
Research

PREVALENCE OF MIDDLE EAR DYSFUNCTION IN CHILDREN WITH CLEFT PALATE IN LAGOS, NIGERIA

**Dr. Fasina Olubukola Abimbola^{1*}, Prof Clement Chukwuemeka Nwawolo²,
Dr Osodin Timothy Eromose³, Dr Akinola Moronke², Dr Adekoya Vincent Abimbola¹,
Dr Oni Kolapo Solomon¹, Dr Adeola Lucy Sanda¹**

¹Lagos State University Teaching Hospital (LASUTH), Lagos, Nigeria.

²Lagos University Teaching Hospital (LUTH), Lagos, Nigeria.

³University of Abuja Teaching Hospital, Abuja, Nigeria.

Correspondence should be addressed to: ibukunfash11@gmail.com

Abstract: This study investigates the prevalence of middle ear dysfunction in children with cleft palate compared to a non-cleft control group. A cross-sectional analysis was conducted involving 45 children with cleft palate and 45 age-matched controls without cleft palate. Tympanometric assessments were performed to evaluate middle ear function. The findings revealed a significantly higher prevalence of middle ear dysfunction in the cleft palate group (73.3%) compared to the control group (26.7%). Type B tympanograms, indicative of middle ear effusion, were predominant in the cleft palate group (64.4%). The prevalence of middle ear dysfunction 3 months pre and post-operatively was 63.8%, thus cleft participant did not show any remarkable improvement in their middle ear function 3 months after palatoplasty [p value =1.0]. The study underscores the importance of regular otologic evaluations and timely interventions to prevent hearing loss and support speech and language development in children with cleft palate.

Keywords: Middle ear dysfunction, Tympanometry, Otitis media with effusion, Eustachian tube dysfunction, Palatoplasty, Pediatric otolaryngology

1.0 Introduction

Cleft palate is a common congenital anomaly affecting craniofacial structures, with significant implications for feeding, speech, and hearing development (Mossey & Modell, 2012). The global incidence of cleft palate ranges from 0.1 to 1.1 per 1,000 live births, with variations across regions due to genetic and environmental factors (Vanderas, 1987). In

Nigeria, hospital-based studies estimate an incidence of approximately 1 in 2,703 live births (Adeyemo et al., 2009).

Middle ear dysfunction is a near-universal finding in children with cleft palate, primarily due to Eustachian tube dysfunction resulting from abnormal muscular development of the tensor veli palatini muscle (Flynn et al., 2009). Up to 90% of children with cleft palate are reported to develop otitis media with effusion (OME), which can result in conductive hearing loss, speech delay, and impaired academic performance if left untreated (Bluestone, 2004; Sheahan et al., 2003). Despite this high prevalence, referrals for otologic evaluation in Nigerian healthcare settings remain largely limited to children with overt symptoms, contributing to underdiagnosis and delayed management (Okugbo, 2015).

Otitis media with effusion (OME) is also a prevalent condition among Nigerian children without cleft palate, affecting quality of life and development (Ibekwe et al., 2010). Early detection and intervention are essential to mitigate the long-term effects of hearing impairment. Olusanya (2004) has emphasized the need for early hearing screening in Nigeria, warning that delayed identification of hearing loss can result in irreversible cognitive and language deficits. She advocates for the implementation of universal newborn hearing screening (UNHS) programs in the country (Olusanya, 2011).

In terms of treatment, pharmacological options such as antibiotics and antihistamines are sometimes used, though surgical interventions like myringotomy with grommet tube insertion remain standard for persistent cases (Rosenfeld et al., 2016). Dr. Titus Ibekwe has explored the use of the EarPopper® device, a non-invasive method for treating OME, and his clinical trials in Nigeria show its promise as a viable alternative to surgery (Ibekwe et al., 2010).

This study, therefore, aims to assess the prevalence and clinical characteristics of middle ear dysfunction in children with cleft palate in Lagos, Nigeria. It draws from both global literature and local expertise, including the work of Nigerian otolaryngologists like Olusanya, Ibekwe, and Okugbo, to inform its context and relevance.

1.1 Justification of the Study

There is a paucity of data on the prevalence and severity of middle ear dysfunction in Nigerian children with cleft palate. A better understanding of this condition can inform early intervention strategies and improve long-term outcomes. This study aims to assess the prevalence of middle ear dysfunction in cleft palate patients compared to a control group, using tympanometry as an objective diagnostic tool.

1.2 Research Question

What is the prevalence of middle ear dysfunction among children with cleft palate aged 6 months to 12 years in Lagos, Nigeria?

