

SELECTED ABSTRACTS

***ORAL
PRESENTATIONS***

IN ORDER OF PRESENTATION



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AMERICAN OTOLOGICAL SOCIETY

Does Frailty or Age Increase the Risk of Postoperative Complications following Cochlear Implantation?

*Steven A. Gordon, MD, MPH; Neil S. Patel, MD
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Objective: Evaluate whether frailty or age increase the risk of postoperative complications following cochlear implant (CI) surgery.

Study Design: Retrospective cohort study

Setting: Tertiary academic center

Patients: Adult patients undergoing CI surgery from 2006-2020.

Interventions: In addition to demographics and postoperative complications, the modified 5-item frailty index (mFI, comprised of pre-operative history of pulmonary disease, heart failure, hypertension, diabetes, and partially/totally-dependent functional status) was calculated for all patients included in analysis.

Main Outcome Measures: The primary outcome was postoperative complications following CI within a three-month period. Major complications included myocardial infarction, bleeding, and CSF leak, among others. Predictors of postoperative complications were examined using odds ratios (OR) and multivariate logistic regression.

Results: There were 520 patients included for review with a mean age of 62.5 ± 0.9 (range 18-94) and a slight male predominance (n=283, 54.4%). There were 340 patients (65.4%) who were robust (non-frail) with an mFI of 0, while 180 (34.6%) had an mFI of ≥ 1 . There were 20 patients who experienced a postoperative complication (3.85%). There was no statistically significant correlation between post-operative complications as a result of pre-operative frailty with either $mFI \geq 1$ (OR 1.56 CI .98-2.48 $p=0.06$) or age as a continuous variable (OR 0.99 CI 0.97-1.02 $p=0.51$).

Conclusions: CI is safe for elderly and frail patients and carries no additional risk of complications when compared to younger, healthier patients. While medical comorbidities should always be considered perioperatively, this study supports the notion that implantation is low risk in older, frail patients.

***Define Professional Practice Gap & Educational Need:** Anecdotally, patients and clinicians may believe that the very elderly should not be considered for cochlear implantation due to the risk of surgery and general anesthesia. While much literature has been devoted to the safety of cochlear implantation in older patients, there is a paucity of studies focused on how an accurate metric for significant medical comorbidities (frailty) directly impacts the postoperative course of these patients. This study suggests that CI is safe for even very frail patients who are deemed potential surgical candidates.

***Learning Objective:** Understanding frailty's predictive ability on postoperative complications following cochlear implantation

***Desired Result:** To offer an additional means to measure pre-operative risk of adult CI patients

Level of Evidence - Level III

Indicate IRB or IACUC: University of Utah IRB: IRB_00105049

Cochlear Implantation and Risk of Falls in Older Adults

David R. Grimm MS, Shayan Fakurnejad, MD; Jennifer C. Alyono, MD

Objective: To examine whether cochlear implantation(CI) increases the risk of falls in older adults.

Study Design: Retrospective analysis of de-identified administrative claims from a US commercial insurance database.

Setting: US hospital and outpatient facilities serving commercially insured patients documented through the Optum database.

Patients: Individuals undergoing CI over age 50.

Interventions: Cochlear implantation.

Main Outcome Measures: Gender, race, income, age, fall diagnosis days one year pre/post CI, and comorbidities documented via ICD9/10 codes.

Results: Between 2003-2019, 3773 patients over the age of 50 underwent CI. Of these patients, 139(3.68%) patients recorded at least one fall diagnosis a year prior to CI, and 142(3.76%) patients recorded at least one fall diagnosis post-CI. The average numbers of days with fall diagnoses per patient with a recorded fall was 3.12 prior to CI, and 2.04 post-CI. In bivariate analysis, age($p<0.0001$) and Charlson Comorbidity Index($p<0.0001$) were predictive of falls, but gender($p<0.10$), race($p<0.72$), and income($p<0.51$) were not. Significant covariates were incorporated into a generalized estimating equation Poisson regression along with fall counts before and after CI. The Poisson regression demonstrated a statistically significant association between Charlson Comorbidity Index and days with fall diagnoses(RR 1.39[95% CI, 1.30-1.49; $p<0.0001$]). No statistically significant difference in falls was seen pre-CI vs post-CI(RR 0.67[95% CI; 0.34-1.33; $p<0.25$]). Age also was not predictive of falls in multivariate analysis.

Conclusions: CI does not appear to increase the risk of falls in older adults. Patient comorbidities correlate most strongly with fall risk, and should be considered in patient selection for CI.

Define Professional Practice Gap & Educational Need: Prevalence of cochlear implantation in an aging population has increased over the past decade and a half. We aim to address concerns whether cochlear implantation will lead to increased fall risk by utilizing a large scale real-world medical claims database.

Learning Objective: To better understand factors contributing to fall risk post cochlear implantation in older adults receiving a cochlear implant for the first time.

Desired Result: Among the patients selected to undergo CI in the United States, cochlear implantation does not appear to increase fall risk.

Level of Evidence - Level IV - Historical cohort or case-control studies

Indicate IRB or IACUC: Exempt

Caregiver Quality of Life after Cochlear Implantation in Older Adults

*Alana Aylward, MD; Morganne Murphy-Meyers, BS; Chelsea McCarty Allen, PhD;
Steven A. Gordon, MD, MPH; Neil Patel, MD; Richard K. Gurgel, MD, MSCI*

Objective: To evaluate factors affecting quality of life (QOL) in caregivers of older cochlear implant (CI) recipients.

Study Design: Cross sectional survey

Setting: Academic medical center

Patients: Adults over age 65 receiving CI between 7/13/2000 and 4/3/2019.

Interventions: Cochlear implantation

Main Outcome Measures: Linear regression models for caregiver QOL measured by Significant Other Scale for Hearing Disability (SOS-HEAR), with independent variables: caregiver role, patient gender, 11 factor modified frailty index (mFI), duration of hearing loss, hearing aid use, age at surgery, time since surgery, change in pure tone average (PTA), processor input type and Nijmegen Cochlear Implant Questionnaire (NCIQ). Correlations between SOS-HEAR and patient speech recognition scores.

Results: Questionnaires were mailed to all 294 living CI recipients. Seventy-one caregivers completed the questionnaire. Only patient gender and mFi were significant predictors of caregiver QOL on both univariate ($p < 0.001$, $\beta = -20.26$ (95% confidence interval -30.21, -10.3); 0.005, -0.72 (-1.20, -0.23) respectively) and multivariate ($p = 0.005$, $\beta = -20.09$, -33.05 to -7.13; 0.003, -0.93 (-1.50, -0.37)) analysis, where caregivers of male patients and those with lower mFI (better health) had better QOL scores. Caregiver QOL was significantly associated with patient's change in PTA and self-reported QOL scores on univariate ($p = 0.041$, $\beta = -0.27$ (-0.52, -0.02) ; 0.024, 0.52 (0.08, 0.96)) but not multivariate analysis. Time since CI was significant only on multivariate analysis (0.041, -0.17 (-0.33, -0.01)). Caregiver QOL did not correlate with patient speech recognition scores.

Conclusions: Caregivers of older CI recipients who have better health and/or are male have higher QOL scores. Patient hearing measurements did not correspond with better caregiver QOL.

***Define Professional Practice Gap & Educational Need:** While it is recognized that CIs benefit older adults, little is known about how CIs affect the caregivers of those older adults.

***Learning Objective:** Understand what factors impact quality of life in caregivers of older patients with CIs.

***Desired Result:** To describe the QOL benefits to caregivers when applicable for CI recipients.

Level of Evidence – Level III

Indicate IRB or IACUC: IRB approved, University of Utah IRB_00088392

Utilization of Aural Rehabilitation and Listening Activities and Its Influence on 3-6 Month Cochlear Implant Outcomes in Adults

*James R. Dornhoffer, MD; Priyanka Reddy, BS, Cheng Ma, BS
Judy R. Dubno, PhD; Theodore R. McRackan, MD, MSCR*

Objective: Assess associations between post-cochlear implant (CI) aural rehabilitation/listening activities and outcomes related to speech recognition and CI quality-of-life (CIQOL).

Study Design: Longitudinal, prospective assessment of aural rehabilitation and listening activity utilization.

Setting: Tertiary academic center

Patients: 64 adults undergoing cochlear implantation for bilateral severe-to-profound hearing loss

Interventions: Self-reported use of three categories of aural rehabilitation at 3-months post-CI: (1) clinician-directed (e.g., speech pathologist), (2) passive patient-directed (e.g., listening to audiobooks), and (3) active patient-directed (e.g., interactive software).

Main Outcome Measures: Consonant-Nucleus-Consonant (CNC) word, AzBio sentence, and CIQOL-35 Profile global and domain scores, at 3- and 6-months post-CI.

