



SOUNDINGS

from the Pennsylvania Academy of Otolaryngology - Head and Neck Surgery

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PRESIDENT'S MESSAGE

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The Pennsylvania Academy of Otolaryngology-Head and Neck Surgery has continued to strive to support all otolaryngologists in the state by addressing educational, legislative, advocacy, and practice management issues. We have had a very productive year as an organization.

One of my goals as President of the PAO-HNS has been to work closely with the Pennsylvania Medical Society (PAMED) to address practice management and political issues of interest to otolaryngologists in the state. Participating in PAMED's Specialty Leadership Cabinet (SLC) has helped us to improve our communication with other state specialty societies and PAMED in general (see brief article in this issue of *Soundings* about the SLC). I have also met with Michael Fraser, PhD, the Executive Vice President of PAMED, and we are actively working together on ways in which the PAO-HNS and PAMED can collaborate to benefit members of both societies. For example, many of the current state legislative priorities for the PAO-HNS would also be pertinent

to other physicians in the state. These issues include preventing taxes on medical procedures, truth in advertising for doctors, tobacco and E-cigarette use, smoking cessation, and medical liability reform. Our own lobbying firm, Milliron and Goodman, LLC, will help us address these issues in the Pennsylvania legislature, but it would be very beneficial to have the support of PAMED, with its much greater resources.

The PAO-HNS has continued to work with the AAO-HNS on legislative and healthy policy issues. We are also thinking about other ways that the two societies can work together to support Pennsylvania otolaryngologists and our patients. Dr. Karen A. Rizzo, our Governor representing the PAO-HNS to the AAO-HNS Board of Governors (BOG), recently traveled to Washington, DC to give a presentation about the success of our state society and to participate in a round table discussion on the importance of state otolaryngology societies at the AAO-HNS Annual Leadership Forum and BOG Spring Meeting. The PAO-HNS continues to be a "model" state society which many others are trying to emulate.

We have also been continuing to update and expand the PAO-HNS website, which was redesigned last year. As chair of the Website Committee, Michael Ondik, MD, has helped us to find ways to make our website more user friendly for our members and our patients. We are preparing to launch a new "Find an Otolaryngologist" function for patients. We are also working to enhance the patient information section of the website.

Our next Annual Scientific Meeting will be held at the Omni Bedford Springs Resort in

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PAO-HNS Surgeons Continue to Lead the Charge in Transoral Robotic Surgery 2016

David Goldenberg, MD, FACS

Robot-assisted surgery has become a popular alternative to many open traditional surgical procedures. While modern robotic surgical techniques have been described since the late 1980s, telesurgery (i.e. surgery done at a distance from the patient) was first successfully performed in 2001, when physicians situated in New York removed the gallbladder of a 62 year-old patient in Strasbourg, France. Since then, technology has improved and remote robotic surgery has become quite prevalent and sophisticated. Used primarily in urology and gynecology at its inception, transoral robotic surgery (TORS) was developed for use in head and neck procedures. The da Vinci System® (Intuitive Surgical Inc., Sunnyvale, CA) is one such advanced robot, studied extensively at the University of Pennsylvania for its application in TORS in order to perfect and standardize its use.

In the April 2009 issue of *Soundings*, PAO members Drs. Greg Weinstein and Bert O'Malley wrote an article entitled Transoral

Robotic Surgery (TORS): Clinical Update 2009. Drs. Weinstein and O'Malley and the team at Penn are undeniably trailblazers in the field of TORS. The Penn group has been instrumental in developing, researching, disseminating and educating head and neck surgeons in TORS. Until recently, the da Vinci robot was the only platform for transoral robotic surgery.

The newest iteration of robot-surgical equipment is the Flex® Robotic System (Medrobotics, Raynham, MA), which improves upon many of the shortcomings of the da Vinci platform.

The Flex® Robotic System gives head and neck surgeons the ability to access anatomical locations that were previously difficult or impossible to reach minimally invasively. Surgeons can steer the flexible robotic arm and camera around anatomical structures with magnified HD for views that may not be possible with other minimally invasive approaches.

The Flex® Robotic System can navigate a nearly 180 degree path to reach challenging surgical targets. Surgeons can then deploy 3mm articulating instruments from a stable surgical platform that extends their reach to perform procedures. The Flex robotic system was FDA approved for head and neck surgery in October of 2015. In November 2015, PAO member Dr. Umamaheswar Duvvuri at UPMC was the first American surgeon to utilize the Flex Robotic System since it received FDA approval. In December 2015, Dr. Goldenberg was the second American surgeon to operate with the Flex System at Penn State University. Both UPMC and Penn State surgeons now have dedicated Flex Systems which have been used to date for radical tonsillectomies, pharyngectomies, tongue base resection, supraglottic laryngectomy, and benign lingual tonsillectomies.