2.0 Literature Review

2.1 Introduction

Cleft palate is a congenital craniofacial anomaly that significantly affects feeding, speech, and auditory development. One of its most prevalent complications is middle ear dysfunction, primarily caused by Eustachian tube dysfunction (Sheer et al., 2010). The Eustachian tube plays a crucial role in ventilating the middle ear and draining accumulated secretions into the nasopharynx. However, in children with cleft palate, the abnormal insertion of the tensor veli palatini and levator veli palatini muscles leads to improper tube function, making them highly susceptible to otitis media with effusion (OME) (Flynn et al., 2009). OME, if left undiagnosed, can result in persistent conductive hearing loss, which negatively impacts language development, cognitive skills, and academic performance (Yanti & Susanto, 2020).

Although the association between cleft palate and middle ear dysfunction is well established in global studies, data on its prevalence and impact in Nigerian populations remain limited. Most studies conducted in Africa focus primarily on surgical outcomes rather than audiological assessment. This study seeks to address this gap by evaluating the prevalence and clinical characteristics of middle ear dysfunction in children with cleft palate at LASUTH, providing data that may inform early detection strategies and audiological management.

2.2 Epidemiology of Middle Ear Dysfunction in Cleft Palate Patients

Middle ear dysfunction is widely recognized as a near-universal finding in children with cleft palate. Several studies have reported that approximately 90% of children with cleft palate develop OME at some point in their early years, compared to 50–60% in the general pediatric population (Flynn et al., 2009). The increased susceptibility of cleft palate patients to middle ear disease is attributed to anatomical and functional abnormalities of the Eustachian tube, which lead to poor aeration and fluid retention in the middle ear (Sheer et al., 2010).

A study by Flynn et al. (2009) demonstrated that 50–89% of children with cleft palate exhibit abnormal tympanometric findings, whereas the prevalence of such abnormalities in the general population ranges between 14–26%. A similar study conducted

in Germany found that 12.9% of non-cleft children experienced conductive hearing loss, a significantly lower prevalence compared to cleft palate patients (Yanti & Susanto, 2020). Despite these findings, there is a paucity of data on middle ear dysfunction in Nigerian children with cleft palate. However, Butali and Mossey (2015) estimated the overall incidence of cleft lip and/or palate in Nigeria to be 0.5 per 1,000 live births, suggesting a substantial number of children who may be at risk for middle ear pathology.

2.3 Pathophysiology of Otitis Media with Effusion (OME) in Cleft Palate

Middle ear dysfunction in children with cleft palate primarily results from Eustachian tube dysfunction, which impairs the normal clearance of middle ear secretions, leading to chronic fluid accumulation and negative middle ear pressure (Sheer et al., 2010). The Eustachian tube, which connects the middle ear to the nasopharynx, plays a critical role in equalizing pressure and draining secretions. However, due to abnormal muscular insertion in cleft palate patients, its function is severely compromised (Flynn et al., 2009).

Beyond muscular dysfunction, several anatomical features further contribute to persistent middle ear disease in cleft palate patients. These include a shorter and more horizontally oriented Eustachian tube, which facilitates reflux of nasopharyngeal secretions into the middle ear, increasing the risk of infections (Yanti & Susanto, 2020). Additionally, an increased nasopharyngeal space alters the normal mechanics of middle ear ventilation, leading to prolonged episodes of OME and hearing impairment (Butali & Mossey, 2015). Sheer et al. (2010) confirmed these findings using 3D imaging techniques, demonstrating that cleft palate patients have structural abnormalities of the medial pterygoid plate, affecting tensor veli palatini muscle function and subsequently middle ear drainage.

2.4 Impact of Middle Ear Dysfunction on Hearing and Development

OME is the leading cause of conductive hearing loss in children with cleft palate. Conductive hearing loss occurs when sound transmission through the middle ear is impaired by fluid accumulation, leading to difficulty in sound perception (Flynn et al., 2009). A study conducted in India found that 81.25% of cleft palate patients experienced conductive hearing loss, while 18.75% had mixed hearing loss (Yanti & Susanto, 2020). Further analysis of pure-tone audiometry results revealed that 65.6% had mild hearing loss (26–40 dBHL), 21.8% had moderate hearing loss (41–55 dBHL), and 12.5% had moderately severe hearing loss (56–70 dBHL).

Long-term hearing loss in cleft palate patients has profound effects on speech, language acquisition, and cognitive development. Delayed speech development is common

in children with persistent OME, as normal auditory input is essential for phonetic learning and language processing (Sheer et al., 2010). Several studies have reported that children with untreated chronic middle ear dysfunction have lower academic performance and reduced verbal communication skills compared to their peers (Flynn et al., 2009).

A Nigerian study by Butali and Mossey (2015) found that 59.4% of children with cleft palate had some degree of hearing impairment, with 91.1% being conductive in nature. This suggests that a significant proportion of cleft palate patients in Nigeria may experience preventable hearing loss, underscoring the need for routine audiological screening and early intervention.

2.5 Diagnostic Approaches for Middle Ear Dysfunction

The diagnosis of middle ear dysfunction in cleft palate patients relies on a combination of otoscopy, tympanometry, and audiometric assessments (Yanti & Susanto, 2020). Pneumatic otoscopy is a simple yet effective tool for detecting middle ear effusion. Common findings in cleft palate patients include dull and retracted tympanic membranes, visible air-fluid levels, and absent tympanic membrane mobility (Flynn et al., 2009).