Results: Of 64 patients, 41 (64%) used one or more rehabilitation resources. Of those, 19% used clinician-directed, 52% passive patient-directed, and 31% active patient-directed. At 3-months post-CI, use of rehabilitation in any category was associated with better speech recognition ($d=1.17-1.18$) and improved global and domain-specific CIQOL scores (d -range=0.15-1.26) at the same timepoint. Use of active patient-directed resources demonstrated greatest effect, with better speech recognition (CNC: $d=0.89[0.24, 1.55]$; AzBio: $d=1.14[0.47, 1.81]$) and global and domain-specific CIQOL (d -range=0.07-1.09). Similar effects were seen 6-months post-CI, with active resources utilization showing the most consistent benefits. Controlling for age, sex, income, and simultaneous utilization of multiple rehabilitation resources, active patient-directed resources at 3-months remained the strongest predictor of CNC, AzBio, and CIQOL scores at 3 months ($\beta=20.6[2.46, 38.73]$, $\beta= 25.18[7.12, 43.23]$, and β -range=6.7-18.7, respectively).

Conclusions: These results suggest that aural rehabilitation and listening activities, especially self-directed, improves early outcomes for CI recipients. Randomized controlled studies are needed to confirm findings and better examine the impact of clinician-directed rehabilitation.

Define Professional Practice Gap & Educational Need: Adult CI recipients are generally recommended to pursue post-implant aural rehabilitation exercises; however, evidence demonstrating the benefit is largely anecdotal or absent.

Learning Objective: To explore patterns of aural rehabilitation that may be associated with improved speech recognition and CI-specific quality of life.

Desired Result: Practitioners and researchers will recognize that the utilization of post-implant aural rehabilitation is associated with improved CI outcomes, and active forms of rehabilitation (e.g., computer programs) may have the strongest impact. As such, clinicians may offer evidenced-based recommendations for specific exercises to optimize outcomes for first-time CI recipients.

Level of Evidence – Level III: Cohort or case-control studies.

Indicate IRB or IACUC: Pro00077593

Insertion Depth and Cochlear Implant Speech Recognition Outcomes: A Comparative Study of 28- and 31.5-mm Lateral Wall Arrays

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Matthew M. Dedmon, MD, PhD; Harold C. Pillsbury, MD; Brendan P. O'Connell, MD*

Objectives: 1) To compare speech recognition outcomes between cochlear implant (CI) recipients of 28- and 31.5-mm lateral wall electrode arrays and 2) to characterize the relationship between angular insertion depth (AID) and speech recognition.

Study Design: Retrospective review.

Setting: Tertiary academic referral center.

Patients: Seventy-five adult CI recipients of fully inserted 28- (n=28) or 31.5-mm (n=47) lateral wall arrays.

Interventions: Cochlear implantation with postoperative computed tomography.

Main Outcome Measures: Consonant-nucleus-consonant (CNC) words assessed with the CI-alone at 12 months post-activation.

Results: The mean AID of the most apical electrode contact for 31.5-mm array recipients was significantly deeper than 28-mm array recipients (628° vs 571°, $p<0.001$). Following 12 months of listening experience, mean CNC word scores were significantly better for recipients of 31.5-mm arrays compared with those implanted with 28-mm arrays (59.6% vs 48.3%, $p=0.004$). There was a significant positive correlation between AID and CNC scores ($r=0.372$, $p=0.001$); however, a plateau in performance was noted around 600°.

Conclusions: On average, CI recipients implanted with a 31.5-mm array experienced better speech recognition than those with a 28-mm array at 12 months post-activation. Deeper insertion of a lateral wall array confers speech recognition benefit up to ~600°, with a plateau noted thereafter. These data provide preliminary evidence of the insertion depth necessary to optimize speech recognition outcomes among CI recipients of lateral wall electrode arrays.

Define Professional Practice Gap & Educational Need: The relationship between angular insertion depth and speech recognition outcomes among cochlear implant recipients remains incompletely understood.

Learning Objective: To understand the non-linear relationship between insertion depth and speech recognition outcomes with lateral wall electrode arrays and to discuss potential underlying mechanisms.

Desired Result: Attendees will be able to apply the knowledge to their cochlear implant practices in regard to the desired insertion depth necessary to optimize outcomes with lateral wall electrode arrays.

Level of Evidence - III

IRB: Approved 10/29/2019 (University of North Carolina at Chapel Hill, # 09-2328)

Comparing Tympanoplasty Outcomes for Porcine Small Intestinal Submucosal Grafting with Temporalis Fascia, Regenerative Tissue Matrix, and Tragal Cartilage Grafting

Evan C. Cumpston, MD; Brian P. Perry, MD

Objective: Porcine small intestinal submucosal (PSIS) grafts have been shown to be effective for tympanic membrane repair in small studies. However, published data regarding outcomes of these grafts is lacking. This study reviews a series of patients who underwent tympanoplasty with PSIS grafts and compares outcomes with patients who underwent tympanoplasty with temporalis fascia, regenerative tissue matrix (RTM), or tragal cartilage.

Study Design: Case Series with Planned Data Collection

Setting: Outpatient Otolaryngology Clinic

Patients: Patients undergoing tympanoplasty

Interventions: Patients underwent tympanoplasty for repair of tympanic membrane defects with either PSIS, temporalis fascia, RTM, or tragal cartilage grafts, determined by the surgeon.

Main Outcome Measures: Percentage of grafts intact on post-operative evaluation

Results: 241 patients underwent tympanoplasty between 2016 and 2020. Six patients were lost to follow-up. Overall, 91.00% of grafts were intact on follow-up. Of porcine PSIS grafts, 95.83% were intact on follow-up. 17 of these cases were primary, 10 were revision (37.00% revision cases). Of temporalis fascia grafts, 91.47% were intact on follow-up. 117 of these cases were primary, 23 were revision (16.43% revision cases). Of RTM grafts, 79.41% were intact on follow-up. 23 of these cases were primary, 16 were revision (43.90% revision cases). Of tragal cartilage grafts, 93.55% were intact on follow-up. 28 of these cases were primary, 5 were revision (15.15% revision cases).

Conclusions: PSIS grafts appear to be as effective as autogenous tissue for tympanic membrane repair and may be superior to RTM grafts. PSIS grafts may be especially useful for revision tympanoplasties or with minimally invasive techniques.

***Define Professional Practice Gap & Educational Need:** Many graft materials for tympanoplasty have been previously described. Several allogenic graft materials have become available that may be especially useful in minimally invasive tympanoplasties and myringoplasties that avoid a graft site incision as well as for revision tympanoplasties in which autogenous grafts are not readily available. Recently, porcine small intestinal submucosal grafts are one such allogenic graft that have become available. To date, published data regarding outcomes of these grafts is limited to a case-series evaluating outcomes of grafts placed endoscopically, a case series evaluating outcomes of grafts used in myringoplasties. This study was performed to review a series of patients who underwent tympanoplasty with porcine small intestinal submucosal grafts with outcomes compared to patients within the same cohort who underwent tympanoplasty with temporalis fascia, regenerative tissue matrix, or tragal cartilage grafting by a single surgeon.

***Learning Objective:** The learner will understand the current gaps in knowledge regarding porcine small intestinal submucosal matrix grafting for repair of tympanic membrane perforations, outcomes of these grafts compared to other commonly grafted materials, and possible applications of these grafts in revision or minimally invasive cases.

***Desired Result:** To provide data regarding tympanoplasty outcomes using porcine small intestinal submucosal matrix grafts which may influence future graft selection with considerations for graft material success, donor site morbidity, and autogenous tissue availability. This study will hopefully also direct further studies regarding these grafting materials in order to further elucidate superior practice patterns and outcomes.

Level of Evidence - Level IV

Indicate IRB or IACUC: Exempt

**Mesenchymal Stem Cells for Treatment of Delayed-Healing Tympanic Membrane Perforations
Using Hyaluronate-Based Laminas as a Delivery System:
An Animal Model with Histopathologic Study**

David Shahal, MD; Stefania Goncalves, MD; Simon I. Angeli, MD

Hypothesis: Bone marrow derived-mesenchymal stem cells (BM-MSCs) improve the healing of chronic tympanic membrane perforations (cTMPs) in an animal model.

Background: cTMPs generate significant morbidity and reduced quality of life, usually requiring advanced surgical assistance. With growing interest in alternative therapies, we sought to evaluate the effect of BM-MSC-therapy on the healing of cTMPs.

Methods: 60 cTMPs were established in C57Bl/6 mice and divided into four groups: hyaluronate scaffold plus BM-MSCs (n = 19 ears), scaffold plus cell culture media (n = 16), scaffold plus phosphate-buffered saline (PBS, n = 12), and no intervention (n = 13). Hyaluronate scaffolds with or without BM-MSCs were applied on 8-week perforated eardrums. After a blinded assessment of perforation sizes at baseline and 2 weeks after treatment, mean perforation reduction rates (%) were compared. Histology characterization was then performed.

Results: Mean perforation size reduction rates were significantly higher for cTMPs that received scaffolds plus BM-MSCs (ANOVA test, $p=0.0207$, 12.3% [95%CI: 7.8-16.7]) and scaffolds plus cell culture media ($p=0.0477$, 11.3% [95%CI: 4.4-18.2]) when compared to no intervention (4.2% [95%CI: 1.2-7.2]). This was not observed when treating eardrums with scaffolds plus PBS alone (7.3% [95%CI: 2.7-11.9]). On histology, BM-MSC-treated eardrums demonstrated restoration of the trilaminar configuration and reduced inflammatory changes, while other groups developed tissue architecture disorganization and hypercellular infiltrates surrounding the perforation site.

