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Otological Manifestations and Tympanometric Assessment in Cleft Palate Patients: A Cross-Sectional Observational Study

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Abstract

Background: Cleft palate patients frequently develop middle ear disease due to Eustachian tube dysfunction, leading to hearing loss that can impair speech and language development. High-altitude conditions exacerbate ear problems through barotrauma. Given limited regional data, early diagnosis and management are essential to prevent middle ear disease, permanent hearing loss, impairment in speech and language development.

Objective: To evaluate the prevalence and characteristics of middle ear disease, otological & tympanometric assessment in children with cleft palate before surgical intervention and to highlight the burden of subclinical middle ear disease and conductive hearing impairment requiring early ear assessment & intervention.

Methods: A cross-sectional observational study was conducted among 70 patients (140 ears) with cleft palate planned for surgical correction. Detailed history, otoscopic evaluation, and tympanometric assessments

were performed. Data were analyzed using Jamovi v28.2 with ANOVA and t-tests, with $p < 0.05$ considered statistically significant.

Results: Among 140 ears examined, 80% had abnormal tympanic membranes (TMs), 16% appeared normal, and 4% showed perforation. Tympanometry revealed a predominant Type B curve (99%), indicating middle ear effusion or dysfunction, and 0.8% exhibited Type C, suggesting Eustachian tube dysfunction.

Conclusion: A high prevalence of otitis media with effusion and type B tympanogram curve seen in majority of patients with cleft palate. The findings underscore the need for routine otological and tympanometric screening in all cleft palate patients to ensure early detection and intervention to prevent permanent hearing loss, impairment in speech and language development.

Keywords: Cleft palate (CP), Tympanometry, Otoscopy, Eustachian tube (ET), Otitis media with effusion (OME).

Introduction

A common congenital craniofacial abnormality, cleft palate is caused by the inability of the palatal shelves to fuse between six and twelfth weeks of pregnancy. This results in functional impairments, including difficulties in feeding, speech abnormalities, and recurrent upper respiratory tract infections due to the communication between the oral and nasal cavities [1].

Environmental factors like maternal exposure to teratogens such as tobacco, alcohol, phenytoin, and isotretinoin, as well as infections like rubella and cytomegalovirus are linked to cleft palate development [2]. Hypernasal speech and minor feeding problems are two symptoms of partial "cleft palate, which" only "affects the soft palate." Speech impairments, nasal regurgitation, and more severe feeding issues are caused by complete cleft palate, which affects both the hard and soft palates. Submucous cleft palate, where the mucosa is intact but underlying structures are not fused, often causes chronic middle ear infections and hypernasal speech but is usually diagnosed later due to subtle symptoms [3].

The effects of cleft palate on health and life quality are significant. Due to Eustachian tube dysfunction, it is linked to recurrent middle ear infections, speech delays, eating issues, and dental malocclusion. [4].

The improper functioning of the Eustachian tube prevents it from opening correctly, resulting in fluid accumulation and negative pressure within the middle ear, which eventually causes otitis media with effusion (OME). Along with OME, patients with cleft palates are also at risk for acute suppurative otitis media (ASOM), a condition in which bacteria invade the middle ear and cause fever, ear discomfort, and discharge.[5]

This study examines ear pathologies in cleft palate patients because the environmental and socio-economic challenges at high altitudes near Himalayan regions necessitate research. This research targets regional environmental and healthcare access barriers to enhance early diagnosis and intervention methods. Early diagnosis and treatment are essential to improve outcomes for affected individuals.[6]

A combination of environmental factors and restricted access to medical facilities and skilled professionals leads to treatment delays and inferior health results. Recognizing regional differences is essential for adapting healthcare services to serve this vulnerable group better. The study also aims to raise awareness about the importance of early diagnosis and regular audiological monitoring in cleft palate patients, enabling better integration of Ear Nose Throat examination and audiological services into multidisciplinary care plans. [6].

