HeadWise™

A Voice for People with Migraine and Headache Disorders
From the National Headache Foundation

Pregnancy and Headache

What to do for your headaches during the 9 months of expectancy

Migraine Treatment

An Update for Patients

What you should know about current options in migraine therapy

Acupuncture

in Headache Treatment

The debate continues—
Is Acupuncture effective for headaches and if so, why?

Book Review: A new book on pediatric headache, *Childhood Headache, 2nd edition*

Kids' Korner: The Role of Sleep in Children with Headache

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Volume 3, Issue 3 • 2013
www.headaches.org

NATIONAL HEADACHE FOUNDATION

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NATIONAL HEADACHE FOUNDATION

If you think a headache is just a headache, think again. Millions of Americans suffer from migraines, cluster headaches and other serious headache disorders. Chances are, headache disorders affect you or someone you love.

Join the cause by becoming a member of the National Headache Foundation, the world's largest voluntary organization for the support of people with migraine and headache disorders. For more than 40 years, the NHF has assisted millions of individuals seeking education and treatment for their various conditions.

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Plus, your donation will support the NHF and help advance headache advocacy, education and research

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FROM THE EXECUTIVE CHAIRMAN:

As we approach the Holiday season, we are pleased with the accomplishments of the National Headache Foundation during this past year. Starting in 2013, the NHF headquarters assumed publication of our quarterly magazine, *HeadWise*™, and changed its direction with greater emphasis on science and headache education.

Over 800 individuals participated in our chat rooms to date in 2013. The chat rooms have been viewed on YouTube by over 4800. Through social networking, we have 8528 followers on Facebook, and 1934 followers on Twitter. Our average weekly engagement on Facebook is 9600 views.

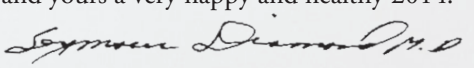
We continue to promote education and public awareness about migraine and headache. At the invitation of Delphi Automotive Inc., we participated in their *Living Well* Program, and presented lectures at various sites for their employees. Our educational brochures: *Your Migraine, Your Symptoms: What You Need to Know* and *A Patient Guide to Menstrual Headache* have been translated into Spanish.

Special lectureships were presented: T*he National Headache Foundation Lectureship* to Wade Cooper, DO (University of Michigan) and *Seymour Diamond, MD Lectureship* to Nasim Maleki, PhD (Harvard University). These lectureships give us the opportunity to recognize new and promising work in headache research and education.

Since its founding in 1970, the NHF has provided over $1.8 million in 208 research grants to physicians and scientists working in the field of headache. These research studies have resulted in over $600,000 of subsequent funding from the National Institutes of Health. These efforts have furthered the mission of the NHF in enhancing the healthcare of those experiencing chronic headache and migraine. In 2013, we will be distributing over $200,000 in research grants.

It is essential that we continue to support headache research and provide a resource for those with chronic headache as well as their families and health care providers. Our work can only continue with the support of our members and friends. I hope that you will consider donating to the NHF during the holiday season. You can visit the NHF website, **www.headaches.org**, to make your contribution.

We thank you in advance for your consideration. And, we wish you and yours a very happy and healthy 2014!



Seymour Diamond, M.D.
Chicago, Illinois

HeadWise™

The National Headache Foundation • www.headaches.org

Mission
To cure headache, and end its pain and suffering.

Vision
A world without headache.

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This publication discusses a broad range of headache information in an effort to inform and educate readers, but is not intended to substitute for the advice of your health care provider. Statements expressed herein are not necessarily those of NHF.

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NATIONAL HEADACHE FOUNDATION ®

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FEATURED ARTICLES

IN EVERY ISSUE

In Memoriam

Dawn A. Marcus, MD

It is with deep regret that we report that our colleague in headache medicine, Doctor Dawn A. Marcus, passed on October 19, 2013, at the age of 52. Throughout the years, she was a great friend to the National Headache Foundation, was often a contributor to *HeadWise*™, and moderated two successful chat rooms for us. In 2007, Dawn received the Excellence in Media Award from the NHF.

Doctor Marcus graduated from medical school at the State University of New York at Syracuse. Her residency in neurology was completed at the University of Pittsburgh Medical Center where, since 1990, she had remained a faculty member, and was currently a professor in the Department of Anesthesiology. Dawn developed a Multidisciplinary Headache Program at the Pain Evaluation and Treatment Institute at the University of Pittsburgh.

She was a prolific author, having contributed over 100 articles on the topics of chronic pain and headache to the professional literature. She also authored several books for healthcare professionals, including *Headache and Chronic Pain Syndromes*. For patients she contributed several texts, such as *10 Simple Solutions to Migraine* and *The Women's Fibromyalgia Tool Kit*. During the last few years, she combined her love of dogs with medicine and published, *Fit as Fido: Follow Your Dog to Better Health* and *The Power of Wagging Tails*, among others.

Doctor Marcus was a well-known lecturer on headache topics including fibromyalgia and headache. She participated in research trials on a variety of subjects, including pain epidemiology, headache pathology and treatment, and women's issues.

On behalf of the Board of the NHF, I would like to extend our condolences to her husband of 28 years, Richard Marcus, MD, and her sons, Steven and Brian. Her loss will be felt by her colleagues and especially the patients to whom she was devoted.

Seymour Diamond, MD
Executive Chairman and Founder
Chicago, IL

Seymour Diamond, MD Lectureship

The 2014 Seymour Diamond, MD Lectureship has been awarded to Doctor Melodie R. Winawer and her colleagues from the G.H. Servievsky Center and Department of Neurology, Columbia University, New York, NY. The lecture will be presented on Friday, February 14, 2014, during the Diamond Headache Clinic Research & Educational Foundation course, *The 27th Annual Practicing Physician's Approach to the Difficult Headache Patient*, which will take place at the Island Hotel Resort, Newport Beach, California.

The lectureship recognizes the most significant paper on headache published during the last year. The award is based on the article, "Evidence for a Shared Genetic Susceptibility to Migraine and Epilepsy," which appeared in the journal, *Epilepsia*, 2013; 54:288-295. Dr. Winawer is an Associate Professor of Neurology at Columbia University. She received her MD from the University of Pennsylvania, and her MS in Epidemiology from the Mailman School of Public Health of Columbia University. Her internship was undertaken at Mount Sinai Hospital in New York, and she completed her neurology residency and fellowship in Epilepsy and Neuroepidemiology at Columbia.

Lunch & Learn

Wade Cooper, D.O. presenting at Delphi Automotive Headquarters, Troy, Michigan.

About 1 year ago, the National Headache Foundation was invited by the wellness coordinator at Delphi Automotive Corporation, to present at several locations for the Delphi LiveWell program. The initial event was held at the Delphi Headquarters in Troy, Michigan on August 14, 2013. Wade Cooper, D.O., of the University of Michigan Headache Center, presented a lecture on "Headache in the Workplace," to Delphi employees. An NHF staff member was in attendance to provide our educational brochures and answer any questions about the Foundation.

During October, similar presentations were made by our former President, Robert S. Kunkel, MD, at the Delphi site in Warren, Ohio. The Director of Operations, Mary Franklin, presented at Delphi plants in Rochester, Amherst, and Lockport, New York and Kokomo, Indiana.

These events provide an opportunity to educate and raise awareness about the impact of headache and migraine in the labor force. The lectures were attended by individuals with headache as well as their supervisors/managers who learned about the problems faced by those with headache.

It is our hope that we can continue this educational outreach to other employers. If you or your employer are interested in the "Lunch and Learn" programs, please contact the Foundation offices at 312-274-2674 or info@headaches.org. We are also happy to provide brochures for any of these educational events.

NATIONAL HEADACHE FOUNDATION Lectureship

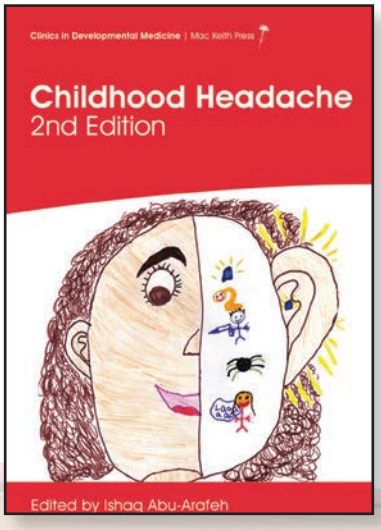
The National Headache Foundation is pleased to announce that Duren Michael Ready, M.D., Director of the Headache Clinic at Baylor Scott & White Health System, in Temple, Texas, has been named the recipient of the 2014 NHF Lectureship. As the premier educational and informational resource for those living with headache disorders, their family members, physicians, allied health professionals, and health policy decision makers, the NHF created this award to preserve the highest level of neurobiological research and advancement in medicine today. Recipients of the award prove themselves to be up-and-coming physicians and scientists who have demonstrated interest in the management of common and complex headache problems.

Doctor Ready will present his lecture, "Tertiary Care for Primary Headaches," at the course, The *27th Annual Practicing Physician's Approach to the Difficult Headache Patient*, which is sponsored by the Diamond Headache Clinic Research and Educational Foundation. The lecture will be presented on Sunday, February 16, 2014, at the Island Hotel, Newport Beach, California.

