2004 Research Posters

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Otology & Neurotology

R001

Once-Daily Ofloxacin Otic Solution for Otitis Externa

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Problem: To evaluate the efficacy and safety of a 7-day regimen of ofloxacin otic 0.3% solution administered once daily to treat otitis externa (OE).

Methods: This was an open-label, multicenter, multinational study (involving 58 sites in the U.S. and Central America). Ofloxacin otic 0.3% solution was administered once daily for the treatment of OE in patients over 6.0 months of age with stable or exacerbating OE of more than 2-weeks' duration. Five drops were instilled once daily in each infected ear of 196 patients aged 6.1 months to 12 years (mean $\pm$ SD = 8.1 ± 3.3 years), and 10 drops in the ears of 294 patients 13 years and older (35.6 ± 16.0 years). Secretion or exudate specimens were obtained for microbiological analysis.

Results: After 7 days of therapy, 298 of 439 clinically evaluable patients (67.9%) were considered cured and 121 (27.6%) clinically improved. At a follow-up visit 710 days later, 398 (90.7%) were considered clinically cured. Forty-three bacterial species were isolated from 253 patients who were clinically and microbiologically evaluable. Overall pathogen eradication rate was 95.7%. The most commonly isolated pathogen, *Pseudomonas aeruginosa*, was eradicated in 153/158 patients (96.8%). *Staphylococcus aureus* was eradicated in 31/32 patients (96.9%). No serious adverse events occurred during the study. The most commonly reported nonserious adverse event (11.2% of patients) was a transient increase in earache.

Conclusion: Ofloxacin otic 0.3% solution is a safe and effective treatment for OE when administered once daily for 7 days.

Significance: Fewer daily dosing and shorter course of therapy will enhance adherence to treatment.

Support: None reported.

R002

In Vivo Measurement of Human Tympanic Membrane Structure

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Problem: To noninvasively quantify the in vivo human tympanic membrane (TM) structure for further explaining some of the variability in long-term hearing improvement after tympanoplasty surgery for chronic otitis media.

Methods: All MR images of 5 female and 5 male volunteers' TM, semicircular canals, and cochlea were acquired by a 3-T MR system (Brucker S630) using a surface coil of 9 cm diameter and 3D SNAP sequences, aged 20 to 35 years. The pixel resolution of the acquired image for the volunteers' right ears was $0.59 \times 0.63 \times 0.47$ mm by 3D SNAP. A 3D solid model of in vivo TM, semicircular canals, and cochlea was then reconstructed based on the acquired MR images. The geometric characteristics of TM, semicircular canals, and cochlea were subsequently determined by 2 indices including surface area and volume.

Results: The surface areas were 108.34, 152.94, and 108.15 square mm, and the volumes were 36.47, 46.02, and 30.18 cubic mm for TM structure of 3 volunteers, respectively. The preliminary data indicated that small surface area and large volume would obtain the thick TM. Variability of dimensional characteristics of 7 more volunteers' TM was further analyzed. The number of volunteers did not reach a statistically significant level.

Conclusion: The dimensional characteristics of in vivo human TM was quantified by using surface area and volume indices. The thickness of TM was then qualified by surface area and volume. Using the proposed measurement method, the spatial configuration of the in vivo TM can be tracked pre- and postoperation noninvasively.

Significance: Knowledge of the structure of TM may help determine the cause of continued problems such as the age-related changes in the mechanics of the TM, and can explain part of the age-related hearing loss observed. Some patients with surgically repaired tympanic membrane perforation still have hearing loss.

Support: None reported.

R003

Histopathologic Findings of Tympanic Membranes from Patients with Ventilation Tubes

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Problem: To evaluate histopathologic changes in tympanic membranes (TMs) of patients with a history of ventilation tubes (VTs).

Methods: Twenty-five temporal bones from 17 cases with history of VTs were included. Ages ranged from 36 to 89 years (mean, 62 years). Tympanic membranes were intact in 13 temporal bones. In 12 there were central perforations. The results were compared with 19 normal age-matched temporal bones. Migration of stratified squamous epithelium was classified as follows: Type I where the mucocutaneous junction ends at the outer surface of the perforation; Type II reaches the inner surface; and Type III is detected at any point within the inner surface. Presence of hyalinization, size, and localization of perforation and thickness of TM were noted.

Results: The perforation site was the posteroinferior quadrant in 4 temporal bones (33%), anteroinferior in 6 (50%), and anterosuperior in 2 (17%). The perforation size ranged between 0.7 mm and 2.2 mm (mean, 1.3 mm). Hyalinization was observed in 8 TMs with central perforations and 7 intact TMs from patients with history of VTs. In 7 (54%) temporal bones with intact TMs, there was thinning in the insertion site. In-growth of stratified squamous epithelium at perforation edges was Type I in 10; Type II in 8; and Type III in 4. In Type III cases average in-growth was 1.16 mm (maximum, 1.96 mm). Intratympanic inclusion cholesteatoma was observed in 2 TMs with a history of VTs.

Conclusion: This study shows that sequelae of ventilation tube insertion are common. The surgeon should take into consideration numerous sequelae such as inclusion pearls, cholesteatoma, hyalinization, thinning, and perforation before making a decision to perform this procedure.

Significance: Ventilation tube insertion is one of the most common surgical procedures. Although ventilation tubes are safe and efficacious for serous otitis media, they are associated with significant sequelae.

Support: None reported.

R004

A Mathematical Model of Trans-Mucosal Gas Exchanges

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Problem: Gas exchanges in the middle ear (ME) are thought to be the cornerstone in the development of atelectasis and cholesteatoma. The purpose of the current study was to validate a mathematical model of trans-mucosal gas exchanges based on ME volume variations.

Methods: According to Fick's law of diffusion, the rate of diffusion of a gas is proportional to the partial pressure difference of the gas between the 2 sides of the diffusion barrier, the solubility and diffusion coefficient of the gas in the diffusion barrier, and the surface area available for diffusion – and inversely proportional to the thickness L of the diffusion barrier. In a first step, we designed an experimental rat model for exclusive study of trans-mucosal gas exchanges. In a second step, a mathematical model of trans-mucosal gas exchanges for N₂ was developed. In order to validate both models, 2 assumptions were tested. First, linearity of gas volume variations should be verified, ie, being constant. Second, the effective thickness of the diffusion barrier that can be deduced from Fick's law should correspond to the actual thickness.

Results: First, normal rat ME gas volume variations exhibited a linear decrease ($= -0.130 \mu\text{L min}^{-1} \pm 0.03$) which lasted $31.1 \text{ min} \pm 8.5 \text{ SD}$. Second, the effective thickness L_e of the diffusion barrier was $71.4 \mu\text{m}$, which is in accordance with that of histologic studies reported in the literature for rats where the thickness of mucosa varies between 9 and $150 \mu\text{m}$.

Conclusion: Since both assumptions were checked for validity, it is now possible to estimate the variation of effective blood flow surrounding the ME in experimental conditions using this mathematical model and knowing the thickness.

Significance: Further studies in inflamed ears may bring informative data on the ME circulation and the role of the ME mucosa in gas exchanges in pathologic conditions.

Support: No support