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ABR thresholds in infants born with CLP and OME and infants with OME

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ABSTRACT

Objectives: The aim of this study was to investigate and compare auditory brainstem response (ABR) thresholds related to otitis media with effusion (OME) in infants with and without cleft palate and/or lip (CP ± L).
Methods: Forty-seven infants with CP ± L and 67 infants with OME participated in the study. Hearing thresholds of ears of infants with OME were compared between groups and within the group with CP ± L.
Results: Infants with CP ± L and OME presented with similar hearing thresholds as infants with OME and not CP ± L. Within the cleft group, infants with isolated cleft palate and OME demonstrated significantly higher hearing thresholds than infants with unilateral cleft lip and palate and OME.
Conclusion: A high prevalence of infants with CP ± L present with OME early in life. Hearing thresholds of these infants are similar to infants without CP ± L, but with OME. The ear status and hearing thresholds of infants with CP ± L needs to be monitored to be able to provide the best access to hearing in order to fully allow speech and language development.

1. Introduction

Children born with cleft palate and/or lip (CP ± L) present with a higher prevalence of otitis media with effusion (OME) than children born without CP ± L. Prevalence of OME has been reported to range from 76 and 97 percent in children with CP ± L between the ages of two and 24 months [1–11]. This high prevalence of OME is most likely due to Eustachian tube dysfunction. The tensor veli palatini and the levator veli palatini muscles are not able to contract properly and open the Eustachian tube [1,12,13]. Therefore, the Eustachian tube is unable to equalize pressure and leads to negative pressure in the middle ear. This negative pressure results in a retracted tympanic membrane and secretion of mucous from the tissues through osmosis into the middle ear cavity [2,7].

OME is associated with a mild to moderate, fluctuating conductive hearing impairment across the speech frequencies [14]. A few studies have investigated this association in young children [15–17]. Gravel and Wallace [15] demonstrated infants at one year of age with an average of four episodes of bilateral OME presented with elevated thresholds (37.8 dB nHL) as compared to a group of infants (20.3 dB nHL) with an average of less than one episode. Other studies have investigated OME and the associated hearing loss in relation to universal newborn hearing screening (UNHS). Aithal and colleagues [17] demonstrated 68 percent of newborns (average of 47.5 days), which had OME also had a hearing loss. For those infants who presented with OME and a hearing loss, an average threshold of 50 dBnHL was recorded when the infant was 49 days old [16]. Second, Boudewyns and colleagues [16] demonstrated 55 percent of the newborns (average 49 days) who failed screening had a hearing loss associated with OME ranging between 40 and 60 dBnHL in both ears. These infants were followed longitudinally and presented with normal hearing by 4.8 months of age. Five of the 64 infants presented with a CP ± L.

Furthermore, there have been several studies focusing on OME and an associated hearing loss in children with CP ± L. Four studies have reported young children with CP ± L exhibit a higher prevalence of hearing impairment than children without CP ± L. Broen et al. [2] demonstrated young children with CP ± L were more likely to fail a hearing screening between 9 and 30 months of age. The other three studies reported a range between 55 and 93 percent of ears of infants and young children with CP ± L and OME to demonstrate a mild to moderate hearing loss [9,10,18]. On the contrary, Jocelyn et al. [6] reported fewer children with CP ± L (25 percent) which exhibited mild to moderate hearing impairment at 12 and 24 months of age as

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compared to zero and six percent in the children without CP ± L. This lower percentage of children with hearing impairment may be due to the significantly higher number of children with ventilation tubes in the group of children with CP ± L [6].

This contradicting evidence is also seen in the hearing screening of newborns with CP ± L. Three studies reported a range of 12 and 28 percent of newborns with CP ± L which failed their newborn hearing screen [19–21]. On the contrary, four other studies described a higher percentage of hearing impairment, between 70 and 84 percent, in newborns with CP ± L with a mild to moderate conductive hearing loss [10,22–24]. This discrepancy may be to audiometry methodology. Newborn hearing screening was conducted either with otoacoustic emission (OAEs) or automated auditory brainstem response (AABR) [19–21]. These methods, which utilized a pass/fail criteria, were used in the studies reporting a lower incidence of abnormal hearing. The other studies obtained a threshold of hearing via an auditory brainstem response (ABR) [10,22,23]. Determining a threshold is a more detailed definition of hearing sensitivity and includes newborns with mild hearing loss, which may have been missed via screening or pass/fail methods. Another factor which may have contributed to the discrepancy is age of the newborn. In the studies with a lower rate of abnormal hearing, the infants were screened at birth; while the studies with a higher rate of abnormal hearing, the infants were tested when they were older, ranging between an average of 43 days up to 14 months of age.