Doctor Ready received his M.D. degree from the School of Medicine at Texas Tech University Health Science Center, Lubbock, Texas. He completed his Family Practice Residency at Brazos Valley Medical Center in Bryan, Texas. Doctor Ready is a Diplomate of the American Board of Family Practice, is a Fellow of the American Headache Society, and is certified in Headache Medicine by the United Council of Neurological Subspecialties. He is also a Certified Diplomate in Pain Management from the American Academy of Pain Management. He currently serves as an Assistant Professor at Texas A&M University Health Sciences Center College of Medicine in the Department of Community and Family Medicine.

book review

by Jack Gladstein, MD, Guest Reviewer



Childhood Headache, 2nd Edition Edited by Ishaq Abu-Arafeh

It is very difficult to write a textbook that covers the topic of pediatric headache. A book to be used by parents as a resource will differ than one for primary care physicians. A book for general headache specialists will be different than one for specialists in the field of pediatric headache. Likewise, psychologists, therapists, or psychiatrists have their own needs when finding a book that helps with their ability to manage childhood headache sufferers. I am happy to report that *Childhood Headache, 2nd Edition*, can satisfy all of these readers. It combines a gentle reading style with various layers of complexity.

The first chapter is a "must read" in order to set the stage. Professor Abu-Arafeh reviews the history of what we know about childhood headache. Previous chapters of headache history relate to adults only, with limited mention of children. From ancient practices to this past century's attempts of inclusion of children in classification outlines, the author establishes the format for the rest of the book, which helps the reader see where we are now. I would have liked to see a brief glimpse of Goadsby's excellent review of physiology in this chapter to show how far we have come in the management of childhood headache.

In Chapter 2, Professor Goadsby reviews our current understanding of pathophysiology. Although he acknowledges that "kids have headaches too," he posits that the physiology of youngsters and adults, at least early in the process, should be similar. He stresses that as the brain matures, so do the physiologic changes associated with migraine. This chapter is more suited to the specialist, although it will also be of interest for the generalist to know how bench research will lead to a better understanding of patient needs.

The third chapter on genetics is up-to-date, although it relates more to epidemiologic aspects of childhood headache than pharmacologic implications of therapy. I am sure that future editions will include an updated section regarding this burgeoning field of headache medicine.

The chapter describing classification is difficult and indicated that childhood headache is not really covered well by current ICHD-II models. The author notes that clinical decision making still trumps classification outlines, but research study inclusion criteria must be based upon uniform accepted standards.

The epidemiology chapter is comprehensive and thorough. Parents educated about headaches who

want to know where their child fits in with a new diagnosis of headache will feel that they understand "the big picture."

Chapters 7 through 13 are mostly geared for primary care physicians. These chapters provide interested practitioners an approach to diagnosis and management of what will present at the office. It offers practical insights into diagnostic decision-making tools, disability assessment, and treatment options.

Chapters 13 through 25 are more geared to the headache specialist, who will evaluate children with either a more severe disability from their common diagnosis, or rare conditions which require more expertise. These chapters were informative to me as a pediatric headache practitioner, but offer the primary care physician a glimpse into the world of the child who experiences more disability from headache.

The last few chapters should not have been placed at the end of the book. The chapter by Professor Osteraus, "Psychological treatment of headache in childhood and adolescents" has practical implications for parents and the primary care physician. This information would have ideally located within chapters 7 to 13. Similarly in Chapter 28, the controversy of changing the diet to prevent headaches is discussed. Primary care physicians will encounter this question earlier than headache specialist. Chapter 29 is an excellent summary of what the primary care physician can and cannot do. I believe that this chapter should have been located after Chapter 14 as a summary. Similarly, Chapter 30 is an excellent review of what the specialist needs in the management of the more severely afflicted youngster. This information should have followed Chapter 25 as a solid review. I love the chapter that discusses what children can teach us about their headaches through their drawings. This discussion would have been a wonderful introduction before Chapter 7. It would have set the stage for describing the diagnostics and therapeutics for both the mildly affected youngster requiring primary care, and the seriously ill youngster requiring a multi-disciplinary headache clinic.

This book is an outstanding addition to the pediatric headache literature. In a small volume, there is enough material to satisfy the novice as well as the seasoned expert. I really enjoyed reviewing this book and am sure that parents and physicians alike will emerge with a better understanding and approach to youngsters with headache. HW

reader mail

You ask. Our headache experts answer.

Tired of searching the internet for answers?

It's time to learn from those in the know. In every issue of *HeadWise*™, our experts respond to reader-submitted questions about migraine and headache disorders.

WHAT'S UP WITH MORNING HEADACHES?

I wake with a headache every morning and go to bed with a headache. When I wake in the morning I always seem to have congestion at the back of my nose. I'm being treated for sinus headache with decongestants and antihistamines but symptoms never go away. This has been going on for 3 years and I'm not sure what to do next. – *Jennifer M.*

Headaches that occur when you wake up in the morning could be caused by several things. First, the nasal congestion you are experiencing could produce sleep apnea. If you cannot breathe through your nose at night then you are likely "mouth breathing" and snoring becomes more likely. Snoring is often associated with sleep apnea particularly if you are sleepy during the day. Your physician could order a sleep study to diagnose this if the above symptoms apply to you. Second, you could be suffering from rhinitis, which could trigger headaches in some people. If your nose becomes engorged with blood upon lying down this could activate the trigeminal nerve in your nose and produce headache. This could be relieved by a variety of medications prescribed by your physicians. Third, you could be experiencing hypnic headaches. These are headaches that wake people from sleep–usually in the middle of the night. These can be treated by a headache physician. Fourth, migraine–particularly chronic migraine–can cause headaches upon wakening. These headaches could be diagnosed and treated by your primary care physician or a specialist in headache disorders. Fifth, cluster headaches commonly occur at night and often awaken patients from sleep. These headaches always occur on the same side of the head, are severe and only last 30 minutes to 3 hours. They also commonly have tearing of the eye or running of the nose on the same side as the headache. Sixth, headaches related to pseudotumor can occur at night and worsen with lying down. Pseudotumor headaches result from increases in the pressure of spinal fluid within the head. They can be suspected by your physician by noting swelling of the optic nerve upon examination and later confirmed by a spinal tap. These headaches also have specific treatments. Therefore, your first step would be to obtain a diagnosis for your morning headaches. If you are having problems I would suggest that you consult a headache physician in your area.

Vincent Martin, MD
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Cincinnati, OH

EFFECTIVE TREATMENT FOR TMJ

I've worn a mouth guard for years and the pain I have from TMJ has never gotten better. Now it has been recommended to me to get jaw surgery to help TMJ and bite issues as well as consistent headaches. Can TMJ surgery help relieve headaches? – *Kris O.*

Migraine is a central nervous system disorder so the jaw is not a primary cause. On the other hand, persistent jaw pain can make daily headaches more likely, even if these are not migraines. Remember, many people with jaw pain are erroneously treated for "TMJ" when their primary problem is clenching. A commonly overlooked cause of clenching is a movement disorder of sleep known as sleep related bruxism. In this syndrome, people involuntarily clench their teeth while sleeping. They usually awaken with feelings of jaw fatigue or jaw pain and their dentists usually tell them they are chipping their teeth or wearing down the enamel. Bite splints can protect the teeth but the muscles are still contracting during sleep, causing pain. This condition is commonly treated with muscle relaxers from the benzodiazepine class and others. Stress management is also an important part of the treatment plan. It is worth considering this diagnosis before agreeing to invasive surgery. TMJ surgery is not the way to treat migraine.

Edmund Messina, MD, FAHS
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Michigan Headache Clinic
East Lansing, MI

ARTHRITIS AND HEADACHE

I have had a headache every day for almost two years. I have been to four different neurologists, and none of them could give me an answer for the headache. They tried almost every drug on the market to no relief. Now I'm on a narcotic patch and they seem to have calmed down. I also started going to a pain center were I finally got an answer. They say I have arthritis in my neck and that is the reason for my headache. Is this common and how do I cope with this? Any help would be appreciated – *Greg M.*

Neck pain is a very common complaint of headache sufferers, especially migraineurs, who may experience neck pain more often than they are nauseous with their headaches. However, cervical spine pathology (neck problems) discovered on an MRI is often seen as we age, even in people with no symptoms of headache or neck pain so it may be difficult to say for certain that your headaches are caused by arthritis in your neck. Also, narcotics will cover up pain of any type but can make patients with headaches worse very quickly, especially as they develop a tolerance to the dose they are using. I would suggest seeing a headache specialist to confirm the diagnosis as chronic narcotics are rarely a good choice for headache sufferers.

David S. Larsen, MD
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WEIGHT LOSS SURGERY AND HEADACHES

Do you know if weight loss surgery would have any effect on migraines or if losing weight would help control my migraines? – *Heather G.*

I am not aware of any significant study which supports weight loss surgery as a treatment for migraine, and we certainly see a lot of headache patients who have lost 100 pounds and are still having headaches. The problem with bypass surgery is the intolerance to nonsteroidal anti-inflammatory agents and other medications. Many bypass people do not absorb their migraine medications very well. On the other hand, this type of surgery has been shown to reduce the risk of type II diabetes, so it should be taken seriously. We see fewer complications in bariatric surgery patients who did not undergo the actual bypass procedure. In general, the more fit you become, especially with regular exercise, the easier your migraines will be to control.

