



Migraine prevention summit proceedings

Part 3 of a 4-part program

Impact of Migraine: Evaluating Patient Disability



Sponsored by Ortho-McNeil Neurologics, Inc.

The National Headache Foundation (NHF) convened an interdisciplinary panel in June 2006 in Chicago, Illinois, to discuss recent developments in the understanding of migraine and current treatment strategies. This monograph is the third in a series of proceedings of the **Migraine Prevention Summit**.

This issue contains important information about the impact of migraine, determining level of impairment, and the need for preventive treatment. In addition, this monograph contains excerpts from the panel discussion and a patient case study.

Other issues include a summary of the **Migraine Prevention Summit** outcomes, information on communicating with patients and evaluating patient disability due to migraine, and a review of the advances in preventive migraine therapies.

Look for the final issue over the next few months or visit the NHF online for NHF **Migraine Prevention Summit** proceedings and other educational materials:

www.headaches.org.

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Prevalence and Impact of Migraine

AMPP Study Results

Migraine is a common condition, affecting 29.5 million Americans. One in every 4 households in the US includes a family member with migraine.¹ Results of the American Migraine Prevalence and Prevention (AMPP) study, the largest study of headache sufferers ever conducted, demonstrate a high prevalence of migraine. In addition, results showed that migraine remains underrecognized and undertreated. In this study, a validated, self-administered questionnaire was mailed to a representative sample of 120,000 US households; 77,879 (65%) households completed and returned the questionnaire. Results showed migraine prevalence of 12%, with a higher prevalence among women than men (17% vs 6%, respectively).²

Further, AMPP results showed a high degree of disability. Only 7% of patients reported being able to function normally during a severe headache. Thirty-nine percent of patients reported some impairment, and 54% reported being severely impaired or requiring bed rest during severe headaches. MIDAS grade assessment of disability showed that 36% of patients experience some degree of disability, with 22% exhibiting moderate or severe disability.²

Medication usage patterns did not reflect optimal use based on level of disability.² In this study of migraineurs, virtually all patients used some form of acute medication for temporary headache relief,³ but a large majority reported their lives are significantly affected by the pain and debilitation

Degree of Impairment	Migraine Frequency (days/month)					
	0-1	2	3	4-5	6-7	11+
Function Normally	Not required	Not required	Not required	Consider prevention	Offer prevention	Offer prevention
Some Impairment	Not required	Consider prevention	Consider prevention	Offer prevention	Offer prevention	Offer prevention
Severe Impairment	Not required	Consider prevention	Offer prevention	Offer prevention	Offer prevention	Offer prevention

- **Offer prevention** (25.7%)*
- **Consider prevention** (13.1%)*
 - If patient's lives are disrupted, even with a lower frequency of migraine or
 - If acute treatment has not been sufficient
- **Not required**

Figure 1. Preventive medication need among migraine cases. Expert consensus recommends preventive treatment based on both frequency of headache attack (days/month) and degree of impairment. *Percentages of people surveyed in the AMPP study.^{2, 4, 5}

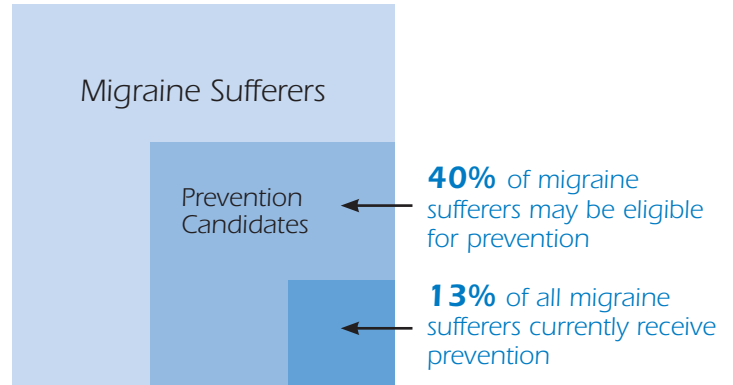


Figure 2. AMPP results demonstrate migraine prevention is underutilized.²

associated with migraine. The investigators determined need for prevention based on headache frequency (days/month) and headache-related impairment (Figure 1). Results showed that approximately 40% of migraine sufferers are eligible for migraine prevention, but only 13% are currently receiving it (Figure 2).² Guidelines for considering preventive therapy are provided in the boxed text below.

