PAO-HNS Otolaryngology The Pennsylvania Academy of Head and Neck Surgery

Soundings

from the Pennsylvania Academy of Otolaryngology - Head and Neck Surgery

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PRESIDENT'S MESSAGE

Jeffrey P. Simons, MD, FACS, FAAP

It is hard to believe that five months have already passed since I began my term as President of the Pennsylvania Academy of Otolaryngology-Head and Neck Surgery. We have had a productive time as an organization and have continued to work on educational, legislative, advocacy, and practice management issues pertinent to all otolaryngologists in the state.

As I mentioned in my last President's Message, the PAO-HNS was awarded the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Model State Society Award in 2015 (for the second time), the highest honor given to a state society by the AAO-HNS Board of Governors (BOG). Dr. Karen A. Rizzo, our BOG Governor, and I were present at the BOG General Assembly Meeting during the AAO-HNS Annual Meeting in Dallas this past September to receive the award.

I was also asked to give a presentation to the BOG during their Rules and Regulations Session about our state society and the things we do which make us a "model state society." This presentation was well-received by the BOG and there was a nice discussion afterwards, with many other state society representatives expressing interest in emulating some of our practices and accomplishments as a society.

I mentioned in my last President's Message that the PAO-HNS is the only organized group in Pennsylvania that helps support advocacy issues specific to otolaryngologists at the state level. I also stated that I wanted to work closely with the Pennsylvania Medical Society (PAMED) to address practice management and political issues of interest to all otolaryngologists in the state. Dr. Rizzo, who recently completed her term as President of PAMED, has been very helpful in helping the PAO-HNS foster our relationship with that society.

Another goal of mine has been to enhance our relationship with the AAO-HNS and its Board of Governors. Jennifer Keeler, the PAO-HNS Executive Director, and I recently had a very productive telephone meeting with Dr. James C. Denneny III, the Executive Vice President of the AAO-HNS, and some of the AAO-HNS staff.

We discussed ways that the two societies can work together to help otolaryngologists in Pennsylvania. The AAO-HNS promised to help us improve communication among various state otolaryngology societies and their staffs and to work with us to help address legislative and health policy issues.

The PAO-HNS recently collaborated with both the AAO-HNS and PAMED to address a health policy issue affecting many otolaryngologists in the state. One of our members brought to our attention that Independence Blue Cross (IBC) has a new policy denying reimbursement for patients on proton pump inhibitor therapy for longer than six months unless prescribed by a gastroenterologist. Our academy has put together a team to help address this issue. We obtained the support of the AAO-HNS, PAMED, and the Pennsylvania Society of Gastroenterologists. We wrote a detailed letter to the Medical Director of IBC explaining that laryngopharyngeal reflux is a common problem in otolaryngology and that management of reflux disorders is within the scope of practice of otolaryngologists. We requested that BC quickly reverse this policy and will continue to work for our members to help resolve this issue.

We are excited about our next Annual Scientific Meeting, which will be held at the Omni Bedford Springs Resort in Bedford, PA on June 17-18, 2016. Our planning committee has been hard at work, under the leadership of our Program Committee Chairperson, Amanda Hu, MD. We already have some excellent speakers lined up on a variety of topics. For example, there will

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Post Facial Palsy Synkinesis: Importance of Recognition and Review of Management

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Synkinesis is a common and distressing sequela of facial palsy, but requires physician awareness for proper diagnosis and management. It is characterized by involuntary muscle contractions that accompany volitional facial movements. Many types exist, such as involuntary eye closure with intentional mouth movements (e.g. smile), involuntary mouth movements with periocular contractions, or involuntary platysmal contractions with facial movements. Synkinesis typically presents within 3-5 months of facial nerve recovery and has been correlated with the severity of initial facial nerve injury as measured by electroneurography, electromyography, and facial nerve grading scales.[1 - 4] Several theories regarding the pathophysiologic basis of development exist, the most widely accepted is the aberrant nerve regeneration model, in which regenerating axons are misdirected to incorrect muscle groups.[5] Although recovery of the facial nerve injury may have occurred, subsequent development of synkinesis may be quite distressing, impairing one's ability to properly express emotion, decreasing quality of life, and limiting social interactions. Physician awareness and recognition of synkinesis is critical, as is the knowledge of treatment options to help care for these patients with post-facial palsy sequelae.

Diagnosis is clinical, with the physician noting the involuntary muscle contractions during volitional movements. Although three main clinician-graded systems incorporating a separate assessment of synkinesis exist, the Sunnybrook Facial Grading System has been shown to meet the most criteria for overall utility and reliability. It includes an evaluation of degree of facial palsy and a discreet assessment of synkinesis.[6] There is also a validated patient-graded instrument, the Synkinesis Assessment Questionnaire, which is easy to administer, reliable, correlates well with the synkinesis component of the Sunnybrook Facial Grading System, and offers a valuable adjunct to follow treatment.[7] In addition, one objective tool, the Mass Eye and Ear Infirmary Facial Assessment by Computer Evaluation program, is available for free, reliable, and easy to use to assess synkinesis based on frontal photographs.[8] Many other attempts at objectively grading synkinesis and outcomes based on photographic or video graphic information have been published, however they tend to be burdensome and difficult to incorporate in busy clinical practices. The instruments noted above allow for clinician -graded assessment, patient-graded evaluation, and objective assessments critical for diagnosis of synkinesis and evaluating outcomes of treatments.

