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Reproducibility of the Forced Response Test in Children with Chronic Otitis Media with Effusion

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Abstract

Hypothesis—Eustachian tube function is stable over time in children with ventilation tubes for chronic otitis media with effusion.

Background—Clinical studies report that Eustachian tube function tests in patients with a persistent tympanic membrane perforation predict the success of myringoplasty and, in patients with ventilation tubes for chronic otitis media predict disease recurrence after the tubes become nonfunctional. In those studies, Eustachian tube function was usually tested only once which presumes a semi-stable basal level of function for greatest diagnostic and prognostic usefulness. We investigated the stability of repeated measurements of Eustachian tube function using the Forced Response Test.

Methods—Thirty-nine children aged 36 to 83 months with bilateral ventilation tubes for chronic otitis media with effusion were evaluated using the Forced Response Test three times at three to four month intervals. The variability across test-sessions in the Eustachian tube opening pressure, closing pressure and dilatory efficiency was estimated using regression/correlation analyses.

Results—For all test parameters, the between-session and between-ear correlation coefficients were significant, but the shared variance in the parameters among test-sessions and between-ears at the same test-session was relatively low. The average slope for each parameter as a function of the time with a ventilation tube was zero.

Conclusion—The low between-test shared variance for the test parameters raises questions as to whether or not a single Forced Response Test captures sufficient information to accurately diagnose the cause of any dysfunction or to predict with high specificity and sensitivity future disease experience or surgical results.

Keywords

Eustachian Tube Function; Forced Response Test; Reproducibility; Correlation; Children

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CONFLICT OF INTEREST

None of the authors have any conflicts of interest to declare in regard to the materials presented in this manuscript.

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INTRODUCTION

The Eustachian tube extends from the middle ear to the nasopharynx and represents a potential communication between those compartments¹. The Eustachian tube supports three biological functions: middle ear pressure-regulation, protection of the middle ear from nasopharyngeal secretions, pathogens and pressures, and clearance of middle ear fluid and debris by mucociliary transport¹. Past studies demonstrate a role for the protective and pressure-regulating functions of the Eustachian tube in preserving middle ear health. Specifically, the Eustachian tube lumen is usually closed by peritubal pressures in excess of those typically generated within the nasopharynx which reduces the likelihood that nasopharyngeal pressures, bacteria and viruses will gain access to the middle ear (i.e. protective function). On the other hand, the tubal lumen in healthy subjects is opened periodically and for short time intervals by contraction of the Tensor Veli Palatini muscle during swallowing and other activities thereby allowing for gradient-driven gas transfers between the middle ear and nasopharynx which equalize the pressures in those compartments (pressure-regulating function)². Studies in animals and humans show that low Eustachian tube periluminal pressures are associated with a susceptibility to the development of acute otitis media³⁻⁵ and to otitis media with effusion⁶, and that inefficient muscle-assisted tubal opening is associated with a susceptibility to the development of chronic otitis media with effusion⁷⁻¹⁰.

While these correspondences between the type of Eustachian tube dysfunction and disease susceptibility are well documented for populations that are characterized by a high prevalence of the specific otitis media expression, there have been few published studies that evidence a one-to-one correspondence between the results of the Eustachian tube function tests for a given individual and his/her disease prognosis (e.g. recovery from their extant disease condition)¹¹. This observation suggests that either the tests currently in use do not capture all aspects of Eustachian tube function important for assigning disease susceptibility to a given ear/person or that there is a significant temporal variability in basal Eustachian tube function. The latter has important implications given that these tests are usually administered only once in assigning a diagnosis of the cause of poor Eustachian tube function and defining its role in disease pathogenesis.

With respect to the latter, a number of past studies using various manometric function tests reported random variability in the measured parameters for the left and right Eustachian tubes at the same test-session and for the Eustachian tubes of the same individual/ear on repeat testing over both short and long time intervals¹²⁻¹⁸. However, those studies used different methods of assessments and/or combinations of assessments to characterize Eustachian tube function (e.g. opening/closing pressures, Valsalva and Sniffing maneuvers, Inflation-Deflation testing) and different test-retest timing which limits interpretations of the study results.