Conclusions: BM-MSCs and cell culture media increased cTMP closure rates. Cell-therapy conferred a restoration of the trilaminar configuration of the eardrum and reduced inflammatory response.

***Define Professional Practice Gap & Educational Need:** cTMPs usually require advanced surgical assistance, with variable healing results. Although recent animal studies suggest a role of mesenchymal stem cells in the healing of acute tympanic membrane perforations, there is a lack of evidence in its more clinically relevant chronic counterpart.

***Learning Objectives:** After completing this activity, participants will learn the effects of topical mesenchymal stem cell therapy on cTMPs using hyaluronate-based scaffolds, including an assessment of perforation closure rates and histologic characterization.

***Desired Result:** Attendees will learn the current evidence on mesenchymal stem cell therapy as a potential nonsurgical alternative to tympanoplasty in a reliable model of cTMP.

Level of Evidence – Does not apply

IACUC: Protocol 19-060 approved by the University of Miami Institutional Animal Care and Use Committee.

Topical Fibroblast Growth Factor-2 for Treatment of Chronic Tympanic Membrane Perforations

*Felipe Santos, MD; Edina Shu; Daniel J. Lee, MD; David H. Jung, MD, PhD; Alicia M. Quesnel, MD
Konstantina M. Stankovic, MD, PhD; D. Bradley Welling, MD, PhD*

Objective: To determine the efficacy of fibroblast growth factor-2 (FGF-2) in treating chronic nonhealing tympanic membrane (TM) perforations.

Method: Double-blinded, randomized placebo-controlled phase 2 clinical trial for patients with chronic TM perforations of more than 3 months duration with a cross-over arm. Patients received either FGF-2 or placebo (sterile water) saturated gelatin sponge in the perforation after rimming the perforation under topical anesthesia. The perforation was then covered with Tisseel fibrin glue. The primary endpoint was complete closure of the TM perforation. Secondary end points included change in hearing and partial TM closure rates. The TM was examined every 3 weeks with otoendoscopy for closure. The treatment was repeated if there was incomplete closure every 3 weeks up to a total of three treatments per arm.

Results: Seventy-four patients were recruited for the study. Fifty-seven met eligibility criteria and fifty-four completed the study. Ten of 14 perforations closed completely in the placebo group (71.4%) and 23 of 40 perforations closed completely in the FGF-2 treatment group (57.5%), P value = .36. Pure tone averages and word recognition scores were not statistically significantly different between study groups post-treatment. After initial complete closure, re-perforation occurred in seven FGF-2 treated patients and two placebo patients making the effective final closure rate 40% for FGF and 57% for placebo, respectively.

Conclusion: No statistically significant difference in tympanic membrane perforation closure rate was found between the FGF-2 and placebo groups. There were no differences in hearing outcomes between the groups.

***Define Professional Practice Gap & Educational Need:** To assess the efficacy of a novel treatment for the closure of chronic tympanic membrane perforations.

***Learning Objective:** Participants will learn that in our study the use of FGF-2 to promote closure of chronic tympanic membrane perforations was not different from placebo.

***Desired Result:** Participants will learn the outcomes of a double blinded placebo-controlled phase 2 clinical trial for patients with chronic tympanic membrane perforations.

Level of Evidence – 1b

Indicate IRB or IACUC: The study was approved by the Massachusetts Eye and Ear Institutional Review Board #2019P000592

Topical Therapy Failure in Chronic Suppurative Otitis Media Is Due to Persister Cells in Biofilms

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Hypothesis: Persister cells mediate treatment failure in chronic suppurative otitis media (CSOM).

Background: CSOM, often caused by *Pseudomonas aeruginosa* (PA) or *Staphylococcus aureus* (SA), is the most common cause of sensorineuronal hearing loss among children in developing countries. Current therapy fails to prevent recurrent otorrhea. Persister cells, which survive antibiotic attack due to low metabolism and robust repair mechanisms, have been implicated in other chronic bacterial infections but not in CSOM.

Methods: Bacterial resistance to ofloxacin and antiseptics was measured via minimum inhibitory concentration (MIC), minimum biofilm eradication concentration (MBEC) and bacterial inhibition zone assay. Persister cell percentages were measured in laboratory strains (PA01, SA25923) and clinical isolates (PA CSOM-1, SA CSOM-1). Colony forming units (CFUs/ml) was measured in a validated PA-01 CSOM murine model treated with trans-tympanic phosphate-buffered saline (PBS) or ofloxacin.

Results: Bacterial strains displayed higher MBEC compared to MIC for ototopical therapies, at higher than clinically achievable levels. Compared to PA-01, PA CSOM-1 displayed more persister cells (0.003% versus 0.0003%, $p < 0.001$), higher MBEC ($> 3,000 \mu\text{g/mL}$ versus $750 \mu\text{g/mL}$) and smaller inhibition zone (6.0 mm versus 38.72) for ofloxacin. Ofloxacin demonstrates lower MBEC and larger inhibition zone compared to antiseptics in most strains. Bacterial load (CFU/mL) *in vivo* was similar for ofloxacin (6.98) and PBS (7.69, $p > 0.05$).

Conclusions: Clinical isolates displayed more persister cells and ototopical resistance compared to laboratory strains. No therapies eradicated biofilms at clinically achievable concentrations. Ofloxacin has limited impact on bacterial load *in vivo*. These data confirm that persister cells mediate CSOM treatment failure.

*Define Professional Practice Gap & Educational Need:

Current CSOM medical therapies are successful in converting active disease to inactive disease in the short term, but many patients relapse over time. The presence of metabolically inactive persister cells may mediate this treatment failure. Although this cell population represents a small fraction of cells in CSOM biofilms, these cells can evade topical medical therapy and lead to recurrence of active CSOM.

*Learning Objective:

- CSOM is a chronic infectious disease of the middle ear that involves recurrent episodes of otorrhea despite current medical therapies.
- Persister cells are metabolically inactive cells in CSOM biofilms that can evade topical antibiotic and antiseptic treatments. These cells have been shown to play an important role in numerous chronic bacterial infections.
- Clinical CSOM isolates contain a higher percentage of persister cells and are resistant to common CSOM therapies at higher than clinically achievable concentrations.

*Desired Result:

Persister cells play a key role in CSOM. These cells can survive topical medical therapy due to low metabolism and robust repair mechanisms, and may account for high rates of CSOM recurrence.

Level of Evidence – Does not apply- basic science study.

IACUC: IACUC 32855, Stanford University

Quinolone Ear Drops Linked to Tendinopathy & Tendon Rupture

Phuong T. Tran, MPH; Patrick J. Antonelli, MD; Almut G. Winterstein, PhD

Objective: Delayed eardrum healing has been observed contralateral to otic quinolone (OQ) exposure in rats. One case report described tendon rupture after OQ. Thus, OQs may have systemic side effects. The aim of this study was to estimate the risk for tendinopathies after OQs.

Study Design: This retrospective cohort study included patients with outpatient diagnosis of otitis externa or media from MarketScan 2005-2015 and Medicaid Analytical eXtrac 1999-2012 databases. We applied a new user, active comparator design with 1-year look-back for baseline characteristics and ceased follow-up at initiation of systemic steroids or quinolones, switch to OQ in the comparator group, external injury, hospitalization and at a maximum of 35 days. We used stabilized inverse probability of treatment weighting to balance comparison groups. Adjusted hazard ratios (HRs) from Cox models were pooled across databases with fixed-effects models. Risk of sport injuries was examined to rule out differences due to varied mobility.

Setting: U. S. outpatient encounters

Patients: < 65 years with private or public insurance.

Intervention/Exposure: OQ versus otic neomycin, amoxicillin or azithromycin

Main Outcome Measures: Achilles or all-type tendon rupture or Achilles tendinitis

Results: We examined 11,288,246 treated otitis episodes. Pooled HRs for OQ exposure were 2.44 (1.46-3.42) for Achilles tendon rupture, 1.20 (1.01-1.39) for Achilles tendinitis, 1.24 (0.96-1.52) for all tendon rupture, and 1.07 (0.89-1.26) for sport injuries.

Conclusions: OQ exposure is associated with increased risk of tendinopathy. Clinicians should consider risk-benefit and counsel patients accordingly. Risk factors for this rare, serious adverse effect deserve further evaluation.

Define Professional Practice Gap & Educational Need: OQ exposure has been linked to the development of tympanic membrane perforations. Less well appreciated from these studies has been the potential for adverse systemic effects.

Learning Objective: To better understand the potential adverse systemic effects with OQ therapy.

Desired Result: Prescribers will more rigorously consider the potential side effects and counsel patients on the risks of commonly used OQs.

Level of Evidence - IV

Indicate IRB or IACUC: University of Florida IRB201903041 (for MAX data) and IRB201701362 (for MarketScan data).

Does Otologic Surgery Result in Meaningful Hearing Improvement?

*Priyanka Reddy, BS; Terral Patel, MD; Ted A. Meyer, MD, PhD
Paul R. Lambert, MD; Theodore R. McRackan, MD, MSCR*

Objective: Little is currently known regarding patients' perception of hearing benefit after otologic surgery. This study examines the degree of meaningful improvement in hearing, as measured using the minimally important difference (MID) using patient-reported outcomes measures (PROMs), and its association with audiological improvement.

