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Individualizing Patient Care for Migraine Prevention

Announcer:

You're listening to ReachMD. This medical industry feature, titled "Individualizing Patient Care for Migraine Prevention," is sponsored by Amgen.

Here's your host, Dr. Charles Turck.

Dr. Turck:

Migraine is a highly prevalent, chronic neurologic disease characterized by attacks of moderate to severe throbbing headaches that are often unilateral in location, worsened by physical activity, and associated with photophobia, phonophobia, nausea, vomiting, and cutaneous allodynia.^{1,2}

While migraine can be managed with acute treatment, preventive treatment, or both, optimizing treatment for individual patients remains challenging.¹

Welcome to ReachMD. I'm your host Dr. Charles Turck. And, joining me today to discuss how we can implement a more patient-centric approach to diagnosing and treating adult patients with migraine are Dr. Jessica Ailani and Dr. Timothy Smith.

Dr. Ailani is a board-certified neurologist and headache specialist based in Washington, D.C. She is a fellow of the American Headache Society, the American Academy of Neurology, and the American Neurological Association.

For the American Headache Society, Dr. Ailani is the secretary, chair of the membership and awards committee, and vice chair of the leadership committee. She was the lead author of the 2021 American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice.

Dr. Ailani, thanks so much for being here!

Dr. Ailani:

Thank you so much. It's my pleasure.

Dr. Turck:

And Dr. Timothy Smith is the President and CEO of StudyMetrix Research. He's also a pharmacist, internal medicine physician, and headache specialist from St. Peters, Missouri.

Dr. Smith is a fellow of the American College of Physicians and the American Headache Society, a Certified Physician Investigator of the Academy of Clinical Research Professionals, and a member of the Board of Directors for the National Headache Foundation.

Dr. Smith, it's great to have you with us!

Dr. Smith:

Thanks for having me.

Dr. Turck:

Dr. Ailani and Dr. Smith have both been compensated by Amgen for participating in this program.

So, let's start with the basics. Dr. Ailani, what can you tell us about the impact of migraine in the United States and around the world?

Dr. Ailani:





Migraine affects more than 16 percent of the global population and is the second-leading cause of years lived with disability worldwide.^{3,4} In the United States alone, nearly 12 percent of the overall population 12 years and older suffer from migraine.⁵ Migraine is about three times more prevalent in women than men.⁵ Migraine can start at a young age. More than 75 percent of patients with migraine may experience their first migraine in adolescence.⁶ However, migraine generally peaks in middle life when patients are between 30 and 49 years of age and can persist until patients are 60 years of age and older.⁵

Dr. Turck

Given the impact of migraine, Dr. Smith, what are some of the challenges clinicians may face in managing these patients?

Dr. Smith:

First, migraine is often underdiagnosed and undertreated, despite having effective options available for acute and/or preventive treatment.⁷ In addition, many patients report not receiving appropriate follow-up care.⁸ Migraine is very cyclical in nature. The frequency of headache days for individual patients may change over time, and high rates of transition between episodic and chronic migraine may affect a patient's diagnosis.⁹ Finally, migraine is a heterogeneous condition that often has a lifetime impact on our patients. As a result, we need to do our best to implement an individualized, patient-centric care approach to help our patients manage their condition.¹

Dr Turck

Let's turn our attention to treatment. We know there are two approaches to managing migraine—acute and preventive treatment. Dr. Ailani, would you tell us about acute treatment for adults with migraine?

Dr. Ailani:

Acute treatment is recommended to reduce and/or alleviate the symptoms of a migraine attack, achieve rapid freedom from pain and symptoms, and restore a patient's ability to function.^{1,2} However, acute treatment can lead to adverse events like tolerability issues or headache associated with medication overuse.¹ There are several acute treatment options available for migraine. The American Headache Society, or AHS, recommends several acute treatments that have established efficacy, including non-steroidal anti-inflammatory drugs, known as NSAIDs, or combination analgesics. Migraine-specific acute treatment options include triptans, ergotamine derivatives, gepants, or ditans.¹

Dr. Turck:

And what about treatment for migraine prevention? Dr. Smith, what are the goals of this type of therapy and considerations for preventive treatment?

