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Spring CME

Prevention of Medical Errors: Root Causes and Strategies to Avoid Errors

Few medical errors are as vivid as those that involve patients who have undergone surgery on the wrong body part, undergone the incorrect procedure or had a procedure intended for another patient. These “wrong-site, wrong-procedure, wrong-patient errors” have been termed “Never Events” as they are errors that should never occur and that demonstrate underlying safety problems. In February 2009, the Centers for Medicare and Medicaid Services announced that hospitals will not be reimbursed for any costs associated with WSPEs. (CMS has not reimbursed hospitals for additional costs associated with many preventable errors since 2007.)

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The mission of the Duval County Medical Society (DCMS) is to “help physicians care for the health of our community.” With the outstanding leadership that we have had through the last few years, this has become an attainable goal. A critical cog in the wheel of our Medical Society is the Journal and Communications Committee. Dr. Raed Assar has been the chair of this committee since 2012. During his tenure, the Society has seen significant growth in its ability to communicate through the website, Facebook, Twitter, radio and television. *Northeast Florida Medicine* (DCMS’ peer reviewed medical journal) has also improved significantly in quality and substance in the last three years. We now also have a biweekly column in the Florida Times-Union/Jacksonville.com titled “Doctors on Call.” This gives us an opportunity to inform and educate the public on current/relevant medical topics through the words of experts in the field. This way we, the health care leaders of Northeast Florida, provide credible, evidence-based guidance to the community at-large.

Dr. Assar is now the President of the DCMS and he has passed the torch of leading the Journal and Communications committee on to me. I am honored and humbled to follow in his footsteps. Over the next year, we will provide four quality issues of *Northeast Florida Medicine*, which will have numerous required CME opportunities for state medical licensure. We will continue to lead discussions regarding timely healthcare topics through television, radio, print and social/digital media. I envision a time when all of the local media outlets look to the DCMS as the definitive authority on important medical issues, from something as simple as viral gastroenteritis to as complicated as healthcare reform. We are fortunate to have knowledgeable Society members that will contribute to this goal. This will enable us to be a model for other local, state and national medical societies to follow. Please feel free to contact me directly if you are interested in contributing to the communications of the DCMS. Finally, I would like to welcome Kristy Wolski as the DCMS Communications Coordinator and Managing Editor for *Northeast Florida Medicine*. She comes to us from Action News Jax with tremendous experience in digital and social media communications. We are fortunate to have her at a time when the DCMS can utilize her unique talents. She would be happy to discuss ways in which you can be more involved with this essential aspect of our Society.

I look forward to working with you all through the upcoming years. Please do not hesitate to contact me with any questions or concerns as we continue “to help physicians care for the health of our community.”
Update on the Mentoring Initiative

First, I would like to thank the Duval County Medical Society (DCMS) community and the outgoing DCMS President, Dr. Mobeen Rathore, for the opportunity to serve as your President in 2015. This is truly an honor and I will treat it as such.

After guidance from many of you, we have embarked on an initiative to help our medical community develop leaders and to support our members through challenges they face in their careers in medicine. Dr. Steven Cuffe, Professor of Psychiatry at UF, and Dr. Uday Deshmukh, Senior Medical Director from Florida Blue, have graciously agreed to lead a taskforce to develop a mentoring program that would also enhance the talent in our medical community.

The Mentoring Taskforce includes Drs. Cynthia Anderson, Tra’Chella Johnson-Foy, William Palmer and Ana Alvarez. The taskforce members met and decided their goal is for DCMS to be recognized nationally for excellence in training and nurturing physician leadership in organized medicine. Over the next few months, DCMS will choose a strategy to implement such a program and structure it to meet the needs of our medical community.

This goal naturally supports the mission of DCMS to “Help physicians care for the health of our community” because stronger leaders create a stronger, more impactful society. Additionally, when we become the engine for physician leadership, that leadership extends beyond the county to the FMA, AMA, WMA, and hundreds of national and regional specialty societies.

The proposed DCMS mentoring program would involve a process of matching new and existing DCMS members with experienced and highly regarded mentors from within our Society. Many of you have led successful local, regional, or national responsibilities, in addition to weathering personal challenges in your careers.

After revealing the early plans for the mentoring initiative, we received an enthusiastic response from many of our medical community leaders who offered to serve as mentors in this initiative. Every DCMS member can also serve in such a role at the level she/he would like to participate. You may choose to meet with others to talk and compare notes. Every level of participation can be valuable. Guidance and camaraderie can address physician burnout, a real threat to the effectiveness of the medical community, by bringing back the joy of helping patients.

If you are interested, please send an email our Communications Coordinator, Kristy Wolski, at kristy@dcmsonline.org and she will follow up. Please make sure to include the needed information below in your email. I encourage you to participate. I truly believe that you receive most when you invest time and effort into strengthening your own community. Please do not hesitate to share your suggestions and thank you for your support!

Needed information:
Name ____________________________________________
Direct Phone Number ________________________________
Email ______________________________________________

Please select from the list below the areas of your interest:
1. Career development
2. Performance improvement
3. Medical Legal issues
4. Work-Life balance
5. Health or physician recovery
6. Public relations
7. Other

Dr. Assar is Aetna’s Medical Director for North Florida. Articles or opinions provided by Dr. Assar do not necessarily reflect the views of Aetna.
From the Executive Vice President’s Desk

The Case for Organized Medicine

As always, the 162nd Duval County Medical Society Annual Meeting was a wonderful time of reflection and celebration. As Dr. Mobeen Rathore passed the mantle of the Presidency to Dr. Raed Assar, it was an opportunity to look to the future as well as the past.

One of the projects I am particularly excited about in 2015 is the Mentorship Task Force. This group was assembled by Dr. Assar to help to strengthen the Medical Society by helping to educate and empower physicians who are the current and future leaders of the Society. (To learn more, read Dr. Assar’s editorial entitled “Update on the Mentoring Initiative” on page 5)

The planning stages are already underway, but as the discussions are occurring, I find it refreshing to observe the true value of organized medicine comes to the forefront.

The DCMS was founded in 1853 by Jacksonville doctors looking to quell an epidemic and understanding the need to work together to improve the public health and their ability to practice medicine. Not much has changed in the subsequent 16 decades.

Today the public health issues are not yellow fever and small pox. Yes, epidemiology is still important with Ebola and Chikungunya both making headlines in 2014. However, today’s Medical Society is tackling political and societal issues such as medical marijuana, scope of practice expansion, tort reform and Maintenance of Certification changes. These issues are critical to today’s physician.

The Medical Society is often called the “Voice of Organized Medicine.” The Society has the ability to convey the will of its members to the Florida Legislature, as well as to other Houses of Medicine like the Florida Medical Association and the American Medical Association.

That “Voice” is embodied by engaged and enthusiastic local physicians who dedicate their time to organized medicine with the promise of improving the profession and helping physicians care for the health of our community and all communities.

Dr. Yank Coble served as the President of the Duval County Medical Society before being asked to serve as the President of the Florida Medical Association, the American Medical Association, and the World Medical Association.

Dr. Alan Harmon is currently the Immediate Past-President of the Florida Medical Association. He is one of many DCMS Past-Presidents who went on to serve at the Florida Medical Association.

The Task Force understands that the ability of the Medical Society to maintain this level of statewide, national and global influence requires a commitment to develop and nurture the physicians in Duval County to become leaders in organized medicine. It starts with service to the County Medical Society, but can prepare physicians to participate in everything from state Medical Associations to National Specialty Societies.

As we embark on this journey, we know that it will be a long one. Certainly it takes many years and a significant amount of sweat equity to reach some of these lofty peaks. However, the process of systematically working to help local physicians maximize their leadership potential will only improve the impact of the DCMS on those issues that continue to face local physicians after more than 162 years.

Bryan Campbell
DCMS Executive Vice President

The Case for Organized Medicine
As the oldest specialty in medicine dating back to 1896, the American Academy of Ophthalmology and Oto-Laryngology initially began as a specialty including Ophthalmology and Ear, Nose and Throat (ENT). These two fields officially separated in 1962 forming separate organizations for both specialties. Otolaryngologists are physicians trained in the medical and surgical management and treatment of patients with diseases and disorders of the ear, nose, throat (ENT), and related structures of the head and neck. Their special skills include diagnosing and managing diseases of the sinuses, larynx (voice box), oral cavity, and upper pharynx (mouth and throat), as well as structures of the neck and face. Otolaryngologists work together with their primary care colleagues in the management of both common problems (otitis media, sinusitis), as well as the unique problems of the head and neck region (acoustic neuromas, juvenile nasopharyngeal angiofibroma). Recognized subspecialties include: Otology/Neurotology (dealing with diseases of the ear and skull base), Rhinology (dealing with the nose), Laryngology (dealing with the larynx and the professional voice), Facial Plastic and Reconstructive Surgery, Head and Neck Oncologic Surgery, and Pediatric Otolaryngology.

I am honored to have several otolaryngology leaders in northeast Florida offer a fresh and updated look at our technology-rich field of medicine. These authors have emphasized recently prepared clinical practice guidelines (CPG) for dealing with common problems of the head and neck region such as chronic sinusitis, otitis media with effusion, sudden sensorineural hearing loss, benign paroxysmal positional vertigo and cerumen impaction. These guidelines have been developed in a multispecialty fashion and are increasingly being viewed as the gold standard for treatment of these common conditions.

I have authored an article entitled “Hearing Loss: Miracles now and in the future,” which highlights the exciting developments taking place in treating adult patients with various types of hearing loss. Stem cell therapy, genetic intervention and hair cell regeneration are all discussed as they relate to the future of treating our patients.

Dr. Drew Horlbeck discusses the constantly evolving improvements in the pediatric cochlear implant world. The “bionic ear,” as the Australians refer to the cochlear implant, has literally changed the lives of thousands of children, and their families, with concomitant changes in oral/auditory education of the deaf.

Drs. Andy Simonsen and Bruce Maddern update our readers on the changing world of pediatric Otolaryngology. Indications for tonsillectomy and tympanostomy tubes, two of the most commonly performed surgical procedures in the US, will be discussed along with other trends in pediatric Otolaryngology.

Drs. Larry Lundy, David Zapala and Megan Kobel from the Mayo Clinic Jacksonville will demystify a recently described entity, Superior Semicircular Canal Dehiscence Syndrome, and will also teach us about recent advances in vestibular assessment.

Dr. John Casler, also from the Mayo Clinic Jacksonville, will provide new perspective for our readers on the devastating problem of Head and Neck Cancer.

Drs. Todd Snowden and Albert ‘Sonny’ Wilkinson will update our readers on “Advances in Rhinology.” Given the frequency and economic impact of acute and chronic sinusitis, all of us should be interested in their review of this important topic.

The rich history of Otolaryngology-Head and Neck Surgery corresponds with a rich history of worldwide, humanitarian service and education. Jacksonville otolaryngologists have contributed to that history having served in Vietnam, Haiti, Nigeria, Zambia, Brazil, Nicaragua, Russia and many other countries around the world. The spirit of giving back to Northeast Florida community and to the rest of the world provides ample motivation to many of us serving in this profession. The biblical proverb is appropriate in this context: “To whom much is given, will much be required.” It is to the spirit of giving back that this journal is dedicated.
University of Florida College of Medicine - Jacksonville's Neurology Residency

By Fahed Saada, MD

With over 400 faculty, as well as 37 clinical sites throughout Northeast Florida, the University of Florida College of Medicine-Jacksonville is a leader in the education of health professionals, a hub for clinical research, and a provider of high-quality patient care. UF COM-Jacksonville has a rich tradition and history in education, which includes being home to Florida’s first residency program. Today, the program has more than 300 residents and fellows who are trained by UF medical faculty.

The UF COM-Jacksonville Neurology Residency is no exception to the rich tradition of the University of Florida College of Medicine-Jacksonville. The program is one of 32 Accreditation Council for Graduate Medical Education accredited residencies and fellowship programs offered to students from all regions of the United States. The program also offers a Council on Dental Accreditation (CODA). Moreover, the stroke program at UF Health-Jacksonville has received a 5-star rating for stroke care from HealthGrades, as well as accreditation by the Joint Commission as a primary stroke center and the Florida Agency for Healthcare Administration as a Comprehensive Center.

The UF COM-Jacksonville Neurology Residency program’s approach to training residents encompasses producing a well-rounded physician in all facets, be it academic, clinical, research or community involvement. Along with rotations in a variety of neurological subspecialties, a strong emphasis is also placed on individual mentorship and guidance to foster well-trained and proficient clinicians, who after residency are qualified to practice neurology in all settings: hospital, private practice or continuing to clinical/research fellowships.

To accomplish its goal, the Neurology program boasts a diverse competency-based curriculum with outstanding opportunities for clinical experience. Residents receive bedside and didactic instruction from well renowned UF faculty, as well as exposure to complex neurovascular cases. The program offers residents the opportunity to be constantly involved in multi-disciplinary teams consisting of highly trained vascular neurosurgeons, neuroradiologists, interventional radiologists, emergency medicine physicians and specialized nurses to provide state-of-the-art patient care, including acute stroke management.

A commitment to research is another important component to the program. During residency, residents are expected to conduct quality improvement projects focusing on advancing patient care and participating in local, regional, and national poster presentation. Residents are continually involved in clinical research and participate, as sub-investigators, in industry funded and NIH-NINDS funded clinical trials on the latest developments in stroke prevention and treatment.

The program instills into its residents from day one the importance of community involvement. Residents have opportunities to provide classroom education to nurses at regional meetings of the American Association of Neuroscience Nurses and at UF Health-Jacksonville campus forums. Resident led education of emergency medical services (EMS) occurs through didactic talks that are conducted at various EMS command centers and via teleconferenced case management conferences that link field EMS personnel with stroke clinicians on our campus. Lastly, but no less important, talks at the monthly “Stroke Busters” meetings enable residents to educate stroke survivors about important secondary stroke prevention strategies. Such opportunities allow residents to connect with patients and outside providers in the community.

The UF COM-Jacksonville Neurology Residency program strives to promote excellence in all aspects of clinical neurology practice and development of the next generation of academic neurologists. It has been a tremendous opportunity to reside in Duval County, provide top quality care to patients with neurological needs, and have the opportunity to be part of the University of Florida College of Medicine-Jacksonville family.
**Sinusitis**

Have you ever had a cold or allergy attack that wouldn’t go away? If so, there’s a good chance you actually had sinusitis.

**WHAT IS SINUSITIS?**

Acute bacterial sinusitis is an infection of the sinus cavities caused by bacteria. It usually is preceded by a cold, allergy attack, or irritation by environmental pollutants.

 Normally, mucus collecting in the sinuses drains into the nasal passages. When you have a cold or allergy attack, your sinuses become inflamed and are unable to drain. This can lead to congestion and infection. Your doctor will diagnose acute sinusitis if you have up to 4 weeks of discolored nasal drainage accompanied by nasal congestion, facial pain-pressure-fullness, or both. The sinus infection is likely bacterial if it persists for 10 days or longer.

**TIPS TO PREVENT SINUSITIS**

To avoid developing sinusitis during a cold or allergy attack, keep your sinuses clear by:

- Using an oral decongestant or a short course of nasal spray decongestant
- Gently blowing your nose, blocking one nostril while blowing through the other
- Drinking plenty of fluids to keep nasal discharge thin
- Avoiding air travel. If you must fly, use a nasal spray decongestant before take-off to prevent blockage of the sinuses allowing mucus to drain
- If you have allergies, try to avoid contact with things that trigger attacks. If you cannot, use over-the-counter or prescription antihistamines and/or a prescription nasal spray to control allergy attacks ♦

What are the symptoms of sinusitis vs. a cold or allergy?

<table>
<thead>
<tr>
<th>SIGN / SYMPTOM</th>
<th>SINUSITIS</th>
<th>ALLERGY</th>
<th>COLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial Pressure /Pain</td>
<td>Yes</td>
<td>Sometimes</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Duration of Illness</td>
<td>Over 10-14 days</td>
<td>Varies</td>
<td>Under 10 days</td>
</tr>
<tr>
<td>Nasal Discharge</td>
<td>Whitish or colored</td>
<td>Clear, thin, watery</td>
<td>Thick, whitish or thin</td>
</tr>
<tr>
<td>Fever</td>
<td>Sometimes</td>
<td>No</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Headache</td>
<td>Ofen</td>
<td>Sometimes</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Pain in Upper Teeth</td>
<td>Sometimes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Bad Breath</td>
<td>Sometimes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Coughing</td>
<td>Sometimes</td>
<td>Sometimes</td>
<td>Yes</td>
</tr>
<tr>
<td>Nasal Congestion</td>
<td>Yes</td>
<td>Sometimes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sneezing</td>
<td>No</td>
<td>Sometimes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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Pediatric Cochlear Implants

By Drew M. Horlbeck, MD

Abstract: Pediatric cochlear implantation has allowed children to overcome social and vocational isolation inherent to their hearing loss. Evaluation of a child for a cochlear implant is a multi-faceted process. The medical and surgical evaluation begins with a thorough medical history and a physical performed by a physician. It includes a focus on prenatal, perinatal and postnatal causes of the child's hearing loss. An integral part of the evaluation process is the speech and language evaluation. This multidisciplinary approach to the cochlear implant evaluation process allows for a comprehensive picture of the child's hearing, listening skills, hearing aid benefit and medical issues.

Cochlear implantation has allowed children to overcome social and vocational isolation inherent to their hearing loss. In 1984, the Food and Drug Administration (FDA) approved the first cochlear implant for use in adults ages 18 and older. Five years later, the FDA approved the first cochlear implant for use in children ages two years and older. In 2000, the FDA approved the implantation of children as young as 12 months of age.

In many cases, hearing loss is identified in children when they are screened for hearing loss as newborns. Although children with hearing loss are identified at a much younger age with newborn screening, we continue to see implant candidates who have had progressive hearing loss. For example, children with hearing loss due to enlarged vestibular aqueduct syndrome and those with mutation of the connexin 26 gene may pass newborn screening and still have progressive loss. In a recent study, up to 30 percent of pediatric cochlear implant recipients were not identified as hearing impaired as newborns.1 This will affect the age at implantation as children identified with newborn screening with hearing loss were implanted at 1.7 years, and those who passed or were not screened were implanted at 2.6 years.1 Once identified, a child then undergoes definitive audiometric testing, which is most likely a sedated auditory brainstem response and otoacoustic emissions. This includes testing for auditory neuropathy/dyssynchrony. Children identified later may be evaluated by age appropriate behavioral audiometry. If the child is found to have a profound hearing loss, the cochlear implant process begins.

Evaluation of a child for a cochlear implant is a multi-faceted process. After review of previous medical records, children will be evaluated by several members of the cochlear implant team. The team consists of an implant surgeon, cochlear implant audiologist, speech pathologist, genetics and ophthalmologist.