It seems that PAO surgeons continue to lead the national and international charge in the field of Transoral robotic surgery. ●

Unilateral Vocal Fold Paralysis in Children

Karen B. Zur, MD



Vocal fold paralysis (or impairment) is the second most common laryngeal abnormality in children and typically presents within the first 24 months of life.^{1,2} The etiology of vocal fold immobility can be categorized as iatrogenic, neurologic or idiopathic.

The iatrogenic causes are most common. Cardiac surgery in children poses a risk to the recurrent laryngeal nerve due to the course of this very small nerve in the neck and chest. The ligation of a patent ductus arteriosus (PDA) is the most common surgical procedure associated with a unilateral vocal fold paralysis. The rates reported in the literature are variable and range from 1 to 25%.^{1,3} The recurrent laryngeal nerve is also at risk of injury following thyroidectomy, trachea-esophageal fistula (TEF) repair and excision of lesions that may lie along the course of the nerve in the trachea-esophageal groove in the neck.

Neurological causes of unilateral vocal fold immobility have been described. These include peripheral nerve disease, agenesis of the corpus callosum, intracranial bleed.^{1,4}

Idiopathic vocal cord paralysis is a diagnosis of exclusion when no other cause can be found. In the Daya review, which spanned a 10-year period at a tertiary referral Children's Hospital in London, 10 of 56 patients had an idiopathic vocal fold paralysis.

Unilateral cases of vocal fold paralysis are often accompanied by a weak cry and

feeding difficulties. In many cases, the aspiration either resolves or improves with dietary modifications, and the issue in older kids post injury to the recurrent laryngeal nerve is more typically that of dysphonia. Some patients can manage the breathiness of a mild dysphonia with voice therapy, and many children with unilateral vocal fold immobility compensate over time, and the normal vocal fold can overcome the midline to achieve full glottic closure and hence, improved vocalization (and swallowing).

Since the time to recovery from paralysis can be highly variable, a method to determine the likelihood of recovery in children is desirable. The laryngeal electromyography (L-EMG) has been established as a useful technique for determining the extent of injury, prognosis for recovery, and may help guide treatment. It is not a well-studied modality in children and has multiple challenges, most importantly due to the need to perform this procedure under anesthesia. The risk of placing a young child under anesthesia for a diagnostic procedure, and the loss of information obtained from the EMG due to the anesthesia, render this test in children not as effective as in the adult population.

In children who undergo a L-EMG under anesthesia, the electrode is inserted into the thyroarytenoid (TA) muscle, comparing the right and left responses. If the child is under a lighter plane of anesthesia that allows for motion of the vocal folds with respiration, the posterior cricoarytenoid (PCA) muscle insertion may provide information about the abductors of the larynx, but the results are not as accurate as in the awake patient. The utility of L-EMG testing in children is currently under investigation along with more standardized modes of examination.

Prognosis for recovery depends on the cause of the paralysis with variability among series. Neurologic causes have the best prognosis for recovery. Iatrogenic paralysis is least likely to resolve, while idiopathic palsies generally resolve but the time to recovery can be from months to over 10 years. This variability impacts the decisions for treatment. Procedures that will permanently alter the structure or function of the larynx

should be used with caution if there is any chance of recovery. Even with a favorable prognosis for recovery, patients with aspiration, respiratory distress, failure to thrive, or significant dysphonia may require treatment

Traditional surgical options can be divided into injection laryngoplasty, laryngeal framework surgery, and reinnervation procedures. The goals of surgery are to provide a midline surface upon which the contralateral vocal fold can appose.⁵ Injection laryngoplasty provides an attractive option for children given the temporary nature and low morbidity of the procedure. Many injectable materials are designed to resorb over 2 to 12 months and can act as a bridge while awaiting return of function. A test injection using a temporary injectable material is useful to provide the parents with a sense of how beneficial this intervention is for the child. The results with injection laryngoplasty in children are not as consistent as in adults, and more research is needed with respect to the types of injectable materials and their efficacy. In my practice, I currently use the Prolarynx Gel for the temporary injection material, and Cymetra or autologous fat as options for the more long-term injectates.

Medialization thyroplasty refers to the placement of an implant through the laryngeal framework to push the affected vocal fold toward the midline. Medialization thyroplasty is difficult in children given the smaller size of the larynx and the inability to perform awake, sedated procedures to assess the quality of the voice intraoperatively (which is how the adult thyroplasty procedures are typically done). There is theoretical concern of disrupting growth centers in the larynx with any surgical intervention, however this has not been found in animal models.⁶ The other potential complication of an implant thyroplasty is medial extrusion of the graft, potentially adversely affecting the airway. There is limited data on these procedures in children. I tend to avoid this surgical option in young children.

The Recurrent Laryngeal nerve reinnervation with the Ansa Cervicalis as a donor source has several advantages over the alternatives.