Results from the AMPP study show a marked undertreatment in this population, and only a small percentage of patients with migraine who could benefit from preventive medication are actually receiving it.^{2,8}

Guidelines for Initiating Preventive Therapy*^{4,6,7}

- Frequency of headache ≥ 2 per month with disability ≥ 3 days per month[†]
- Recurring migraines that, in the patient's opinion, significantly interfere with daily routines
- Use of acute (over-the-counter or prescription) medications more than 2 times a week
- Acute medications are contraindicated, not tolerated, or ineffective

* Adapted from the US Headache Consortium Guidelines for the Management of Migraines. Members include the National Headache Foundation, the American Academy of Neurology, the American Academy of Family Physicians, and the American College of Physicians-American Society of Internal Medicine.

[†] Even patients with < 2 attacks per month may experience disability severe enough to require preventive treatment.

Migraine Diagnosis and Treatment

International Headache Society diagnostic criteria⁹ are the most commonly accepted for diagnosis of migraine with or without aura, although individual patients may present with a variety of symptoms. Diagnosis according to the presence of 2 out of 3 key characteristics — photophobia or phonophobia, nausea or vomiting, and inability to function — is generally accurate.⁸ Treatment plans for individual patients are based on headache frequency, symptom severity, and co-morbid conditions, as well as patient expectations and treatment goals. A comprehensive treatment plan includes patient education; avoidance of triggers to minimize attack frequency; use of nonpharmacologic treatments, such as relaxation and biofeedback techniques; and use of acute or preventive medications or both as needed. Acute medication aims to relieve the pain associated with an attack and stop progression of the attack. Preventive therapies reduce attack frequency, severity, and duration. The table below summarizes FDA-approved acute and preventive medications. Lifestyle modification, including maintaining a regular schedule with adequate sleep, exercising, and stopping smoking, remains a main focus of disease management. Periodic re-evaluation of the treatment plan is needed to ensure the patient is receiving the optimal benefit from available therapies.¹⁰

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FDA-Approved Acute and Preventive Treatments for Migraine

Acute Medications	
Analgesics	
Ergot derivatives	
Triptans	
Preventive Medications	
TOPAMAX®*	(topiramate)
Inderal®*-LA	(propranolol)
Depakote®*	(divalproex sodium) Tablets
Blocadren®*	(timolol maleate)

*TOPAMAX is a registered trademark of Ortho-McNeil Neurologics, Inc. Inderal is a registered trademark of Wyeth Pharmaceuticals Inc. Depakote is a registered trademark of Abbott Laboratories. Blocadren is a registered trademark of Merck & Co., Inc.

Evaluating Impairment

Consideration of preventive therapies is based on frequency of migraine attacks (number of migraine days), level of impairment, and disruption of daily life during and between attacks.^{4,5} Determining level of impairment may be challenging, as patients do not always volunteer specific information about how migraine affects their lives.⁸

A recent study, the American Migraine Communication Study (AMCS), highlighted the need for improved communication between patients and healthcare professionals. This study was designed to assess how patients interact with healthcare professionals. The study included 22 community-based healthcare professionals (primary care physicians, neurologists, nurse practitioners, and physician assistants who treat >20 patients/week for migraine) and 60 patients with migraine. Visits were video- and audio-recorded and later transcribed, and post-visit interviews with both healthcare professionals and patients were conducted.¹¹

Results showed that the vast majority (91%) of communication consisted of closed-ended questions. Although providers asked an average of 13 migraine-related questions per visit, they most often discussed attack frequency, triggers, and symptoms. Despite the focus on attack frequency, post-visit interviews showed that patients and healthcare professionals were misaligned on frequency in 55% of cases and on severity in 34% of cases. This misalignment appeared to affect treatment plans. Of 35 patients not prescribed a preventive therapy for migraine, 20 met AMPP study criteria for preventive treatment. Prevention was not discussed in half of these cases (Figure 3).¹¹