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Pregnancy and Headache

Meredith Barad, MD
Clinical Assistant Professor,
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Stanford University

Sheena Aurora, MD
Clinical Associate Professor,
Department of Neurology
Stanford University

Although a large study has never been conducted, headache is probably the most frequent complaint in pregnancy. Tension-type headache is probably the most common headache type noted during pregnancy, and migraine is second. Initially, let's talk about some of the ominous headaches which are very rare:

Headaches Due To Cerebral Venous Sinus Thrombosis (CVT):

This type of headache is a very rare occurrence during pregnancy although it is the most common secondary reason to have a headache—which means there is an identified cause. The overall incidence of CVT is very low with 3 to 4 cases per million in adults. The cause of this condition is thought to be due to the hormonal surge during pregnancy which increases the risk of blood clots. Some of the early signs of CVT include an increasing severity of headaches, in other words headaches that continue to worsen. These headaches may be accompanied by symptoms such as nausea, stroke-like symptoms (i.e. numbness or weakness on one side of the body, new visual symptoms, seizures).

The most practical advice for pregnant women is to become ever more alert to unusual conditions because of an increased risk of problems with blood clotting. It is important that pregnant women maintain adequate fluid intake, particularly during travel. Although the "morning sickness" most evident during the first trimester can cause dehydration, their fluid intake should be closely monitored.

Tension-type Headache:

The features of tension-type headache during pregnancy are similar to those in the general population. These headaches are usually not accompanied by nausea, vomiting, or light or sound sensitivity—symptoms associated with migraine. The headaches are usually described as more of a nuisance. In general, these headaches are not disabling. The recommended treatment for tension-type headaches is relaxation exercises, deep breathing, massage, and if needed, low doses of acetaminophen.

Migraine Headaches:

We encourage patients who have a migraine history to consider options during the pre-pregnancy state. During pregnancy, we try to collaborate with the obstetrician, and if available a perinatologist, and if needed, a pregnancy pharmacologist. Recently, an NIH sponsored study from Swedish Medical Center in Seattle has demonstrated that pregnant migraineurs are more at risk for vascular complications (i.e. preeclampsia, placenta abruption). Migraineurs, compared to controls, also experienced more sleep abnormalities and seemed to be more overweight. Because of these findings, we ask our migraine patients

to control other vascular risk factors, such as high blood pressure, elevated cholesterol, and smoking.

In general, we ask patients to carefully evaluate their lifestyle. Nutrition, hydration, exercise, and sleep are factors which need to be considered. We also ask the patients to recognize stressful situations and consider use of stress relaxation, meditation, yoga, or massage. Adequate sleep, attention to sleep hygiene, and stress relaxation also becomes paramount.

During pregnancy, we advise our patients about the one-third rule. A third of the pregnant migraineurs improve during pregnancy, one-third maintains the status quo, and the remaining one-third experience an exacerbation of their headaches. Very rarely, migraines develop for the first time during pregnancy. In general, patients with menstrually-associated migraine improve during pregnancy. It is believed that hormonal fluctuations are probably the main trigger for migraine.

Migraine Treatment During Pregnancy

Three classifications for drug safety during pregnancy have been established. The U.S. Food and Drug Administration (FDA) categorizes the drugs into Category A through X (Table 1), Classifications have also been developed in Sweden and Australia.

There is one additional category, "Pregnancy Category N", which is a transitional identification indicating that the FDA has not yet classified the drug into a specified pregnancy category.

Acute Treatment

Recently, a large observational prospective study was conducted in Norway involving pregnant women. In the Norwegian Mother and Child Cohort Study, 1535 pregnant women received triptans. This study does provide some reassurance to women who may need to continue to use triptans during pregnancy. These women were compared to 373 migraine controls who had used a triptan during the 6 months prior to pregnancy. During the first trimester, 90% of the approximately 1400 patients used a triptan. In this relatively large cohort of pregnant patients exposed to the triptans during their first trimester, no increased risk of malformations in the fetuses was observed.

A pregnancy exposure registry is a study that collects health information from women who take medicines or vaccines while they are pregnant. The FDA does not run pregnancy studies, but it keeps a list of all registries that are current. Most pregnancy registries are sponsored by pharmaceutical companies, and maintained by an independent research company.

In general, we consult with a perinatologist and if available, a pregnancy toxicologist, in order to consider other risk factors such as maternal age, health, smoking, alcohol or other drug use, to assist in decisions of whether or not to continue the use of triptans during pregnancy. Probably, sumatriptan has the largest pregnancy registry. If a triptan is deemed low risk, we tend to recommend it over those with higher risk to the fetus.

The largest available data on opiates and pregnancy are based on retrospective exposure studies from the National Birth Defects Registry (NBDR). In these studies, data on over 17,000 cases were examined, with over 6000 controls, excluding mothers with exposure to street drugs, preexisting diabetes, or malformations with less than 200 cases or <4 exposures. Of the mothers interviewed, 2.6% reported use of opiates during the month prior or 3 months into their pregnancy, while 2.0% of controls reported a similar exposure. The predominant opiate exposures were to codeine and hydrocodone (34.5% each). A significant association was found between opiate use and congenital heart defects, as well as spina bifida, hydrocephaly, glaucoma or anterior chamber eye defects, and gastroschisis. Gastroschisis is a congenital defect characterized by a defect in the anterior abdominal wall through which the abdominal contents freely protrude. It is usually to the right of the umbilicus (belly button).

Finally, maternal obesity is another factor that needs to be considered. Maternal obesity has been associated, in and of itself, with increased risk of neural-tube defects and congenital heart defects. A neural tube defect (NTD) is an opening in the spinal cord or brain that occurs very early in human development and fails to close. Unfortunately, few studies have examined the effect modification based on obesity, which may be due to the pharmacokinetics of many of the medications. The term, *pharmacokinetics*, describes what happens in the body once a drug is administered. This includes the mechanisms of absorption and distribution, as well as the chemical changes (metabolism) of the substance in the body and how it is excreted from the body.

Pregnancy Planning in the Migraineur:

Preventive Therapy

The biggest concern with preventive medication use during pregnancy is the risk of congenital malformations.

Congenital malformation rates differ between countries but are generally around 3% of 4 million US annual live births and are the leading cause of infant mortality in the United States. About 4% of congenital malformations are caused by teratogens, agents that can cause abnormalities in the form or function of a developing fetus. Specific teratogens include infectious agents, maternal disease, physical exposures, and chemical exposures (medications). A more recent area of research has focused on the cognitive development of children exposed to medications *in utero*.

Anti-Epileptic Drug

Teratogenicity is the capability of causing birth defects. Much of the literature regarding the teratogenicity of anti-epileptic drugs (AEDs) is derived from the pregnancy registries for drugs used to treat epilepsy, and therefore, is not completely compatible with the migraine population. A recent study examining data from the National Birth Defects Prevention study (NBDPS), showed similar rates of major congenital malformations (MCMs) in the epilepsy group and in the seizure-free group taking the medication, but not in the non-medicated epilepsy group. This result suggests a drug specific effect. Unless noted, no data are available on dose and for many of the newer AEDs, the numbers enrolled are not sufficient to draw any final conclusions.

The North American AED Pregnancy Registry (NAAED) released their most recent data in 2012. Although only 1% of the enrollees were migraineurs, the prospective study provided some insight into MCMs due to AEDs in North America.

Valproate is a Category D drug, although the FDA is considering a possible change to Category X. Considered the most teratogenic AED, the available drug registries state the malformation rate with valproate ranges from 5 to 11%. The NAAED study showed valproate's MCM rate was 9.3%. Valproate monotherapy is associated with an increased risk of neural tube defects, cardiac septal defects, oral cleft defects, and hypospadias. This association has also been reported in other pregnancy registries. The NAAED also considered polytherapy and noted that the malformation rate with lamotrigine and valproate was 9%, and 15% for carbamazepine plus valproate. The NAAED study showed the median average daily dose during pregnancies with malformation was 1000mg versus 750mg for pregnancies without malformation. Futhermore, valproate is the one preventive agent in which *in utero* exposure has been associated with cognitive dysfunction in childhood with a decreased IQ. This association with *in utero* use of valproate, prompted FDA consideration of a category change from D to X (Table 1).

Phenobarbital is a category B/D agent (depending on the brand). The NAAED recently published data showing a 5.5% risk of MCMs, including hypospadias, cardiovascular anomalies, and oral cleft defects with the use of phenobarbital. This finding is similar to Tomson et al, who compiled 21 different review articles and found that 27 of 765 (3%) patients exposed to barbiturates reported cardiac malformations, two with cleft palate, and two with neural tube defects.

Lamotrigine is classified as a Category C drug. Lamotrigine is the only drug among the newer AEDs for which registries have enrolled sufficient numbers of pregnant women to permit reasonably firm conclusions of a 2 to 3% MCM rate which is equal to that of the general population. The NAAED reported first trimester use of lamotrigine carries a risk of oral cleft defect of 4.5 per 1000. This seems to be the only major MCM reported and in general, this medication is used preferentially in the epilepsy population.

Topiramate is classified as a Category D agent. To date, 569 cases are reported in the registries combined with 26 MCM. The major risk appears to be oral cleft defects. The NAAED reported that the prevalence of oral clefts was 1.4% in infants exposed to topiramate during the first trimester of pregnancy, versus 0.38% to 0.55% for infants exposed to other antiepileptic drugs, and 0.07% with no exposure. Topiramate can also cause metabolic acidosis which may result in adverse effects and fetal death and needs to be monitored during pregnancy, particularly during the second and third trimesters. Metabolic acidosis occurs when the body produces too much acid or the kidneys fail to remove enough acid from the body.