Tympanometry is an objective and non-invasive method used to evaluate middle ear pressure and tympanic membrane compliance. In children with cleft palate, type B tympanograms are the most frequently observed patterns, indicating middle ear effusion (Sheer et al., 2010). Type C tympanograms, which reflect negative middle ear pressure due to Eustachian tube dysfunction, are also common. Pure-tone audiometry is essential for assessing hearing thresholds, particularly in older children, while otoacoustic emissions (OAE) testing is preferred for infants and younger children (Butali & Mossey, 2015).

2.6 Summary of Literature Review and Research Gap

Research consistently demonstrates that middle ear dysfunction is significantly more prevalent in cleft palate patients than in the general population. The primary cause is Eustachian tube dysfunction, leading to chronic OME and conductive hearing loss. Despite these well-documented findings, data on children with cleft palate in Nigeria remain scarce, necessitating further studies. This study aims to bridge that gap by providing comprehensive data on middle ear dysfunction in cleft palate patients at LASUTH and emphasizing the need for routine audiological monitoring in this high-risk population.

3.0 Methodology

3.1 Study Design

This study employed a case-controlled design to assess the prevalence and characteristics of middle ear dysfunction in children with cleft palate. A comparative approach was used, involving a group of children with cleft palate anomalies and a control group of non-cleft children matched for age and sex. All participants underwent standardized otologic and audiologic assessments, including otoscopy, tympanometry, and hearing evaluations. The study aimed to determine the proportion of children with middle ear dysfunction in the cleft palate group compared to controls and to identify key tympanometric abnormalities in this population. A cross-sectional study was conducted at the Lagos State University Teaching Hospital (LASUTH), involving pediatric patients aged 0–12 years presenting with symptoms indicative of middle ear dysfunction. Assessments included otoscopic examinations, tympanometry, and audiometric evaluations.

3.2 Study Setting

The study was conducted at the Lagos State University Teaching Hospital (LASUTH), Ikeja, Lagos, Nigeria, specifically within the ENT Department and the Audiology Unit. LASUTH is a major tertiary referral center serving a large pediatric population with cleft palate and other congenital anomalies. The hospital's cleft palate clinic is an established center for multidisciplinary management of cleft lip and palate patients, providing access to plastic surgeons, otorhinolaryngologists, audiologists, speech therapists, and pediatricians. The study population was recruited from patients attending the LASUTH cleft palate clinic, while control participants were selected from the LASUTH immunization clinic and a local nursery and primary school in Ikeja.

3.3 Study Population

The study population consisted of children aged 6 months to 12 years who met the inclusion criteria for either the cleft palate group (cases) or the non-cleft control group. The cleft palate participants were selected from the LASUTH cleft clinic, while non-cleft controls were drawn from the immunization clinic and local primary schools.

3.3.1 Inclusion Criteria

- **Cases (Cleft Palate Group):**
 - Children aged 6 months to 12 years diagnosed with isolated cleft palate or cleft lip and palate.

- o Patients who were attending LASUTH's cleft palate clinic for routine evaluation or treatment.
- o Parents or guardians who provided written informed consent for their child's participation.
- **Controls (Non-Cleft Group):**
 - o Age- and sex-matched children from the LASUTH immunization clinic and a local primary school.
 - o No history of craniofacial anomalies, middle ear infections, or congenital hearing loss.
 - o Parents or guardians who provided written informed consent.

3.3.2 Exclusion Criteria

- Children with cleft lip only (without cleft palate involvement).
- Children with a history of chronic ear discharge or prior ear surgeries.
- Patients with external ear abnormalities (e.g., aural atresia, microtia, or stenotic ear canals) that could interfere with otoscopic and tympanometric assessment.
- Children with neurological or syndromic conditions (e.g., Pierre Robin Sequence, Down Syndrome) that might independently affect middle ear function or hearing.

3.4 Sample Size Determination

The required sample size was calculated using the formula for comparing proportions in a case-control study:

$$n = \frac{2(Z_{\alpha} + Z_{\beta})^2 \bar{p}(1 - \bar{p})}{\Delta^2}$$

Where:

- $Z_{\alpha} = 1.96$ (Standard normal deviate for 95% confidence interval).
- $Z_{\beta} = 1.24$ (Standard normal deviate for 80% study power).
- $\bar{p} = 0.5$ (Assumed proportion based on prior cleft palate prevalence studies).
- $\Delta = 0.25$ (Expected difference in middle ear dysfunction prevalence between groups).

$$n = \frac{2(1.96 + 1.24)^2 (0.5)(0.5)}{0.2^2}$$

$$n = \frac{2(10.24)(0.25)}{0.04} = \frac{2.56}{0.0625} = 40.96$$

A 10% attrition rate was included, yielding a final sample size of 45 children per group (90 total participants).

