Tuboimpedance – A New Test of Eustachian Tube Function

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Abstract

Objective

Eustachian tube (ET) dysfunction is most frequently caused by a failure of the ET to adequately open, however there is currently no reliable method of assessing this. Tubomanometry has recently shown good inter-individual repeatability as a measure of ET function, by measuring middle ear pressure after the application of regulated nasopharyngeal pressures during swallowing. We present the first reports of a novel test: middle ear impedance measurements during standard nasopharyngeal pressure application (tuboimpedance). We assess repeatability in healthy ears, and any advantages over tubomanometry.

Study Design

Exploratory cohort diagnosis study.

Setting

Tertiary referral center.

Subjects

20 screened, healthy ears (10 volunteers).

Methods

Tubomanometry and tuboimpedance tests were performed while individuals swallowed with applied nasopharyngeal pressures of 20, 30, 40 and 50mbar.
Eustachian tube opening detection rate and test repeatability (measured by intraclass correlation coefficient) for immediate and delayed repeats at each pressure were compared.

Results
ET opening was detected more frequently using tuboimpedance, with a 100% detection rate using a nasopharyngeal pressure of 30mbar or more, compared to 88-96% with tubomanometry. Detection of ET opening at 20mbar was possible with tuboimpedance. Repeatability of both tests was mostly strong (ICC >0.7) for both immediate and delayed repeats. Repeatability for the tubomanometry R value was only fair to moderate.

Conclusion
Tuboimpedance may provide a repeatable measure of ET opening that is easier to perform, due to lower nasopharyngeal pressures required and fewer issues with poor ear-probe sealing. Further assessment in patients with different forms of ET dysfunction is required.

Word count 246
Introduction

Normal function of the Eustachian tube (ET) permits atmospheric equalisation of middle ear pressure and mucociliary clearance of secretions, while protecting the tympanic cavity from nasopharyngeal sounds and secretions. These processes are facilitated through the intermittent and brief opening of the normally closed ET.

Despite a significant level of morbidity from Eustachian tube dysfunction (ETD)\(^1\), there has been no consensus on the optimal clinical test to detect ET opening, and diagnosis is currently largely made on the basis of clinical history and examination\(^2\).

It is desirable to develop a simple and reliable test of ET function, in order to permit objective diagnosis and quantification of ETD. In most cases ETD is obstructive in nature, due to a reduced rate or absence of ET opening\(^1\). A large number of different tests for ET opening have been described, each with its own strengths and weaknesses\(^3\). Many tests require a patient to generate a nasopharyngeal pressure, which is then transmitted to the middle ear if the ET opens. Patients are taught to generate these pressures by performing a manoeuvre such as a Valsalva (forcibly exhaling with the nose and mouth occluded). However, the nasopharyngeal pressures generated by individuals significantly vary, limiting the comparability of results between ears\(^4\).

Tubomanometry has established itself as a test of ET function in recent years as it enables the standardisation of nasopharyngeal pressures. The test is performed using a device to automatically increase the nasopharyngeal pressure to typically 30, 40 or 50mbar via a sealed nosepiece. This pressure increase is timed to coincide with patient swallowing. Tympanic pressure increases caused by ET opening are then transmitted to the external auditory canal (EAC) via the mobile tympanic membrane, and recorded with a sealed earpiece. By removing the need for the patient to perform
a Valsalva it not only ensures an adequate nasopharyngeal pressure is created, but it allows the individual to swallow simultaneously. Tubomanometry therefore measures both active ET opening (due to paratubal muscle activity with swallowing), and passive forced opening due to the high positive pressure at the nasopharyngeal ostium. This standardised, dual-assessment of both active and passive opening is not possible if relying on patient manoeuvres alone, and tubomanometry has shown good inter-individual repeatability.

Another method of detecting ET opening is with tympanic membrane impedance. Our group has found that continuous impedance monitoring during various patient manoeuvres provides a simple and repeatable method for detecting ET opening. Unlike external auditory canal (EAC) manometry, the use of continuous impedance assessment has been not been commonly used to assess ET opening.

