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Middle ear findings and need for ventilation tubes among pediatric cleft lip and palate patients in northern Finland

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ABSTRACT

Purpose: Middle ear problems are common in cleft patients. This study aimed to determine the need for ventilation tubes (VTs) and complications such as tympanic perforation and cholesteatoma.
Material and methods: Data of 156 children with clefts managed in northern Finland spanning 15 years from 1997 to 2011 were collected from 6 hospitals. The following were recorded: birth date, gender, cleft type, surgery timing, surgery type, number of tube insertions, tube material, middle ear findings, and tube placement timing. Clefts were divided into 4 groups: cleft palate (CP), cleft lip and palate (CLP), cleft lip (CL), and submucous cleft palate. The prevalence of middle ear findings was reported.
Results: Mucous secretion was noted in 96.8% of CLP patients, 69.2% of CP patients, and 13.0% of CL patients. In all, 82.7% of study group had 1 or more VTs placed during follow-up. All CLP patients required more than 1 VT placement. A total of 94.5% of CP patients required VTs compared to 13.0% of CL patients. In the presence of residual oral nasal fistula, the mean number of tube insertions was 5.3. The prevalence of tympanic perforations in clefts was 35.9% and cholesteatoma in 2.6% of patients.
Conclusions: CLP and isolated CP patients have frequent middle ear infections requiring multiple VT placements.

1. Introduction

Cleft lip and/or palate is the most frequent congenital anomaly occurring in the craniofacial region (Härtel et al., 1991; Khan et al., 2013; Esmail et al., 2014). Clefts are divided into three groups: cleft lip (CL), cleft lip and palate (CLP), or isolated cleft palate (CP). Cleft lip can also occur as unilateral or bilateral manifestations. The incidence of clefts varies between countries and racial or ethnic groups (Schutte and Murray, 1999). Generally, the incidence of clefts is estimated to be between 1 and 2.21 cases per 1000 live births (Derijicke et al., 1996) or 1 in 500 infants to 1 in 1000 infants (Khan et al., 2013). The overall incidence of clefts in Finland is remarkably high at 2.56 cases per 1000 live births and abortions, and the incidence of isolated cleft palate is among the highest in the world (Lithovius et al., 2014).

Children with cleft lip and palate may suffer from feeding, swallowing, speech, hearing difficulties, and cosmetic problems as well as poor dental health (Bian et al., 2001). The successful treatment of a cleft patient consists of multidisciplinary surgical and nonsurgical treatments that are performed from birth to adulthood (Shaw et al., 2001; Fitzsimons et al., 2013). The goal of the cleft palate surgical treatments is to ensure normal development, facial growth, and appearance for the patient, as well as normal hearing, speech, and breathing (Pearson and Kirschner, 2011). In Finland, the surgical treatment for cleft children begins during infancy. A cleft

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lip is normally repaired at the age of 3–6 months and a cleft palate at the age of approximately 9 months. However, the timing of surgical treatment may vary depending on the characteristics of the individual case (Rautio et al., 2010).

Secretory otitis media (SOM), otitis media with effusion (OME), or glue ear is a condition in which mucous fluid accumulates in the middle ear instead of pus and can lead to conductive hearing impairment (Shaw et al., 2003). OME (effusion longer than 3 months) is usually treated with ventilation tube (VT) placement. A Finnish study showed that 8.5% of non-cleft children under the age of 7.5 years had OME and had undergone VT placement (Karma and Sipilä, 1988). OMEs resulting from a malfunction of the Eustachian tube are reported to be even more common among cleft patients (Klockars and Rautio, 2012).

Eustachian tube malfunction and its treatment in cleft patients is a controversial topic (Bütow et al., 1991). The benefits of tympanostomy are ventilation of middle ear and improvement of conductive hearing loss (Reiter et al., 2009). The possible adverse effects of repeated VT insertions include hearing loss, tympanic perforations, and cholesteatoma (Moller, 1981; Shehan et al., 2002; Hartzell and Dornhoffer, 2010). Middle ear infections and conductive hearing loss are closely related. Speech development in cleft patients can be affected by velopharyngeal structural abnormalities and hearing loss. Early VT placement in children with clefts may improve their speech ability, reduce hearing loss, and improve the long term clinical, audiologic, and radiologic outcomes (Klockars and Rautio, 2012). Closing the cleft palate and placing VTs concurrently has been reported to be effective treatment for cleft patients with OME (Huang et al., 2012). However, some studies reported that early elective VT placement may lead to reduced hearing loss in comparison to placing the VT as symptoms appear (Hubbard et al., 1985). Some authors claim that early ventilation tube placement may not result in better hearing and may result in morbidity including otorrhea and persistent perforation (Robinson et al., 1992).