Study Design: Retrospective review of a prospectively maintained database

Setting: Tertiary academic center

Patients: 102 adults undergoing otologic surgery

Interventions: Stapedectomy, tympanoplasty/mastoidectomy with/without ossicular chain reconstruction (OCR)

Main Outcome Measures: Whether or not patients obtained a MID in PROMs scores (HHIA and SSQ) and various audiologic measures [post-surgical interaural pure tone average (PTA) difference, ipsilateral low frequency PTA (LF PTA), four frequency PTA (PTA), word recognition score and air-bone gap (ABG)]

Results: Overall, 34 (33.3%) and 32 (31.4%) patients reported obtaining a MID (+MID) using the HHIA and SSQ, respectively. All patients receiving stapedectomy reported either +MID (75-76.2%) or no change (23.8-25%) in PROM scores. For those undergoing OCR, 23.1-41.7% of patients obtained +MID, 41.7-65.1% no change, and 7.7-16.7% worse PROM scores (-MID). Change in PTA and change in LF PTA had the greatest associations with PROM scores, demonstrating low to moderate correlation values ($r=0.45-0.54$). Using ROCs, improvement in PTA, LF PTA, and ABG had a fair capacity to differentiate +MIDs (AUC=0.775-0.786).

Conclusions: Although there might be improvements in audiological outcomes after a patient undergoes otologic surgery, this does not definitively result in patient-perceived functional improvement. This study provides support for the use of PROMs to monitor patient outcomes after otologic surgery and preliminary evidence for the relation between change in audiologic measures and patient-perceived benefit.

Define Professional Practice Gap & Educational Need: The effect of otologic surgery on a patient's real world, functional perception of hearing is not well described. The standard method of determining post-surgical improvement, audiologic measures, also has yet to be detailed in relation to patients' perceived hearing benefit.

Learning Objective: This study will examine the degree of hearing improvement after otologic surgery based on PROMs and will determine the association between audiologic outcomes and PROMs.

Desired Result: Clinicians will be more cognizant of the effect of otologic surgery on patients' functional improvements and may consider using PROMs as a routine outcome measure.

Level of Evidence - Level IV: Historical cohort or case-controlled studies.

Indicate IRB or IACUC : The study was approved by the Medical University of South Carolina IRB - Pro00071518

Audiologic Outcomes of Footplate Drillout for Obliterative Otosclerosis

*Robert M. Conway, DO; Pedrom C. Sioshansi, MD; Amy Schettino MD
Dennis I. Bojrab MD; Seilesh C. Babu MD; Christopher A. Schutt, MD*

Objective: Examine the audiologic outcomes of thickened stapes footplates requiring drill out for obliterative otosclerosis.

Study Design: Retrospective chart review of patients undergoing stapedotomy

Setting: Single tertiary care center

Patients: Adult patients undergoing primary stapedotomy with laser fenestration. Drill out was performed for cases of obliterative otosclerosis with thickened footplates.

Interventions: Stapedotomy with either laser fenestration or footplate drill out.

Main Outcome Measures: Audiologic outcomes were based on pre- and postoperative pure tone averages (PTA) and air-bone gap (ABG) in decibels (dB). Complications compared between the two groups include postoperative perilymphatic fistula, facial paralysis, BPPV, or reparative granuloma.

Results: Five hundred eighty-eight patients underwent primary stapedotomy and were included: 518 with standard laser fenestration and 70 with thickened footplates requiring additional drill out. Pre-operative ABG for laser and drill groups were 26.47 dB and 26.55 dB, respectively ($p=.949$). Initial post-operative ABGs were 8.61 dB and 10.16 dB for the laser and drill group, respectively, which were not significantly different ($p=.058$). Average bone conduction threshold improved from 29.8 dB preoperatively to 25.7 dB postoperatively ($p<.001$). There was no difference in complications between the two groups.

Conclusions: Audiologic outcomes are excellent following stapedotomy for obliterative otosclerosis. Hearing is comparable in cases of thickened footplate drillout and standard laser fenestration without increased risk of sensorineural hearing loss or surgical complications.

***Define Professional Practice Gap & Educational Need:** Establish outcomes of footplate drillout stapedotomy for obliterative otosclerosis.

***Learning Objective:** Understand the audiologic outcomes and complication profile of drill and laser stapedotomy

***Desired Result:** Expand evidence for utilization of fenestration using drill if required by certain circumstances/physician preference

Level of Evidence - IV

Indicate IRB or IACUC: 1130957-4

Audiologic Outcomes following Transmastoid and Middle Cranial Fossa Approaches for SSCD Repair

*Susan E. Ellsperman, MD; Steven A. Telian, MD; Paul R. Kileny, PhD
Christopher M. Welch, MD, PhD*

Objective: To describe postoperative hearing outcomes following transmastoid (TM) and middle cranial fossa (MCF) approaches for semicircular canal dehiscence (SSCD) repair

Study Design: Retrospective review

Setting: Academic, tertiary referral center

Patients: Adults with SSCD who underwent repair between 2005 and 2019

Interventions: Pure tone audiometry pre- and postoperatively after SSCD repair

Main Outcome Measures: Change in air-bone gap (ABG) at 250 and 500 Hz, pure tone average (PTA) bone conduction (BC) and air conduction (AC) thresholds at 500, 1000, 2000, and 4000 Hz for patients undergoing TM and MCF approaches for SSCD repair

Results: The average change in AC and BC PTA for patients undergoing TM (n = 29) and MCF (n = 25) SSCD repair was not significantly different between the two groups. The first and final postoperative PTAs were recorded an average of 3.3 (range 0.30 to 34.9) and 31.9 (range 1.9 to 154) months postoperatively. The average changes in AC PTA for patients who underwent MCF repair were 2.5 dB (*p* 0.44) and -0.4 dB (*p* 0.92) at first and final audiogram respectively compared to -0.04 dB (*p* 0.99) and -4.0 dB (*p* 0.43) for patients who underwent TM repair. The average changes in BC PTA for patients who underwent MCF repair were 2.3 dB (*p* 0.35) and 0.5 dB (*p* 0.86) at first and final audiograms respectively compared to 0.0 dB (*p* 0.99) and -3.2 dB (*p* 0.47) for patients who underwent TM repair. The average changes in ABG for patients undergoing MCF repair were -6.3 dB (*p* 0.38) and -6.8 dB (*p* 0.04) at first and final audiograms respectively compared to -2.9 dB (*p* 0.27) and -4.7 dB (*p* 0.08) for patients who underwent TM repair. These ABG closures did not differ between the two approaches (*p* 0.44)

Conclusions: Both TM and MCF approaches to SSCD repair can be performed with long-term preservation or improvement in AC thresholds, though not statistically significant. ABGs were reduced in each treatment group, and were not statistically different depending on the approach.

***Define Professional Practice Gap & Educational Need:** To establish that SSCD repair can be consistently performed with preservation of preoperative audiologic function

***Learning Objective:** To demonstrate audiometric outcomes for different approaches to SSCD repair

***Desired Result:** To document stable hearing after SSCD repair and affirm use of either TM or MCF approach for SSCD repair depending on surgeon preference and patient selection

Level of Evidence - Level V

Indicate IRB or IACUC: IRB review considers this study exempt (HUM00169949)

Hearing Outcomes in Superior Canal Dehiscence Syndrome with Concurrent Tegmen Tympani Defects

Eric J. Formeister, MD, MS; Lisa Zhang, BS; John P. Carey, MD

Objectives: To describe the prevalence and audiometric profiles of subjects with superior canal dehiscence syndrome (SCDS) with concurrent tegmen mastoideum or tegmen tympani dehiscences (TMD, TTD).

Study Design: Retrospective case-control study.

Setting: Tertiary referral center.

Patients: Subjects with SCDS who underwent middle fossa craniotomy (MFC) for plugging/resurfacing.

Main Outcome Measures: Operative findings of TTD and/or TMD, pre- and postoperative low frequency air-bone gaps (LF-ABGs, in dB HL) and ocular vestibular evoked myogenic potential (oVEMP) amplitudes in those with and without TTD with dural contact of the ossicles.

Results: 136 patients (avg. age, 56 years, 55.1% female) underwent MFC for repair of SCDS. Concurrent tegmen dehiscences were commonly found intraoperatively (TTD 19.9% [15% with dural herniation onto exposed ossicles], TMD 28.7%, both 5.9%). There were no differences in preoperative LF-ABGs between patients with TTD with dural herniation and those without (average 250 Hz and 500 Hz ABG 28 dB and 18 dB vs. 27 and 16 dB; $p=0.77$ and $p=0.51$, respectively) nor at long-term follow-up (average reduction at 250 Hz and 500 Hz, 22 dB and 13 dB vs. 19 dB and 9 dB; $p=0.48$; $p=0.32$, respectively). Finally, oVEMP amplitudes did not differ between those with and without a TTD (average 25.4 μ V versus 31.4 μ V, respectively; $p=0.25$).

Conclusions: Preoperative oVEMP amplitude and correction of LF-ABG postoperatively does not differ in those with SCDS and TTD with dural herniation compared to those with SCDS alone after MFC for canal plugging and resurfacing. Ipsilateral concurrent tegmen dehiscences are extremely common in SCDS.