In our evaluations of suspected Eustachian tube dysfunction in infants, children and adults with non-intact tympanic membranes (e.g. patent ventilation tubes), we use a simple manometric test protocol, the Forced-Response test, to measure the passive and active properties of the Eustachian tube¹⁹. That protocol has been used to evaluate Eustachian tube function in monkeys⁹, chinchillas⁴, ferrets²⁰, otologically healthy adults^{21,22} and children and adults with or “at risk” for the different expressions of otitis media^{3,7,10,22-25}. The test evaluates two parameters included in some of the above mentioned protocols (Eustachian tube opening and closing pressures), but also measures active tubal function associated with the magnitude of muscle assisted dilation of a pre-dilated Eustachian tube.

For individuals with different disease presentations, there is a variability among individuals in each population with respect to the degree of Eustachian tube function. Past studies using a variety of tests methods in children/adults with persistent tympanic membrane perforations provided evidence that individuals with “better” Eustachian tube function had a high success rate for closure of the perforation, while poorer function had no predictive value²⁶⁻²⁸. Recently, we observed in children with ventilation tubes for chronic otitis media with effusion that one measure of the Forced Response Test (high dilatory efficiency) and long functioning ventilation tubes were associated with non-recurrence of the disease during the 12 months after the tubes became non-functional (Mandel, personal communication). These results suggest that, despite the above cited results, there is a semi-stable level of Eustachian tube function characteristic of the individual/ear such that a single test done at a specific time is prognostic of those outcomes. The present study was designed to test the hypothesis that the parameters of the Forced Response Test are stable over time and similar for the right and left Eustachian tubes. Rejection of this hypothesis calls into question the clinical significance of single tests of Eustachian tube function for purposes of diagnosing Eustachian tube dysfunction, disease prognosis and the use of those test results as a surrogate outcomes for clinical studies that focus on past and newly developed techniques for improving Eustachian tube function by various interventions^{29,30}.

METHODS

Enrollment

Eighty-five children aged 36 to 83 months were enrolled within 6 weeks of having bilateral ventilation tubes inserted for chronic otitis media with effusion into a longitudinal study of Eustachian tube function and its role in the pathogenesis of otitis media. Children were excluded from the study if they had cleft palate or other syndromes predisposing to OM, a history of complications of OM or its treatment, or were unable to cooperate during testing. The protocol included bilateral evaluations of Eustachian tube function using the Forced Response Test in all enrolled children at approximately three month intervals from entry until the ventilation tube became non-functional. The present report focuses on the reproducibility of the Forced Response Test measurements. To that end, we examined the data set for the 85 children and identified 39 subjects who had a minimum of three evaluable bilateral Forced Response Tests done at an approximate between-test interval of three to four months. The other subjects did not meet these criteria for a variety of reasons (e.g. recent enrollment, early withdrawal from the study, missed visits, incomplete tests, insufficient time with ventilation tubes). The study was approved by the Institutional Review Board of the University of Pittsburgh (PI=EMM:IRB0605013) and written Informed Consent was obtained from a parent before enrolling their child in the study.

Forced Response Test Methods

At each test-session, a modification of the Forced Response Test described by Cantekin and colleagues was used to assess bilateral Eustachian tube function¹⁹. Briefly, a hermetically sealed probe was introduced into the ear canal ipsilateral to the Eustachian tube being evaluated. The probe was coupled to a flow sensor, pressure transducer and, via a valve, to a constant flow pump. For testing, the pump delivered ≈ 23 ml/min (QO) of air-flow to the ME. This caused the middle ear pressure to increase and the Eustachian tube to passively open at a measured pressure (opening pressure). Continued delivery of air-flow resulted in a semi-stable system (i.e. intra-luminal Eustachian tube) pressure (PS) and transtubal air-flow (QS) which was approximately equal to QO. The child was instructed or induced to swallow, an action associated with Tensor veli palatini muscle contraction, and the pre-swallow system pressure (PA) and maximum transtubal air-flow during the swallow (QA) were recorded. The pump was then turned off allowing the Eustachian tube to passively