Treatment of synkinesis is largely non-surgical and minimally-invasive, with surgery being reserved for the most severe cases. A large body of research has been devoted to the use of biofeedback and mime therapy for treatment of facial palsy, and to a lesser degree treatment of synkinesis. Mime therapy incorporates both facial exercises and relaxation techniques to improve facial strength while decreasing unwanted movements. It has been shown in both short and long-term studies including randomized controlled trials to decrease synkinetic contractions and improve quality of life.[9] Biofeedback involves patients performing discrete expressions and isolating muscle contractions either in front of a mirror or with electromyographic feedback. Both forms of therapy have been shown to be effective in decreasing synkinesis and are valuable in the treatment of this patient population.[10]

More pertinent to the practicing physician, a mainstay of treatment for synkinesis is the use of chemodenervation with *botulinum toxin A* injections to temporarily weaken the synkinetic musculature. This has been found to provide significant improvement in symmetry with a decrease in involuntary contractions and improvement in physician and patient-graded scales as well as objective measurements of eye opening.[11] Although chemodenervation is a temporary phenomenon, requiring repeat injections every 3-5 months, injections are well-tolerated and complications are rare, offering a strong tool for improving quality of life in this patient population.

For a select group of patients who have severe synkinesis despite the above therapies, targeted surgical interventions may be considered. Interventions include neurolysis, myectomy, nerve grafting, and even free tissue transfer. Very little exists in the literature examining the efficacy of these treatments for synkinesis, although good results are noted in case series.[12] As most patients improve with non-invasive therapies, surgery is typically reserved for recalcitrant cases.

In conclusion, development of post-facial palsy synkinesis adversely affects patients' quality of life. The most important step in care of these patients is physician recognition of the abnormal involuntary facial contractions during volitional movements. Validated subjective and objective tools exist to assist the physician in following clinical outcomes and should be incorporated in the care of these patients. Multiple non-invasive therapies exist with *botulinum toxin* A injection playing an integral role in moderating the synkinetic movements and improving quality of life.

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Reflux Disease and Laryngeal Cancer

Mir-Muhammad Razavi, BA, Mursalin M. Anis, MD, PhD and
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In 2015, there were an estimated 13,560 new cases of laryngeal cancer with an estimated 3,640 individuals who died from the disease.[1] Nearly 90,000 people with laryngeal cancer currently reside in the United States. Smoking and alcohol use are the two primary risk factors for the development of laryngeal cancer. Gastric reflux has been suggested as a risk factor, but conflicting results found in different studies, all of which have shortcomings.[2,3] The effect of extraesophageal reflux disease on the larynx has been well characterized.[4] Laryngeal mucosa is susceptible to injury from gastric refluxate containing acid and activated pepsin. Furthermore, chronic exposure to pepsin has been shown to play a role in carcinogenesis in a hypopharyngeal squamous cell line.[5] Nevertheless, the association between chronic laryngeal injury secondary to laryngopharyngeal reflux and development of laryngeal cancer has not been well elucidated.[2]

Gastroesophageal reflux disease (GERD) affects approximately 20% of North Americans. Given this high prevalence, it is pertinent to elucidate the possible association between reflux disease and laryngeal cancer.[7] Both smoking and alcohol increase reflux through their effect upon the lower esophageal sphincter.[2] Laryngopharyngeal reflux (LPR) and gastroesophageal reflux disease (GERD) are two distinct clinical entities with a shared mechanism of gastric refluxate – induced mucosal injury.[4,6]

A significant challenge to overcome in any case-control study examining reflux disease and laryngeal cancer is the confounding variables of coexisting tobacco and alcohol use. Ideally, a control population of patients without laryngeal cancer should have the same prevalence of tobacco and alcohol use as patients with laryngeal cancer. Due to the infrequent reporting of tobacco and alcohol use, previous case-control studies have struggled with matching of cases and controls.[8] Comparing newly diagnosed laryngeal cancer patients with controls matched with respect to age, gender, and ethnicity, Vaezi et. al. had demonstrated that GERD, as defined by ICD-9 designation and symptoms, was associated with laryngeal cancer.[9] Unfortunately, the 96 cases were not matched with the 192 control patients with regards to smoking. Despite this, multivariate analysis between GERD and smoking revealed that for any given amount of tobacco use, patients with GERD had increased likelihood for developing laryngeal cancer.[9] Bacciu et al. demonstrated that even among lifetime non-smokers and non-drinkers, there was a significant association between GERD and laryngeal cancer, although the number of laryngeal cancer patients was small at 36.[10] A retrospective study of the U.S. Department of Veterans Affairs patient database found an association between GERD and laryngeal and pharyngeal cancers in a predominantly Caucasian male population.[11] Their control groups were cancer-free and noted to have less documentations of tobacco and alcohol use.[11] In a pilot prospective study, Lewin et. al. showed an 85% incidence of laryngopharyngeal reflux, as measured by dual-probe pH monitoring in patients with premalignant laryngeal lesions but there were no matched controls who were tested.[12]

An association between reflux and laryngeal cancer cannot be made without accounting for the confounding variable of tobacco smoking.[3] In a retrospective study conducted at Temple University Hospital System (unpublished data), we accounted for tobacco smoking by using a control population of lung cancer patients. Both patient populations had a diverse ethnic composition who share similar risk factors yet develop different end-organ malignancies. During a 13-year study period beginning in 2000, the medical records of 290 laryngeal cancer patients and 2440 lung cancer patients were examined. Tobacco use was reported in 11% of laryngeal cancer patients and 10% of lung cancer patients. This underestimates the prevalence of tobacco smoking among both patient groups but the lack of reporting in ICD-9 nomenclature was distributed equally between the two groups.[8,11] In our study, 20% of laryngeal cancer patients and 14% of lung cancer patients had an ICD-9 designation of GERD. This correlates well with the 18% - 28% reported prevalence of GERD in North America.[7] There was a modest association between GERD and laryngeal cancer. However, the association between GERD and laryngeal cancer represents a first approximation for several reasons. Similar to other studies on this topic, we found a lack of objective criteria, such as pH probe monitoring, used to assign study patients to an ICD-9 diagnostic code for GERD. Moreover lack of ICD-9 designation for LPRD prevented a more biologically relevant association study based on diagnostic coding. Finally, implication of an association and causality can only be made if exposure precedes outcome.[8,11] The retrospective nature of these studies pose a significant challenge to establish a temporal relationship between exposure (GERD) and outcome (laryngeal cancer).