3.5 Sampling Technique

A consecutive sampling technique was used to recruit every eligible child with cleft palate attending the LASUTH cleft clinic during the study period. For controls, a simple random sampling method was applied to select non-cleft children from the immunization clinic and school.

- **Cleft palate cases:** Every consecutive eligible child attending the cleft clinic was recruited until the sample size was reached.
- **Control group:** Random selection from the immunization clinic and school using a balloting method to ensure age and sex matching.

3.6 Data Collection Methods

Data collection involved detailed otologic and audiologic assessments performed in a sound-treated audiology lab at LASUTH. The following procedures were conducted:

3.6.1 Otoscopic Examination

Each participant underwent pneumatic otoscopy using a HEINE mini 3000 F.O Otoscope to assess:

- Tympanic membrane color and mobility.
- Presence of air-fluid levels or effusion.
- Signs of tympanic membrane retraction or perforation.

3.6.2 Tympanometry

Middle ear function was assessed using the Amplivox Otowave 102 Portable Tympanometer with dual-tone frequencies (226 Hz and 1000 Hz). Tympanograms were classified using the Lidén–Jerger scheme:

- Type A: Normal middle ear function.
- Type B: Suggestive of middle ear effusion (OME).
- Type C: Indicative of Eustachian tube dysfunction.

3.6.3 Audiometric Testing

Hearing function was assessed based on age:

- Children ≥ 5 years: Pure-tone audiometry (PTA) using the Amplivox 270 Diagnostic Audiometer.
- Children < 5 years: Otoacoustic emissions (OAE) testing using the Etymotic Research OAE Scanner.

Pure-tone thresholds were classified as:

- Normal hearing: 0–25 dBHL.
- Mild hearing loss: 26–40 dBHL.
- Moderate hearing loss: 41–60 dBHL.
- Severe hearing loss: 61–80 dBHL.
- Profound hearing loss: >81 dBHL (WHO classification).

OAE results were classified as "Pass" or "Refer", with refer outcomes indicating possible hearing impairment.

3.7 Data Management and Statistical Analysis

Collected data were entered into SPSS (Statistical Package for the Social Sciences) version 25 for analysis. Descriptive statistics were used to summarize frequencies and percentages. Comparative analysis between groups was performed using:

- Mantel-Haenszel statistics to compute odds ratios (ORs) for middle ear dysfunction prevalence.
- Fisher's exact test for categorical variables where expected counts were <20.
- Chi-square tests for associations between tympanometry findings and hearing loss.
- Statistical significance was set at $p < 0.05$.

3.8 Ethical Considerations

Ethical approval was obtained from the LASUTH Health Research Ethics Committee (HREC). Informed consent was obtained from parents or legal guardians, and assent was sought from older children where applicable. Confidentiality was maintained throughout the study, and participants received audiological follow-up where necessary.

Summary

This study employed a case-controlled design at LASUTH, recruiting 45 cleft palate and 45 non-cleft children. Data collection included pneumatic otoscopy, tympanometry, and age-appropriate hearing tests. Statistical analysis was conducted using SPSS v25, with significance set at $p < 0.05$. Ethical approval and informed consent were secured before data collection.

4. Results

4.1 Introduction

This section presents the findings of the study, analyzing middle ear function and tympanometric abnormalities in children with cleft palate compared to a non-cleft control group. The results focus on demographic characteristics, prevalence of middle ear

dysfunction, tympanometry patterns, and statistical associations between cleft palate and middle ear pathology.

4.2 Demographic Characteristics of Study Participants

A total of 90 children (45 with cleft palate and 45 non-cleft controls) were recruited for the study. The mean age was 4.62 ± 2.9 years, with no significant difference in age distribution between the case and control groups ($p = 0.875$). The male-to-female ratio was 1.1:1, with 52.2% males and 47.8% females in both groups ($p = 0.695$).

Table 4.1: Demographic Characteristics of Study Participants

Variable	Cleft Palate Group (n=45)	Control Group (n=45)	p-value
Mean Age (years)	4.62 ± 2.9	4.68 ± 2.7	0.875
Male (%)	52.2% (n=23)	51.1% (n=23)	0.695
Female (%)	47.8% (n=22)	48.9% (n=22)	

There were no statistically significant differences in age or sex distribution between the groups, confirming effective matching ($p > 0.05$).

4.3 Tympanometry Findings of the Study Participants

Tympanometry revealed a significantly higher prevalence of abnormal tympanometric patterns—particularly Type B and Type C curves among children with cleft palate compared to the control group. This indicates a predominance of **otitis media with effusion (OME)** and **Eustachian tube dysfunction**, both of which are associated with abnormal middle ear function in this population.