Dr. Smith:

Preventive treatment is used to reduce attack frequency, severity, and duration, and to improve responsiveness to and avoid escalation in the use of acute medications.¹ It may also help with everyday functioning and reduce the overall cost associated with treating migraine.¹ Potential limitations of preventive treatments include adverse events, poor tolerability and issues with long-term patient adherence.¹ Treatments nonspecific to migraine include anticonvulsant drugs, beta blockers, antidepressants, ACE inhibitors, angiotensin-receptor blockers, and neurotoxins.^{1,10} Newer therapies approved for use in the United States include migraine-specific medications like anti-CGRP pathway monoclonal antibodies and gepants.^{1,11,12} It's important to note that some patients with migraine who have frequent and/or severe attacks² may require both acute and preventive treatment to manage their condition.^{1,2}

Dr. Turck

For those just tuning in, you're listening to "Individualizing Patient Care for Migraine Prevention" on ReachMD. I'm your host Dr. Charles Turck and speaking with me today about personalized care for adult patients with migraine are Drs. Jessica Ailani and Timothy Smith.

Dr. Turck:

So, Dr. Ailani, before we dive into individualizing treatment plans for adult patients with migraine, would you tell us a bit about the AHS Consensus Statement published in May 2021?¹

Dr. Ailani:

First, the AHS Consensus Statement is not a clinical practice guideline. It was developed in response to newer migraine-specific therapies being approved for use in the United States, including ditans and gepants for acute treatment and anti-CGRP pathway monoclonal antibodies for preventive treatment.¹ There were gepants approved for the preventive treatment of episodic migraine after the publication of the AHS Consensus Statement. As a result, they were not included in these recommendations.^{1,11,12}

The aim of the AHS Consensus Statement is to improve outcomes in patients with migraine who have unmet treatment needs and to





help clinicians identify and develop successful, evidence-based treatment plans for those most likely to benefit from a trial with a novel therapy.¹

When considering acute and preventive treatment for migraine, the AHS recommends following a generalized step-care model where traditional therapies are used first and then treatment is adjusted to meet the specific medical needs of individual patients.¹

Individualized treatment plans are more likely to provide appropriate therapy at the initial consultation and spare patients a series of failed therapeutic efforts, resulting in better clinical outcomes and lower healthcare costs.¹

Dr Turck

And Dr. Smith, now turning to the National Headache Foundation, known as the NHF. In January 2022, the NHF released a position statement reflecting their views on the management of patients with migraine.¹³ What is the position of the NHF on the use of newer treatments?

Dr. Smith:

The NHF agrees with the AHS that patient-centric care is often critical and advocates that the clinician, in partnership with each patient, makes key decisions related to treatment and achieving treatment goals.^{1,13} The scientific understanding of migraine has advanced considerably in recent years, bringing better tolerated and better studied treatments to patients – most notably anti-CGR P pathway monoclonal antibodies, gepants, and agents targeting serotonin receptors. This has contributed to growing awareness among clinicians that expectations for successful migraine control have evolved.¹³ Like the AHS, the NHF reinforces the importance of personalizing patient care when considering acute and preventive treatment for adults with migraine.^{1,13} The appropriate treatment for migraine prevention should not be determined solely by a step-care approach or a one-size-fits-all algorithm. The NHF recommends a model driven by treatment outcomes.¹³ The NHF supports primary care providers, including nurse practitioners and physician assistants, prescribing migraine-specific preventive drugs and not relegating the use of newer treatments to just headache specialists.¹³

Dr. Turck:

Both the AHS and NHF provide evidence-based therapy recommendations for acute treatment and migraine prevention. 1,13 Let's turn our attention to preventive treatment. Dr. Ailani, in which patient types is initiation of an anti-CGRP pathway monoclonal antibody generally appropriate based on the AHS Consensus Statement?

Dr. Ailani:

When considering the use of anti-CGRP pathway monoclonal antibodies, the AHS recommends that initial treatment be prescribed by a licensed clinician when a patient is 18 years or older and has been diagnosed with migraine, and meets the criteria for one of three patient types. The first patient type has four to seven monthly migraine days and is unable to tolerate due to side effects or has had an inadequate response to an eight-week trial of two or more preventive treatments, as outlined in the AHS Consensus Statement, at a dose established to be potentially effective and has had at least moderate disability. Moderate disability is defined as either a Migraine Disability Assessment or MIDAS of 11 or higher or a Headache Impact Test-6 or HIT-6TM of greater than 50. The second patient type has eight to fourteen monthly migraine days and is unable to tolerate due to side effects or has had an inadequate response to an eightweek trial of two or more preventive treatments, as outlined in the AHS Consensus Statement. The third patient type has a diagnosis of chronic migraine and is either unable to tolerate due to side effects or has had an inadequate response to an eight-week trial of two or more preventive treatments, as outlined in the AHS Consensus Statement, or is unable to tolerate or has had an inadequate response to at least two quarterly injections of onabotulinumtoxinA over a six month period. That said, according to the AHS Consensus Statement, with an attestation by the prescribing clinician about medical risk, a trial of two traditional therapies may not be required before initiating treatment with an anti-CGRP pathway monoclonal antibody.