The medical and surgical evaluation begins with a thorough medical history and a physical performed by a physician. It includes a focus on prenatal, perinatal and postnatal causes of the child’s hearing loss. Family history of a hearing loss is also important. Then, the diagnostic work-up proceeds. The use of routine laboratory testing is not needed in most children with hearing loss. Laboratory testing should be performed on a case by case basis, depending on the possible cause of the hearing loss. The use of routine laboratory testing has a low yield in establishing the diagnosis of hearing loss ranging from zero to two percent.2,3

Children with newly diagnosed hearing loss will require imaging. There is controversy, however, regarding the appropriate imaging study to obtain. The long time standard has been a computerized tomography scan (CT) of the temporal bones. Magnetic resonance imaging (MRI) in the past was considered expensive and required sedation. MRI for hearing loss, however, is faster and provides excellent anatomic information of the temporal bone.4 In addition, there is some suggestion that since some studies have found no association between GJB2-positive children and temporal bone abnormalities, these children do not need imaging if they have a hearing loss not requiring cochlear implantation.5,6

An integral part of the evaluation process is the speech and language evaluation. Often times, young children are incapable of speech or language and cannot complete traditional speech perception testing. The speech language pathologist on the cochlear implant team will complete appropriate testing and observation of a child to assess benefit from hearing aids. An aural rehabilitation/speech-language evaluation for a cochlear implant can be difficult to define. The process varies depending on the age of the child, the current mode of communication and overall language ability. Young infants and toddlers are not typically given formal assessments; the evaluation primarily includes parent questionnaires, play-based interactions and clinician...
observation. Pre-school and school-age children are given an auditory perception assessment, a language assessment and an articulation assessment, if appropriate. Children who experience the notable difficulties with the auditory perception portion of the evaluation are most often the better candidates for a cochlear implant. Additionally, if a child demonstrates little to no improvements or a decline in improvements over a given period of time, he or she may also qualify for a cochlear implant.

The audiological, or hearing, evaluation may include one or more testing sessions where a child’s hearing is tested by a cochlear implant audiologist to see if the hearing loss falls within candidacy criteria, if their hearing aids fit properly and if they are providing optimal benefit. If a child has speech and language, speech perception testing will be completed to assess their understanding abilities. Testing includes word and sentence tests of varying difficulties based on the child’s current capabilities or language age. A child’s score on the tests will allow the team to evaluate if they fall into candidacy criteria. If the child is too young or has not acquired spoken language, this testing cannot be completed. Parent questionnaires are often administered to evaluate a child’s hearing capabilities, hearing aid use and development.

The candidacy criteria for children typically include:
• Bilateral severe-profound sensorineural hearing loss
• Ages 12 months to 18 years
• Demonstration of marginal to no significant benefit from hearing aids following appropriate use, therapy and intervention (use of hearing aids during all waking hours)
• Commitment to oral communication
• Evidence of strong family support and motivation
• Appropriate expectations of family for the outcomes for each individual child
• Receptive and supportive educational system if appropriate
• Physically capable of undergoing the surgical procedure and no contraindications to surgery

Conclusion

This multidisciplinary approach to the cochlear implant evaluation process allows for a comprehensive picture of the child’s hearing, listening skills, hearing aid benefit and medical issues. The cochlear implant team meets to discuss each candidate to formally make a decision if a cochlear implant is appropriate for a child. A formal counseling session with the family informs them of the team’s decision, reviews the remainder of the CI process and the devices, as well as a discussion of post-operative appointments and therapies to ensure maximum benefit from the cochlear implant.

References

4. Licameli G, Kenna M. Is computed tomography (CT) or magnetic resonance imaging (MRI) more useful in the evaluation of pediatric sensitineuronal hearing loss. Laryngoscope. 2010;120:2358-2359.
Update on Pediatric Otolaryngology: New Techniques and Better Outcomes

By Andrew R. Simonsen, DO, FAAP
Bruce R. Maddern, MD, FAAP, FACS

Abstract: Conditions involving the ears, nose, and throat affecting the pediatric population generate a significant number of primary care visits and subspecialty referrals each year. The most common of these include adenotonsillar conditions, obstructive sleep apnea, otitis media, hearing loss, and rhinosinusitis. The following review will focus on the current recommendations for the diagnosis and treatment of these conditions as they specifically relate to the pediatric population. Key topics include indications for polysomnography in children, current indications for adenotonsillectomy, indications for tympanostomy tubes, the early diagnosis and treatment of sensorineural hearing loss, and recurrent rhinosinusitis.

Obstructive Sleep Apnea (OSA)

Sleep disordered breathing (SDB) and Obstructive Sleep Apnea are a spectrum of illness and continue to be prevalent, affecting one to four percent of children. Several clinical practice guidelines have been published by different specialties adding to our information base, but they also offer sharply conflicting recommendations. For clinicians, this continues to be an area of confusion in evaluation and treatment options. Controversy remains as to how best to manage these patients.

Polysomnography (PSG) for children is now readily available with separate standards and equipment for pediatric testing. Discussion continues on exact interpretation criteria for severity of OSA, utility of REM findings and relationship of central sleep apnea to overall illness. Nadir oxygen saturation and end tidal carbon dioxide levels remain very useful physiologic metrics in children.

PSG is described as the “gold standard” of testing, but is ordered in fewer than 10 percent of children who eventually undergo adenotonsillectomy. Clinicians have considerable reservation about the utility of this expensive and cumbersome test for the evaluation of the routine, otherwise healthy, patient with a clear history and physical findings of OSA requiring adenotonsillectomy. In a recent survey of pediatric otolaryngologists, only 10 percent order sleep studies for SDB. Quality of life surveys after adenotonsillectomy T/A for SDB or OSA show significant improvement with or without sleep studies.

Polysomnography can be useful in the equivocal patient when symptoms or physical findings are out of proportion. PSG is recommended for the “at risk” child such as those with Down syndrome, neuromuscular disease or craniofacial dysmorphism. PSG may be helpful as a predictor of severity which may assist the operative team in management of narcotics, anesthesia and placement as inpatient or outpatient. Most practitioners treat even suspected OSA with additional precautions. Local standards for care vary based on available pediatric testing facilities, inpatient services and dedicated pediatric anesthesia.

Home testing for OSA in children is not readily available or reliable. Equipment issues have improved, but compliance and financial concerns remain. Home sleep video with today’s

Address correspondence to:
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10475 Centurion Parkway North, #302
Jacksonville, FL 32256
readily available smart phones and correlated sleep questionnaires are simple tests to help document thresholds of clinical findings and indications for surgery.

**Adenotonsillectomy (T/A)**

There are more than 500,000 adenotonsillectomies performed in children each year in the United States (US). It is the second most common surgical procedure performed in children after myringotomy and tube placement. T/A remains the gold standard procedure for the treatment of OSA and recurrent chronic upper respiratory illness. More T/A are performed for SDB than upper respiratory illness by a wide margin. The mean age of T/A has declined significantly during the last 20 years. A variety of newer surgical and anesthesia techniques have improved patient safety and outcomes. Inpatient admission for T/A has sharply declined. A 50 percent reduction in admission was seen from 1977 to 1989 and rates continue to decline as perioperative management techniques continue to improve.

Despite this evolution in care, several children die each year from “routine” adenotonsillectomy. Exact data is very difficult to verify, but highly publicized case reports, malpractice claims and anecdotal information should alert professionals and the public to the fact that T/A is not a simple or minor procedure. Mortality is due to failure to recognize potential airway, respiratory, medication and comorbid conditions such as OSA. Patient selection and family education are critical in the management of children undergoing T/A. Dedicated pediatric professionals and facilities improve safety and care.

Though newer surgical techniques are often touted as minimally invasive or less painful, T/A remains a painful, anxiety-provoking and unpredictable procedure during the important postoperative period. Limited use of narcotics, due to an FDA “black box” warning about codeine, and increased use of nonsteroidal anti-inflammatory medications are recent changes in postoperative care intended to meet individual patient needs. Some increases in postoperative bleeding rates have been noted as these changes have emerged. Bleeding after T/A is a well known adverse event and may occur in as many as three percent of patients.

Clinical practice guidelines for adenotonsillectomy have been developed by several interested specialties individually or as part of OSA, PSG or other management protocols. These evidence based paradigms create discordance across specialties, but help add needed perspective on having dedicated care protocols to improve safety and care in this common and still controversial procedure.

The American Academy of Otolaryngology (AAO) guideline made several important recommendations including:

1) The importance of watchful waiting for recurrent but not chronic illness;
2) The utility of surgery for other conditions including antibiotic allergy or intolerance, periodic fever and abscess;
3) The importance of other conditions associated with SDB/OSA such as growth retardation, poor school performance and behavioral problems;
4) Improvement in overall health after T/A for OSA/SDB;
5) Important perioperative management needs including the use of steroids and pain medications;
6) Requirement for quality reporting such as bleeding rates.

**Otitis media**

Tympanostomy tube insertion is the most common outpatient surgical procedure requiring general anesthesia performed in the US. In an era of increasing attention to the cost of healthcare and access to medical resources, it is not a surprise that there is increasing attention on the treatment of otitis media with effusion and recurrent acute otitis media. The last two years saw the publication of two important reviews of surgical treatment of otitis media with effusion (OME) in children:


Surprisingly until 2013 there was no clinical practice guideline for tympanostomy tube insertion in the US. There have been various recommendations that were followed based on the best available literature. Many of these established practice recommendations have found their way to the guidelines with a few notable exceptions. In summary, the question of “to tube or not to tube” is answered by the guidelines is as follows:

- Tympanostomy tubes should be recommended if:
  - Chronic (three months or longer) bilateral OME with hearing difficulty (documented)
  - Chronic OME with symptoms
  - Recurrent (three episodes in six months or four in 12 months with at least one in the last six months) acute otitis media (AOM) with middle ear effusion (MEE) at the time of evaluation by the Otolaryngologist.
o Any AOM or OME in an at risk child
• Tympanostomy tubes should NOT be recommended if:
  o Recurrent AOM without MEE on Otolaryngology evaluation
• For uncomplicated acute tympanostomy tube otorrhea only ototopical drops should be used without oral antibiotics.
• Routine water precautions are not recommended for children with tympanostomy tubes.

The recommendation causing the most debate among diverse specialties is the opinion against tube placement for children who meet criteria for recurrent AOM, but who do not have middle ear effusions at the time of consultation with their Otolaryngologist. The support for this recommendation is based on the favorable natural history of recurrent AOM and the low risk of delaying tubes.11 Important exceptions to this recommendation are children who have complications from AOM, history of difficult to treat AOM or multiple antibiotic allergies, or are otherwise at risk.11

Another departure from common practice is to not recommend use of ear plugs in children with tympanostomy tubes. This is based primarily on one large randomized controlled trial that found that the average child with tubes would have to wear ear plugs for 2.8 years to prevent one episode of otorrhea.12 Other prior studies support these findings. Exceptions to this are children who have persistent or recurrent otorrhea, those with risk factors such as immune dysfunction, and deep diving or simply ear discomfort with swimming.

Sensorineural hearing loss:
Early diagnosis and treatment

According to the Centers for Disease Control and Prevention (CDC), more than 97 percent of newborns in the US were successfully screened for hearing loss in 2011 highlighting the huge success of the newborn infant hearing screening programs.13 The current focus is timely diagnosis of those children who are deaf and hard of hearing (D/HH) and referral for early intervention (EI). Many children who are D/HH can achieve communication skills on par with their peers of similar age and cognitive ability with appropriate intervention prior to six months of age. Achieving these results in the majority of children with hearing loss requires equal access to the required services on a local and state level and awareness among the primary care medical community.

The most comprehensive guideline is the 2007 position statement by the Joint Committee on Infant Hearing which was updated in 2013.14,15 A brief summary is provided below:
• By one month of age: Physiologic hearing screen (ABR or OAE).

Pediatric Rhinosinusitis

The treatment of acute rhinosinusitis in children remains controversial. This has been discussed in the literature which has been summarized in a clinical practice guideline by the American Academy of Pediatrics.16 The last decade has seen very little in the way of new evidence that alters or supports our current understanding of recurrent acute and chronic sinusitis in children.

When faced with the chronically “snotty” child, it is important to distinguish between recurrent viral upper respiratory infections and bacterial sinusitis which can be accomplished using the following definitions16:
• Acute bacterial sinusitis is defined as any URI (nasal discharge or daytime cough) that: lasts longer than 10 to 14 days, worsens after initial improvement, or is severe in onset with temp higher than 39°C and purulent rhinorrhea for at least three days.

o Rescreening of an initially failed screen can be done prior to hospital discharge, but no later than one month after discharge.
• By three months of age: Infants who fail the initial hearing screen should receive a comprehensive audiologic, an otolaryngologic evaluation along with fitting of amplification devices (when appropriate). Genetic evaluation should be offered at this stage as well.
• Within 48 hours of confirmed hearing loss: referral to early intervention services.
• By six months of age: A child with confirmed hearing loss should be enrolled in early intervention services.
• On-going hearing screening for all children based on AAP well visit schedule.
• Cochlear implantation: Should be considered for all children with sensorineural hearing loss who are not benefiting from appropriate amplification.
• FDA guidelines for cochlear implantation:
  o Older than 12 months of age
  o Bilateral severe to profound sensorineural hearing loss
• Bone anchored hearing aids (BAHA): should be considered for children with permanent conductive and mixed hearing loss.
• FDA guidelines for BAHA:
  o Older than 5 years of age
  o Less than 65 dB conductive hearing loss for a pure tone average
• Recurrent acute bacterial sinusitis: Recurrent episodes of bacterial sinusitis lasting less than 30 days and with at least 10 symptom free days between episodes. Authors often require four or more episodes per year or three in six months.

• Chronic bacterial sinusitis: Bacterial sinusitis lasting 90 days or longer.

When considering recurrent acute or chronic bacterial sinusitis underlying conditions should be ruled out including allergic and non-allergic rhinitis, immune deficiency, gastroesophageal reflux, cystic fibrosis and ciliary dysmotility.

Imaging of the sinuses may be helpful in the management of recurrent and chronic sinusitis, but is not recommended in the setting of acute sinusitis unless there is concern for complications such as orbital or intracranial involvement. CT remains the study of choice as bony detail is most helpful. There is legitimate concern about the cumulative long term effect of repeated radiation exposure via CT scans beginning in childhood. For this reason CT scanning a child for chronic or recurrent sinusitis should be reserved for those patients who have failed medical therapy and for whom surgical intervention is being considered.16

Medical treatment of acute bacterial sinusitis should include antibiotic therapy.16 Judicious use of adjuvant therapies including nasal saline, antihistamines, decongestants, mucolytics, and intranasal steroids offer symptomatic relief and shorter duration of illness. For the prevention of recurrent or chronic sinusitis medial options include nasal steroid sprays, allergy therapy if applicable, and nasal saline irrigations. A comprehensive allergy workup should be recommended for these children of an appropriate age with appropriate therapy to follow. Long term prophylactic antibiotics have been shown to be effective but the risk of bacterial resistance may outweigh the benefits.

Surgical options for chronic or recurrent sinusitis refractory to medical therapy include adenoidectomy with or without maxillary sinus lavage for children and possible tonsillectomy. Endoscopic sinus surgery may be considered in older children. Age is important when considering sinus surgery of any kind due to the progressive development of the sinuses. Most children are born with small, but existing maxillary and ethmoid sinuses. The sphenoid sinus develops around six years of age, and the frontal may not be present until the second decade of life.

Balloon sinuplasty and children

A new, and often advertised, treatment for chronic sinusitis is balloon sinuplasty. Results have shown to be effective in adults, but less so for children, however, it is no more than an alternative surgical instrument to perform endoscopic sinus surgery. Much like the multiple techniques available to remove tonsils, this is also true for sinus surgery. Balloon technology is considerably more expensive and long term results, especially in children, are still pending. When used in adult patients the procedure can be done in the office leading to a net cost savings but this is not an option for children.

Conclusion

Pediatric Otolaryngology has seen significant advancements during the last decade that have occurred in concert with progress in other medical specialties, basic sciences and biotechnology. Recent guidelines have helped to clarify indications and focus attention on reducing complications and ultimately improving outcomes for many of the most common medical treatments and surgical procedures in children. Those questions that remain unanswered and the continued need for additional, high quality, research is also highlighted. As with all medical specialties, improving the health of children requires access to specialized care and treatment. Addressing disparities in access to pediatric care will be increasingly important as science and technology continue to advance.  

References

6. Poster session and personal communication, American Society of Pediatric Otolaryngology, May 2014, Las Vegas, NV.


Prevention of Medical Errors:  
Root Causes and Strategies to Avoid Errors

Background:
The Duval County Medical Society (DCMS) is proud to provide its members with free continuing medical education (CME) opportunities in subject areas mandated and suggested by the State of Florida Board of Medicine to obtain and retain medical licensure. The DCMS would like to thank the St. Vincent's Healthcare Committee on CME for reviewing and accrediting this activity in compliance with the Accreditation Council on Continuing Medical Education (ACCME).

This issue of Northeast Florida Medicine includes an article, “Prevention of Medical Errors: Root Causes and Strategies to Avoid Errors” authored by Vicki-lynne Gloger, MSSM, SFHM, which has been approved for 2 AMA PRA Category 1 credits. For a full description of CME requirements for Florida physicians, please visit www.dcmsonline.org.

Faculty/Credentials:
Vicki-lynne Gloger is the Administrator for Baptist Health System Hospitalist Programs in Jacksonville, FL.

Objectives:
1. To identify preventive actions to avoid surgical wrong site, wrong patient, wrong procedure events.
2. To identify preventive actions for avoiding diagnostic errors in the office setting.
3. To identify overall strategies to avoid medical errors.

Date of release: March 1, 2015  Date Credit Expires: March 1, 2017  Estimated Completion Time: 2 hours

How to Earn this CME Credit:
1. Read the “Prevention of Medical Errors: Root Causes and Strategies to Avoid Errors” article.
2. Complete the posttest and email your test to Patti Ruscito at patti@dcmsonline.org or mail it to 1301 Riverplace Boulevard, Suite #1638, Jacksonville, FL 32207.
3. You can also go to www.dcmsonline.org to read the article and take the CME test online.
4. All non-members must submit payment for their CME before their test can be graded.

CME Credit Eligibility:
A minimum passing grade of 70% must be achieved. Only one re-take opportunity will be granted. A certificate of credit/completion will be emailed within four to six weeks of submission. If you have any questions, please contact Patti Ruscito at 904.355.6561 or patti@dcmsonline.org.

Faculty Disclosure:
Vicki-lynne Gloger reports no significant relations to disclose, financial or otherwise with any commercial supporter or product manufacturer associated with this activity.