To date, the NAAED has only 145 reported cases of exposure to gabapentin and 1 MCM. In reviewing all the pregnancy registries, 328 cases have been reported with four MCMs. Although the data seem hopeful, this number is considered inadequate for any significant determination. Ninety cases with zonisamide have been reported with zero MCM at this point. The NAAED reports a larger group with levetiracetam, with 450 reported cases and 11 MCMs or 2.4%. Worldwide, 903 cases of levetiracetam use have been described with 36 reported MCMs.

The Neurodevelopmental Effects of Antiepileptic Drugs Study (NEAD) is a prospective study evaluating cognitive

outcomes at 6 years of age after exposure to monotherapy with valproate, carbamazepine, lamotrigine, or phenytoin. Interim results at 3 years in 309 children show that children exposed to valproate had an average IQ score nine points lower than children exposed to lamotrigine, seven points lower than those exposed to phenytoin, and six points lower than those exposed to carbamazepine. IQ scores did not differ significantly between lamotrigine, carbamazepine, or phenytoin. A subsequent analysis of 216 children from the same group revealed that verbal abilities were lower than non-verbal abilities in children exposed to each of these AEDs. It was recently revealed that these effects persisted at 6 years of age as well. The association between exposure to valproate and autism spectrum disorder has recently been confirmed in a population-based Danish register study.

Antidepressants

The Swedish National Birth Registry, from 1995-2007, was reviewed. This is a prospective study that included almost all pregnant women in Sweden. More than 14000 women had an exposure to an antidepressant, with over 12000 with an early exposure as defined before the first prenatal visit at 10 to 12 weeks. This review noted a statistically significant increase in preterm births. This effect was strongest with exposure to the tricyclic antidepressants (TCAs) (predominantly clomipramine in this group), SNRI (predominantly venlafaxine), and less with the SSRIs. Low birth weight was also noted with the largest effect in the SNRI group.

The most recent study to examine teratogenicity in SSRIs showed that the aggregate effect for major malformation is driven specifically by paroxetine and fluoxetine, and less significant with citalopram and sertraline. As demonstrated in previous meta-analyses, there was an increased risk of cardiac malformation in infants exposed to paroxetine.

Other studies have not found any MCM association with the TCAs. Nulman et al, followed 84 children exposed either to an SSRI or TCA and found no significant differences in language skills, IQ, temperament, mood, arousability, activity level, distractibility, or behavior problems.

Summary

In summary, the general guidelines that should be followed in the migraineurs of childbearing age include:

1. If you are planning to become pregnant and are being treated for a chronic condition (migraine, seizure disorder, depression), you should discuss options with your primary care physician and/or your obstetrician. Your physician will reassess the indication for treatment and consider gradual withdrawal before you become pregnant.
2. If pregnancy is a possibility in the near future, certain medications should be avoided, including valproate, carbamazepine, phenytoin, paroxetine, and fluoxetine.
3. If you are considering pregnancy, and are being treated with AEDs, your physician may start you on folic acid supplements.
4. If SSRIs have been effective and you are considering pregnancy, your physician may switch to citalopram or sertraline at the lowest dose possible.

It is essential that you discuss your reproductive plans and birth control methods with your physician before starting your migraine therapy. The use of regular opiates instead of other medications is no longer an acceptable form of therapy.

Case Study

NP is a 36-year-old social worker who started experiencing headaches at age 12 years. When she was younger, the headaches were usually triggered by sunlight and dehydration. Sleep would make the headaches better. During college, the headaches worsened with stress and her menstrual period. She started missing classes during her senior year, and she was placed on nortriptyline 25 mg. Her headaches improved and after 2 years, she was weaned from the medication.

The patient's headaches were then relatively well under control until her early thirties. She intermittently used rizatriptan for the acute headaches. Her headaches worsened dramatically since she started Clomid, a drug that is used mainly in female infertility. Clomid is used to start or induce ovulation in females who are not experiencing normal cycles. It is also used to hyperstimulate the ovaries during an *in vitro* fertilization procedure.

After consulting with the patient's obstetrician, we started Magnesium gluconate 500 mg and riboflavin 50 mg. She continued to complain of severe headaches and she was allowed to use rizatriptan dependent on negative pregnancy tests. The headaches continued to be severe and she was treated in the clinic with intravenous magnesium. Again, after consulting with her obstetrician, the patient was started on low-dose propranolol (20 mg). Propranolol has been used since the 1970s for migraine prevention. The headaches improved and the patient continued the Clomid.

The patient became pregnant after 2 to 3 months on propranolol treatment. Her headaches worsened during her first trimester and she was treated with acetaminophen and metoclopramide which is an effective anti-nauseant drug. The headaches improved during the second and third trimesters, and she occasionally required acetaminophen. The patient successfully delivered a healthy baby girl. **HW**

TABLE 1

Pregnancy Risk Factors

A Controlled human studies show no risk. Controlled studies in pregnant women fail to demonstrate a risk to the fetus in the first trimester with no evidence of risk in later trimesters. The possibility of fetal harm appears remote.

B Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women, or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester and there is no evidence of a risk in later trimesters.

C Risk cannot be ruled out. Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal effects or other) and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefits justify the use.

D Positive evidence of risk: There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (eg, if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

X Contraindicated in pregnancy: Studies in animals or human beings have demonstrated fetal abnormalities or there is evidence of fetal risk based on human experience, or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

Medications

TABLE 2

Acetaminophen	B
Opiates:	C
hydrocodone, codeine, methadone	
hydromorphone	
tramadol	
Oxycodone	B
SSRIs:	
Paroxetine	D
Fluoxetine	C
Sertraline	C
SNRIs:	
Duloxetine	C
Venlafaxine	C
TCAs	C
NSAIDs	C/D
	> 30 weeks
AEDs:	
Valproate	D
Phenobarbital	B/D
-manufacturer dependant	
Lamotrigine	C
Topiramate	D
Gabapentin	C
Pregabalin	C
Levitiracetam	C
Triptans	C
DHE	X
Benzodiazepine	D
Antihypertensives:	
Propranolol	C
Verapamil	C
Losartan	C/D
in second and third trimester	
Dopamine Antagonists:	
Metoclopramide	B

Trial Enrollment Information:

Healthcare providers may enroll patients in the Lamotrigine Pregnancy Registry by calling **(800) 336-2176**.

Patients may enroll themselves in the NAAED registry by calling **(888) 233-2334**.

Additional information is available at **www.aedpregnancyregistry.org**

[MIGRAINE TREATMENT]

An Update for Patients

Gary Ruoff, M.D.
Westside Family Medical Center,
Kalamazoo, MI

> Migraine has never been a big subject in medical school. But it is one of the most common reasons patients seek medical care. Those of us on the front lines know that a correct diagnosis and effective treatment can make all the difference. Without quality care, someone who starts with an occasional attack can end up with a chronic condition that needs the attention of a specialist.

About 15 years ago, a team of headache experts created basic, "evidence-based" guidelines–nstructions for how and when to use each drug–to help non-specialists treat migraine patients. Besides recommending how and when to use medication, the experts also suggested that anyone who treats patients with migraine should try to:

1. Involve them in caring for their own condition
2. Make final decisions about treatment with their patients, not just for them

The point is to make sure everyone understands the game plan, just like the coach and players on a good sports team.

It has been a long time since the guidelines were published, and that is why I am writing this article.

When I realized how many studies have been published since then, I noticed that there might be some room for change and improvement. I also saw that patients could start putting this kind of cutting-edge information to practical use immediately.

What You Should Know

Acetaminophen (Tylenol®)

For more than a decade, doctors have been told not to use acetaminophen for migraine. But at least two studies have shown that as long as the attack does not make you vomit or need to lie down, acetaminophen may be able to help relieve the pain of a migraine attack. Its effect on the other symptoms of migraine (nausea, etc.) is less clear.

Aspirin, Ibuprofen (Advil®, Motrin®), and Naproxen sodium (Aleve®)

Aspirin, ibuprofen and naproxen sodium are grouped together in the current guidelines. They are only considered appropriate for the pain of mild or moderate migraine attacks. If you have a severe attack or a sensitive stomach, you should avoid them.

Since the original guidelines were published, most of these medications have been studied and shown to be effective for patients with migraine. The important points to remember about them are:

- They are all better than placebo (sugar pill) for pain
- Ibuprofen seems to be better than aspirin or acetaminophen

Some patients say these drugs help with nausea, light sensitivity, and returning them to work. Remember that the safety precaution for sensitive stomachs still applies.

Acetaminophen, Aspirin, Caffeine (Excedrin®)

A drug which combines aspirin and acetaminophen with caffeine is used to relieve migraine attacks. In the current guidelines, this combination is preferred over aspirin or acetaminophen alone for mild or moderate migraine attacks. However, newer studies suggest that this guideline may change in the future. The combination of acetaminophen, aspirin, and caffeine is not only highly effective at relieving even the worst migraine pain, but it also helps relieve your nausea and sensitivity to light and sound, allowing you to return to your regular daily activities, such as work or school. This combination drug also appears to work better than two tablets of ibuprofen.

Migraine-specific medications

Some drugs are created specifically to work on migraine attacks. Examples of migraine-specific drugs include the triptans and dihydroergotamine (DHE-45®). The triptans (Table 1) are a group of drugs used for the treatment of migraine that are available by prescription only. In the current guidelines, doctors are told to use triptans as the first drug for:

- Attacks that are moderate or severe
- Patients whose headaches respond poorly to aspirin, ibuprofen, or a combination drug containing acetaminophen, aspirin, and caffeine

Since those guidelines were published, newer research has confirmed the efficacy and relative safety of the oral triptans.