Our initial hypothesis was that cleft children from northern Finland have more middle ear problems than non-cleft children. The authors also hypothesized that northern Finnish children with clefts have more VT placements than non-cleft children. The aim of this study was to examine the middle ear problems in cleft patients uniquely treated in northern Finland, where the incidence of isolated cleft palate is known to be high. The second goal was to examine the need for VTs and problems related to their use, such as the occurrence of tympanic perforation and cholesteatoma. The study aimed to compare the results associated with different cleft types, age groups, and genders.

2. Material and methods

2.1. Patients and procedures

The study was carried out using the Oulu University Hospital patient registry data and data from the referring network of hospitals including Lapland Central Hospital, Kajaani Hospital, Kemi Hospital, Kokkola Hospital, and Raahe Hospital with the collective permission of the six hospitals (permission number 10/2012). The data were analyzed without personal identifying details. No separate permission from the hospital ethical committees was required. Permission from the registry holder (Oulu University Hospital, Lapland Central Hospital, Kajaani, Kemi, Kokkola and Raahe Hospitals) was considered to be sufficient for this retrospective register-based study.

Material for this retrospective population-based follow-up study was collected from the Oulu University Hospital patient registry and the registers of the other 5 listed hospitals comprehensively covering the 15-year period from 1997 to 2011, which covers the period during which cleft patients have been managed in Oulu. The goal was to provide a representative sample of cleft patients treated in northern Finland. Data from patients who had received treatment at the cleft center in Helsinki were not available. Data of patients managed in Oulu included 214 patients. The records of these patients were collected and analyzed together by all of the authors.

Exclusion criteria comprised those patients who possibly had received tube insertions from the outside hospitals, as these records were not available. Patients who had moved away from northern Finland during follow-up were also excluded. Inclusion criteria comprised all cleft patients from northern Finland with complete clinical follow-up records. The data consisted of the medical records of a total of 156 cleft patients (72.9%) who satisfied the above inclusion and exclusion criteria.

The following factors were recorded: date of birth, gender, cleft type, time of surgery, surgery type, number of ventilation tube (VT) insertions, tube material, middle ear findings, and the date and time of the particular finding. The clefts were divided into 4 groups including cleft palate (CP), cleft lip and palate (CLP), cleft lip (CL), and submucous cleft palate (SMC). The prevalence of middle ear findings was reported.

All patients with cleft palate had a 1-stage palatal, 3-layer closure, in which the hard and soft palate were closed and an intravelar veloplasty was performed (Kriens, 1970). The VTs were inserted proactively before or at the time of palatoplasty, as children often develop painful OME following palatoplasty. The patients were followed by an otolaryngologist 1–3 times per year or more often if necessary. Tubes were replaced according to the Oulu University Hospital protocol, which included the diagnosis of glue ear or recurrent otitis media at least 3 times over a 6-month period or more than 4 infections in a year.

2.2. Statistical analysis

The cleft children were counted and their cleft type determined. Data related to middle ear findings were gathered in connection with VT placements. Gender, age, tube material, and fistula were registered separately. Dates were gathered separately for tympanostomies, middle ear findings, and surgeries including cleft repair surgery and speech improvement surgery.

The number of clefts, tube insertions, and the association of middle ear findings were determined by using the Pearson χ^2 test or Fisher exact test. A t-test, Mann–Whitney test, or Kruskal–Wallis test were used to compare the average age at VT insertion between cleft types. The test was selected on the grounds of the distribution of age, number of cleft types, or number of VT insertions. The statistical differences between groups were determined by using the significant P value ($P < 0.05$). Statistical analyses were performed using SPSS version 20.0 (SPSS Inc., Chicago, IL, USA).

3. Results

In this study, 78.9% of patients with all types of clefts including CLP, CP, and CL had secretion products in their middle ear cavities during the follow-up period. Mucous secretions were discovered in 69. 9% of all subjects, serous secretions in 36. 5%, and purulent secretions in 23.7% (Table 1). Mucous secretion referring to glue ear was detected in 96.8% of the cleft lip and palate patients, 69.2% of the cleft palate patients, and 13.0% of the cleft lip patients.

Almost all patients in the study group ($n = 121$ of 156, 82.7%) had 1 or more VT placements during the follow-up period. There was a difference in the need for VT placement according to the cleft