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The Voice of Texas Neurology

## President's Message

Tommy Yee, MD



**Happy Holiday Season to all!** As your president, I have had the honor of representing the Texas Neurological Society in two very important meetings and would like to inform you of them. The first was the American Academy of Neurology State Society Roundtable in Minneapolis where I had a chance to meet other state leaders from over twenty other states. I learned that we all have common issues and share many goals in an effort to provide the best neurological care and that our national Academy is vitally interested in providing support to state societies.

The other fact I learned is that the Texas Neurological Society, YOUR SOCIETY, is considered among our other peers to be the

strongest, best organized, and largest of all other state societies including those from New York, California, and Florida. Other state leaders inquired how we were able to become such an organization providing the best CME courses, advocacy, and other services to our members. My answer was simple: (1) we have the best and most supportive membership (2) our Board members, current and past providing the strongest leadership, and (3) the Texas Medical Association providing invaluable assistance in our infancy days and their continued support of us. For us to maintain these lofty standards, YOU must continue to support your Society.

At the state level I attended the Texas Medical Association/Specialty Society State Advocacy Retreat in Austin recently in November. Listening to the other specialty societies leaders, the TMA legislative staff, and its lobbyists was most enlightening as each was able to discuss the challenges and possible solutions to continue to provide the best medical care in our state. The common theme among all the participants was **ADVOCACY** at the local, regional, and state level which includes contributions to our TexPac and on a national basis, BrainPac. For us to succeed we must be proactive at all levels of the political scene.

Your Texas Neurological Society has a firm foundation, but as medicine is changing, we too must continue to evolve to meet the new challenges. Our CME courses have been the most visible example of our success and will remain the core with the Board constantly striving to be responsive to your CME needs. With the changing medical economic climate for neurology, we are in the process of establishing a medical economics committee as a permanent part of the Society to be informative to our members to enable each of us to make the best decisions in our neurological practice.

It has been an honor to be your President and to lead your Society this past year with it being very rewarding in meeting and interacting with so many individuals at all different levels. I wish to thank all the Board members for all their hard work and to Rachael Reed, our executive director for keeping the Society running so smoothly.

In closing I want to impart to you the importance that each and every one of you to stay involved with your Society to continue to keep it the best in the nation! Hope to see you at our Winter Conference in Austin, February 25-27, 2011.



#### I4TH ANNUAL WINTER CONFERENCE

February 25-27, 2011

Hyatt Regency Austin on Lady Bird Lake More details inside

### Report From the October Texas Carrier Advisory Committee (CAC) Meeting

Stuart B. Black, MD, FAAN — Chief of Neurology, Co-Medical Director, Baylor University Medical Center at Dallas, Chair, TNS Medical Economics Committee

The most recent Texas CAC meeting covered several topics, including a report from Dr. David Nilasena regarding the Medicare and Medicaid EHR (Electronic Health Record) incentive program. This program was established by law as part of the American Recovery and Reinvestment Act of 2009 to encourage use of EHRs in hospitals and by individual professionals. The programs differ for Medicare and Medicaid, with the Medicare program being federally funded and run by CMS. The Medicaid program is run by the individual States and is voluntary. Incentives are based on the individual eligible professional, and not by the practice. Medicare eligible individuals include doctors of medicine and osteopathy; dental surgery or dental medicine; podiatric medicine; optometry; and chiropractors. Eligible professionals may not be hospital based (90% of their covered professional services in either an inpatient or emergency room of a hospital).

An overview of the incentive payments is as follows. The incentive amounts are based on Fee-for –Service allowable charges, with maximum incentives of \$44,000 over 5 years. These incentives begin in 2011 and will decrease if starting an EHR after 2012. The eligible professional must begin using EHR by 2014 to receive incentive payments, which cease in 2016. There will be only 1 payment per year. There are requirements specified for "meaningful use" which among other things will require reporting data through attestation. For more information and specifics about the program, visit http:// healthit.hhs.gov/certification or http://healthit.hhs.gov/ standardsandcertification. Resources for help can also be found at http://www.cms.gov/EHRIncentivePrograms. It is also important to note that a Medicare professional who does not demonstrate meaningful use of EHR by 2015 will be subject to payment adjustments in their Medicare reimbursement schedule. There is also information on the American Academy of Neurology website regarding various EHR programs at www.aan.com/go/practice/hit.

There was also a presentation regarding the new Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers (DEMPOS) competitive bidding program. The competitive bidding areas for this new program include the Dallas-Fort Worth and Arlington area in Texas. DEMPOS suppliers must submit bids to be awarded a contract in their area. Contract suppliers will be those who offer low prices; meet eligibility, quality and financial standards; and are accredited by an independent organization. Products included in the program include oxygen, its equipment and supplies; power wheelchairs and scooters; CPAP devices; hospital beds; and walkers, amongst others. The program does not affect which physician or hospital is used, but patients may need to change their DEMPOS supplier to continue Medicare coverage. If you have any questions, you can email them to Rodney McDonald, Nurse Consultant for the CMS Dallas office at rodney.mcdonald@cms.hhs.gov

### TNS 14th Annual Winter Conference Preview Alan Halliday, MD, Program Director



The 14th Annual Winter Conference will be held at the Hyatt Regency Austin on Lady Bird Lake. The dates of the Conference are February 25-27.

Friday morning will focus on Pediatric Neurology and Friday evening will host a welcome reception for you to catch up with fellow neurologists.

The attendee can obtain up to 18 CME credits including one hour of ethics. The cost is only \$225 for TNS members who register by February 3.

Go to www.texasneurologist.org

## Editor's Notes

Randolph W. Evans, MD

I thank all of our contributors for their excellent articles which keep you current on TNS and current political, coding, practice, and treatment issues. Alan Halliday and the education committee have done a terrific job planning the February 25-27 Winter Conference in Austin. Be sure to get your hotel room at the discounted rate while available and preregister.

#### Migraine: From Maimonides to Weisel

In November, 2008, I presented a lecture at the First International Headache Summit held in Tel-Aviv, Israel. Just before the meeting, I made a brief pilgrimage with my wife, Marilyn, to the tomb of a revered headache expert, Moses Maimonides (also know as the Rambam from his Hebrew acronym; 1135-1204 ad), in Tiberias, on the western shore of the Sea of Galilee (see photo). Maimonides was a rabbi, physician, and philosopher and a prolific author of numerous influential works including "Guide for the Perplexed," "Mishneh Torah," and "Medical Aphorisms of Moses." Born in Cordova, Spain, he lived most of his adult life in Cairo, Egypt where he became court physician to the Sultan Saladin. His treatises became influential for generations of physicians.