Table 1 Examples of Triptan Medications

TRIPTANS		
Chemical name	**Brand name**	**Forms Available**
Sumatriptan	Imitrex®, Zecuity®	Oral, nasal, injectable, transdermal
Rizatriptan	Maxalt®	Oral
Naratriptan	Amerge®	Oral
Zolmitriptan	Zomig®	Oral, nasal
Eletriptan	Relpax®	Oral
Almotriptan	Axert®	Oral
Frovatriptan	Frova®	Oral

**May be sold under more than one brand name.*
Ask your doctor for more information.

Two newer triptan drugs are now available. The first, Treximet®, combines sumatriptan with naproxen sodium to provide relief for some migraine patients. The second, Zecuity®, is a patch that contains sumatriptan and can be applied to the skin–similar to nicotine patches. If your attacks or your medications sometimes make you nauseated, ask your doctor about the new sumatriptan patch.

Two migraine-specific medications that use the same active ingredient, dihydroergotamine, are currently recommended for moderate or severe attacks: injectable DHE-45® and the nasal spray, Migranal®. Both of these medications are effective for migraine, but many patients complain of nausea after taking them.

Opioids

Opioids are medications that relieve pain by reducing the intensity of pain signals reaching the brain. They also reduce pain by affecting the parts of the brain that control emotion. Sometimes, opioids are combined with another pain reliever, such as aspirin or acetaminophen . Several examples of opioids are listed in Table 2.

Table 2 Examples of Opioid Medications

Chemical name	Brand name
Hydrocodone	Vicodin®
Oxycodone	OxyContin®
Morphine	Kadian®
Codeine	Codeine®

**May be sold under more than one brand name. Ask your doctor for more information.*

Currently, the guidelines say drugs that mix opioids with pain relievers may be used for migraine in some situations. More recent research agrees with that recommendation. However, some experts believe the risks of addiction and overdose, outweigh the benefits of these drugs and avoid prescribing them for safety reasons. Opioids can be useful when other medications fail to work. However, they can lead to serious problems if they are not used appropriately.

If your doctor prescribes an opioid for migraine, it is important to remember that you should never take opioids on a regular basis. Use them only as a "rescue" drug–after you have taken another migraine medication which you are sure has not relieved your attack.

What You Can Do

Although new evidence may result in changes in some of the recommendations in the "evidence-based" guidelines, many will remain. For instance, the recommendation to use prescription drugs for moderate or severe attacks is not likely to change–newer studies confirm that they can be effective and are generally safe for use in migraine.

For over-the-counter drugs (OTC), there may be some changes. Published studies on the use of acetaminophen, aspirin, ibuprofen, and the combination drug containing aspirin, acetaminophen, and caffeine reported after publication of the guidelines show their efficacy in migraine treatment. Because some of these studies did not include data from patients with the most severe attacks and some did not report improvement in nausea or in helping patients return to work, the recommendation to use them for mild or moderate attacks will probably not change.

But are all these drugs similar? Not if you look closely at the research. Based on a review of the research data, if ibuprofen is more effective than aspirin or acetaminophen in treating acute migraine, and the combination agent of acetaminophen, aspirin, and caffeine (relieves pain better and faster than

Caffeine Cuts Both Ways in Migraine

Not sure what to think about caffeine? Don't worry; you're not alone. When it comes to migraine, caffeine is a sword that can cut both ways.

On One Hand . . .

Moderate caffeine intake produces no increased risk to health, according to the US Food and Drug Administration. For many years, doctors have been using caffeinated medications to treat patients with migraine. For migraine patients, pain relievers with caffeine work much better than those same pain relievers without caffeine.

On the Other . . .

Too much caffeine can cause withdrawal symptoms, such as headache, sleepiness, and impaired concentration. To experience these symptoms, most people need to drink about 2 or more cups of coffee (or a similar amount of caffeinated soda or "energy" drinks) every day for at least 2 weeks. Since the combination agent with acetaminophen, aspirin, and caffeine should never be used more than once per day or 2 times per week for migraine, you cannot get enough caffeine to cause withdrawal symptoms unless you misuse it. But you can reduce the effectiveness of the medication by consuming excessive amounts in your diet. As far as the combination agent causing "rebound headache"—where medications end up triggering headache rather than relieving it—all medications used to treat migraine put you at risk.

Since everyone is different, it is important that you work with your physician and pay attention to how caffeine affects you.

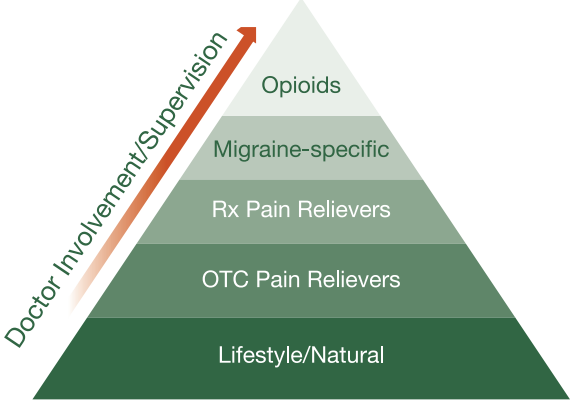
ibuprofen, then the combination agent should be the over-the-counter (OTC) drug of choice in treating a migraine headache. According to headache experts, the caffeine used in the combination agent can make a big difference (see sidebar). Just a small amount–about the same as that contained in a regular cup of coffee–makes the combination agent about 40% more effective than painkillers without caffeine, like acetaminophen or aspirin.

Like every treatment decision, a lot depends on you. You should work closely with your doctor to make sure you understand and are comfortable with any approaches that may be recommended.

The Self-Care Pyramid

To explain how migraine self-care is supposed to work, I ask my patients to view the situation as a pyramid (Figure 1).

As you work your way up the pyramid, the doctor's active role increases.



At the base, where patients can do the most to help themselves, it is important to remember that treating migraine is often not limited to finding the right medication. Lifestyle choices, such as proper diet and exercise, and efforts such as correct posture can be very important factors. Avoiding common dietary triggers–foods that can trigger an attack (Table 3)–can be one of the best ways to reduce the chances that you will experience an attack.

Common Dietary Triggers for Migraine

Aged cheeses	**Chocolate**
Alcohol*	**Nuts**
Caffeine	**Processed meats**
***Especially red wine**	

Another way to help prevent attacks is with the use of natural remedies (such as feverfew) and self-regulation techniques (biofeedback or relaxation). A number of my patients have been successful with a treatment that combines magnesium, riboflavin, and coenzyme Q10 in a single tablet.

The next step up the pyramid are the OTC medications, which require more supervision on the physician's part. This stage is followed by the prescription-only painkillers and the migraine-specific medications, which require an office visit and considerably more active supervision by the doctor. At the top are the opioids, which requires very close supervision of the patients, often on a daily basis. As we work our way up the pyramid, we work closely together as a team. However, the physician's active role increases as the patient's active role decreases.

For every level of the pyramid–with every drug and for every patient–it is essential that migraine medications not be used more than 9 days per month. More frequent use often increases the risk of rebound headache and, potentially, more serious health problems. In addition to taking care of the immediate problem–painful, disabling migraine attacks–I always try to identify and address other conditions, such as depression or sleep problems, that can affect the severity of the headache attacks, as well as the frequency of the headaches.

The Bottom Line

Many people with migraine miss the benefits of therapies that can help them. That's why my main goal, after a diagnosis is established, is to start patients on the right medication as soon as possible. The newer studies with OTCs may place a greater emphasis on self-care – similar to other diseases, such as arthritis–but that does not mean you are on your own. Rather, you will continue to work with a professional to find ways for you to play a more important role in managing your condition. With newer data showing that OTC drugs can be effective and safe for migraine, the good news is that more patients than ever will be able to benefit from this cost-effective class of medications. The next time you discuss your headaches with a medical professional, remember to ask about the new research. Working together, you may be able to make small changes that can make a big difference in your future! HW

In Memory/Tributes

The practice of asking for donations to a favorite charity in memory of a deceased relative or friend is very thoughtful. A gift may also be given as a tribute in the name of a friend or relative to commemorate significant occasions, such as birthdays, anniversaries, or special events.

During the past year, such requests have resulted in donations which benefit the National Headache Foundation. Acknowledgments of memorial gifts and tributes are mailed to the family or individual. We thank those benefactors and their families who have supported the NHF and its mission.

In Memoriam

Marlene Barber
Lee Benton, Esq.
Yvonne Groves
Barbara Kaplan (Libby Fund)
Albert H. Kurz
Sylvia Rigrodsky

In Tribute

Baylor Neuroscience Department
José Biller, M.D.
Dr. Diane Counce
Tesa D'Ardenne
Mitchell Garber
Libby Kandel
Debbie Keith
Robert Kunkel, M.D.
Tayloe LePore
Greg Lutter
Nepemocema Martinez
Mimi Waite

For adults with Chronic Migraine, 15 or more headache days a month, each lasting 4 hours or more,

BOTOX® is the first and only preventive treatment proven to reduce headache days every month.

BOTOX® is the only FDA-approved, preventive treatment that is injected by a doctor every 3 months for people with Chronic Migraine. BOTOX® prevents up to 9 headache days a month, versus up to 7 days for placebo. BOTOX® is not approved for adults with migraine who have 14 or fewer headache days a month.

