Topiramate Reduces Chronic Headache Days

BY BETSY BATES
Los Angeles Bureau

LOS ANGELES — The anticonvulsant drug topiramate significantly eased chronic daily headaches, one of the most intractable forms of headache to treat, in a randomized, placebo-controlled trial conducted at 46 U.S. centers.

Although subjects continued to experience headaches on about half of the days in a given month, the relief they obtained had a significant impact on their daily functioning, reported Dr. Stephen D. Silberstein at the annual meeting of the American Headache Society.

With this multicenter study, topiramate has demonstrated "the best efficacy of any drug [used in the treatment of] chronic daily headache," he said in an interview following the meeting.

At baseline, patients enrolled in the trial experienced headaches about 20-21 days a month, including 17 days in which their headaches were migraines or had migraine features, including unilateral pain, pulsatility, worsening of pain with movement, and nausea and/or vomiting.

The group of 328 patients included mostly women. On average, they had suffered chronic, near-daily headaches for more than 9 years.

The mean number of days per month patients had migraine or "migrainous" headaches declined by 6.41 days in patients randomized to topiramate, compared with 4.67 days in those on placebo, said Dr. Silberstein, director of the Jefferson Headache Center at Thomas Jefferson University Hospital in Philadelphia.

Patients who took 100 mg/day of topiramate for 3 months after a washout period and a 4-week titration phase had strictly defined migraines less often than did those on placebo: 4.1 days versus 5.6 days, he reported.

Although total average headache severity was not significantly improved by topiramate, peak severity decreased substantially, suggesting that topiramate reduces the migrainous component of headaches, Dr. Silberstein said.

Topiramate, marketed as Topamax, is Food and Drug Administration approved for the prevention of episodic migraine headaches, defined as those occurring less than 15 days/month.

In addition to this pivotal U.S. study, it was the subject of a companion study conducted in Europe that produced similar results in patients with chronic daily headaches, even when those patients suffered from medication overuse headaches.

In real life, physicians tend to increase the doses to higher levels than those used in the study.

DR. SILBERSTEIN

Dr. Silberstein acknowledged the suggestion by one audience member that the results were "significant but not overly dramatic," but he noted the limitations of any clinical trial with regard to its clinical application.

"I think it's extremely important to point out that in real life … we'll increase the dose to get significantly higher levels," he said.

In his clinic, it is not uncommon for patients with severe, long-standing chronic daily headaches to receive 800 mg to 1 g of topiramate per day.

The most common side effect seen in both the U.S. and European trials was paresthesia, seen in about 30% of topiramate patients, especially during titration. Adverse events leading to withdrawal from the trial occurred in 11.3% of the topiramate patients and 6.2% of those receiving placebo. Mental confusion was an uncommon adverse effect. There were no serious adverse events in either group.

Dr. Silberstein disclosed that he receives grant support and serves on the advisory board and as a speaker for Ortho-McNeil Neurologics Inc., the manufacturer of topiramate. ■

Open-Ended Question Can Reveal Impact of Migraine

BY BETSY BATES
Los Angeles Bureau

LOS ANGELES — Health care providers asked lots of questions during videotaped, real-life office visits by patients with migraines, but almost always failed to ask the one question that would indicate whether they should prescribe a preventive medication.

That question: "Can you tell me how your headaches impact your daily life?"

The American Migraine Communication Study, presented at the annual meeting of the American Headache Society, found that providers asked an average of 13 questions in the average 12-minute office visit with a patient seeking care for migraine headaches.

Of those questions, 91% were closed-ended or short-answer questions that patients could respond to with one or two words.

An example of a closed-ended question would be: "Is your headache pain one-sided?" as opposed to, "Can you tell me about your headache pain?"

In more than three-fourths of 60 videotaped office visits, not a single open-ended question was asked, reported Dr. Steven R. Hahn, professor of clinical medicine at the Albert Einstein College of Medicine, New York.

