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Hearing sensibility and middle ear status with and without ventilation tube in cleft lip and palate

Sensibilidade auditiva e condições de orelha média com e sem tubo de ventilação na fissura labiopalatina

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ABSTRACT

Purpose: To characterize and compare hearing and middle ear status in patients with cleft lip and palate with or without a history of ventilation tube insertion. **Methods:** Retrospective study that involved the analysis of 463 medical records of patients with non-syndromic repaired unilateral cleft lip and palate. Otoscopy, immittance measures, audiometry and ventilation tube history over 10 years were analyzed. **Results:** From 440 medical records included in the study, 254 (58%) had a history of VT insertion, while 186 (42%) did not. The percentage of abnormal findings in otoscopic examination was consistently higher for ears with a history of VT and statistical analysis revealed an association between history of VT and fluid in the middle ear ($p<0.001$); tympanic opacification ($p<0.001$); tympanic retraction ($p<0.001$) tympanic perforation ($p<0.001$) and tympanosclerosis ($p<0.001$). The type B tympanometric curve was observed in 46.4% of ears with a history of present VT, compared to 16.3% in individuals with an absent history of VT ($p<0.001$) and the difference of 30.1% between groups was significant ($p<0.001$), indicating association between VT and type B curve. Hearing loss was more frequent in ears with a history of VT (34.2%), when compared to ears without this history (10.4%), with a statistically significant difference ($p<0.001$), indicating positive association between VT and hearing loss. **Conclusion:** Worse otoscopic and auditory results were found in patients with cleft lip and palate with a history of VT.

Keywords: Cleft palate; Hearing loss; Otitis media; Middle ear ventilation; Ventilation tube insertion

RESUMO

Objetivo: Caracterizar e comparar a audição e o estado da orelha média na fissura labiopalatina nas condições com ou sem história de tubo de ventilação. **Métodos:** Estudo retrospectivo de 463 prontuários de pacientes com fissura transforame unilateral não sindrômica, operados. Foram analisadas otoscopia, imitanciometria, audiometria e história de TV ao longo de dez anos. **Resultados:** Dos 440 prontuários incluídos no estudo, 254 (58%) apresentaram história de TV, enquanto 186 (42%) não apresentaram. As alterações encontradas nos exames de otoscopia foram mais frequentes nas orelhas com história de TV, e o resultado estatístico revelou associação significativa entre presença de TV e ocorrência de fluido ($p<0,001$); ocorrência de opacificação ($p<0,001$); ocorrência de retração ($p<0,001$); ocorrência de perfuração na membrana timpânica ($p<0,001$) e ocorrência de timpanosclerose ($p<0,001$). A curva tipo B foi observada em 46,4% das orelhas com história de TV, comparada a 16,3% no grupo sem TV ($p<0,001$) e a diferença de 30,1% entre os grupos foi significativa ($p<0,001$), indicando associação relevante entre TV e ocorrência de curva tipo B. A perda auditiva foi mais frequente para as orelhas com TV (34,2%) do que sem TV (10,4%) e a diferença foi significativa ($p<0,001$) indicando associação expressiva entre TV e perda auditiva. **Conclusão:** Foram encontrados piores resultados otoscópicos e auditivos em pacientes com fissura labiopalatina com história de tubo de ventilação presente.

Palavras-chave: Fissura palatina; Perda auditiva; Otite média; Ventilação da orelha média; Inserção de tubo de ventilação

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INTRODUCTION

Several studies associate Cleft Lip and Palate (CLP) with hearing changes related to Otitis Media with Effusion (OME), resulting from anatomical and functional alterations in the auditory tube[1–3]. For some authors, the auditory tube in children with cleft palate does not work properly because the tensor veli palatini muscle does not perform its function, presenting a rigid insertion the palate or changes in its pathway[4,5]. Hearing loss is the most common complication of acute otitis media (OM) and otitis media with effusion[6], while conductive hearing loss is common in patients with cleft lip and palate. Otitis media, therefore, is associated with the periodic degradation of sound stimuli input, which can result in problems with speech discrimination, affecting verbal skills and learning performance[7].