FOR ADULTS WITH
CHRONIC MIGRAINE

BOTOX®
onabotulinumtoxinA

Find a headache specialist near you at
BotoxChronicMigraine.com

BOTOX® is a prescription medicine that is injected to prevent headaches in adults with Chronic Migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years or older. It is not known whether BOTOX® is safe or effective to prevent headaches in patients with migraine who have 14 or fewer headache days each month (episodic migraine).

IMPORTANT SAFETY INFORMATION

BOTOX® may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:

- **Problems swallowing, speaking, or breathing,** due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months.
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat Chronic Migraine.

Please see additional Important Safety Information on adjacent page.

MEDICATION GUIDE
BOTOX® and BOTOX® Cosmetic (Boe-tox) (onabotulinumtoxinA) for Injection

Read the Medication Guide that comes with **BOTOX** or **BOTOX Cosmetic** before you start using it and each time it is given to you. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

What is the most important information I should know about BOTOX and BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic may cause serious side effects that can be life threatening, including:

- **Problems breathing or swallowing**
- **Spread of toxin effects**

These problems can happen hours, days, to weeks after an injection of BOTOX or BOTOX Cosmetic. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX or BOTOX Cosmetic:

1. Problems swallowing, speaking, or breathing. These problems can happen hours, days, to weeks after an injection of BOTOX or BOTOX Cosmetic usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with **BOTOX** or **BOTOX Cosmetic**.

- People with certain breathing problems may need to use muscles in their neck to help them breathe. These people may be at greater risk for serious breathing problems with **BOTOX** or **BOTOX Cosmetic**.
- Swallowing problems may last for several months. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving **BOTOX** or **BOTOX Cosmetic** have the highest risk of getting these problems.

2. Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:

- loss of strength and muscle weakness all over the body
- double vision
- blurred vision and drooping eyelids
- hoarseness or change or loss of voice (dysphonia)
- trouble saying words clearly (dysarthria)
- loss of bladder control
- trouble breathing
- trouble swallowing

These symptoms can happen hours, days, to weeks after you receive an injection of **BOTOX** or **BOTOX Cosmetic**.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving **BOTOX** or **BOTOX Cosmetic**?"

There has not been a confirmed serious case of spread of toxin effect away from the injection site when **BOTOX** has been used at the recommended dose to treat chronic migraine, severe underarm sweating, blepharospasm, or strabismus, or when **BOTOX Cosmetic** has been used at the recommended dose to treat frown lines.

What are BOTOX and BOTOX Cosmetic?

BOTOX is a prescription medicine that is injected into muscles and used:

- to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents (urge urinary incontinence), a strong need to urinate right away (urgency), and urinating often (frequency) in adults when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to treat leakage of urine (incontinence) in adults with overactive bladder due to neurologic disease when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day.
- to treat increased muscle stiffness in elbow, wrist, and finger muscles in adults with upper limb spasticity.
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

BOTOX is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

BOTOX Cosmetic is a prescription medicine that is injected into muscles and used to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary).

It is not known whether **BOTOX** is safe or effective in people younger than:

- 18 years of age for treatment of urinary incontinence
- 18 years of age for treatment of chronic migraine
- 18 years of age for treatment of spasticity
- 16 years of age for treatment of cervical dystonia
- 18 years of age for treatment of hyperhidrosis
- 12 years of age for treatment of strabismus or blepharospasm

BOTOX Cosmetic is not recommended for use in children younger than 18 years of age.

It is not known whether **BOTOX** and **BOTOX Cosmetic** are safe or effective to prevent headaches in people with migraine who have 14 or fewer headache days each month (episodic migraine).

It is not known whether **BOTOX** and **BOTOX Cosmetic** are safe or effective for other types of muscle spasms or for severe sweating anywhere other than your armpits.

Who should not take BOTOX or BOTOX Cosmetic?

Do not take **BOTOX** or **BOTOX Cosmetic** if you:

- are allergic to any of the ingredients in **BOTOX** or **BOTOX Cosmetic**. See the end of this Medication Guide for a list of ingredients in **BOTOX** and **BOTOX Cosmetic**.
- had an allergic reaction to any other botulinum toxin product such as *Myobloc*®, *Dysport*®, or *Xeomin*®
- have a skin infection at the planned injection site
- are being treated for urinary incontinence and have a urinary tract infection (UTI)
- are being treated for urinary incontinence and find that you cannot empty your bladder on your own (only applies to people who are not routinely catheterizing)

What should I tell my doctor before taking BOTOX or BOTOX Cosmetic?

Tell your doctor about all your medical conditions, including if you:

- have a disease that affects your muscles and nerves (such as amyotrophic lateral

sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome). See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"

- have allergies to any botulinum toxin product
- had any side effect from any botulinum toxin product in the past
- have or have had a breathing problem, such as asthma or emphysema
- have or have had swallowing problems
- have or have had bleeding problems
- have plans to have surgery
- had surgery on your face
- have weakness of your forehead muscles, such as trouble raising your eyebrows
- have drooping eyelids
- have any other change in the way your face normally looks
- have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence. Symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever.
- have problems emptying your bladder on your own and are being treated for urinary incontinence
- are pregnant or plan to become pregnant. It is not known if **BOTOX** or **BOTOX Cosmetic** can harm your unborn baby.
- are breast-feeding or plan to breastfeed. It is not known if **BOTOX** or **BOTOX Cosmetic** passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products. Using **BOTOX** or **BOTOX Cosmetic** with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX or BOTOX Cosmetic in the past.**

Especially tell your doctor if you:

- have received any other botulinum toxin product in the last four months
- have received injections of botulinum toxin, such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA) in the past. Be sure your doctor knows exactly which product you received.
- have recently received an antibiotic by injection
- take muscle relaxants
- take an allergy or cold medicine
- take a sleep medicine
- take anti-platelets (aspirin-like products) and/or anti-coagulants (blood thinners)

Ask your doctor if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take BOTOX or BOTOX Cosmetic?

- **BOTOX** or **BOTOX Cosmetic** is an injection that your doctor will give you.
- **BOTOX** is injected into your affected muscles, skin, or bladder.
- **BOTOX Cosmetic** is injected into your affected muscles.
- Your doctor may change your dose of **BOTOX** or **BOTOX Cosmetic**, until you and your doctor find the best dose for you.
- **Your doctor will tell you how often you will receive your dose of BOTOX or BOTOX Cosmetic injections.**

What should I avoid while taking BOTOX or BOTOX Cosmetic?

BOTOX and **BOTOX Cosmetic** may cause loss of strength or general muscle weakness, or vision problems within hours to weeks of taking **BOTOX** or **BOTOX Cosmetic. If this happens, do not drive a car, operate machinery, or do other dangerous activities.** See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"

What are the possible side effects of BOTOX and BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic can cause serious side effects. See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"

Other side effects of BOTOX and BOTOX Cosmetic include:

- dry mouth
- discomfort or pain at the injection site
- tiredness
- headache
- neck pain
- eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes.
- urinary tract infection in people being treated for urinary incontinence
- painful urination in people being treated for urinary incontinence
- inability to empty your bladder on your own and are being treated for urinary incontinence. If you have difficulty fully emptying your bladder after getting **BOTOX**, you may need to use disposable self-catheters to empty your bladder up to a few times each day until your bladder is able to start emptying again.
- allergic reactions. Symptoms of an allergic reaction to **BOTOX** or **BOTOX Cosmetic** may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of **BOTOX** and **BOTOX Cosmetic**. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about BOTOX and BOTOX Cosmetic:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about **BOTOX** and **BOTOX Cosmetic**. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about **BOTOX** and **BOTOX Cosmetic** that is written for healthcare professionals. For more information about **BOTOX** and **BOTOX Cosmetic** call Allergan at 1-800-433-8871 or go to www.BOTOX.com.

What are the ingredients in BOTOX and BOTOX Cosmetic?