To investigate the association of reflux disease and laryngeal cancer there has been new tools in development. Lee et al. have established an immortalized cell line derived from posterior commissure squamous epithelium, which receives the greatest amount of exposure to refluxate in the larynx.[13] Various in vitro studies can then be done to characterize the molecular mechanisms of any premalignant and malignant processes inside these cells subjected to refluxate. Additionally, prospective clinical studies can be designed to examine the contribution of objectively verified reflux by pH probe on the development of premalignant and malignant lesions will lend stronger evidence for a causal association between reflux and laryngeal cancer.

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A Review of Outcomes after Transoral Robotic-Assisted Surgery

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Transoral robotic surgery (TORS) first gained FDA approval almost 10 years ago in the treatment of certain head and neck cancers. As time has passed, the indications for TORS have expanded to encompass different head and neck cancer sites, and also to encompass non-oncologic surgeries of the head and neck. More recently, clinicians have advocated for and are currently recruiting for randomized trials to evaluate the benefit of surgery (with or without adjuvant radiation) as compared to radiation (with or without chemotherapy) in the treatment of head and neck cancers. In addition to oncologic cure, it is also important to determine the efficacy of surgery in preserving function. We (with co-authors Anuraag Parikh, MD and Derrick Lin, MD) recently published a review of the current literature to summarize what the current retrospective reviews suggest about oncologic as well as functional outcomes after TORS.

In reviewing the literature, the MEDLINE database was evaluated for publications related to TORS and the initial review revealed 390 articles. Only those articles that were in English, and specifically addressed patient outcomes and also stratified their population by subsite were included. A total of 26 studies were included, specifically including the subsites of the oropharynx, and larynx, as well as the management of the unknown primary.

A total of 15 studies were found to look at outcomes of oropharyngeal resections. The review noted an increased need for free flap reconstruction in patients undergoing TORS in the salvage setting, though one article by White et al reported no need for free flap reconstruction amongst 64 patients in the salvage setting. A decreased need for free flaps was noted in comparison to open surgical techniques. The hospital length of stay was less than in the open surgical population. The articles reviewed indicated a low rate of surgical complications. Amongst patients who underwent concomitant neck dissection, Moore et al described a 28% intraoperative communication between the oropharynx and neck, with only 4% of all patients developing a fistula after surgery. In contrast, there were no fistulas reported in those articles that did the neck dissection in a staged fashion (2-4 weeks after the TORS resection).

In comparison to open surgery, the articles suggested TORS had a lower rate of wound infection and pharyngocutaneous fistula.

Amongst the articles reviewed, the rate of positive margins was noted to be between 1.5-22%. Lee et al found no difference in margin positivity when evaluating TORS, traditional transoral surgery an open surgery. There was a noted higher T stage associated with open surgery. No study compared the margin status amongst different surgical techniques while controlling for disease stage, and in general, institutions performing both open surgery and TORS reserved open surgery for more advanced disease. In this review, it was noted that between 0-59% of TORS patients underwent planned tracheotomy with the majority undergoing decannulation. Some of the articles reviewed did discuss unplanned tracheotomy for sleep apnea, oropharyngeal edema, airway protection secondary to hemorrhage, or during adjuvant therapy.

As expected, the articles reviewed described swallowing dysfunction after oropharyngeal surgery. With TORS, however, the need for gastrostomy tube placement was less and for a shorter duration as compare to open surgery, both in the primary and salvage setting. The need for gastrostomy tube was noted to be associated with T-stage and the need for adjuvant therapy.

Genden et al compared swallowing function between those treated with TORS versus chemoradiation and they demonstrated better eating and diet outcomes 2 weeks post treatment with TORS though this difference was not significant at 3-12 months after treatment. Regarding speech outcomes, no specific differences were

noted between chemoradiation and TORS. Some articles suggest the minimal impact on speech from TORS is secondary to frequently sparing the base of tongue and soft palate with the surgical resection.

A total of nine articles were reviewed regarding TORS as it pertains to laryngeal cancers. Largely, these articles looked at supraglottic carcinomas though some studies did include glottis carcinomas as well (two). Neck dissections were performed largely if there was evidence of node positive disease though one study used sentinel lymph node mapping and another performed neck dissections in all patients. Perioperative complications included bleeding and both tracheal and supraglottic stenosis. Those studies that reviewed glottis carcinomas noted that all patients presented with early stage disease (T1-T2) and had a shorter length of stay as compared to the supraglottic population. Park et al compared open partial laryngectomy to TORS supraglottic laryngectomy and found TORS to be associated with a shorter hospital stay, quicker return to oral diet as well as decannulation. When compared to transoral laser surgery, Ansarin et al demonstrated that TORS had a shorter operative time, though the authors noted increased difficulty with visualizing the tumors in the TORS group.

Functionally, some authors noted no need for tracheotomy, while others noted a quick decannulation after tracheotomy within 48 hours. Patients demonstrated a safe swallow 2-29 days after surgery. Few patients required long term gastrostomy tube dependence. Oncologically, patients required adjuvant treatment for advanced nodal disease and, amongst a few patients, for positive margins. Amongst the reviewed literature, survival rates that were reported ranged from 66.7 to 100%, but were all measured at 2 years and for early stage tumors.

When evaluating the unknown primary, TORS has been utilized to help identify the primary lesion from which there was a nodal metastasis. As such, it is being used to both remove an identified primary and/or perform a lingual tonsillectomy to identify a primary. Two articles reviewed this strategy and noted an increase in the overall identification of a primary with the addition of a TORS lingual and palatine tonsillectomy, to a rate of 77.2% and 72.3% in the two studies, respectively.

