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Assessing the Efficacy of Tragal Pumping: A Randomized Controlled Trial

Nathan H. Boyd, MD¹, and Joshua A. Gottschall, MD¹

Abstract

Objective. Tragal pumping is the practice of pushing on the tragus to raise pressure in the external auditory canal. This is a study to determine if tragal pumping improves middle ear penetration of ototopical medications via a patent pressure equalization tube.

Study Design. Prospective, randomized controlled trial.

Subjects and Methods. Children with chronic otitis media scheduled for routine placement of bilateral pressure equalization tubes were offered enrollment in the study. After pressure equalization tube insertion, an otic preparation of 0.3% ofloxacin solution dyed with methylene blue was applied sequentially to both ear canals by the operating surgeon. Tragal pumping was performed on the experimental ear, and the opposite ear served as a control. A second operator, blinded to the randomization process, used an operating microscope to determine if otic drops had entered the middle ear as demonstrated by methylene blue staining of the promontory mucosa.

Results. Twenty-four patients with a mean age of 3.6 years were enrolled in the study. Middle ear penetration of otic drops was present in 33% (8/24) of control ears and in 75% (18/24) of experimental ears, resulting in a statistically significant difference ($P = .0094$).

Conclusion. Tragal pumping improves the middle ear penetration of ototopical medications via a patent pressure equalization tube.

Keywords
general otolaryngology, otitis media, pressure equalization tubes, myringotomy, tragal pumping, ototopicals, otorrhea

Otorrhea after pressure equalization tube (PET) insertion is a common complication with an incidence of 10% to 29% in some series to as high as 74% in others.¹² Ototopical medications are the cornerstone of treatment for PET-associated otorrhea. Tragal pumping—the practice of pushing on the tragus to raise pressure within the external auditory canal (EAC)—is a commonly recommended adjunctive maneuver believed to facilitate the introduction of ototopical medications into the middle ear via a patent PET. Review of the medical literature revealed a small number of nonclinical studies supporting the efficacy of tragal pumping.³⁴ No clinical studies were found. This is a prospective, blinded, randomized controlled trial to determine if tragal pumping improves the middle ear penetration of ototopical medications.

Methods

Children younger than 8 years of age scheduled for routine bilateral PET placement for chronic otitis media were offered enrollment in the study (Figure 1). Patients with stenotic ear canals, middle ear atelectasis, middle ear granulation, or cholesteatoma were excluded from the study. Patients served as their own control, with 1 experimental and 1 control ear. The experimental ear was randomized by coin flip. The EAC was dilated to the largest size aural speculum possible, and a standard myringotomy was performed in the anterior-inferior quadrant. The middle ear was aspirated and a Medtronic (Minneapolis, Minnesota) 1.27-mm fluoroplastic collar-button tube was placed. Four drops of methylene blue–impregnated 0.3% ofloxacin otic solution (0.1 mL/5 mL) were placed in the ear canal without an aural speculum. On the experimental side, 4 tragal pumps were performed. On the control side, 4 tragal pumps were simulated. A second operator, blinded to the randomization process, suctioned the EAC and determined if the otic drops had entered the middle ear. A result was considered positive if the promontory mucosa was stained with blue dye. $P$ values were calculated with the McNemar test. This study was approved by the Kaiser Permanente Northern California (KPNC) institutional review board.

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sure gradient (11 cm of H2O) between the EAC and liquids through a PET occurs only after a significant pre-

Scholl demonstrated in vitro that spontaneous passage of water to the passage of ototopical medications. Pashley and others showed middle ear penetration of dye in 92% (11/12) of experimental ears, resulting in a statistically significant difference \((P = .0094, \text{ McNemar test})\). The number needed to treat (NNT) for the tragal pumping maneuver was calculated to be 3.0 \(\pm\) 1.5 to 6.2. Subset analysis was performed to evaluate whether maximum speculum size (ie, ear canal size) or the presence of a middle ear effusion affected the efficacy of tragal pumping. However, no such trend was noted. Results for a given patient were considered discordant when the middle ear penetration of dye differed in the control and experimental ears. Discordance was noted in 50% (12/24) of patients, and it was the experimental ear that showed middle ear penetration of dye in 92% (11/12) of these cases.

