ORIGINAL ARTICLES

ASSESSMENT OF HEARING THRESHOLD AMONG POST REPAIRED CLEFT PALATE PATIENTS IN KORLE-BU TEACHING HOSPITAL, GHANA

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Abstract

Objective: The aim of the study was to assess the hearing threshold in patients with repaired cleft palate and to determine the degree of hearing loss in various types of cleft palate.
Methods: This was a cross-sectional study which was conducted on 97 consenting patients with clinical diagnosis of repaired cleft palate at the Plastic and Reconstructive surgery unit, Korle Bu Teaching Hospital. The hearing loss threshold levels in the right and left cleft palates were then compared using Chi-square test of independence.
Results: A total of 97 participants who had cleft palate were seen that is 194 ears were examined. Most of patients had cleft of secondary palate (n=65, 67.0%), only one participant had cleft of primary palate only (1.0%) and the rest had cleft of both primary and secondary palate (n=31, 32.0%).
The age range of patients in this study was between the ages of 6 years to 12 years with a mean (±SD) age of 7.43 (3.85) and the male to female ratio was 1:1. Out of the total ear examined, 76 were mild conductive hearing loss and 95 ears had abnormal tympanogram. The overall prevalence rate for the abnormal tympanograms (B, C1, C2) in both ears is 49%. There was no statistically significant association between the level of hearing loss and the type of cleft palate for the left ear and the right ear respectively as well as the association between the type of tympanogram and the type of cleft palate for the left ear and the right ear respectively ($p>0.05$).
Conclusion: Prevalence rate of hearing loss among post repaired cleft palate subjects is 33%. This hearing loss is usually mild conductive hearing loss only. Mild conductive hearing loss and abnormal tympanogram was common between the ages of 6-8years irrespective of the type of cleft palate.

Key Words: *Sensory Neural Hearing Loss, Otitis Media with Effusion, External Auditory Canal, Unilateral cleft Lip and Palate, Bilateral Cleft Lip and Palate, Tympanic Membrane*

Introduction

Hearing loss in cleft palate is a congenital conductive hearing loss caused by otitis media with effusion. In Otitis media with effusion, there is fluid in the middle ear with intact tympanic membrane for a continuous period of 3 months due to eustachian tube dysfunction. Treatment is required to prevent the impact of hearing loss on language acquisition, education and social development[1]. The WHO defines hearing loss as not being able to hear well, as someone with normal hearing threshold of 25 decibels or better in both ears[2]. Hearing loss can be mild, moderate, severe, or profound. This can affect one ear or both and lead to difficulty in speech acquisition especially in children, and hearing conversational speech.

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Cleft palate patients are more prone to otitis media with effusion because of the anatomical defect of cleft palate[3]. The tensor and levator veli palatine muscles which originate from the eustachian tube and insert at the midline of the soft palate are not able to contract. As a result, tensor and levator veli palatini muscles are not able to open the eustachian tube like a normal person does during yawning, swallowing and talking and therefore have eustachian tube dysfunction. The cleft palate defect also allows contamination of the nasopharynx and eustachian tube by food during feeding. The contamination causes constant inflammation and change in nasopharyngeal flora.

In addition, cleft palate patients have short posterior cranial base, backward and upward position of the maxilla, shorter mastoid depth and height than normal subjects[4]; and these predispose them to otitis media with effusion which causes conductive hearing loss. Paradise et al[5] deduced that middle ear disease probably develops in all cleft palate patients. Bilateral secretory (serous) or suppurative otitis media was found without exception in 50 infants with cleft palate who were 20 months of age or younger. However, more recent studies have confirmed this figure to be around 90%[6–8].