Authors[8] have further reported that the surgical correction of cleft lip and palate can potentially reduce OME occurrence, but according to the literature, many children continue to suffer from middle ear problems during childhood and even into early adulthood. Thus, due to the high prevalence of otitis media with effusion in children with cleft lip and palate, other authors[9] indicated that the most common solution is to use a ventilation tube (VT) to drain the effusion and ventilate the middle ear. In the management of middle ear conditions associated with CLP, ventilation tubes remain one of the most recommended treatments for the recovery of auditory tube dysfunction and chronic OM[10]. Tympanostomy tube placement is believed to be beneficial to promote middle ear ventilation. However, there is a controversy the literature regarding the indication of surgery for ventilation tube insertion in patients with cleft palate. One group of authors considers that the placement of ventilation tubes is necessary to prevent hearing loss and enable the correct development of speech[11,12]. Whereas another group of authors emphasizes the importance of a more conservative treatment, since the use of the ventilation tubes is correlated with an increase in the occurrence of cholesteatoma and other middle ear complications[13–15].

The present study sought to contribute furthering the knowledge on this topic through the characterization and comparison of both the hearing and the state of the middle ear among patients with a history of unilateral transforame cleft (UTC), with and without the use of the ventilation tube.

METHODS

The present study was initiated after the Ethics Committee approval of the institution in which the research was conducted (Certificate of Presentation for Ethical Consideration, CAAE No.: 39865120.4.0000.5441) and involved the analysis of 463 medical records of individuals of both genders with isolated unilateral transforame cleft. The inclusion criteria were the presence of recorded otological history (otoscopic examination), audiological history (immittance and audiometry tests) and history of use of ventilation tube (absent or present) for over ten years or more, as per documented in the patient's medical record.

The audiometric tests analyzed herein were conducted with children and adolescents aged between 3 and 13 years. The pure-tone audiometry was performed in all patients, in both ears, to evaluate the tonal thresholds by air and bone conduction. The mean air thresholds of four frequencies (500 Hz, 1000 Hz, 2000 Hz and 4000 Hertz) were calculated for each ear and hearing loss was considered present upon finding a mean threshold greater than or equal to 20 dBHL, in accordance with World Health Organization (WHO) recommendations[16]. Once hearing loss was confirmed, bone thresholds were analyzed to determine the type of loss: conductive, mixed or sensorineural[17].

Immittance testing with a 226 Hz probe was performed to obtain more information on the middle ear functioning of all participants from 2 years of age on. The acoustic immittance measure classification was based on a previously described categorization[18,19], being considered normal with peak pressure around 0 daPa, which may vary up to –100 daPa (type A curve). In cases with alterations, the curves obtained were divided into a type B curve (absence of maximum compliance peak), type C curve (maximum compliance peak shifted to negative pressure above –100 daPa), type Ar curve (maximum compliance peak with reduced amplitude) and type Ad curve (maximum compliance peak with increased amplitude, open curve).

The otoscopic examinations analyzed in the present study were conducted with children and adolescents aged between 2 and 13 years, performed by the hospital's otorhinolaryngologist to verify the presence of a normal middle ear, checking for fluid, opacification, retraction, perforation, cholesteatoma and tympanosclerosis.

Clinical records of myringotomy for ventilation tube insertion were identified and used to separate the data into two groups: no history of ventilation tube (absent) and with history of ventilation tube in both ears (present). The hypothesis that middle ear complications and hearing losses would be more prevalent in the population that received the ventilation tube was verified with inferential statistics (Chi-square test). This study also applied the analysis of pre-existing anonymized data using spreadsheets and was granted an Informed Consent Form (ICF) waiver, according to opinion No. 4,424,918.

RESULTS

From the total sample comprising 463 medical records of patients with isolated UTC studied herein, 440 (95%) presented the data of interest and were included in the present study. Among these, 186 (42%) had no history of ventilation tube (Absent-VT group) and 254 (58%) had a history of ventilation tube (Present-VT group). The cases studied herein consisted of a total of 5304 examinations performed in patients between the ages of 2 and 13 years, with 1532 audiometries, 1737 immittance tests, and 2035 otoscopies (Table 1). Subsequently, 12 exams were analyzed sequentially, on average, per patient, being divided into 3 audiometries (1 to 6 exams per patient with Present-VT and 1 to 5 exams per patient with Absent-VT), 4 immittance tests (1 to 6 exams per patient with Present-VT and 1 to 6 exams per patient with Absent-VT) and 5 otoscopies (1 to 7 exams

Table 1. Distribution of the evaluations analyzed according to the history of ventilation tube (absent or present) and type of assessment (audiometry, immittance test, otoscopy)

Ventilation Tube	Audiometry	Imittance Test	Otoscopy
Absent (2228)	639	740	849
Present (3076)	893	997	1186
Total (5304)	1532	1737	2035

per patient with Present-VT and 1 to 6 exams per patient with Absent-VT), for each case.