Based on this review, the current literature suggests that patients undergoing TORS demonstrate similar survival to non-surgical techniques and also to open surgical techniques. It is important to note that the current literature does not report on 5 year survival. The data suggests a decreased need for free flap reconstruction, decreased length of stay, and both a decreased need for tracheotomy as well as earlier decannulation. The review also suggests decreased complications and increased return to swallowing function as compared to open surgery, though some of these findings were not statistically significant. Its use in laryngeal cancers also demonstrates a quick return to swallowing function with limited need for tracheotomy and high survival in a 2 year time frame. TORS is also being applied to algorithms for treating patients with an "unknown primary" with success. Continued research is needed to evaluate these outcomes for the relevant subsites. Additionally, the information gained from randomized controlled clinical trials will be invaluable in evaluating TORS and how it fits in to current and future clinical paradigms.

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American Thyroid Association Releases the First Pediatric-Specific Guidelines

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The American Thyroid Association (ATA) has released its inaugural guidelines on pediatric thyroid nodules and thyroid cancer. Prior to these new guidelines, it was recommended that the management of the pediatric population with thyroid nodules and differentiated thyroid cancer (DTC) follow the adult guidelines. The pediatric population, however, has distinct biology, clinical findings, and prognosis versus adult patients. Potential for long-term adverse effects from treatment, such as an increase in all-cause mortality for pediatric patients surviving DTC consequent to post-radiation second malignancies, is also of higher concern in children versus adults.
These reasons, and the paucity of level I evidence surrounding pediatric thyroid cancer, prompted the ATA to formula pediatric specific guidelines intended for children up to 18 years of age, with a transition to adult care through age 21 years. "Management Guidelines for Children with Thyroid Nodules and Differentiated Thyroid Cancer" was published by The American Thyroid Association Guidelines Task Force on Pediatric Thyroid Cancer on April 21, 2015, in *Thyroid*.

The task force reviewed evidence regarding a variety of topics from the role of fine-needle aspiration cytology, to the use of ultrasound, to the indications for radioactive iodine therapy, to the utility of laboratory studies such as thyroglobulin. Algorithms for the evaluation and management of thyroid nodules and papillary and follicular thyroid cancers are proposed.

Knowing that disease-specific mortality for children and adolescents with DTC is lower than adults, and that children and adolescents have a presumably longer post-treatment lifespan, decreasing the adverse side effects of therapy was a primary goal of these first pediatric guidelines. One strategy proposed in these guidelines is to stage DTC preoperatively and again postoperatively in an attempt maintain low disease-specific mortality while decreasing potential complications of radioactive iodine treatment.

There are 34 distinct management and treatment recommendations comprising these guidelines. Some of those which are most applicable to otolaryngologists are summarized below.

- Children with DTC should be operated on and cared for by high-volume teams of thyroid surgeons, nuclear medicine physicians, and pediatric endocrinology. Care should be sought in centers with multidisciplinary teams and a network of pediatric and oncologic resources.
- All pediatric patients with suspicious thyroid nodules should have an ultrasound-guided FNA biopsy. Ultrasound characteristics and clinical context should be used rather than size alone to identify nodules that need to undergo FNA biopsy. This recommendation differs from the adult guidelines which incorporate size of the nodule. A thyroid nodule is the most common presentation for DTC in children, according to background information presented in the guidelines. There is also a greater risk of malignancy in nodules diagnosed in children as compared to adults, with ~25% risk in most pediatric series. If a nodule is thought to be hyper-functioning, however, preoperative FNA is not warranted as the nodule will be removed regardless of FNA results. Lastly, surgery, defined as lobectomy and isthmusectomy, is preferred in the setting of indeterminate cytology as opposed to repeat FNA biopsy.
- Regarding benign nodules, lesions should be followed by serial ultrasound with repeat FNA if there is continued growth or development of suspicious features. Even in apparently benign nodules, lobectomy should be performed in solid nodules >4cm, lesions demonstrating growth, or in children with other clinical signs of malignancy.
- Surgical resection, usually lobectomy, is recommended for autonomous nodules in the pediatric population. Autonomous nodules are defined in the guidelines as patient with a suppressed TSH with a thyroid nodule, confirmed with increased uptake on thyroid scintigraphy.
- In the management of DTC, total thyroidectomy is recommended to the majority of children, based on the higher likelihood of multi-focal and bilateral disease in children and adolescents. Furthermore, central neck dissection is recommended for children with malignant cytology on pre-operative FNA of neck lymphadenopathy and for children with clinical evidence of gross extrathyroidal invasion or loco-regional disease. Dissection should follow levels of the neck; "berry picking" is discouraged.
- Importantly, the guidelines recommended a novel grouping system for pediatric thyroid cancer based on the TNM classification system: "ATA Pediatric Low Risk", "ATA Pediatric Intermediate Risk", and "ATA Pediatric High Risk". This risk stratification is largely based on regional lymph nodes and distant metastasis staging, as the extent of nodal disease in the neck at diagnosis may be the best correlate with the risk for distant metastasis or disease requiring additional treatment. Children and adolescents should be staged again within 12 weeks of surgery. Low-risk patients may be followed with a TSH-suppressed thyroglobulin alone. A TSH-stimulated thyroglobulin and a diagnostic whole body scan are typically recommended for intermediate- and high-risk patients.

- Neck ultrasound if recommended in the follow up of children with papillary thyroid cancer, and should be performed at least 6 months after initial surgery, and then at 6-12 month intervals for pediatric intermediate- and high-risk patients and annually for low-risk patients.
- Children with differentiated thyroid cancer should be followed for life, as recurrence has been reported up to 40 years after initial therapy.