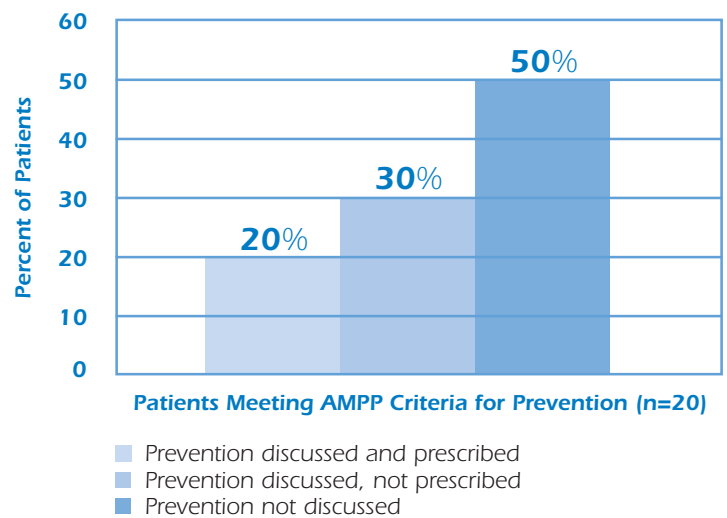


Figure 3. AMPP study results: discussion of prevention among 20 patients meeting AMPP study criteria for preventive treatment.¹¹

Investigators concluded that use of open-ended questions (such as “How do migraines impact your daily life?”) may lead to more effective assessment of the total degree of impairment experienced by migraineurs, including how migraine can impact patients’ lives even when they are not having an attack.¹¹ See boxed text for examples of open-ended questions.

The second phase of AMCS (AMCS II) assessed an educational intervention designed to improve health professional-patient communication. Healthcare professionals who had all

participated in the first phase of AMCS (8 primary care physicians, 5 neurologists, and 2 nurse practitioners) participated in an interactive, 1.5-hour, Web-based training session. During the session, participants learned to use the ask-tell-ask technique to assess attack frequency and open-ended questions (such as “How does migraine impact your daily life?” and “How does migraine make you feel—even when you are not having an attack?”) to assess impairment during and between attacks.¹²

Results showed the use of open-ended questions improved discussion and healthcare professional understanding of migraine impairment during and between attacks, yielding narratives in 75% of visits—significantly more frequently than closed-ended questions or no impairment questions (52% and 30%, respectively; $P < .05$). In addition, healthcare professional-patient alignment on impairment and frequency were improved with the use of open-ended questions compared with AMCS I results (61% vs 49% and 56% vs 45%, respectively) and 45% of participants in AMCS II asked about worry between attacks, compared with none in AMCS I. Importantly, length of office visit was not increased with the use of open-ended questions. In fact, although the median length of impairment discussion was 1 minute, 24 seconds with open-ended questions, compared with 1 minute without, the median visit length was shorter in AMCS II than in AMCS I (median of 9 minutes, 36 seconds vs 11 minutes).¹²

Summary

Migraine is a common condition, resulting in disability and compromised function in a substantial proportion of patients. Yet, migraine remains undertreated, as demonstrated by AMPP study results. Nearly 40% of migraine sufferers may be eligible for prevention, but only 13% currently receive it.^{1,2} Use of open-ended questions may help identify patients who are candidates for prevention and help assess migraine impairment during and between attacks.¹¹

Open-Ended Questions to Evaluate Disability From Migraine^{8,11}

1. How does migraine make you feel — even when you aren't having an attack?
2. How does migraine impact your daily life?
3. How does migraine impact your work, family, and social life?
4. What activities have you given up because of your migraine? [Probe to see if the patient avoids participating in hobbies and/or leisure activities out of worry a migraine attack may occur.]

Burden of Migraine: Panel Discussion Highlights

Following are excerpts from the **Migraine Prevention Summit** panel discussion, addressing the impact of migraine, assessing patient disability, and AMPP and AMCS results. See the next issue, **Advances in Preventive Therapies for Migraine**, for more excerpts on treatment options and designing individual treatment plans.

Understanding Migraine as a Chronic Disorder

MODERATOR: What is the impact of migraine, and how does migraine affect patients?