Chu et al analyzed results of otoscopy ,pure tone audiometry and tympanometry of Chinese children and young adult with cleft lip/palate and compared with previous studies of western population and found out that, the prevalence of hearing disorder was different with western studies that showed much higher rate of audiological problems in children and young adults with cleft lip /palate[9]. Race was the main factor affecting the hearing of cleft lip/palate but not factors like timely ENT medical and surgical interventions and cleft repair. In cleft palate patients, early identification of otitis media with effusion and treatment is important in the management of hearing loss in children. Treatment is usually medical in most patients (conservative management)[1]. However, some require surgical management like, insertion of ventilation tubes to aerate the middle ear and prevent middle ear scarring (tympanosclerosis), acute otitis media and its complications that will further worsen the hearing. Hearing aids are also used in management of hearing loss in cleft palate. Cleft palate repair rarely improves hearing[10].

According to the World Health Organization (WHO), the prevalence of disabling hearing loss generally worldwide is 1.7%, 1.9% in sub-Saharan Africa (SSA), 0.9% in Middle East and North Africa, and 2.4% in South Asia which is the highest[2]. Musa et al in Kaduna Nigeria found high prevalence (59.4) of conductive hearing loss hearing loss in patients with cleft palate anomaly compared with control (12%) using pure tone audiometry in a prospective study in adults and children not less than 5years of age with repaired or unrepaired cleft lip and palate attending Etomie Smile Train Centre Kaduna[11].

This research was aimed at determining the threshold of hearing in repaired cleft palate and the relationship between various degrees of hearing loss and their relation to the types of cleft palate as classified by Kernahan and Stark[12].

Subjects and Methods

Study Design

The research was a cross sectional study conducted on all consenting consecutive patients with clinical diagnosis of cleft palate that has been repaired, who were healthy and seen at the cleft clinic of the Plastic and Reconstructive surgery unit of Korle- Bu Teaching Hospital (KBTH) between 1th March 2017 and 1th June 2019.

Study Site

This study was conducted at the ENT department of the Korle Bu Teaching Hospital.

Study Population

The study population was all post-repair cleft palate patients presenting to the outpatient department of the cleft panel clinic under the Reconstructive and Plastic Surgery Centre (RPSC) which is the treatment site for cleft lip and palate patients at KBTH.

Sample size calculation

With a confidence level of 95% and error margin of 3%, the expected sample size for this study was approximately 75, which was calculated using the normal approximation to hypergeometric distribution formula for small populations[13] with an attrition rate of 20%. Thus, the total sample size needed was 94 participants.

Procedure

The participants were enrolled at cleft panel clinic as they presented and taken to the ENT clinic for a full ENT examination. After the preliminary assessment (screening) with regards to the inclusion and exclusion criteria which will be found in the history taking, the whole procedure was explained to them and their consent were sought after which a structured questionnaire was administrated. Each participant was assigned a serial number. After answering the questionnaire, each participant was seated in a comfortable chair in the ENT clinic. The Bull's lamp was placed at eye level over the participant's left shoulder. With the aid of light from the lamp and head mirror, a full ear, nose and throat examination was done. Otoscopy was done for visual clarity of Tympanic Membrane. The ears were examined for congenital abnormalities of the pinna and especially, EAC narrowing. TM examination was very essential to this research and was done preferably with otoscope because of the narrow nature of the EAC in cleft palate patients. TM was examined for retraction, bulging, scaring, perforation, ventilation tube, and attic retraction. The tip of the nose was lifted with the thumb so that the nasal vestibule could be examined for any obvious lesions. Anterior rhinoscopy with a Thudichum /Kilian nasal speculum was done to inspect nasal mucosa, septum, lateral nasal wall and floor of nasal cavity for any pathology. The lip, oral cavity and oropharynx were examined to confirm the type of repaired cleft especially in the lip, hard palate, soft palate, side of cleft, number of clefts, and dentition as documented from the surgical notes. A tongue depressor was used to depress the tongue and buccal mucosa so that the buccal mucosa, teeth, alveolar ridges and opening of the parotid duct, soft and hard palate could be examined. Nose and Oropharyngeal examination were guided by documentation in the folder with regards to the type of cleft palate that was repaired. Those who met the inclusion criteria were referred to the Hearing Assessment Centre for hearing assessment. The type of assessment used depended on the age of the participants which was between the ages of 6 to 12 years. The hearing assessment was performed by principal researcher under supervision by the audiologist. This was done once or twice depending on the performance of the patient during the hearing assessment to verify the hearing threshold. This involved the use of subjective test. The Subjective test was done for each participant using pure tone audiometry.