Maimonides' description of the symptoms and causes of migraine headaches, which echoes Hippocrates and Galen, is as follows: "Some people with unilateral headaches called migraine feel the pain sensation outside the membranes of the brain whereas others feel the pain into the depths of the head. The pain in sufferers of unilateral headaches only extends to the linea mediana which separates the two halves of the skull. If it is due to biliary humors, the pain is burning. If it is due to an excess of humors [whose vapors ascend to the brain], a sensation of heaviness is also felt. If the heavy sensation is associated with a red appearance and warmth, these excessive humors are sharp. If it is not associated with redness or warmth, these excessive humors are without sharpness." (from "Medical Aphorisms of Moses." Also see Rosner F. Headache in the writings of Moses Maimonides and other Hebrew Sages. Headache 1993; 33:315-319)

#### Thomas Willis

How many other physician memorial sites are widely visited? I can think of the site of one other, who was also a headache expert, Thomas Willis (1621-1675), who is buried at Westminster Abbey. Willis, who was Sedleian Chair of Natural Philosophy at Oxford on recommendation from King Charles II (be thankful that you don't need royal recommendations for promotion committees), first introduced the vascular

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### **Member News**

Jim Grotta, MD received the Eugene Braunwald Academic Mentorship Award from the American Heart Association at their national scientific session in Chicago on November 13.

#### Ronald Devere, MD, FAAN

and co-author Marjorie Calvert has just published, "Navigating Taste and Smell Disorders," by "Neurology Now" for patients, families, and caregivers with taste and smell disorders which may also be helpful for healthcare providers.

#### Amitabh Shukla, MD has been

appointed as a Stroke Director at Methodist Hospital Sugar Land. In addition to adult neurology, Dr. Shukla is Board Certified in Vascular Neurology as well as sleep medicine by the American Board of Psychiatry and Neurology.

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need your help to convince Congress to fix Medicare now. Please	Ame
sign the petition and send it to your friends to sign as well.	Ame
Please fix Medicare by developing a rational Medicare physician	Ame
payment system that automatically keeps up with the cost of running a practice and is backed by a fair, stable funding	Ame
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www.ipetitions.com/ petition/meltdown theory of migraine. Willis, of course, coined the term "neurology" (from the Greek "neurologia") in 1664 and was the founder of our field as well as a pioneering neuroanatomist and neuroscientist. (His income, by the way, was said to be the highest of anyone at Oxford.) His descriptions of migraine are similar to ours including the migraine prodrome, some triggers, and the following probable first description of a patient with chronic migraine (Anne, Countess of Conway, who was also treated by William Harvey and Robert Boyle):

"Some twenty years since, I was sent for to visit a most noble lady, for above 20 years sick with an almost continual headach, at first intermitting. She was of a most beautiful form, and a great wit, so that she was skilled in the liberal arts, and in all forms of literature, beyond the condition of her sex, and as if it were thought too much by nature, for here to enjoy so great endowment without some detriment, she was extremely punished with this disease. Growing well of a feavour before she was 12 years old, she became obnoxious to pains in the head, which were wont to arise, sometimes of their own accord, and more often upon every light occasion. This sickness being limited to no one place of the head, troubled her sometimes on one side, sometimes on the other, and often thorow the whole encompass of the head. During the fit (which rarely ended under a day and a night's space, and often held for two, three or four days) she was impatient of light, speaking, noise, or of any motion, sitting upright in her bed, the chamber made dark, she would talk to no body, nor take any sleep, or sustinance. At length about the declination of the fit, she was wont to lye down with a heavy and disturbed sleep, from which awakeing she found herself better, and so by degrees well, and continued indifferently well till the time of the intermission. Formerly, the fits came not but occasionally, and seldom under 20 days of a month, but afterwards they came more often: and lately she was seldom free. Moreover, upon sundry occasions, or evident causes (such as the change of the air, or the year, the great aspects of the sun and moon, violent passions, and errors in diet) she was more cruelly tormented with them. But although this distemper, most grievously afflicting this noble lady, above 20 years (when I saw her) having pitched its tents near the confines of the brain, had so long beseiged its regal tower, yet it had not taken it: for the sick lady, being free from a vertigo, swimming in the head, convulsive distempers and any soporiferous symptoms, found the chief faculties of her soul sound enough." (from Pearce JMS. Historical aspects of migraine. JNNP 1986; 49:1097-1103; you may also want to read Rengachary SS, et al. The legendary contributions of Thomas Willis (1621-1675): the arterial circle and beyond. J Neurosurg. 2008;109(4):765-75 and Magiorkinis E, et al. Headaches in antiquity and during the early scientific era. J Neurol. 2009;256:1215-1220)

You may want to read the excellent biography of Willis by Carl Zimmer, "Soul Made Flesh: the Discovery of the Brain and How It Changed the World," 384 pp, 2005 (You can buy it from Amazon for the price of a cup of coffee. If you don't have time for the book, you may want to read an extensive review and commentary, Feindel W. Brain. 2004:127:2373–2380)

#### Elie Wiesel

The keynote address of the Headache Summit was delivered by Boston University humanities professor, Nobel laureate, and awardee of the Congressional Medal of Freedom, Elie Wiesel. He is the author of 57 books, most prominently "Night," about his experiences in Auschwitz and Buchenwald. Excerpts from his address were recently published (Lagniappe. Wiesel's headache. Headache; 2010; 50: 1087-1088). Here are some of his comments:

"Now, I must tell you, Dr. Mauskop, you kindly asked me to come and see you for my headaches. I didn't come because I did not want to embarrass you, to cause you to have to admit failure, because nothing has ever helped me. I began having headaches — I'm speaking to you as a patient—at age 7. At age 7, I already was taking pills for headache; everybody in my family was! My mother had headaches; my father had headaches; my grandfather had headaches. So I lived with headaches from my childhood on.

But then something bizarre happened: the day I entered Auschwitz, the headaches disappeared. I studied what you told me about pressure, about headaches as the result of pressure. But that seemed a contradiction. If ever I had pressure, it was there. In the camp. Every moment was pressure. But the headaches disappeared.

The moment I arrived at the first orphanage in France, after Liberation, they came back. The first doctor I went to I saw for my headaches. They are still with me. And they are not rare; they are still frequent. I get up every day with a headache, and once a week, I have what I call the "deluxe" version, a real headache. My problem is if I have to give a lecture that day—and I teach full time—or that evening, what do I do? If I take strong pills, I'm afraid it could affect my thought processes. I try to cope. I didn't come to see you. I thought, why should I give you pain by realizing that you cannot help my own? ...My headache is so faithful to me; it's so loyal that it

remains present always.

I got up this morning with a very, very bad headache. So, I said to my headache, "You won't win." I speak to my headache; I personalize it. I say, "I know who you are, and I know what you want, and it won't work." And the pain says to me, "Let's see,Wiesel." And so we fight.