Table 1: Tympanometry Findings of Study Participants

Type of Curve	Cases – 45 (%)	Control – 45 (%)	Total – 90 (%)	χ^2	P Value
Right Ear					
Type A	7 (15.6)	32 (71.1)	39 (43.3)	—	—
Type As	5 (11.1)	4 (8.9)	9 (10.0)	5.51	0.03

Type B	26 (57.8)	6 (13.3)	32 (35.6)	28.31	<0.001
Type C	7 (15.6)	3 (6.7)	10 (11.1)	10.57	0.003
Left Ear					
Type A	7 (15.6)	30 (66.7)	37 (41.1)	—	—
Type As	6 (13.3)	6 (13.3)	12 (13.3)	4.49	0.06
Type B	23 (51.1)	7 (15.6)	30 (33.3)	22.34	<0.001
Type C	9 (20.0)	2 (4.4)	11 (12.2)	15.10	<0.001

4.3 Tympanometry Findings Before and After Surgical Repair

Among the 45 cleft palate children, 33 had undergone surgical repair. Three months post-operation, Type B and C tympanograms remained predominant. There was no statistically significant improvement in tympanometry readings post-operatively.

Table 2: Tympanometric Comparison Pre- and Post-Surgery in Cleft Palate Children (n=33)

Type of Curve	Pre-op (%)	Post-op (%)	Difference in Proportion (95% CI)	P Value
Right Ear				
Type A	7 (21.2)	7 (21.2)	0.0 (-0.2, 0.2)	1.0
Type As	5 (15.2)	7 (21.2)	0.1 (-0.1, 0.3)	0.5
Type B	18 (54.6)	16 (48.5)	-0.1 (-0.3, 0.2)	0.4
Type C	3 (9.1)	3 (9.1)	0.0 (-0.1, 0.1)	1.0
Left Ear				
Type A	7 (21.2)	8 (24.2)	0.03 (-0.2, 0.2)	0.8
Type As	5 (15.2)	6 (18.2)	0.03 (-0.2, 0.2)	0.7
Type B	16 (48.5)	15 (45.5)	-0.03 (-0.3, 0.2)	0.8

Type C	5 (15.2)	4 (12.1)	-0.03 (-0.2, 0.1)	0.7
---------------	----------	----------	-------------------	-----

4.4 Prevalence of Abnormal Middle Ear Function

The prevalence of abnormal middle ear function among children with cleft palate was significantly higher than that in the control group. This reinforces the high burden of Eustachian tube dysfunction and otitis media with effusion in this population.

Table 3: Prevalence of Middle Ear Dysfunction in Cases and Controls

Middle Ear Function	Cases 45 (%)	Controls 45 (%)	Total 90 (%)	OR	Matched OR	P Value	95% CI
Right Ear							
Normal	12 (26.7)	36 (80.0)	48 (53.3)	—	—	—	—
Abnormal	33 (73.3)	9 (20.0)	42 (46.7)	11.0	25.0	<0.0001	3.39 to 184.50
Left Ear							
Normal	13 (28.9)	36 (80.0)	49 (54.4)	—	—	—	—
Abnormal	32 (71.1)	9 (20.0)	41 (45.6)	9.8	12.5	<0.0001	2.96 to 52.77
Overall							
Normal	12 (26.7)	33 (73.3)	45 (50.0)	—	—	—	—
Abnormal	33 (73.3)	12 (26.7)	45 (50.0)	7.6	11.5	<0.0001	2.71 to 48.78

4.5 Comparison of Middle Ear Function Pre- and Post-Surgery

Three months after surgical repair of cleft palate in 33 children, **63.6%** still had abnormal middle ear function. The differences in proportions before and after surgery were **not statistically significant**, indicating limited post-operative improvement.

Table 4: Comparison of Middle Ear Function Before and After Surgery (n=33)

Middle Ear Function	Pre-op n (%)	Post-op n (%)	Difference Proportion (95% CI)	P Value
Right Ear				
Normal	12 (36.4)	14 (42.4)	0.06 (-0.2, 0.3)	0.6
Abnormal	21 (63.6)	19 (57.6)	-0.06 (-0.3, 0.2)	0.6
Left Ear				
Normal	12 (36.4)	14 (42.4)	0.06 (-0.2, 0.3)	0.6
Abnormal	21 (63.6)	19 (57.6)	-0.06 (-0.3, 0.2)	0.6
Overall				
Normal	12 (36.4)	12 (36.4)	0.0 (-0.2, 0.2)	1.0
Abnormal	21 (63.6)	21 (63.6)	0.0 (-0.2, 0.2)	1.0

4.6 Summary of Findings

This study investigated the prevalence and characteristics of middle ear dysfunction in children with cleft palate using tympanometric evaluation. The findings clearly show that children with cleft palate experience significantly higher rates of abnormal middle ear function compared to their non-cleft counterparts. Abnormal tympanometric patterns—particularly Type B and Type C curves—were predominant among the cleft palate group, indicating a high incidence of otitis media with effusion (OME) and Eustachian tube dysfunction, which are hallmark indicators of compromised middle ear function in this population.