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Unilateral Vocal

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This procedure does not require an awake child to attain excellent results; it avoids implantation of a foreign body; and is unlikely to affect development of the larynx during puberty as the architecture of the larynx is preserved. The goal of the reinnervation is to provide tonic stimulation to the vocal fold and to the interarytenoid muscle, aiding in medialization of the affected vocal fold and closure of the posterior glottis. A recently published analysis of a comparison between children who underwent an injection laryngoplasty and a reinnervation showed that in 12 children who underwent an ansa cervicalis- to- recurrent laryngeal nerve (ANSA-RLN) reinnervation, voicing started to improve within 3-6 months and there is a gradual improvement over time, up to 20 months post reinnervation. There was an improvement in volume of vocalization, less raspy vocal quality and there was objectively improved parental perception and acoustic perception of the voice handicap as evidenced by universally improved standardized parental surveys and expert interpretation of the acoustics.

In contrast to some past concerns, there does not seem to be a correlation between the post-injury time to reinnervation and voicing results, making this an excellent option for children with dysphonia due to RLN injury.⁷ Furthermore, the ANSA-RLN procedure seems to benefit those patients who were diagnosed with aspiration as well as dysphonia as demonstrated by more recent cases that I had taken care of.

In summary, the goals of managing children with unilateral vocal fold immobility are to provide them with a serviceable voice, ensure a safe swallow, and minimize the risk of airway compromise following intervention. The recurrent laryngeal nerve reinnervation is an excellent option for long-term management of children with symptoms of paralysis that have not resolved over a period of observation. It is a safe, relatively quick ambulatory surgical procedure that has given children and their families a second chance.

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World Voice Day – April 16, 2016

Amanda C. Hu, MD



April 16th marks the international celebration of World Voice Day. The goal of World Voice Day is to raise public awareness and appreciation for voice disorders. Since its inception in 2002, voice professionals like laryngologists, speech language pathologists, singing teachers, singers, and patients have paused to appreciate the wonder of the human voice.

The human voice is more than just a means of communication. It allows people to express emotions in song, prose, and speech. Professional voice users also use their voices in their livelihoods. Actors and singers are not the only professional voice users – teachers, lawyers, secretaries, telemarketers, and

priests all rely on their voices for their jobs. The average person also needs his or her voice every day. It is often taken for granted until one has a voice problem.

World Voice Day is supported by major societies, like the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (www.entnet.org), the American Laryngological Association (www.alahns.org), the Voice Foundation (<http://www.voicefoundation.org>), and

the National Association of Teachers of Singing (NATS) (<http://www.nats.org/>). The Academy's World Voice Day theme this year was "Explore Your Voice". World Voice Day is also celebrated internationally in countries like Brazil, Sweden, Nigeria, and Hong Kong.

A variety of World Voice Day events are hosted each year on April 16th: Free head and neck cancer screenings, lectures on vocal health and hygiene, concerts, fundraisers, etc. Here in Philadelphia, the Voice Foundation held a concert and happy hour with the Academy of Vocal Arts, a premier finishing school for opera singers. A collection of World Voice Day events can be found at (<http://world-voice-day.org/>).

Don't worry if you missed World Voice Day this year. Mark your calendars for April 16th, 2017 and join voice professionals next year for this international celebration! ●



Plan to Attend the PAO Annual Scientific Meeting — Bedford Springs June 17-18, 2016

Amanda Hu, MD

On behalf of the scientific planning committee, I cordially invite you to join us for the PAO Annual Meeting at Bedford Springs on June 17-18, 2016. The planning committee has been working hard since last year to create the best program to fit the needs of our membership. Topics were chosen based on feedback from previous attendees.

There will be four sections this year: 1) Human Papillomavirus (HPV), 2) Otolaryngology update, 3) Resident research, 4) Business practice.

The HPV Section will be a multidisciplinary panel with experts in head and neck surgery (Dr. Jeff Liu – Temple and Dr. Umamaheswar Duvvuri – UPMC), pediatric ENT (Dr. Sri Kiran Chennupati MD – Drexel), laryngology (Dr. Libby Smith – UPMC), and obstetrics/gynecology (Dr. Kate Simons). HPV is a topic that spans several subspecialties of ENT. Dr. Liu, the section chair, will be presenting a panel of case studies.

The Otolaryngology Section was created from audience feedback. Dr. Andrew McCall (UPMC)

and Dr. Pamela Roehm (Temple) are the section co-chairs and they will be presenting on endoscopic ear surgery. Dr. Thomas Wilcox (Jefferson) will be discussing an update on the management of acoustic neuromas. Dr. Douglas Bigelow (UPenn) will be giving us an update on newer indications for cochlear implantation.

The ever popular Resident Research Section will return with Dr. Jessyka Lighthall (Hershey) and Dr. James Kearney (UPenn) as the section co-chairs. This year, we received 65 abstracts and the top abstracts will be presented. Cash prizes will be awarded to the top oral and poster presentations. We will also have a jeopardy bowl and residency programs are encouraged to form teams to compete for the title. Last year's winner was the Philadelphia College of Osteopathic Medicine (PCOM).