RICHARD B. LIPTON, MD: Our understanding of migraine has really evolved substantially over the past fifteen or twenty years. This evolving understanding has important implications for how we conceptualize treatment. As a medical student, I learned migraine is an episodic pain disorder. And what do you do with episodic pain disorders? You treat them with acute analgesics. The thinking changed somewhat and we began to think of migraine as a disorder of the trigemino-vascular system. Of course, triptans are agents that interact with this system to relieve the pain of migraine.⁸

Now, I think, most people think of migraine as a chronic disorder with episodic manifestations, which in some cases can be progressive. And this conceptual framework has implications for treatment as well. Migraine is a disorder of brain hyperexcitability, a disorder in which the threshold for headache attacks is lowered, not just on days when attacks take place, but everyday. In this context, using preventive therapy to modulate and reduce brain hyperexcitability makes sense. And trying to devise strategies for identifying people at risk for disease progression and intervening to prevent progression also makes sense.⁸

Migraine is a chronic disorder of the nervous system, characterized by brain hyperexcitability, that manifests in episodic attacks.

Burden of Migraine: Costs to Society

MODERATOR: What are the costs associated with migraine?

RICHARD B. LIPTON, MD: The indirect costs or the costs of lost productive time due to migraine are far greater than the cost of medical care for migraine. The best available estimates say that migraine costs US employers roughly \$13 billion per year. That lost labor cost is divided into the cost of absenteeism when people actually miss work because of headache and the cost of presenteeism when people go to work but function at a reduced level of effectiveness.⁸

Presenteeism is far more costly than absenteeism. For most attacks, people with migraine tend to go to work or stay at work with their headache. Quite often they function at a substantially reduced level and are less productive than usual.⁸

If we compare the \$13 billion that we lose in the form of lost labor costs with the two or three billion dollars that we spend on treating migraine, it becomes apparent that there is an opportunity to improve cost-effective management of migraine. If we spent a little more money on treating migraine and produce better patient-centered outcomes, we might, as a society, save money in terms of the total burden of illness.⁸

Migraine costs society \$13 billion each year in indirect costs, including lost productive time, which far outweighs the cost of treating migraine.

Patient Impairment and the Interictal Burden of Migraine

MODERATOR: How do you determine patient impairment from migraine?

RICHARD B. LIPTON, MD: Headache-related disability is usually measured in terms of lost time, but, unlike the indirect cost estimates that we were talking about a moment ago, it's lost time just not at work, but lost time in doing household work and chores, lost time in family, social, leisure activity. And, from that perspective, migraine has a tremendous impact.⁸

One limitation of disability measures is that they very much focus on the burden that migraine produces on days when headache is present. Most days, migraine sufferers do not have headaches. But between attacks, migraine also has an impact on individual headache sufferers and on their families. And that component, the interictal burden, is very substantial and takes several forms. One way of capturing the interictal burden of migraine is to look at health-related quality-of-life measures, which capture more global aspects of function on every day during an extended period of time. Another aspect of the interictal burden of migraine is that migraine interferes with people's ability to make plans. If you know, a few times a month, you might be struck out of the blue by a headache attack, that makes it difficult to make work, family, and social plans. Almost at any given moment, your life can be completely disrupted. And it's that unpredictable aspect of migraine that disability measures don't capture and it's something that I think we really need to focus on.⁸

In population studies, migraine sufferers often say they refuse promotions, they decline work opportunities that they worry might make their headaches worse or where their headaches might really interfere. So there's a very substantial interictal burden of headache.⁸

Migraine impacts patients and their families, even between attacks (the "interictal" burden), by limiting patients' participation in normal activities. They live with worry about when the next attack may strike. Healthcare professionals need to determine the impact of migraine, both during and between attacks, to better assess when patients may be appropriate candidates for preventive therapy. In addition, it is important to recognize how migraine affects other aspects of the patient's life, such as family and work life.

Burden of Migraine Between Attacks: Impact on the Patient and Family

MODERATOR: How does migraine affect patients and their families between attacks?

KATHLEEN CAHILL, MS, CNS, ARNP: A good example, in the summer in Florida, which is storm season, patients for whom changes in barometric pressure may trigger a migraine attack just put their lives on hold, for the most part. This is the time when their children are out of school, when they should be planning family vacation time, and they're not. They're actually trying to cut back in anticipation of these problems.⁸

CHRISTINE LANTIN, PA-C: Patients often want an extra prescription just in case. They've got a picnic coming up, they've got a huge family vacation they have to attend and they want to be there and be present with the family. They'll be calling me for medication to use as a backup. And then patients also withdraw, because of the disabling nature of the headaches, they just withdraw from their families, they're not going on vacations.⁸