Active ingredient: botulinum toxin type A

Inactive ingredients: human albumin and sodium chloride

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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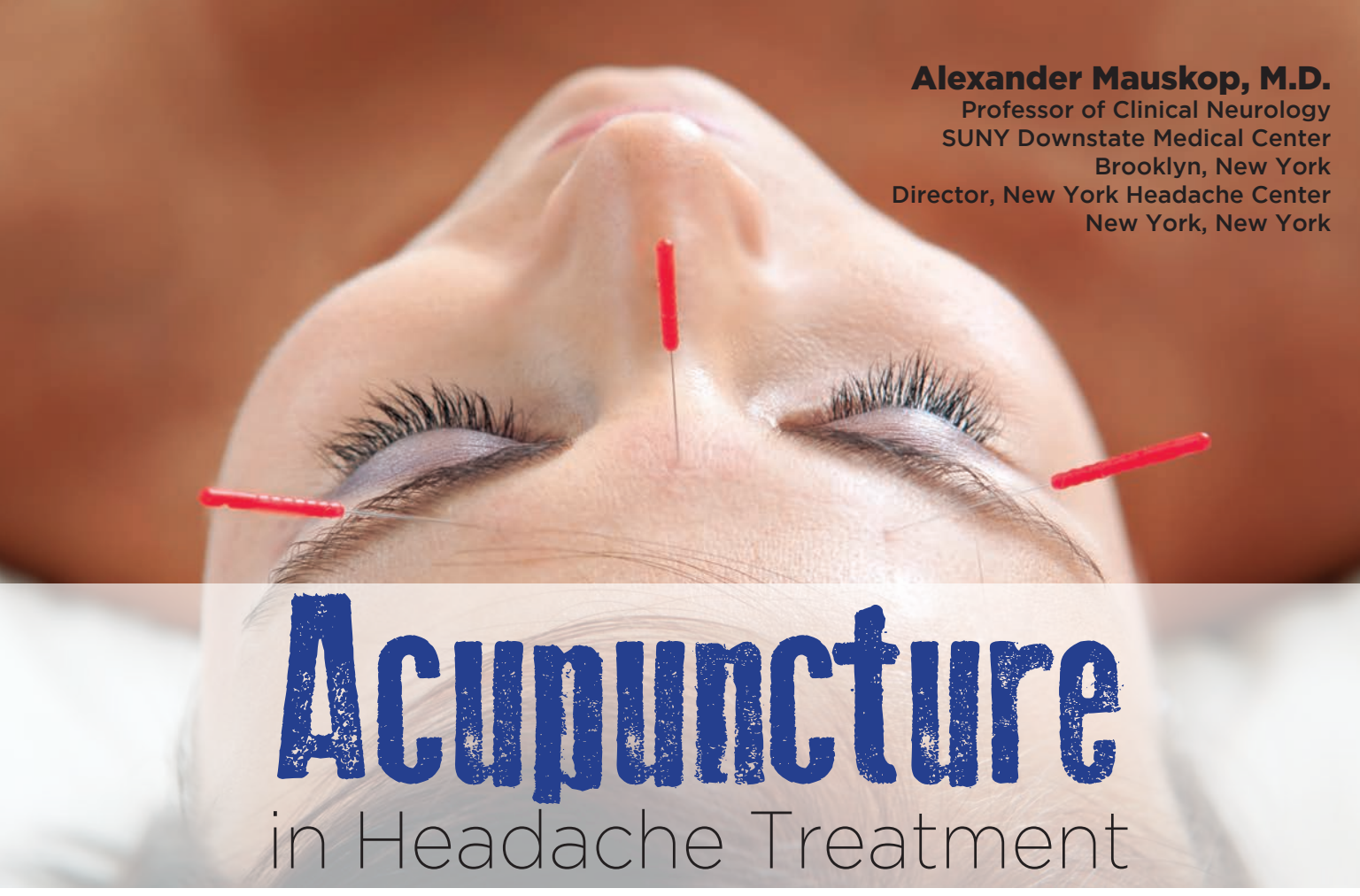


Acupuncture in Headache Treatment

This ancient Chinese treatment has been subjected to hundreds of animal studies, which have established that acupuncture may exert its effect by causing release of natural pain-relieving substances such as endorphins (endogenous morphine). This pain-relieving effect can be reversed in animals by injecting naloxone, an antidote given for narcotic overdose. Other possible mechanisms of action discovered via animal experiments are through the brain's serotonin, histamine, and GABA systems.

A very large number of clinical trials have also been performed in humans. Only a small number of these trials were rigorous and provided reliable information. A detailed review of 14 trials of acupuncture used in the treatment of recurrent headaches was published by Melchart and his colleagues in the international headache journal, *Cephalalgia*, in 1999. This report noted that the majority of 14 trials comparing true and sham acupuncture showed at least a trend in favor of true acupuncture.

A British study, led by Vickers, evaluated the effect of acupuncture on chronic headaches in 401 patients in a primary care setting. Patients in the acupuncture group received 12 weekly treatments and the control group received the usual headache treatment. Both groups were followed for 12 months. The headache score dropped by 34% in patients receiving acupuncture versus 16% reduction in the control group. Medication use was 15% less in the acupuncture group. Several quality of life measures were better in the acupuncture group who also reported 25% fewer visits to their general practitioner.

The most significant studies were funded by the German government. The first study included 302 patients with migraine who were randomly assigned to one of three groups: a group of patients who were treated with acupuncture; a group receiving sham acupuncture; and, a group of patients assigned to a waiting list for 3 months who were subsequently treated by acupuncture. The study revealed that both in the real and sham acupuncture groups about 50% of the patients responded. The responder rate in the waiting list group was only 15%.

The second study was a prospective, randomized, multicenter, double-blind, parallel-group, controlled, clinical trial, which is considered the most rigorous and scientific method. Patients reported 2 to 6 migraine attacks per month, and were randomly assigned to

true acupuncture (313 patients), sham acupuncture (339 patients), or standard therapy (308 patients). The primary outcome showed a mean reduction of 2.3 days of headaches in the true acupuncture group, 1.5 days in the sham acupuncture group, and 2.1 days in the standard therapy group. The proportion of responders, defined as patients with a reduction of migraine days by at least 50%, 26 weeks after randomization, was 47% in the true acupuncture group, 39% in the sham acupuncture group, and 40% in the standard group.

The noted German headache expert, H-C Diener who led these trials, concluded that acupuncture is as effective as drug therapy, but that sham acupuncture is as effective as 'real' acupuncture. Diener's interpretation of the results was that acupuncture should be offered to patients who do not respond to prophylactic treatment with drugs, are experiencing side effects to drug treatment, or have contraindications to drug treatment. Unfortunately, the German government decided that acupuncture would not be reimbursed by their national health insurance—most likely due to the costs involved.

The largest acupuncture study conducted in patients with headaches was performed and reported by Jena and her colleagues in the journal *Cephalalgia* in 2008. This trial was the largest but not as scientifically rigourous as other trials. It involved 15,056 patients with migraine and tension-type headaches who were assigned to receive, over 3 months, either conventional treatment (1,569 patients) or conventional treatment in addition to 15 acupuncture treatments (1,613 patients). During the study, 11,874 patients refused to be randomized, received acupuncture, and were placed into a third group. Significant difference in quality of life and in headache days per month were observed in two acupuncture groups. The number of headache days per month dropped from 8.4 to 4.7 days, while in the control group the drop was only from 8.1 to 7.5 days. Improvement persisted for 3 months following the completion of treatment.

Chinese doctors led by Li published another rigorous study in 2011, "Acupuncture for migraine prophylaxis: A randomized controlled trial." This investigation involved 480 patients who received 20 treatments over 4 weeks. They divided these patients into three treatment groups with various types of acupuncture and one sham acupuncture group. In all 3 true treatment groups, a significant reduction of days with migraine was noted in comparison to sham acupuncture, and the improvement lasted 12 weeks following the treatment.

One may question why the sham acupuncture often gives the same results as traditional acupuncture. It is likely that the endogenous opiod system is involved both in true acupuncture and placebo analgesia. However, some studies suggest that there is a difference between true and sham acupuncture. A study by R. Harris and his group compared both short- and long-term effects of traditional acupuncture and sham acupuncture on the endogenous pain system in various parts of the brain. A positron emission tomography (PET) scan was done during the first treatment session and a month after the last, eighth treatment. Similiar brain changes were found in both groups, but true acupuncture therapy also produced some short-and long-term changes that were absent in the sham group. This study suggests that true acupuncture may be superior but clinical trials performed to date have failed to prove this.

All of these studies indicate that acupuncture is at least as effective as drugs used to prevent migraine headaches. However, acupuncture carries a much lower risk of side effects. It appears that sham acupuncture, that is sticking needles into random places, produces the same results as when the needles are inserted into the traditional acupuncture points.

This finding is also supported by another German study that compared the efficacy of acupuncture when performed by different medical specialists. This study reviewed 454,920 patients with at least one of three chronic pain conditions including headache, low back pain, and osteoarthritis. These patients were treated by 8,727 medical acupuncturists who were covered by the government research program. Fifty-three percent of the patients were treated by general practitioners, 19% by orthopedists, and 9% by internists. Eighty percent of the patients were female with a mean age of 54 years. The primary indication for acupuncture was low back pain (45%), headache (36%), and osteoarthritis (12%). The mean time since the initial diagnosis was 3 years. On average, 8.5 sessions of acupuncture were administered. In 28%, other treatments were also reported. Physicians rated the improvement as marked in 22% of the patients, as moderate in 54%, as minimal in 16%, and in 4% as poor (unchanged). In 8% of the patients, mild side effects were reported, while severe side effects occurred in 13 patients (0.003%). Orthopedists rated the effectiveness of acupuncture lower and also showed shortest time for face-to-face contact with the patient. More acupuncture training did not correspond to better treatment results, as assessed by physicians. These results showed that acupuncture provided by qualified therapists is safe, and

patients benefitted from the treatment.

So, what are the drawbacks of acupuncture? The primary one is cost since most American insurance companies do not cover it. Prices range from $25 to $150 a session. It is usually less expensive when performed by a non-physician acupuncturist. The second drawback is that this form of therapy is time consuming. Treatments are performed at least once a week and a typical course is comprised of at least 10 sessions. However, in my experience, if a patient does not feel some effect after 4 or 5 sessions, further sessions are not likely to help. Another predictor of success that can be observed even on the first session is a sense of deep relaxation or an overall pleasant feeling.