Otoscopy findings

The data from the otoscopic examinations presented in Figure 1 illustrate the state of the middle ear in the studied patients, being divided into the following aspects: fluid, opacification, retraction, perforation, cholesteatoma and tympanosclerosis.

Overall, the mean percentage of changes was consistently higher for the Present-VT group. Among the observed alterations, the opacification of the tympanic membrane was the most frequent symptom and cholesteatoma the least frequent, for both groups studied. The statistical analysis showed a significant association between the ventilation tube presence and signs of fluid, opacification, retraction, perforation or tympanosclerosis (Table 2). Only cholesteatoma did not present a statistically significant difference in the comparison between the groups with Present-VT and Absent-VT.

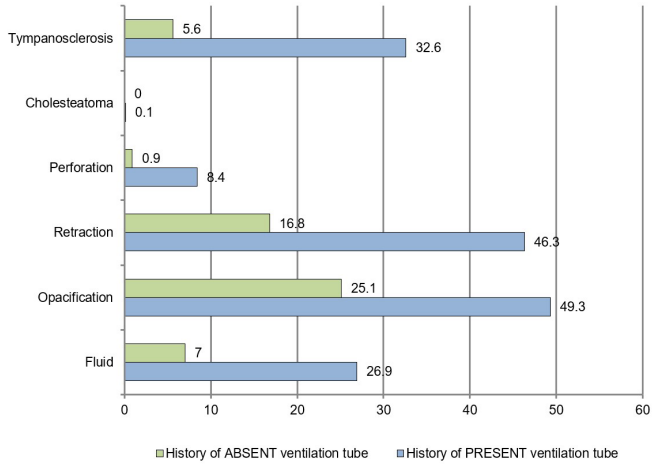

Figure 1. Distribution of the mean percentage of retraction, opacification, fluid, perforation, cholesteatoma and tympanosclerosis occurrence observed during otoscopy in the groups with history of present and absent ventilation tube

Immittance findings

Altogether, the mean percentage of the type B curve was consistently higher for the Present-VT group. Different results were found in the Absent-VT group, in which the type A curve was the most observed. Statistical analysis showed a significant association between the presence of the ventilation tube, the occurrence of a type B curve and the non-occurrence of type A curve ($p<0.001$). The data from the immittance measurements presented in Table 3 illustrate the types of curves (A, B, C, Ar, Ad) found for the studied patients.

Audiometry findings

The mean percentage of hearing loss was higher for ears with Present-VT (34.2%) than for those with Absent-VT (10.4%). The difference in cases with hearing loss between the groups with Present-VT and Absent-VT was significant ($p<0.001$), indicating a meaningful association between the VT presence and the occurrence of hearing loss. The data from the audiometric assessments illustrate the occurrence of hearing loss in the ears studied herein (Table 4).

As for the hearing loss types (conductive, mixed and sensorineural), the conductive hearing impairment was the most prevalent type of loss observed in both groups, with a higher occurrence in the Present-VT group. Table 5 depicts the mean percentage of hearing loss types (conductive, mixed and sensorineural) for both groups.

