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Eustachian Tube Function in 6-Year-Old Children With and Without a History of Middle-Ear Disease

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Abstract

Objective—Test the hypothesis that Eustachian tube opening efficiency measured as the fractional gradient equilibrated (FGE) is lower in 6-year-old children with no middle-ear disease but a well-documented history of recurrent acute otitis media when compared to children with a negative disease history (Control).

Study Design—Cross-sectional study

Setting—Tertiary-care pediatric hospital

Subjects and Methods—Bilateral Eustachian tube function was evaluated in 44 healthy 6-year-old children (19 male, 29 white). None had middle-ear disease at the time of testing, but 23 had a history of recurrent acute otitis media. Twenty-one had no significant past otitis media. Eustachian tube function was measured using a pressure-chamber protocol that established negative middle-ear gauge pressures (referenced to the chamber pressure) and recorded that pressure before and after a swallow. FGE was calculated as the change in middle-ear gauge pressure with swallowing divided by the pre-swallow pressure. Between-group comparisons of the pre-swallow pressures and FGEs were made using a 2-tailed Student's t test.

Results—FGE was independent of the pre-swallow middle-ear gauge pressure. For the 39 and 44 evaluable ears in the control and recurrent acute otitis media groups, the mean pre-swallow pressures were -194 (95% CI= -211 to -177) versus -203 (95% CI= -216 to -190) daPa ($P>0.40$) and FGEs were 0.32 (95% CI= 0.21 to 0.43) vs 0.16 (95% CI= 0.08 to 0.24) ($P=0.016$), respectively.

Conclusion—In children with past recurrent acute otitis media, residual Eustachian tube opening inefficiency is maintained after the child has “outgrown” their middle-ear disease.

INTRODUCTION

Otitis media (OM) is a very common disease in the pediatric population.^{1–3} The per child incidence and population prevalence of OM show a curvilinear decrease from a peak at

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about 6 months to 7 years of age.⁴⁻⁶ New OM episodes usually occur with a viral upper respiratory infection, can present either with (acute OM [AOM]), or without (OM with effusion [OME]), the symptoms and signs of bacterial infection of the middle ear (ME) mucosa, and are typically self-limited and of short duration.⁷ However, in some children, the ME inflammation and effusion characteristic of OM persist from months to years, a troublesome disease condition called chronic OME (COME). In others, the AOM episodes repeatedly recur in the same ear, a disease expression called recurrent AOM (RAOM).⁶

The relative efficiency of the Eustachian tube (ET) opening mechanism referred to as the efficiency of ET function (ETF) is one predictor of an ear's COME and RAOM risks, with lower efficiencies associated with higher disease risk.⁸ Past studies show that ETF efficiency is transiently worse during a viral upper respiratory infection,⁹⁻¹² is poorer in young children when compared to adults,¹³⁻¹⁴ and progressively improves throughout early childhood.¹⁵ Also, certain measures of ETF efficiency can accurately assign ears to "no disease" versus "disease"¹⁶ but not to RAOM versus COME¹⁷ groups and predict OM recurrence within one year after tympanostomy tubes inserted for COME become non-functional.¹⁸ These observations suggest that the temporal pattern characterizing the decreasing prevalence and incidence of OM in a population maps onto the ETF maturation curve during childhood. There, it is expected that the ETF maturation curve is different in children at low and high risk for the various OM presentations. When compared to individuals at low disease risk, the maturation curve in high risk individuals is characterized by a lower initial ETF efficiency coupled with a lesser rate of ETF improvement with advancing age. This delayed maturation could be expressed as a lower ETF efficiency at complete maturation of the system which is the basal level of constitutive ETF efficiency for the ear in adulthood. If so, the lower basal ETF efficiency in individuals at high disease risk in childhood would place them at higher risk for the various OM expressions during adolescence and adulthood. Typically, this risk would be expressed as disease during periods with comorbidities that in themselves downgrade constitutive ETF efficiency (e.g. nasal allergy, viral upper respiratory infections, gastro-esophageal reflux disease).¹⁹

To explore the validity of this description, the data for one test of ETF efficiency, the forced-response test, for 20 adult subjects without OM that were collected to establish "normative" test values²⁰ were reanalyzed to compare the ETF efficiency between subgroups with (n=5) and without (n=15) a history of OM in childhood. That analysis documented lower ETF efficiencies in the former when compared to the latter group. Following up on that observation, a formal study was done to measure ETF efficiency by sonotubometry in a group of 33 otherwise healthy adult subjects without ME disease at the time of testing. Sixteen of those subjects had a positive history for significant OM defined by past tympanostomy tube insertions while the remaining 17 had a negative history for OM at any time. Significant between-group differences in those test parameters measuring ETF efficiency were documented, such that the group of healthy adults with a positive OM history had the poorer ETF efficiency.²¹ Together, those results were interpreted as evidence of an incomplete maturation of ETF efficiency during growth and development in those adults who experienced OM in childhood. The present study continued the development of this theme by testing the hypothesis that ETF efficiency, measured as the fractional gradient equilibrated (FGE), is poorer in 6-year-old children with a history of RAOM that had

resolved by the time of testing when compared to same aged children with a negative history for significant OM.