Both providers and patients knew they were being videotaped in the observational linguistic study conducted in community-based private practices. Separate postvisit interviews were conducted with patients and the 14 primary care providers, 8 neurologists, and 6 nurse practitioners or physician assistants who agreed to participate.

Most of the questions posed by providers addressed headache frequency; yet, more than half the time their understanding of their patients' headache frequency was not aligned with patients' own reports once the visits concluded.

Similarly, their understanding of their patients' headache severity was misaligned with their patients' perspective following 34% of visits.

Just 10% of office visits touched upon the degree of impairment experienced by migraine patients, even though an expert consensus panel in 2005 pointed to impairment as a key determinant in the decision about whether to consider or prescribe preventive medications.

The 2005 American Migraine Prevalence and Prevention Study guidelines recommend preventive medications for patients with frequent headaches that severely affect their lives, defined by at least one of the following: migraines on more than 6 days/month; more than 4 days/month of missed school/work due to migraine; or more than 3 days/month of severe impairment or bed rest due to headache.

The guidelines call for consideration of preventive medication for patients with less severe impairment, such as 3 days/month of migraine with some impact on daily function.

Preventive medications might include anticonvulsants, blood pressure medications, antidepressants, serotonin antagonists, or unconventional treatments such as magnesium salts or vitamins.

Among 60 patients in the communication study, 20 met the criteria for preventive therapy but were not receiving preventive medication. In office visits with 10 of these patients, prevention was never discussed. In the remaining visits, prevention was discussed and medication prescribed in two and was discussed but no medication was prescribed in three.

Dr. Hahn agreed with audience members who deplored the brevity of office visits addressing a topic as complex as migraines. However, time constraints are a reality. "I can tell you from this study that one question very quickly reveals the information that was missing from these encounters," he said.

That open-ended question, "Can you tell me how your headaches impact your daily life?" would often be enough to elicit a succinct description of impairment that could guide decision making about preventive therapy, he said.

"It is actually a time-efficient approach," he said. ■

Managing Chronic Pain: Gaps Problematic in Primary Care

BY ROXANNE NELSON
Contributing Writer

SAN ANTONIO — Clinicians in the field vary greatly in their comfort and confidence in assessing and managing chronic pain, according to a survey presented at a poster session at the annual meeting of the American Pain Society.

"Primary care providers are uncomfortable in treating pain and desire help, especially in opioid management," Dr. William McCarberg, director of the chronic pain management program at Kaiser Permanente in Escondido, Calif., said in an interview. "Specialists are more comfortable but also would like help."

Recent warnings from the Food and Drug Administration and increased investigations by the Drug Enforcement Agency have helped to create a confusing environment for chronic pain management, he wrote.

The primary objective of the survey was to confirm the perception that there are gaps in education, comfort, and regulatory understanding among practitioners when it comes to prescribing opioids.

A secondary objective was to evaluate physicians' perceived need for improved assessment, management, and documentation of chronic pain.

Physicians in 133 practices (49% primary care physicians, 36% pain specialists, and 15% other), located in five U.S. regions, evaluated their level of knowledge and comfort in assessing and managing patients with chronic pain, using a scale of 1 to 6 (with 1 being "not at all" and 6 being "extremely"). They also rated their interest in additional resources in the areas of time management, patient counseling, and treatment documentation.

"Education was the main concern in primary care," Dr. McCarberg said. "Regulatory oversight was judged as an issue as well. Primary care practitioners also felt they did not have enough time to take care of pain patients adequately."

Overall, the pain specialists generally felt more informed on current trends in chronic pain, while the primary care physicians offered far more varied responses, ranging from extremely well informed to very uncomfortable.

A strong interest in greater access to educational tools was observed for both physician education (rated 4.68 by primary care physicians and 5.12 by pain specialists) and patient education (4.82 for primary care and 5.02 for pain specialists), as well as a need for patient counseling resources (5.14 for primary care and 5.39 for pain specialists). Physicians also expressed a strong interest in treatment documentation resources (5.29 for primary care and 5.45 for pain specialists). ■