Table 2. Distribution and statistical analysis of the otological findings according to the history of ventilation tubes (present or absent)

Findings	Present-VT	Absent-VT	Difference	P-value
Fluid	331 (26.9%)	62 (7%)	269 (19.9%)	< 0.001*
Opacification	607 (49.3%)	204 (25.1%)	403 (24.2%)	< 0.001*
Retraction	570 (46.3%)	147 (16.8%)	423 (29.5%)	< 0.001*
Perforation	104 (8.4%)	8 (0.9%)	96 (7.5%)	<0.001*
Cholesteatoma	3 (0.1%)	1 (0%)	2 (0.1%)	0.870
Tympanosclerosis	402 (32.6%)	49 (5.6%)	353 (27%)	<0.001*

Chi-square test; *Statistically significant values ($p<0.001$)
Subtitle: VT = Ventilation Tube; < = less than

Table 3. Distribution and statistical analysis of the tympanometry findings according to the history of ventilation tubes (present or absent)

Curve	Present-VT	Absent-VT	Difference	P-value
A	451 (20%)	759 (45.8%)	308 (25.8%)	<0.001*
B	1044 (46.4%)	270 (16.3%)	774 (30.1%)	<0.001*
C	447 (20%)	354 (22.5%)	93 (2.5%)	0.257
Ar	135 (6%)	177 (10.7%)	42 (4.7%)	<0.001*
Ad	105 (4.6%)	87 (5.2%)	18 (0.6%)	<0.001*

Chi-square test; *Statistically significant values ($p<0.001$)
Subtitle: VT = Ventilation Tube; < = less than

Table 4. Distribution and statistical analysis of the audiometry findings according to the history of ventilation tubes (present or absent)

	Present Tube (n=1788)	Absent Tube (n =1280)	P-value
With hearing loss	611 (34.2%)	133 (10.4%)	<0.001*

Chi-square test; *Statistically significant values (p<0.001)
Subtitle: < = less than

Table 5. Distribution and statistical analysis of the audiological results according to the type of hearing loss and history of ventilation tubes (present or absent)

Hearing Loss	Present-VT	Absent-VT	Difference	P-value
Conductive	376 (21%)	70 (5.4%)	306 (15.6%)	<0.001*
Mixed	64 (3.5%)	13 (1%)	51 (2.5%)	<0.001*
Neurosensory	6 (0.4%)	6 (0.6%)	0 (0.2%)	0.7721

Chi-square test; *Statistically significant values (p<0.001)
Subtitle: VT = Ventilation Tube; < = less than

Due to the lack of cooperation of some patients during the audiometry exam, it was not possible to obtain masked bone thresholds, hindering the characterization of the hearing loss type in 9.2% of the Present-VT group and in 3.4% of the Absent-VT group exams .

DISCUSSION

Children with cleft palate often present middle ear changes that evolve to otitis media with effusion (OME). OME complications may include conductive hearing loss, tympanic membrane retraction, tympanosclerosis as well as chronic otitis media[20], it can lead to delays in children's speech and language development, as well as chronic middle ear problems, which may persist into adulthood[13]. Treatment modalities for OME comprise watchful waiting, antibiotic therapy or surgical intervention (myringotomy and/or ventilation tube)[21]. Ventilation tubes are usually used for OME management in cases where conservative treatments fail, performing the function of preventing the rapid eardrum closure by the scarring process, temporarily replacing the function of the auditory tube and providing middle ear aeration to allow the reversal of mucosal changes[22,23].

Although vastly recommended and frequently used in the population with cleft palate, the ventilation tube itself can trigger important consequences for the anatomical integrity and functioning of the middle ear[13-15,21].

Before anything else, the present study analyzed the otoscopy data. Otoscopy is sensitive to physical alterations that are visually present in the external auditory canal and tympanic membrane, enabling the diagnosis of external and middle ear pathologies[24]. Overall, the percentage of otoscopic changes observed was consistently higher for patients with a history of ventilation tube presence, when compared to a history of tube absence. The results confirmed the hypothesis that middle ear complications occur in a higher percentage in ears that present a ventilation tube, corroborating the findings of several studies[4,7,10,13,19, 25–29].

Among the middle ear findings studied herein (fluid, opacification, retraction, perforation, cholesteatoma, tympanosclerosis), only the presence of cholesteatoma was not significantly different between the Present-VT and the Absent-VT groups. According to some authors, there is a prevailing theory that most secondary cholesteatomas arise from retraction pockets caused by increased exposure to negative middle ear pressure during otitis episodes, thus suggesting that, in patients with cleft palate, it is the auditory tube dysfunction and the persistent otitis media that increase the risk of developing cholesteatoma, and not the inserted ventilation tubes [10,27]. Authors[30] have further described how ventilation tube inserts alone are not able to influence the formation of cholesteatomas.