... And to this day I have not found a way of handling my own headache except in my own fashion, which is to live with it. It hasn't slowed down my work. I teach full-time, and I am a very obsessive professor. In some 40 years, I don't think I've ever given the same course twice. I want to be the best student in the class. That's how I learn and grow with the students. And all that with my constant companion, this headache. Now maybe once I've finished, you will have a session and say, "Now what can we do for Elie Wiesel's headaches?" But don't bother; even if you were to try, I don't think you could help. But perhaps you can use my example to encourage your patients. Patients will come to you and say, "Why can't you help me?" And you can say, "Look. He couldn't get cured, and nevertheless he works. He goes on, functioning, studying, teaching."

Maybe psychologically I need the headaches to work? I'm sure some of you have had that idea in mind. Maybe he needs the added challenge ... this extra burden. In that case, why did I have headaches at age 7? And 8 ... 9 ... 10? Hereditary? Sure. Pressure? No. What pressure? School pressure? I was a good student.

So do I need these headaches? Personally, I think not. I think I could work as well without them. Are they part of me? Are they part of my psyche? Is my headache part of who I am? If so, what a terrible analysis . . . what a terrible definition of self!Am I my own pain?

... So, how might I use even the pain of headache for the benefit of someone else? How can I do that? By doing my work, sure. So I go on; I'm a writer; I'm a teacher; I go around the world trying to do my best to improve some conditions here and there, always failing—but it doesn't matter . . . I will go on trying.

One last thing to add, something perhaps to tell your patients: when a person says, Leave me alone, I have a headache, it's wrong. Never leave me alone. Never think that you bother me. I may have the worst headache in my life, but if someone needs me, I have no right to say, "But I have a headache."That is not a sufficient excuse."



### The Way We Were

Stuart B. Black, MD, FAAN — Chief of Neurology, Co-Medical Director, Baylor University Medical Center at Dallas, Chair, TNS Medical Economics Committee

"The history of modern medicine in America is said to have begun when the pilgrims came from England. Miles Standish, the commander of the Mayflower, was a physician. Although he had no formal medical education, his medical knowledge was achieved by observing and studying with other English physicians. There was another physician on the Mayflower, Dr. Samuel Fuller. Dr. Fuller was unique in that he practiced both as a physician and surgeon. As early America developed, doctors were scarce, leaving many colonists on their own in meeting the medical needs of their families. Treatment by physicians was also most often reserved for the wealthiest colonists. In addition, those who were physicians in colonial America usually received their training and knowledge directly from other physicians. In the colonial days, few physicians performed surgery. Most surgery was done by barbers. It was not until 1745 when surgery was separated from the barbershop. At that time, physicians who also performed surgery were recognized as "surgeons" within the practice of medicine.

Prior to the 1800s, medicine in the United States was carried out in private homes and occasionally in a private doctor's office. Most doctors traveled by foot or horseback to the patient's home. The physician was limited by the number of tools and drugs he could fit into a hand-held case or saddlebag. Throughout the nineteenth century, surgery was also performed in the home. Early American medical practice, especially in the rural or frontier areas, required doctors to work in a wide geographic area. They were expected to treat everything from gunshot wounds to toothaches. Doctors were also expected to treat sick livestock. Like today, the 19th century doctors usually charged their patients for their services. However, one major difference from doctors of today is that the 19th century doctors were not often paid by monetary reimbursements but rather "in kind" with whatever produce, services, or goods were available to the patient. That was soon to change.

By the end of the nineteenth century and early twentieth century, there was a population shift from rural environments to urban centers. During the Industrial Revolution, more hospitals were built, primarily in the larger cities. As industrialization in America began to develop, the household economy depended upon the primary wage earner staying healthy. By the 1920s, hospitals started to become the centers for surgery and more advanced medical care. However, at the same time, money became scarce and people started to loose their jobs. Black Tuesday occurred on October 29, 1929. With the Great Depression, there was an increased urban migration as Americans sought employment. This also changed the way doctors and hospitals were paid. The concept of prepaid hospital insurance grew out of the Great Depression. In 1929, the first prepaid hospital insurance plan was started and in 1939, the first prepayment plan to cover physician fees was started. These plans later became known as Blue Cross and Blue Shield respectively. The long awaited merger of the Blue's was not completed until 1982.

In 1941, America entered World War II. Due to the labor shortage in America, Congress passed the 1942 Stabilization Act which imposed price and wage freezes. Employers, however, were allowed to offer extended benefit packages to attract employees. This included employee health insurance plans which were nontaxable and amounted to receiving more salary. The concept of employer's providing medical insurance for workers became the primary mechanism for providing health insurance coverage in America. After World War II, the post war economy prospered. The political atmosphere became favorable toward insuring senior citizens who were no longer working and did not have employment based coverage. On July 30, 1965, at the Truman Library in Independence, Missouri, Medicare was signed into law by President Johnson. The first American to receive a Medicare Card and first Medicare beneficiary was former President Harry Truman.

Because of rising Medicare expenses, in January 1992, new legislation went into effect which established a Medicare fee schedule for physician services instead of paying physicians according to what they billed. The Resource Based Relative Value Scale (RBRVS) is what we currently use to determine Medicare reimbursements. The Evaluation and Management (E/M) model was part of the RBRVS system. There have been numerous changes involving Medicare reimbursements and health care legislation since 1992. The most recent change which has been a major and ongoing point of discussion has been the Patient Protection and Affordable Care Act which Congress signed into law March 2010. The Affordable Care Act (ACA) includes a full range of innovative delivery reforms including Accountable Care Organizations (ACOs) which are intended to achieve the goals of higher quality and more efficient service delivery while slowing the growth of health care costs.

Due to professional and media exposure, the term Accountable Care Organization is familiar to most physicians. In fact, over the past year, this model of health care delivery has gained support from health care policy experts, state and national legislators, and even among groups of physicians as the most promising way to deal with the nation's health care dilemma of how to reduce costs and improve quality. But what exactly is an ACO? There are different definitions which all encompass the same principal. The ACO concept envisions the development of legal agreements between various health care providers; those agreements are focused upon improving the quality of health care while slowing the growth of health care costs. An ACO may be defined as a group of primary care physicians, specialists, hospitals, and potentially other facilities who accept joint responsibility for the quality and cost of care of a defined population. In other words, an ACO is a collaboration of physician and health care providers that accepts accountability for medical costs and quality.

(continued)

But, what is an ACO, really? Definitions of ACOs seem to evolve which makes it difficult to nail down an exact model. The concept seems to be more of a philosophy than an actual model of care. The philosophy is that the ACO is accountable for organizing and aligning health care services to deliver seamless, coordinated care but the actual structure may be a single corporate structure or an organized network of independent but associated health care professionals. An ACO may be centered around physician organizations such as Independent Physician Associations (IPA) or multispecialty physician groups. An ACO could be organized by a hospital system or could be formed by other medical provider groups incorporated under the ACO umbrella. In a market as often seen in cities where there are larger hospitals, an ACO may be a single organization formed by competitive integrated hospital systems. Some ACOs may be ambulatory outpatient entities while others may be inpatient organizations. These last two models could eliminate the complexity of trying to force a business relationship between physicians and hospitals. There may also be "virtual" ACOs where smaller physician practices that are not economically or formally integrated may collaborate to achieve the ACO goals of cost and quality improvements. In other words, there appears to be much flexibility in defining an ACO structure. If one reviews the different potential models that have been associated with the ACO concept, it appears there are no single rigid structures but instead a range of models involving health care providers who accept the willingness to alternative payment arrangements.