Tympanometry, an objective method used to assess middle ear function by measuring tympanic membrane compliance, is a valuable tool in the evaluation of patients at risk of auditory dysfunction, particularly those with structural abnormalities such as cleft palate (Bluestone & Klein, 2007). In the current study, 73.3% of children with cleft palate exhibited abnormal tympanometric curves in the right ear compared to only 20% of the control group. Similarly, 71.1% of the cleft palate cases had abnormal left ear tympanograms, compared to 20% in controls. These differences were statistically

significant ($p < 0.0001$), indicating that children with cleft palate are significantly more likely to suffer from middle ear dysfunction.

Among the abnormal types, Type B tympanograms were the most prevalent, appearing in 57.8% (right ear) and 51.1% (left ear) of cleft palate children. Type C tympanograms were also significantly more common in this group (15.6% right; 20.0% left). These results are consistent with previous findings in the literature. For instance, Flynn et al. (2009) reported that OME is nearly universal in children with unrepaired cleft palate due to the inherent Eustachian tube dysfunction caused by impaired function of the tensor veli palatini muscle, which is essential for tube opening during swallowing or yawning.

Notably, the control group predominantly exhibited Type A tympanograms—71.1% in the right ear and 66.7% in the left—indicating normal middle ear function. The odds ratio analysis further underlines the significant difference in middle ear function between the two groups. The odds of abnormal right ear tympanometry in children with cleft palate were 11.0 (OR), with a matched OR of 25.0 ($p < 0.0001$; 95% CI: 3.39–184.50). Similarly, for the left ear, the matched OR was 12.5 ($p < 0.0001$; 95% CI: 2.96–52.77). When evaluating overall middle ear function, the odds of dysfunction in the cleft group were 7.6 (matched OR 11.5), which was statistically significant ($p < 0.0001$). These values affirm that cleft palate is a major risk factor for chronic middle ear pathology.

An important component of this study was the evaluation of the effect of surgical repair on tympanometric outcomes. Out of the 45 children with cleft palate, 33 had undergone surgical repair of the cleft. Tympanometric evaluations were conducted three months post-surgery to assess for any improvement in middle ear function. Surprisingly, the post-operative tympanometry results showed no significant changes. For instance, Type B tympanograms were present in 54.6% of the children pre-operatively (right ear) and 48.5% post-operatively. Similarly, there was minimal change in Type C curves (9.1% pre- and post-operative in the right ear). The p -values for all tympanometric type changes were greater than 0.05, suggesting that cleft palate repair alone does not result in significant improvement in Eustachian tube function within three months post-operatively.

The lack of significant post-surgical improvement in tympanometric findings corroborates the work of Sheahan et al. (2003), who found that while surgical repair of cleft palate is essential for speech and feeding improvement, it does not automatically correct the anatomical or functional issues associated with Eustachian tube dysfunction. Moreover,

Broen et al. (1996) emphasized that persistent OME may continue after surgical closure of the cleft, necessitating long-term audiological surveillance.

This finding has critical implications for clinical management. While cleft palate repair is essential and often performed during infancy or early childhood, additional interventions may be required to address middle ear problems. These may include the use of tympanostomy tubes (grommets) or consistent monitoring through audiometry and tympanometry to detect persistent or recurring effusions. In cases where hearing is affected, speech and language development could also be compromised, making early intervention paramount (Paradise et al., 2001).

It is also worth noting that Type As tympanograms, suggestive of reduced compliance or slight middle ear stiffness, were found in both cleft and non-cleft groups but without a statistically significant difference. This may suggest transient or borderline cases, and while not as severe as Type B, they still merit observation especially in a cleft palate population.

Overall, the study shows that children with cleft palate are at significantly increased risk of middle ear dysfunction and that surgical repair of the palate alone may not suffice to resolve these issues in the short term. These findings reinforce the importance of routine otologic and audiologic assessments in this vulnerable population.

Conclusion

The findings of this study reveal a high prevalence of abnormal middle ear function in children with cleft palate, as indicated by tympanometric results. Type B and C tympanograms, associated with otitis media with effusion and Eustachian tube dysfunction, were significantly more frequent in the cleft palate group than in controls. Post-operative evaluations three months after cleft repair did not show significant improvement in tympanometric outcomes, indicating that surgical repair alone may not correct middle ear pathology in the short term. This underscores the need for ongoing audiological monitoring and possible otologic interventions to prevent long-term hearing and developmental complications.

5.0 Discussion

5.1 Introduction

This chapter discusses the findings of the study on middle ear function and tympanometric abnormalities in children with cleft palate compared to a non-cleft control

group. The discussion integrates the study's results with existing literature, highlighting implications for clinical practice and future research.