Disclosure of Conflicts of Interest:
St. Vincent’s Healthcare (SVHC) requires speakers, faculty, CME Committee and other individuals who are in a position to control the content of this educations activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly evaluated by SVHC for fair balance, scientific objectivity of studies mentioned in the presentation and educational materials used as basis for content, and appropriateness of patient care recommendations.
Prevention of Medical Errors: Root Causes and Strategies to Avoid Errors

By Vicki-lynne Gloger, MSSM, SFHM

Abstract: This article focuses on medical errors and the root causes for why they occur, case reviews of some types of errors and strategies to avoid them. After reading this article, the physician should be able to identify common medical errors according to the Board of Osteopathic Medicine and the Board of Medicine, at least two root causes for each and at a minimum of two strategies to effectively avoid these medical errors.

According to the Florida Board of Osteopathic Medicine, the most common medical errors as of 2014 involved inappropriate prescribing of opioids in patients where there may have been a diagnostic omission or commission related to addiction, psychiatric conditions or diversion, delay or failures in diagnosing cancer, retained foreign objects in surgery and wrong site/wrong patient surgery, surgical and pre-operative evaluation complications/errors and prescribing, dispensing, administering or using non-FDA approved medications and devices. The Florida Board of Medicine has identified the following as the top five most misdiagnosed conditions currently as being cancer related conditions, neurological related conditions, cardiac related conditions, timely response to surgical and post-operative complications and urological related conditions. This article focuses on several medical errors, the root causes and prevention techniques.

Wrong Site/Procedure/Patient Surgery

Few medical errors are as vivid as those that involve patients who have undergone surgery on the wrong body part, undergone the incorrect procedure or had a procedure intended for another patient. These “wrong-site, wrong-procedure, wrong-patient errors” (WSPEs) have been termed “Never Events” as they are errors that should never occur and that demonstrate underlying safety problems. In February 2009, the Centers for Medicare and Medicaid Services (CMS) announced that hospitals will not be reimbursed for any costs associated with WSPEs. (CMS has not reimbursed hospitals for additional costs associated with many preventable errors since 2007.)

When the then-president of the Joint Commission, surgeon Dennis O'Leary, MD, unveiled mandatory rules to prevent operations on the wrong patient or body part, he did not mince words. “This is not quite ‘Dick and Jane,’ but it's pretty close,” he declared in an interview with the Washington Post on January 21, 2011, about the “universal protocol” to prevent wrong-site surgery. These rules require preoperative verification of important details, marking of the surgical site and a timeout to confirm everything just before the procedure starts.

Effective errors prevention activity that O'Leary cited includes ensuring that x-rays are carefully reviewed, accurately documented and, if hung, hung correctly, checking arm bands and having all team members reaffirm patient identity and planned procedure. However, in 2012, researchers and patient safety experts said that the rate of WSPEs in the United States had not improved, but may actually be getting worse. Forty-eight cases were reported in Minnesota in 2010, up from 44 in 2009 and Pennsylvania has averaged about 64 cases for the past few years. Based on data provided by individual states, Joint Commission officials estimate that wrong-site surgery occurs 40 times a week.

Mark Chassin, MD, current TJC president, speaking at the Joint Commission Center for Transforming Healthcare Conference on June 29, 2011 said he thinks errors are increasing, in part, because of escalating time pressures and throughput demands on surgical teams. Preventing wrong-site surgery also “turns out to be more complicated to eradicate than anybody thought,” he said, because it involves changing the culture of hospitals and getting doctors who typically prize their autonomy, resist checklists and underestimate their propensity for error, to follow standardized procedures and work in teams. Studies of wrong-site errors have consistently revealed a failure by physicians to participate in a timeout. Timeout is the minimal delay just before incision to ensure correct patient, procedure and site according to Dr. Chassin and co-presenters: Mary Cooper MD, Lisa Lewis, RN, and Rudy Manthei, MD.

Philip F. Stahel, MD, director of orthopedic surgery at Denver Health Medical Center was lead author of a 2010 study evaluating 132 WSPE cases reported to a Colorado malpractice carrier. The cases were reported between 2002 and 2008, and one-third resulted in death or serious injury. Among them were three men who underwent prostate cancer surgery although they were cancer-free. In 72 percent of cases there was no timeout.
The objective of the study was to determine the frequency, root cause and outcome of WSPE procedures. The researchers analyzed a prospective physician insurance database and de-identified cases were screened. The database contained 27,370 self-reported adverse occurrences. Dr. Stahel and his cohorts generated descriptive statistics and examined the number of adverse events reported per year, and the root causes and occurrence-related patient outcomes. They reported that: “A total of 25 wrong-patient and 107 wrong-site procedures were identified during the study period. Significant harm was inflicted in five wrong-patient procedures (20 percent) and 38 wrong-site procedures (35.5 percent). One patient died secondary to a wrong-site procedure (0.9 percent). The main root causes leading to wrong-patient procedures were errors in diagnosis (56 percent) and errors in communication (100 percent), whereas wrong-site occurrences were related to errors in judgment (85 percent) and the lack of performing a ‘time-out’ (72 percent).”

Hospitals and surgical centers permit non-compliance with “Universal Protocol,” albeit the American Academy of Orthopedic Surgeons states that orthopedic surgeons have a 25 percent chance of making a wrong-site error during their career. The Academy launched a voluntary “Sign Your Site” campaign in 1997, putting up billboards across the country in an attempt to educate patients. The billboard at O’Hare Airport in Chicago, for example, had a hand holding a Sharpie marker and the caption indicated that the marker may be the most important tool your surgeon uses.

The problem is certainly not isolated to the US—as indicated— in Great Britain’s “Health Reporter” on Thursday, December 12, 2013 which reported that, “Surgeons at a National Health Service hospital carried out heart surgery on the wrong patient, it was revealed today, following the release of new statistics on major errors within the health service. Overall there were 148 “never events” - medical mistakes that according to guidelines should never happen - at NHS trusts between April and September 2013. Foreign objects such as needles, swabs and even a glove being left inside a patient were the most common type of error - occurring 69 times. “Surgery was performed on the wrong part of the body 37 times, and at one hospital, a cardiac operation was performed on the wrong patient. One patient had the wrong toe removed, and another received surgery on their left foot for a condition affecting their right foot.”

The figure does not represent a major increase on previous years. Between 2012 and 2013 there were 326 “never events,” said Dr. Mike Durkin, NHS England’s national director for patient safety, noting that investigations into the events were on-going and it was not yet known how many had resulted in death. “It is important to remember that all ‘never events’ should trigger a root causes analysis investigation and subsequent improvement in safety, even where the patients come to minimal harm,” he said.

The following should be the “Always” standard of practice to avoid wrong site, wrong procedure, and wrong patient surgery:

1. The surgeon should review the actual diagnostic studies performed by the referring physician to ensure he/she agrees that the proposed procedure is indicated and appropriate and that the level/lateral of the proposed procedure is consistent with the study results.

2. The surgeon should ensure that radiologic reports are carefully reviewed, appropriately documented and if hung, then hung correctly.

3. The “Universal Protocols” for correct site, patient and procedure should be consistently complied with for all cases, regardless of operating room turn-around times.

a. Every member of the surgical team speaking with the patient pre-operatively should reaffirm a patient’s identity.

b. Every member of the surgical team speaking with the patient should reaffirm the planned procedure and location of the procedure (level, side, etc.).

c. The surgeon should consistently sign the surgical site.

4. In the event of surgical error or mishap, the surgeon as “captain of the ship” should always take the lead in disclosing what occurred to the patient/family, in making a sincere apology and in working with the patient/family in resolving resulting issue according to major malpractice. Any attempt to leave vital information out, cover up errors or omissions will likely exacerbate the situation.

OB/GYN Complications

Studies conducted by the Centers for Disease Control (CDC) and the American College of Obstetricians and Gynecologists (ACOG), conclude the leading causes of maternal/pregnancy death are: hemorrhage, hypertensive disorder, pulmonary embolism, amniotic fluid embolism, infection and pre-existing chronic conditions. One study that spanned ten years indicated that the numbers of deaths related to hemorrhage declined, while mortality attributable to other conditions (e.g. cardiovascular, pulmonary and neurologic) significantly increased.

It has become evident that heightened physician awareness, coupled with screening of pregnant women with pre-existing condition/associated risk factors, will help preclude adverse outcomes. Without comprehensive medical and social histories, underlying factors may go unrecognized and result in morbidity or mortality.

Hospital Corporation of America (HCA) examined individual causes of maternal deaths among 1.5 million births within 124 hospitals occurring between 2002 and 2007. HCA
concluded that while the majority of maternal deaths could not be avoided some could have been prevented by the physician(s). According to the study, the most preventable errors are failure to adequately control blood pressure in hypertensive women, failure to adequately diagnose and treat pulmonary edema in preclamptic patients, failure to monitor/respond to vital signs following Cesarean section (C-section) and failure to control hemorrhage following C-section.9

Steven L. Clark, MD, Medical Director of Women and Newborn Services for HCA, stated, “The data showed the individual causes of death to be very heterogeneous and that the only cause of maternal death amendable to nationwide systematic prevention efforts is pulmonary embolism. Pregnancy is a known major risk factor for venous thrombosis and pulmonary embolism.”10

Unlike nearly all other adult patients undergoing major surgery, women undergoing C-sections have traditionally not received prophylactic measures for the prevention of venous thromboembolism (VTE) afforded similar surgical patients who lack this risk factor. Between 1991 and 2003, the US rate of severe complications and conditions associated with pregnancy was 50 times more common than maternal death.11

A review of settled obstetrical malpractice claims reveals that adverse outcomes often result from under-responding to abnormal vital signs, failing to recognize or notice indications that complications occurred, and practicing in a state of denial. It is imperative to establish protocols with triggers for appropriate responses. For example, adopting VTE prophylaxis measures, coupled with comprehensive programs for identifying and responding to hemorrhage can have a significant impact.12

The bottom line in avoiding preventable pregnancy related morbidity and mortality is that, in addition to the safe guards discussed at the end of this article, the following should be the standard of practice:

A comprehensive history and physical should be taken when care is initiated, which includes family and social history and underlying medical conditions.

• Reassessment at the time of every office visit and upon hospitalization is crucial.

• The “young and healthy” status of women in labor, during delivery and post-partum should not exclude requirement that physicians recognize and respond to changes in a patient’s condition. Whether or not the hospital has a process, the physician should require that his/her patients be monitored throughout hospitalization from admission to discharge, recognizing and responding as soon as a patient’s condition appears to be worsening.

• Physicians who care for women with underlying medical conditions should be attuned to the additional risks that could be imposed if pregnancy were added, how to discuss these risks with patients, the use of appropriate and acceptable contraception, and pre-conceptual care and counseling. The attending physician at delivery should communicate identified pregnancy risks to all members of the health care delivery team.

• The physician managing pregnant patients should evaluate for, identify and respond to pre-existing medical conditions such as hypertension, diabetes, morbid obesity and advanced maternal age.

• The physician’s orders should identify specific triggers for responding to changes in the mother’s vital signs and clinical condition, and should stipulate interventions for responding to the changes.

• VTE prophylaxis should be ordered for C-section patients at risk for pulmonary embolism.

• Patients at high risk for thromboembolism should be evaluated for low molecular weight heparin for postpartum care. 5,6,7,8,9,10,11

Diagnosis Failures

Diagnosis errors are frequent and important, but can be challenging to detect and dissect to ascertain how to best avoid them in the future or the root causes. A study conducted by a team of physicians led by Gordon D. Schiff, MD and representing Cook County John H. Stroger Hospital, Rush University Medical Center, Hektoen Research Institute, University of Illinois at Chicago, College of Pharmacy and the University of Illinois at Chicago Medical School identified why diagnostic errors occur and what can be done to avoid them.13

The study, published in Advances in Patient Safety: From Research to Implementation, describes what federally funded programs have accomplished in understanding medical errors and implementing programs to improve patient safety during the last five years. This compendium, sponsored jointly by the Agency for Healthcare Research and Quality and the Department of Defense (DoD)-Health Affairs, catalogues a series of ideas for change.13

• Reengineering follow-up of abnormal test results

• Standardizing protocols for reading x-rays and lab tests, particularly in training programs and after hours

• Identifying “red flag” and “don’t miss” diagnoses and situations

• Using manual and automated check-lists
• Engaging patients on multiple levels to become “co-producers” of safer medical diagnosis practices

• Weaving “safety nets” to mitigate harm from uncertainties and errors in diagnosis\(^\text{14,15}\)

Creating and maintaining a patient problem list can help prevent and avoid diagnosis errors. It can ensure that each active problem is being addressed, with reminders about diagnoses, allergies, and unexplained findings. It is also useful in ensuring follow-up of health maintenance. Likewise, an up-to-date medication list, reconciled at each patient visit (or admission) is essential for patient safety.\(^3\)

A Harris poll commissioned by the National Patient Safety Foundation found that one in six people had personally experienced a medical error related to misdiagnosis.\(^4\) Most medical error studies find that on average, 20 percent of errors are errors in diagnosis. They further reported that a recent review of 53 autopsy studies found an average rate of 23.5 percent major missed diagnoses. Selected disease-specific studies also show that substantial percentages of patients averaging at 30 percent experienced missed or delayed diagnoses. While the studies used different criteria and methodologies, what emerged was compelling evidence for the frequency and impact of diagnosis error and delay.

Physicians are frequently confronted with rapid changes in diagnostic testing and care pathway expectations. New imaging modalities, lab tests and testing recommendations have been introduced, often leaving physicians confused about what to order or how to interpret contradictory results (from one sub-specialist to the next). If diagnosis errors are to be avoided, physicians must be aware of the limitations of diagnostic tests they order.

A normal mammogram in a woman with a breast lump does not rule out the diagnosis of breast cancer, as test sensitivity of test is only 70 to 85 percent. A recurring theme of case reviews was failure to appreciate pitfalls in weighing test results in the context of the patient’s pretest disease probabilities. Local factors, such as the variation in quality of test performance and readings, combined with communication failures between radiology/laboratory and ordering physicians (results reported as “positive” or “negative,” overlooking subtleties and limitations) provide further sources of error.\(^16\)

Active listening is an essential component of an accurate diagnosis, and too often the physician has only partial information, which can result in diagnostic errors. The physician can fall victim to bias based on what he/she did hear and as a result “went down the incorrect biased diagnostic pathway.”\(^17,18\)

### Diagnostic Pitfalls

Errors occur when physicians are trying to make an accurate diagnosis of a medical problem. Some closed case reviews help us understand why errors in ascertaining the correct diagnosis occur.

**Case One:**

A recent malpractice case highlights missing an early diagnosis and causation of harm. The litigant had a family history that included breast cancer diagnoses for two female relatives (one was her mother) who had breast cancer in their forties. At 33, she began getting annual screening mammograms, which showed dense breasts. She complained of a small palpable mass. However, no mass was seen on a mammogram, and the diagnosis was fibrocystic changes. No additional tests were ordered. Within six months, the mass was enlarging, and she was diagnosed with infiltrating ductal cancer that had advanced from a Stage I to a Stage III. The plaintiff’s attorney made his case that, based on her history, she should have been tested for the BRCA mutation and given various treatment options. Additionally, he noted that no ultrasounds or MRIs were done, which possibly could have detected the cancer at an earlier treatable stage. According to “The Doctor’s Practice” magazine of the Doctors Company, published in September 2013, “A woman’s risk of developing breast and/or ovarian cancer greatly increases if she inherits a BRCA1 or BRCA2 gene mutation.\(^19\) Widespread screening is not required because together these mutations account for only five to 10 percent of breast cancers. Those with the BRCA1 mutation have a 55–65 percent chance of developing breast cancer by age 70, and those with the BRCA2 mutation have a 45 percent chance.” Women have about a two percent chance of getting ovarian cancer, but if they have a BRCA2 mutation, that risk increases to 40 to 60 percent. The following risk factors should be assessed by the physician with actions taken as indicated for existence:\(^19\)

- Maternal or paternal blood relatives with breast cancer diagnosed before the age of 50
- Pancreatic, colon or thyroid cancers present in family members
- Both breast and ovarian cancer in a patient’s family, especially in one individual
- Women in a patient’s family with bilateral breast cancer
- Patient with Ashkenazi Jewish heritage
- A male blood relative with breast cancer
- Relative with BRCA1 or BRCA2 mutation
Case Two:

This case involves a patient who had been under the care of the same primary care physician for nine years. He complained intermittently of back problems and fatigue. He was prescribed B12 injections, multivitamins, iron and folic acid during the ensuing years.

At the age of 43, the patient presented with complaints of rectal bleeding and had hemoglobin of 14.6. His physician ordered a barium enema and found diverticular disease. At a follow-up office visit two weeks later, the patient again reported rectal bleeding. A high fiber diet and Cipro were recommended. No rectal exam is recorded at either of these office visits. Nearly 22 months later, the patient returned to the office. CBC revealed hemoglobin of 10.7, although he reported having had no rectal bleeding for a year. Again no rectal exam recorded.

The next visit was seven months later, about 18 months after anemia was first confirmed and 3.5 years after the initial complaint of rectal bleeding. A rectal exam was done, confirming blood and the presence of “an internal hemorrhoid.” The colonoscopy performed four weeks later revealed a “lobulated, ulcerated mass at two to five cm from the anal verge.” A small polyp was removed 20 cm from the anus. Biopsies of the smaller polyp were non-diagnostic at pathologic exam, but pathology confirmed the rectal mass as adenocarcinoma.

Referral was made to a colorectal surgeon who ordered an abdominal and pelvic CT scan. The CT was negative for metastatic disease. Also, the Chest x-ray was normal. The surgeon recommended neoadjuvant chemo-radiation which was completed without incident.

Five months later the surgeon performed a recto-lower sigmoid resection and sigmoid colostomy. The resected specimen revealed adenocarcinoma extending into the perirectal tissues with two nodes revealing malignancy. Following the surgery, adjuvant 5FU was prescribed and given for approximately four months.

Five months after completion of the adjuvant chemotherapy, and now one year after surgical resection, a pulmonary nodule showed on PET scan and was biopsied. The biopsy report was positive for malignancy. An outside expert confirmed the tissue was most consistent with metastatic disease from the primary rectal carcinoma. Also at this time, the patient developed cardiomyopathy with rather severe congestive heart failure and atrial fibrillation.

The patient died approximately 1.5 years following his diagnosis. The lawsuit subsequently filed alleged delay in the diagnosis of rectal cancer by the primary care physician. After months of negotiation, they settled the case for a large amount. The errors which led to this outcome are clear in retrospect.