METHODS

Children with a well-documented history of RAOM and with no significant OM history (Control) were enrolled at 3 years of age into an ongoing longitudinal study to characterize the changes in ET anatomy and function between 3 and 8 years of age. Children were excluded if they: (1) had cleft palate or other syndromes predisposing to OM; (2) had a history of significant orthodontic treatment, or had planned orthodontic treatment that would be expected to modify facial growth; (3) had cholesteatoma or other past ear surgery other than tympanostomy tube insertion; or (4) were unable to cooperate with testing.

Data on ET system anatomy from anthropometry, dental casts, cephalometrics and MRI scans and on ETF by the Forced-Response test²² for ears with non-intact tympanic membranes and by a standard Pressure-Chamber test protocol^{12,23} for ears with intact tympanic membranes are being collected at one-year intervals from 3 through 7 years of age. Group assignment was made at study entry using standard criteria based on history and review of personal physician and, when available, hospital records. RAOM was defined as 3 or more episodes of symptomatic OM in one year or 5 or more episodes by study entry, with at least 2 episodes in the previous year. "No significant history of OM" was defined as not having previous tympanostomy tube insertion and not meeting the criteria for RAOM or chronic OME (3 or more consecutive months of bilateral ME effusion or 6 consecutive months of unilateral ME effusion, or 3 or more episodes of OM lasting for at least 2 months each with at least one episode of OM in the year prior to entry).

Presented here is a between-group comparison of the ET opening efficiency measured using the pressure-chamber test for all enrolled children who had achieved 6 years of age and had bilateral disease-free MEs and intact tympanic membranes at the "6-year-old" visit. The study protocol was approved by the Institutional Review Board of the University of Pittsburgh, and the parent(s) of enrolled children provided written informed consent for their child's participation.

At the time of the "6-year-old" visit, the child with a parent(s) or parent-designated adult presented to the Middle Ear Physiology Laboratory at the University of Pittsburgh. An interim history was taken and the child had a standard ENT examination done by a study physician or nurse practitioner that included pneumatic otoscopy and tympanometry (Titan, Interacoustics USA, Eden Prairie, MN). The child was excluded from testing in the pressure chamber if he/she had a non-intact TM, a concurrent cold, signs and/or symptoms indicative of active allergic rhinitis, or evidence of extant ME effusion. All non-excluded children had ETF testing using a standard pressure-chamber protocol previously described.^{12,23} Briefly, the child and a technician entered a modified 6-person hypo-/hyperbaric pressure-chamber (Hypertec 9100, Olney, Texas) which was then sealed and locked to the ambient environment. The test protocol consisted of a series of applied chamber-environment pressure gradients chosen to create positive and negative ME-chamber pressure gradients, that is, ME gauge pressures measured by tympanometry, on the order of +200 and -200

daPa, respectively. A gauge pressure is defined as the pressure difference between the total pressure within a structure and the atmospheric pressure. The volume flow rate across an open communication linking a structure to the environment is proportional to the pressure-gradient across the communication measured as the gauge pressure. At each applied chamber pressure, tympanometry was done before and after the child swallowed and the pre- and post-swallow results were recorded by a second technician responsible for chamber operation. On completion of the test sequence, the chamber pressure was adjusted to ambient, the doors unlocked and opened, and the technician and child exited.

For analysis, the tympanometric pressures recorded before and after swallowing at each applied chamber pressure were double-entered by two persons into a computer file with mismatches reconciled with the source data. For each child, those data were examined for pairings characterized by a negative pre-swallow ME gauge pressure on the order of -200 daPa (accepted range = -100 to -300 daPa). For all such measures, the Fractional Gradient Equilibrated by swallowing (FGE) was calculated as the difference between the pre- and post-swallow tympanometric pressures divided by the pre-swallow tympanometric pressure.¹² FGE is a measure of the active ET opening efficiency at a "negative" ME pressure (ref. atmosphere), is expectedly independent of the pre-swallow pressure gradient and is scaled from 0 (low) to 1 (high efficiency).

