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Treatment of persistent middle ear effusion in cleft palate patients

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ABSTRACT

Objectives: The goals of the research project are to learn how to individualize otologic care for cleft palate patients and to be able to counsel families of children with cleft palate on the benefit of tympanostomy tubes, hearing issues and risks of multiple sets of tubes.
Methods: The study is a retrospective chart review. Patients with a cleft palate with or without a cleft lip born between 1 January 2000 and 31 December 2005 referred to the Connecticut Children's Medical Center Craniofacial Department were included in the study. The patients were offered individualized ear surgery (PE tube placement) only if persistent middle ear fluid was present for over 3 months with a conductive hearing impairment. The primary outcome measures included the newborn hearing screening results, number of ear tube surgeries, and complications of PE tube insertion.
Results: There were 86 patients with cleft palate spectrum with or without cleft lip (45 females and 41 males). Twelve had undocumented newborn hearing evaluations. Of the 74 evaluable results, 61 (82%) passed the newborn hearing screening, 8 (11%) failed and 5 (7%) were inconclusive. By 5 years old, 84 (98%) patients received at least one set of ear tubes for persistent middle ear fluid with conductive hearing impairment, while 2 received no tubes (2%). Of those who received ear tubes, the range was 1–6 with a mean of 1.7. Twelve patients (14%) had tympanosclerosis. Eight patients (9%) had eardrum perforation. One patient had myringoincudopexy. Of the 86 patients, 12 had undocumented newborn hearing evaluations. Of the 74 evaluable results, 61 (82%) passed the newborn hearing screening, 8 (11%) failed and 5 (7%) were inconclusive.
Conclusions: (1) The majority of children born with cleft palate do not have middle ear fluid at birth. (2) Most children with cleft palate will likely develop persistent middle ear fluid with conductive hearing loss. Risks of complications from ear tubes in cleft palate patients are few and manageable using standard sized ear tubes.

1. Introduction

There has long been a clear association between children born with cleft palate and middle ear pathology. Historically, the incidence of persistent otitis media with effusion (OME) has been estimated to be between 80 and 95% in these children within the first few years of life [1–3]. Paradise et al. demonstrated that the 96% of cleft patients had the finding of middle ear fluid, and coined the term the universality of otitis media in cleft plate children [4]. However, there remains some controversy on the true incidence of persistent middle ear fluid in the cleft palate population. Furthermore, there is a paucity in the literature on the incidence at birth of middle ear fluid in children with cleft palate.

The pathogenesis for the OME is a result of Eustachian tube dysfunction. Many identifiable variables contribute to the OME [5], with functional obstruction and an inability to clear the middle ear fluid. The persistent OME occurs during a critical period of a child's growth and development. The conductive hearing loss associated with cleft palate has been hypothesized to have a significant impact on a child's educational, language, cognitive, and psychosocial development.

Koempel and Kumar examined the long-term otologic status of 50 adolescents and adults (age range 12–27) with a history of repaired cleft palate. They advocated a more aggressive approach to pressure-equalizing (PE) tube placement at a younger age, even in asymptomatic cleft children, to provide better speech, language, and psychosocial development [6].

In contrast, a more recent study by Sheahan et al. questioned the efficacy of aggressive and prophylactic management of OME

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using PE tubes. Their findings, based on a questionnaire, demonstrated an association of conductive hearing loss and multiple PE tube placements [7]. Additional reports have advocated a conservative approach for PE tube placement due to the complications of PE tube surgery and the questionable benefit they might provide during development [8,9].

The purpose of this study is to better answer the following questions in cleft palate patients from birth to 5 years old: (1) What percentage of neonates with cleft palate are born with middle ear fluid? (2) What percentage of patients with cleft palate eventually develop the middle ear fluid and the conductive hearing loss by 5 years old? (3) What percentage of parents whose children have persistent middle ear fluid with conductive hearing loss choose to have PE tubes placed? (4) What is the average number of PE tubes by 5 years old? (5) What were the complications of PE tube placement in this cohort who received standard-sized tubes? (6) Do children have better speech outcomes who receive PE tubes than children who did not receive PE tubes?