close while retaining a residual middle ear pressure (closing pressure). Passive Eustachian tube conductance (CS) was calculated as QS/PS and active Eustachian tube conductance (CA) was calculated as QA/PA . The ratio of active to passive conductance is defined as the dilatory efficiency. The test was then repeated for the contralateral Eustachian tube using an identical procedure. All analyses of the pressure-flow waveforms for each test were done independently by two trained technicians and these data were reconciled prior to inclusion in the database. Three Forced Response Test parameters were analyzed in this report. These are the opening pressure which is a measure of the summed extra and intra-luminal forces acting to passively close the Eustachian tube, the closing pressure which is a measure of the periluminal pressure acting to close the Eustachian tube lumen; and the dilatory efficiency which is a measure of muscle-assisted Eustachian tube opening.

Analysis 1: Effect of subject's age on Eustachian tube function

It has been suggested that, like children without disease, older age in subjects with chronic otitis media with effusion is associated with better Eustachian tube function. To determine if there is an effect of the subject's age on the three parameters, for each of the three test-sessions, we independently regressed the opening pressure, closing pressure and dilatory efficiency on the age of the subjects at the time of their respective tests. We determined if any of the slopes of the functions relating those parameters to age were significantly different from zero (no relationship) using a Student's "t" test.

Analysis 2: Change with time in an individual's Eustachian tube function

It is possible that Eustachian tube function improves in ears with chronic otitis media during the period of time between ventilation tube insertion and extrusion/non-function. Because there were only three points (sessions) for each subject, we regressed the Eustachian tube function parameters on the age of each subject/ear at the three sessions and then averaged the values of the slopes across the population for each parameter. We used a Student's "t" test to determine if the average slopes were significantly different from a value of zero (no change).

Analysis 3: Effect of session and side (left-right) in the context of demographic variables

The values of the three Forced Response Test parameters for the left and right Eustachian tubes at the three test-sessions for the 39 subjects and the associated demographic information (bracketed age, sex, and race) were included in the analysis. We used a repeated-measures ANOVA to determine if any of the three parameters were different across test-sessions (repeated measure $\times$ 3), between the left and right Eustachian tubes (repeated measure $\times$ 2) and/or dependent on any of the demographic variables.

Analysis 4. Relationship between bilateral Eustachian tube function at each test-session

We determined whether or not the values of each Forced Response Test parameter for the right and left Eustachian tubes at each test-session were correlated by calculating the left-right Pearson Product Moment Correlation Coefficient (r) over all test-sessions. Because it is possible that test-session had an effect on this analysis, we also calculated that correlation coefficient between left and right Eustachian tubes for each test-session independently and then averaged the coefficients across the three test-sessions.

Analysis 5. Relationship between paired test-sessions and the Eustachian tube function parameters

Finally, for each parameter, we calculated the correlation coefficient for each Forced Response Test parameters over all individual Eustachian tubes between paired test-sessions. Because we combined the left and right ears in those calculations, we then re-calculated the

correlation coefficients between paired test-sessions for the left and right Eustachian tubes separately and then averaged the left and right correlations for each paired test-session.

Statistical Programs

All data were analyzed using the NCSS Statistical Package (Kaysville, Utah). The format used in presenting summary data in the text is the average $\pm$ standard deviation.

RESULTS

Population

The average age of the 39 children at the time of ventilation tube insertion was 5.9 ± 1.2 years (range=3.7 to 6.9 years). Of those children, 21 (54%) were male and 30 (77%) were white, 8 (21%) black and 1 (2%) of mixed race. The average time from tube insertion to test-session 1 was 83 ± 87 days, from test-session 1 to test-session 2 was 97 ± 54 days and from test-session 2 to test-session 3 was 124 ± 66 days. The average number of days between ventilation tube insertion and test-session 3 was 318 ± 118 days. The averages and standard deviations of the opening pressure, closing pressure and dilatory efficiency at each of the three test-sessions for the population are presented in Table I.