It is important for all otolaryngologists managing children and adolescents with thyroid nodules and thyroid cancer to be familiar with these new ATA pediatric guidelines. Ultimately, they will help to decrease variability of care and improve outcomes for children with thyroid nodules and thyroid cancer.

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be a multidisciplinary panel on Human Papilloma Virus, an otology session, and a patient advocacy/practice management session. There will also be a session geared towards residents, including the popular resident bowl competition. We will continue to encourage resident research through our poster and podium presentations and research awards. The meeting will be a great opportunity for practicing otolaryngologists, residents, and fellows to network and socialize in a beautiful setting. I encourage you all to mark these dates on your calendar and plan to attend.

I wish you all a happy, healthy holiday season. I am honored to serve as your President. I encourage you to contact me with any questions or issues that arise.

Drug Induced Sleep Endoscopy (DISE) for Evaluation of Sleep Disordered Breathing:

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Obstructive sleep apnea syndrome (OSAS) is a disorder characterized by collapse of the upper airway leading to cessation and reduction of airflow associated with oxygen desaturation. It is caused by both anatomic abnormalities as well as alteration in neuromuscular tone, which lead to collapse of the upper airway.

The disorder affects roughly 2% females and 4% of males impacting an estimated 18 million Americans. It is responsible for significant decrease in quality of life and related to poor sleep for both the patient and bed partners. In addition, it has been causally linked to a significant increase in morbidity and mortality. Some of the many disease processes that have been associated with untreated OSA include: myocardial infarction, depression, CHF, CVA, and diabetes.[1]

Traditional treatment for OSA centers on continuous positive airway pressure (CPAP) therapy. CPAP is effective in reducing the airway obstruction in the majority of patients and has been shown to have significant short and long term benefits including: improved sleep quality, alertness, depressive symptoms, blood pressure control, heart function, and mortality.[2] However, despite the documented improvements in morbidity and mortality, tolerance to the device is not universal and treatment adherence remains an ongoing issue. In a meta-analysis by Weaver and Grunstein, non-compliance to CPAP therapy ranged from 46-83% leaving many patients untreated.[3]

Given this underserved population, alternative therapies for treatment of OSA have emerged. These include but are not limited to: expiratory positive airway pressure (EPAP), oral appliances (mandibular repositioning devices), and surgical intervention. Literature exists in support of all of these therapies.[4,5,6] However, outcomes are inconsistent and providing the optimal treatment for an individual patient must take into account patient preferences and as well as the therapy that has the best potential to relieve the airway obstruction. This remains one of the biggest challenges in treating OSA afflicted individuals owing to significant variability in the anatomy and physiology that can be responsible for the airway obstruction. In addition, there is compelling evidence that surgery for OSA may have poor outcomes if the site and mechanism of airway obstruction are not appropriately assessed. As such it is critical to accurately characterize the nature of a patients airway obstruction in order to optimize results.

Some of the tools for evaluation of the OSA airway include: comprehensive physical examination, nasopharyngolaryngoscopy, and diagnostic imaging (cephalometry, computed tomography, and magnetic resonance imaging). While these all remain important aspects of patient care, little evidence suggests that they can reliably improve outcomes. The static nature of these tests may not accurately depict the dynamic airway collapse and the fact that they are typically performed in an awake patient may not reflect what occurs during sleep.

Thus, a newer modality for examination of the airway has surfaced called drug induced sedated endoscopy (DISE). This was originally described by Croft and Pringle in 1993.[7] They used midazolam as a sedating agent and demonstrated the utility of passing a fiberoptic endoscope to assess the airway for sources of obstruction. Despite its initial description, the technique did not gain more widespread acceptance until more recently. The goal of DISE is to pharmacologically reproduce airway obstruction that occurs during sleep so that it is possible to identify not only sites of airway obstruction but also the mechanism by which these areas collapse.

Indications for DISE include any patient with an established diagnosis of OSA for whom surgery or a mandibular advancing device is being considered in the treatment algorithm. It is not considered mandatory for all patients and is not necessary in patients who are already successfully utilizing CPAP or other alternative therapies. In addition, contraindications for use include: nasal obstruction that would prohibit safe passage of a fiber-optic scope, pregnancy,

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or an unsafe airway that could not be easily managed by the operative and anesthesia team.

The technique for performance of DISE is as follows: patients are brought to an operating room or endoscopy suite with cardiorespiratory monitoring. A topical decongestant can be administered to one or both nostrils and an anticholinergic agent is administered intravenously (to minimize secretions). The patient is laid supine in as natural a sleeping position as possible (e.g. use of pillows as warranted). Sedation is administered by an anesthesiologist, most commonly with a propofol bolus of 1.5mg/kg or continuous infusion (midazolam has also been well described). Medication is titrated to induce loss of consciousness without over sedation (this can cause loss of upper airway tone and yield incorrect assessment of airway obstruction).

A bispectral index score (BIS) system can be helpful to monitor depth of anesthesia but is not critical for success. A flexible endoscope is passed transnasally to perform a comprehensive examination of the upper airway including: the nasal cavity, nasopharynx, velum, oropharynx, tongue base and hypopharynx. Ideally the flexible endoscope has video recording capabilities so that the study can be reviewed postoperatively as necessary. During the DISE, a chin lift and jaw thrust should be performed with analysis of the airway during the maneuvers. This can help assess the therapeutic affect of head positioning during sleep as well as the potential success of mandibular repositioning devices. Additionally, if there is a question as to the efficacy of mandibular repositioning device that a patient has been using, the study can be conducted with this in place to objectively identify its impact. After the study, findings are documented and patients can be counseled regarding recommendations for treatment.