***Define Professional Practice Gap & Educational Need:** Audiologic improvement in air-bone gap after superior canal plugging surgery is variable, and may be related to concurrent tegmen tympani dehiscence with dural herniation onto the ossicular chain. However, no prior study exists that examines intraoperative findings and pre- and postoperative audiometric findings. Similarly, oVEMP findings could be less sensitive for subjects with an additional cause for conductive hearing loss, such as in the case of concurrent tegmen tympani dehiscence with impingement of dura on the head of the malleus, but no report has been generated to address this.

***Learning Objective:** The learning objectives are to describe the prevalence of concurrent tegmen dehiscences, both tympani and mastoideum, in subjects with SCDS and to examine audiologic outcomes after repair in those with dehiscences compared to those without concurrent dehiscences.

***Desired Result:** Improved understanding of the high prevalence of concurrent tegmen dehiscences in subjects with SCDS and enhanced education regarding expected audiologic outcomes according to the presence or absence of concurrent tegmen dehiscences.

Level of Evidence - IV

Indicate IRB or IACUC : The following study was approved by the Johns Hopkins University Institutional Review Board, IRB Number 00192330, effective 12/10/2018.

Otologists Are at Risk for Surgical Noise-Induced Hearing Loss

*Nathan D. Cass, MD; Elizabeth L. Perkins, MD
Todd A. Ricketts, PhD; Marc L. Bennett, MD*

Objective: Evaluate surgeon, staff, and patient risk for noise-induced hearing damage as a result of otologic procedure-related noise exposure.

Background: The National Institute for Occupational Safety and Health (NIOSH) recommends regulation of occupational noise exposures above 85 dBA. Recent research indicates that noise levels causing transient threshold shifts, previously believed to be safe and without long-term consequence, result in cochlear synaptopathy with resultant degeneration of spiral ganglion neurons, degradation of neural transmission in response to suprathreshold acoustic stimuli, and difficulty understanding in background noise.

Study Design: Prospective observational.

Setting: Tertiary care center.

Subjects: Surgeons.

Main Outcome Measures: Surgeon noise exposure in A- and C-weighted decibel scales (dBA, dBC), including average equivalent (LA_{eq}) and peak (LA_{peak} , LC_{peak}) levels, time-weighted averages (TWA), and projected daily noise dose.

Results: Sound measurements taken at the ear with continuous recording equipment during otologic surgery demonstrated LA_{eq} 80-83 dBA, LA_{peaks} of over 100 dBA, and LC_{peaks} of nearly 130 dBC. TWA was approximately 70 dBA, and projected daily noise dose even for sessions 20–40 minutes long was between 28–61%.

Conclusions: Noise exposure to surgeons, staff, and patients in the operating room (resulting from high-speed otologic drill systems, suction and suction irrigators, other powered equipment, instruments, music, and conversation) reach unacceptably high levels which may be dangerous to cochlear health. Such noise exposures may be powerful enough to result in noise-induced cochlear synaptopathy, with concomitant functional difficulty achieving suprathreshold word discrimination in background noise.

Define Professional Practice Gap & Educational Need: Otologic surgeons, while offering hearing health care and hearing rehabilitation to patients, expose themselves, their staff, and their patients, to high levels of noise in the operating room. Recent developments regarding the far-reaching consequences of previously believed ‘safe levels’ of noise, now known to cause permanent reduction in neural signal transmission due to cochlear synaptopathy, merit evaluation of operating room noise exposure to those tasked with safeguarding hearing health.

Learning Objective: Characterize noise exposure of surgeons during otologic surgery.

Desired Result: This study provides context for discussion regarding reducing noise exposure to surgeons, staff, and patients during otologic surgery.

Level of Evidence: III

Indicate IRB or IACUC: Exempt

Histopathologic Analysis of Temporal Bones with Otosclerosis following Cochlear Implantation

Sarah Hodge, MD; Gail Ishiyama, MD; Ivan Lopez, PhD; Akira Ishiyama, MD

Hypothesis: Osteoneogenesis following cochlear implant (CI) surgery in patients with otosclerosis is significantly affected by surgical techniques which affects the outcome on hearing function.

Background: When advanced otosclerotic disease extends to the otic capsule, severe and profound sensorineural hearing loss necessitates consideration of a cochlear implant. Histopathological analysis of the human temporal bone after implantation in the patient with otosclerosis may reveal important variables that predict CI success.

Methods: Histopathological evaluation of archival human temporal bones from subjects with a history of CI for cochlear otosclerosis. 7 human temporal bones (HTB) were analyzed.

Results: Histopathological studies revealed extensive osteoneogenesis from the site of insertion extending throughout the temporal bone along the electrodes, more prominent in the basal turn when cochleostomy insertion technique had been used. In cases with translocation, the degree of osteoneogenesis in patients with otosclerosis was more severe. In cases of cochleostomy insertion of CI, there was concomitant fibrosis and tissue formation near the ductus reuniens, which was associated with cochlear hydrops. Osteoneogenesis and/ or fibrosis was much more prominent at the cochleostomy insertion site in the basal turn of the cochlea, when compared with the osteoneogenesis and / or fibrosis in the case of round window insertion.

Conclusion: Round window insertion is preferred when performing CI surgery in otosclerosis patients given the extensive amount of osteoneogenesis and fibrosis seen with cochleostomy. The soft technique is preferred to minimize translocation which triggers more pronounced osteoneogenesis. The round window technique should be prioritized in this patient population to optimize hearing outcomes.

***Define Professional Practice Gap & Educational Need:** Clinical outcomes of cochlear implantation in patients with otosclerosis has been widely studied. However, detailed histopathologic study of CI patients with otosclerosis has not yet been performed. This study will thus help elucidate histologic changes in the cochlea to ultimately highlight important surgical considerations in this patient population.

***Learning Objective:** To describe the fundamental anatomical changes of the cochlea after CI surgery in patients with otosclerosis using histopathologic analysis.

***Desired Result:** To provide evidence of the different histopathologic changes seen in the cochlea after CI using different insertion techniques in patients with otosclerosis.

Level of Evidence – Level IV

Indicate IRB or IACUC : #10-001449, UCLA

Cochlear Implantation through Intracochlear Fibrosis: A Comparison of Surgical Techniques

*Anne K. Maxwell, MD; Jacob B. Kahane, MD; Rahul Mehta, MD
Moises A. Arriaga, MD, MBA*

Objective: While the implications of ossification on cochlear implantation (CI) have been extensively described, there is a paucity of data regarding the fibrotic stage. We examined the outcomes of different insertion techniques for managing intracochlear fibrosis.

Study Design: Retrospective review of case series with case-control comparison

Setting: University-based tertiary-referral otology-neurotology practice

Patients: Between 2009 to 2020, 384 patients underwent CI. Of those, 7 patients (8 ears) demonstrated intracochlear fibrosis. Etiology was meningitis (63%), labyrinthitis (13%), or idiopathic (25%).

Interventions: CI performed 1-4 months following meningitis/labyrinthitis and 12-24 months after idiopathic sudden SNHL. Fibrosis removal (38%, using microsurgical dissection \pm laser) or dilation (63%, using depth gauge and/or angiocatheters) permitted implantation. Round window insertion was achieved in 88%; cochleostomy was required to bypass obstruction in 13%. A styleted electrode was used in 63% due to dense fibrosis.

Main Outcome Measures: Postoperative audiometry with CI in place, additional comparisons with audiometric outcomes in age-matched controls.

Results: Full insertion achieved in all except one ear with partial ossification. Mean ipsilateral pure tone average (PTA) improved to 29 ± 15 dB (range 13-55dB) and speech discrimination to 72 ± 28 % (range 32-96%). Fibrosis removal vs. dilation resulted in no PTA differences ($p=0.76$). Poorest outcomes occurred with the longest time to surgery: 4 months after meningitis (50dB PTA), and 24 months after idiopathic SSNHL (55dB PTA). Follow up duration ranged from 1-62 months.

Conclusions: Good CI audiologic outcomes in the setting of cochlear fibrosis can be achieved and are independent of technique. Instead, they vary with time to implantation. Every attempt should be made to intervene as early as possible.

Define Professional Practice Gap & Educational Need: Limited data exists on cochlear implantation techniques in the setting of intracochlear fibrosis.

Learning Objective: To compare different surgical techniques to manage intracochlear fibrosis including microdissection, laser vaporization, various dilation methods.

Desired Result: To understand the outcomes of fibrosis dissection and dilation techniques.

Level of Evidence: Level V

Indicate IRB or IACUC: Louisiana State University Health Sciences Center-New Orleans IRB, protocol #19-971.

Understanding Public Perceptions Regarding Cochlear Implant Surgery in Adults

*Lisa Zhang, BS, BA; Andy S. Ding, BA; Deborah X. Xie, MD
Francis X. Creighton, MD*

Background and Objective: Approximately 6% of adults eligible for cochlear implantation (CI) undergo surgery. We aim to understand general perceptions about CI to investigate barriers explaining this low utilization.