2. Patients and methods

The study was a retrospective chart review at a single institution. The protocol was reviewed and approved by the IRB at the Connecticut Children's Medical Center. Children with cleft palate born between 1 January 2000 and 31 December 2005 that had been referred to the Craniofacial Team at the Connecticut Children's Medical Center were identified as potential patients in the study. A HIPAA waiver was obtained to access the charts for review. One hundred fourteen patients were identified for study. Twenty-eight patients were excluded from the study. Eight of the patients moved out of the state, 10 were lost to follow-up, five had prior surgeries out of state, and five had significant medical co-morbidities. We attempted to contact those that were lost to follow-up. The cleft type and newborn hearing screen data that was available for these patients were used in the analysis. The charts in the Otolaryngology Department and the Craniofacial Team Department were reviewed for each patient. All patients were examined at least once in every 6 months to document the middle ear status regardless of ear tube status. All patients were offered ear tubes if fluid was present at the time of cleft lip surgery, and then thereafter if documented bilateral middle ear effusion for greater than 3 months and bilateral conductive hearing impairment greater than 25 dB.

Specific data extracted from each chart included cleft type, newborn hearing status, other medical diagnoses, type and date of surgeries, and pertinent otologic findings during surgery or in follow-up care. Means and ranges were calculated for the above variables.

3. Results

There were 41 males and 45 females included in the study. The most common type of cleft recorded in this study was the soft palate cleft, which comprised 35% of the study cohort. Table 1 provides details of the cleft type in relation to gender.

Table 1
Cleft type versus gender.

Cleft type	Number of males (41)	Number of females (45)
Bilateral palate ± lip	7	5
Left lip and palate	13	8
Right lip and palate	6	3
Hard and soft palate	5	7
Soft palate	10	20
Unspecified	0	2

Table 2
Results of newborn hearing screen with palate type.

Cleft type	Passed newborn screen	Failed newborn screen	Inconclusive exam
Bilateral palate ± lip	10	1	0
Left lip and palate	12	2	0
Right lip and palate	8	1	1
Hard and soft palate	8	2	0
Soft palate	22	2	4
Unspecified	1	0	0

Table 3
Number of BMTs for cohort.

Number of bilateral tube surgeries	Number of patients
0	2
1	32
2	32
3	14
4	5
5	0
6	1

Table 4
PE tube surgeries versus abnormal otologic findings.

Abnormal otologic findings	Number of bilateral PE tube surgeries					
	0	1	2	3	4	5
Tympanosclerosis	0	1	4	5	1	1
Perforation	0	1	5	1	1	0
Thickened eardrum	0	3	2	0	0	0
Myringoincudopexy	0	1	0	0	0	0
Atelectasis	0	0	1	0	0	0

Of the 86 patients included in the study, 74 of them had a documented, evaluable newborn hearing exam. In 12 patients the newborn hearing exam was not recorded. Sixty-one patients passed the newborn exam, whereas eight failed the screen and were referred for further testing. Five patients had inconclusive exams. Table 2 demonstrates the results of the newborn hearing exam with respect to the cleft type.

Table 3 illustrates the number of bilateral PE tube surgeries. Within the study group, 84 had at least one bilateral PE tube surgery. The average number of bilateral PE tubes placed was 1.7 with a range of 0–6. Two of the patients never underwent PE tube placement. There were no unilateral PE tube surgeries. All patients in the study were followed every 6 months until 5 years old validating the otologic status, and potential recollection of middle ear fluid in patients without ear tubes.

Table 4 lists the otomicroscopic findings with respect to the number of PE tube surgeries. The highest incidence of abnormal findings occurred in the group with two bilateral PE tube surgeries. The most common abnormality was tympanosclerosis with 12 patients. Eight patients had a persistent perforation during the study follow-up period. Five patients had thickened tympanic membranes. One patient had bilateral myringoincudopexy and one patient had bilateral atelectasis.

4. Discussion

The literature regarding otologic care of children with cleft palate has several small retrospective studies, but few large, longitudinal studies to support conclusions and recommendations for parents. Our study has the advantage of a large enough cohort (86 patients) to be meaningful and provide a measure of guidance. By only performing ear tube surgery on patients with documented middle ear fluid and conductive hearing impairment, we avoid the