Data Management and Analysis

Data captured from the structured questionnaires were entered into Microsoft Excel spreadsheet for data management such as editing, recoding. It was then exported into SPSS version 25 for analysis. Demographic variables were represented using tables and charts while summary statistics were done using means and proportions. The hearing loss threshold levels in cleft palate patients were then compared using Chi-square test of independence. P-value < 0.05 was used in judging the significance of the associations.

Ethical Consideration

The study was performed in accordance with the declaration of Helsinki and ethical approval obtained from the Korle-Bu Ethical Review Board. Written informed consent was obtained from their parents or their care givers before the investigation (Date of issue: February 1, 2017; protocol identification number: KBTH-STC 00072/2016). Participants were assured of anonymity and confidentiality of the information provided.

Results

A total of 97 participants who had repaired cleft palate were seen and 194 ears were examined. The Prevalence of hearing loss in the 194 ears of repaired cleft palate is 33%. Repaired Cleft palate was divided into cleft of primary palate only, cleft of secondary palate only, and cleft of primary and secondary palate. Most of participants had cleft of secondary palate (n=65, 67.0%), only one participant had cleft of primary palate only (1.0%) and the rest had cleft of both primary and secondary palate (n=31, 32.0%) as shown Table 1.

Table 1: Components of the type of cleft palate

Type of repaired Cleft	Frequency (N=97)	Percentage
Primary Palate only (n=1)		
Unilateral Right complete	1	1.0
Secondary Only (n=65)		
Complete	22	22.7
Incomplete	38	39.2
Sub Mucous	4	4.1
Primary and Secondary palate (n=31)		
Right Complete	8	8.2
Left Complete	9	9.3
Right Incomplete	1	1.0
Left Incomplete	4	4.1
Median Incomplete	2	2.1
Bilateral Complete	8	8.2

The age range of participants in this study was between the ages of 6 years to 12 years with a mean (±SD) of 7.43 (3.85) years. Majority of whom are between the ages of 6-8 years (n=66, 68.0%). The males to female ratio was 1:1, the males were 49.5% and females 50.5%. The Akan tribe were the dominant ethnic group in the study (n= 49, 50.5%) followed by the Ewe's (n= 30, 30.9%), Ga Adangbe (n=15, 15.5%), 2 (2.1%) were Kassena and only one participant was a Dagaati. All of the participants (n=95, 97.9%) had cleft palate and were aware they had it but only two participants did not know they had cleft palate as depicted in Table 2.

Table 2: Demographic Statistics

Variables		Frequency	Percent
Age group	6-8 years	66	68
	9-10 years	20	20.6
	11-12 years	11	11.3
	Total	**97**	**100**
Mean Age (±SD)		**7.43 (3.85)**	
Gender	Male	48	49.5
	Female	49	50.5
	Total	**97**	**100**
Ethnic group	Akan	49	50.5
	Ewe	30	30.9
	Ga Adamgbe	15	15.5
	Kassena	2	2.1
	Dagaati	1	1.0
	Total	**97**	**100**
Do you have Cleft	Yes	95	97.9
	No	2	2.1
	Total	**97**	**100**

More than half of the participants were referred from other facilities (n=74, 76.3%) and the rest came to the hospital as results of delayed speech (n=23, 23.7%). Inability to suck was the most reason why participants were referred followed by Cleft lip, speech related problems, recurrent URTI (Upper Respiratory Tract Infection) and Bilateral cleft as depicted in table 3.