Methods: Participants completed an online survey regarding their perceptions about cochlear implantation. They were asked to rank CIQOL-10 Global priorities and corresponding risk tolerance for minor complications (changes in taste, vertigo) and major complications (infections requiring hospitalization, meningitis, reimplantation, facial paralysis, and cerebrospinal fluid [CSF] leak).

Results: A total of 249 responses (male 60%, mean age 38 years [range 20-75]) were included. Respondents identified issues with insurance (31%) and fear of undergoing surgery (29%) as barriers preventing eligible adults from receiving CI. Regarding surgical risk, respondents significantly underestimated rates of minor complications ($p < 0.01$) and overestimated rates of major complications (all $p < 0.0001$). The ability to hear strangers in noisy environments was identified as the highest priority for CI (33%). Respondents were willing to accept higher rates of most complications except vertigo to achieve their highest quality of life priority (all $p < 0.005$). With the option to improve hearing loss without surgery, older age and occupation in healthcare were significant positive predictors of higher willingness to pay ($p = 0.006$, $p = 0.003$, respectively).

Conclusions: Respondents identify insurance coverage and fear of surgery as primary reasons for low utilization of adult CI in the US, but also significantly overestimate the rate of major postoperative complications. Respondents also indicate they are willing to accept much higher complication rates than existing to achieve their highest quality of life priorities.

***Define Professional Practice Gap & Educational Need:** Many previous studies have identified low rates of cochlear implantation in the United States versus other developed nations and have postulated various reasons explaining this trend. However, to our knowledge, there have been no studies that have directly assessed public opinions on cochlear implantation to understand their most pressing priorities with regard to postoperative quality of life and risk tolerance. Our study investigated possible causes of this discrepancy and identified concerns about surgical risk and insurance coverage as primary reasons, opening the door for public education discussions centered on these topics.

***Learning Objective:** The learning objectives were to understand the general public's perceptions on quality of life priorities following cochlear implantation and their associated tolerance for postoperative complications.

***Desired Result:** We hope our study will help frame discussions about cochlear implantation in the clinical setting with regard to identifying top quality of life priorities and managing expectations in risk tolerance.

Level of Evidence - NA

Indicate IRB or IACUC: Exempt

Hearing Loss and Incident Dementia: Claims Data from the New York SPARCS Database

Alexander Chern, MD; Rahul K. Sharma, BS; Justin S. Golub MD, MS

Objective: Hearing loss (HL) may be a risk factor for incident dementia. The objective was to use population-based claims data from the New York Statewide Planning and Research Cooperative System (SPARCS) to establish if HL is associated with incident dementia.

Study Design: Secondary analysis of prospective claims database

Setting: Comprehensive all-payer data reporting system established by the New York State Department of Health (2007-2017)

Patients: 217,694 subjects >60 years (15,323 with HL, random sample of 202,371 without HL)

Interventions: none

Main Outcome Measures: The main outcome was incident dementia, measured by initial dementia diagnosis (ICD-9/ICD-10 code) associated with a patient visit/insurance claim. The main exposure was HL, measured by at least 2 separate HL diagnoses associated with claims prior to dementia diagnosis. Cox proportional-hazards models were used to examine the relationship of baseline HL with incident dementia, adjusting for age, gender, cardiovascular disease, cerebrovascular disease, diabetes, and smoking.

Results: Dementia incidence rates per 1000 person-years were 16.3 (subjects with HL) and 9.13 (subjects without HL). HL associated with fewer (2-10) claims (n=14,175) was associated with 1.17 (95% CI=1.09-1.26, p<0.001) times the hazard of incident dementia, adjusting for covariates. HL associated with greater (>10) claims (n=1,148) was associated with 1.36 (95% CI=1.09-1.68, p=0.006) times the hazard of incident dementia, adjusting for covariates.

Conclusions: HL diagnosis was associated with increased risk of incident dementia based on a comprehensive all-payer data reporting system. Individuals with a more established diagnosis of HL (more HL diagnoses associated with claims) demonstrated an increased hazard ratio.

Define Professional Practice Gap & Educational Need: Hearing loss is highly prevalent and severely undertreated. Studies have suggested that hearing loss may be a risk factor for incident dementia. However, this finding needs replication and extension through novel and unique methods of analysis for generalizability. Understanding this association will help inform healthcare personnel of hearing loss as a risk factor for incident dementia

Learning Objective: After this presentation, the learner will be able to describe the relationship between age-related hearing loss and incident dementia.

Desired Result: Otolaryngologists will better understand the relationship between hearing loss and incident dementia.

Level of Evidence – Level III

Indicate IRB or IACUC: Columbia Irving University Medical Center IRB-AAAT2769 (ENT Outcomes in SPARCS)

Association of Vitamin D Levels with Benign Paroxysmal Positional Vertigo Outcomes

*Leah H. Cobb, MSc; Victoria O. Bailey, BSc; Yuan F. Liu, MD
Michael T. Teixido, MD; Habib G. Rizk, MD*

Objective: To determine the effects of vitamin D levels and supplementation on occurrence and recurrence of benign paroxysmal positional vertigo (BPPV) symptoms.

Study Design: Retrospective chart review with follow-up phone surveys. The National Health and Nutrition Examination Survey (NHANES) database was utilized as a control group.

Setting: Tertiary referral center, neurotology clinic (Medical University of South Carolina Department of Otolaryngology)

Patients: Patients seen between 5/2017-5/2020 who met the criteria of: ≥ 18 years old, diagnosed with BPPV (confirmed by positive Dix-Hallpike), with vitamin D levels collected within 6 months of diagnosis.

Interventions: Vitamin D supplementation for treatment of BPPV

Main Outcome Measures: BPPV recurrence rates, ranking of recurrence severity, number of series, date of last visit

Results: 174 patients met the criteria for inclusion in the study. Of these, 75.3% were female with an average age of 65.9 ± 12.3 years. The most common co-morbidities were hyperlipidemia (38.5%), hypertension (23.6%), and thyroid disease (19.0%). Our patient demographics had a significantly greater proportion of Caucasians ($d=0.411$ [0.194,0.629]), higher average age ($d=1.709$ [1.556,1.863]) and females ($d=0.231$ [0.056,0.406]) than the NHANES group. Furthermore, our patients had a higher mean vitamin D level at diagnosis (31.3 ng/nL, ± 16.5) than the NHANES control (26 ng/nL, ± 11.2). The mean vitamin D level of patients who had no recurrences (37.6 ng/nL) was significantly greater than those who had ≥ 1 recurrence (29.0 ng/nL) ($d=0.571$, [0.139,1.001]). No other significant associations were determined when comparing our patient population to the NHANES national data, in terms of Vitamin D levels and BPPV outcomes.

Conclusions: Based on our findings, Vitamin D levels may indicate a propensity for BPPV recurrence. Vitamin D supplementation may serve as a cost-effective, positive prophylactic treatment in those with BPPV. Interestingly, it was not significantly correlated with initial BPPV occurrence, as the average vitamin D level of our patient population was actually higher than that of the NHANES group. The significant differences in demographics between our patient population and the NHANES database (race, age, and sex) appear to validate known risk factors for BPPV. In the future, comparison of our patient population to age and sex-matched loco-regional data may provide clarity of associations of BPPV to vitamin D levels.

***Define Professional Practice Gap & Educational Need:** Therapeutic options for BPPV are limited. Previous studies have shown a correlation of osteoporosis to BPPV, stimulating the hypothesis that there may be a role of vitamin D in BPPV pathogenesis. If related, Vitamin D supplements could become a first-line treatment for an otherwise debilitating disease.

***Learning Objective:** First, to confirm whether Vitamin D levels are a predictive factor for BPPV occurrence and subsequent recurrence. Second, to objectively evaluate the utility of Vitamin D supplementation in the treatment of BPPV.

***Desired Result:** If vitamin D levels are indeed related to BPPV occurrence and recurrence, Vitamin D supplements may serve as a cost effective and attractive therapeutic option. Currently, there are limited treatment options for BPPV, despite how common the disease is and the discomfort it inflicts on those afflicted.

Level of Evidence – Level III

IRB: Pro00095413 Medical University of South Carolina

**The Correlation of Clinical Corticosteroid Responsiveness with Expression of IL-6
in Peripheral Blood Immune Cells (PBMC) in Patients
with Autoimmune Inner Ear Disease (AIED)**

Scott W. Gorthey, MD; Shresh Pathak, PhD; Andrea Vambutas, MD

Hypothesis: AIED patients will differentially express IL-6 based on clinical corticosteroid responsiveness.

Background: AIED is characterized by periods of acute sensorineural hearing loss (SNHL). Seventy percent of these patients will respond to corticosteroids, however, after 3 years only 14% remain responsive. The mechanisms that controls corticosteroid responsiveness have not been fully elucidated.

Methods: Thirty five AIED patients and 13 control subjects were enrolled in this study. Steroid responsive (n=15) and steroid resistant AIED patients (n=20), were characterized based on audiometry before and after treatment for acute SNHL. Plasma and PBMC were obtained at the time of acute SNHL to quantify plasma IL-6, sIL-6R and CCL3. PBMCs were treated with dexamethasone. Release of soluble IL-6, sIL-6R, and CCL3 protein into conditioned supernatants from stimulated PBMC was measured. Plasma IL-6 was also correlated to serum CRP, cardiac CRP, ESR.

