International Journal of Pediatric Otorhinolaryngology 97 (2017) 102–108

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: http://www.ijporlonline.com/

Hearing thresholds and ventilation tube treatment in children with unilateral cleft lip and palate

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ARTICLE INFO

Article history:
Received 9 November 2016
Received in revised form
20 March 2017
Accepted 26 March 2017
Available online 28 March 2017

Keywords:
Cleft lip and palate
Hearing impairment
Higher frequencies
Otitis media with effusion
Ventilation tube

ABSTRACT

Objective: Children with cleft lip and palate have a high prevalence of otitis media with effusion (OME) which is often associated with a fluctuating, conductive hearing loss in the low and mid-frequencies and a risk for permanent hearing loss in the higher frequencies. Although common, there is no consensus on the treatment of OME with ventilation tubes. The aim of this study is to document if the risk for permanent hearing loss and acquired cholesteatoma increases due to treatment with ventilation tubes (VT treatments) during childhood in a group of children with cleft lip and palate.
Methods: A retrospective medical chart review of 33 children (25 boys and 8 girls) born with unilateral cleft lip and palate (UCLP) was completed. Audiological data (results of hearing sensitivity tests, the total number of hearing tests, and number of VT treatments) were extracted from medical records from when the children were 4–7 and >7–10 years of age.
Results: The hearing thresholds in the speech frequencies improved with age ($p < 0,05$) but a minority of the children continued to present with elevated hearing thresholds in the higher frequencies at >7–10 years of age. There were no significant correlations between number of VT treatments and hearing thresholds at >7–10 years. Four of the 33 children presented with complications: two children exhibited perforations of the ear drum (6.1%) and two children developed unilateral cholesteatoma (6.1%).
Conclusion: In the current study, the hearing sensitivity of children with cleft lip and palate improved with age. However, this improvement was not seen in the higher frequencies. Twelve percent of the children experienced complications following VT treatments. Due to these complications, it is recommended that all children with cleft palate should have routine follow-ups by an ENT doctor and audiologist. As part of the routine follow-up care, hearing assessments should be performed before and after VT treatments.

1. Introduction

Cleft lip and palate is a congenital anomaly occurring during fetal development. It is one of the more common birth anomalies with an incidence of 2 per 1000 births [1]. Children with cleft palate with/without cleft lip (CP ± L) demonstrate difficulties with feeding, speech, dentition, and hearing. More specifically, children with CP ± L frequently have a high prevalence of otitis media with effusion (OME) [2,3]. Several studies have reported a higher prevalence of OME in children with CP ± L than in children without cleft [2,4,5]. The high prevalence of OME in children with CP ± L may be due to Eustachian Tube (ET) dysfunction [6]. The muscles responsible for opening the ET include the m. tensor veli palatini and the m. levator veli palatini and these muscles insert abnormally in children with CP ± L. Abnormal insertion results in the muscles not contracting properly which leads to a lack of ventilation. This lack of proper ventilation can result in a retracted tympanic membrane and fluid in the middle ear cavity and there are different theories about the pathophysiology [7,8]. ET dysfunction may lead to OME which can last several years, often more than five years after palatal

Abbreviations: CP ± L, Cleft palate with/without cleft lip; ET, Eustachian Tube; OME, Otitis media with effusion; PTA4, Four frequency pure tone average (500-1000-2000-4000 Hz); PTAHF, Pure tone average high frequencies (6000–8000 Hz); dB HL, decibel hearing level; UCLP, Unilateral cleft lip and palate; VT, Ventilation tube.

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http://dx.doi.org/10.1016/j.ijporl.2017.03.031
0165-5876/

repair [8].

The prevalence of otitis media and OME often declines with age in the children with CP ± L [9,10]. OME is associated with a conductive hearing loss between 30 and 45 dB. Hearing loss may be persistent or recurrent, variable in degree, and affect one or both ears. Only one study to date has compared hearing thresholds between children with CP ± L and OME and children with OME and no CP ± L. It has been demonstrated that hearing loss in children with CP ± L and OME may be elevated as compared to children with OME and no CP ± L [4].

Another complication associated with OME is hearing loss in the higher frequencies, which has been demonstrated in children and adults with a positive history of OME without CP ± L [11–13] and with CP ± L [10,14] In children without CP ± L, normal middle ear impedance [12] and normal distortion product otoacoustic emissions [11] were shown when the extended high frequency hearing loss (8000–20000 Hz) was present. Therefore, this hearing loss was considered not to be of a conductive nature. When children with CP ± L were compared to children without CP ± L and positive OME histories and to children without CP ± L and minimal history of OME, children with CP ± L and children without CP ± L and positive OME histories demonstrated similar thresholds in the extended high frequencies (8000–20000 Hz) [14]. This suggests that the OME rather than the CP ± L may have caused the hearing loss in the higher frequencies. Flynn et al. [10] showed that the hearing thresholds in the low to mid frequencies in children with CP ± L improved over time but when children became 5 years and older, the hearing in the high frequencies did not significantly improve. This elevation in the high frequencies was also noted in young adults with unilateral cleft of the lip and palate (UCLP) as compared to young adults without CP ± L [10].