Children with cleft palate are particularly susceptible to persistent middle ear disease because the anatomical and functional abnormalities of the palatal musculature can interfere with normal Eustachian tube opening. As a consequence, negative middle ear pressure and fluid accumulation may develop repeatedly or persist for prolonged periods. Otitis media with effusion may remain clinically silent, especially in infants and young children, despite producing conductive hearing impairment. Therefore, normal caregiver observation does not necessarily exclude clinically important middle ear dysfunction, and objective assessment is important even in children without obvious ear-related complaints.[9,12]

Persistent or recurrent conductive hearing impairment during the early years of life may adversely affect auditory input during an important period of speech and language development. For this reason, otological and audiological surveillance has become an important component of multidisciplinary cleft palate care. Otoscopy provides direct information regarding tympanic membrane appearance and mobility, whereas tympanometry provides an objective assessment of middle ear compliance and pressure and can help identify effusion or Eustachian tube dysfunction. Combining these assessments may facilitate early recognition of otherwise subclinical disease and allow appropriate referral and intervention before long-term auditory and developmental consequences occur.[11,15]

Materials and Methods

Study design and setting: An observational cross-sectional study was carried out in Department of Otorhinolaryngology, Himalayan institute of medical sciences Dehradun over a period of 18 months from (28th May 2023 to 30th November 2024).

Patient selection: Subjects were recruited from the OPD under the Smile Train Project, who were planned for surgery for cleft palate. Detailed history, clinical examination, and otoscopic evaluation and tympanometric assessment was done by Tympanometry. Data recorded and statistical analysis was done using ANOVA and Independent t test, also written informed consent was taken and prior permission was obtained from the ethical committee. The data was analyzed subsequently.

Inclusion Criteria

1. Patients with age group from 6 months to 5 years.
2. Patients with clinical diagnosis of Cleft palate with or without cleft lip.

Exclusion criteria

1. Prior operation for cleft palate.
2. Syndromic cleft lip and palate patients.
3. Patients with a grommet in the ear and history of any ear surgery.

Data collection

Detailed History: Each of the patients selected for the study was subjected to a detailed history and complete ear, nose, and throat examination.

Demographic and Clinical Information - A detailed clinical history was recorded, including the type of cleft (unilateral or bilateral), any associated anomalies, and family history of hearing loss & cleft palate. Physical examination included the assessment of ear, nose, and throat conditions.

Otoscopy: Each patient underwent an otoscopic examination to evaluate the external ear canal for any abnormalities such as cerumen impaction, perforation, retraction, cholesteatoma, or other external ear abnormalities, Then Middle Ear Evaluation done to look for presence of any effusion, tympanic membrane

condition (e.g., Retraction, perforation, scarring), and other signs of middle ear pathology were noted

Tympanometry: To each subject Tympanometry was performed using a calibrated impedance audiometer (e.g., Interacoustics AT235). Tympanograms were recorded to assess middle ear function, including compliance, tympanic membrane mobility, and the presence of effusion (Type B, C, or A tympanograms).

Statistical Analysis: The data were collected and entered in MS Excel 2010. Different statistical analyses were performed using Jamovi software version 28.2. The one-sample Kolmogorov-Smirnov test was employed to determine whether the data sets differed from a normal distribution. Normally distributed data were analysed using parametric tests, and non-normally distributed data were analysed using non-parametric tests. Descriptive statistics were calculated for quantitative variables. Frequencies along with percentages were calculated for qualitative and categorical variables. Graphical representation of the variables was shown to understand the results clearly, and categorical data were analysed using Chi-square tests for qualitative variables. The difference in means was compared using the independent t-test for two groups and ANOVA for more than two groups. Correlation was assessed to evaluate the strength of the relationship between quantitative variables. A p-value of less than 0.05 was considered statistically significant.

Results

Table 1: Distribution of patients based on Age and Gender

Age (Months/Year)	Male	Percentage (%)	Female	Percentage (%)	Total	Percentage (%)
0.5–1 Year	12	17.1	9	12.8	21	30
1–2 Year	14	20.0	17	24.2	31	44.2
2–3 Year	5	7.14	5	7.14	10	14.2
3–4 Year	2	2.8	4	5.7	6	8.5
4–5 Year	1	1.4	1	1.4	2	2.8
Total	34	48.5	36	51.4	70	100

Among the 70 participants, the 1–2-year age group had the highest representation (44.2%), with a nearly equal distribution between males (48.5%) and females (51.4%).