In the analysis, the FGE and pre-swallow pressure were treated as continuous variables and the ear was considered to be the unit of measure. Pre-swallow gauge pressure was included as an outcome variable because it represents the extant pressure-gradient between the ME and chamber at the time of an ET opening. Between-group comparisons of those measures for the full data set and of the FGE in selected data subsets were made using a 2-tailed Student's t-test evaluated for significance at $\alpha = 0.05$. All data analyses were done using the NCSS 2007 statistical software package (Kaysville, Utah). All summary data are presented as the mean and 95% confidence interval (CI, lower to upper).

RESULTS

The analysis included data for 21 children entered into the Control group and 23 children entered into the RAOM group; 10 (48%) and 9 (39%) were male, and 14 (67%) and 15 (65%) were white, respectively. By 6 years of age, no Control child had undergone tympanostomy tube insertion, but only 1 (4%) RAOM child had not had tubes. In the RAOM group, 13 children (57%) had 1 set of tubes, 6 (26%) had 2 sets, and 3 (13%) had 3 or more sets. Five (24%) children in the Control group had undergone adenoidectomy as had 12 (52%) in the RAOM group. None of the tested children had any evidence of ME disease at the time of testing. One child (2 ears) in the Control group and 7 children (10 ears) in the RAOM group had OM in the preceding 3 months and that child in the Control group and 12 children (18 ears) in the RAOM group had OM in the previous 12 months. During testing, 1 ear of 3 subjects in the Control group and 1 ear of 2 subjects in the RAOM group failed to develop a negative ME-chamber pressure-gradient within the target range, and those ears were excluded from the analysis.

For the two groups, Table I presents the numbers of evaluable ears and the means with 95% confidence intervals for the pre-swallow ME gauge pressure and the FGE. Also reported are the values of the t-statistic and associated probability value for the between-group comparisons. The mean pre-swallow ME pressures for the Control and RAOM groups were -194 (CI -211 to -177) and -203 (CI -216 to -190) daPa, respectively. As expected, there was no significant between-group difference in those pressures ($p=0.40$). In contrast, the mean FGE's for the Control and RAOM groups were 0.32 (CI 0.21 to 0.43) and 0.16 (CI 0.08 to 0.24), respectively. This between-group difference was statistically significant with the Control group characterized by the higher FGE, i.e. greater ET opening efficiency ($p=0.016$). To explore the possibility that this poorer ET opening efficiency in the RAOM group simply reflects the existing between-group differences in the distribution of ears with more recent OM episodes, the comparative FGE analysis was re-run for Control and RAOM ears with no known OM episodes in the last 3 months (Subset A) and again for all ears with no OM episodes in the last year (Subset B, Table II). When those subjects who were known to have had OM in the 3 months prior to testing were excluded, the mean FGE for the remaining subjects in the Control group was 0.34 (CI 0.22 to 0.44) compared to 0.15 (CI 0.07 to 0.23) in the RAOM group ($p=0.01$). Excluding subjects known to have OM in the previous 12 months, the FGE was 0.34 (CI 0.22 to 0.44) in the Control group and 0.18 (CI 0.07 to 0.29) in the RAOM group ($p=0.05$). Despite the lower power for those statistical comparisons consequent to the reduced samples sizes, the between-group differences in FGE for both subsets retained statistical significance at the assigned cutoff of 0.05 .

DISCUSSION

The results for this study are consistent with the tested hypothesis. Specifically, they show that ETF efficiency as measured by the FGE for a swallow is significantly less in 6-year-old children with healthy MEs and a history of RAOM when compared to similar children with a negative history for any OM presentation. Moreover, when restricted to ears without evidence of OM within the previous 3-month and 1-year periods, the comparisons remained statistically significant. Thus, compared to children with healthy ears and no history of OM, ETF efficiency is relatively poorer in children with healthy ears but a history of RAOM at age 6 years, a time when most children have "outgrown" their OM risk.⁸ This poorer function was also seen in adults with healthy MEs but a history of OM in childhood.²¹ Of note, the mean FGE measured at 6 years of age in ears with a negative OM history in the present study, 0.32 (CI 0.21 to 0.43), is slightly greater than but within the range of values measured previously for adults with no history of significant OM, 0.26 (CI 0.18 to 0.34). This suggests that maturation of ETF efficiency was complete or nearly complete at that age.¹²