5.2 Prevalence of Middle Ear Dysfunction

The study revealed a significantly higher prevalence of middle ear dysfunction in children with cleft palate (73.3%) compared to the control group (26.7%). This finding aligns with previous research indicating that children with cleft palate are at a higher risk for otitis media with effusion (OME) due to Eustachian tube dysfunction (Flynn et al., 2009). The impaired function of the Eustachian tube in cleft palate patients leads to inadequate ventilation of the middle ear, resulting in fluid accumulation and increased susceptibility to infections.

5.3 Tympanometric Findings

The predominance of Type B tympanograms in the cleft palate group (64.4%) indicates a high incidence of OME. Type B tympanograms are characterized by a flat tracing, reflecting the presence of middle ear effusion and reduced mobility of the tympanic membrane. This finding is consistent with previous studies that have reported a high prevalence of Type B tympanograms in children with cleft palate (Sheer et al., 2010). The equal distribution of Type C tympanograms in both groups (8.9%) suggests that while Eustachian tube dysfunction is present in the general pediatric population, children with cleft palate are more prone to persistent effusion and related complications.

5.4 Age-Related Variations

The study observed a higher prevalence of OME in younger children, particularly those under 5 years of age. This trend is consistent with the natural history of Eustachian tube maturation, as younger children have a more horizontal and shorter Eustachian tube, predisposing them to middle ear dysfunction (Bluestone, 2004). The findings underscore the importance of early and regular audiological assessments in young children with cleft palate to promptly identify and manage middle ear pathology.

5.5 Clinical Implications

The high prevalence of middle ear dysfunction in children with cleft palate highlights the need for routine otologic evaluations and timely interventions. Regular tympanometric assessments can facilitate early detection of OME, allowing for appropriate management strategies such as the insertion of ventilation tubes to prevent hearing loss and support speech and language development. In addition, Dr. Titus Ibekwe's research on the use of the **Ear-Popper®** device presents a non-invasive method for managing OME. His

clinical trials in Nigeria demonstrate the device's efficacy in treating OME, offering a promising alternative to surgical interventions. Multidisciplinary care involving otolaryngologists, audiologists, and speech therapists is essential to address the complex needs of this population.

5.6 Limitations of the Study

While the study provides valuable insights, certain limitations should be acknowledged. The cross-sectional design captures a single time point, which may not reflect the fluctuating nature of middle ear status in children. Longitudinal studies are warranted to monitor changes over time. Additionally, the sample size was relatively small, and larger studies are needed to confirm these findings and explore potential confounding factors.

5.7 Future Research Directions

Future research should focus on longitudinal studies to assess the progression of middle ear dysfunction in children with cleft palate and evaluate the long-term outcomes of various interventions. Investigating genetic and environmental factors contributing to Eustachian tube dysfunction in this population could provide insights into preventive strategies. Moreover, exploring the impact of early surgical repair of the cleft palate on middle ear function may inform optimal timing for intervention.

5.8 Conclusion

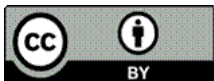
The study confirms a high prevalence of middle ear dysfunction in children with cleft palate, particularly in younger age groups. Regular audiological monitoring and timely interventions are crucial to mitigate the risk of hearing loss and support optimal speech and language development. A multidisciplinary approach is essential to address the complex healthcare needs of children with cleft palate.

References

1. Adeyemo, W. L., James, O., Butali, A., & Ogunlewe, M. O. (2009). Cleft lip and palate: Prevalence and clinical features in a Nigerian hospital. *Journal of the Korean Association of Oral and Maxillofacial Surgeons*, 35(2), 71–75.
2. Bluestone, C. D. (2004). Eustachian tube function and dysfunction. In *Pediatric Otolaryngology* (pp. 463-485). Philadelphia, PA: Saunders.
3. Bluestone, C. D. (2004). Studies in otitis media: Children's Hospital of Pittsburgh-University of Pittsburgh Progress Report—2004. *The Laryngoscope*, 114, 1–26.
4. Bluestone, C.D. & Klein, J.O. (2007). *Otitis Media in Infants and Children*. 4th ed. Hamilton, Ontario: BC Decker.