ROGER K. CADY, MD: But what I think is most striking is the amount of negotiation and time people spend mentally focusing on the disease of migraine between attacks of headaches. It's like, "Is today my headache day? Is tomorrow my headache day?" "Should I treat this headache? Is it really going to be a migraine? Oh, I'm taking too much medicine, oh, I'm not taking enough medicine, I'm not taking it early enough" and there's this whole thought process. I'm all for treating people who are chronic, but if we really wanted to impact something well, we should be understanding how people are getting to become chronic so we can prevent what we don't want, rather than wait for it to happen.⁸

So I think, in many ways, the biggest disservice is associating migraine and headache as synonymous with each other and they're not. Migraine is a far more pervasive, larger process. And the more frequently those attacks occur, the less likely people are to return back to a normal level of biologic function.⁸

Patients often limit work and leisure activities or modify social and professional plans due to worry that a migraine attack may occur.

Patient Communication and Assessing Level of Impairment

MODERATOR: What role does communication between healthcare professionals and patients play in diagnosing and treating migraine?

RICHARD B. LIPTON, MD: A number of us around the table were involved in a study called the American Migraine Communication Study. In this study, encounters between healthcare professionals and patients were videotaped. Subsequently, the healthcare professional and patient were separately debriefed by a lay interviewer. Those videotapes showed that healthcare professionals asked close-ended questions like, “Are you nauseated? Are you sensitive to light or sound?” Oftentimes, the healthcare professionals underestimated the disabling consequences of headache for the patient, because those questions don’t give the patient an opportunity to explain the impact of headache on the patient’s life.⁸

The lay interviewer would ask questions like, “How does migraine affect your daily life?” And, in response to that simple open-ended question, a patient might say, “I’m a lawyer and sometimes I miss court appearances because of my migraine. I hate to let my clients down.” A patient might say, “I worry about my ability to take care of my children. Sometimes, when I’ve got these bad migraine attacks, I can’t....” The bottom line is that there’s a communication gap about migraine-related impairment. As a consequence, the impact of migraine is not recognized and the impact of the illness on individual patients is underestimated.⁸

So, it seems like one of the ways of closing the treatment gap is to address the communication gap and the strategy for doing that is by asking open-ended questions like “Tell me how migraine affects your daily life.”⁸

RICHARD G. WENZEL, PharmD: I’ve always maintained that, if someone’s motivated enough to seek professional help, that’s a bad sign right there. And, odds are, it’s probably migraine or it’s something that needs to be addressed. If they can control it on their own with just OTCs, they never show up at the physician’s office. Just the simple fact that they’re there talking to you about their condition suggests it may be migraine, particularly when it’s recurrent and debilitating. All recurrent, debilitating headaches should be considered migraine until proven otherwise.⁸

ROGER K. CADY, MD: I ask people to tell me about the life between migraine attacks, and I hear everything from “Well, everything’s fine” to a list of various symptoms. Then I have them go through a day with a migraine attack, starting when they wake up and reviewing what decisions they made to treat the attack. It doesn’t take very long to do that. And I do the same thing with a day they didn’t wake up with a migraine attack. Patients may say life is perfect, but then they describe a life that really isn’t. What they’re really

doing is making choices and decisions and thinking about what they can and can’t do.⁸

RICHARD G. WENZEL, PharmD: The other big red flag is, if you need your acute drug every day or every other day, that’s a bad sign. In my mind, that’s a sign for either more intensive preventive therapy — or a referral. Pharmacists should be educated to look for early refills and overuse of over-the-counter medications. Those are red flags that somebody needs help.⁸

ROGER K. CADY, MD: Patients who use acute medications, either prescription or over-the-counter, more than twice a week may be candidates for migraine preventive therapy.⁸

KATHLEEN CAHILL, MS, CNS, ARNP: One of the things I ask them is, “What have you given up? What are the things that you’ve had to give up because of your migraine attacks?”⁸

RICHARD G. WENZEL, PharmD: I get the “a-ha” moments when I say, “How many days per month are you completely headache free?”⁸

Discussing typical days with and without a migraine attack may reveal more about patient activities and impairment than simply assessing attack frequency and severity. In addition, probing for treatment strategies patients employ may reveal acute medication overuse. Both strategies can be used to help identify patients who may benefit from preventive therapy.