Furthermore, these studies do not compare the hearing in newborns with CP ± L to newborns without CP ± L, but with OME. Children with CP ± L and OME have been shown to present with higher thresholds than children without CP ± L, but with OME [7]. Flynn et al. [7] demonstrated children with unilateral cleft lip and palate (UCLP) with OME and a hearing impairment exhibited significantly higher hearing thresholds than children without UCLP, but with OME and a hearing impairment [7]. Therefore, it is critical to investigate when this significant difference may occur as this is a sensitive period for the development of auditory, speech, and language skills.

There is insufficient data to conclude the timing and possible long-term benefits of the placement of ventilation tubes [25]. The NICE guidelines specify, ventilation tubes should only be placed at palatal closure after careful otological and audiological assessment, not prophylactically [26]. However, Klockars and Rautio [11] demonstrated the majority of infants with ventilation tubes placed at four months of age during time of soft palate repair resulted in a lower prevalence of OME at 12 months of age as compared to infants who received ventilation tubes at four months of age but with soft palate repair at 12 months of age [11]. It was hypothesized that the earlier repair of the soft palate aided the Eustachian tube to function effectively and allow the ventilation tubes to not become occluded. Ventilation tubes were placed either following the diagnosis of OME by otomicroscopy or paracentesis during surgery or prophylactically. Hearing levels were not reported.

As it is controversial when to place ventilation tubes, it is crucial to define the possible prevalence of an associated hearing impairment in newborns with and without CP ± L. This may lead to changes in protocol for the placement of ventilation tubes. Therefore, the aim of this study was to investigate and compare auditory brainstem response (ABR) thresholds related to otitis media with effusion (OME) in infants with and without CP ± L.

2. Materials and methods

2.1. Materials

The study was a retrospective chart review at a single hospital (Karolinska University Hospital, Sweden). Medical files between January 2011 and January 2013 were reviewed for two groups of possible participants. The two groups included infants with CP ± L (cleft group) and infants without cleft, but with OME (non-cleft group). For the non-cleft group, all infants with a medical record containing a diagnosis of OME and ABR threshold levels were included in the study. Infants in the non-cleft groups were excluded if they had a medical diagnosis or syndrome, a malformation, or a hearing impairment not caused by OME. Infants in the cleft group were excluded if they had an additional medical diagnosis or malformation, a syndrome, or a sensori-neural hearing impairment.

The first group (non-cleft group) included infants who failed the newborn hearing screening and were diagnosed with OME. Sixty-six infants (41 males and 25 females) with a mean age of 97 days (range: 37–197 days) were diagnosed with either unilateral or bilateral OME. The second group (cleft group) consisted of 50 infants (32 males and 14 females) with a mean age of 65 days (range: 25–145 days). Twenty-six infants presented with an isolated cleft of the palate (ICP), 14 infants with unilateral cleft lip and palate (UCLP), and ten infants with bilateral cleft lip and palate (BCLP).

2.2. Methods

Data were collected from the medical records at the time of the diagnostic ABR during clinical routine visits between January 2011 and January 2013. Hearing thresholds from the ABR and otomicroscopy examination were collected.

2.2.1. Hearing sensitivity

The click evoked ABR was obtained while infants were sleeping using the Interacoustics EP25 (Denmark). The click evoked ABR was utilized as it is clinical protocol at the Karolinska University Hospital following a failed OAE screen. Rarefaction pulses were delivered at a rate of 39.1 stimuli/second through ER-3A ABR insert earphones. The recording window was 15 ms. Initial stimuli were presented at 50 dBnHL. Stimuli intensity was increased or decreased in 10 dB increments and 5 dB increments when necessary. Thresholds were tracked using wave V. A minimum of 1700 sweeps for each waveform were obtained. Twenty dBnHL was the lowest stimuli presented and 90 dBnHL was the maximum level presented. Threshold was determined when two recordings were repeated.

The click evoked ABR was performed during natural sleep on both ears of the infant. If the infant woke during the measurement, any further collection of data was discontinued until the infant went back to sleep. Fourteen infants in this study underwent two ABR assessments. The second ABR was performed due to an incomplete assessment due to lack of sleep or restlessness. The lowest estimated threshold obtained was used during the analysis.

2.2.2. Ear status

A pediatric otolaryngologist performed otomicroscopy on the day of ABR testing to determine ear status. Results were classified as normal or abnormal (fluid filled middle ear cavity or retracted tympanic membrane).

2.3. Statistical description and analysis

Statistical analysis of the results was performed using the *t*-test to compare the mean hearing thresholds between the cleft and non-cleft groups and the ANOVA to compare cleft types within the cleft group. Effect size was analyzed with Cohen's d. The data were analyzed using SPSS for Windows (Version 22).

Data collection and analyses were carried out according to ethical principles for medical research involving human subjects and with permission from the Head of the Clinical Department of