The last section is a Business Practice Section and our theme is patient advocacy. Dr. Karen Rizzo, Immediate Past President of the PA Medical Society, is the section chair. She will be presenting on the impact of the Insurance Industry on the Practice of

Otolaryngology in Pennsylvania. Dr. Ellen Deutsch, the Medical Director PA Patient Safety Authority, will discuss Simulation to Improve Systems. Dr. Michael Fraser, Executive VP of the PA Medical Society, will talk about Politics, Practice, and Patient Advocacy in PA. Larry Simon, Past President of the Young Physicians Section of AAO-HNS, will present on Academy Payment and Legislative Advocacy Efforts Over the Past Two Years.

The PAO meeting is planned on the weekend of Father's Day every year. We aim to make the meeting a family friendly event. Bedford Springs is a beautiful resort with golf, hiking, outdoor swimming pool, and a spa. Some of our planned social events include a clam bake and S'mores by the fire.

A special thanks to our PAO coordinators, Jennifer Keeler and Jessica Winger. Thank you also to our leadership, Dr. Jeff Simons, President of PAO. **I hope to see you all at the PAO Annual meeting!** ●

Relax with family and friends while earning CME credits at the beautiful Omni Bedford Springs Resort.

Levamisole-Adulterated Cocaine Lesions of the Nose and Ears

Michael P. Ondik, MD



Levamisole-adulterated cocaine (LAC) has become a significant health issue over the past several years. First identified in case reports in 2009, there have been multiple descriptions of LAC and its effects. Patients using LAC may develop purpuric or ecchymotic lesions of the nose, ears or other body areas. The ears are one of the most common sites of involvement and therefore patients may first present to otolaryngologists.

Levamisole is a compound originally used as an immunomodulatory drug for multiple diseases, including Crohn's disease, rheumatoid arthritis and cancer. Due to its toxicity, it was removed from the market for human use, but is still in use as an antihelminthic drug in veterinary medicine. Unfortunately, it has become a popular additive to cocaine due to its cheap cost and its mood-elevating properties. Estimates indicate that levamisole may be present in over 70% of available cocaine.

Patients with LAC cutaneous vasculopathy will typically present with purpura or ecchymosis of the pinna (at the helical margins), nose, malar area or lower extremities. The lesions are typically tender and may be necrotic. It is believed that the lesions are the result of an immune mediated process. LAC may also produce two other clinical syndromes: cocaine-induced midline destructive lesion (presenting with hard palate perforation and agranulocytosis).

There are, of course, many other conditions to consider in the differential when evaluating lesions suspicious of LAC cutaneous vasculopathy including: Wegener's granulomatosis, cryoglobulinemia, microscopic polyangiitis, idiopathic thrombocytopenic purpura, and warfarin or heparin-induced skin necrosis.

Patients suspected of using LAC should be questioned about their history of drug-use. Testing for levamisole directly is difficult because of the drug's short-half life. Directly testing for the compound requires the use of gas chromatography-mass spectrometry GC-MS or liquid chromatography-tandem mass spectrometry. Since this testing is not readily available most clinicians should order a urine toxicology screen for cocaine followed by CBC, liver and renal function tests, ANCA, cryoglobulins, antiphospholipid antibodies, lupus anticoagulant, and antihuman elastase antibody.

Most patients will see resolution of their skin lesions if they stop using LAC. There have been reports of some success with using steroids, but ultimately treatment should include cessation, local wound care and reconstruction, if necessary. Lesions typically recur if the patient resumes using LAC.

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Specialty Leadership Cabinet Report

Jeffrey P. Simons, MD,
FACS, FAAP

As the President of the Pennsylvania Academy of Otolaryngology-Head and Neck Surgery (PAO-HNS), I have had the opportunity to participate in the Pennsylvania Medical Society's (PAMED's) Specialty Leadership Cabinet (SLC). The SLC meets three times per year at the PAMED Headquarters in Harrisburg. These meetings provide an opportunity for the leadership of all of the medical specialties in the state to get together in order to share ideas and discuss issues that may be relevant across several specialties. Recent topics discussed have included the epidemic of opioid abuse in Pennsylvania, preventing wrong site procedures, legislation regarding requirements for prior authorization, legislation about nurse practitioners' scope of practice, and evaluating aging and impaired physicians. I feel that it is important for the PAO-HNS, our state specialty society, to have a seat at the table during the discussion of many of these issues. Participation in the SLC meetings will help the PAO-HNS improve our communication with other state specialty societies and with PAMED. I will keep our members up to date about any pertinent issues that arise at the SLC meetings. ●

Improved Swallow Outcomes Following Injection Laryngoplasty in Unilateral Vocal Fold Motion Impairment