Acupuncture can be administered in several ways. Most methods involve placing needles in various parts of the body and the head, and then twirling the needles from time to time. Instead of twirling, some acupuncturists attach electrodes to the needles and pass electric current through them using a battery-operated device. We are not sure if this electro-acupuncture is more effective than the traditional acupuncture. Auriculotherapy, a version of acupuncture used by a small number of acupuncturists, involves the placement of needles limited into the ears. Similar to reflexology (foot massage) in which all organs are thought to be represented on the foot, ear acupuncture is based on the premise that all of the organs are represented by points in the ears. Some acupuncturists use burning herbs that are placed at the tops of acupuncture needles to strengthen the effect of acupuncture. This is called moxibuxtion. At times, moxibuxtion is performed without needles by bringing a burning cigar-shaped roll of herbs close to the patient's skin. Moxibuxtion has not been studied in any scientific trials.

Acupuncture is clearly much safer than prescription and over-the-counter drugs, but it is not free of side effects and complications. The most common side effects include fainting, especially during the first session, due to patients' anxiety and fear of needles. Also, acupuncture can worsen headaches or other pains, usually after the first session. Fainting can also occur from pain when the acupuncturist twirls the needles, although most patients do not find acupuncture to be painful. Bruising and bleeding are rare because the needles are typically very thin. Acupuncture can also cause an infection; however, this occurs rarely since virtually all acupuncturists use disposable needles, which are very inexpensive. There have been reports of lung collapse when a long and thick needle is used and it punctures the lung. A long needle can also potentially damage the spinal cord or the heart. Needles can break, although this is rare because needles are very thin and flexible. However, if a needle does break, it can cause an infection or it can travel under the skin. Most of these complications can be avoided by consulting experienced acupuncturists who use short, disposable needles.

Some doctors advise pregnant women to avoid

"Acupuncture is a useful alternative to drug therapy in patients experiencing migraine, sinus and tension-type headaches"

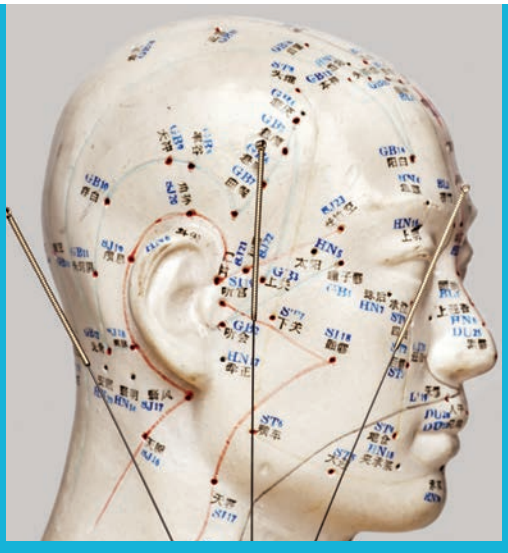
acupuncture because it can cause premature labor. However, there are no scientific reports indicating this occurs. A 2002 Australian study on the safety of acupuncture for nausea in early pregnancy confirmed that there is no increased risk of congenital anomalies, miscarriage, stillbirth, placental abruption, pregnancy-induced hypertension, preeclampsia, premature birth, or other problems when women receive acupuncture during pregnancy. The study was conducted during the first trimester of pregnancy when fetal development is most vulnerable.

In summary, acupuncture is a useful alternative to drug therapy in patients experiencing migraine, sinus, and tension-type headaches. The use of acupuncture in migraine treatment has the most evidence in regards to efficacy and safety. It has been used effectively and safely, but it is time consuming and relatively expensive. If the headache specialist does not incorporate acupuncture into the management of the headaches, the patient can request a referral. The patient can also review a list of acupuncturists online. Forty-three states require licensure for acupuncture therapists. If your state has this requirement, you could check online to determine if your therapist is licensed.

Case Report

A 70-year-old woman was referred to a headache clinic by her primary care physician due to recent onset of daily headaches for one month. She could not identify an obvious trigger for her headaches. The headaches started in the front of her head and often radiated to the rest of the head. She described a few episodes of mild nausea which occurred when the headache was severe. An MRI scan of the brain and blood tests were normal. She had tried gabapentin for the prevention of these headaches, but she felt tired and dizzy while on this drug. Also, she tried a course of steroids, other preventives, and Botox injections without relief. A combination drug containing butalbital, caffeine, and acetaminophen seemed to work well, but she needed to take it on a daily basis. Because daily intake of this type of drug is known to exacerbate headaches (so called medication-overuse headaches) and no other drugs had helped, the patient agreed to try acupuncture.

The patient underwent eight weekly acupuncture treatments with needles placed in her ears, arms, and legs. She reported a dramatic relief of her headaches. During the subsequent 5 years, the patient continued to experience occasional headaches, which never became daily or frequent. Interestingly, 2 years after the onset of her headaches, the patient developed a very painful outbreak of shingles, which was more effectively helped by acupuncture than by narcotic pain killers. **HW**



Arthur H. Elkind, MD (President of the National Headache Foundation) noted: Acupuncture is difficult to establish with a definite scientific proof as to its effectiveness. The placebo effect is noticeable. In patients who are not helped by standard therapies, it is "worth a try." I would emphasize it is an invasive procedure. The subject/patient must be sure disposable needles are used and one should seek licensed qualified physicians to administer the injections with the long needles. Although fortunately, serious complications are very rare, these adverse effects have been encountered. The use of contaminated needles could expose the patient to Hepatitis B and C, as well as HIV.

The Role of Sleep in Children with Headache

Sleep is important. Unfortunately, in today's society, sleep is frequently one of the first things eliminated from the to-do list in order to make room for other things. This behavior carries over to our children, which has led to 15 million children in the United States being reported as sleep deprived.

In children with migraine, sleep is even more important. Sleep disruption is a common trigger for children with migraine. Sleep is also is one of the most effective treatments in aborting a child's migraine. When counseling parents and patients about effective, non-medication based treatments for migraine, I always include a discussion about obtaining good quality and quantity sleep.

There are many benefits to sufficient sleep. Sleep is known to help consolidate learning from the day. It restores normal cognitive function and alertness and allows other organs of the body to rest and recover. The necessary amounts of sleep changes throughout our lifetime. Toddlers require 12 to 13 hours a day, 3 to 5 year olds need 11 to 12 hours, 6 to 12 year olds need 10 to 11 hours, and 12 to 18 year olds require 9 hours. As children get older, particularly into preteen and teen years, these numbers are much harder to attain. On average, most teens get 7 hours a night meaning that around 70% of teens are getting insufficient sleep. It is even harder for children experiencing migraine. These children are four times more likely than their peers to report sleep difficulty. Children with migraine report that sleep is more difficult to maintain and is of a poorer quality. There is also a higher incidence of sleep talking, teeth grinding, and bad dreams.

Irregular sleep patterns are a common cause for migraine attacks. Sleep deprivation is a trigger for about 25% of migraine sufferers and up to 6% report that oversleeping is a trigger. Insufficient sleep also makes it much harder to cope with pain during the day, making the pain of migraine more severe. Stress, which is a trigger for 80% of migraine sufferers, is much harder to ease when sleep deprived.

Sleep difficulty can also be an indicator of other underlying problems. Children with migraine are more likely to have sleep-related breathing disorders, such as

"Sleep hygiene is a series of practices that allow for normal, good quality sleep. Many of the problems surrounding sleep are related to poor sleep hygiene."

sleep apnea. Headache can be one of the only signs of sleep apnea, particularly if headaches occur in the morning. Other possible symptoms of sleep-related breathing disorders include snoring, restless sleep, excessive daytime sleepiness, and difficulties with attention. Mood disorders like depression and anxiety also make falling and staying asleep much more difficult. In a child with migraine and insomnia, questions about feeling sad and/or anxious should always be asked.

Sleep hygiene is a series of practices that allow for normal, good quality sleep. Many of the problems surrounding sleep are related to poor sleep hygiene. Other contributing factors include not allowing enough time for adequate sleep as guided by the age requirements stated above, excessive daytime napping, and caffeine consumption. In addition, technology and electronics are notorious sleep disruptors, making it very hard for us to fall asleep.

So, how do we fix all of this? First, all children with migraine should be getting the recommended amount of sleep. Reasons that are delaying a child's bedtime should be identified and addressed. If homework is the cause, the start time of homework should be moved earlier, or possibly some homework should be completed during free periods in the school day. If extracurricular activities are taking up the majority of the evening, some may need to be eliminated or done at a reduced frequency. Next, all children with migraine should practice good sleep hygiene. The importance of a steady routine cannot be understated. There should be a strict bedtime and awakening time that should remain the same on weekdays and weekends. The time leading up to bedtime should involve quiet activities, avoiding things that are stimulating including homework, exercise, and electronics. This is a good time to practice some meditation or relaxation exercises. The routine leading up to bedtime should be similar each night to create positive associations with going to sleep. Daytime caffeine should be reduced or eliminated and children should stay away from excessive fluids prior to bedtime. Napping during the day should be avoided, unless it is for brief and structured periods of time. The bedroom itself should be dark and quiet with a temperature that is in the low 70s. Children should learn to fall asleep alone without the presence of a parent. Electronics should be removed from the bedroom. There should be no television, computer, or tablet available at bedtime and phones should be charged in a different room overnight.

With good sleep hygiene, 50% of sleep issues will resolve completely and an additional 40% will at least partially resolve. The longer one practices good sleep hygiene the more engrained and, thus easier, it becomes. With good sleep practices, migraine frequency will reduce, often significantly. All of those with migraine should make sleep high on the priority list, as sleep can be a migraine sufferer's biggest ally. In addition, good sleep practices learned in childhood will carry through adulthood helping to keep migraine frequency low and improve overall health and well-being. HW

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