A possible mechanism to explain the observed difference between groups of ears with and without a history of OM in ETF efficiency at age 6 years and adulthood can be developed by looking at the observations made in past studies of ETF efficiency and OM risk. Those studies consistently reported that: 1) young children with relatively inefficient ETF are at higher risk for RAOM (and COME) when compared to similarly aged children with more efficient ETF,^{17,24} 2) ETF efficiency improves with growth and development until about age 7 years,^{13-15,24} 3) the temporal pattern of change in ETF efficiency maps onto that for the

age-related decrease in OM prevalence,^{4,8} 4) ETF efficiency is lower in adults who have completed ETF maturation and have a history of OM in childhood when compared to adults with a negative OM history,²¹ and 5) ETF efficiency in adults predicts their OM risk.¹⁶ Taken together, these observations suggest that the pattern of maturation of ETF efficiency, the maturation curve, during growth and development depends on early OM risk, a condition itself dependent on the ear's ETF efficiency. Specifically, irrespective of the exact characteristics of the "normal" ETF maturation curve in children with no history of OM, that curve for persons presenting with significant OM in early childhood is displaced toward lower efficiency throughout. This is expressed as the lesser efficiencies measured in those children at age 6 years and in adulthood. Because OM risk at any age depends on ETF efficiency, the specific ETF maturation curve prescribes the temporal pattern of changing OM risk throughout childhood, adolescence and adulthood.

In this study, the lesser ETF efficiency documented at age 6 years in the ears with a history of RAOE was not associated with existing OM, though those ears as a group had a higher probability of recent OM presentations (within 1 year of testing) when compared to control ears. Because of the difficulty in measurement and inherent complexities in study design¹⁸, few studies have attempted to map the probability of risk of OM onto existing ETF efficiency. Two early longitudinal studies of ETF in children with ventilating tubes (VTs) inserted for OM reported no measureable improvement in the test parameters reflecting "active" ET opening function during the period of intubation despite the low rate of OM recurrence after extubation and restoration of an intact tympanic membrane.^{25,26} However, the significance of that observation can be questioned given that the test instrument and outcome measures used were relatively insensitive to changes in ETF efficiency and the post-extubation follow-up period was short. Indeed, a more recent study that used more sophisticated test procedures and a more sensitive measure of ETF efficiency reported that the probability of OM recurrence in children with COME after VTs inserted for that condition became dysfunctional is inversely related to the ETF efficiency at the time of tube extrusion.¹⁸

Of relevance to the question of OM risk are the results for studies in monkeys, a species with a ME anatomy and physiology similar to humans. Those studies showed that procedures abolishing ET openings reproducibly effected a persistent disease condition similar to COME²⁷ and that lesser insults that downgraded ETF efficiency increased the risk for disease as reflected in repeat recurrences.²⁸ Of note, the measured rate of physiologic ME gas loss in monkeys during periods without ET openings requires a frequency of pressure-regulating ET openings of about one per day to prevent OM.²⁹ Mathematical simulations of ME pressure-regulation for the human ME show that an FGE as low as 0.1, when coupled with an opening frequency of 1/30 minutes, is sufficient to preserve a disease-free ME.¹⁹ Thus, the probability that the OM risk specified by a given ETF efficiency is realized depends on other conditioning factors as, for example, the presence of certain comorbidities known to lower ETF efficiency such as viral upper respiratory infections, nasal allergies and GERD.¹⁹

In summary, the results for the present study show that a history of RAOE in early childhood is causally associated with a lower ETF efficiency at 6 years of age. Expectedly,

that lesser efficiency increases the risk for OM in those individuals at later ages. Expression of that increased risk is dependent on other factors that in themselves moderate ETF efficiency, such as the presence of comorbid disease.

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Number of evaluable tests (N), and the Mean and 95% confidence Interval of the pre-swallow ME Gauge Pressure (Pressure) and Fractional Gradient Equilibrated (FGE) for the Recurrent Otitis Media (RAOM) and Control groups, and the "t" statistic (t-value) and probability level (P-Level) for the between-group comparisons.

Table 1

	COMPARISON	N	MEAN	95% CI	STAT
PRESSURE	CONTROL	39	-194	-177 to -211	
	RAOM	44	-203	-216 to -190	
	T-VALUE				0.89
FGE	P-LEVEL				0.40
	CONTROL	39	0.32	0.21 to 0.43	
	RAOM	44	0.16	0.08 to 0.24	
	T-VALUE				2.45
	P-LEVEL				0.016

Number of evaluable tests (N), and the mean and 95% confidence interval (CI) for the Fractional Gradient Equilibrated in subsets of ears in the Control and Recurrent Acute Otitis Media (RAOM) groups that had no otitis media (OM) in the 3 months (subset a) and in 1 year (subset b) before testing. The Student's t statistic (T-Value) and associated probability (P-Level) are listed for the comparisons between the FGEs of the Control and RAOM subsets.

Table II

GROUP	SUBSET	N	MEAN	CI	T-Value	P-Level
CONTROL	a,b*	36	0.34	0.22 to 0.44		
RAOM	a	34	0.15	0.07 to 0.23	2.62	0.01
RAOM	b	25	0.18	0.07 to 0.28	2.01	0.05

* Control subsets a and b are identical