Treatment continuation with a newer preventive agent beyond three months if administered quarterly is appropriate when there's either a reduction in mean monthly headache days or headache days of at least moderate severity by at least 50 percent versus the pre-treatment baseline or there's clinically meaningful improvement.¹ Clinically meaningful improvement may be determined by MIDAS, or, migraine physical function impact diary, known as MPFID, or HIT-6TM.¹ I want to stress again that the AHS Consensus Statement is very clear about the fact that evidence-based preventive treatment plans should be case-dependent and designed to meet the medical needs of individual patients with migraine.¹ This generalized step-care strategy should be adjusted accordingly so the appropriate therapy is provided, and patients can achieve better clinical outcomes and potentially lower healthcare costs.¹

Dr. Turck:





Dr. Smith, when it comes to using newer preventive treatments and personalizing patient care, the NHF takes a slightly different approach than the AHS. 1,13 What's the perspective of the NHF?

Dr. Smith:

Unfortunately, current payer and health insurance care models have not kept pace with recent treatment advances that may help migraine sufferers achieve treatment goals earlier. ¹³ As a result, clinicians must often adhere to a stepwise approach for all patients which includes using prescription drugs that are nonspecific to migraine. ¹³ The NHF views a migraine day as a standard 24-hour day during which a patient's ability to function is interrupted or impaired by one or more symptoms of migraine. ¹³ For patients with four to seven migraine days per month, the NHF recommends a modified step-care model in which a patient should first try one generic drug for migraine prevention unless the patient has a contraindication or, in the clinician's judgment, is not fit to receive it. ¹³ These generic medications include anticonvulsant drugs, beta blockers, antidepressants, and angiotensin-receptor blockers. ^{10,13} For patients with a minimum of eight migraine days per month, clinicians should have the ability to select the most suitable preventive therapy with unrestrained access to FDA-approved preventive medications. ¹³

If one of these generic medications has failed to provide the patient with benefits in the severity and/or frequency of migraine or is found to have intolerable side effects, the clinician should be free to select the next most suitable FDA-approved preventive therapy based on the individual patient's needs and situation.¹³ In the modified step-care model for preventive care recommended by the NHF, a patient is considered to have "tried and been failed by" a given drug if the patient does not experience an adequate treatment response after a two- to four-month trial, or they cannot tolerate the drug due to its side effects, or they have a comorbidity or contraindication that precludes the clinician from prescribing the drug.¹³ An adequate treatment response is defined as a 50 percent reduction in the number of migraine days per month during preventive therapy as compared with the number of migraine days per month prior to the start of therapy.¹³ These recommendations support the NHF's patient-centric, stratified approach to migraine care that take into account the degree to which migraine episodes adversely affect a patient's ability to function, work, and interact with others.¹³

Dr. Turck:

Dr. Smith, thanks for breaking down the NHF recommendations for us. Now, Dr. Ailani, we're almost out of time for today, so before we close, what key takeaways would you like to leave with our listeners?

Dr. Ailani:

There are several evidence-based medications available for acute and preventive treatment of migraine.¹ Patients who have severe, disabling, or frequent migraine attacks, as well as those who cannot tolerate or are nonresponsive to acute treatment, should be considered for preventive treatment.¹ Choosing the right treatment for adults with migraine, evaluating patient response to acute treatment, and measuring the benefits of preventive treatment are based on overall efficacy, tolerability, patient satisfaction, and a range of other critical factors.¹ However, ultimately, the goal is always to personalize care to meet the needs of individual patients and for treatment selection to be a patient-driven decision made in partnership with medical professionals.^{1,13}

Dr. Turck:

And, Dr. Smith, I'll turn to you. Your final thoughts?

Dr. Smith:

We know a one-size-fits-all approach doesn't work for adult patients with migraine, so it's important for clinicians to consider implementing a modified step-care model for migraine prevention. The benefit-risk profiles of newer treatments will continue to evolve as clinical trial and real-world data become available, and this emerging evidence will certainly have implications on our clinical practice. But at the end of the day as Dr. Ailani mentioned, adult patients with migraine are best served by a patient-centric care model where the clinician, in collaboration with the patient, makes treatment decisions to address each patient's goals and needs. 1,13

Dr. Turck:

With those final considerations in mind, I'd like to thank my guests, Drs. Jessica Ailani and Timothy Smith for sharing their perspectives with us about how we can incorporate a more patient-centric approach to migraine prevention in adults.

Dr. Ailani and Dr. Smith, it was great speaking with you today.

Dr. Ailani:

Thank you so much! It's been my pleasure to be here.

Dr. Smith:



Yes, thank you for having me.

Dr. Turck:

I'm Dr. Charles Turck and thanks for tuning in.

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