Abdominal Condition Diagnosis

Acute abdominal pain is one of the most common symptoms bringing patients to the emergency department. Appendicitis can be easily missed if the clinical presentation isn’t classic, as seen in almost half the cases. While overall mortality for appendicitis is low (0.2 deaths per 100,000 cases), delay can lead to perforation and an increased risk of death. When evaluating a patient with abdominal pain, an organized and evidence-based approach should be utilized.

Acute abdominal pain of less than one to two weeks duration accounts for up to 10 percent of admissions to the ED. Of those, 20 to 40 percent are admitted to the hospital for investigation and symptom management. The reason for the acute pain remains undetermined in approximately half of these patients. The spectrum of diseases that present as abdominal pain ranges from life- threatening to benign, and often the diagnosis can’t be established in a single encounter. It may be most prudent to exclude life-threatening etiologies than to make a specific diagnosis.

A focused assessment is critical, related to the characteristics of the pain, (location, quality, severity, onset pattern, radiation and aggravating/relieving factors) presence or absence of associated symptoms that are systemic, and those that are organ-specific (e.g. nausea and vomiting or vaginal bleeding) must be assessed. A general physical examination is essential, as is noting vital signs blood pressure, heart rate, respiratory rate, temperature and O2 saturation. The exam should include inspection, auscultation, percussion and palpation of the abdomen and external genitalia. A speculum and bimanual pelvic examination may be indicated.

There are some myths related to the examination. First, is that rebound tenderness is a good indicator of peritonitis. Second, that all patients with abdominal pain should undergo a digital rectal examination. Third, that administration of opioid analgesics contaminates the examination. Trials consistently demonstrate that giving morphine doesn’t alter the physical exam, and in one study at Brigham and Women’s Hospital in Boston, administration of intravenous morphine actually enhanced diagnostic accuracy. The fourth is that the White Blood Count (WBC) is an excellent indicator for diagnosis of the acute abdomen. Plain abdominal x-rays also have limited use. A clear indication, though, is a suspected bowel obstruction.

Urinalysis is cheap, simple and readily available. Either the dipstick test or routine analysis with microscopy exhibits high yield when results fit with the clinical scenario. A screening urine pregnancy test is recommended for all women of child-bearing potential.

The two features that have the highest positive impact on correct diagnosis are pain in the Right Lower Quadrant
(RLQ) and migration of initial periumbilical pain. In ruling out appendicitis, a few features of the history proved to be useful absence of RLQ pain. Microscopic hematuria and pyuria are present in 20 to 30 percent of patients with appendicitis, but they also occur in many other conditions and asymptomatic individuals.

Contrast-enhanced CT of the abdomen has become the most favored of tests to diagnose most intra-abdominal surgical conditions. It is highly sensitive and specific for detecting appendicitis, diverticulitis, perforation, abdominal aortic aneurysm, abscess formation and mesenteric ischemia.16

Medication Errors

The Institute of Medicine (IOM) issued a press release on July 20, 2006, stating that medication errors account for the largest number of errors within the health delivery system, and annually injure 1.5 million people and treatment of consequences of medication errors costs $3 billion.26 Medication packaging, labeling, prescribing and administration systems are fraught with opportunities for error and breakdown. It has the biggest exposure for error due to multiple ways medications are procured, and the constant changing of the look and feel of various medications as they are created and reincarnated in iterations of generic medications. The mainstream popularity of over-the-counter medications and supplements make the situation even more complex. The report estimates that hospitalized patients incur an average of one medication error per day. It is of interest that with the advent of increasingly universal EMR use, the incidence of medication errors has not been reported as dropping or improving. Luckily, most cause no real harm. Again with the topic of communication, inadequate/untimely communication between physician offices can exacerbate the problem when patient medication regimes are altered or augmented and interactions are not recognized.25, 26, 27

To avoid preventable medication errors, the following should be considered:

• Improve prescription/over-the-counter medication communication with printed hand-outs
• Improve communication between physicians having the PCP as the central repository for medication prescribing information for the patient
• Utilize of the National Library of Medicine as an information repository
• Use IT devices to store prescription and over-the-counter medication data
• Use E-scribing universally in place
• Use of E-Force, a data base from pharmacies throughout Florida, to identify which medications patients are actually filling
• Review medications with the patient at each visit updating the medical record accordingly.26

Overall Strategies to Avoid Medical Error

Unfortunately, medical errors will probably always occur in some measure. However, there are some key strategies that, if instituted, can help avoid such errors. 20, 26, 27, 28, 29, 30, 31, 32

In no particular order:

• Comprehensive review of problem and medication lists with the patient at each visit.
• Effective follow-up systems for managing diagnostic study results and routinely advising the patient of the results, on a timely basis. Patients should be advised when to expect results.
• Documentation of phone conversations with patients during and after office hours, including what the patient reported and what the physician advised.
• Regular, thorough patient assessments (include social and family history) documented for inpatients and outpatients.
• Monitoring of patients for changes in condition with actions taken to address the changes, as needed, and the converse noting when patients have repeated recurrences.
• Documentation of each patient encounter as contemporaneously as possible.
• Documentation that every test ordered or recommended was discussed/explained.
• Documentation of discussions regarding non-compliance with orders and recommendations and the risks of non-compliance.
• Taking an active role in the event a patient’s insurer denies a strongly recommended service, medication, diagnostic study, etc. either by appealing the denial or having them appeal it depending on their health plan requirements.
• Documentation for high-risk cases, that the referral physician is advised of the concerns and reasons for referral.
• Review of the patient’s chart before the exam including diagnostic studies and reports from other physicians and discussing with the patient during the visit.
• Documentation that the preventive health screens recommended by the physician’s professional association and societies are offered to the patient and that the patient is encouraged to undergo them.
• An effective, appropriate hand-off/sign-out system.
• For inpatients, reassessment throughout hospitalization with a thorough examination at discharge.
• Consistent adherence with “Universal Protocols” before the first incision for every procedure.

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Prevention of Medical Errors CME Test – Spring 2015

CME Questions & Answers (circle one answer)/Free to DCMS Members/$55.00 charge non-members*
(Return by March 1, 2017 BY MAIL: 1301 Riverplace Blvd. Suite 1638, Jacksonville, FL 32207 or ONLINE: www.dcmsonline.org.)

1. The physician should take the following actions when a patient is non-compliant with instructions to have diagnostic studies:
   a. Document that every test ordered or recommended was discussed/explained.
   b. Discuss and document the non-compliance with orders and recommendations and the risks of non-compliance.
   c. Dismiss the patient from the practice
   d. Drive the patient to the testing facilities
   e. A&B above

2. Signing of surgical sites is a good way to help avoid wrong side surgery.
   a. True
   b. False

3. All surgical procedures require signing of surgical sites.
   a. True
   b. False

4. Social and family histories should be:
   a. Obtained at initial assessment
   b. Updated at reasonable intervals
   c. Vague to protect the patient from being denied health insurance
   d. All of the above
   e. A & B above

5. If a referral physician orders tests, he/she is the only one responsible for reviewing the results with the patient.
   a. True
   b. False

6. Which of the following actions help avoid medication errors and problems?
   a. Thorough medication reconciliation at admission and discharge from levels of care
   b. Use of E-scribing
   c. Use of e-force to identify potential abuse
   d. Discussion at each office visit of medication
   e. Calling the patient’s pharmacy to identify what is being filled
   f. All of the above
   g. A, C, D above

7. One of the biggest reasons for medical error is poor communication between providers.
   a. True
   b. False

8. The American College of OB/GYN began the campaign for surgical time out and site signing.
   a. True
   b. False

1. What will you do differently as a result of this information? ____________________________________________________________
   ________________________________________________________________________________________________________________
   ________________________________________________________________________________________________________________

2. How will you apply what you learned to your practice? ________________________________________________________________
   ________________________________________________________________________________________________________________
   ________________________________________________________________________________________________________________

Evaluation questions & CME Credit Information
(Please evaluate this article. Circle one number using this scale: 1 = Strongly Agree to 5 = Strongly Disagree)
The articles met the stated objectives: 1 2 3 4 5
The articles were appropriate to my practice: 1 2 3 4 5
The topics were current and well presented: 1 2 3 4 5
Comments: ____________________________________________________________

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Three Advances in Vestibular Assessment

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Abstract: Many forms of dizziness can be managed once the underlying cause is recognized. However, individuals who complain of persisting dizziness, vertigo or imbalance can pose a diagnostic challenge. In these cases, formal vestibular and balance assessment can be enlightening. This article summarizes three advances in the evaluation and management of vestibular disorders: benign paroxysmal positional vertigo (BPPV) assessment and management using the Epley Omniax Chair; vestibular assessment using the video head impulse and vestibular evoked myogenic potential tests; and recognition of chronic subjective dizziness. Cases are presented demonstrating how these advances have broadened the understanding of dizziness and vestibulopathy.

Introduction

Dizziness is a common and sometimes frustrating complaint for the primary care provider. Dizziness can emanate from several metabolic, neurologic, ophthalmologic and otologic conditions. Medication interactions and psychiatric cofactors can further complicate the differential. Many forms of dizziness resolve spontaneously or can be managed once the underlying cause is recognized. However, there exists a subset of individuals who will complain of persisting dizziness, vertigo or imbalance without a clear etiology. In these cases, formal vestibular and balance assessment can be enlightening. This article will highlight three advances in the area of formal vestibular assessment and show how they contribute to the management of the dizzy patient.

By way of review, each membranous labyrinth contains five areas of sensory epithelia responsible for translating head movement into useful neuronal signals (Table 1). There are two otolith organs (utricle and saccule) and three semicircular canals (anterior/superior, horizontal and inferior/posterior). The otolith organs detect head tilts and accelerations which drive vestibular spinal and autonomic reflexes. The semicircular canals detect angular head movements – head turns. In each ear, there are three semicircular canals oriented in orthogonal planes. No matter how the head turns about the cervical spine, the semicircular canals will encode the movement and drive compensatory eye movements via the vestibular ocular reflex (VOR). The otolith organs also contribute to the

Table 1.
Overview of vestibular labyrinthine structures and function.

<table>
<thead>
<tr>
<th>Semicircular Canal</th>
<th>Otolith Organ</th>
<th>Primary Sensory Input</th>
<th>Vestibular Nerve Branch</th>
<th>Primary Reflex Associated with Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superior / Anterior</td>
<td>Angular tilt (forward directed)</td>
<td>Superior</td>
<td>VOR</td>
<td></td>
</tr>
<tr>
<td>Horizontal</td>
<td>Yaw turn</td>
<td>Superior</td>
<td>VOR</td>
<td></td>
</tr>
<tr>
<td>Utricle</td>
<td>Static tilt and horizontal linear acceleration</td>
<td>Superior</td>
<td>VSR / Autonomic</td>
<td></td>
</tr>
<tr>
<td>Posterior / Inferior</td>
<td>Angular tilt (backward directed)</td>
<td>Inferior</td>
<td>VOR</td>
<td></td>
</tr>
<tr>
<td>Saccule</td>
<td>Vertical surge and anterior / posterior tilts</td>
<td>Inferior</td>
<td>VSR / Autonomic</td>
<td></td>
</tr>
</tbody>
</table>
VOR by triggering small corrective torsional movements that compensate for changes in head tilt (ocular counter roll). Thus the otolith mediated VOR aligns the horizontal meridian of the retina with the horizon while the semicircular canal mediated VOR maintains stable vision during head rotations.1

The otolith organs also interact with cerebellar structures to maintain muscle tone in the large anti-gravity muscles in the neck, spine and lower limbs. They also influence autonomic control of digestion and certain cardiovascular reflexes to compensate for changes in gravitational and inertial forces that vary with changes in body posture and movement. Not surprisingly, the cardinal signs of vestibulopathy are vertigo (VOR mediated illusions of rotation or head movement), lightheadedness or heavy-headedness sensations and imbalance (absent or aberrant VSR reflexes,) nausea and other autonomic symptoms.1,2

The visual and proprioceptive systems also contribute to balance and spatial orientation. As a cause of dizziness, the contribution of vision is often overlooked. The human visual system is really two separate systems. Each provides important cues about head and body position in space. With head movement, macular vision can detect changes in the relationships between objects in the environment (visual perspective). The depth of field cues arising from binocular vision can provide additional information about fore/aft sway.

Peri-macular vision is particularly sensitive to movement arising from head movement or movement arising from the environment. When visual motion is detected in a large portion of the visual field, vestibular sensory information helps resolve the source of the movement. If the vestibular system does not detect head movement, something must be occurring “out there” in the environment. If head movement is detected, the brain correlates the two information streams to determine if there is any additional movement in the external environment. This necessitates a careful registration between vestibular and peri-macular “visual flow” sensory information.

The sensory inputs from all three systems are both synergistic and redundant. “Synergistic” meaning that some information from each sense is unique and is interpreted optimally with context from the other systems; “Redundant” means that some information provided by any particular sense is also available from the other senses. Synergism and redundancy underpins resiliency in spatial orientation and balance abilities. Redundancy is also important for maintaining the registration of converging sensory information—particularly when there are changes in the fidelity of any one sense. When registration is faulty, dizziness and imbalance can occur. Anyone who has had to adjust to prescriptive eye glasses for the first time has experienced this form of dizziness. With redundancy, the brain can adapt to lawful changes in visual flow by correlating the visual flow with vestibular information. When adjusting to new eye glasses, central adaptation is complete over the course of a few days and dizziness resolves.

With age or disease, sensory fidelity may deteriorate. If two or more senses are impaired, even to a seemingly trivial extent, loss of registration can be a serious disruption in the person’s ability to stand, walk or otherwise remain spatially oriented.

### BPPV and the Epley Omniax Chair

**Case #1:** An 84-year-old diabetic male with peripheral neuropathy and periventricular shunt was referred by neurosurgery for persistent dizziness and fall history. His fall history began four months earlier with an inadvertent stumble and blow to the head. Prior to his fall, he ambulated with a cane. Following the fall, he was wheelchair bound. After an extensive work-up (including continuing control of intracranial pressure), no clear cause of his inability to walk could be found. He was subsequently referred for vestibular evaluation.

On presentation, he was a tall gentleman complaining of chronic lightheadedness and disequilibrium. His audiological evaluation demonstrated a bilateral symmetrical mild sensorineural hearing loss. His vestibular assessment demonstrated mild bilateral vestibular weakness. These were in keeping with his stated age. There was no evidence of acute or focal vestibulopathy.

This gentleman had significant neck kyphosis. As a result, standard Dix-Hallpike maneuvers were difficult to perform. He did not complain of vertigo so this could have been easily overlooked. He did undergo evaluation for positional dizziness using an Epley Omniax Chair. The Epley Omniax Chair is a motorized device that can tilt patients into positions that can provoke BPPV symptoms emanating from any semicircular canal. Because the patient is immobilized in the chair with full body support, the head can be moved into any attitude without flexing or extending the neck. On this evaluation, he was found to have bilateral posterior canal canalithiasis.

This patient subsequently underwent treatments for bilateral posterior canal BPPV using the Epley Omniax Chair. After four treatments he was no longer dizzy and returned to using a cane to ambulate. Over time, his appetite improved and he gained leg strength. Three years later, he has had recurrences of BPPV about every six to eight months. When he is clear, he is able to safely walk with a cane.
Comment: Benign paroxysmal positional vertigo (BPPV) is by far the most common cause of vertigo in adults. The vertigo is typically transient and provoked when moving into a specific provocative position. Diagnosis can usually be made using the Dix–Hallpike maneuver. Symptoms can be relieved in the office or at home using a simple Epley Maneuver (Figure 1). For the majority of cases, BPPV occurs spontaneously and in the absence of any other vestibular disease. However, the risk of developing BPPV increases in the wake of other vestibular disease or head trauma.

In this case, bilateral post traumatic canalithiasis went undetected - likely because the patient did not move into positions that provoked full vertiginous sensations. In isolation, BPPV would not typically affect a person’s ability to stand. The combination of unstable vestibular input in the setting of prior peripheral neuropathy was the final "straw" that took away this person’s ability to walk.

The Epley Omniax chair is perhaps a luxury. However, it has an important role to play in the detection and management of complex forms of BPPV. It has a particularly useful role in the treatment of post traumatic BPPV, which is commonly bilateral. Standard Epley reposition maneuvers will clear unilateral BPPV. But if applied to the wrong side, the maneuver can actually make BPPV worse. In bilateral BPPV, there is always a "wrong side." With the Epley Omniax Chair, head positions can be selected that treat both ears at the same time – using full body 360 degree backward rotations. In our experience, this capability cuts treatment time in half.

Points:

• Consider a BPPV cofactor when vertigo, dizziness or imbalance persists.

• The Epley Omniax Chair is particularly helpful in the management of patients with positional vertigo that is unresponsive to standard Epley Maneuvers, patients with limited neck range of motion, or patients with bilateral BPPV.

Video Head Impulse Tests (vHIT) and Vestibular Evoked Myogenic Potentials (VEMPs)

Traditional vestibular evaluation (video- or electro-nystagmography; VNG or ENG respectively) has been used in the vestibular laboratory for more than 50 years. The test only measures horizontal semicircular canal function and subsequently misses many forms of vestibulopathy. Two new tests have emerged that overcome these limitations: the vestibular evoked myogenic potential (VEMP) and video Head Impulse Tests (vHIT).

VEMPs reflect small changes in muscle tone that result from stimulation of the otolith organs. They are recorded using the same signal averaging methods and equipment as employed in other types of sensory evoked potential testing. Instead of recording neural field potentials, they capture changes in surface EMG potentials over specific muscles. With an appropriate acoustic stimulus, the otolith organs are transiently stimulated and evoke a corresponding transient changes in muscle tone. VEMPs recorded from the sterno-cleidomastoid muscle (cVEMPs) largely reflect activation of the saccule, inferior vestibular nerve and portions of the descending vestibule-spinal pathways. Ocular responses (oVEMPs), recorded from the inferior oblique and inferior rectus muscles at the inferior portion of the orbit, reflect activation of the utricle, superior vestibular nerve and parts of the ascending vestibular ocular pathways.
The vHIT uses high speed infrared recordings of eye position to measure VOR driven eye movements in response to short, rapid head accelerations. These head impulses can be made in the planes of each SSC to estimate canal specific VOR responses. The vHIT can show two types of abnormalities: weak VOR responses (decreased VOR gain) or near normal eye movements accomplished by centrally driven corrective saccades. The latter reflects brainstem/cerebellar generated compensatory behaviors.

The value of vHIT and VEMP tests can be understood in relationship to the innervation patterns the membranous labyrinth. The three major branches of CN VIII innervate only a few of the sensory structures in the membranous labyrinth (Figure 2). By recognizing patterns of test results, specific nerve syndromes can be appreciated. These relationships are shown in Table 2. When single nerve branches are involved, recovery potential is high. When multiple branches are involved, however, recovery will be sub-optimal, and the risk of retro-labyrinthine disease increases.