Results: Statistically significant differences were seen in the plasma IL-6 between AIED patients and controls (2.37 vs. 2.03 pg/mL, $p<0.01$), plasma IL-6 and CCL3 between responders and nonresponders (0.136 vs. 3.84 pg/mL, $p<0.005$; 30.5 vs. 32.4, $p<0.05$) and released IL-6 from dexamethasone stimulated PBMC in AIED patients compared to controls (0.54 vs. 1.12 pg/mL, $p<0.001$). There was a correlation between plasma IL-6 levels of AIED patients to both serum CRP and cardiac CRP ($R^2=0.83$, $R^2=0.88$).

Conclusions: We observed AIED patients and specifically nonresponders expressed greater levels of IL-6. Elevated IL-6 levels in AIED patients correlated with CRP levels, potentially providing a commonly available laboratory test that may aid in rapid clinical decision-making in these patients.

***Define Professional Practice Gap & Educational Need:** Further investigation into the pathophysiology of AIED is required to elucidate potential treatments as well as guide clinician's plan of care for these patients.

***Learning Objective:**

1. The pathophysiology of AIED includes alteration in the IL-6 inflammatory pathway.
2. Variations in IL-6 expression between corticosteroid responders and nonresponders suggest differing inflammatory responses between these two groups of patients.
3. There may be useful correlations between the diagnostic and prognostic value of IL-6 levels with common clinical laboratory tests.

***Desired Result:** Provide learner with evidence to support a clearer understanding of the pathophysiology of autoimmune inner ear disease that includes the differential production of the cytokine IL-6 between AIED patients and controls as well as between steroid responders and nonresponders.

Level of Evidence – Level V

Indicate IRB or IACUC: 05-110T, 9/11/2017, Feinstein Institute for Medical Research

Utilizing Single Cell RNA-Sequencing to Implicate Cell Types and Therapeutic Targets for SSNHL in the Adult Cochlea

Lacey Nelson, BS; J. Dixon Johns, MD; Shoujun Gu, PhD; Michael Hoa, MD

Objective: To identify genetic targets implicated in sudden sensorineural hearing loss (SSNHL) and localize their expression in the cochlea in order to further explore potential pathogenic mechanisms and treatment strategies.

Study Design: Systematic literature review and bioinformatics analysis

Data Sources: The following databases and grey literature sources were searched from inception through July 2, 2020: PubMed-NCBI, MEDLINE, Embase, CINAHL, Cochrane Library, ClinicalTrials.gov, OpenGrey, GreyNet, GreyLiterature Report, and European Union Clinical Trials Registry.

Study Selection: Studies with a primary focus on genetic targets associated with SSNHL were included. Exclusion criteria included studies unrelated to SSNHL, studies that did not include genetic analysis, full-text articles in a foreign language, and other systematic reviews.

Data Extraction: Data from included studies was extracted and compiled using a standardized electronic data collection sheet. The Oxford Centre for Evidence-Based Medicine levels of evidence was used to grade the strength of clinical data.

Data Synthesis: Previously published single-cell and single-nucleus RNA-Seq datasets of the adult mouse stria vascularis were utilized for localization of SSNHL-related genes curated through literature review. Gene ontology analyses were performed using EnrichR. Potential therapeutic gene targets and associated pharmacologic agents were identified.

Conclusions: We report 92 unique polymorphisms in 76 different genes that have been investigated in relation to SSNHL in the literature. Gene ontology analysis identifies potentially involved biological processes. We demonstrate that a subset of these genes are expressed by cell types in the adult mouse stria vascularis.

***Define Professional Practice Gap & Educational Need:** To better understand cell types and potential therapeutic targets involved in SSNHL.

***Learning Objective:** Identify potential genetic targets involved in SSNHL and describe their localization in the cochlea.

***Desired Result:** Increase understanding of the role of genetics in SSNHL pathogenesis, and use knowledge of potential genetic targets to guide treatment strategies.

Level of Evidence – N/A

Indicate IRB or IACUC: Exempt

Opioids Are Infrequently Required following Ambulatory Otologic Surgery

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Dillan F. Villavisanis, BA; Enrique Perez, MD, MBA
George B. Wanna, MD; Maura K. Cosetti, MD*

Objective: To determine the frequency with which ad hoc opioid prescriptions are used in ambulatory otologic surgery.

Study Design: Retrospective chart review

Setting: Tertiary otology-neurotology practice

Patients: Patients (n= 218) given over-the-counter acetaminophen and ibuprofen following ambulatory otologic surgery between July 1, 2019 and June 30, 2020.

Interventions: Opioid prescription upon request due to unresponsive pain.

Main Outcome Measures: Patient, disease, and surgical variables such as age, sex, past medical history (PMHx), chronic pain condition, surgical procedure, primary versus revision surgery, and endoscopic versus microscopic approach were examined for relationship to ad hoc opioid prescription rate.

Results: Of 218 patients (mean age 43.9 years, range 8.4 months - 88.5 years), 7 were taking opioids at baseline for external medical conditions. 37 (17.0%) patients were prescribed opioid analgesia for postoperative pain, most commonly oxycodone-acetaminophen 5/325 mg on the day of surgery or postoperative day (POD) one (range, POD 0–11). Procedures with concurrent canaloplasty ($p= 0.004$), PMHx of a chronic pain syndrome or cancer diagnosis ($p< 0.001$), and baseline opioid prescription ($p= 0.002$) were associated with need for opioids. Mastoidectomy - including canal wall up (CWU), canal wall down (CWD) and radical -, cochlear implantation, stapedectomy, and tympanoplasty were not. Age (when controlled for pediatric cases), sex, other PMHx, revision surgery, and endoscopic vs. microscopic techniques were not predictive of opioid prescription.

Conclusions: Pain following ambulatory otologic surgery may be adequately managed with OTC pain medication in the majority of cases. Opioids may be necessary in those with pre-existing pain conditions or in those taking opioid prescriptions at baseline.

Define Professional Practice Gap & Educational Need: Opioids may be prophylactically prescribed following ambulatory otologic surgery despite adequate pain control with OTC pain medications for the majority of procedures.

Learning Objective: Postoperative pain following ambulatory otologic surgery is often sufficiently managed with OTC pain medication, and opioids should only be prescribed due to recalcitrant pain.

Desired Result: Reduction in rate of opioid prescription for ambulatory otologic surgery.

Level of Evidence – Level IV

Indicate IRB or IACUC: Exempt

The Cell Phone Vibration Test: A Telemedicine Substitute for the Tuning Fork Test

*Alex Yang, BA; Nora Watson, PhD
Robert J. Lewis, MD; Anthony M. Tolisano, MD*

Objective: An at home test for differentiating between conductive and sensorineural hearing loss remains elusive. With the rise of telemedicine, virtual physical examination maneuvers are increasingly important. Our goal was to validate the novel cell-phone vibration test (CPVT) against the Weber tuning fork test (WTFT) and to assess if the CPVT can be reliably self-administered by patients.

Study Design: Cross-sectional.

Setting: Academic otolaryngology clinic.

Patients: Consecutive adults with a recent audiogram within 6 months and no report of recent hearing changes.

Interventions: The CPVT involves placement of a vibrating cell-phone on the center of the forehead to determine which ear is subjectively louder. Group 1 consisted of 20 patients who were examined by the provider with the CPVT and WTFT using various tuning forks (256Hz, 512Hz, 1024Hz). Group 2 consisted of an additional 20 patients who received instructions on self-administering the CPVT.

Main Outcome Measures: Kappa statistics were calculated to assess concordance between the CPVT, WTFT, and audiometric findings for Group 1 and between patient self-administered and provider administered CPVT and WTFT for Group 2.

Results: Concordance between CPVT and WTFT in Group 1 was high (Kappa coefficient: 0.76 for 256Hz, 0.92 for 512Hz, 0.92 for 1024Hz) with similar concordances between actual and expected results based on audiogram (Kappa coefficient: 0.49 for CPVT, 0.59 for WTFT). Concordance between patient-administered and provider-administered CPVT showed perfect agreement (Kappa coefficient: 1.0).

Conclusions: The CPVT provides consistent results when compared to a formal WTFT and can be reliably self-administered by patients with appropriate instructions.

Define Professional Practice Gap & Educational Need: The ability to perform simple and effective physical examination of the ear and differentiate sensorineural and conductive hearing loss is limited when patients are evaluated via telemedicine.

Learning Objective: To describe a simple at home test for differentiating between conductive and sensorineural hearing loss for the otologic patient treated via telemedicine.

Desired Result: Physicians will be able to reliably differentiate between conductive and sensorineural hearing loss for their patients treated via telemedicine.

Level of Evidence – Level V

Indicate IRB or IACUC: Department of Research Programs, Walter Reed National Military Medical Center (IRB #WRNMMC-EDO-2020-0553)

Developmental Disruptions of the Human Stapes

Thais Abrahao, MD, PhD; Felipe Santos, MD

Objective: To evaluate and classify developmental malformations of the human stapes.

