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Post-Palatoplasty Eustachian Tube Function in Young Children with Cleft Palate

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Abstract

Objective—Characterize Eustachian tube function (ETF) using the Forced-Response Test (FRT) in young children with cleft palate (CL/P) after palatoplasty with tympanostomy tubes inserted pre-palatoplasty and compare these results to those of a 1986 study that evaluated a similar population using identical methods.

Setting—Outpatient Research Clinic.

Patients/Participants—34 children with CL/P were tested at an average age of 18.6±4.0 months.

Main Outcome Measures—Passive and active measures for the FRT.

Results—Thirteen ears could not be tested and tests on 24 ears were incomplete. The FRT showed that the passive ETF parameters were similar to those of normal adults and children. The percent of ears that showed tubal dilation with swallowing was 60%. The active resistance and dilatory efficiency were similar to a normal adult population.

Conclusions—A 1986 study of ETF in post-palatoplasty subjects with CL/P (37 ears) aged 15 to 26 months documented ET dilation with swallowing in 84% of the ears. In the present study that focused on a similar population, the frequency of tubal dilation was 60%. Nonetheless, both frequencies are significantly greater than the dilation frequency of 27% reported for 56 ears of subjects with CL/P tested between 3 months and 18 years with tympanostomy tubes inserted for persistent otitis media with effusion. This suggests that dilation during the FRT may be a prognostic marker for those children with CL/P who will resolve their ear disease at an early age.

Keywords

Cleft Palate Children; Eustachian tube function; Persistent Otitis Media with Effusion

Orofacial clefts including cleft palate (CL/P) and cleft lip are common congenital abnormalities (Centers for Disease Control, 2006) with a prevalence of approximately 1.6/1000 live births. In the 1960's, it was reported that infants and children with CL/P have a

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near universal prevalence of persistent otitis media effusion (pOME) (Manzini and Marenzi 1964; Stool and Randall 1967; Paradise et al. 1969). Other studies showed that this prevalence decreased with advancing age. For example, in a prospective study of 150 children with CL/P enrolled between 2 and 18 months of age, Robinson et al. (1992) reported a 92% prevalence of pOME before palatoplasty, no short-term change after palatoplasty, but a reduced prevalence to 70% at 4 years of age. Almost identical results were reported by Duroux et al. (1993). Moller (1981) described a universal prevalence of pOME at less than 3 years, a decreasing prevalence between 3 and 5 years and a stable prevalence from 6 years into adolescence that was estimated by others at between 10 and 30% (Gordon et al. 1988). However, it is not known what factors influence the time to resolution of pOME in children with CL/P.

Like other populations “at risk” for or with pOME (Beery et al., 1979; Takahashi et al., 1989; Cantekin, 1985; Swarts and Bluestone, 2003), past observations suggest that pOME in patients with CL/P is consequent to an impaired muscle-assisted opening function of the Eustachian tube (ET) (Bluestone et al., 1975; Doyle et al., 1980). For example, an early study using the inflation-deflation test evaluated the ability to open the ET at applied positive and negative middle ear pressures during swallowing (a maneuver associated with paratubal muscle activity) in older children with CL/P with tympanostomy tubes inserted for pOME. This study demonstrated poorer ET muscular opening function when compared to an age-matched control group (Bluestone et al., 1975). Using that test and the Forced Response Test (FRT), ET function was evaluated in 56 ears of 41 children and adolescents with CL/P aged 3 months to 18 years (2 pre-palatoplasty, median age 7 years) with tympanostomy tubes inserted for pOME. The results showed that the ET of these children could not reduce applied positive or negative middle ear pressures by swallowing, indicative of poor muscle-assisted ET openings, and that 74% of the FRT tests were characterized by a decreased transET airflow of a pre-dilated ET during swallowing, a phenomenon termed “tubal constriction” and characteristic of extremely poor muscle-assisted ET function (Doyle et al., 1980). In a later study, those tests were used to evaluate ET function in 37 ears of 24 children post-palatoplasty aged 15 to 26 months with tympanostomy tubes inserted pre-palatoplasty (Doyle et al., 1986). In that population, 84% of the ears tested increased the transET airflow of a pre-dilated ET (16% constriction) with swallowing. Together, and acknowledging that the frequencies of pOME and poor ET function decreases with age, these results suggest that ET constriction in young CL/P children may be a prognostic marker of disease persistence into late childhood and early adolescence (Doyle et al., 1986) but, to date, this hypothesis has not been tested.

Because no study in the last 25 years has evaluated ET function using the FRT in young children post-palatoplasty with tympanostomy tubes inserted pre-palatoplasty, the previously reported relatively high frequency of tubal dilation with swallowing in this population (Doyle et al., 1986) has not been validated. However, that frequency is an important consideration in developing studies to test the above stated hypothesis. The purpose of this report was to estimate the parameters of the FRT and the frequency of ET dilation post-palatoplasty in a second group of young children with tympanostomy tubes inserted pre-palatoplasty.

