A prospective study of the role of sinonasal disease in Eustachian tube dysfunction

Lay Summary:
Chronic rhinosinusitis (CRS) is a disorder where swelling/infection of the nose and sinuses causes symptoms of nasal blockage, a runny nose, headaches and a poor sense of smell. The tube that connects the ear to the back of the nose can also become involved in this process (Eustachian tube dysfunction - ETD) and although patients with this disorder often complain about it, the extent of the problem and the effect of any treatment has yet to be studied. This study will therefore ask patients with CRS to undergo two measurements before and after sinus surgery - ear drum compliance (tympanometry) and nasal airflow/resistance (rhinomanometry). As a comparison, patients undergoing nasal surgery (septoplasty) where swelling/infection of the nose and sinuses is not present will also be invited to undergo the same measurements. If patients with CRS are found to have a significant problem with ETD then it will help direct treatment to alleviate this and will help doctors who treat CRS to be more aware of the problem.

Background:
Rhinosinusitis (including nasal polyps) according to the European guidelines is defined as inflammation of the nose and the paranasal sinuses characterised by two or more symptoms, one of which should be either nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip) as well as either facial pain/pressure and/or reduction or loss of smell. These symptoms should be confirmed by either endoscopic signs (polyps and/or mucopurulent discharge primarily from middle meatus and/or oedema/mucosal obstruction primarily in middle meatus) and/or CT changes such as mucosal changes within the ostiomeatal complex and/or sinuses. In the American Task Force guidelines, the diagnosis of rhinosinusitis is reached using a combination of major and minor symptoms with the latter including otalgia. Rhinosinusitis is characterised by varying forms of inflammatory response affecting the respiratory mucosa of the nose and sinuses. Given that the Eustachian tube and the middle ear cavity also contain the same epithelial lining, it is likely that the pathophysiological processes that give rise to rhinosinusitis will also affect these areas. Although the common link between these adjacent areas has been realised for decades, the studies that have examined this interaction and the effects of any interventions are few and mostly from the point of view of otitis media with effusion in children. In the absence of inflammatory changes, the role of septoplasty to address Eustachian tube dysfunction has limited evidence to support it. It is therefore evident that both inflammatory and mechanical factors have a role to play in contributing to Eustachian tube problems. As stated by Stoikes et al, symptoms of tubal dysfunction are commonly reported by patients with rhinosinusitis and the SNOT-22 questionnaire features a specific question to address this. Over 250 new patients with chronic rhinosinusitis and over 200 new patients with septal deviations come through the Rhinology clinic at the James Paget University Hospital each year.
Aims:
- To evaluate the incidence of subjective and objective Eustachian tube dysfunction in adults with chronic rhinosinusitis (CRS) and septal deviation (DNS)
- To examine the impact of endoscopic sinus surgery and septal surgery on Eustachian tube dysfunction
- To evaluate the correlation between any changes in the subjective and objective assessments following intervention

Methods:
All patients listed to endoscopic sinus surgery or septoplasty would be invited to participate in the study by undergoing anterior rhinomanometry and tympanometry at the time of being added to the waiting list and at 4 and 12 week intervals post-operatively. Over the course of 1 year, a target of 100 patients would be recruited – 50 with CRS and 50 with DNS. A total of 100 participants with CRS and DNS would allow the estimation of the incidence with a 95% CI of maximum width of 0.28. A sample size of 47 individuals in each group will allow for the detection of a correlation of 0.4 with 80% power. Their consent would be obtained following an explanation of the study and an opportunity to read a patient information sheet. These measurements would be performed using the Atmos diagnostic cube with tympanometer and rhinomanometer attachments. Readings for both the left and right ears and nostrils would be obtained for both measurements as “independent” systems. These tests would be performed in the clinic by a research fellow or research nurse with prior training on how to use the equipment. These readings take approximately 5-10 minutes to perform and are not likely to cause any discomfort. Tympanometry involves a silicone-tipped probe being placed into the entrance to the ear canal and rhinomanometry involves the patient holding a mask over their nose and mouth whilst breathing through their nose for a few minutes. All patients in the Rhinology clinic at the James Paget Hospital are routinely given the SNOT-22 questionnaire to complete at all clinic visits before and after any surgical (and medical) interventions, thus providing a subjective evaluation of ear discomfort that is graded (0-5). All readings would be transferred to an encrypted spreadsheet for collation and further analysis.

Inclusion criteria:
- Chronic rhinosinusitis (with/without polyps) – as defined above and present for at least 3 months (includes subgroup of allergic fungal rhinosinusitis)
- Septal deviation

Exclusion criteria:
- Age less than 18
- DNS in the CRS group and vice versa

Outcome measures:
- SNOT-22 scores including specific question on ear discomfort
- Tympanometry readings (dPA)
- Rhinomanometry (flow rate/resistance in cm³/sec)
Analysis:

Data collated in the secure spreadsheet will be anonymised and transferred to SPSS statistical software package for analysis. A McNemar test will be used to compare the results of tympanometry (trace) and a paired t-test to compare changes in compliance (daPa) before and after intervention. A t-test will also be used for the rhinomanometric readings. Comparison between groups will be performed using a t-test, although adjustment for confounding variable will be carried out using linear regression. Correlation with symptom scores and tympanometry will be performed using Pearson’s correlation coefficient. If the assumptions of the above analyses are not met then non-parametric methods will be used.

References