Steven Zuniga MD, Barbara Ebersole MA CCC-SLP, Chetan Safi BS, Kathleen Moran MS CCC-SLP, Liane McCarroll MS CCC-SLP, Nausheen Jamal MD

Unilateral vocal fold motion impairment (UVFMI) is a known complication of head and neck and thoracic surgery, usually resulting from manipulation or transection of the recurrent laryngeal nerve (RLN)¹. As a result, the ipsilateral true vocal fold may assume a paramedian or lateral position, putting the patient at risk for dysphonia, poor cough reflex, exercise intolerance, dysphagia, and aspiration². Several techniques have been developed to address the glottic insufficiency caused by UVFMI, including voice therapy, medialization thyroplasty, arytenoid adduction, and injection laryngoplasty (IL)¹⁻⁵. An abundance of data exists supporting the safety and efficacy of injection laryngoplasty in treating glottic insufficiency resulting from VFMI^{3,4,5}. Further, given that this procedure may be performed at bedside, the dangers associated with general anesthesia for patients with a myriad of medical comorbidities may be avoided^{3,4,5}.

Many studies have described the utility of IL in improving voice quality of patients with UVFMI, but studies solely assessing its efficacy in improving swallow outcomes have been limited. While it makes intuitive sense that restoring glottic competence should result in reduced aspiration and/or penetration events, there is a relative paucity of data supporting the hypothesis that injection laryngoplasty improves swallow function in patients with VFMI. Dysphagia that leads to laryngeal penetration or tracheal aspiration can impact quality of life due to necessary diet restrictions and/or the use of postural maneuvers to prevent potentially serious complications such as pneumonia^{6,7}. Our goal in this study was to evaluate objective and subjective measures of swallow function before and after IL in patients diagnosed with UVFMI to determine potential benefits to swallow function.

A retrospective chart review was completed across a two year period on all patients diagnosed with new-onset UVFMI as determined by an otolaryngologist at a comprehensive cancer center. In order to be included in the review, patients needed to demonstrate laryngeal penetration or tracheal aspiration during functional endoscopic evaluation of swallowing (FEES) performed by a Speech and Language Pathologist. Following IL, the patient underwent repeat FEES to assess for improvement in swallow function (i.e., reduced or absent penetration or aspiration). In addition to swallow evaluation by FEES before and after IL, patients were also required to subjectively assess their swallow by completing the Eating Assessment Tool-10 (EAT-10). Recommended diet and/or diet modification, as well as behavioral modifications while eating/drinking, were also assessed before and after IL.

Eleven patients met the inclusion criteria for this study, the majority of whom suffered from UVFMI as a result of iatrogenic surgical injury or malignant invasion by local or metastatic malignancy. 3 out of 11 patients were made strictly nil per os (NPO) prior to injection laryngoplasty due to frank aspiration of all ingested contents; the remainder were required to adhere to behavioral modifications (e.g. chin tuck) with oral intake.

The 3 patients who were made NPO due to unsafe swallow were able to return to an oral diet following injection, obviating the need for alternate enteral access. All patients in the series reported improvement in their perception of swallow, including improved sensation of food bolus transit during swallow and reduced feeling of retained material in the pharynx after swallow. The 8 patients who were allowed oral diets with the use of behavioral modifications upon initial evaluation by FEES were able to discontinue the use of those behavioral modifications

(i.e. chin tuck, head turn) following IL, and reported decreased cough with thin liquids. Further, a statistically significant difference was observed between patients' pre- and post-injection EAT-10 scores, with improvement noted after injection.

Many of the patients in our cohort developed UVFMI as a result of a thoracic surgical procedure. Thoracic surgery patients often possess compromised pulmonary status and decreased pulmonary reserve as a result of disease, treatment, or other medical comorbidities, making the sequelae of aspiration notably more detrimental in this patient population⁸⁻¹¹. This is also often the case in the chronic smoker population among head & neck cancer patients. The need for alternate enteral access in those with an unsafe swallow also produces a detriment to patient quality of life and levies a psychological burden on patients already suffering from other serious disease processes¹². This preliminary, retrospective study suggests an association between injection laryngoplasty in patients suffering from UVFMI and improved swallow outcomes. IL may promote advancement of diet in patients made NPO secondary to an unsafe swallow, and improve or obviate the need for behavioral modification techniques in patients with impaired swallow function.

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Pathogenesis and Management of Radiation-Induced Xerostomia in Head and Neck Cancer Patients: A Review

James M. Hamilton, MD and David M. Cignetti, MD



Radiation is a primary component of cancer treatment – offered alone or as part of multi-modality therapy to more than 75% of head and neck cancer (HNC) patients. Survival outcomes from contemporary treatment regimens have come at the cost of debilitating toxicity in a significant proportion of patients.¹ Side effects reduce a patient's ability to tolerate and complete an entire course of radiation and many long-term survivors develop chronic toxicities that negatively impact their quality of life.