METHODS

The study was approved by the University of Pittsburgh Institutional Review Board (IRB). Prior to palatoplasty, the parent(s) of non-syndromic infants with CL/P were approached during a scheduled visit to the Cleft Palate Craniofacial Clinic at the Children’s Hospital of Pittsburgh concerning enrolling their infant with CL/P into this longitudinal study. The study design, parental obligations and study procedures were explained to those parents expressing

interest; and, if in agreement, an IRB approved Informed Consent was obtained. In this report, we present the first post-palatoplasty FRT results for those enrolled subjects who have completed that testing session to date.

The FRT requires the presence of a patent tympanostomy tube (or a non-intact tympanic membrane) with no evidence of otorrhea. Infants seen at the Cleft Palate Craniofacial Clinic of the Children's Hospital of Pittsburgh have bilateral tympanostomy tubes placed prior to palatoplasty. On presentation for testing, otoscopy was done by a study physician to document the lack of otorrhea and the patency of the tympanostomy tube. Tympanometry was also done to document the patency of the tympanostomy tube. For FRT testing, the child was seated in the parent's lap and gently restrained. A hermetically sealed plastic probe was introduced into the ear canal. The probe was coupled to a flow sensor, pressure transducer and, via a 3-way valve, to a variable-speed, constant flow pump as described by Cantekin et al. (1979). For testing, the constant flow pump was set to deliver ≈ 23 ml/min of air-flow to the middle ear. Preliminary studies showed that lesser flow rates did not maintain an open tubal lumen and that higher flow rates caused discomfort. The application of air-flow to the middle ear increased its pressure to a point where the ET passively opened (Opening pressure-PO). Continued delivery of air-flow usually resulted in a semi-stable system pressure (PS) with the flow rate through the ET being equal to that delivered by the pump (QO). The child was induced to swallow by drinking liquid from a cup or bottle which caused activity of the two paratubal muscles, the tensor veli palatini and levator veli palatini muscles. The activity of these muscles can be associated with either further dilation of the pre-dilated ET lumen or constriction of the pre-dilated ET lumen. These events are measured by recording the pre-swallow system pressure (PA) and maximum air-flow (QA) during the swallow. The pump is then turned off, allowing the ET to passively close (PC). The FRT variables analyzed for this report are those representing the passive characteristics of the ET (PO, PC and passive ET resistance [$RS=PS/QO$]), and those representing the active, muscle-assisted function of the ET (ET constriction/dilation, active ET resistance [$RA=PA/QA$] and ET dilatory efficiency [$DE=RS/RA$]). Note that DE values less than 1 are associated with ET constriction during swallowing. However, in analyzing the results, the convention from previous studies is to not include DE values less than 1 or the corresponding RA values in calculating summary statistics and we indicate this as DE* and RA* in calculating the average and standard deviations.

Where possible, this test protocol was done bilaterally. For some ears, the FRT was not done because the tympanostomy tube was occluded or displaced, or otorrhea or acute OM was observed. The results for a number of the testings were not complete usually because the child failed to cooperate and the test session was interrupted.

The results are summarized as the percent of tests evidencing an increase in airflow for the pre-dilated ET lumen (ET dilation), the average and standard deviations of PO, PC and RS for all tests (where recorded), and those summary statistics for RA* and DE* only when ET dilation was documented.

RESULTS

A total of 34 children were studied post-palatoplasty (28 White, 4, African American, 2 Asian; 22 male, 12 female). The average age at the time of palatoplasty was 14.3 ± 3.4 months, the average time between palatoplasty and FRT testing was 4.4 ± 2.1 months, and the average age at the time of testing was 18.6 ± 4.0 (range=14.2 to 31.0) months. One child was classified as Veau I, 6 as Veau II, 18 as Veau III and 9 as Veau IV. All subjects had their palate repaired using a double opposing z-plasty. There is an insufficient sample size to test the effects of these variables on the results of the FRT.

Five left ears and eight right ears could not be tested because of otorrhea, displacement or blockage of the tympanostomy tubes, or a lack of subject cooperation. Additionally, tests on 13 left ears and 11 right ears were incomplete generally due to lack of subject cooperation. For the left and right ears and the combined data set for both ears, Table 1 reports the values for the tubal opening (PO) and closing (PC) pressures, the passive resistance (RS) and, for ears with documented ET dilation, the active resistance (RA*) and dilatory efficiency (DE*). Also reported is the percent of tests that evidenced tubal dilation with swallowing where tubal constriction equals 100% minus percent tubal dilation. Data are presented for all ears tested including those with incomplete test results.

The results showed that the average values of the variables representing the passive function of the ET were similar to those recorded for normal and abnormal adults and children. The percent of ears that increased transET airflow during swallowing was 60%. The active resistance and dilatory efficiency were similar to a normal adult population and the older children with CL/P with tympanostomy tubes inserted for pOME but less than the average values for the post-palatoplasty children with CL/P with tympanostomy tubes inserted prepalatoplasty recorded in the previous study.