Table 2: Distribution of subjects based on Residence, Geographical Area, Socioeconomic Status and Type of Palate (N = 70)

Variable	Category	Number (n)	Percentage (%)
Residence	Rural	32	45.7
	Urban	38	54.2
Geographical area	Plain	42	60.0
	Hilly	28	40.0
Socioeconomic Status	Upper middle	38	54
	Lower middle	32	45.7

Type of Palate	Complete	55	78.57
	Incomplete	15	21.45

Among all participants, 54.2% resided in urban areas and 45.7% in rural areas. Most participants were from plain areas (60%). More than half belonged to the upper middle socioeconomic class (54.2%). Complete cleft palate was present in 55 (78.57%) patients, whereas 15 (21.45%) had incomplete cleft palate.

Table 3: Distribution of subjects based on Symptoms(N = 70)

Symptoms	Number	Percentage (%)
Feeding difficulty	42	60.0
Ear discharge	15	21.4
History of ear pain	9	12.8
Change in character of voice	8	11.4
Mouth breathing	4	5.7
Hearing loss	1	1.4

Feeding difficulty was the most common symptom (60%), followed by ear discharge (21.4%), ear pain (12.8%), and change in voice (11.4%). Hearing loss was the least common symptom (1.4%).

Table 4: Otoscopic Findings of Tympanic Membrane (N = 140 ears)

Finding	Right	Left	Percentage (%)
Normal	11	11	15.7
Dull TM	58	57	82.1
Mobile	7	10	12.1
Restricted mobility	62	58	85.7
Retraction	62	58	85.7
Perforation	1	2	2.1
Total	70	70	140 ears

Otoscopic examination showed dull tympanic membranes in 82.1% of ears, restricted mobility and retraction in 85.7%, while only 2.1% had perforation, indicating chronic middle ear disease.

Table 5: Distribution of subjects based on Type of Tympanogram (N = 140)

Type of curve	Right	Left	Percentage (%)
A	-	-	0
B	70	69	99.28
C	0	1	0.71
As	-	-	0
Ad	-	-	0
Total no. of ears	70	70	140 (100%)

Tympanometry demonstrated a predominance of Type B tympanograms (99.28%), indicating middle ear dysfunction. Only one ear (0.71%) showed a Type C tympanogram, suggesting Eustachian tube dysfunction.

Discussion

The present study evaluated the otological and tympanometric assessment of 70 children with cleft palate and demonstrated a high prevalence of middle ear effusion and tympanic membrane retraction. These findings reinforce the well-established association between cleft palate and Eustachian tube dysfunction, which predisposes affected children to otitis media with effusion and conductive hearing loss, as reported in previous studies. [5,10,11] The majority of patients belonged to the 1–3-year age group, highlighting the importance of early identification and multidisciplinary management. The near-equal gender distribution suggests that auditory complications occur irrespective of sex [4,13.]

Clinically, feeding difficulty was the most common presenting complaint, followed by ear discharge and ear pain. Although overt hearing loss was infrequently reported by caregivers, audiological evaluation revealed a substantially higher prevalence of subclinical hearing impairment. This discrepancy emphasizes that many children with cleft palate may harbor significant middle ear disease despite the absence of obvious symptoms, supporting recommendations for routine audiological surveillance.[9,12,15]

Otoscopic examination frequently demonstrated dull and retracted tympanic membranes with restricted mobility, findings suggestive of chronic middle ear effusion. Tympanometric assessment predominantly revealed Type B tympanograms, indicating poor middle ear ventilation and fluid accumulation. These observations are consistent with the study conducted by Gautam et al.[5] who also reported a high incidence of abnormal middle ear function in cleft palate patients. Similar findings have been documented in international studies by Ahmed et al.[6], Souza et al.[7], and James et al.[10], supporting the concept that structural abnormalities of the palate interfere with normal Eustachian tube function.