Thus, the philosophy that defines an ACO may be a broad variety of entities, including group practices or networks of individual physician practices. However, whatever the model, clinical integration of the practices and physician collaboration will be mandatory. This type of integration would have to include mechanisms that control utilization, benchmarks for quality, practice protocols that are designed to improve care, information databases and an efficient database for sharing treatment information, as well as a potentially substantial investment of the financial capital needed to create the necessary ACO infrastructure. In addition, ACOs must have a formal legal structure to receive and distribute finances, must have a minimum of 5000 beneficiaries, must agree to at least three years of participation, must have leadership and management structure that includes clinical and administrative services, must prospectively establish the organization's budget and resource needs, promote evidence based medicine with reports on quality and cost measures, and produce reports demonstrating the management of patient care across a continuum of settings.

When discussing ACOs, one must also ask "what are the barriers to forming an ACO?" One obvious major issue is overcoming physician preferences favoring autonomy and individual accountability over a management or provider network environment. Doctors typically practice in small organizations. The AMA Physician Practice Information survey of 2007-2008 indicates that 78% of office based physicians in the U.S. are in practices in sizes of 9 physicians and under, with the majority being in either solo practice or in practices of between 2 and 4 physicians. It is also important to emphasize that despite all the various potential ACO models discussed above, it appears that the larger health care systems and hospitals are more actively pursuing the development of ACOs. This could be a major challenge for any health care system, especially one that does not enjoy a strong affiliation with physician groups who have admitting privileges. Even those hospitals that do have good support and relations with their physician staff may be challenged by physician groups who are already part of integrated health systems.

Another crucial question is "what about physician barriers?" Are doctors willing to give up their independence and become fully integrated within a hospital ACO? Based on the history of physician behavior, it is reasonable to conclude that many physicians would resist capitation and potential penalties related to the rules and regulations that the hospital model ACO and hospital provider network may propose. There may also be disagreement between the physicians and health care system over what may be considered to be the appropriate use of potential shared savings. Thus, while larger hospitals and health care systems are currently more active in forming fully integrated ACOs, physicians are more reluctant to change their organizational structures and processes of care in order to partner with large health care systems in a new delivery system with new and untested payment reforms. The crucial question regarding health care reform is who will actually control the ACO marketplace in the future. Will it be physician controlled ACOs where physicians affiliate and independently contract with hospitals, thereby, controlling the flow of funds through the system? Or will it be the hospital controlled ACO that will either employ physicians or develop integrated partnerships with physicians?" The latter process has already begun within the State of Texas, where some health care systems and large insurance companies have been engaged in collaborative discussions regarding establishing ACOs.

As can be projected from the above discussion, how ACOs play out over the next few years is likely to have a lasting implication on the future of medicine. Although in an ideal situation, the ACO should be a win/win relationship for physicians and hospitals, a good business analysis would suggest that whoever controls the market will likely be in a position to capture the largest profit. In regards to physicians organizing into an ACO, there would be a number of historical hurdles to overcome. Certainly on the top on anyone's list would be collaboration on clinical, administrative and economic issues; something doctors have not done well in the past. There is also no current formula which defines how to divide profits between primary care physicians and specialists or between surgical and cognitive specialties. One can also predict that proceduralists would end up losing income and would resist the needed structural changes to make the ACO successful. In addition, as indicated above, clinical integration of patient information as well as developing an integrated network is an expensive undertaking. The clinically integrated network would also need to be transferable to the commercial health insurance market. The bottom line is creating an ACO, with the quality and cost control infrastructures, is costly. Doctors would

### The Way We Were (continued)

have to agree on this type of investment of financial capital to create the ACO infrastructure. In addition, the question of how to divide profits among different physician groups could be contentious.

If physicians were to dominate the ACO marketplace, there is a possibility that hospital revenue could decline as a result of decreased census. Conversely, at the present time, hospitals and health care systems are frequently at the center of the modern health care marketplace. If the number of hospitals that are being constructed (especially in large Metroplex areas as DFW) is any indicator, health care systems appear to be quite profitable. If hospitals were to dominate the ACO marketplace, and either employed physicians or developed an economic partnership with physicians, there is strong evidence expressed in the literature that the hospital would be in a good position to accrue significant economic benefit from the new delivery system. This has lead to concern, as expressed by a number of physician organizations that physician income and status as an independent professional could decline. In addition, to build a successful ACO, hospitals will also need to shift to a more outpatient – focused coordinated care model. Although a number of larger hospitals have already begun to open outpatient clinics, there is still a learning curve regarding how to integrate their outpatient services within the federal rules and regulations that are designed for hospital accreditation. Essentially, to a large extent a hospital outpatient clinic is still governed under the same rules that govern the inpatient facility. This is further complicated by the fact that Medicare and most private carriers reimburse physicians at a lower rate if their patients are seen in a hospital outpatient facility as opposed to the physician's personal office. However, because hospitals currently have better organized professional management teams, have accounting capability and IT systems in addition to higher bond ratings and cheaper access to capital than most physician groups, the health care systems seem to be in a better position toward the development of an ACO.

Since the implementation of ACOs is not an easy undertaking, how could the government or private industry incentivize providers to develop integrated care systems? What can incentivize providers to risk a decrease in income? One answer is that something that is nonsustainable cannot be sustained. Economists believe that our current spending on health care is not sustainable. The Congressional Budget Office (CBO) projected that Medicare costs will nearly double from \$528 billion this year to more than \$1 trillion in 2020. There are estimates that as our population ages, Medicare enrollment will grow 3% per year and that in 5 years, 45% of Americans may be on Medicare. If this were true, even if physicians in the United States were to receive a 20% cut in Medicare, costs could still double.

So, how does an ACO model improve things? To answer that question, it is important to recognize the general perception that the three types of payment methods

currently utilized, fee-for-service, discounted fee-for-service, and capitation, are driven by a volume-based payment system. By switching to a "value-based" payment model, the ACO and payer would establish a benchmark for the total projected annual cost for ACO enrollees. If costs were reduced while improving quality, and financial targets were met, the shared savings would be paid to the providers in the form of a bonus. It is even possible that fee-for-service would be continued but paired with incentive-based payments. However, there are those who also strongly favor "bundled payments" with some type of formula to define distribution of payments to various providers. Whatever the payment model, the ACOs payment structure would ultimately depend largely upon the level of clinical and financial integration. The degree of integration within the system also influences the amount of financial risk the ACO is willing to take. Basically, ACOs would be classified into one of three tiers. Level 1 is where the ACO would bear minimal financial risk. There would still be shared savings but the organization would mainly be a legal entity able to provide performance measures. Level 2 is where the ACO would be eligible for a larger share of savings, but would also be liable to penalties if costs were greater than predetermined targets. This level would also be required to meet greater performance measures. Lever 3 is the ACO with the most risk. Payments would be through full or partial capitation. The providers could also qualify for substantial bonuses for meeting quality and expenditure targets. This level also would have public reporting of outcomes and a comprehensive set of performance measures. Although there are three risk-reward payment models discussed in the literature, it must be emphasized that these are only proposals and no payment approach for ACOs has been adopted.

