapeutic needs might change based on attack characteristics and lifestyle demands. Thus, the patient is an integral part of this decision-making process. The need for an effective abortive therapy for patients with potentially disabling migraine cannot be overemphasized.

Several studies have demonstrated that use of sumatriptan succinate reduces overall patient costs relative to nontriptan therapy and placebo. These studies demonstrate cost savings from decreased emergency depart-

Figure 1. Patient satisfaction with previous nontriptan migraine therapy compared with satisfaction after treating 3 migraines with naratriptan hydrochloride.

Figure 2. Patient preference for first-line migraine therapy after treating 3 migraines with naratriptan hydrochloride.

Figure 3. The percentage of patients preferring naratriptan hydrochloride as first-line migraine therapy who were previously using analgesics or nonsteroidal anti-inflammatory drugs (NSAIDs), narcotics, or combination products.
ment utilization, office visits, and work absenteeism. Again, this underscores the need to evaluate treatment need in a comprehensive manner that emphasizes the functional status of the patient.

Studies of sumatriptan and zolmitriptan have demonstrated the marked improvement in efficacy of treating mild migraine. In these studies, pain-free response was noted within 2 to 4 hours for 80% to 84% of patients treating mild migraines. Pain-free responses were noted by fewer than 50% of patients treating moderate to severe migraines. Thus, early intervention with migraine-specific therapy can significantly improve the likelihood of complete migraine pain relief and early return of function. Delaying effective therapy in deference to cost concerns may decrease the opportunity for maximal therapeutic advantage of migraine-specific agents, allow patients to become disabled, and result in increased costs.

There are several factors to keep in mind when interpreting the results of this study. First, this was an open-label study without placebo. Benefits of being in this study, including receiving medication free of charge, were not controlled; however, this treatment approach parallels clinical practice. Furthermore, the fact that patients were enrolled in a study with their migraines receiving special attention creates a second bias. The study was designed to treat only 3 migraine headaches; therefore, long-term satisfaction was not adequately addressed.

In conclusion, naratriptan as a first-line therapy for migraine is preferred by most patients over nontriptan therapies. Reasons most commonly reported by patients were that naratriptan therapy was more efficacious, restored ability to function more quickly, and did not cause tiredness compared with previous nontriptan therapies. In addition, the number of patients who reported being very satisfied with migraine therapy increased more than 8-fold, from 4% at baseline with nontriptans to 33% at follow-up with naratriptan.

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Reprints: Roger Cady, MD, Headache Care Center, 1230 E Kingsley, Springfield, MO 65804.

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