Discussion

Surface tension in a hollow tube is inversely related to the tube’s radius. Standard PETs have a radius of about 1.3 mm, making surface tension a potentially formidable barrier to the passage of ototopical medications. Pashley and Scholl demonstrated in vitro that spontaneous passage of liquids through a PET occurs only after a significant pressure gradient (11 cm of H2O) between the EAC and middle ear has been achieved. Multiple studies have confirmed this finding, although the pressure gradient needed to promote passage of liquids through PETs has varied (0.1-60 cm of H2O) according to the liquid and in vitro model employed.\(^4\,7-10\) Saunders and Robinson demonstrated that tragal pumping can create a pressure gradient of up to 20 cm of H2O between the EAC and middle ear and suggested that this would be sufficient to propel most liquids through a PET. Hebert et al\(^4\) tested the efficacy of tragal pumping in vitro with a variety of common ototopicals as well as plain and soapy water—tragal pumping resulted in a near 100% transmission rate of ototopicals into the middle ear.

The current study is the first to evaluate tragal pumping in vivo. Enrollment was limited to patients younger than 8 years of age to control for age-related variations in auricular growth that could affect tragal pumping via changes in ear canal volume or soft tissue elasticity. Ofloxacin 3% otic solution was chosen as the experimental ototopical agent because it is often prescribed for PET-related otorrhea and has chemical properties that are representative of many other ototopicals.

A direct comparison of control and experimental ears showed tragal pumping to significantly improve the penetration of ototopicals into the middle ear \((P = .0094)\). Although spontaneous middle ear penetration was noted in 33% of control ears, tragal pumping increased penetration to 75%. This result was further validated by examining cases in which the control and experimental ears differed with respect to middle ear penetration of dye within the same individual (ie, the results were discordant). In all but 1 case of discordance, it was the experimental ear that resulted in middle ear penetration of dye. The NNT for the tragal pumping maneuver was calculated to be 3. This means that given a standard treatment regimen for otorrhea—administration of ear drops 2 times a day for 5 days (10 separate administrations of ototopicals)—tragal pumping will result in middle ear penetration in 3 or 4 applications that would not have otherwise occurred spontaneously.

One potential confounding factor was the potential for ear drops to enter the middle ear via the myringotomy rather than the PET. In certain cases, it was noted that the promontory was stained blue with no evidence of dye within the PET. This factor would tend to lessen the observed effect of tragal pumping by creating false positives within the control group. Although our study did not specifically look at clinical outcomes for treating PET-associated otorrhea, it is reasonable to assume that improved middle ear penetration of ototopical medications is desirable and may hasten clinical recovery.

The mechanism of action of tragal pumping may be inferred by the experimental data and real-time observations made with a rigid endoscope. Tragal pumping results in a rise in EAC pressure. The extent of this rise in pressure depends on the total volume of the EAC, the amount to which this volume is reduced by tragal pumping, and the elasticity of the surrounding tissues. In the presence of a patent PET, the starting EAC volume includes the middle ear and mastoid spaces and is large. Tragal pumping does not result in a significant rise in pressure within the EAC when the starting volume is large. However, when the PET is covered by a “puddle” of ototopical drops, the starting EAC volume is small, and tragal pumping results in a large rise in EAC pressure. As EAC pressure rises, it will either exceed the force of surface tension within the PET, propelling the ototopical drops into the middle ear, or be dissipat-ed into the soft tissues surrounding the EAC.

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**Figure 1.** Flow diagram demonstrating patient enrollment and progress in the randomized controlled trial.\(^5\)
Conclusion
Tragal pumping significantly improves the middle ear penetration of ototopical medications via a patent PET. Tragal pumping should be recommended to patients whenever ototopical medications are used for the treatment of tube-associated otorrhea.

Author Contributions
Nathan H. Boyd, study design, institutional review board application, data gathering, analysis, article composition; Joshua A. Gottschall, study design, institutional review board application, data gathering, analysis, article editing.

Disclosures
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