Table 3: Reason for coming to the Hospital

Variables	Frequency (N=97)	Percent
Reason for coming to the Hospital		
Delayed speech	23	23.7
Referral	74	76.3
Reasons for Referral		
Inability to suck	24	46.2
Cleft lip	19	36.5
Speech related problems	7	13.5
Recurrent URTI	1	1.9
Bilateral Cleft	1	1.9

Half of the participants had speech problems which were nasal speech problems (n=54, 55.7%) and the rest did not have speech problems (n=43, 44.3%). More than half of them were not seeing the speech therapist (n=64, 66.0%) whereas half of the mothers knew their children

had hearing loss because of the cleft (n=53, 54.6%) as shown in Table 4.

Table 4: Speech problems of Participants

Variables	Frequency (N=97)	Percent
Speech Problem		
Yes	54	55.7
No	43	44.3
If yes, what type		
Nasal Speech	54	100
Delayed speech	0	0
Stuttering	0	0
Patients seeing Speech Therapist		
Yes	33	34
No	64	66
Does Parent know Child has hearing loss		
Yes	53	54.6
No	44	45.4

Table 5 shows the hearing threshold of both ears of the participants. In the left ear, 32 (33.0%) participants were in the mild hearing threshold whereas the rest of the participants in the normal hearing loss (n=65, 67.0%) whereas in the right ear, 44 (45.4%) of the participants were in the mild hearing loss threshold and the rest of the participants were in the normal threshold (n=53, 54.6%).

Table 5: Hearing threshold of both ears

Hearing Threshold	Left ear		Right ear	
	N	%	N	%
Normal	65	67	53	54.6
Mild hearing loss	32	33	44	45.4
Total	97	100	97	100

N= Frequency %= Percentage

Comparing the hearing threshold with the age group of participants, it was determined that in the left ear, among the normal threshold, 46 of the participants were between the ages of 6-8 years, 15 were between 9–10 years and the rest were in 11-12 years (n=4). In the Mild hearing loss threshold, majority of the participant were between 6-8 years (n=20), 5 were in 9-10 years and 7 were in 11-12 years. It also indicated that there was no statistically significance association between the age group and the hearing threshold of the left ear (p>0.05). In the right ear, among the normal threshold, 39 of the participants were between the ages of 6-8 years, 11 were between 9 -10 years and the rest were in 11-12 years (n=3). In the Mild hearing loss threshold, majority of the participant were between 6-8 years (n=27), 5 were in 9-10 years and 7 were in 11-12 years. It also indicated that there was no statistically significance association between the age group and the hearing threshold of the right ear (p>0.05).

The Pure tone average analysis that was done on both ears shows that 118 ears were normal and 76 ears had mild hearing loss which was conductive hearing loss. No sensorineural hearing loss was recorded. No moderate, severe, profound or total hearing loss was also recorded as shown in figure 1.

Fig 1: Pure Tone Analysis of both ear

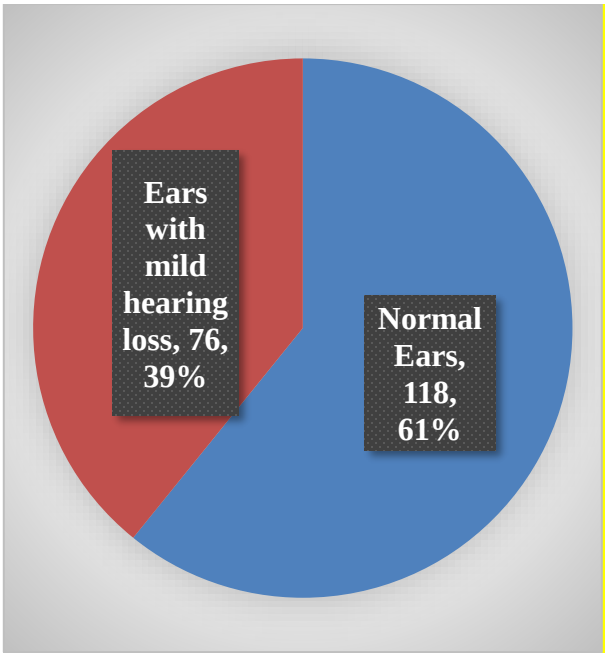

Table 6 shows the laterality of the ears, 13 out of the 23 patients had laterality in the left ear and the rest in the right ears. In the left ear, all 13 patients had both primary and secondary cleft palate and in the right ear, 8 had both primary and secondary cleft palate whereas 1 patient had primary cleft palate only and 1 in secondary cleft palate only each. There was no statistically significant association between the type of palate and laterality of cleft palate and hearing loss in both ears (p>0.05).