Different classification schemes have been proposed to describe the airway during DISE and surgeons should utilize a system with which they feel comfortable will provide a standardized means of analysis. One system that is commonly employed is the VOTE classification. Kezirian et al originally proposed this in 2011.

This breaks down the airway into the: velum, oropharynx, tongue base, and epiglottis. At each site, the degree of obstruction can be noted as none (less than 50%), partial (50-75%) and complete (greater than 75%). Additionally, commentary can be made as to whether collapse occurs at each site in ananterior-posterior, lateral or concentric pattern.[8]

Complications of DISE may include: epistaxis secondary to passage of the endoscope, laryngospasm, loss of airway, and aspiration. Because sleep apnea patients, by definition, have abnormal airways, the potential for airway loss should always be anticipated and it is critical to have an operative team that includes an anesthesiologist and equipment that would allow positive pressure ventilation if needed. Despite the potential for complications, described adverse effects have been exceedingly rare.

Critics of DISE as a technique suggest that pharmacologically induced sleep does not represent normal sleep. Certainly, it is not possible to replicate all the different stages of sleep with propofol or other sedating agents and this could confound the ability to truly understand a patient's physiology and anatomy. However, to refute this, a study by Berry et al found that asymptomatic patients did not snore during target controlled propofol infusion whereas all symptomatic patients elicited snoring in similar circumstances.[9]

Additionally, given the subjective nature of the evaluation, there is question as to the reliability of DISE. Kezirian addressed this concern in a study in which they identified moderate to substantial inter-rater reliability.[10] Additionally, Rodriguez-Bruno noted that DISE has good reliability particularly in assessment of hypopharyngeal obstruction.[11]

To date, there have been no studies that assessed whether the findings by DISE can reliably predict success of surgical treatment in patients with OSAS. There is one publication that reported that the findings altered surgical decision-making in 62% of cases. However, it did not make reference as to whether it improved the surgical success.[12]

With the advent of newer techniques for airway modification, (e.g. expansion pharyngoplasty, Z-palatopharyngoplasty, TORS, etc.) there is a need for improved assessment of the airway to individualize treatment and optimize outcomes. DISE is one tool that may help achieve this goal. Additionally, it is considered a critical component of evaluation of patients who are being considered for upper airway stimulation as a treatment of their OSA.[13, 14]

Overall, DISE is a safe and reliable tool in the assessment of the sleep apnea airway. When used appropriately, it may be possible to individualize treatment for both surgery and mandibular repositioning devices. Clearly, further scientific study is needed to see how this diagnostic modality is best utilized to optimize outcomes.

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Pennsylvania Medical Society Quarterly Legislative Update September 2015

As of this writing, Pennsylvania's state budget for the 2015-2016 fiscal year is nearly three months overdue, with little indication that Gov. Wolf and legislative leaders are getting any closer to reaching an agreement on taxes and spending.

Of course, the situation could change quickly, and hopefully by the time you read this there will be some sort of breakthrough. In the meantime, school districts and social service agencies are beginning to feel the pain that comes with the lack of their annual state funding.

However, the state budget stalemate has not prevented legislative and regulatory action on other issues, many of which are health care-related. Following is an update on some of those actions that have occurred over the summer.

Expunging Minor Violations from a Practitioner's Disciplinary Record

SB 538, legislation that would expand the obligation of professional licensees to notify their licensing board when they run afoul of the criminal law or another state's licensing body, is just one step away from the governor's desk, needing only Senate approval of amendments added by the House, which could occur in the near future.

One of the House amendments could benefit physicians and other licensees who have a minor transgression on their disciplinary record. Should the bill become law, certain violations could be expunged (erased) from a licensee's record, provided that certain conditions have been met.

The types of violations that would be eligible for erasure fall into one of two categories:

1. failure to complete continuing education requirements or practicing for six months or less on a lapsed license, registration, certificate or permit.
   At least four years must have elapsed since the final disposition of the disciplinary record at the time of application for expungement; and
2. any violation, except those which resulted in license suspension or revocation, in which at least 10 years have elapsed since the final disposition of the disciplinary record at the time of application for expungement.

Thus, only minor violations would be eligible for expungement, and some time needs to have gone by since the problem was resolved. Anything serious enough to have warranted a license suspension or revocation would stay on a licensee's disciplinary record permanently.

Other conditions would also have to be met in order for a licensee to apply to have a disciplinary black mark removed. Specifically:

1. the licensee must make written application for expungement not earlier than four years from the final disposition of the disciplinary record;
2. the disciplinary record must be the only disciplinary record that the licensee has with either the commissioner or a licensing board or commission under the commissioner's jurisdiction;
3. the licensee must not be the subject of an active investigation related to professional or occupational conduct;
4. the licensee must not be in a current disciplinary status, and any fees or fines assessed must be paid in full; and
5. the licensee must not have had a disciplinary record previously expunged by the commissioner. You only get one bite at this apple.

As indicated, the bill may be enacted soon, and if so PAMED will provide all the information physicians need to initiate the process of requesting expungement of old, minor violations from their disciplinary record.

Gov. Wolf's 2015 Regulatory Agenda

On July 25, the Governor's Office released its Regulatory Agenda for calendar year 2015. The purpose of the Governor's Regulatory Agenda is to provide advance notice of upcoming regulatory activity. The publication represents the Administration's intentions regarding future regulations.

Following is a brief summary of the regulations proposed for action:

Achieving Better Care by Monitoring All Prescriptions Programs: The Department of Health plans to release proposed regulations to support the implementation of the forthcoming prescription drug monitoring program—Achieving Better Care by Monitoring All Prescriptions Programs (ABC-MAP)—in Spring 2016. The Department anticipates that these regulations will (1) improve the quality of patient care in Pennsylvania by providing prescribers and dispensers access to information about all controlled substances dispensed to a patient, and (2) aid regulatory and law enforcement in the detection and prevention of fraud, drug abuse, and criminal diversion of controlled drugs.