We have investigated the feasibility of performing continuous impedance recording using the tubomanometry method of inducing metered nasopharyngeal pressures in time with swallowing, i.e. ‘tuboimpedance’. As a first investigation into this new technique, the detected ET opening rate, and the repeatability of this method using immediate and delayed repeats in healthy ears are compared to paired tubomanometry results.

Methods

Independent ethical approval was obtained from the UK National Research Ethics Service (South Cambridgeshire Committee).

Candidates
Volunteers without ear disease were recruited by advertisement and each volunteer had both ears assessed independently. All volunteers underwent otoscopy, and those with an abnormal tympanic membrane were excluded. In addition, volunteers were required to score less than 14 on the 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) \(^8\), and have bilateral Jerger Type A tympanograms \(^9\) (226Hz tone at 85dB SPL, Titan IMP440, Interacoustics, Assens, Denmark).

**Equipment**

A tubomanometry device (Tubomanometer, Spiggle & Theis, Overath, Germany) was used to generate nasopharyngeal pressures via a two-pronged nosepiece fitted to both nostrils. To start the testing the tubomanometer EAC pressure sensor was sealed into the right ear canal. A probe producing a 226Hz 85dB SPL tone was sealed in the left ear canal for continuous impedance recording (JK-05AD, Rion Co., Tokyo, Japan). The JK-05AD was also connected to the nasal circuit to allow the nasopharyngeal pressure to be displayed alongside the impedance trace. The apparatus is illustrated schematically in Figure 1.

**Data collection and interpretation**

Volunteers were requested to swallow a small water bolus, automatically triggering the nasopharyngeal pressure increase. Measurements from both ears were recorded simultaneously. Nasopharyngeal pressures selected for investigation were 30, 40 and 50mbar, according to current standard practice \(^6\). In addition 20mbar was trialled to assess if a lower pressure might be adequate for testing, while being better tolerated by the volunteers. Nasopharyngeal pressures were applied in order of increasing magnitude, and testing at each pressure was repeated twice (immediate repeat data). After a set of results was collected, the tubomanometry and impedance earpieces were
swapped, and a further data-set of two repeats at each pressure was recorded from the opposite ears. The complete process was then performed again after an interval of around 15 minutes, to record delayed values for each of the tests in both ears (delayed repeat data).

Impedance was measured in units of equivalent volume of air in ml \(^{10}\), and a positive deflection from baseline \(\geq 0.05\) ml was considered positive for ET opening \(^{7}\). For tubomanometry, a positive EAC pressure increase greater than 0.1mbar was recorded as an opening. Based on the shape of the pressure or impedance traces, recordings were assigned to one of two groups: persistent or non-persistent middle ear pressure. Volunteers were requested not to swallow immediately following the test, and if the impedance or EAC pressure trace was maintained at greater than 50% of the peak value at one second after nasopharyngeal pressure returned to normal, the middle ear pressure was recorded as persistent (Figure 2). As has become standard practice, the R-value, a measure of the latency of the middle ear pressure change (opening) with respect to the nasopharyngeal pressure was also calculated \(^5\). Early opening of the ET (\(R \leq 1\)) is thought to indicate normal ET function, and late opening (\(R > 1\)) to suggest impaired ET opening \(^6\).

Data were analysed at the single-ear level using Microsoft Excel and IBM SPSS. Test results were assessed for the repeatability of both immediate and delayed repeats with the intraclass correlation coefficient (ICC), calculated with a mixed effects model assessing absolute agreement. The ICC is measured on a scale of 0 to 1, where 1 represents perfect reliability with no measurement error, and 0 indicates no reliability.

**Results**
Twenty healthy ears from ten volunteers (five male, mean age 22) were recruited. The mean ETDQ-7 score was nine (range 7-12). All volunteers were able to complete the assessment in full.

Results from tuboimpedance and tubomanometry testing are presented in Table 1. ET opening was detected more frequently with the tuboimpedance method, with a 100% detection rate using a nasopharyngeal pressure of 30mbar or more. Between 57% and 88% of middle ear pressure changes were classed as persistent.

Repeatability of the tests for equivalent volume values (tuboimpedance) and EAC pressure values (tubomanometry) was very good for both immediate and delayed repeats, as measured by ICC. Where the mean of two immediate repeat values was used, the ICC values obtained when comparing the initial and delayed measurements was further improved. Immediate and delayed repeatability for the tubomanometry R-value was variable between 0.2 (poor) and 0.83 (almost perfect), and overall R-value repeatability was poorer than that of EAC pressure.