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Presentation of AMPP Study Results — the Need for Prevention

RICHARD B. LIPTON, MD

A large epidemiological study sponsored by the National Headache Foundation and funded by Ortho-McNeil Neurologics, Inc., the American Migraine Prevalence and Prevention Study (AMPP) evaluated a national sample of 120,000 US households and looked at migraine prevalence and the use of preventive medications among migraine sufferers. The study involved 162,576 individuals who completed a screening questionnaire where they reported the characteristics of their headache and how they treated them. Two rounds of follow-up in the individuals identified who had severe headache have been completed. The strength of the study is that it’s the largest study of headache epidemiology that’s ever been conducted and contains detailed information about prevalence, healthcare utilization, allodynia, and co-morbid depression and many other variables. Results showed that 17% of American women and 6% of American men had migraine, which translates to an estimated 29.5 million Americans who currently suffer from migraine.^{1,2,8}

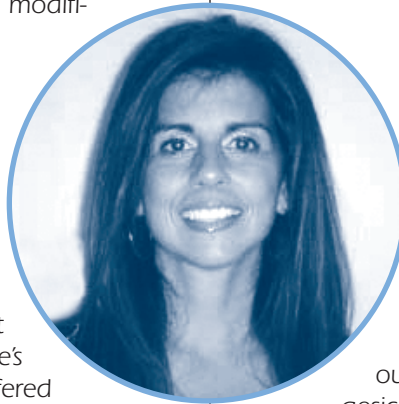
The vast majority reported that headache interferes with their lives, with 87% reporting some degree of impairment during severe headaches. On average, the attack frequency was 8.3 over a 3-month period, and 26% of respondents experienced 10 or more headache days in that period. So, there are a fair number of people who have a pretty high attack frequency.^{2,3,8}

Based on the results of the study, our estimate was that about 40% of people with migraine in the United States have attacks with a frequency and degree of disability where preventive therapy should be offered or considered. Not everyone with migraine needs to take medication on a daily basis. Those with infrequent headaches who respond very well to acute treatment and don't have severe headache-related disability or other indications for prevention can be managed with acute treatment plus lifestyle modification.⁸

Then we asked the question, "Well, based on frequency and disability, what proportion of people should be offered or should consider preventive therapy?" and, as I said, that number was approximately 40%. And then we asked, "Well, what proportion of migraine sufferers currently get preventive therapy?" and that estimate was about 13%. So these data demonstrate that there's a gap between individuals who should be offered or where preventive medication should be considered and those who actually get it.⁸

And if we looked at the people in whom preventive therapy should be offered or considered, not surprising, in comparison to the contrasting group, their headaches were worse. Their attacks were more frequent, more disabling, they were more likely to have nausea, they were more likely to vomit, they were more likely to have aura, they were more likely to have allodynia. They were more likely to have co-morbid depression. By virtually any measure you could think of, the group who should be offered or should consider preventive therapy was worse off than the group where we thought that preventive therapy was not indicated.⁸

The AMPP study demonstrated that the need for preventive migraine care is high in the United States and that preventive treatment is considerably underutilized in patients with migraine.



Patient Case: Delayed Diagnosis of Frequent Migraine⁸

- 40-year-old married woman and mother of 2 (ages 7 and 16), with frequent migraine attacks for previous 10 years.
- Currently treated with triptans and over-the-counter analgesics.
- Current symptom control is inadequate, and attacks are increasing in frequency.
- Preventive treatment with TOPAMAX[®] (topiramate) is initiated, resulting in reduced migraine attack frequency.

Symptomatic Progression

Debbie was first diagnosed with migraine approximately 10 years ago, believing that she experienced headache attacks only with menstruation and suffered from frequent sinus headaches. She was prescribed acute migraine medication, consisting of a triptan, by her primary care physician. She simultaneously self-medicated using over-the-counter analgesics and combination sinus and pain relievers.

Over several years, Debbie's migraine attacks became more frequent and increased in severity. Despite use of triptan medications, she experienced 4 migraines per month, each typically lasting for 3 to 5 days, resulting in up to 20 migraine days per month. She often consumed up to 8 to 10 sinus headache pills per day during her migraine attacks. Typically, Debbie employed an incremental approach to treating each migraine attack, beginning with caffeine and progressing to over-the-counter analgesics or sinus and pain medication and finally to a triptan to control her headache pain.