Analysis 1

The subjects showed a wide variability in age at entry. For the population of subjects/ears, we tested whether or not there was a linear trend in the values of any of the test parameters as a function of the subject's age at testing for the three test-sessions. Those regression analyses showed no linear relationship between any the Eustachian tube parameters and age at any of the three sessions. All calculated slopes were not significantly different from zero.

Analysis 2

Each subject had three measures of the three parameters at approximately three month intervals. For each subject/ear and each parameter, we regressed the value for parameter on the age at which the test was done and then averaged the calculated slopes over all individuals/ears. For opening pressure, closing pressure and dilatory efficiency, these average slopes were: 0.0008 ± 0.0007 daPa/year, -0.0027 ± 0.1308 daPa/year and -0.2901 ± 1.383 /year, none of which was significantly different from zero.

Analysis 3

Repeated-measures ANOVA was used to determine if the three parameters were different among test-sessions, between ears or dependent on the values of the tested demographic factors. There were no significant differences for any parameter by demographic factor or between ears, but differences among sessions in the dilatory efficiency ($P=0.02$) and opening pressure ($P<0.01$) were documented.

Analysis 4

At each session, data were collected on the right and left Eustachian tubes. Table II summarizes the left-right (over individuals and test-sessions) Pearson Product Moment correlation coefficient and the significance level of the correlation for each parameter. All 3 left-right correlations were statistically significant ($P<0.05$). The percent shared variance ($r^2\times 100\%$) ranged from 11% for opening pressure to 16% for dilatory efficiency. Because there may have been a difference in these correlations among sessions, for each parameter we calculated the left-right correlations for all individuals at each test-session and then averaged these correlations across test-sessions. The calculated averages and standard deviations of the left-right correlations for opening pressure, closing pressure and dilatory

efficiency were 0.42 ± 0.20 , 0.38 ± 0.22 and 0.47 ± 0.23 , respectively (all $P < 0.05$). The average left-right percent shared variance for the opening pressure, closing pressure and dilatory efficiency were 18, 14 and 22%, respectively.

Analysis 5

We also explored the relatedness of each test parameter when measured at different times (test-sessions). There, we calculated the pair-wise (by session) Pearson Product Moment Correlation Coefficients (r) and their significance levels when compared to a value of zero. These results are summarized in Table II. All correlation coefficients were positive ($r > 0$) and significantly greater than zero. For the between test-session correlations, the percent shared variance ranged from 7% for dilatory efficiency at the test-session 1 vs. test-session 2 comparison to 46% for closing pressure at the test-session 2 vs. test-session 3 comparison. In general, for all measures the between test-session correlation was less for the test-session 1 vs. test-session 3 comparison when compared to those for the test-session 1 vs. test-session 2 and test-session 2 vs. test-session 3 comparisons suggesting that the between test-session correlations for each parameter were greater for sessions conducted more closely in time. Because there may be differences between ears in these correlations, for each parameter, we calculated the correlation coefficient for the paired between test-session data for each Eustachian tube and then averaged the coefficients across left and right Eustachian tubes. For opening pressure, closing pressure and dilatory efficiency, the averages and standard deviations of the between test-session correlations were: 0.61 ± 0.13 , 0.44 ± 0.23 and 0.28 ± 0.24 for the test-session 1 vs. test-session 2 comparison, 0.42 ± 0.16 , 0.34 ± 0.20 and 0.34 ± 0.29 for the test-session 1 vs. test-session 3 comparison, and 0.62 ± 0.01 , 0.70 ± 0.06 and 0.33 ± 0.23 for the test-session 2 vs. test-session 3 comparison, respectively. All correlations were significantly different from zero.

DISCUSSION

In our laboratories, we frequently test Eustachian tube function in young children (1-3 years of age), older children, adolescents and adults with suspected Eustachian tube dysfunction^{11,23-25}. For individuals/ears with patent ventilation tubes or tympanic membrane perforations, our choice of test methodology is a modification of the Forced Response Test originally described by Cantekin and colleagues¹⁹. The advantages of that test (especially in young children) are the relatively short time required for the procedure and the limited participatory effort required of the test subject, while still capturing information on the passive (opening pressure, closing pressure) and active (dilatory efficiency) properties of the Eustachian tube.