There is controversy over the possible auditory sequelae resulting from OME and the associated fluctuating, conductive hearing loss in the short and long term. It has been suggested that the fluctuating, conductive hearing loss associated with chronic OME is a form of auditory deprivation and therefore, may lead to challenges in acquiring speech and language [11,15]. The higher prevalence of OME in infancy and early childhood, which are important periods for language learning, has led to the use of ventilation tube (VT) treatments in young children. VT:s are often inserted prophylactically at the time of surgical repair of the lip and palate to ensure optimal hearing. Although there are some prospective studies regarding optimal treatment strategy of OME in children with CP ± L, there are few well-conducted, high-quality, and adequately powered randomized controlled trials (RCT:s) [16]. There is insufficient evidence to support any assertions regarding the optimal timing of VT insertion as there may be complications following treatment. In a systematic review of the effectiveness of VT insertion for OME in children with CP ± L by Kuo et al. [17] seven of the nine included studies reported post-VT complications and sequelae. Eardrum perforations (incidence 1.3–19% during 1–9 years of follow-up) were the most commonly reported sequelae. Post-VT insertion cholesteatoma was reported in two retrospective cohort studies in this review article (incidence 0–3.8% at 18 months to > 9 years). However, the available evidence was insufficient to enable a specific comparison of each complication between VT and non-VT-groups.

The aim of this study is to describe the hearing sensitivity of a group of children with UCLP between 4 and 10 years of age and try to examine if the hearing thresholds change with increasing age. Furthermore, this study reports the number of VT treatments, and the number of VT treatments in relation to hearing sensitivity. Finally, the number of complications following OME and VT treatments is described.

2. Material and methods

2.1. Material

This study was a retrospective medical chart review. A consecutive series of 37 children (28 boys and nine girls) born with UCLP were included. All children were born in Stockholm between 1998 and 2006 and were patients at the Karolinska University Hospital and treated by the Stockholm Craniofacial Team. The children were part of a larger randomized trial on palatal surgery (the Scandcleft project) [18].

Participating children did not present with additional malformations and/or syndromes and had at least one caregiver who spoke native Swedish at home. Children were randomly divided into two palatal closure techniques: one-stage and two-stage closure. The mean age (SD) of primary palatal closure surgery in the one-stage group was 13.2 (0.88) months. In the two-stage closure group, children underwent the soft palate repair at a mean age (SD) of 4.2 (0.56) months and the hard palate repair at 12.8 (0.68) months [19]. Four children were excluded from the study; two children moved from the area and two children had incomplete audiometric data. This resulted in 33 children (25 boys and 8 girls) included in the present study.

2.2. Methods

All medical records from the Otolaryngology Department at Karolinska University Hospital were reviewed longitudinally and retrospectively for each participating child. Specific data was extracted from each medical record and was subdivided in two groups, from when the children were 4–7 and >7–10 years of age. Data included results of hearing sensitivity tests, the total number of hearing tests, and number of VT treatments.

2.2.1. Hearing sensitivity

Hearing sensitivity was assessed using pure-tones or warble-tones under TDH-39P headphones. The audiometers follow the international standard IEC 60645 and were calibrated according to ISO 389. Conditioned play audiometry or standard audiometry was utilized to obtain ear specific thresholds for 500, 1000, 2000, 4000, 6000, and 8000 Hz. A four frequency average (PTA4) of 500, 1000, 2000, and 4000 Hz and a high frequency average (PTAHF) of 6000 and 8000 Hz were calculated for each ear. Seventeen children aged 4–7 years were audiometrically screened at 10, 15 or 20 dB hearing level (HL) according to clinical protocol. Only one child was audiometrically screened at 15 dB HL at >7–10 years of age. Audiometric screening implies that the absolute thresholds are not necessarily determined and longitudinal changes cannot be adequately examined.

Normal hearing was considered to be PTA4 ≤ 20 dB HL in the better ear. Mild hearing loss was categorized with a PTA4 over 20 dB HL and less than 40 dB HL in better ear. Moderate hearing loss was categorized with a PTA4 over 40 dB HL and less than 70 dB HL in better ear. Severe hearing loss was categorized with a PTA4 over 70 dB HL and less than 95 dB HL in better ear (Table 1) [20].

2.2.2. Ventilation tube (VT) insertion

The age at the first VT insertion and the total number of VT:s in each ear was documented. The number of ears with perforation of the ear drum after VT insertion and the number of ears with acquired cholesteatoma were also documented. Unfortunately, there was limited documentation of time with VTs due to children attending local ENT-clinics for follow-up after VT insertion.

All the children did not have their ENT follow-up at the Karolinska University Hospital due to long travelling distances. Instead