Tympanometry is a dynamic and objective test that provides information on the mobility of the tympano-ossicular system according to air pressure changes in the external auditory canal[31], allowing the detection of OME, especially in the pediatric population[32]. As for the immittance test, more altered curves were observed in patients with a history of ventilation tubes, with the type B curve being the most occurring in this group, present in 46.4% of the exams (and in only 16.3% of the group with a history of absent tube), which can be explained due to the auditory tube dysfunction persistence after the VT treatment period[31]. Ventilation tube surgery is effective to immediately improve hearing, nevertheless, the auditory tube function improvement in children with cleft palate is generally longer than in children without cleft palate[33]. A study[34] compared groups of patients with cleft lip and palate who underwent VT insertion surgery only once (group 1) or repeatedly (group 2), and found a predominance of type B tympanogram for both groups, with worse results for individuals with repeated VT insertion (57.1% and 75.3%, respectively).

Tonal audiometric thresholds are important measures to assess the severity and effects of OME[35]. Based on the patient's responses, it is possible to establish the degree and type of hearing loss, assisting in the topodiagnosis of the alteration[36]. Still in the subject of hearing, a worse result was found for the group with a history of ventilation tube presence, moreover, in the group with a history of ventilation tube absence, only 10.3% of the patients presented hearing loss, compared to 34.1% with hearing loss in the group with ventilation tube presence, suggesting a direct relationship between middle ear changes and hearing loss. This result was similar to the findings of a study[20] where, after the analysis of 147 medical records of patients with cleft lip and palate submitted to the insertion of a ventilation tube, it was found that 38.8% of the individuals presented hearing loss in the final follow-up. Another study[13] reported hearing loss in 50% of cleft lip and palate patients with

a history of ventilation tubes presence. Authors[37] emphasized that is essential to pay attention to possible hearing losses, since it occurs during the period in which children are developing important socialization and learning skills. Further authors[31] also reported that the concern with persistent OME in children is due to the potentially adverse effect of hearing loss on speech, language and mental development, an effect that may linger long after OME has been treated and hearing has returned to normal.

Conductive hearing loss, as expected, was the most occurrent type found in the present study, confirming previous studies[29,38]. These findings, in turn, are justified by the fact that the Presen-VT group exhibited the most compromised tympanic-ossicular system.

A possible justification for the results of the present study is the fact that the surgical indication for the insertion of a ventilation tube is based on a set of evaluations, including otorhinolaryngological and audiological assessments, defining the appropriate conduct for each case. Therefore, all patients were evaluated; and those whose tympano-ossicular system was in a better condition did not undergo otological surgery. Consequently, the individuals in the group with a history of absent ventilation tubes analyzed herein were the ones with the most favorable middle ear condition, allowing to infer that this group was composed of the best cases. Whereas the patients with a history of ventilation tube insertion presented alterations during the evaluations and, thus, underwent otological surgery. As such, the individuals in this group had the most compromised tympanic-ossicular system, leading to the assumption that this group was composed of the worst cases. Several researchers also questioned whether the worse results found in the group of patients who underwent surgery to insert the ventilation tube are correlated to the surgery sequelae itself, or to the more aggressive middle ear pathology progression observed in these individuals[4,10,14, 20, 25].

The findings herein not only validate the literature, but also characterize the hearing and the state of the middle ear of Brazilian patients with a history of unilateral transforame cleft (UTC). Among the limitations of the present study, it is important to highlight that, in the the immittance data analysis, there was the possibility of underestimating the middle ear changes, since no other measures were obtained to confirm the data found, such as the gradient and tympanometric width, or the association of compliance measures and peak pressure rates with the presence of the acoustic reflex[39]. Another limitation was the lack of joint analysis of the assessments, which would allow a better overview of middle ear functionality in these patients.

It is therefore implied the importance of evaluating the hearing sensitivity and middle ear conditions at the end of treatment (after 18 years of age) in future studies .

CONCLUSION

It was found in the studied population (n=440) that 58% of patients used ventilation tubes. Otoscopic complications (opacification, retraction, tympanosclerosis and tympanic membrane perforation) as well as hearing loss were significantly more frequent in cleft lip and palate patients with a history of a ventilation tube presence, confirming the hypothesis postulated herein.

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