Anesthesia Regulations: The State Board of Dentistry plans to issue proposed regulations updating the standards for administration of general anesthesia, deep sedation, moderate sedation, minimal sedation, and nitrous oxide/oxygen analgesia in dental offices to conform to and adopt the current standards used by the dental profession.

Child Abuse Reporting Requirements: This winter, the State Board of Medicine and the Osteopathic Board of Medicine, plan to issue regulations to update the Board's existing rules regarding the mandatory reporting of suspected child abuse pursuant to the recent amendments to the Child Protective Services Law (CPSL).

Compounding Regulations: This fall, the State Board of Pharmacy will issue, as proposed, updated regulations to improve the profession's safe, sterile practices and procedures for the compounding of pharmaceutical products for patients.

Health Care Worker Identification Badge Regulations: Specific provisions of the 2011 Photo Identification Tag Regulations law went into effect on June 1, 2015. Even though the law related to the use of titles (e.g., Doctor, Nurse, etc.) and their precise placement on the badge did not go into effect until June 2015, many of those affected by the law (particularly physicians) have been in compliance with all components of the law since it was passed in 2011. This fall, the Department of Health plans to release proposed regulations for this law.

Injectable Medications, Biologicals, and Immunizations: The Board of Pharmacy plans to issue proposed regulations to implement the 2015 amendments to the Pharmacy Act this winter. These amendments allow a pharmacist to administer influenza vaccine to patients beginning at age nine and allow pharmacy interns to administer injectable medications, biologicals, and immunizations.

Laser Regulations: This fall, the State Board of Medicine will issue proposed regulations to clarify the requirements for the use and delegation of the use of medical lasers. The proposed rule will bring the Board's regulations in line with the majority of other states with regulations related to these devices.

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Osteopathic Prescribing Regulations: This fall, the State Board of Osteopathic Medicine anticipates its release of regulations to outline the minimum acceptable standards of practice that an osteopathic physician or physician assistant licensed by the Board must follow when prescribing, administering, or dispensing controlled substances or one specific additional drug which shares serious potential for addiction and abuse (butalbital). According to the Board, butalbital is a barbiturate that is known to have addictive and abuse potential and is prone to overuse by the consumer.

Medical Marijuana

Legislation to legalize medical marijuana has cleared the state Senate by a vote of 40-7, and now awaits House action. Senate Bill 3, introduced by Sen. Mike Folmer (R-Lebanon County), was the subject of House and Senate public hearings earlier this year.

PAMED testified at the hearings, repeating our position that the FDA should relax marijuana's status as a Schedule I drug to facilitate testing of a substance that seems to have some promise in treating children with epileptic seizure disorders, nausea in cancer patients, and other conditions. PAMED also believes the state should fund pilot studies that the Department of Health laid the groundwork for last year. However, until solid research results are in hand, the Society believes legalization would be premature.

The bill's scope is broad, and goes beyond the legalization of cannabidiol, the non-psychoactive component of marijuana that seems to help some children with seizure disorders.

SB 3 would also legalize THC, the psychoactive component of marijuana, to treat cancer, epilepsy and seizures, ALS, cachexia/wasting syndrome, Parkinson's disease, traumatic brain injury and post-concussion syndrome, multiple sclerosis, Spinocerebellara Ataxia (SCA), post-traumatic stress disorder, severe fibromyalgia, HIV/AIDS, glaucoma, and other conditions authorized by the Department of State pursuant to review initiated by a patient petition.

The bill originally would have permitted the medical use of marijuana edibles, raising concern over the risk of diversion and unintended harm. However, the Senate State Government Committee deleted edibles from the bill on April 21, while adding nebulizing (smoking and vaping would be prohibited).

The bill would authorize up to 65 growers and another 65 processors, raising questions about product consistency.

The bill as introduced would have permitted physicians, CRNPs, nurse midwives and physician assistants to all "recommend" medical marijuana to patients. However, the committee-approved amendment restricts that authority to physicians.

The bill provides that the Commonwealth cannot be held liable for any deleterious outcomes resulting from the medical use of cannabis by a registered patient. However, no similar protection is given to health care practitioners who would actually "recommend" non-FDA approved marijuana medications to their patients.

PAMED was recently joined by the following physician specialty societies in sending House members a joint letter expressing opposition to premature legalization of medical marijuana:

Pennsylvania Society of Anesthesiologists
American College of Physicians
Pennsylvania Allergy and Asthma Association
Pennsylvania Neurosurgical Society
Robert H. Ivy Society of Plastic Surgeons
Pennsylvania Society for Pulmonary Disease
Pennsylvania Rheumatology Society
Pennsylvania Chapter of the American College of Cardiology
Pennsylvania Occupational and Environmental Medical Society
Pennsylvania Academy of Otolaryngology
Pennsylvania Chapter of the American Academy of Pediatrics
Pennsylvania Psychiatric Society
Pennsylvania Chapter American College of Emergency Physicians

Nevertheless, there appears to be considerable rank and file support for medical marijuana among House members, though House leaders have taken a cautious, go-slow approach, and have spent much of the summer working to address concerns with the Senate legislation. Watch for a more modest House proposal to emerge early this fall.

Controlled Substances Database Progress Update

It now appears certain that the long-awaited statewide controlled substances database will not be operational until sometime in 2016. That word comes from the Department of Health, which is charged with housing the program.

The law creating the database, Act 191 of 2014, set June 30, 2015, as the date it was supposed to be operational, but that didn't happen, for a number of reasons.

First, creating a robust, interactive system that will be used daily by thousands of health care practitioners is no small task. And while it's disappointing that Pennsylvania is the only state besides Missouri that doesn't have an operational database, we do benefit from the opportunity to look at what other states have done and identify best practices. The Department is doing that now, and it takes some time.