At ours and other laboratories^{6,10,16,22,26,28,30,31} that use different tests to evaluate Eustachian tube function, the specific test protocol is usually done only once. The results of that single test often form the basis for diagnosing the presence/absence of Eustachian tube dysfunction, defining the underlying cause of a documented dysfunction, predicting future disease course and providing guidance as to possible treatments. When paired pre-post-treatment tests are done, the test results are also used as a surrogate outcome to evaluate the efficacy of the treatments with respect to improving tubal function and/or resolving related otologic diseases. For these purposes, there needs to be sufficient variability in Eustachian tube function within the population tested to make such evaluations informative and single evaluations need to capture the constitutional level of tubal function for the individual/ear such that repeated assessments, if done, would yield similar results under the same testing conditions (subject age, presence/absence of a cold etc). In the present study, we explored a number of issues related to the inter- and intra-individual/ear variability in Eustachian tube function as measured by the Forced Response test at 3 month intervals in children with ventilation tubes inserted for documented chronic otitis media with effusion.

Past studies reported that the results of Eustachian tube function tests can be used to predict the success of myringoplasty or tympanoplasty in children and adults with persistent tympanic membrane perforations²⁶⁻²⁸ and we observed that higher dilatory efficiency was one predictor of a lack of disease recurrence in children with chronic otitis media with effusion after the ventilation tubes were extruded (Mandel, personal communication). These observations require that there is sufficient inter-individual/Eustachian Tube variability in tubal function for those populations such that some members have relatively good function and others relatively poor function. Our data for the variability (standard deviations) in the Forced Response Test parameters in the tested population (See Table I) suggest that this condition is met.

In otherwise healthy children with no history of middle ear disease, the efficiency of Eustachian tube function increased with advancing age³². In our population there was a wide range of ages. All children had chronic otitis media with effusion, and therefore, presumably a degree of Eustachian tube dysfunction irrespective of age. We questioned whether or not the age-related improvement in Eustachian tube function documented for normal children contributed to the variability in the Forced Response Parameters observed for the population of children with chronic otitis media with effusion; i.e. do older children with chronic otitis media have better Eustachian tube function than younger children with the disease? If true, test results would need to be referenced to the age of the individual tested. Our analyses showed that the slopes of the functions relating the Eustachian tube function parameters to age at testing were not significantly different from zero. This observation fails to support an effect of the child's age on measures of the Forced Response Test parameters in children aged 3 to 8 with ventilation tubes inserted for chronic otitis media.

Other variables may affect Eustachian tube function and therefore need to be considered in interpreting the test results. However, at the population level, we did not demonstrate a difference in any of the test parameters as a function age, race, gender or laterality, but our analyses did identify significant differences in the opening pressure and dilatory efficiency among sessions. A similar effect on opening pressure was reported by others^{14,17}, and Bunne and colleagues also identified an effect of gender on opening pressure¹⁵. These results indicate that demographic factors do not contribute to the observed variability in Eustachian tube function for the population.

There are few studies that explored whether or not the time with ventilation tubes contributes to the variability in Eustachian tube function for individual children and adults with chronic otitis media with effusion. One study by Berry and colleagues used a Eustachian tube function test protocol that included measures of the opening pressure and closing pressure. Thirty-two Eustachian tubes of 27 children 5 to 15 years old with ventilation tubes inserted for chronic otitis media with effusion were tested at 6-week intervals over 12 to 30 months⁸. For most individual Eustachian tubes, those parameters showed a zero slope for the function relating the parameter to time with ventilation tubes. Our data are much more limited in extent, but the results are similar with a slope of zero for the test parameters over the period of time when the ventilation tubes were functional. These observations suggest that insertion of ventilation tubes does not improve the basal level of Eustachian tube function and that this variable does not need to be considered in interpreting test results.