The severity and type of cleft also influenced the degree of otological involvement. Children with complete cleft palate demonstrated more severe tympanometric abnormalities and greater hearing impairment compared with those with incomplete or lip-predominant clefts. However, incomplete clefts also showed significant middle ear dysfunction, suggesting that all cleft palate patients remain vulnerable to auditory complications regardless of the extent of the defect. These findings are in agreement with observations reported by Azman et al.[16] and Acharya et al.[14], who identified a relationship between cleft severity and middle ear pathology.

The present study further highlights the value of objective diagnostic tools such as tympanometry and acoustic reflex testing in identifying early auditory dysfunction. Since many children are asymptomatic, these non-invasive investigations provide a reliable method for early detection of middle ear disease before irreversible complications develop. Early diagnosis and timely intervention, including otological management and audiological rehabilitation, can significantly reduce long-term speech, language, and developmental consequences.[8,9,11]

Overall, the findings of this study align with both Indian and international literature and emphasize the importance of incorporating routine otological and audiological screening into standard pre-operative and follow-up protocols for cleft palate patients. A multidisciplinary approach involving otorhinolaryngologists, audiologists,

pediatricians, and plastic surgeons is essential to optimize hearing outcomes and improve quality of life in these children.

The very high frequency of Type B tympanograms in the present cohort is clinically important because a flat tympanogram, when correlated with otoscopic findings, is strongly suggestive of reduced middle-ear ventilation and/or middle-ear effusion. In this study, 99.28% of the examined ears demonstrated a Type B curve, while dullness, restricted mobility, and tympanic membrane retraction were also frequent on otoscopy. The combination of these findings provides objective evidence that middle-ear dysfunction was largely subclinical and present even when caregivers did not report hearing difficulty. Earlier Indian work has likewise demonstrated a high burden of otitis media with effusion in children with cleft palate, supporting the consistency of the present observations across different clinical settings.[17,18]

The mechanism underlying these findings is closely related to abnormal palatal muscle function. The tensor veli palatini muscle normally contributes to opening of the Eustachian tube during swallowing, whereas altered palatal anatomy and muscle insertion in cleft palate can impair active tubal opening. Persistent Eustachian tube dysfunction produces negative middle-ear pressure and favors accumulation of sterile effusion. Longitudinal tympanometric research has shown that normalization of Eustachian tube function may be delayed for many years in children with cleft palate, emphasizing that middle-ear disease should not be regarded as a transient problem limited to infancy.[19,20] The present findings in children aged 6 months to 5 years therefore represent an important period in which surveillance can identify disease before it becomes clinically obvious.

The present study also has relevance to the timing of hearing assessment. Only one child was reported by caregivers to have hearing loss, yet objective examination showed abnormalities in almost every ear. This marked difference illustrates the limitation of relying on parental observation alone, particularly in very young children who may not be able to communicate hearing difficulty. Prospective evidence has demonstrated substantially higher rates of otitis media with effusion and associated conductive hearing loss in children with cleft lip and palate than in children without clefts.[18] In addition, persistent otologic problems, including tympanic membrane perforation, tympanostomy tubes, and conductive hearing loss, have been documented well beyond early childhood, supporting continued follow-up rather than a single preoperative assessment.[19]

The relationship between cleft severity and middle-ear disease deserves careful interpretation. In the present study, complete cleft palate constituted the majority of cases and was associated with more pronounced abnormalities, while incomplete clefts were also affected. Although some studies suggest that greater cleft width may be associated with more severe Eustachian tube dysfunction and a greater number of otologic procedures, other longitudinal work has found that the eventual normalization of tympanograms is not necessarily predicted by the severity of palatal clefting.[20,21] These apparently differing observations indicate that cleft morphology is only one component of risk and that individual variation, age, surgical factors, recurrent upper respiratory infection, and access to follow-up may also influence outcomes. Therefore, all children with cleft palate should remain eligible for surveillance rather than restricting monitoring to those with complete or apparently severe clefts.