Table 7 depicts the PTA assessment of the type of cleft palate of both ears. In the left ear, PTA of 65 ears had normal hearing. Out of the 65 ears with normal hearing, 1ear had primary cleft palate only, 42 ears had secondary cleft palate only and 22 ears had primary and secondary cleft palate only. A total of Thirty-two ears had mild hearing loss in the left ear. Out of the 32 ears, no ear had primary cleft palate only, 23 ears had secondary cleft palate only and 9 ears had both primary and secondary cleft palate. There was no statistically significant association between the type of cleft palate for the left ear and the level of hearing loss (p>0.05).

Table 6: Laterality of both ears

Type of Cleft palate	Laterality		Total	P-value
	Left ear	Right ear		
Primary Cleft palate only	0	1	1	0.241
Secondary cleft palate only	0	1	1	
Primary and Secondary Cleft palate	13	8	21	
Total	**13**	**10**	**23**	

Table 7: Pure Tone Average (PTA) and Type of Cleft for both ears

Type of Cleft palate	Pure Tone Average for Left ear			
	Normal	Mild Hearing loss	Total	P-value
Primary palate only	1	0	1	0.644
Secondary palate only	42	23	65	
Primary and Secondary palate	22	9	31	
Total	65	32	97	
Type of Cleft palate	**Pure Tone Average for Right ear**			
	Normal	**Mild Hearing loss**	**Total**	**P-value**
Primary palate only	1	0	1	0.411
Secondary palate only	33	32	65	
Primary and Secondary palate	19	12	31	
Total	53	44	97	

Table 8: Tympanogram for both ears

Tympanogram for both right and left ear	Frequency	Percent
A	99	51.0
B	53	27.3
C1	28	14.4
C2	14	7.2
Total	**194**	**100.0**

Table 9: Tympanogram and Type of cleft palate for both ear

Type of Cleft	Pure Tone Average for Left ear					
	A	B	C1	C2	Total	P-value
Primary palate only	1	0	0	0	1	0.865
Secondary palate only	35	15	11	4	65	
Primary and Secondary palate	17	5	8	1	31	
Total	53	20	19	5	97	
Type of Cleft	**Pure Tone Average for Right ear**					
	A	**B**	**C1**	**C2**	**Total**	**P-value**
Primary palate only	1	0	0	0	1	0.508
Secondary palate only	31	22	8	4	65	
Primary and Secondary palate	14	11	1	5	31	
Total	46	33	9	9	97	

In the right ear, a total of 53 ears had normal hearing. Out of the 52ears, 1 ear had primary cleft palate only, 33 ears had secondary cleft palate only and 19 ears had both primary and secondary cleft palate. A total of Forty-four ears on the right had mild hearing loss. Out of these 44 ears with mild hearing loss, none had primary cleft palate only,32 ears had secondary cleft palate only and 12ears had both primary and secondary cleft palate. There was no statistically significant association between the type of cleft palate for the right ear and the level of healing loss ($p>0.05$).