A superior vestibular nerve syndrome is the most commonly encountered cause of acute vertigo in the clinic, after

<table>
<thead>
<tr>
<th>Test</th>
<th>Structure Assessed</th>
<th>Superior Nerve Syndrome</th>
<th>Inferior Nerve Syndrome</th>
<th>Superior/Inferior Syndrome</th>
<th>Global Syndrome (all branches involved)</th>
</tr>
</thead>
<tbody>
<tr>
<td>vHIT</td>
<td>Superior / Anterior SSC</td>
<td>Abnormal</td>
<td>Normal</td>
<td>Abnormal</td>
<td>Abnormal</td>
</tr>
<tr>
<td>vHIT</td>
<td>Horizontal SSC</td>
<td>Abnormal</td>
<td>Normal</td>
<td>Abnormal</td>
<td>Abnormal</td>
</tr>
<tr>
<td>oVEMP</td>
<td>Utricle Otolith</td>
<td>Abnormal</td>
<td>Normal</td>
<td>Abnormal</td>
<td>Abnormal</td>
</tr>
<tr>
<td>vHIT</td>
<td>Posterior / Inferior SSC</td>
<td>Normal</td>
<td>Abnormal</td>
<td>Abnormal</td>
<td>Abnormal</td>
</tr>
<tr>
<td>cVEMP</td>
<td>Saccule Otolith</td>
<td>Normal</td>
<td>Abnormal</td>
<td>Abnormal</td>
<td>Abnormal</td>
</tr>
<tr>
<td>Audiogram</td>
<td>Cochlea</td>
<td>Normal or Symmetric Hearing Loss</td>
<td>Normal or Symmetric Hearing Loss</td>
<td>Normal or Symmetric Hearing Loss</td>
<td>Hearing Loss Greater in the Involved Ear</td>
</tr>
</tbody>
</table>

Table 2.

vHIT, VEMP and audiogram test result patterns for various vestibular nerve syndromes.

Figure 2.
Cranial Nerve VIII Innervation Pattern.
(Figure Copyright 2014, Mayo Clinic Foundation for Medical Education and Research.)

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BPPV. Most of these cases will be recognized as vestibular neuronitis. For anatomical reasons, the superior vestibular nerve is thought to be more vulnerable to neuronitis.\textsuperscript{13} Patients with this syndrome may complain bitterly of vertigo. But, the prognosis for recovery is favorable. Symptoms will last a shorter duration and fall risk is lower than when more nerve branches are involved (Table 2). Additionally, the risk for retro-labyrinthine tumor (vestibular schwannoma, meningioma) is relatively low.\textsuperscript{1}

**Points:**
- vHIT and VEMP tests improve recognition of vestibular syndromes and help predict recovery.

### Chronic dizziness

Why is the passenger in a car driving down a winding road more likely to become motion sick than the driver? Both are exposed to the same visual, vestibular and proprioceptive inputs. The difference is that the driver is controlling the car and can anticipate postural adjustments. In contrast, the passenger has an imprecise idea of the car's path and speed. They must await the arrival of several streams of sensory information and then react (organize the sensorium to estimate how the car is or will be moving, develop and execute a motor plan and monitor to determine if it was accurate). The reactive process is more complex, time intensive and error prone than the drivers’ task. Moreover, with uncertainty and fear (is the car going to drive off a cliff?), there is a tendency to over-rely on visual sensory information. Visual information takes longer to process and is prone to ambiguities. Over-reliance on vision can result in motion sickness.

**Case #2:** An anxious 60-year-old woman presents with chronic debilitating dizziness, spinning vertigo and fear of falling. Her symptoms developed three years prior with a severe disabling vertigo that lasted several days. The vertigo gradually diminished, but never fully left her. She is constantly dizzy, and feels better with her eyes closed. Head movements and complex visual scenes are particularly troubling. She has been to several specialists with only marginal relief. She has been treated for BPPV several times over the past three years. These treatments initially helped, but symptoms continued. She has also undergone several rounds of vestibular rehabilitation by competent physical therapists without relief.

Her audiological evaluation demonstrated normal hearing; vestibular evaluation demonstrated a right superior vestibular nerve deficit with signs of strong central compensation. There was no BPPV noted. However, she resisted laying on her right side for fear of re-provoking severe vertigo. Her neurootologic evaluation was otherwise normal. She was diagnosed with prior vestibular neuronitis, quiet benign paroxysmal positional vertigo and chronic subjective dizziness. Management involved three sequential goals:

1. Stabilize the unstable ear – monitor for and aggressively treat BPPV.
2. Mitigate fear: Make any persistent dizziness sensations from chronic vestibulopathy predictable; Ensure the patient understands that there is a benign reason for her chronic symptoms; Include cognitive behavioral therapy as a component of vestibular rehabilitation to address dizziness induced anxiety.
3. Consider referral to psychiatry should symptoms persist despite optimal management.

**Comments:** It is likely that this patient experienced frequent recurrences of BPPV. BPPV frequently develops following a superior vestibular nerve based syndrome. When present, vestibular output is unstable and vestibular sensory information cannot be reliably re-registered with the other senses. This often induces a visual over-reliance. Even when BPPV has resolved, the brain may choose visual over-reliance to register body sway. Such over-reliance will result in an ambiguous sensorium, and may lead to a self-reinforcing perception of chronic dizziness, fear of falling, catastrophic thinking and heightened anxiety.\textsuperscript{14,15} When this becomes habitual, the syndrome of chronic subjective dizziness (CSD) has developed and may persist despite the resolution of any vestibular deficit.\textsuperscript{16,17} CSD can sometimes be addressed through cognitive behavioral therapy and vestibular rehabilitation that focuses on learning to move into provocative positions or movements.\textsuperscript{18,19} However in some cases, psychotropic medications may be needed. In this case, the stratified approach of stabilizing vestibular output, demonstrating vestibular compensation and addressing fear reactions through cognitive behavioral therapy seemed to be rational first steps in managing CSD. Ultimately, this patient was referred to a psychiatrist specializing in chronic subjective dizziness, and her symptoms did improve with the addition of a Selective serotonin reuptake inhibitor (SSRI) to her management plan.

**Points:**
- Before making the diagnosis of CSD, careful evaluation to exclude unstable vestibular conditions such as BPPV, perilymph fistula or superior canal dehiscence is necessary.
- A cause for dizziness may not be the cause. In this case, treating BPPV or the residual vestibular weakness did not resolve dizziness complaints. Psycho-physiologic interactions are real and need to be addressed to optimize outcomes.
Conclusion

There have been several advances in the ability to recognize and treat dizziness and imbalance. Additionally, there have been improvements in the ability to recognize and treat the many forms of BPPV, better able to assess all of the sensory structures within the vestibular labyrinth, and gain a greater understanding about how psycho-physiologic interactions can induce chronic, seemingly unexplainable dizziness. The emerging picture is that in cases of chronic dizziness, a multi-disciplinary and holistic management approach will likely lead to optimal outcomes.

References


Update on the Management of Head and Neck Cancer

By John D. Casler, MD, FACS

Abstract: The past decade has seen remarkable progress in the evaluation and treatment of cancers affecting the head and neck region. The discovery of the association of the Human Papilloma Virus (HPV) with some head and neck cancers has changed the demographics of the disease, and our approach to it. Innovations have occurred across a broad multi-disciplinary front. New diagnostic methods have emerged that take advantage of recent discoveries in tumor genetic markers. Significant advances in have also taken place in the fields of surgery, radiation oncology, and medical oncology and are described.

Introduction

Cancer of the head and neck is not a single disease, but rather a heterogeneous group of cancers that affect various anatomic sub-sites, producing a different form of disability depending on the region involved. These sub-sites include salivary glands, nasal cavity and paranasal sinuses, lip, oral cavity, oropharynx, larynx and hypopharynx, thyroid, skin, ear and temporal bone. Fortunately, these cancers are relatively rare, representing approximately 3.2 percent of all cancers. The economic impact of head and neck cancer is significant at $3.6 billion annually. According to the National Cancer Institute (NCI), the incidence of head and neck cancer has decreased over the past several decades, but the decline levelled off in 2003; despite this, overall mortality rate has continued to decline. The NCI estimates that there were 55,070 new cases of head and neck cancer in 2013, and there were an estimated 12,000 head and neck cancer deaths.

Men have a higher incidence of head and neck cancer than women. Tobacco and alcohol consumption play an important etiologic role, particularly in cancer of the larynx and hypopharynx. Human Papilloma Virus (HPV) has been associated with an increase in incidence of cancers located in the tonsil and base of tongue. While HPV associated tumors have only relatively recently been described, viral associated head and neck cancer is not a new discovery. Nasopharyngeal carcinoma has long been associated with the Epstein-Barr Virus. Other risk factors include betel nut chewing, periodontal disease and chronic trauma for oral carcinoma, and radiation exposure for thyroid cancer and sarcomas of the head and neck. Other head and neck cancers (e.g., sinonasal carcinomas) have been traced to occupational exposure including chromium, wood dust and various solvents. Fire breathing has been linked to high rates of oral carcinoma.

For decades, the standard treatment for head and neck cancer was surgery, often associated with a range of cosmetic and functional deficits. This frequently required complex reconstruction of the surgical defect using local, regional or microvascular free tissue flaps. Radiation therapy came into play as an adjuvant treatment in advanced stage tumors (III or IV) in the 1970s and 1980s. In the 1990s, chemotherapy was combined with radiation therapy and emerged as first line therapy for a number of tumor sites with survival rates equivalent to surgery, but offering the possibility of organ preservation. Severe toxicities, including xerostomia, mucositis, dysphagia, and even death were seen with some of these treatment protocols, fueling the search for approaches that maximized cure rates while minimizing treatment side-effects. This article discusses some of the more significant discoveries of the past decade.

HPV

First reports of the association of the Human Papilloma Virus (HPV) and oropharyngeal carcinoma began to surface in 1983. HPV-related tumors appeared to be a different sort of cancer than that typically associated with heavy tobacco and alcohol usage. Subtyping of the HPV virus revealed that p16 and p18 were the most commonly associated subtypes of the virus, with rates of 90 percent and five percent respectively. Additionally, Patients with HPV-associated tumors had improved survival, and HPV-associated tumors appeared (at least in vitro) to be more sensitive to radiation.
In 2008, Dr. Carol Fakhry and her group from The Johns Hopkins University published the results of a prospective evaluation of therapeutic response and survival among 96 patients with stage III or IV head and neck squamous cell carcinoma involving the oropharynx and larynx. Patients received two cycles of induction chemotherapy with paclitaxel and carboplatin followed by concomitant weekly paclitaxel and standard radiation therapy. Tumors were analyzed for the presence or absence of HPV. Two year overall and progression-free survival was estimated for HPV-positive (HPV+) and HPV-negative (HPV-) patients. HPV+ patients had statistically significantly higher response rates to induction chemotherapy and to concomitant therapy (P = 0.01). They also had statistically significantly better two-year survival (95 percent vs. 62 percent, P = 0.005). Hong et al7 showed that HPV+ tumors responded to all forms of treatment better than HPV- tumors. One hundred ninety five patients with stage III and IV oropharyngeal squamous cell carcinoma were included in this retrospective study. HPV status was determined for all patients. Forty two percent were HPV+. Patients were further divided into treatment groups. Fourteen received surgery alone, while 110 received surgery with post-operative radiation therapy. Twenty four were treated with radiation therapy alone, and 47 were treated with radiation therapy and chemotherapy. Loco-regional recurrence rates and overall survival were analyzed. The surgery alone group was too small to analyze for HPV effect. The other groups all showed improved survival for HPV+ patients regardless of treatment form.

Improved survival of HPV+ patients has led to proposals that these tumors could be treated “less aggressively.” It was speculated that HPV+ tumors might require less post-op radiation therapy and that chemotherapy could be avoided in some patients, even in the presence of extra-capsular nodal extension. Such notions have yet to be proven and are the subject of prospective trials.8

Also of note is the suggestion that if these tumors are HPV-related, vaccination against HPV might prevent the development of cancers in “at risk” individuals. This led to recommendations that both males and female be vaccinated with the quadrivalent vaccine, Gardisil®. Gardisil® protects against the p16 and p18 subtypes associated with cervical and oropharyngeal carcinoma, as well as p6 and p11 subtype associated with respiratory papillomas in both children and adults.

Minimally Invasive Surgery

Otolaryngologists have used trans-oral surgical techniques since the 1920s to eradicate lesions of the aerodigestive tract. Recently, investigators have expanded use of these techniques to include treatment of oral cavity, oropharyngeal and hypopharyngeal tumors. Instrumentation was augmented, and lasers were adapted for use in these trans-oral tumor extractions. Known as “Trans-oral Laser Microsection” or “TLM,” this technique was developed in Europe and brought to the U.S. in the 1990s.9 Oncologic results have been excellent.

In 2011, Dr. Bruce Haughey from the University of Washington School of Medicine in St. Louis published a study involving 204 patients with stage III and IV cancer involving the tonsil and the base of tongue treated with TLM. The study was conducted across three sites, and included patients treated between 1996 and 2006. Three year overall survival was 86 percent. Disease specific survival was 88 percent. Disease free survival was 82 percent. Local control of tumor was achieved in 97 percent. Eighty seven percent of patients had normal swallowing at the end of the study.11 Advantages of TLM include:

• no need for tracheotomy in most cases
• elimination of the need for elaborate flap reconstruction
• decreased hospital stay
• rapid return to normal swallowing function

The key to the success of this technique is proper patient selection.

The DaVinci Surgical Robot has also been applied to the treatment of selected head and neck cancers. In 2005, Dr. Gregory Weinstein of the University of Pennsylvania, introduced the use of the DaVinci robot for treatment of head and neck tumors by reporting on a supraglottic laryngectomy successfully performed in a canine model.12 The use of angled telescopes, highly flexible articulated arms, and the adaptability to flexible laser fiber technology has allowed head and neck surgeons safe access to previously difficult to reach tumors. Initial robotic experience in humans was confined to small tumors, usually in the tonsil. Subsequently, robotic techniques have been expanded allowing surgeons to successfully operate on tumors in the base of tongue, oropharynx and the larynx. Published reports have validated the technique, known as TORS (TransOral Robotic Surgery), citing decreased length of stay, less pain, faster return of swallowing function and excellent oncologic results.13

Both TLM and TORS have given head and neck surgeons new tools and techniques to provide options for selected patients that result in excellent tumor control while minimizing toxicity and long-term morbidity of treatment.
Endoscopic surgical techniques have been adapted to the treatment of many endonasal, sinus and skull base tumors – both benign and malignant. These techniques are often combined with image-guided navigational systems that synchronize the surgical instruments with pre-operative images – CT, MRI or both. This provides pinpoint surgical accuracy. Studies have shown decreased rates of complications (CSF leakage, etc.), decreased pain, decreased hospital stays, and more complete tumor resection. Patient and tumor selection is critical. These surgical cases are usually performed by a team of skull base surgeons comprising both otolaryngologists and neurosurgeons.

Proton Beam Radiation

In 1946, Dr. Robert Wilson proposed using protons for cancer treatment. The first patient was treated at UC Berkeley eight years later. Loma Linda University Medical Center opened the first hospital based proton center in 1990. In 2008, there were five proton facilities in the U.S. There are now ten centers, with seven more planned at a cost of $150 million to $200 million apiece. Proton beam radiation has a theoretical advantage over other radiation techniques in that peak doses of radiation can be delivered to a pre-programmed tissue depth, without having the full dose of radiation pass through all tissues in the path of the beam. This is called the Bragg Peak. This property of protons theoretically allows proton beam radiation to be delivered in a very precise manner, sparing adjacent tissues. This has advantages in treating tumors in close proximity to brain, nerve and orbital structures.

There have been numerous reports describing the use of proton beam radiation therapy for head and neck tumors. In a recent review, Holliday and Frank examined 18 articles describing proton beam treatment for a total of 1,074 patients with head and neck tumors. Studies showed that it was possible to deliver high doses of radiation to these tumors, resulting in good local control rates and overall survival; neurotoxicities did occur, however. Proton beam radiation was used successfully for retreatment of recurrent chordomas in one series, with a local control rate of 85 percent and overall survival of 80 percent at two years.

Several studies looked at proton beam radiation for nasal cavity and paranasal sinus tumors. Local control rates ranged from 86 percent to 93 percent at two years. Earlier stage tumors did better. Some reports combined surgery or photon external beam radiation therapy with proton beam radiation. Toxicities were occasionally significant. In one study of 39 patients from Japan, one patient died from cerebrospinal fluid (CSF) leakage, and four other patients suffered grade 3 and 4 toxicities including cataracts, visual impairment, cranial nerve palsy and osteonecrosis.

Currently, standard treatment protocols for nasopharyngeal carcinoma call for radiation therapy alone or concurrent treatment with chemotherapy and IMRT. At the Massachusetts General Hospital, a phase 2 trial is underway using proton beam radiation with concurrent cisplatin and fluorouracil to treat stage III and IVB nasopharyngeal carcinoma. The local control rate at 28 months was 100 percent. Two year disease free survival was 90 percent, and overall survival was 100 percent. Toxicities were acceptable.

Proton beam radiation has been proposed for treatment of oropharyngeal carcinoma with hopes of reducing xerostomia and dysphagia. Loma Linda University Medical Center reported on a series of patients with stage II to IV oropharyngeal carcinoma treated with a combination of photon and proton beam radiation to a total dose of 75.9Gy. Local-regional control was 84 percent at five years. The incidence of grade 3 toxicity was 16 percent, compared to 26.8 percent to 37.2 percent in series with conventional radiation.

Proton beam radiation is significantly more expensive than conventional forms of radiation therapy, such as Intensity Modulated Radiation Therapy (IMRT). To date, randomized clinical trials have not been completed which directly compare IMRT and proton beam radiation in terms of survival benefit and rates and severity of toxicities. Until such studies are conducted and the superiority of proton beam radiation is proven, it will not be considered standard of care for most head and neck cancers. One exception to this might be its use in treatment of skull base tumors.