It is expected that 90-100% of HNC patients treated with radiation will develop some degree of oral complication.² Radiation effects are seen both during and long after treatment in virtually all of the targeted orofacial tissues. Direct damage to the salivary glands resulting in hypofunction and xerostomia is the most prevalent radiation side effect in the head and neck. Xerostomia is consistently reported as the major cause of decreased quality of life following treatment.³

Xerostomia can be defined objectively as a measured reduction in salivary output to 0.1 mL/minute, which often only becomes symptomatic when this represents less than 25% of a patient's baseline.^{4,5} Clinically these

numbers are not regularly measured and more frequently it is a subjective diagnosis. Scales have been developed for purposes of reporting and tracking, but their use among clinicians is inconsistent. Furthermore, the majority of research shows that there is a weak correlation between the objective measurements of salivary flow and patients' subjective complaints and difficulties.^{6,7}

Early in the course of radiation treatment, patients complain of thickened saliva and oral dryness that is typically not resolved by drinking. Discomfort caused by this dryness ranges from mild irritation to a severe, persistent burning sensation that results in difficulty swallowing and speaking. Symptoms begin shortly after initiation of therapy. Tenderness and swelling of the glands can start within 24 hours of the first day's treatment.⁵ A steep and rapid reduction of salivary flow results in a 50-60% decrease within first 3 days. By the final week of treatment, salivary flow diminishes to an average of 20% of baseline.⁸ Over the first year and a half, some recovery is possible but after that, xerostomia generally persists as an irreversible problem.^{9,10}

The mechanism behind the vulnerability of the salivary glands is non-classical. Acinar cells are highly differentiated and, unlike the epithelial cells of the oral mucosa, are almost non-cycling and therefore would not be expected to be so radiosensitive.⁸ The process occurs via two distinct mechanisms. Initially, irradiated cells do not disappear but experience disruption of membrane signaling which compromises their ability to react to neural secretion stimuli thus hampering water excretion after the first few treatment sessions. Production of amylase is initially unaffected and the resultant saliva becomes very thick and sticky early on while the population of acinar cells remains stable. As accumulated dose increases, classical cell



kill effect of radiation results in a reduction of acinar cells and damage to the extra-glandular neural, vascular and connective tissue reduces the functioning of residual cells.^{4,8}

Chronically, diminished production of saliva causes xerostomia syndrome – a collection of long-term, secondary effects including increased dental cavity formation, higher rates of acute gingivitis, difficulty with speaking, impaired taste, intraoral fungal infections and neuropathic pain symptoms in the tongue. Greater than 60% of patients will continue to experience some disability beyond three years post-treatment.¹¹

Changes attributed to hyposalivation are multifactorial. Plaque clearance is decreased and results in a shift in oral microflora creating an environment conducive to the development of dental caries.¹² Alterations in the intraoral soft tissues also lead to chronic mucosal inflammation, which gives way to atrophy and ulceration. Increased exposure can lead to necrosis of oral cavity soft tissues and bones of the craniofacial skeleton. Chronically dry oral mucosa has reduced resistance to painful bacterial infections. Increased friction makes wearing dentures painful. Difficulty with speech begins in the

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Pathogenesis

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acute phase but is long lasting. Dryness-induced challenges of bolus formation, mastication, and swallowing cause patients to make permanent changes to diet, gravitating toward softer, carbohydrate-based foods that place them at increased risk of malnutrition.⁴

A number of measures can be taken – medical, technical, and surgical - that have proven efficacy in preventing or at least mitigating these effects. Cytoprotective drugs administered during and after radiation have been shown to reduce damage to the salivary glands. Among these, amifostine is the most widely studied. A derivative of thiol selective for normal cells, it neutralizes free radicals thereby protecting the nucleus and cell membranes. Its side effects, however, including nausea, vomiting and hypotension make it challenging to administer. Additionally, evidence suggests that it is not effective when chemotherapy is added to radiation, thus limiting its use in a large number of HNC patients.^{13,14}

Pilocarpine was the subject of an RTOG study. It is an oral procholinergic that stimulates salivary flow in non-irradiated glands. Side effects include hyperhydrosis, increased bowel and bladder motility and flushing to the extent that compliance is difficult for many patients. It is contraindicated in patients with asthma, COPD, and cardiac disease – comorbidities that commonly exist in HNC patients. This study showed no effect on objective or subjective prevention of xerostomia or quality of life. Furthermore, 40% of the subjects in the treatment group discontinued the drug due to intolerable side effects.¹⁵