The second problem is money. The $2.1 million earmarked to build and operate the system for the next year is tied up in the ongoing state budget stalemate. How long it will take to resolve that impasse is anyone's guess. Fortunately, the state recently received a $900,000 grant that can be used to get the ball rolling financially.

The board that is to run the database, made up primarily of Gov. Wolf cabinet members, held a public meeting on Sept. 15, and revealed that the process of selecting a vendor to build the system is now under way. That process should be complete before the end of the year, but then comes the task of actually creating the database. Hence, the likelihood that the program won't be operational until 2016.

Allowing Traveling Team Physicians to Treat Players without a Pennsylvania License

Most sports fans are aware that college and professional teams often bring their team physicians with them when they travel to another state to compete. This makes sense, because the team physician would be most familiar with the players, along with any injuries or other medical conditions they may be dealing with.

This seemingly straightforward situation becomes complicated if the out-of-state team physician actually treats a player while they are competing in Pennsylvania, because our state law requires physicians to be licensed in Pennsylvania in order to practice here. Thus, under the letter of the law a duly licensed out-of-state team physician who has an established physician/patient relationship with the team's players, and who may be treating them for anything from asthma to post-concussion follow-up to a sore knee, technically must stand aside and allow a Pennsylvania-licensed physician, who likely doesn't know the players at all, to treat them when the team is playing in Pennsylvania.

In order to address this situation, 21 states currently allow for visiting team physicians to practice in their state without meeting home state licensing requirements.

As indicated above, Pennsylvania is not among them. However, Sen. Jake Corman (R-Centre County), whose district includes Penn State's main campus in State College, has introduced legislation that would ease our physician licensing requirements in those circumstances.

SB 685 and 686 (one for MDs and one for DOs) provide that any visiting team physician who is licensed in their home state and has an agreement with a sports team to provide care for the team while traveling, may treat the team's players while they compete in the Commonwealth without a Pennsylvania license.

Specifically, under the bills a physician who is licensed in good standing to practice in another state is exempt from the licensure requirements of Pennsylvania's Medical Practice Act and Osteopathic Medical Practice Act while practicing in the Commonwealth if either of the following apply:

(1) The physician has a written or oral agreement with a sports team to provide care to the team members and coaching staff traveling with the team for a specific sporting event to take place in the Commonwealth, or

(2) The physician has been invited by a national sport governing body to provide services to team members and coaching staff at a national sport training center in this Commonwealth or to provide services at an event or competition in this Commonwealth which is sanctioned by the national sport governing body (think Little League World Series) so long as: (i) The physician's practice is limited to that required by the national sport governing body, and (ii) The services provided by the physician must be within the area of the physician's competence.

A physician who is exempt from Pennsylvania licensure under the bills would not be permitted to provide care or consultation to any Commonwealth resident other than those specifically allowed by the legislation, or practice at a health care clinic or health care facility, including an acute care facility.

The Senate Consumer Protection and Professional Licensure Committee approved the bills without objection on Sept. 17, and the measures could receive consideration by the full Senate in the near future.

Milliron and Goodman Legislative Update

Budget Update

Pennsylvania's budget stalemate is in its fifth month. Democratic Governor Tom Wolf and lawmakers are still working out the details of a plan that could possibly end the budget stalemate or have an agreement in place by the end of November. While the conversation is still fluid, we are hearing that the preliminary framework includes a sales tax increase, expanded school property tax cuts and hundreds of millions of new dollars for public schools.

The potential deal involves an increase from 6 percent to 7.25 percent in the state sales tax, generating $2 billion that would be used to reduce property taxes. Two other tax increases originally proposed by Gov. Wolf — a hike in the personal income tax and the establishment of a severance tax on natural gas drilling — are not part of the discussion. Other revenue sources, including a tobacco tax, are also being discussed.

Gov. Wolf's proposed budget called for expanding the sales tax to dozens of new goods and services, including healthcare services. Adding the sales tax to healthcare services would be very substantial to your patients. Milliron and Goodman has been and continues to be actively engaged on this issue.

Post-Election Update: Democrats Take Control of PA Supreme Court; State Senate GOP Gains Seat; Four Legislators Win Municipal/Judicial Elections

Voters across the Keystone State headed to the ballot box on November 3 to fill a variety of county and local offices. Statewide, voters filled seats on the three appellate courts and a special election was also held to fill the 37th District state Senate seat. Democrats won big, sweeping the Pennsylvania Supreme Court, Superior Court and Commonwealth Court races while Republicans captured a Senate seat in western Pennsylvania. Four members of the Pennsylvania General Assembly were also declared winners in this year's municipal and judicial elections. For details on the recent election, visit the Members Only page at www.otopa.org.

Grassroots Advocacy

Grassroots advocacy is a powerful tool and an important complement to the lobbying efforts of the Milliron & Goodman team. Elected officials want to hear from their constituents, the people that elected them and can re-elect them. Building strong, personal relationships with legislators and their staff is one of the most important aspects of advocacy.

In the short-term, you are putting a face on an issue that allows legislators to connect beyond the facts and figures. In the long-term, you are developing legislative champions that will seek your advice and be your voice in the Capitol.

With the comings and goings of the Pennsylvania General Assembly, there are fewer legislators with in-depth knowledge of otolaryngologist issues. This session alone there are over thirty first-term legislators and we anticipate another new wave of faces next year. It is now more important than ever to get to know your legislators and inform them about crucial healthcare issues important to PAO-HNS members and their patients.

Whether it's a reception to introduce yourself, having coffee or lunch to discuss an issue, or inviting your legislator to your office, all are examples of grassroots advocacy and effective ways to build relationships with your legislators. If you have any questions, please do not hesitate to contact M&G at 717.232.5322. We have an open door policy.

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