Thyroid Cancer

Thyroid cancer is increasing in prevalence in this country. It is estimated that in 2014, there will be 62,980 new adult cases of thyroid cancer. It is also estimated there will be 1,890 thyroid cancer deaths in 2014. There has been a 2.6 fold increase in thyroid cancer between 1973 and 2006. It is not clear whether this increase is due to a true increase in the incidence of the disease or whether it is due to an increase in diagnosis through better screening techniques. While the incidence has increased, the death rate has remained steady. Additionally, the cure rate is quite high. Overall, the five year survival for thyroid cancer is 97.8 percent. A notable exception to this is anaplastic thyroid carcinoma, which, unfortunately, still carries a very poor prognosis.
Surgery remains the mainstay of treatment for most thyroid cancers. Recently, the use of intraoperative nerve monitoring of the recurrent laryngeal nerve (RLN) has become increasingly widespread in this country. Unfortunately, a meta-analysis of nearly 65,000 nerves at risk failed to show any significant change in rates of permanent nerve injury.25 Studies have shown a decreased rate of complications (RLN injury and hypoparathyroidism), decreased length of stay, and decreased total costs when surgery is performed by high-volume thyroid surgeons (100 or more cases per year) compared to low-volume surgeons (less than 10 cases per year).26

Several newer remote access surgical techniques have been developed for thyroid surgery. These include transaxillary, transoral, transmammary and robotic surgery via a facelift approach. These approaches are most frequently utilized for treatment of benign disease and are intended to avoid a cervical incision with its resultant scar. These approaches require careful patient selection.27

Research has led to a greater understanding of the signaling pathways that lead to malignant transformation in thyroid cancers. Mutations have been identified at several points. These include BRAF, NRAS, HRAS, KRAS and other mutations. Recently, molecular or genetic testing of some thyroid nodules (follicular or indeterminate) has allowed clinicians to identify patients who are at increased risk for malignancy. There are several commercial laboratories that offer this testing. Veracyte (based in California) offers Afirma® testing which analyzes 142 genes to reclassify indeterminate Fine Need Aspiration (FNA) samples as “benign” or “suspicious.” Veracyte quotes a 95 percent negative predictive value (NPV) for its Afirma® testing.28 Another company, Asuragen, uses its miRInform® Thyroid test, which analyzes FNA samples for the presence of seventeen molecular markers to help in the analysis of indeterminate thyroid nodules. The need for surgery may be eliminated in some patients with indeterminate nodules whose molecular testing characterizes the lesions as benign.

New Medical Treatments

In 2006, the FDA approved the use of Erbitux (cetuximab) for use in non-metastatic head and neck squamous cell carcinoma in combination with radiation or as a single agent. Erbitux is a chimeric monoclonal IgG antibody with affinity for the epidermal growth factor receptor, which is expressed in the majority of head and neck squamous cell carcinomas. Erbitux functions as an EGFR antagonist. A Phase III trial demonstrated significantly improved locoregional control when cetuximab was combined with radiation therapy compared to radiation alone. The addition of Erbitux to standard radiation therapy led to a 26 percent decrease in the risk of death and improved median survival time of 49.0 months, compared to 29.3 months with radiation alone.29 In a subsequent publication, Bonner demonstrated a 5-year survival rate of 45.6 percent for patients treated with Erbitux plus radiation therapy, compared to a 36.4 percent rate for radiation therapy alone.30 In 2011, the FDA expanded its approval for the use of Erbitux to include metastatic disease.

In April 2011, the FDA approved Caprelsa (vandetanib), a tyrosine kinase inhibitor, for use in patients with advanced medullary thyroid carcinoma (MTC) who are ineligible for surgery and have progressive disease with symptoms. Approval was based on a study by Wells et al, which showed that patients receiving the drug lived an average of 11.2 months without tumor growth as compared with four months in the control group receiving placebo. There was a reduction in tumor size experienced by 27 percent of the study group. The effect lasted 15 months on average.31 A second drug, Cometriq (cabozantinib), was approved for similar indications in November 2012.

In November 2013, the FDA approved Nexavar (sorafenib) for use in the treatment of progressive differentiated thyroid carcinoma (papillary and follicular) that cannot be treated with radioactive iodine (I-131). This medication is known as a dual inhibitor. First, it targets the signaling pathway that leads to malignancy transformation (targeting RAF, MEK, ERK). Secondly, it inhibits angioneogenesis (required for tumor growth) by interfering with the vascular endothelial growth factor (VEGF) and the platelet-derived growth factor (PDGR) receptors in tumor vascular tissue.32

The search continues for effective treatments for the most aggressive form of thyroid cancer – anaplastic thyroid carcinoma.33

Summary

The past decade has seen numerous changes in the management of head and neck cancer. Innovative diagnostic techniques, less invasive surgical procedures and improved medical therapies offer renewed hope in the fight against this devastating set of diseases. Better functional outcomes and improved survival rates have benefitted the lives of thousands of patients. We look forward to even more advances in both treatment and prevention in the decades to come. ☺
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A Personal Approach To Your Financial Independence

Life can get complicated. But there’s no need to make it more complicated than it has to be. At Petros Estate & Retirement Planning, we’re here to help you shoulder the burden of your financial life, to and throughout retirement... and beyond, to leave you free to spend more time with your family.

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Abstract: The field of rhinology, involving the medical and surgical treatment of nasal and sinus disorders, has seen considerable innovation over the past decade. Recent surgical advances include balloon-assisted sinus surgery, a less-invasive alternative to conventional surgery. While undeniable the help of balloon-assisted surgery still has a limited scope of applicability. Stereotactic image guidance offers improved delineation of surgical anatomy and may reduce surgical risk; such image guidance has also expanded the area of transnasal skull base surgery and intracranial surgery. Biocompatible, resorbable intranasal dressings have improved patient comfort after surgery. Medically, alternatives to oral or IV antibiotics have been developed in the form of compounded topical antibiotics applied intranasally. Antibiotics continue to be prescribed in accordance with clinical guidelines and, when appropriate, endoscopically-guided sinonasal culture results. For epistaxis, particularly given the variety of new anticoagulants on the market, new topical hemostatic medications are fortunately available. For refractory epistaxis, newer options for treatment include endoscopic sphenopalatine artery ligation and transarterial embolization.

The diverse field of Otolaryngology (ENT) creates a wide variety of opportunities for innovation and change. Within the ENT field, one area that exemplifies this particularly well is Rhinology. Rhinology involves the medical and surgical treatment of nasal and sinus disorders.

Balloon-Assisted Sinus Surgery

One of the more innovative developments in sinonasal surgery in recent years has been the advent of balloon-assisted sinus surgery. Contrary to opinions which persist among some members of the public, modern endoscopic sinus surgery has shifted far away from the “sinus stripping” procedures of the pre-endoscopic era. Instead, modern sinus surgery has taken the approach of attempting to respect natural sinus physiology by facilitating natural sinus drainage and ventilation patterns. Balloon-assisted surgery takes this a step further by permanently dilating natural sinus ostia while preserving as much natural mucosa as possible.

Types

There are several types of balloon-assisted sinus surgical equipment on the market. The original and most commonly-used technology involves a Seldinger-type placement of a dilating balloon into a sinus aperture over a guide wire. Biocompatible, resorbable intranasal dressings have improved patient comfort after surgery. Medically, alternatives to oral or IV antibiotics have been developed in the form of compounded topical antibiotics applied intranasally. Antibiotics continue to be prescribed in accordance with clinical guidelines and, when appropriate, endoscopically-guided sinonasal culture results. For epistaxis, particularly given the variety of new anticoagulants on the market, new topical hemostatic medications are fortunately available. For refractory epistaxis, newer options for treatment include endoscopic sphenopalatine artery ligation and transarterial embolization.

Figure 1.
Modern video-assisted endoscopic sinus surgery. Video screen shows placement of balloon catheter guide between septum and turbinates.
Another risk with any new and promising therapy is over-utilization. We are all familiar with the adage, “when all you have is a hammer, everything looks like a nail.” Because of its advantages, balloon sinus procedures have been used in acute sinusitis, headaches and other situations where its efficacy may be unproven or even dubious. These authors have been performing balloon sinus surgery for years but would still recommend a measure of restraint when recommending this as an office or solo procedure.

Finally, balloon-assisted techniques are not effective in treating nasal obstruction due to deviated septum or enlarged turbinates. Since nasal obstruction is a common presenting complaint in patients with chronic sinonasal infection, an exclusively balloon-based technique (whether in office or operating room) may not address all of the patient’s complaints. Simply put, balloon-assisted sinus surgery is not a panacea and is unlikely to eliminate the need for additional, more established endoscopic sinus techniques in the surgeon’s armamentarium.

**Stereotactic Sinus Surgery**

Another technique which has gained popularity and wide acceptance is stereotactic or “image guided” sinus surgery. Using special equipment in the operating room, thin-slice axial CT scans are compiled into a three-dimensional model which can be used to locate the position of instruments within the head, much like a “GPS for the sinuses.”

**Pros and Cons**

The potential advantages of balloon sinus surgery are significant and attractive, in that the technique offers potentially less scarring, bleeding, and postoperative pain than more aggressive and traditional techniques. Balloon sinus dilation can also be performed in an office or clinic setting, often eliminating the need for general anesthesia.

As with many new surgical techniques there are potential drawbacks, as well. The most obvious is that balloon-assisted sinus surgery may not be appropriate or applicable in all cases. Balloon-assisted surgery works most effectively when there is a single bony ostium or outflow tract, such as with the frontal or sphenoid sinus. The ethmoid sinuses, on the other hand, are a group of small sinuses without a single outflow channel; to date, there has not been a widely-accepted balloon solution to chronic ethmoid disease.

Although data exists to support its use in the maxillary sinus, there has been mixed success at eliminating chronic maxillary disease with balloon dilation alone.

**Seldinger-type balloon dilation of sphenoid sinus (lateral view) under fluoroscopy. Note soft-tip guidewire in sphenoid sinus. Radiopaque marks along wire indicate anterior and posterior margins of balloon to be inflated.**

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**Pro and Cons**

The disadvantages to the image guidance system (IGS) primarily involve cost and availability. IGS equipment requires the use of disposable cables and guides which add cost to a patient’s surgical bill and may be superfluous in cases of mild or limited sinusitis. Image guidance also requires specially-formatted CT scans: if original sinus CTs are not done with IGS in mind, scanning may need to be repeated to create compatible images. Finally, due to its cost, IGS may not be available in smaller hospitals or surgery centers.

Another potential disadvantage is the radiation exposure from CT scans, currently the only imaging modality for which stereotactic guidance is widely available. Concern over
cancer risks associated with ionizing radiation has increased in recent years due to the rising incidence of children’s cancer. CT scans should be adjusted for the weight and size of the patient to allow the lowest radiation dose possible. Although today’s CT scanners allow high-resolution images at smaller radiation doses, the use of these studies should be weighed against their potential benefit. It is axiomatic that imaging studies, particularly CT scans, should be done only when they may influence the physician’s clinical decision.\(^6\)

**Biocompatible Dressings**

A third major development in sinonasal operative technology is the appearance of biocompatible dressings. These have been developed in the form of powders, sprays, gels and sponges, but they share the common characteristic of being largely resorbable. For many surgeons, this has eliminated the need to place traditional packing materials in the nose postoperatively. Because most of these materials are also hemostatic, this change in technique has occurred without an increased risk in bleeding. In fact, these authors have observed less bleeding, since it is no longer necessary to disturb the nasal passages 24 to 48 hours after surgery with solid packing removal. This also increases patient comfort after surgery, and considerably reduces patient anxiety about packing removal.\(^7,8\)

Resorbable packing material follows the trend of splintless nasal septum surgery. Although some surgeons continue to use internal nasal splints after septoplasty with good results, the community trend for some years has moved away from these. Instead, resorbable intranasal sutures are used which fall out on their own after one or two weeks. This, too, reduces patient anxiety and improves patient comfort after surgery.\(^9\)

**ENT Challenges**

Not all the recent changes within Otolaryngology have been positive. Economic recession and the changing realities of the third-party payor system have challenged medical progress across all specialties. Within ENT, the wide selection of prescription medications available in the 1990s—including nasal steroids, antihistamines, and antibiotics—has been narrowed by the imposition of formulary restrictions. Although the change to generic prescribing has resulted in cost savings for many patients, choice and efficacy have suffered. When considered alongside the paucity of new antibiotics on the market, conventional pharmacotherapy is inarguably more limited than it was 10 to 15 years ago.

This change has required adaptation in the way sinonasal disease is treated medically. With respect to antibiotic treatment, bacterial identification and determination of antibiotic susceptibilities can improve the effectiveness of therapy. Endoscopically-acquired sinus cultures have been proven as a highly sensitive and accurate method of acquiring this information. Beyond conventional sinus cultures, polymerase chain reaction (PCR) assay has become increasingly available as a send-out test for qualitative determination of specific bacterial infection.

Another treatment modality to adapt despite these restrictions is compounded topical therapy. Topical antibiotic therapy has evolved from a fringe treatment to a mainstay of sinonasal care, particularly for post-surgical patients. Compounded topical therapy allows the administration of stronger antibiotics, such as vancomycin or amikacin, directly to the nasal mucosa without the need for IV therapy. Newer, portable nebulizing devices have been developed such as Sinus Dynamics’ NasaT ouch device, a lightweight and handheld device which holds 15 mL of solution and atomizes 2 mL (1 treatment) in just 30 seconds.\(^10\) Such devices allow for quick administration of powerful antibiotics previously available only for parenteral administration. When combined with the results from endoscopic sinus culture or PCR assay, select patients with chronic sinus infection can be treated more easily and effectively.\(^11\)

**Updated Guidelines**

As in other specialties, economic realities of medical care coupled with desire for better outcomes have prompted Otolaryngologists to develop evidence-based treatment guidelines. In 2007, the American Academy of Otolaryngology-Head and Neck Surgery published multidisciplinary clinic practice guidelines for adult sinusitis.\(^12\) These guidelines were composed based on input from a broad range medical specialties including allergy and immunology, infectious disease, emergency medicine, family medicine, internal medicine and radiology.

The AAO-HNS Adult Sinusitis guidelines emphasize appropriate diagnosis and provide management options that include observation, antibiotic therapy and additional testing. A strong recommendation was made to distinguish acute bacterial sinusitis from that caused by colds, viruses and non-infectious conditions. The guidelines defined acute sinusitis as purulent nasal drainage accompanied by nasal congestion and facial pain/pressure/fullness lasting up to four weeks. For viral and mild bacterial sinusitis, observation and symptomatic treatment was recommended. Amoxicillin for seven days is indicated as first-line therapy in non-penicillin-allergic individuals. A distinction was made between chronic sinusitis (lasting 12 weeks or longer) and recurrent acute sinusitis (four episodes per year with no symptoms in between). (Short-course amoxicillin was not recommended, nor is it necessarily appropriate, for chronic or recurrent acute sinusitis). Routine sinus x-rays were discouraged for the diagnosis of sinusitis. Instead, for
persistent sinonasal symptoms, CT scan, nasal endoscopy and allergy testing were recommended. Explicit recommendations were made to encourage patients to stop smoking and to use saline nasal irrigation. Some changes at the point of care have occurred in the diagnostic arena. Typically, treatment of chronic sinusitis has been empiric, based on presenting symptoms such as persistent nasal congestion, facial pressure and cough. Sinus CT, the gold standard for diagnosis, is typically reserved for persistent or refractory symptoms (as mentioned above). Some practitioners have chosen to offer in-office CT, allowing them to quickly distinguish true sinusitis from other conditions such as allergies, migraine or tension headache before initiating therapy. This is far superior to in-office sinus x-ray, which has a fairly low sensitivity and specificity. The cost of this equipment is still prohibitive for many physicians so that in-office CT remains limited in availability.

Nose-Bleeding

Stepping away from chronic sinonasal infection, another problem whose treatment has seen significant innovation is epistaxis (aka nosebleed). Nosebleeding remains a common medical and surgical problem, particularly in this era of therapeutic anticoagulation. “Old-school” intervention with extensively layered packing gauze and Foley catheter insufflation is rarely used today. Instead, we have shifted toward newer techniques, facilitated by new medical devices and interventional techniques, which have greatly improved outcomes and lessened morbidity. Most nosebleeds emanate from the anterior septum in an area known as Kiesselbach’s plexus, a confluence of blood vessels from the internal and external carotid arterial system. For minor anterior nosebleeding, newer resorbable hemostatic powders such as NasalCease (topical calcium alginate) can be obtained over the counter and used at home. For patients who present to an urgent care center or emergency department with nosebleeding, premanufactured and non-absorbable packing such as Merocel® sponges or the newer Rapid Rhino® inflatable nasal packing are now available and play a useful role in treating nosebleeds. In addition to being generally effective, they can also be placed easily and later removed by trained, non-specialist providers.

When available, anterior nasal cautery may have several advantages over nasal packing. Very anterior bleeding sites can often be treated successfully with chemical cautery by nonspecialist providers. More difficult bleeding can often be controlled by direct or endoscopic cautery using chemical or electrothermal cautery. This can be comfortably performed in an office or outpatient setting with application of topical anesthetic. Retrospective studies have confirmed that this technique can result in decreased need for subsequent intervention. Intranasal cauteration has also been shown to result in shorter hospital stays versus treatment with packing.

Continual epistaxis also warrants investigation and treatment for various medical conditions. Hypertension, congenital coagulopathies, Wegener’s granulomatosis, sarcoidosis and hereditary hemorrhagic telangiectasia are all diagnostic possibilities. Frequent, anticoagulated cardiac patients may need to temporarily stop their warfarin or even consider reversal if the epistaxis is profuse enough to cause an acute anemia.

Next-generation anticoagulants such as dabigatran, rivaroxaban, and apixaban present additional challenges in cases of epistaxis. Dabigatran is a thrombin inhibitor, while rivaroxaban and apixaban are factor Xa inhibitors. These novel anticoagulants have been popular because of their shorter half-life and lack of necessary blood level monitoring. When bleeding complications occur, however, reversal of these agents is problematic. There is no role for Vitamin K in reversal of these new oral anticoagulants, and fresh frozen plasma administration is ineffective. Instead, options include hemodialysis, recombinant factor VIIa, prothrombin complex concentrate, and activated PCC. Several promising reversal agents are currently under investigation, but none has been FDA-approved in humans yet. To date, there has been no proven reversal agent or antidote for these novel anticoagulants.

If bleeding persists or continually recurs despite local cautery or packing, further intervention is warranted. Typically, this involves the use of surgical ligation or arterial embolization. The technique for surgical ligation has been greatly enhanced with the use of nasal endoscopes. In the past, ligation necessitated a Caldwell Luc surgical procedure through the maxillary sinus anterior and posterior walls with resulting postoperative hospitalization, pain, numbness, and swelling. With use of the nasal endoscopes, the sphenopalatine artery can be isolated intranasally as it exits from the sphenopalatine foramen. Surgical clips can be applied directly to the artery. The patient can be discharged postoperatively with little associated morbidity. Statistical success from sphenopalatine artery (SPA) ligation approaches 100 percent.