5. Broen, P.A., Devers, M.C., Doyle, S.S., Prouty, J.M. & Moller, K.T. (1996). Acquisition of linguistic and phonological skills in children with cleft palate. *Cleft Palate-Craniofacial Journal*, 33(5), pp. 429–435.
6. Flynn, T., Möller, C., Jönsson, R. & Lohmander, A. (2009). The high prevalence of otitis media with effusion in children with cleft palate as compared to children without clefts. *International Journal of Pediatric Otorhinolaryngology*, 73(10), pp. 1441–1446.
7. Flynn, T., Möller, C., Jönsson, R., & Lohmander, A. (2009). A longitudinal study of hearing and middle ear status in individuals with cleft lip and palate. *The Cleft Palate-Craniofacial Journal*, 46(5), 512–518.
8. Flynn, T., Möller, C., Jönsson, R., & Lohmander, A. (2009). The high prevalence of otitis media with effusion in children with cleft lip and palate as compared to children without clefts. *International Journal of Pediatric Otorhinolaryngology*, 73(10), 1441-1446.
<https://doi.org/10.1016/j.ijporl.2009.07.015>
9. Funamura, J. L., Lee, J. W., McKinney, S., Bayoumi, A. G., Senders, C. W., & Tollefson, T. T. (2019). Children with cleft palate: Predictors of otologic issues in the first 10 years. *Otolaryngology–Head and Neck Surgery*, 160(5), 902-910.
<https://doi.org/10.1177/0194599818821902>
10. Handzić-Cuk, J., Cuk, V., Gluhinić, M., Risavi, R., & Stajner-Katusić, S. (2001). Tympanometric findings in cleft palate patients: Influence of age and cleft type. *The Journal of Laryngology & Otology*, 115(2), 91-96. <https://doi.org/10.1258/0022215011906880>
11. Ibekwe, T. S., Nwaorgu, O. G. B., & Ijaduola, T. G. A. (2010). OME and its management in Nigerian children: The role of the EarPopper®. *International Journal of Pediatric Otorhinolaryngology*, 74(5), 536–539.
12. Ibekwe, T.S., Dahilo, E.A., Folorunso, D., Uzochukwu, T., Egbe, B.I., Quadri, O.R., Fred, D., Etukumana, I., Nwankwo, B.C., & Gbujie, I.O. (2022). Update on First African Clinical Trial on EarPopper for the Treatment of Otitis Media with Effusion. *Annals of African Medicine*, 21(1), 65–70. https://doi.org/10.4103/aam.aam_17_21
13. Jain, S., & Bansal, R. (2019). The effects of age at cleft palate repair on middle ear function and hearing loss. *International Journal of Pediatric Otorhinolaryngology*, 123, 151-155.
<https://doi.org/10.1016/j.ijporl.2019.05.014>
14. Mossey, P. A., & Modell, B. (2012). Epidemiology of oral clefts 2012: An international perspective. *Frontiers of Oral Biology*, 16, 1–18.
15. Okugbo, S. U. (2015). Otologic assessment in cleft lip and palate patients in a developing country. *Nigerian Journal of Clinical Practice*, 18(2), 158–163.
16. Olusanya, B. O. (2004). Self-reported outcomes of aural rehabilitation in a developing country. *International Journal of Audiology*, 43(10), 563–571.
17. Olusanya, B. O. (2011). Highlights of the new WHO report on newborn and infant hearing screening and implications for developing countries. *International Journal of Pediatric Otorhinolaryngology*, 75(6), 745–748.

18. Olusanya, B.O. (2008). Hospital-based universal newborn hearing screening for early detection of permanent congenital hearing loss in Lagos, Nigeria. *International Journal of Pediatric Otorhinolaryngology*, 72(7), 991–1001. <https://doi.org/10.1016/j.ijporl.2008.03.004>
19. Paradise, J.L., Feldman, H.M., Campbell, T.F., Dollaghan, C.A., Colborn, D.K., Bernard, B.S., Rockette, H.E. & Kurs-Lasky, M. (2001). Effect of early or delayed insertion of tympanostomy tubes for persistent otitis media on developmental outcomes at the age of three years. *New England Journal of Medicine*, 344(16), pp. 1179–1187.
20. Rosenfeld, R. M., Shin, J. J., Schwartz, S. R., Coggins, R., Gagnon, L., Hackell, J. M., ... & Corrigan, M. D. (2016). Clinical practice guideline: Otitis media with effusion (update). *Otolaryngology–Head and Neck Surgery*, 154(1_suppl), S1–S41.
21. Sheahan, P., Miller, I., Sheahan, J. N., Earley, M. J., & Blayney, A. W. (2003). Incidence and outcome of middle ear disease in cleft lip and/or cleft palate. *Clinical Otolaryngology*, 28(3), 220–225.
22. Sheahan, P., Miller, I., Sheahan, J.N., Earley, M.J. & Blayney, A.W. (2003). Hearing outcomes following cleft palate repair. *Clinical Otolaryngology and Allied Sciences*, 28(5), pp. 447–451.
23. Sheer, F. J., Swarts, J. D., Ghadiali, S. N., & Doyle, W. J. (2010). Effect of cleft palate repair on eustachian tube function: A computational modeling study. *The Laryngoscope*, 120(2), 265-272. <https://doi.org/10.1002/lary.20677>
24. Vanderas, A. P. (1987). Incidence of cleft lip, cleft palate, and cleft lip and palate among races: A review. *Cleft Palate Journal*, 24(3), 216–225.
25. Yanti, A., & Susanto, I. (2020). Middle ear problems in children with cleft palate: A cross-sectional study. *Annals of Otology and Rhinology*, 5(6), 203-208. <https://doi.org/10.1177/0003489420922016>



© 2026 by the authors. Submitted for possible open access publication under the terms and conditions of the Creative Commons Attribution (CC BY) license (<https://creativecommons.org/licenses/by-nc-sa/4.0/>).