Through the use of intensity modulated radiotherapy (IMRT), exposure of salivary glands can be restricted through either the selective sparing of the contralateral gland in a lateralized tumor or by reduction of the dose to bilateral glands in tumors located such that they cannot be excluded from the field. Xerostomia is dose dependent. Eisbruch et al established 26 Gy as the mean dose threshold -after which damage increases exponentially and is generally irreversible. In the acute phase, glands

receiving doses below 26 Gy retained a substantial fraction of salivary output and at higher doses showed very little or non-measurable flow. Glands receiving doses below the threshold may make recovery over time. Glands receiving higher doses will not recover.¹⁰ Nutting et al published the results of the PARSPORT trial in 2011, proving its efficacy at preventing xerostomia. IMRT was directly compared with conventional radiotherapy in patients treated either definitively or adjuvantly for oropharyngeal and hypopharyngeal disease. At one year, 40% of the IMRT group had grade 2 or greater xerostomia compared with 74% of those treated conventionally based on both observer and patient-reported measures as well as objective measures of salivary flow. At two years, the benefit was increased to 29% versus 71% and, importantly, there was no difference noted in disease control.¹⁶

Though it has limited application, Jha et al demonstrated the efficacy and reproducibility of surgical relocation of one submandibular to the submental space thus sparing the gland from full dose irradiation. Their results found that clinically relevant xerostomia was prevented in 83% of patients at two years from treatment. Not available to patients with oral cavity cancer or bilateral cervical lymph node involvement, it is an option that may be most beneficial for patients in developing countries without access to IMRT techniques.¹⁷

The HPV related HNC population poses a particular challenge for long term sequelae of radiation due to its young demographic and high survival rate. Transoral robotic surgery and radiation de-escalation are being studied as means to minimize the use and dose of radiation in this group of patients.

In patients with established xerostomia, current options for the treatment are limited to the use of saliva substitutes or to stimulation of residual salivary gland capacity. Pilocarpine as well as several other pro-cholinergics may have a role in this setting. To maintain oral hygiene these patients should also be advised to self-administer daily fluoride treatments as well as chlorhexidine rinses to make every effort to prevent rapid destruction of their teeth. There is some evidence that acupuncture can result in improvement of objectively measured salivary flow rates but those studies showed no corresponding

improvements in subjective quality of life scores.^{4,18,19}

In conclusion, radiotherapy saves patients' lives and is a necessary and effective part of HNC treatment. Studies show that providers underestimate the severity of radiation-induced effects and their impact on patients' quality of life. Functional consequences not just of disease but also of its therapies contribute to the experience of patients as cancer survivors and have deleterious effects on their most fundamental human activities. These effects should be anticipated so that they may be prevented wherever possible and intervened upon early to minimize their long-term impact.

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President's Message

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Bedford, PA on June 17-18, 2016 (see update in this issue of Soundings about the Annual Scientific Meeting). Our program coordinator, Amanda Hu, MD, and the planning committee have created an outstanding program that includes topics that will be of interest to all practicing otolaryngologists as well as to residents, fellows, medical students, and advanced practice professionals. The meeting will be a great opportunity to learn, network, and socialize in a beautiful setting. I look forward to seeing you all in Bedford this June.

Finally, I feel it is important to thank our staff for all they do and recognize their hard work. I am grateful to Jennifer Keeler, our Executive Director, Kelley Richwine, Assistant Executive Director, Jessica Winger, Meeting Manager and Melanie Dupont, Member Service Specialist.

I am honored to serve as your President. I encourage you to contact me with any questions or issues that arise. ●

Board of Governor's Update

Karen A. Rizzo, MD, FACS

The Leadership Forum of the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) occurred in Alexandria, Virginia from March 18 – 21st. The forum allows physicians to access timely information that optimizes their ability to continue to deliver the highest quality health care to their patients. Physicians need information that helps knowledge gaps and offers best practices in leadership development, quality improvement, practice management, and patient education.

This year's highlights included an update on the **Regents** registry. **Regents** is the ENT clinical data registry developed by the American Academy of Otolaryngology, that will help define quality, facilitate quality reporting and meaningful use, enable the development of performance measures for our specialty, and become the foundation for research, maintenance of certification, licensure, and product and device surveillance. ICD-10 questions were addressed regarding the use of unspecified codes. Anthem, Cigna, Humana, and United Health Care will continue to accept an unspecified code if it is the most accurate reflection of the patient's condition. The health policy team works with the Academy's physician payment policy or *3P Workgroup* to address national practice management issues and monitor private payer denials experienced by members at the state and local level. Template appeal letters and advocacy statements are available to assist members with denials on specific procedures. Examples include: cerumen removal denial template, diagnostic imaging studies reimbursement, stereotactic computer-assisted navigation template, and balloon sinus ostial dilation template letter and Academy advocacy statement. To access these templates, visit www.entnet.org and search for "Template Letters" in the search function.