Percutaneous embolization is another alternative that offers great success in treating recalcitrant nosebleeds. Typically performed by an interventional radiologist, this technique was developed in 1974 and involves selective embolization of the internal maxillary artery as well as the sphenopalatine artery. The procedure is performed with IV sedation and involves the use of polyvinyl alcohol, gelfoam, or more commonly, Embosphere® microspheres. Results are permanent, approaching a 90 percent success rate. Risks involved in this procedure, although quite rare, include headache, soft tissue necrosis, facial paralysis and less than one percent chance of stroke.
Sinonasal oncologic surgery has also advanced significantly with the advent of intraoperative surgical navigation systems and high-definition fiberoptic nasal endoscopy. This has transformed the area of conventional skull base surgery and intracranial surgery into a new discipline. Surgical access to the anterior cranial fossa can now be obtained transnally, obviating the need for craniotomy and extensive facial degloving surgery and their inherent risks of increased morbidity and mortality. Surgical access can be obtained from the cribiform plate of the anterior cranial fossa to the foramen magnum in an anterior-posterior plane. Endoscopic skull base procedures can now be performed by a team of otolaryngologists and neurosurgeons, allowing removal of pituitary tumors, meningoceles, meningiomas, chordomas, and esthesioneuroblastomas.

Conclusion

It is an exciting time in the field of Rhinology. Promising areas of ongoing investigation include the expanded use of transnasal balloon technology for conditions such as Eustachian tube obstruction. Efforts are also underway to combine sinus balloon technology with intraoperative stereotactic navigation. Given the pace of change witnessed over the past decades and as long as the medical payment system supports the uses of new technology, these authors expect significant advances to continue.

References

Vestibular Disease Update – Superior Semicircular Canal Dehiscence

By Larry B. Lundy, MD and David A. Zapala, PhD

Abstract: Most causes of dizziness are non-vestibular in etiology, and most vestibular dizziness is benign, self-limiting, and managed medically. There are relatively few causes of dizziness that potentially benefit from surgery. A relatively newly recognized cause of vestibular dizziness is superior semicircular canal dehiscence. The diagnosis and management can present a challenge to all physicians.

Introduction

In 1892 Ewald discovered that individual labyrinthine semicircular canal stimulation with a “pneumatic hammer” resulted in specific movements of the eyes of pigeons. This was a major discovery, as the resultant nystagmus was specific with respect to the particular vectors of specific canals. Tullio discovered in 1929 that loud sound could result in dizziness if there was a fenestration of a semicircular canal, a perilymph fistula, Meniere’s syndrome, post surgery, and vestibulofibrosis. Tullio created openings in the semicircular canals of pigeons and demonstrated that sound waves spread primarily into the canals at the site of the opening. The “Tullio phenomenon” is therefore dizziness due to exposure of loud sound. Hennebert’s sign is dizziness and nystagmus from pressure such as nose blowing, straining or applying pressure to the ear canal. Fistulas, or dehiscences, of the labyrinth historically have been considered a rare cause of dizziness. However, in 1998, Minor described the dehiscent superior semicircular canal syndrome, which has become recognized as a relatively frequent cause of dizziness.

Clinical Example

A 29 year old female presented with imbalance beginning in the fall of 2012. She described her sensations as listing to the right when she walked, like a rug was moving under her, unsteadiness, feeling off balance, and being cloudy headed. In retrospect, she noted right-sided pulsatile tinnitus since 2007. At that time she had a computerized tomography (CT) scan of her head, which was negative. As her pulsatile tinnitus persisted, she had a CT scan of temporal bones 2009 (standard axial and coronal views), which was normal. With her onset of disequilibrium, she underwent a magnetic resonance imaging (MRI) scan of the brain with and without contrast on December 30, 2012, which was also normal. She presented to us in February 2013. Her audiogram revealed normal hearing. Her vestibular testing did show an abnormal oVEMP (ocular vestibular evoked myogenic potential) for the right ear, with increased amplitude and a low threshold. Her FGA (functional gait assessment) score was 15 out of a possible 30. An FGA score should be at least 24 or greater, with the mean for normal patients being 28.9. She underwent an MRI of the brain with and without contrast on December 30, 2012, which was normal. She underwent a repeat CT scan using protocol for obtaining sub-millimeter slice reconstruction in the oblique axial and oblique coronal planes, which revealed a dehiscent right superior semicircular canal. She underwent surgery on March 18, 2013, a transmastoid cartilage cap procedure, and on formal follow-up on June 5, 2013, she reported feeling remarkably better with no dizziness, no imbalance, no limitation to her physical activities, and resolution of her right pulsatile tinnitus. Her only symptom was mild autophony when singing loudly. Her postoperative FGA score was 29. By communication in March 2014, she indicated continued resolution of her symptoms.

Pathology and Pathophysiology

The pathologic correlate is a bony defect, or dehiscence, of the superior semicircular canal. The most commonly accepted theory is that of postnatal failure of skull bone development over the superior semicircular canal in the floor of the middle cranial fossa. Although histologic temporal bone studies are limited, one review of 1,000 temporal bones from 596 adults found a complete dehiscence in 0.5 percent of specimens (0.7 percent of individuals), with another 1.4 percent having abnormally thin bone overlying the superior semicircular canal. This estimation of 0.7 percent of individuals equates to approximately one in 142 people.

Pathophysiology

The symptoms are due to a “third” mobile window. The normal bony cochlea/labyrinth complex is filled with perilymph, within which is suspended the membranous
labyrinth (cochlea duct, semicircular ducts, utricle and saccule). (Figure 1) In the normal condition, there are two windows – the oval window and the round window. The oval window houses the stapes, which vibrates from sound stimulation and compresses the perilymph, resulting in fluid waves. As the perilymph is incompressible, the round window membrane serves as a relief mechanism.

In the dehiscent superior semicircular canal condition, there is a third, pathological window in the bony labyrinth of the superior semicircular canal. Pressure and sound energy is diverted through this third, pathological window. This dehiscence results in both auditory and vestibular symptoms. The underlying result of having the third window is hyperstimulation of the cochlea and labyrinth. Of particular importance in understanding the pathophysiology of a dehiscent superior semicircular canal is that there is no primary pathology of the neurosensory elements of the cochlea and labyrinth. The symptoms are a result of overstimulation of normal, or non-pathologic, neurosensory elements from diminished resistance and shunting of sound and pressure energy within the bony labyrinth and cochlea due to the “third” mobile window.

Evaluation

Most patients present with vague, difficult to describe symptoms of dizziness, such as giddiness, lightheadedness, intoxication, being off balance and unsteadiness. There are numerous conditions with similar vague, nonspecific symptoms (sleep disturbance, medication side effects, anxiety, anemia, chronic fatigue, depression, diabetes and hypertension to name a few). The symptoms that raise the index of suspicion for a dehiscent superior semicircular canal are those evoked by sound (Tullio phenomenon) or pressure (Hennebert phenomenon). Loud sounds evoke a sensation of significant dizziness and can result in falls. Examples of inciting sounds include movie theaters, music (bars, concerts or church), heavy equipment, power tools and sporting events. Patients report they feel like their eyes “jump, jiggle, vibrate” when exposed to intense, loud noise.

There are also auditory symptoms that are unrelated to loud noise. Autophony (hearing one’s own voice “inside my head,” echo sensations as if in a tunnel or barrel), pulsatile tinnitus, abnormally loud chewing, even hearing the sound of normal eye movements are the result of hypersensitivity of a normal cochlea.

The physical exam is typically normal and unrevealing by the absence of signs, a normal ear canal and eardrum, no head and neck masses, no cervical or cardiac bruits, normal extraocular movements, and no nystagmus.
Often times, these symptoms, without an explainable cause, will prompt imaging studies such as an MRI of the brain, CT of the sinuses and temporal bones, carotid ultrasound, CT angiogram, and MR angiogram. Very often these tests are normal or have incidental, unrelated findings that do not reveal an underlying condition or diagnosis attributable to the symptoms. Patients and providers are often frustrated with a negative evaluation, leading to self-doubt by the patient and concerns about the legitimacy of the symptoms by the provider. Patients have usually been referred to multiple specialists and have often been told, “I cannot find anything wrong.”

The key to diagnosis is the high resolution CT scan of the temporal bones without contrast, with reconstructions in Poschl’s (Figures 2 & 3) and Stenver’s planes. These reconstructions are not typically done in the routine, high resolution CT scan of the temporal bones. Standard high resolution CT scans of the temporal bones without these specific planes of reconstruction will overlook the dehiscence of the superior semicircular canal.

### Treatment

Current treatment involves either simple conservative treatment or surgical intervention. There are not any medications that are known to be effective in relieving symptoms. Most patients are content with observation and expectant management once they know there is an abnormality that explains their unusual symptoms. Once reassured of a specific diagnosis and their symptoms are not occult manifestations of a more sinister diagnosis, the symptoms are usually much better tolerated.

The surgical management is evolving. There are two primary surgical strategies: plugging the defect directly or resurfacing the defect. The surgical approaches for plugging involve either a middle fossa craniotomy or a transmastoid labyrinthotomy. The surgical approaches for resurfacing also involve a middle fossa craniotomy or a transmastoid approach.

### Table 1.

**CT scan protocol**

<table>
<thead>
<tr>
<th>- 64 Slice multi-detector scanner</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Collimation for acquiring data: 0.6 mm at 0.3 mm intervals</td>
</tr>
<tr>
<td>- Reconstruction in oblique sagittal and oblique coronal planes (0.8 mm thickness at 0.2 mm intervals)</td>
</tr>
</tbody>
</table>

### Table 2.

**Comparison of surgical approaches**

<table>
<thead>
<tr>
<th>Surgical approach</th>
<th>Length of stay</th>
<th>Superior canal function</th>
<th>Operative risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle fossa plugging</td>
<td>2 – 5 days</td>
<td>Diminished</td>
<td>Moderate</td>
</tr>
<tr>
<td>Middle fossa resurfacer</td>
<td>2 – 5 days</td>
<td>Preserved</td>
<td>Moderate</td>
</tr>
<tr>
<td>Transmastoid plugging</td>
<td>2 – 5 days</td>
<td>Diminished</td>
<td>Low</td>
</tr>
<tr>
<td>Transmastoid cartilage cap</td>
<td>Outpatient</td>
<td>Preserved</td>
<td>Low</td>
</tr>
</tbody>
</table>

### Table 3.

**Outcome metrics**

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>FGA</td>
<td>Functional Gait Assessment (21)</td>
<td>Physical therapy</td>
</tr>
<tr>
<td>DHI</td>
<td>Dizziness Handicap Inventory (22)</td>
<td></td>
</tr>
<tr>
<td>ABC</td>
<td>Activities-specific Balance Confidence scale (23)</td>
<td></td>
</tr>
<tr>
<td>GAD 7</td>
<td>Generalized Anxiety Disorder (24)</td>
<td></td>
</tr>
<tr>
<td>PHQ 9</td>
<td>Depression Questionnaire (25)</td>
<td></td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analog scale (Tullio, Hennebert, autophony)</td>
<td></td>
</tr>
</tbody>
</table>

### Figure 4.

**Normal superior semicircular canal, Stenver view.**

### Figure 5.

**Dehiscent superior semicircular canal, Stenver view.**
The concept behind plugging of the dehiscence is to close the "third" mobile window by filling the lumen of the bony superior semicircular canal with bone wax and/or tissue. The middle fossa craniotomy allows direct visualization of the dehiscence from above. The transmastoid approach to plugging involves creating two holes: one anterior and one posterior, adjacent to the dehiscence area from the side of the superior semicircular canal in order to wall off the dehiscence area.

The concept behind resurfacing is to cover, or seal, the defect without introducing material into the lumen of the semicircular canal. As in plugging, there are the same two approaches, middle fossa craniotomy (from above) or transmastoid (from the side).

There are advantages and disadvantages to each strategy. The advantage of plugging is complete closure of the bony defect. Usually, the presenting symptoms and chief complaint symptoms are resolved. The disadvantage of plugging is that the membranous labyrinth is compressed and is potentially irreversibly damaged, resulting in chronic disequilibrium of a different nature. The advantage of resurfacing is avoidance of manipulation of the membranous labyrinth. The disadvantage of resurfacing is the potential for incomplete sealing of the defect, resulting in incomplete resolution of presenting symptoms. The substance used for resurfacing plays a large role in the sealing of the defect, avoidance of potential trauma to the membranous labyrinth, and successful resolution of symptoms.

Initial attempts at surgical management of a dehiscence explored resurfacing versus plugging, both through a middle fossa craniotomy. This approach allowed direct visualization of the dehiscence from above. In the early stages of surgical management, a bone plate (with or without fascia) was used to resurface the defect. Based on a limited number of cases, this was found to be less successful than plugging, and was abandoned early in the evolution of treatment in favor of plugging. The most commonly used technique today is the middle fossa craniotomy plugging of the dehiscence.

As experience has accumulated with plugging, either via a middle fossa craniotomy or transmastoid approach, there appears to be a tradeoff between the complete plugging of the defect and the subsequent high incidence of chronic disequilibrium due to loss of function of the superior semicircular canal. When a plug is pushed into the bony defect, compression of the membranous labyrinth inevitably occurs, with distention or rupture of the membranous labyrinth and cupula. The result is dysfunction of the superior semicircular canal cupula, with a different form of vestibulopathy. This secondary morbidity has prompted a re-evaluation of resurfacing, with the material used for resurfacing being a critical factor. In retrospect, the unsatisfactory result from the middle fossa resurfacing was likely the result of the substance used for resurfacing—the bone plate. From a technical standpoint, the bone of the floor of the middle fossa around the area of the dehiscence is irregular and undulating. Placement of a rigid bone plate over this irregular bony surface of the floor of the middle cranial fossa around the dehiscence is not likely to provide a good seal of the dehiscence. An incomplete sealing would not correct the pathological defect, and therefore the symptoms would persist.

Retrospective analysis by various surgeons led to the concept of using cartilage to resurface the defect. Cartilage (from the auricle or tragus) is soft enough to conform to the floor of the middle fossa around the defect and seal it, and is firm enough to not prolapse into the lumen of the semicircular canal. The cartilage cap accomplishes resurfacing and sealing of the dehiscence without incidental compression of the membranous labyrinth. Furthermore, the cartilage cap is placed via a transmastoid approach, therefore avoiding the need for a middle fossa craniotomy. One potential disadvantage of placing the cartilage by a transmastoid approach is the lack of visualization and direct confirmation of the exact location of the dehiscence. This potential disadvantage is overcome by intraoperative confirmation of the bony labyrinth, use of highly accurate intraoperative image guided navigational system, and use of a piece of cartilage many times larger than the dehiscence. A typical dehiscence is two to three mm long, and the cartilage cap is at least 10 x 10 mm, more than adequate to cover the defect and surrounding areas.

Operative morbidity is also a factor in recovery after surgery. Typically, the middle fossa craniotomy with plugging involves a three to five day hospitalization, including ICU stay, with physical therapist necessary to assist in ambulation. The postoperative course is also true of plugging via a transmastoid approach. Either method of plugging will result in compression and subsequent dysfunction of the membranous superior semicircular canal and cupula. The transmastoid cartilage cap resurfacing is done as an outpatient in the vast majority of cases, and post-operative morbidity is much less.

Outcomes

As dizziness is such a vague symptom with multiple etiologies, metrics for outcomes are difficult to establish. Patient report, and provider interpretation of successful outcomes and resolution of symptoms is often helpful, but highly subjective and rarely provide a complete picture. Most reports in the literature discuss patient report, such as symptoms related to the dehiscence are resolved, or symptoms are improved, etc. Audiograms can objectively
quantify hearing changes, but do not provide information regarding symptoms of autophony and pseudoconductive hyperacusis. Standard vestibular tests primarily measure horizontal semicircular canal function, which is uninvolvement by the pathology of the superior semicircular canal. Advanced vestibular testing, such as cVEMP (cervical vestibular evoked myogenic potential), oVEMP (ocular vestibular evoked myogenic potential), and rotary chair testing (on axis and eccentric axis) measure otolith (saccule and utricle) function, which also are uninvolvement by the pathology of the dehiscent superior semicircular canal. The only accurate way to measure superior canal function is with scleral search coils, a research tool which is not widely available. A relatively new system, vHIT (vertical head impulse test) can measure superior semicircular canal function, but has been available commercially for only about one year, and lacks accepted norms and standardization.18,19

Therefore, the most realistic metrics for outcome are standardized, validated patient survey questionnaires (DHI – dizziness handicap inventory and/or ABC Scale – activities specific balance confidence scale). One well accepted objective metric for gait and balance is the FGA – functional gait assessment – a standardized, age normed, and validated test of gait and balance. The FGA is a 10 item assessment, typically administered by a physical therapist, and includes challenges such as walking while turning the head side to side and up and down, walking backwards, stepping over obstacles, pivot and turn, etc.

Since July 2009, the cartilage cap technique has been exclusively used for the surgical management of a dehiscent superior semicircular canal.1,20 Prior to July 2009, the middle fossa and transmastoid plugging techniques were used, with variable success. Preliminary data for more than 90 patients who have undergone the cartilage cap surgical procedure are quite encouraging. The above metrics, and more are used commercially for only about one year, and lacks accepted norms and standardization.18,19

Summary

A dehiscent superior semicircular canal is a pathological condition that manifests a spectrum of symptoms from nuisance autophony to debilitating dizziness and disequilibrium. Most patients require only reassurance and conservative treatment once the diagnosis is made. Patients with debilitating vestibular symptoms are candidates for surgical management. Surgical management is evolving, with cartilage cap resurfacing providing a less involved, less morbid procedure with much shorter hospitalization and comparable outcomes to plugging. ◊

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Hearing Restoration: Miracles Now and for the Future

By J. Douglas Green, Jr., MD, FACS

Abstract: Hearing loss affects all of us in some way, shape or form, either personally or through a family member or friend. Hearing loss may occur as a result of a problem in the outer, middle or inner ear, or even from the central nervous system with resulting impairment in communication. Frequently, hearing loss is multifactorial with environmental factors superimposed on a genetically disturbed cochlea. Better understanding of the effects of isolation and development associated with hearing loss have highlighted the importance of proper identification and treatment. Improvements in amplification, cochlear implantation and diagnostics have allowed earlier identification and better treatment options for our patients. Future improvements in the use of molecular, genetic and stemcell therapies are on the horizon and give additional hope to those afflicted with hearing loss.

Introduction

Hearing loss represents a very common affliction in the United States (US) and abroad. Approximately 40 million Americans suffer from hearing loss representing greater than 10 percent of the United States population.1 The incidence of hearing loss is significantly greater in the senior adult population with 30 percent of patients older than the age of 65 suffering from a significant hearing loss. In the US, approximately 1.4 million children younger than 18 years of age are currently suffering from varying degrees of hearing loss. Hearing screenings of newborns result in approximately three in 1,000 infants being identified with a severe to profound hearing loss in the US. It is estimated that the prevalence of disabling hearing loss in some regions of the developing world is approximately twice the incidence in US.2

Hearing loss results in significant isolation for the affected patient with increased stress and aggravation. Recent studies have shown an association between hearing loss and dementia; potentially in part related to isolation and reduced stimulation of the auditory cortex.3 Other studies have shown that decreased job performance for patients with hearing loss results in a significant decreased earning potential. Unfortunately, a significant number of adults are not treated for their hearing loss, due to lack of identification and due to financial constraints. Only one in five adults in the US needing hearing aids actually obtains them to help with their problem.1 Unfortunately, only 13 percent of primary care physicians in US currently routinely screen their patients for hearing loss.1 Simple screening tools are available such as an otoscope, which produces a tone to screen for hearing loss, and can be purchased fairly inexpensively. More sophisticated tests such as otoacoustic emissions and auditory brainstem response testing are also available. Additionally, basic testing with tuning forks can help to differentiate among the various forms of hearing loss.