Discussion

This study demonstrates the feasibility of performing tuboimpedance, a hybrid of the increasingly popular tubomanometry test and the continuous impedance test.

At all pressures tested, tuboimpedance detected more openings than tubomanometry, with a maximum difference of 12% at 30mbar. As our results for the two tests came from a single cohort of ears, this difference suggests that tubomanometry fails to detect some openings that can be detected by tuboimpedance. The reason for this finding is not clear, but it may be that tuboimpedance can detect subtle changes in TM
stiffness that do not translate to a TM movement, and therefore EAC pressure does not change. Despite the small numbers, our tubomanometry data are comparable to published data, reinforcing this finding: In our cohort of healthy ears we were unable to measure ET opening in a mean of 8% of test repeats across the 30-50mbar pressures, while Esteve et al. and Schroder et al. reported rates of 7% 5 and 4% 6 respectively.

We also found that the tuboimpedance test is better at detecting ET opening than standard continuous impedance testing that relies on patient manoeuvres to generate pressures. In initial work from our group using a similar healthy cohort, impedance testing detected passive ET opening in 88% of Valsalva manoeuvres. Only one other published account of the continuous impedance technique for ET testing could be found, with a Valsalva-associated ET opening rate of 93% in healthy ears 7. In comparison, in our tuboimpedance data, using the standard tubomanometry pressures of 30, 40 and 50mbar, 100% of tests resulted in detection of ET opening. This increase in opening detection over Valsalva testing is likely due to the combined active and passive ET opening occurring with both paratubal muscle contractions, and a large positive pressure differential across the ET. It is desirable to test active, as well as passive opening when assessing ET function, as failures of either action alone may lead to ETD 2.

Most middle ear pressure changes appeared to persist beyond the applied nasopharyngeal pressure, with similar findings in both tests. The persistence is due to trapping of pressure within the middle ear, in the absence of swallowing to actively open the ET. Typically, even in traces classed as persistent, there was some loss of middle ear pressure from escape along the ET. It is hypothesised that persistence was
less frequent at higher nasopharyngeal pressures as the larger induced middle ear pressures were more likely to passively force the ET open and leave a residual pressure <50% of the peak pressure. The magnitude of residual middle ear pressure both before after further swallows may provide additional diagnostic information in ETD cases.

The rationale behind using three different pressures in tubomanometry is that it allows quantification of ETD, with individuals experiencing less severe ETD demonstrating opening and normalisation of R-values at higher applied pressures \(^5\). Through clinical use, we have found that some individuals struggle to perform tubomanometry using the highest (50mbar) pressure, as it can be difficult to obtain a seal for the nosepiece, and some do not tolerate the sudden large pressure increase. While the range of nasopharyngeal test pressures is a useful feature of the test, it is desirable for these to be as low as possible, to ease test performance and reduce patient discomfort.

At the non-standard, lower pressure of 20mbar, tubomanometry detected opening with 86% of swallows. However, the opening detection rate was better maintained with tuboimpedance, which at 91% is more similar to rates seen at 30mbar in tubomanometry \(^5,6\). It may be that tuboimpedance could routinely be used with 20, 30 and 40mbar pressures, maintaining the ability to quantify ETD severity, but making it easier to perform and more feasible to use routinely in a clinical setting. This would be of particular use for those who might struggle with 50mbar pressures, such as children and the elderly.

Tuboimpedance has been shown to have good repeatability. With both immediate and delayed repeat testing, the consistency of equivalent volume and EAC pressure
values for tuboimpedance and tubomanometry respectively were very good, as measured by the ICC. For both tests, by taking the mean of two immediate test repetitions, the repeatability of results over a 15 minute delay can be improved. Performing each test more than once and using the mean value may therefore have a role in clinical use, particularly given the inherent variation found with each swallow.