Method: 25 temporal bone specimens from 18 patients with congenital stapes malformations were identified in the Mass Eye and Ear temporal bone collection. Serial sections stained with Hematoxylin and Eosin were examined by light microscopy and the morphology of the stapes was compared to age matched controls.

Results: Each case of stapes malformation could be classified into one of four malformation types based on our current understanding of the embryologic origin of the subunits of the stapes and timing of development. 27% of stapes malformations had a Type I morphology characterized by a hypoplastic or absent inner footplate and hypoplastic to absent mesoderm footplate or oval window. The crura and capitulum may be absent, monopodal or dysmorphic. 11% expressed a Type II malformation with dysmorphic or monopodal capitulum and crura and a fixed footplate. 27% were of Type III with a dysmorphic or monopodal capitulum and or crura. The footplate, and thereby oval window is present and without fixation. The most common malformation, Type IV, was isolated footplate fixation observed in 33% of cases.

Conclusion: Malformations of the human stapes follow consistent patterns of early or late disruptions of the stapes subunits of mesodermal and/or neural crest origin. While the molecular events, including temporal coordination, that lead to a normally formed stapes are not yet fully understood, the observed patterns of human stapes malformation can be consistently classified into one of four patterns of developmental disruption.

***Define Professional Practice Gap & Educational Need:** New findings in animal studies of the embryologic development of the ossicles inform previously unrecognized patterns in human stapes malformations.

***Learning Objective:** To provide a better understanding of stapes malformation based on the embryologic origin of the stapes subunits.

***Desired Result:** Participants will have a better understanding on the embryologic origin of the stapes and why specific malformations are observed.

Level of Evidence - III

Indicate IRB or IACUC: Exempt

Congenital Aural Atresia with Cholesteatoma – Diagnosis and Outcome

Geoffrey C. Casazza, MD; Rachel H. Jonas, MD; Bradley W. Kesser, MD

Objective: Compare outcomes of congenital aural atresia (CAA) with/without cholesteatoma

Study Design: Retrospective case control

Setting: Tertiary care center

Patients: CAA patients

Interventions: surgery for CAA

Main Outcome Measures: Patients with CAA undergoing surgical repair from June 2004 to July 2020 were identified from an institutional database. Included patients were divided by presence of a canal cholesteatoma. Clinical history, pre- and post-operative audiometric data, and clinical outcomes were compared.

Results: Of the 283 patients (300 ears), 18 (19 ears) had a canal cholesteatoma. Patients with cholesteatoma were more likely to be younger (9.2 ± 6.6 vs. 11.5 ± 9.2 ; $p = 0.015$), female (66.7% vs. 38.1%; $p = 0.02$; OR 3.2, 95% CI 1.18-8.9), and have normal/Grade I microtia (47.4% vs. 9.6%; $p < 0.0001$; OR 0.12, 95% CI 0.044-0.32), but not a history of draining ear (5.3% vs. 0%; $p = 0.05$; OR 0.06, 95% CI 0.004-0.999). Pre-operative audiometric data demonstrated a lower mean air-bone gap (ABG) (45.8 dB vs. 52.3 dB; $p = 0.009$) and better speech reception threshold (48.7 dB vs. 57.4 dB; $p = 0.0004$) in cholesteatoma patients. Post-operatively, patients with cholesteatoma were more likely to close the ABG within 20 dB ($p = 0.001$; OR 0.19, 95% CI 0.072-0.52). No patient in the cholesteatoma group developed post-operative bony/soft-tissue stenosis (0% vs. 9.7%; $p = 0.65$; OR 1.61; 0.21-12.6) or required revision surgery (0% vs. 11%; $p = 0.38$; OR 2.46, 0.32-19).

Conclusions: Patients with CAA and cholesteatoma have better audiometric outcomes and likely a more durable repair with a decreased need for revision possibly secondary to greater development of the ear canal and middle ear space despite the cholesteatoma.

***Define Professional Practice Gap & Educational Need:** management of congenital aural atresia/stenosis with cholesteatoma

***Learning Objective:** to better understand clinical characteristics of patients with congenital aural atresia and their outcomes after surgery

***Desired Result:** improved understanding of clinical characteristics of patients with congenital aural atresia/stenosis with cholesteatoma

Level of Evidence – Level IV

Indicate IRB or IACUC : Approved, University of Virginia IRB no. 22575

Epidemiological and Long-term Medical and Surgical Outcomes in Chronic Suppurative Otitis Media

Anthony Thai, BA; Ksenia A. Aaron, MD; Adam C. Kaufman, MD, PhD; Peter L. Santa Maria, MBBS, PhD

Objective: Report epidemiological and long-term outcomes in chronic suppurative otitis media (CSOM), given paucity of such data in developed countries

Study Design: Retrospective cohort study; medical claims analysis

Setting: Tertiary referral center; national claims databases

Patients: Patients with ICD diagnosis of CSOM in MarketScan and Optum databases were included in national claims analysis. For the tertiary center cohort, patients with ICD diagnosis of CSOM, at least 6 months of follow up, and at least one documented episode of active CSOM (defined as tympanic membrane perforation with otorrhea) were included. This cohort included 48 patients (mean age 48.2 years, 56.3% female).

Interventions: Retrospective analysis

Main Outcome Measures: CSOM prevalence; number of healthcare visits; recurrence rate of active CSOM.

Results: CSOM prevalence ranges from 0.05% to 0.47% in the US. In our tertiary center cohort, patients displayed average follow-up time of 6.8 ± 3.8 years, with an average of 13.3 ± 9.7 visits. Following medical management, 86.4% either continued to display active CSOM, or temporarily converted to inactive CSOM prior to recurrence (mean time to recurrence: 4.4 months). Patients undergoing surgical management underwent an average of 2.2 CSOM surgeries, with a recurrence rate of 51.9% (mean time to recurrence: 45.5 months). On the most recent audiogram, 70% of patients displayed sensorineuronal hearing loss in the affected ear.

Conclusions: In our cohort, CSOM patients display high healthcare utilization. Surgical management was superior to medical management in both relapse rate and mean time to relapse and should be considered earlier in the disease course.

***Define Professional Practice Gap & Educational Need:**

Although previous studies indicate high resolution rates for CSOM with topical antibiotics and antiseptics, these studies often have short follow-up periods of less than one month. This long-term study indicates that current therapies for CSOM display poor outcomes, and argues for consideration of surgical management earlier in the disease course.

***Learning Objective:**

CSOM prevalence in the United States is similar to slightly lower than other developed countries.

CSOM patients often have multiple episodes of active disease leading to high healthcare utilization, including numerous visits, prescriptions and surgeries.

Surgical management is superior to medical therapy for CSOM, although both have poor long-term outcomes.

***Desired Result:** Long-term outcomes in CSOM patients are inferior compared to previous reports with shorter follow-up time. Surgical management is superior to medical management and should be considered earlier in treatment.

Level of Evidence - IV

Indicate IRB or IACUC : IRB Protocol 56466, Stanford University

Eustachian Tube Dilation Outcomes at a Tertiary Academic Center

Micah M. Gibson, MD; Shubham Patel, BS; Esther X. Vivas, MD

Objective: To investigate and report the subjective and objective outcomes for balloon dilation of the Eustachian tube (BDET) in patients with Eustachian tube dilatory dysfunction (ETDD).

Study Design: Retrospective case series

Setting: Tertiary referral center

Patients: Patients 18 years of age or older who underwent BDET between 01/01/2017 to 2/28/2020.

Interventions: BDET using the ACCLARENT AERA™. Patients responded to the Eustachian Tube Dysfunction Questionnaire (ETDQ-7) before and after BDET. Pre- and post-operative pure tone audiometry was performed.

Main Outcome Measures: Pre- and post-operative ETDQ-7, pure tone audiometry, tympanometry, otomicroscopic examination.

Results: BDET was performed on 42 ears. There were no complications. Mean follow up was 8.4 months (range 1-23 months). ETDQ-7 score improved in 83% of ears. Mean ETD-7 score improved from 5.10 to 2.55. 78.6% of middle ear effusions resolved with BDET. Of 6 patients undergoing simultaneous BDET and tympanoplasty, all grafts were intact at follow up. 7 out of 8 patients undergoing BDET with tympanoplasty or other middle ear surgery demonstrated improved air conduction thresholds. Follow up has been hindered by limited clinical access during the COVID-19 pandemic.

Conclusions: BDET demonstrates subjective and objective measures of improvement in treating ETDD. It may be a useful adjunct to improving tympanoplasty outcomes.

***Define Professional Practice Gap & Educational Need:** In 2016, the FDA approved a device that employs a balloon to endoscopically dilate the Eustachian tube. According to a clinical consensus statement from the AAO-HNSF, the benefit of BDET performed with concurrent tympanoplasty or other middle ear surgery has not been determined, and more outcomes assessments are needed. The purpose of this work is to support the utility of BDET by reporting outcomes in a single-surgeon case series.

***Learning Objective:** BDET is a safe treatment for ETDD demonstrating subjective and objective results, and BDET may be beneficial when performing tympanoplasty.

***Desired Result:** BDET leads to improved ETDQ-7 scores, air conduction hearing thresholds, and tympanograms in patients with ETDD.

Level of Evidence - V

Indicate IRB or IACUC : Approved by Emory University Institutional Review Board