State and Federal Legislative Issues affecting Otolaryngology

The AAO strongly believes a physician-led hearing healthcare team with coordination of services is the best approach for providing the highest quality care to patients. It believes it is inappropriate for nonphysician provider's to expand the scope of practice beyond their education and training. The AAO opposes HR 2519 a bill that would provide audiologists with unlimited direct access to Medicare patients without a physician referral and inappropriately include audiologists in Medicare's definition of a physician. The AAO continues to oppose taxation of medical procedures as unfair for patient's, violating patient privacy, and requiring physicians to be tax collectors. It continues to advocate for increased transparency and clarity

in patient communications and interactions to help avoid confusion in the health care delivery system. With the emergence of clinical doctorate programs for nonphysician providers, many degree holders refer to themselves as doctors creating growing confusion within the patient population about the level of training and education of their healthcare providers. The AAO continues to strongly support comprehensive medical liability reform to stabilize and reduce professional liability premiums, ensure continued access to care by patient's, and eliminate frivolous lawsuits. For more information on State or Federal legislative issues or specific measures contact govtffairs@entnet.org.

Lastly, a presentation was made on behalf of our state specialty society highlighting our **Model Society Award of 2015**, demonstrating our dedication, passion, organization, and commitment to assisting otolaryngologists in Pennsylvania. ●

Karen A. Rizzo, MD, FACS (r), receives 2015 Model State Award from Wendy B. Stern, MD, Past Chair of the AAO-HNS Board of Governors. Congratulations to the PAO-HNS!





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Legislative Update

Milliron and Goodman

Budget Update

After nine months of partisan gridlock and faced with pressure from lawmakers in his own party, Pennsylvania Democratic Governor Wolf has allowed a \$6 billion supplemental budget to become law without his signature. The latest version is intended to fill in the gaps of the partial budget signed by the Governor in December. This action completes the 2015-16 budget and sets the final state spending at slightly more than \$30 billion without the need for a tax increase. It also allows critical dollars to flow to schools, hospitals and universities facing layoffs and closings. While Governor Wolf says he does not like the budget, he wants to move on and address the challenges of the 2016-17 state budget, which starts July 1. However, we expect the deep divide and differing views on the budget to continue. To wipe out the \$2 billion deficit and boost school spending, Governor Wolf is pushing for nearly \$3 billion in new and higher taxes for fiscal year 2016-17, while Republican leaders say they are committed to addressing the deficit without a tax increase.

The state House and Senate recently wrapped-up budget hearings on the Governor's 2016-17 budget proposal. During the hearings with the state Department of Health, Department of Drug and Alcohol Programs, and Department of Human Services, much of the discussion focused on the growing heroin

and opioid crisis in Pennsylvania. Governor Wolf's proposed 2016-17 budget includes \$34 M to continue the efforts to combat the heroin and opioid epidemic. The funding would be used to open 50 Department of Human Services' Opioid Use Disorder Centers of Excellence. These centers, also referred to as health homes, would serve as a hub for coordination of care services. These centers would coordinate care for people with Medicaid. Treatment would be team-based and "whole person" focused, with the goal of integrating behavioral health and primary care. In addition, the administration is moving forward with implementing the state's prescription drug monitoring program – Achieving Better Care - Monitoring All Prescriptions (ABC-MAP). The program, running a year behind schedule, is expected to launch August 2016. The program is intended to identify individuals that are at risk of opioid addiction and to get them into therapy. The Pennsylvania Department of Health recently announced the selection of Meghna Patel, MHA to lead the state Prescription Drug Monitoring Program (PDMP) Office. Patel will be responsible for developing and launching the PDMP online database that allows prescribers and dispensers of controlled substances to monitor who is obtaining opioids, who is prescribing opioids, and how often they are prescribed. Ms. Patel previously worked in various roles at Geisinger Health System. The program is expected to go live in August 2016.

Health Care

The General Assembly has introduced numerous pieces, including taxation and regulation, on electronic cigarettes. We will continue to monitor and advocate for changes to the law

in regard to e-cigarettes. We have also seen legislation introduced that would increase the age on cigarette purchase from 18 to 21. Our office and the Academy will continue to monitor these bills to help ensure the safety of patients. Chairman of the Health Committee, Representative Matt Baker introduced "World Voice Day" on our behalf. The Resolution was introduced last month and we are advocating for its passage in the very near future. This is the third session in a row we have pushed this very important recognition of the profession and patients. Legalized medical marijuana is one step closer to the governor's desk. The state House voted 149-43 for legislation (SB 3) that would allow patients with specific ailments to take the drug in pill, liquid or oil form. The bill now goes back to the Senate for its consideration of the House version. Governor Wolf has urged lawmakers to pass legislation to legalize medical marijuana and his spokesman says he is ready to sign the bill once it hits his desk. There are numerous other bills that are connected to Otolaryngology, including Truth in Advertising and Independent Practice that we continue to work on with the PA Medical Society.

Addendum to this Update:

Since this article was written the PA House has adopted April 16th to be recognized in Pennsylvania as "World Voice Day."

The Medical Marijuana bill has been approved by the Senate and was signed by the Governor on April 16.

Please do not hesitate to contact us at Milliron and Goodman Government Relations if we can be of further assistance or you have questions, (717) 232-5322. ●