DISCUSSION

The FRT is capable of measuring both the passive and active properties of the ET (Cantekin et al., 1979). For the passive properties, the opening pressure is associated with a mechanical or organic obstruction of the ET lumen, the closing pressure is associated with the intraluminal pressures required to maintain a patent lumen and passive resistance is associated with the periluminal pressures acting on the tubal lumen. Most ET function tests in infants and children with a history of pOME and tympanostomy tubes (Beery et al., 1979; Cantekin, 1985; Takahashi et al., 1989) including children with CL/P (Doyle et al., 1980, 1986) show similar values for the passive tubal measures when compared to control subjects without a history of otitis media (Cantekin et al., 1979) and to adult subjects with experimental myringotomies but no extant pOME (Swarts et al., 2011). These results discount an organic or mechanical obstruction of the ET lumen as a cause of pOME in the majority of ears with that disease. In contrast, the active function variables provide a measure of the ability of the paratubal muscles to actively open the ET lumen and these are abnormal in patients with pOME which has been termed a ‘functional’ obstruction of the ET (Cantekin et al., 1979; Doyle et al., 1980; Cantekin, 1985).

The presence of tubal constriction is an extreme form of poor active function. In one study of 47 children aged 2 to 11 years with tympanostomy tubes for pOME, only 11% could actively dilate their ET during the FRT (Cantekin, 1985), while in a study of 18 otherwise normal adults with unilateral myringotomies, that frequency was 78% (Swarts et al., 2011). In a study of older children with CL/P aged 3 months to 18 years with tympanostomy tubes inserted for pOME, only 27% evidenced tubal dilation on FRT testing (Doyle et al., 1980), but in a study of young post-palatoplasty children aged 15 to 26 months, that frequency was 84% (Doyle et al., 1986). These results suggested to us that tubal dilation on the FRT may be a marker for early resolution of pOME in children with CL/P.

The present study was designed to validate the frequency of ET dilations in young children post-palatoplasty. For the 37 ears tested, FRT data related to the behavior of the pre-dilated ET during swallowing showed 60% with tubal dilations and 40% with tubal constrictions. These values lay intermediate between those for the older patients with CL/P with pOME and the young, post-palatoplasty patients and the differences in these frequencies (versus present study) were statistically significant ($\chi^2=9.93$, $p=0.002$; $\chi^2=5.39$; $p=0.020$, respectively). Also, the DE* was less in the current population (DE*=2.3) when compared

to those for infants in the previous study with tests done after their palatoplasties ($DE^*=6.9$), to the older CL/P population studied ($DE^*=3.4$) and to the otherwise healthy adults with no concurrent ear disease ($DE^*=4.4$).

In summary, the high frequency of ET dilations reported in the 1986 study of young infants post-palatoplasty (Doyle et al., 1986) was not reproduced in this study which evaluated a similar population using the same methods. However, that frequency was significantly greater than that reported for older patients with CL/P with tympanostomy tubes inserted for pOME (Doyle et al., 1980). The reason for the discrepancy in the data for the current and 1986 study are unknown, but a variety of factors may have contributed including differences in the surgeons performing the procedures, differences in the method of palatoplasty, differences in the underlying distribution of palatal cleft type, differences in the technical personnel performing the tests and pre-selection of the 1986 subjects for their cooperation with the testing procedures.

As evidenced by the number of incomplete tests on both ears, testing in these young patients with CL/P represents a challenge for the technician, parent and child. Also limiting the ears tested is the frequency of otorrhea and blocked or displaced tympanostomy tubes. However, the lower frequency of tubal dilation in this population when compared to the 1986 population does not rule out testing the hypothesis that those young children evidencing tubal dilation will resolve their pOME at an earlier age than those evidencing tubal constriction given that the dilation frequency is significantly greater than that for older children with CL/P with tympanostomy tubes for pOME. In that regard, we plan to follow these children by otoscopy and the FRT at approximately yearly intervals and to expand our population of young post-palatoplasty children for enrollment and first testing. We suspect that the children will be more cooperative on repeat testing as they age and that the results of the FRT will be more stable and more easily interpretable. If successful, we will be in a position to test the above stated hypothesis.

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TABLE 1

Results of the Forced Response Test for the left, right and total ears

All Tests					
	N	AVG	STD	%Dilate	
Left					
PO	29	369.2	140.6		
PC	19	141.9	70.2		
RS	24	9.1	5.5		
RA*	12	3.3	2.1		
DE*	12	3.7	1.9	60 (n=20)	
Right					
PO	27	367.7	121.7		
PC	18	132.9	81.2		
RS	20	8.5	3.1		
RA*	10	3.5	2.3		
DE*	10	3.5	2.7	59 (n=17)	
All					
PO	56	368.5	130.6		
PC	37	137.5	74.8		
RS	44	8.8	4.5		
RA*	22	3.4	2.1		
DE*	22	3.6	2.3	60 (n=37)	

* Calculated only for ETs with tubal dilation