One must also consider the fact that ACOs will need to be protected by antitrust laws, along with a multitude of other legal protections which do not currently exist. Protection should be provided to physicians concerning physician self-referral, federal anti-kickback laws, as well as civil and monetary penalty laws which may be important to ensure a successful physician participation in any shared savings programs. In addition there are complex financial formulas, political debate and organizational issues which need to be addressed and resolved before ACOs are widely adopted. Physicians must recognize that currently there are significant gaps in exactly how an individual ACO may be structured. It should also be emphasized that whereas "quality" is a critical component of an ACO, there are no established ACO quality benchmarks or guidance on how to define appropriate quality measures relative to process, outcome, or value added results in the treatment of chronic disease states.

Indeed, modern medicine has come a long way with many changes from the past. It has been about 390 years since the Mayflower sailed from a site near the Mayflower Step in Plymouth, England and landed in Plymouth, Massachusetts in 1620. The 102 passengers and crew of 25-30, including the physicians Miles Standish and Samuel Fuller, would probably be rather surprised at how far medicine has progressed.

### New Program Assists Health Professionals with Impairment Issues

A new, statewide program aims to protect the public by encouraging health professionals to seek early assistance with drug or alcohol-related problems or mental or physical conditions that present a potentially dangerous limitation or inability to practice medicine with reasonable skill and safety.

The Texas Physician Health Program, or TXPHP, is a confidential, nondisciplinary program for physicians, physician assistants, acupuncturists and surgical assistants licensed by the Texas Medical Board or who have applied for licensure.

TXPHP, launched in February 2010, was created by Senate Bill 292 of the 81st Legislative Session that went into effect September 1, 2009. It is modeled on other states' programs and was a joint effort of the Texas Medical Association, the Texas Osteopathic Medical Association, and the Texas Medical Board. TXPHP is self-funded through user fees. The cost for participation in the program is \$1,200 per year.

TXPHP accepts self-referrals as well as referrals from the Texas Medical Board, concerned colleagues, hospitals and others. The program is overseen by experts in mental health and substance abuse issues. TXPHP recommends treatment for physicians when clinically indicated, and monitors their ongoing recovery. A monitoring program may include random drug screens; written reports from counselors or therapists; self reports provided by the physician in recovery; and written verification of attendance at self-help or support group meetings.

Individuals are not eligible to participate in the program if they have violated the standard of care as a result of drugs or alcohol, committed a boundary violation with a patient or patient's family or been convicted of a felony.

TXPHP is administratively attached to the Texas Medical Board, but overseen by an 11-member governing board. Governing board members, recently appointed by TMB President Dr. Irvin Zeitler, are: Brady Allen, M.D., of Dallas; Eugene Boisaubin, M.D., of Houston; Mary Boone, LCSW, LCDC, of Austin; Ronald Brenz, D.O., of San Antonio; Judy Googins, M.D., of Tyler; John Jackson, M.D., of Fort Worth; Alison Jones, M.D., of Austin; Helaine Lane of Houston; Anand Mehendale, M.D., of Kerrville; Melinda Moore, PA-C, of Sugar Land; and Russell Thomas Jr., D.O., of Eagle Lake. The Medical Director of the TXPHP is Lloyd Garland, MD.

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## A Case Report

**Opioids and Chronic Migraine** 

Deborah Carver, MD

Assistant Professor, University of Texas Health Science Center at San Antonio, Department of Neurology

#### **Case History:**

This is a 41 year old female who presented with daily headaches. She has a history consistent with migraine without aura for 10 years averaging twice a week previously until 3 months ago relieved by over the counter medication (OTC). She went to the Emergency Department (ED) three months ago for a headache that was not relieved with her typical over the counter medication (OTC) treated with Demerol and phenergan. She was sent home on hydrocodone which was then refilled by her pcp on subsequent visits. A MRI of the brain was negative. She has since developed daily headaches improved with hydrocodone 2-5 daily.

**Questions:** What is chronic migraine? How frequently do migraineurs use opioids to treat their headaches? What are the problems associated with using opioids for migraines?

#### **Expert Opinion:**

Chronic migraine is defined by the ICHD -2 as a type of chronic headache (headache on 15 or more days per month for at least three months), with at least eight headaches days per month meeting the criteria for migraines. Previously first described as transformed migraine by TNS member Ninan Mathew, chronic migraine is a disorder that often begins as episodic migraine that evolves into a daily or near daily headache pattern often with medication overuse.

As part of the American Migraine Prevalence and Prevention (AMPP) study in 2004, patients with migraine were surveyed regarding what medications they used to treat their headache. It was found that only 19% of patients with episodic migraines used migraine-specific medications (triptans or ergots) to treat their migraines. Opioids were routinely used by 11%, and 6% used barbiturates. These medications were taken an average of 5.7, 9.7, and 7.3 days per month respectively. In patients with chronic migraine, 22% used migraine-specific medications whereas 20.8% used opioids.<sup>1</sup>

The use of opioids for non cancer related pain has doubled from 1980 to 2000 with 19% of the chronic opioid therapy prescriptions being for headache pain.<sup>2</sup> This is a disproportionably high percentage of opioid usage for migraine given that opioids are not recommended by the US headache Consortium Guideline as first choice for migraine treatment. Like the case example, many migraineurs first seek treatment for their headaches, not in a neurologist office, but at a local ED. Unfortunately, most patients who go to the ED for migraines are given opioids as their first line treatment compared to any other treatment (45.7% vs 26%). Of those recipients, 77% did not receive any other abortive therapy prior to the opioid treatment.<sup>3</sup> Without proper education, these patients could wrongly assume that opioids are the most effective means for aborting migraines, without even trying migraine specific medications.