The relative stability of the test parameters at different assessment times is important for determining if a single test is sufficient to capture the information needed to address the stated goals of function testing. Therefore, we measured the percent shared variance ($r^2 \times 100$) for right-left parameters at each test-session and that for individual ears between test-sessions. In the limit, the right and left Eustachian tubes can be considered to be

independent observations (no effect of the individual) if the percent shared variance for the different measures at each session approaches zero¹⁶, while stability of the repeated measures of the parameters would be supported if the percent shared variances between session approaches 100%. However, the average left-right percent shared variance for the opening pressure, closing pressure and dilatory efficiency were 18, 14 and 22%, and those for the average percent shared variance among sessions was 30, 24 and 10%, respectively. A similar low between test-session reproducibility for the opening and closing pressures was reported by Bunne and colleagues^{15,33} and for different measures of Eustachian tube function by others^{12,13}. These results suggest that caution be employed in treating functional measures of the left and right Eustachian tubes as independent and in extrapolating from single observations of Eustachian tube function to past and future function.

In summary, the results of this study in children 3 to 8 years of age with ventilation tubes inserted for chronic otitis media with effusion who had 3 bilateral Eustachian tube function assessments using the Forced Response Test showed that: 1) the population variance in Eustachian tube function is sufficient to include children who have marginally good function and, thus, may achieve disease resolution in the near term; 2) there is no linear relationship between a child's age at the time of testing and Eustachian tube function; 3) the Eustachian tube function parameters are not affected by race, gender or laterality, 4) the Eustachian tube function parameters are independent of the time with ventilation tubes, 5) Eustachian tube function for the right and left Eustachian tubes is not independent, and 6) Eustachian tube function parameters measured at a single time may not be representative of measures of those parameters at other times. The last point may limit the maximum accuracy, sensitivity and specificity of a single measure of Eustachian tube function by the Forced Response Test for diagnosis of Eustachian tube dysfunction and prognosis of future disease course. It is not known if this variability in the Forced Response Test parameters is an inherent characteristic of the test or of the Eustachian tube. Presently, we are exploring these issues.

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TABLE I

Average (AVG) and Standard Deviation (STD) of the Opening Pressure (PO), Closing Pressure (PC) and Dilatory Efficiency (DE) for the Right and Left Eustachian Tubes Recorded at Each of the Three Test-sessions

		PO*	PC*	DE**
Test-session 1 (right)	AVG	311.6	67.6	1.59
	STD	107.8	29.1	1.36
Test-session 2 (right)	AVG	329.7	83.2	3.50
	STD	144.3	49.0	5.44
Test-session 3 (right)	AVG	367.6	91.7	2.24
	STD	143.1	46.5	2.90
Test-session 1 (left)	AVG	312.6	85.0	2.16
	STD	120.0	49.5	2.22
Test-session 2 (left)	AVG	349.8	103.7	3.07
	STD	144.3	60.7	3.71
Test-session 3 (left)	AVG	357.4	93.7	2.67
	STD	143.5	52.2	2.22

* Pressure is measured in daPa

** Dilatory Efficiency, the conductance ratio, is dimensionless

TABLE II

The Pearson's Product Moment Correlation Coefficient (r) and Associated Probability for the Opening Pressure (PO), Closing Pressure (PC) and Dilatory Efficiency (DE) Recorded During Tests Conducted on the Right and Left Eustachian Tubes at the Same Test-Session and for Tests on Individual Eustachian Tube's Conducted at Session 1 vs. Session 2, Session 1 vs. Session 3 and Session 2 vs. Session 3.

		PO*	PC*	DE**
Right vs. Left	Pearson's r	0.33	0.34	0.41
	P-Value	<0.01	<0.01	<0.01
Test-session 1 vs. 2	Pearson's r	0.62	0.52	0.26
	P-Value	<0.01	<0.01	0.02
Test-session 2 vs. 3	Pearson's r	0.61	0.68	0.27
	P-Value	<0.01	<0.01	0.01
Test-session 1 vs. 3	Pearson's r	0.42	0.34	0.35
	P-Value	<0.01	<0.01	<0.01

* Pressure is measured in daPa,

** Dilatory Efficiency, the conductance ratio, is dimensionless,