Anatomy

The ear can be divided into an outer, middle and inner portions. (Figure 1) The outer ear consists of the pinna and ear canal, and serves to funnel sound into the ear canal and down to the tympanic membrane. The ear canal is one-third cartilage and two-thirds bone. The middle ear starts with the tympanic membrane and is typically filled with air. The...

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middle ear contains the ossicles (malleus, incus and stapes), which have an active role in the transfer of the sound from the air of the ear canal into the fluids of the cochlea. The sound transfer mechanism is accomplished by the lever action of the ossicular chain and the size differential of the tympanic membrane to the oval window. This results in an extremely efficient transfer mechanism allowing a minimal loss of sound (two decibels). The inner ear is filled with fluid and consists of the snail shaped cochlea (two and three quarter turns) and the balance structures. The cochlea has a tonotopic arrangement with high frequencies being received in the basal (outer) turn of the cochlea and low frequency sounds being picked up in the apical (inner) portion of the cochlea. There are approximately 16,000 hair cells within the inner ear, which have the varying roles in the sound transduction process. There are 30,000 to 40,000 afferent neurons, which relay sound information to the central nervous system. The outer hair cells act to fine tune the region of the cochlea stimulated by a particular sound narrowing the frequency response and giving greater clarity and acuity to the sounds being received (Figure 2). The inner hair cells, when deflected, open ion channels resulting in stimulation of the hair cell. These inner hair cell signals are transmitted through dendritic connections to the spiral ganglia and from the spiral ganglia along the cochlear nerve to the brain. The brain plays an extremely important role in sound processing with the basic sound processing taking place in the brainstem, and more sophisticated sound processing occurring within the supratentorial portion of the brain, specifically within the auditory cortex. The ears have an efficient system to detect sound, detecting a movement of the tympanic membrane of only a single angstrom (the size of a hydrogen molecule).

Hearing loss may be due to either a mechanical problem resulting in a conductive hearing loss or may be due to a problem with either the cochlea or the cochlear nerve called a sensorineural hearing loss. At times, a conductive component and a sensorineural component may be involved leading to a mixed hearing loss. The simplest cause of a conductive hearing loss is an accumulation of cerumen within the ear canal. Recent clinical practice guidelines produced by the American Academy of Otolaryngology-Head and Neck Surgery have emphasized the importance of proper diagnosis and treatment of cerumen impaction for affected patients. Cerumen impaction should be diagnosed when symptoms of hearing loss or occlusion are present, or when visualization of the tympanic membrane and ear canal are hindered by the cerumen accumulation. The patient affected by cerumen impaction should be assessed for modifying factors such as tympanic membrane perforation, stenosis of the external auditory canal, exostosis, diabetes mellitus, immunocompromised status or the use of anticoagulants. Observation of non-impacted cerumen that is not symptomatic and does not compromise visualization is acceptable. Treatment of cerumen impaction is appropriate for affected patients and may consist of the use of cerumenolytic ear drops, irrigation with saline or manual disimpaction either by using a microscope or an otoscope with appropriate instrumentation. Avoidance of Q-tips is important as they frequently push cerumen deeper in the ear canal and against the tympanic membrane. The Food and Drug Administration (FDA) has advised against the use of ear candling as a technique for removal. Hearing aids will routinely exacerbate cerumen accumulation, and patients who use hearing aids should be assessed more frequently for cerumen accumulation. It is important to assess the patient after irrigation or cerumen removal to be certain of the completeness of the removal.

Figure 2.
Scanning electron microscope imaging of the native hair bunding from the mouse inner ear. (Used with permission of J. R. Holt et al., Cell 108, 371-381 (2002))
The ear canal can be the source of a conductive or mixed hearing loss due to ear canal stenosis, the presence of exostosis, or congenital atresia of the external auditory canal. Another important potential cause for transient hearing loss is otitis externa. Acute otitis externa is typically caused by pseudomonas aeruginosa, which is normally present in the external auditory canal, and results in infection in the warm moist environment of the ear canal. This frequently follows swimming, bathing or other water activities leading to the accumulation of moisture within the ear canal. It is important to distinguish acute otitis externa from other potential causes, and to assess for modifying factors such as a tympanic membrane perforation, prior tympanostomy tube placement, diabetes mellitus, immunocompromised status, or the presence of prior radiotherapy. Assessment for pain and use of analgesics is appropriate depending upon the severity of symptoms. The use of oral antibiotics is inappropriate unless there is evidence of spread of the infection from the ear canal in the form of cellulitis or possibly in the case of an immunocompromised patient. Topical antipseudomonal otic drops are appropriate as the initial therapy for otitis externa. It is also important to enhance the medical delivery of the otic drops through appropriate aural toilet by cleaning the ear canal and also by the use of an otic wick. Non-oticotoxic drops should be used in the case of a non-intact tympanic membrane or if a tympanostomy tube has been previously placed. A repeat assessment is appropriate 48 to 72 hours later for these patients. Diabetic or immunocompromised patients who fail to respond to standard treatment should be assessed for necrotizing otitis externa where osteomyelitis of the temporal bone has developed.

The middle ear is another potential source of a conductive or mixed hearing loss. Infectious etiologies predominate with tympanic membrane perforations, cholesteatoma of the middle ear, and tympanosclerosis as common problems resulting in hearing loss. Effusions of the middle ear space in children are extremely common and will be discussed in more detail in the article by Drs. Maddern and Simonson. Adults will also develop middle ear effusions, most commonly due to eustachian tube dysfunction. Temporal bone trauma may cause ossicular discontinuity resulting in hearing loss. Congenital ossicular fixation is an uncommon cause of hearing loss in children. Otosclerosis, the most common cause of a conductive hearing loss in middle age adults, is the result of an abnormal balance of the process of bony remodeling of the osteoclasts and osteoblasts within the otic capsule. The disproportion of certain cytokines within the otic capsule is thought to be the cause of this bony remodeling problem, and has led to the recent use of bisphosphonates in patients with otosclerosis affecting the neural function of the cochlea. Stapes surgery in the form of stapedotomy or stapedectomy, which involves replacement of the stapes bone, continues to be an appropriate form of therapy for patients with a significant conductive component to their hearing loss. This yields significant hearing improvement in 85-90 percent of properly selected patients. Another commonly misdiagnosed form of conductive hearing loss is that of superior semicircular canal dehiscence syndrome. These patients appear to have a low frequency conductive hearing loss, but on CT scanning of the temporal bone are found to have dehiscence of the superior semicircular canal resulting in the loss of sound pressure and noise-induced dizziness. Drs. Lundy and Zapala discuss this problem in greater detail in their article in this journal.

Great progress has been made in the diagnosis and treatment of a variety of forms of sensorineural hearing loss. The most common preventable form of sensorineural hearing loss is that of noise induced hearing loss. While liability concerns have resulted in improvement in corporate and industrial noise exposure, noise exposure from music, military work, and other hobbies such as hunting or woodworking involve significant noise exposure and continue to be an ongoing problem. The simple use of foam earplugs will prevent a significant amount of noise-induced hearing loss.

Genetic causes of hearing loss are myriad and are better understood than in the past. Studies of single nucleotide polymorphisms in genome-wide association studies have led to the identification of many genetic loci responsible for hearing loss. More than 300 genetic loci have been implicated with approximately 70 causative genes identified. Most genetic hearing loss is nonsyndromic with the majority being of the autosomal recessive variety. The most common autosomal recessive cause is due to JGB2 chromosomal changes with resultant malformation in the gap junction proteins within the cochlea. This accounts for as much as 50 percent of patients with congenital sensorineural hearing loss. Syndromic causes of hearing loss are also fairly common with Waardenburg syndrome, Usher syndrome, Pendred syndrome and Jervell and Lange-Nielsen syndrome. Alport’s syndrome, which is an X-linked syndromic cause of hearing loss, is associated with kidney dysfunction. Mitochondrial genetic abnormalities have been recently described, which fail to follow traditional Mendelian genetics. Surprisingly, these are only transmitted from the female and are as a result of genetic material within the mitochondria, which may be disordered. There is a significant variable expressivity with this type of hearing loss. An excellent information source for genetic hearing loss is the Hereditary Hearing Loss Homepage.

Otoxic causes of hearing loss are not uncommon and thankfully have been reduced in the past several years. These are primarily related to the use of aminoglycosides,
but also include chemotherapeutic agents such as cisplatinum and loop diuretics. Unfortunately, the incidence of ototoxic sensorineural hearing loss is much higher in the developing world where aminoglycosides represent an inexpensive treatment option for infections and blood levels are frequently not monitored. Ménière’s disease represents an idiopathic cause of hearing loss characterized by fluctuation of hearing and spells of vertigo, which demonstrates hydropic changes of the endolymph on histopathologic examination of the temporal bone.

A sudden sensorineural hearing loss may occur for unknown reasons. This represents a 30 decibel decline in sensorineural hearing in three consecutive frequencies over a three day period of time. While multiple etiologies have been suggested, including a viral origin or vascular origin, the ultimate cause is unknown in 85 to 90 percent of patients. The hearing loss may manifest as a sensation of blockage in the ear and may or may not have associated tinnitus and balance related issues. Again, recent guidelines from the American Academy of Otolaryngology-Head and Neck Surgery have important implications for the recovery of these patients. Multiple studies have demonstrated that patients who have more rapid access to treatment have a higher rate of hearing recovery. Poor prognostic factors for hearing recovery include:

- a profound hearing loss
- associated balance symptoms
- a higher frequency loss.

Academy guidelines also suggest differentiating a sensorineural hearing loss from a conductive hearing loss by expeditiously performing an audiogram. We consider this an audiologic emergency at our facility. These patients should be assessed for other neurologic changes, which might imply a vascular etiology or an evolving cerebrovascular accident. A CT scan is of little value in these patients, and most patients with a sudden significant sensorineural hearing loss should undergo a gadolinium enhanced MRI with special attention to the internal auditory canals. Routine laboratory studies are also of little value, and patients should be educated about the natural course of this disease at the time of the diagnosis. Once the diagnosis of a sudden sensorineural hearing loss has been established, oral corticosteroids may be offered to the patient, typically beginning at 60 mg of prednisone daily for 10 days followed by rapid taper. Intratympanic steroid injections have been found to be beneficial in several studies and may be offered either as a rescue procedure for patients who fail to respond to oral steroids or the injections may be given concomitantly with the oral corticosteroids. Antiviral therapy, thrombolytics, vasoactive medications or antioxidants are of little benefit with sudden sensorineural hearing loss and should be avoided. Follow-up audiometric testing within six months of the onset is appropriate and should be offered to patients. Hyperbaric oxygen is also a reasonable treatment option, although it is more commonly used outside the US.

**Treatment**

**Amplification**

Great changes have occurred to hearing aids over the past several decades. Miniaturization of hearing aids has allowed the older body worn hearing aid to be replaced by an ear level aid, and subsequently by very small hearing aids completely hidden within the ear canal. As amplification has improved, small Receiver in Canal (RIC) hearing aids are being used with greater frequency because of the lack of an occlusion sensation with the open fit molds used in these aids. Patients with mid and high frequency sensorineural hearing loss find these hearing devices to be helpful. The ability to connect to a variety of sound sources via wireless connectivity through a streamer has greatly enhanced the functionality of hearing aids. Bluetooth technology allows sound from a cellular phone, television, remote microphone, or even a computer to be directly inputted to the patient. Some newer hearing aids are even able to connect to various sound sources without a streamer being worn around the neck by using a smartphone to connect to the sound source.

Improvements in microphone technology and in the amplification circuitry have also greatly improved the performance of hearing aids. Directional microphone technology using paired microphones allows the funneling of sound from in front of the patient into the hearing aid limiting the sound field and thereby reducing some background noise. Improvements in feedback control, coupled with automatic gain control, allow repackaging of the speech signal to fit within the dynamic range of the patient’s hearing. The use of digital technology has become routine among most hearing aids that are sold today with digital noise reduction, and digital signal processing has also become extremely common.

Hearing aids in Florida may either be purchased from a licensed audiologist or from a hearing aid dispenser. Patients need to be aware of the 30-day trial period that accompanies the purchase of a hearing aid during which time they can return the hearing aid for any reason if they are not satisfied. The audiologist or hearing aid dispenser may retain a fitting fee if the hearing aid is returned during this time frame.

Implantable hearing devices have also entered the discussion for patients with significant hearing loss. Many patients inquire about the Esteem Envoy device, an implantable device, which utilizes a piezoelectric crystal for both the reception of sound and also direct coupling with the ossicular system.
Cochlear Implants

Cochlear implants have undergone significant and progressive improvement during the past 40 years. These devices allow transduction of the acoustic signal to an electrical signal, which is delivered directly to the remaining auditory elements in the cochlea. There are currently three cochlear implant companies with FDA approval in the US: MED-EL, Cochlear and Advanced Bionics. As of December 2012, 324,200 people worldwide have received cochlear implants with approximately a third of those being in the US. There are 58,000 adults with cochlear implants and 38,000 children with cochlear implants in the US. While cochlear implants were initially developed for patients with a complete loss of hearing, progressive improvement in the function of the cochlear implants has allowed patients with residual hearing to improve their hearing with the implants. Hearing preservation with cochlear implant surgery has been refined significantly in the past few years. Remarkably, 90 percent of patients with residual hearing can have some or all of their hearing preserved when they receive their cochlear implant. Recent approval of the Hybrid cochlear implant by the Cochlear Corporation greatly expands on this group of patients with residual hearing who are potential cochlear implant candidates. The hybrid device combines a hearing aid for the low frequency hearing and electrical stimulation for the middle and high frequency hearing. The hearing results for these patients are amazing with patients reporting a tenfold increase in satisfaction over hearing aids alone, and a two fold increase in hearing overall in both quiet and noise. Most cochlear implant patients (both hybrid and standard cochlear implants) are able to make use of the telephone with more than 80 percent of patients queried on recent studies using the telephone on a regular basis. Wireless connectivity for cochlear implants has provided additional hearing improvement for patients with hearing loss improving understanding on the telephone and when watching television. Collaboration between cochlear implant companies and hearing aid companies has allowed patients with a hearing aid in one ear and a cochlear implant in the other ear to have stereo hearing with the wireless, Bluetooth connectivity allowing an extremely pure auditory signal with background noise.

Cochlear implant processors are rapidly becoming waterproof as several different manufacturers have developed waterproof coverings for the processors. Advanced Bionics has developed a waterproof processor, the Neptune. The MED-EL implant has recently been granted approval for MRI compatibility with a 1.5 tesla scanner using approved scanning techniques. Additional applications for cochlear implants are also on the horizon. Cochlear implants in Europe and Canada have received the CE, the European equivalent of FDA approval, mark for use in patients with unilateral severe to profound sensorineural hearing loss. These patients have found improvement in hearing, particularly in noise, along with tinnitus reduction. It is anticipated that in the next several years, cochlear implantation for unilateral sensorineural hearing loss will be possible in the US, as well.

Developments for molecular, gene, and stem cell therapies for deafness

Unlike lower vertebrates, humans do not have the capacity to regenerate hair cells within the cochlea. With the large number of affected patients and improved understanding
of the genetic causes of hearing loss, the search for hearing restoration through molecular, gene and stem cell therapies is rapidly moving forward. Successful manipulation of the genes within the cochlea of laboratory animals has led to human trials. The transfer of genetic information into the human genome for patients affected with Usher’s Syndrome 1B is one such example. This genetic transfer corrects for the abnormal myosin, which occurs in the ears and eyes (MYO7A) of these patients. Several animal studies are currently underway looking at introduction of genetic information to correct for DFNB1, which codes for a gap junction protein representing the most common cause of autosomal recessive genetic deafness. Human clinical trials using Atoh1, a basic, helix-loop-helix transcription factor have recently been approved for patients with acquired deafness to allow for hair cell regeneration. (Figure 3) Other trials are underway looking at the use of brain derived neurotrophic factor (BDNF) to help preserve/regenerate spiral ganglion cells. BDNF also is being incorporated in cochlear implant electrode arrays to help direct dendritic growth towards the electrodes.

The use of stem cells for regeneration of hair cells is also showing great hope for patients with genetic and acquired hearing loss. Several studies have demonstrated the ability to grow hair cells in vivo using step-wise differentiation from inner ear progenitor cells. Problems persist in the orientation of these stem cells, as well as the ingrowth of dendritic connections from the spiral ganglion. Nevertheless, it represents a tremendous step forward to help our patients with various forms of hearing loss. Efforts to generate spiral ganglion auditory neurons from stem cells are also underway. These efforts may help patients undergoing cochlear implantation who have a severe loss of ganglion cells limiting the effectiveness of the cochlear implant.

Endogenous signaling mechanisms allow the pluripotent supporting cells of the cochlea to develop into functional hair cells in birds and lower vertebrates. Better understanding of these signaling mechanisms has led to the use of pharmacologic agents such as a gamma-secretase inhibitor to block notch signaling and thereby reduce lateral inhibition between hair cells and supporting cells. The use of an antisense oligonucleotide (ASO) in a mouse model of Usher Syndrome 1C has also shown promise in allowing growth of functional hair cells. While effective only at a very early developmental stage, this therapy may prove to be an alternative to inserting genetic material into the cochlea.

**Conclusion**

As the complexities of hearing are better understood, new strategies for helping our patients with deafness will undoubtedly unfold. These strategies will need to target multiple areas of the inner ear and central nervous system. The timing of various treatment options within the developmental process from the otic placode stage to the fully developed cochlea will also need to be considered. The miracle of hearing with connection to others represents one of our most important sensory systems with incredible opportunities to ease the burden of those suffering from hearing loss. Sound strategies to help our patients are available now with more exciting treatment options on the horizon.

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**Figure 3.**
A hair-like cell generated via a gene-therapy strategy and viral-mediated delivery of the transcription factor Atoh1 into the inner ear of a deaf guinea pig. (Reprinted from Kawamoto et al., J Neurosci 23, 4395-4400 (2003))
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Artwork Date – May 8, 2015

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Editorial Date – October 30, 2015
Artwork Date – November 6, 2015

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