Debbie experienced side effects of triptan medications, including somnolence and feeling "disconnected," and was unable to drive while taking her acute medication. Side effects and inadequate efficacy in controlling her migraine symptoms prompted her to change triptan medication. In addition, her frequent migraine attacks caused her to rely on samples and drug-seek to fill her increasing need for acute medication.

After 10 years of managing her migraine on her own with over-the-counter medications and triptans, Debbie sought evaluation at a headache center for the first time. Her visits included evaluation of her headache severity, migraine-related disability, and acute medication use.

She learned more about her disease, identifying triggers, and proper use of acute medications and undertook lifestyle changes to help reduce attack frequency. Due to severe symptoms, high attack frequency, and acute medication overuse defined as use of acute medications more than 2 times a week, Debbie was considered a candidate for preventive therapy.

TOPAMAX[®] (topiramate) in conjunction with a 10-day regimen of an oral steroid was employed to discontinue the patient's use of over-the-counter sinus medication and pain relievers and end her rebound headaches. After completion of this protocol, steroid use was terminated and TOPAMAX was continued as preventive migraine therapy, with a triptan used as acute medication for breakthrough migraine attacks. In the first 12 weeks of treatment, headache frequency was dramatically reduced to 3 headache days per month. With continued treatment, the patient experienced further reduction of migraine frequency over the next 12 weeks to <1 headache day per month. She now experiences a migraine attack only once every 4 months.

Indication:

TOPAMAX[®] for Migraine: TOPAMAX[®] (topiramate) Tablets and TOPAMAX[®] (topiramate capsules) Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX[®] in the acute treatment of migraine headaches has not been studied.

IMPORTANT SAFETY INFORMATION

TOPAMAX has been associated with serious adverse events, including:

- Hyperchloremic, non-anion gap metabolic acidosis—lowering of bicarbonate levels in the blood. Measurement of baseline and periodic serum bicarbonate is recommended.
- Acute myopia and secondary angle-closure glaucoma—patients should be cautioned to seek medical attention if they experience blurred vision or ocular pain.
- Oligohidrosis and hyperthermia—decreased sweating and increased body temperature, especially in hot weather. The majority of reports have been in children.
- Cognitive/psychiatric side effects, including cognitive dysfunction, psychiatric/behavioral disturbances including suicidal thoughts or behavior, and somnolence and fatigue.

Most common adverse events associated with TOPAMAX 100 mg vs placebo were: paresthesia, 51% vs 6%; anorexia,* 15% vs 6%; fatigue, 15% vs 11%; nausea, 13% vs 8%; diarrhea, 11% vs 4%; weight decrease, 9% vs 1%; taste alteration, 8% vs 1%.

The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products with TOPAMAX.

Patients should be instructed to maintain an adequate fluid intake in order to minimize the risk of renal stone formation.

*Anorexia is defined as a loss of appetite.

Please see enclosed full US Prescribing Information.

**In Her Own Words:
Debbie Sacchetti Talks About Her Disease**

*At the **Migraine Prevention Summit**, Debbie spoke about her experience with migraine, from her initial attempts to self-manage the disease resulting in mistreatment with sinus medications and overuse of over-the-counter pain killers and triptans to her evaluation at a headache clinic that led to development of a more appropriate treatment plan, including preventive medication. Below are excerpts of Debbie's comments about her disease and treatment.*

Debbie learned more about her disease:

I wasn't really given the definition of migraine and what it was, so I didn't really understand the neurological reasons involved. It's not just episodes of headaches; it is an entire disease that I have. It's hard, but I do realize that that's what it is now. Now I realize that it's not just something that I want to stop when I get it. I want to prevent it from happening, because I'm going to continue to get it. The frequency is getting worse and worse. I used to just get a headache once or twice a month and, as I was getting older, as it was progressing, I was getting 15, 20, 25 episodes a month, so my goal was to stop the disease from getting worse, because, at that point, I was thinking, "How much worse can it get now?"⁸

I was misdiagnosing myself and thinking I was always having sinus headaches. It wasn't until I went to a migraine center that I realized they weren't sinus headaches, they were migraine. So I didn't realize, until a year ago, that I was having chronic headache problems.⁸

Debbie learned that preventive therapy was an option for her:

Prevention was never discussed until I went to the headache center. My primary care physician did not discuss preventive therapy with me. He only gave me acute medications and said, "Here, when you have migraine, take this and that'll treat it. Take one or take two, just keep taking that." And then, when one would stop working, he would just say, "Well, now try this one," and, if that stopped working, you didn't like the side effects, then try this one. And I got a little disgusted, so I would stop going and I would just try treating it myself.⁸

When I went to the headache center, I was just looking for a better acute medication, something that didn't make me totally disconnected and tired and, you know, I couldn't drive. I wanted something that would treat it a little better. Once I realized that all those sinus headaches were migraines and it really scared me when I realized I was having a migraine almost every day of the month. This was the disease now.⁸

Debbie experienced substantial impairment from migraine, including worry between migraine attacks:

When you know a migraine attack is coming and you can't stop it, it's very frustrating, it's very upsetting. You can't make plans. For me, I know it's going to be five days. If it's starting today, I know the next few days are going to be bad. So, I know either I'm going to be taking a triptan every day and feeling lousy or I'm just going to be having the headache. So I know, with the family it's going to be hard. I know I'm going to miss things.⁸

Debbie began preventive therapy and soon noticed improvement in migraine attack frequency:

When I first started taking TOPAMAX[®], within the first couple of weeks, my migraine episodes were reduced. I was probably only getting about three a month at that point. They were just getting less and less frequent, and then it was two a month, one a month, and they were only lasting a day. If I would wake up with a headache, I would right away take a triptan, and within 10 or 15 minutes, it would take the headache away and that would be the end of it. I wouldn't get it back anymore that day, and I wouldn't wake up the next day with it.⁸

Individual results may vary.

Learn more about Debbie's treatment program and outcome in the next issue, **Advances in Preventive Therapies for Migraine**.

Counseling Patients Who Are Initiating Migraine Preventive Therapy

Below are important points to remember when talking to patients who are initiating migraine preventive therapy.

Set appropriate patient expectations regarding treatment efficacy and tolerability.

- Patients may expect to see a reduction in migraine attack frequency, but should not expect a 100% reduction.
- Explain possible side effects of treatment and how to manage them.
- Although effects may be seen at 1 month, it may take up to 2 to 3 months of continuous treatment to reach full clinical effectiveness. Encourage patients to give therapy an adequate trial.^{5,13}
- Start low and go slow: use a slow titration strategy to reach the target dose.⁵
- Dose and titration rate should be guided by clinical judgement.

NHF Migraine Prevention Summit Consensus Statement

The interdisciplinary panel developed the following consensus statement highlighting the key findings of the **Migraine Prevention Summit**.

- Migraine is a chronic disorder, rather than an episodic disorder. Healthcare professionals treating patients with migraine must be educated about recent advances in the understanding of migraine and current treatment options.⁸
- Proper use of acute medications is essential to maximize their efficacy. Acute medications should be taken at the first sign of migraine (or during the aura, if present).⁸
- Acute medication is not always adequate to control migraine attacks. Preventive therapy should be considered in patients requiring acute medication more than 2 days per week and in those experiencing frequent disability during and between migraine attacks.^{2,8}
- Healthcare professionals need to determine patient disability and the total level of impairment migraine has on a patient's life, both during and between attacks, to better assess when patients may be appropriate candidates for preventive therapy. In addition, it is important to recognize how migraine affects other aspects of the patient's life, such as family and work life.⁸
- Preventive therapies include both medications and behavioral modifications. Patients need realistic expectations about treatment outcome, specifically time to response. Preventive therapies may take 6 weeks or longer to reach clinical effect. In addition, patients should be counseled on what side effects to expect and should be titrated slowly to the target dose.¹³
- Patients are important partners in the management of migraine. Open communication about treatment options and healthcare professional-patient support is essential to ensure treatment plans are followed. Adherence to treatment regimens, including both lifestyle changes and medications, is necessary to achieve optimal effect.⁸
- Migraine is a manageable disease. With communication and cooperation between patients and healthcare professionals, most patients can achieve greater control of their disease and reduce their disability.⁸

NHF Migraine Prevention Summit Proceedings

Issue 1: Overview of Migraine

Issue 2: The Importance of Communicating With Patients

Issue 3: Impact of Migraine: Evaluating Patient Disability

Issue 4: Advances in Preventive Therapies for Migraine

Learn more about migraine prevention and treatment, download patient education materials, and view all 4 issues in this series at www.headaches.org.

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