There is growing evidence that overuse or frequent use of opioids is a major risk factor for progression into chronic migraine. Opioids may decrease the effectiveness of migraine-specific medications and may also increase the frequency and severity of headaches in patients who already have migraines.<sup>4</sup>

The increased risk of transformation from an episodic migraine pattern to a chronic migraine pattern in patients who over use symptomatic medications is well known. Previously described as analgesic rebound headache, Saper proposed that the use of analgesics exceeding two or three times per week, week after week, caused chronic migraines.<sup>2</sup> More recently, the AMPP study showed that opioid exposure in patients with episodic migraine in 2005 doubled the chance of transformation into a chronic migraine pattern in 2006 with the critical level of exposure to opioids at only eight days per month.<sup>5</sup>

Not everyone who takes frequent opioids develops chronic daily headaches. In a study of patients using daily opioids for control of their bowel motility after having colectomies for ulcerative colitis, only the patients with a history of migraines developed chronic daily headaches.<sup>6</sup> Other primary headache types can also be associated with medication overuse including chronic tension-type headache, hemicrania continua, new daily persistent headache, and cluster headache patients (with a personal or family history of migraine).<sup>7</sup>

Opioid use has also been reported to decrease the effectiveness of more specific migraine treatments. Two recent studies showed that even prior use of opioids can make specific treatments less effective. Jakuboski et al, found that the patients who did not respond to ketorolac infusions previously used opioids.

#### Broca's Area

Specifically 9 out of the 9 nonresponders took opioids vs 1 out of the 19 responders who took opioids.8 Prior use of opioids has also been reported to have a reduced two hour pain freedom and reduced response to rizatriptan treatment.<sup>9</sup> Although there has been a concern that preventive medications may not be effective for those with medication overuse, recent studies have shown that topiramate can still be effective for some with medication overuse.10

Opioid related adverse effects may also be a determent to patients with migraines. The most common reported adverse effects include nausea and constipation. Potentially more significant adverse reactions for migraine patients includes anxiety, depression, neurocognitive impairment, and sleep disturbance such as insomnia, daytime sleepiness, and central sleep apnea.<sup>2</sup> Recent research suggests that opioids can also cause another adverse response described as opioid induced hyperalgesia. This is a paradoxical response to opioid therapy that makes patients more sensitivity to pain and potentially may aggravate their preexisting pain.<sup>11</sup>

The pathophysiology of opioid induced hyperalgesia is likely related to the upregulation of compensatory pronociceptive pathways. There appears to considerable overlap with the mechanism mediating central sensitization, chronification of migraine, and opioid induced hyperalgesia. Peripherally, opioids increase expression of CGRP in trigeminal primary afferent neurons. Centrally, they increase excitatory neurotransmission at the level of the dorsal horn and nucleus caudalis. In addition, opioids can enhance the processes of descending pain facilitation arising from the rostal ventromedial medulla. Collectively these neuroadaptive changes result in a state of hypersensitivity to normally non-noxious stimulation thus increasing the likelihood of migraine attacks from normally ineffective triggers. These neuroadaptive changes are also reported to persist for long periods even after opioid withdrawal.<sup>11-13</sup>

As neurologists, how can we best stop this epidemic of overuse of narcotics and thus prevent the progression from episodic migraine into chronic migraine? The first step would be to prevent migraineurs from ever starting down this road by not initiating opioids in the first place. This, however, is not always possible since occasionally there are no better options available. Most importantly, we should all do a better job educating our migraine patients that the opioids they have been using may actually be making their headaches worse, not better.

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### Jorge E. Weibel, MD 1922-1910

It is with deep sadness that we learn of the passing of TNS charter member, Jorge Emilio Weibel, MD on 12/27/10 at the age of 88.

A native of Chile, Dr. Weibel did his neurology residency at Baylor. He pioneered a new method for performing cerebral angiograms that later became known as the "Weibelgram".

He was an author of several medical publications including the well known book, "Atlas of Arteriography in Occlusive Cerebral Vascular Disease." in 1969.

Dr. Weibel worked closely with giants of the medical world such as the late Michael DeBakey, M.D. and Denton Cooley, M.D. and was on the staff of the Methodist and St. Luke's Episcopal Hospitals in Houston.

Dr. Weibel was active in numerous local, state and national medical associations and enjoyed a well respected 50 year career as a physician. He was also involved in numerous humanitarian efforts receiving commendations from the governments of Mexico and Chile.

Dr. Weibel is survived by his wife of 51 years, Elena Victoria Valls, and their children and grandchildren.

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### The Origins of the Texas Neurological Society

William J. Riley, MD, past president, TNS

Dr. Evans asked me to give you a brief vignette of the history of the founding of the Society. In the early 1970s, the organizational structure of the Texas Medical Association made provision for sections representing medical specialties. Neurology was part of the neuropsychiatry section. The impact of managed care was not far off but there were already many factors that were causing some increasing separation between the interests of practitioners of psychiatry and those of neurology. There was little sentiment for considering a formation of a section with neurosurgery which was, at that time, actively moving to form its own section.

For this reason, the late Dr. William Fields, the chairman of Neurology at the University of Texas Medical School at Houston and chief of Neurology at Hermann Hospital convened a phone conference with Dr. Robert McMasters, chief of the division of Neurology at the University of Texas Medical School at San Antonio, and myself, then chief of Neurology at St. Luke's Episcopal Hospital in Houston. It was determined that it would be desirable to send a letter of inquiry to the 70+ neurologists in the state of Texas to inquire if we should form this new neurological society. We decided that the letter would come from me with private practice letterhead rather than on institutional stationery so clinicians would not think that this would be a purely academic oriented organization. I drafted and mailed a letter embodying the sense of our inquiry to the neurologists of the state and included a return address post card with a place for the neurologist to respond as to whether or not we should go forward with the formation of a separate organization under the umbrella of the Texas Medical Association. An exceedingly high proportion of these were received with only one dissenting view.

With this mandate, we announced our first meeting would be held during the Texas Medical Association annual meeting in 1974 which was held at the Shamrock Hilton Hotel (demolished in 1987) in Houston. In a second floor conference room of the Towers Hotel (demolished in 2004) across the street from the Shamrock, I chaired the initial meeting with 35-40 neurologists in attendance. Dr. Fields convened a founding group which developed the charter of the Texas Neurological Society and arranged for its ratification between 1974 and 1975.

From that time forward, the Texas Neurological Society has had a splendid growth curve and has managed to avoid duplication of activities better served within the family of medicine by other organizations such as ethical concerns or specific advocacy issues. The leadership of the organization looked into the cost effectiveness of these and many other activities and has stayed focused admirably on its missions and goals of serving well the cltizens of the state of Texas, the family of medicine in Texas, and our colleagues in the neurologic sciences to the betterment of health of Texans and the strength of the medical profession in the state of Texas. We continue to develop and be blessed by noteworthy past presidents such as providing the immediate past president of the Texas Medical Association, Dr. William Fleming, and the current president of the Harris County Medical Society, Dr. William Gilmer. Many other noteworthy figures have grown in being fostered by and serving our society.

P.S. I have not spoken with Dr. McMasters in over 30 years after he moved to New York and would very much like to speak with him again. I have tried unsuccessfully to contact him at his last available address and phone number in El Paso. If Dr. McMasters reads this or anyone has his contact information, please contact me (at 713-621-9291) or Rachael Reed (email: exec@ texasneurologist.org).