The R-value is a derived value used in tubomanometry to reduce inter-subject variability, and classify ears with ET opening as either $R \leq 1$ (normal), or $R > 1$ (mild ETD). A similar value could be derived from tuboimpedance traces if desired, however we found the repeatability for the tubomanometry R-value to be worse than that of the pressure values. When used simply to classify ears as $R \leq 1$ or $R > 1$ Schroder et al. reported ICC values of 0.83-0.90, but our comparable ICC values were 0.48-0.52 for immediate repeats and 0.62-0.69 for delayed repeats. The reason for this difference is not clear.

An advantage of tuboimpedance over tubomanometry was that fitting the impedance earpiece was straightforward and reliable, as although the earpiece requires a secure fit, it does not need to be hermetically sealed. In contrast, maintaining an air-tight seal in the external auditory canal for pressure tubomanometry measurements proved challenging.

The main drawback of tuboimpedance is that it cannot be performed if the tympanic membrane is perforated or has a grommet in situ, whereas tubomanometry can still be performed by adjusting the scale on the EAC pressure display. Both techniques will fail to reliably record openings in the presence of a middle ear effusion.
Swallowing causes reflex contraction of both the paratubal muscles and the tensor tympani muscle. Tensor tympani contraction has been shown under normal auditory canal pressures to increase tympanic impedance during swallowing, and there is therefore the potential for false positive impedance findings during swallows. However, tensor tympani contracts for approximately 300ms during swallowing, whereas the majority of traces at each pressure demonstrated persistence of the impedance change after the nasopharyngeal pressure had returned to normal, and long after the initiating swallow. False positive findings due to tensor tympani contraction are therefore not thought to be significant.

The thresholds used to assign recordings as openings were set based on published literature and past experience with the devices. The lack of a reference standard for detecting Eustachian tube opening prevents confirmation that these thresholds are optimised to reduce false negatives or positives, and further experience with the techniques in ETD cases is required to refine this.

**Conclusion**

ETD is a common condition where a lack of diagnostic tools and outcome measures has hindered clinical practice and research into new treatments. Tuboimpedance is a novel hybrid test, with our pilot testing indicating that it may be superior to tubomanometry in its ability to detect ET opening in healthy ears, as well as being easier to use. Tuboimpedance is at an early stage of development, but should now be trialled in adult and paediatric patients with ETD to assess whether diagnostic accuracy can match or improve upon that measured with tubomanometry.

**Acknowledgments**
None
References


Table 1. Detected Eustachian tube opening rate and repeatability with tuboimpedance and tubomanometry

<table>
<thead>
<tr>
<th>Test</th>
<th>Naso-pharyngeal pressure</th>
<th>% opening detected</th>
<th>% ME pressure persistent</th>
<th>Immediate repeat ICC</th>
<th>Delayed repeat ICC</th>
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<tbody>
<tr>
<td>Tuboimpedance Equivalent Volume</td>
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<td>91</td>
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<td></td>
<td>30mbar</td>
<td>100</td>
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<td>0.71</td>
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<td></td>
<td>40mbar</td>
<td>100</td>
<td>68</td>
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<td>50mbar</td>
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<td>60</td>
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<td>Tubomanometry EAC Pressure</td>
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<td>78</td>
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<td>96</td>
<td>57</td>
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<td>NA</td>
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<td>0.20</td>
<td>0.28</td>
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</table>
Figure / Table Legends

Figure 1.
The Tubomanometer was connected in the usual way, with probes sealed in the EAC and nose. The impedance probe was sealed in the contralateral ear, and a feed taken from the nosepiece so that nasopharyngeal pressure could be displayed on both machines.

Figure 2.
Diagram representation of persistent and non-persistent impedance or EAC pressure traces. If the trace height was >50% of the peak height 1 second after the nasopharyngeal pressure returned to normal the middle ear pressure was recorded as persistent.

Table 1.
Percentage of detected openings with swallows and intraclass correlation coefficient (ICC) for tuboimpedance and tubomanometry repeats. Immediate repeats were performed consecutively and delayed repeats after approximately 15 minutes. The mean values of the immediate repeats were also compared. Intraclass Correlation Coefficient (ICC) can be interpreted as follows: 0-0.2 poor agreement; 0.3-0.4 fair agreement; 0.5-0.6 moderate agreement; 0.7-0.8 strong agreement; and >0.8 almost perfect agreement. EAC – External auditory canal.