From a management perspective, the high prevalence of abnormal tympanometry in this cohort supports integration of otological and audiological assessment into cleft-palate care pathways. Tympanometry is relatively objective and non-invasive, and it can be particularly useful when behavioral hearing testing is difficult because of young age. However, tympanometry should be interpreted together with otoscopy and, when developmentally appropriate, formal age-appropriate audiometry. The decision to use ventilation tubes should remain individualized because evidence indicates potential hearing and speech benefits in selected children with cleft palate and otitis media with effusion, while tube-related complications such as tympanic membrane retraction and tympanosclerosis also need to be considered.[22] Long-term outcome data further suggest that early treatment can result in favorable hearing outcomes, although repeated procedures may be required in some children.[23]

Recent literature continues to emphasize that otitis media with effusion is extremely common in cleft palate and that surveillance should continue over time because Eustachian tube dysfunction may persist after palatal repair.[24] More recent evidence also suggests that multiple clinical and anatomical factors may influence the risk of otitis media, reinforcing the value of individualized rather than purely anatomy-based follow-up strategies. [25]

Recent studies further support the high burden of middle ear disease in children with cleft palate. Wijnants et al. (2025)[26], in a retrospective cohort of 44 children undergoing cleft palate repair, reported otitis media with effusion in 88.6% of patients, with conductive hearing loss in 31.8%, and demonstrated significant improvement in hearing following tympanostomy tube placement. Similarly, McGlone et al. (2026)[27] highlighted that otitis media with effusion is extremely common among patients with cleft palate and remains an important cause of middle ear dysfunction and hearing impairment. These recent findings are consistent with the present study, which demonstrated abnormal tympanic membrane findings and Type B tympanograms in the vast majority of examined ears, emphasizing the importance of routine otological and tympanometric assessment in children with cleft palate.[28]

There are several limitations that should be considered when interpreting the present findings. The cross-sectional design provides a snapshot of otological status and does not establish the duration or natural history of middle-ear disease. The study was conducted at a single center with a relatively small sample of 70 children, which may limit generalizability to other populations. Hearing assessment was not described in the results with the same level of detail as tympanometry and otoscopy, and therefore the relationship between the tympanometric abnormalities and measured hearing thresholds cannot be quantified fully from the available data. In addition, no postoperative or longitudinal follow-up was included to determine whether the observed middle-ear abnormalities resolved after palatal repair. Future prospective studies with larger multicenter cohorts, serial tympanometry, age-appropriate audiometry, and postoperative follow-up would help clarify the natural history and identify children at greatest risk of persistent hearing impairment. Taken together, the present study adds regional evidence that middle-ear dysfunction is highly prevalent in young children with cleft palate and may be substantially under-recognized on the basis of symptoms alone. The combination of otoscopy and tympanometry detected abnormalities in a large proportion of ears, supporting the use of objective ear assessment as part of routine cleft-

palate evaluation. Early recognition, appropriate audiological follow-up, and coordinated otological management may help reduce the risk of persistent conductive hearing loss and its downstream effects on speech, language, and development.

Overall, the findings of this study align with both Indian and international literature and emphasize the importance of incorporating routine otological and audiological screening into standard pre-operative and follow-up protocols for cleft palate patients.[5–16] A multidisciplinary approach involving otorhinolaryngologists, audiologists, pediatricians, and plastic surgeons is essential to optimize hearing outcomes and improve quality of life in these children.

Conclusion

This cross-sectional study demonstrated a high prevalence of middle ear effusion & retraction among children with cleft palate, primarily due to Eustachian tube dysfunction. Most patients showed abnormal otoscopic and tympanometric findings, with Type B tympanograms being common. Complete clefts were associated with more middle ear disease, although significant abnormalities were also observed in incomplete clefts. The study emphasizes the importance of routine otological and audiological screening, including tympanometry and hearing assessment, for early detection and timely intervention to prevent middle ear effusion, other middle ear diseases, permanent hearing loss, long-term speech, language, and developmental complications in cleft palate patients.

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