## **Expert Opinion**

### New Daily Persistent Headache. A Question and Answer Review

By Randolph W. Evans, MD, Clinical Professor of Neurology, Baylor College of Medicine, Houston, Texas, subspecialty certified, Headache Medicine

About 4% of the adult population have one of the primary types of chronic daily headache of long duration which occurs on at least 15 days per month with untreated headache lasting longer than 4 hours for more than 3 months with primary types (not related to structural dysfunction or other illness) diagnosed after the exclusion of the many possible causes of secondary headaches by history, examination, and testing, as indicated which include chronic migraine, chronic tension-type headache, hemicrania continua, and new daily persistent headache (NDPH). Vanast provided the first description of NDPH in 1986.<sup>1</sup>

## What are the symptoms of NDPH? What are the diagnostic criteria?

In order to meet the diagnostic criteria as defined by the International Classification of Headache Disorders 2nd edition (ICHD-2) in 2004, the headache must occur daily and be unremitting from within three days of onset.<sup>2</sup> The onset is often so striking that most patients can identify the exact day that their headache disorder began.<sup>3,4</sup> The headaches can vary greatly in their clinical presentation and duration. Eighty percent of patients experience a constant headache throughout the day with no pain-free period.<sup>5</sup> For most patients, the baseline level of pain is mild to moderate in intensity and bilateral in up to 94%.

The headaches are typically described as throbbing and/or pressure-like, generalized or unilateral in 11% and localized to any head region with migraine symptoms such as nausea, photophobia, phonophobia, and lightheadedness present in over 50% with occasional vomiting.<sup>6,7</sup>

Cranial autonomic symptoms occur with painful exacerbations in 21% and cutaneous allodynia may be present in 26% .7 There are rare reports of an associated visual aura and unrelated frequent episodic bilateral facial flushing with painful exacerbations (usually lasting for a few minutes).<sup>7</sup> A history of prior depression or anxiety is present in 51% and symptoms of current depression is present in 62%.

The ICHD-2 criteria are overly restrictive because it excludes the presence of more than one migraine feature which are present in about 50% of children and adults with abrupt onset chronic daily headaches.

Robbins et al have proposed a revised version of ICHD-2 criteria, creating a NDPH-ICHD subset (the current guidelines) and a NDPH-mf subset (those with migraine type features).<sup>7</sup> They further divided these groups into 3 prognostic subgroups: persisting type with a continuous headache from onset, a remitting type where the headache either resolves completely or occurs less than 5 days per month for at least 3 months, and a relapsing-remitting type where pain free periods are interspersed among times of continuous headaches. The authors found that the two subtypes (NDPH-ICHD and NDPH-mf) had very similar

demographic, clinical and prognostic features.

#### What is the epidemiology?

The age on onset ranges from 6 to greater than 70 years old, with a mean of 35 years.<sup>6,7</sup> NDPH is more common in females with a 2.5:1 ratio in adults<sup>7</sup> and 1.8:1 ratio in children.<sup>8</sup> NDPH is rare. A population based cross sectional study of 30,000 persons aged 30-44 years found a one-year prevalence of .03%.<sup>9</sup> In patients with chronic daily headache seen in tertiary headache clinics, NDPH is diagnosed more often in children and adolescents (13-35%) than in adults (1.7-10.8%).<sup>8</sup> In one study, 25% had a preexisting history of a primary headache disorder (episodic tension type headache in 18.3% or episodic migraine 7%).<sup>7</sup>

#### What is the pathophysiology?

The pathophysiology of NDPH is unknown. There have been several studies postulating a link between a preceding flulike or upper respiratory infection in 14-30%,<sup>6,7</sup> a stressful life event in 10-12%,<sup>5,6,7</sup> or extracranial surgery in 7-12%,<sup>5,6</sup> Cervical joint hypermobility and defective internal jugular venous drainage<sup>12</sup> have also been suggested as causes.

#### What is the differential diagnosis?

The diagnosis of primary NDPH is one of exclusion as appropriate of a long list of other daily headaches.<sup>13</sup> Remember the definition of NDPH requires a daily unremitting occurrence within 3 days of onset which helps distinguish NDPH from chronic migraine and tension-type headache which begin as episodic types with gradual escalation. There may be overlap of symptoms with hemicrania continua as 11% of cases of NDPH may be unilateral and cranial autonomic symptoms may be present with exacerbations. However, indomethacin produces complete and sustained pain relief in hemicrania continua but not in NDPH.

A few series provide information on the potential yield of neuroimaging. For example, Wang et al.<sup>14</sup> retrospectively reviewed the medical records and MRI images of 402 adult patients (286 women and 116 men) who had been evaluated by the neurology service with a primary complaint of chronic headache (a duration of 3 months or more) and no other neurologic symptoms or findings. Major abnormalities (a mass, caused mass effect, or was believed to be the likely cause of the patient's headache) were found in 15 patients (3.7%) including a glioma, meningioma, metastases, subdural hematoma, arteriovenous malformation, 3 with hydrocephalus, and 2 Chiari I malformations. They were found in .6% of patients with migraine, 1.4% of those with tension headaches, 14.1% of those with atypical headaches, and 3.8% of those with other types of headaches.

Secondary headaches to consider or NDPH mimics include the following: medication overuse, postmeningitis headache, chronic meningitis, sphenoid sinusitis, neoplasms, chronic subdural hematoma, posttraumatic headaches, hypertension, *(continued)* 

## Expert Opinion (continued)

spontaneous intracranial hypotension, pseudotumor cerebri (idiopathic and secondary intracranial hypertension), cervical artery dissections, cerebral venous thrombosis, arteriovenous malformation, dural arteriovenous fistula, unruptured intracranial saccular aneurysms (possibly), Chiari malformation, temporal arteritis, cervicogenic, and temporomandibular joint dysfunction.

For example, spontaneous intracranial hypotension (SIH) syndrome often presents with a headache that is present when a patient is upright but is relieved by lying down, or by an orthostatic headache. However, as SIH syndrome persists, a chronic daily headache may be present without orthostatic features. Neck or interscapular pain may precede the onset of headache in some cases by days or weeks. MRI abnormalities of the brain and spine are variably present in perhaps 90% of cases. An MRI scan of the brain may reveal diffuse pachymeningeal (dural) enhancement with gadolinium without leptomeningeal (arachnoid and pial) involvement and, in some cases, subdural fluid collections, which return to normal with resolution of the headache.

Cervical artery dissections, which can present with headache or neck pain alone,<sup>16</sup> can be a rare cause of new daily headaches. Occasionally, the headaches can persist intermittently for months and even years and can lead to a pattern of chronic daily headaches especially after cervical carotid artery dissection. Magnetic resonance angiography is the study of choice for detection as carotid ultrasound is operator dependent and less sensitive.

Temporal arteritis should always be considered with new onset headaches over the age of 50. As the rare exception, in a Canadian study of 141 consecutive patients presenting to a neuro-opthalmology practice, there was one patient under the age of 50 (age 47).<sup>17</sup>

#### What is the treatment?

There are no prospective placebo controlled trials of preventive treatment. NDPH is typically treated empirically using the same preventive medications for chronic tension type<sup>18</sup> or chronic migraine alone or in combinations. Muscle relaxants such as baclofen or tizanidine may be helpful.<sup>5</sup> For some patients, headache escalations may respond to triptans.7 In children and adolescents, the most commonly used medications include the tricyclic antidepressants (amitriptyline) and antiepileptics (topiramate, valproic acid, gabapentin) and less often propranolol, selective serotonin reuptake inhibitors and muscle relaxants.<sup>19</sup> Medication overuse can be present in up to 45% of patients.7 In a small series of patients, Grosberg has found clonazepam 0.5mg qhs up to 1mg bid with an extra 0.5mg - 1mg prn for breakthrough pain effective (Brian Grosberg, MD, personal communication). Although continuous opioid therapy is sometimes used for refractory headaches including NDPH, this therapy is usually not effective and needs to be carefully monitored by experienced physicians for adverse events.

An inpatient regimen of IV DHE may be of benefit.<sup>20</sup> Intravenous haloperidol<sup>21</sup> and intravenous magnesium may be efficacious. Some patients may benefit with greater occipital nerve blocks.<sup>22</sup> Some patients anecdotally benefit from cervical trigger point injections and physical therapy.

It is not known whether Botox injections are efficacious as there is only a single case report published. Intravenous methylprednisolone (1000 mg daily for 5 days) in 9 patients followed by oral steroids (60 mg of prednisolone daily) for 2-3 weeks in 6/9 was reported as producing complete resolution in all patients with NDPH and a history of antecedent extracranial infection but 0/2 without.<sup>23</sup> However, only 4/9 cases had the NDPH for 3 months or longer.

Alternative therapies are sometimes tried without evidence of efficacy including riboflavin, butterbur, coenzyme Q10, magnesium, massage, acupuncture, exercise, physical therapy, chiropractic manipulation, weight loss, and yoga. Some patients undergo surgical procedures such as septoplasty and occipital nerve decompression without reports of efficacy. Although neuromodulation especially occipital nerve stimulation may be of benefit for some primary headaches, I can find no reports of efficacy for NDPH although this would be of interest.

#### What is the prognosis?

Robbins et al study of 71 patients found three prognostic categories of NDPH patients: 76.1% with persistent headaches, 15% with remission (time to remission ranged from 4 months to 54 years with a median duration of 21 months), and 8% with a relapsing-remitting type (range to first remission 3-24 months).7 In a study of 28 children and adolescents, 20/28 continued to have headache 6 months to 2 years later and only 8/28 were headache free (3 within 1 year and 4 within 2 years).<sup>24</sup> NDPH can be one of the most difficult to treat headache type which can result in impairment and disability. Better treatments are clearly needed.

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## **Expert Opinion**

Indications for Induced Hypothermia

George A. Lopez M.D., Ph.D., Associate Professor of Neurology The University of Texas Health Science Center at Houston Medical School

#### Case:

MJ is a 40 year old attorney in good health, who was found down is his home by his wife after she heard him fall to the ground. He was pulseless and apneic. Paramedics arrived soon thereafter. On cardiac monitor he was found to be in ventricular fibrillation. He received ACLS protocol and was resuscitated with return of spontaneous circulation in less than 30 minutes. Upon transport to the hospital and arrival to the Emergency Department, he was deeply comatose, with no spontaneous respirations, and having decerebrate posturing.

#### **Questions:**

Is he a candidate for induced hypothermia? What are the indications for treatment? What are the inclusion and exclusion criteria for treatment with hypothermia? Are there other indications for using induced hypothermia? Is there any data using hypothermia for acute ischemic stroke patients?

In February 2002, the results of 2, prospective, randomized, clinical trials were published back-to-back in the New England Journal of Medicine. The odds ratio for a good neurologic outcome with hypothermia as compared with normothermia was 5.25 in the first study but there was no statistically significant difference in mortality between the groups. In the second, larger trial, similar findings of improved neurologic outcomes were found, but there was a statistically significant improvement in mortality in the patients that were randomized and received treatment with hypothermia. Mild hypothermia is the only therapy applied in the post arrest setting that has been shown to increase survival rates.

The patient who presents with a witnessed cardiac arrest and is successfully resuscitated and remains comatose should be considered for treatment with induced hypothermia. Although the patient's neurologic status was such that he was exhibiting extensor posturing reflexes, the 2 trials did not exclude patients from randomization based on neurological examination. All comatose survivors were included.

Patients with sudden cardiac arrest from a presumed cardiac origin were included presenting with either ventricular fibrillation, or non-perfusing ventricular tachycardia as the initial cardiac rhythm. Although the 2 trials only enrolled patients with these specific presenting cardiac rhythms, newer published case series treating patients with other cardiac rhythms still show a benefit of induced hypothermia for cerebral protection and improved neurologic outcomes and mortality. The patients who may benefit from this treatment have not been fully investigated, and the exact induction technique, target temperature depth, duration, and rate of rewarming have to be further studied. The trials were very protocolized and therefore had strict inclusion and exclusion criteria. The patients were excluded if they were less than 18 years of age or more than 75 (no upper age limit in the second trial), had cardiogenic shock, had a terminal illness, had other reasons for being in a coma, or began showing signs of return of consciousness.

Current guidelines recommend the use of induced hypothermia for comatose survivors of cardiac arrest. This recommendation is also part of the newest ACLS guidelines from the American Heart Association. Unfortunately the results of using hypothermia for acute traumatic brain injury did not reveal a benefit of this therapy, however several arguments have been proposed as to why it was not effective (trial design and protocol adherence). The use of hypothermia has also been studied in newborn infants suffering from perinatal asphyxia injury. In one study it was found that treatment of infants born with asphyxia with whole body hypothermia reduced the risk of death or disability in infants with moderate or severe hypoxic-ischemic encephalopathy.

Experimentally, hypothermia has been shown to be the most effective and pluripotent neuroprotectant studied. Not surprisingly, it has been used in numerous different models of acute brain injury and cell injury models. In the laboratory animals, hypothermia is effective in reducing neuronal cell injury and death. In humans however, the trials to date have been either small or case series.

We have just begun a new clinical trial called, The Intravascular Cooling in the Treatment of Stroke 2/3 (ICTuS 2/3) Trial (see http://clinicaltrials.gov/ct2/show/ NCT01123161). This will be the largest, randomized, prospective clinical trial evaluating the role of hypothermia in acute ischemic stroke patients. We have just now begun enrolling patients into this trial; the first site is in Houston, Texas. Stay tuned.

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