Table 8 shows tympanogram analysis for both ears, 51% of the ears were normal and the rest were abnormal (B, C1 and C2). Table 9 shows the analysis of the tympanogram on the type of cleft palate for both ears the tympanogram in the left ears showed that 53 ears had Types A, 20 ears had B, 19 ears had C1 and 5 ears had C2. Out of the 53 normal Tympanograms (A) ,1 ear had primary cleft palate only, 35 ears had secondary cleft palate only and 17 ears had primary and secondary cleft palate. No type B, C1 or C2 tympanograms were recorded for primary cleft palate only. Secondary cleft palate only recorded, 35 ears for type A, 15 ears for type B,11 ears for type C1, and 4 ears for type C2 tympanograms. Primary and secondary cleft palate participants had 17 ears for type A,5 ears for type B, 8 ears for type C1, and 1ear for C2 tympanogram. There was no statistically significant association between the type of palate for the left ear and the type of tympanogram ($p>0.05$). The tympanogram in the right ears showed that 46 ears had type A, 33 ears had type B, 9 ears had type C1 and 9 ears had type C2. In the Primary palate only, only one participant had Type A tympanogram. In the Secondary cleft palate only, 31 ears for type A tympanogram, 22 ears for type B, 8 ears for C1 and 4 ears for C2. In both Primary and secondary cleft palate, 14 ears had type A tympanogram, 11 ears had type B,1 ear had type C1 and 5 ears C2 tympanogram. There was no statistically significant association between the type of cleft palate for the right ear and the type of tympanogram ($p>0.05$).

Discussion

The participants in this research were between the ages of 6 to 12 years. Mild conductive Hearing loss was found mostly between ages 6 to 8 years and improve generally by age group 11 to12 years. There was no statistically significance association between the age group and the hearing threshold ($p>0.05$) in this work. Male to female ratio in this work is 1:1. This finding of improvement of hearing with increasing age is similar to other studies done[14–20]. A similar prospective study used pure tone audiometry alone as a tool for hearing assessment[11].

Most participants had cleft of secondary palate only (n=65, 67.0%), only one participant had cleft of primary palate only (1.0%) and the remaining had cleft of both primary and secondary palate (n=31, 32.0%). This classification is different from what Thanawirattananit et al[15] and other studies used according to laterality[11,18]. Classification used in this study is similar to a study done by Wei Zheng et al[14]. This work classified cleft palate according to the anatomical part (primary and secondary cleft palate) which is what is used by KBTH plastic surgery unit. There were 97 participants and 194 ears seen. There was only conductive hearing loss but no sensorineural or mixed hearing loss recorded in this work. Conductive hearing loss was only mild hearing loss. No moderate, severe, profound and total hearing loss were recorded. 60.82% had normal hearing, 39.18% of the ears had mild conductive hearing loss with majority on the right (n=44) and on the left (n=32). There was no statistically significant association between the type of cleft palate and Pure Tone Average whether unilateral or bilateral ($p>0.05$). Normal hearing (60.82%) is higher in this research as compared to a study done in Kaduna[11]. A study by Handziae -Cuk et al revealed that most cleft palate have moderate and severe conductive hearing loss[21]. These variations are probably due to the age variations used in the studies. The Prevalence of hearing loss in the 194 ears of repaired cleft palate is 33% in this work using bilateral hearing loss. The overall prevalence rate of hearing loss among post repaired cleft palate subjects using better hearing ear is 23.9% in bilateral hearing loss. The prevalence of hearing loss in better ear among post repaired cleft palate participants in the left ear is 35.8% and right ear is 14.1%. There was no moderate, severe, profound and total hearing loss to compare and get the better hearing ear calculation. In this research pure tone average for repaired cleft palate ranged from 10 to 40dB for both right and left ears. This variation in hearing threshold could be due to the different age bands used (6 to 12years and 5 to 50 years) inclusion and exclusion criteria (syndromic and non-syndromic). However, Daniel et al[21] used Pure Tone Average (PTA) based on hearing threshold 0.5kHz, 1kHz and 2kHz for conductive hearing loss just like this research but PTA more than 20dB is abnormal whiles more than 25 is abnormal for this research.

There was no statistically significant association between the type of cleft palate for the left ear and the right ear and the levels of hearing loss ($p>0.05$). This finding compare favorably with reports of previous studies that the severity of the type of cleft palate does not correlate with the severity of hearing loss[15]. This means that, Eustachian tube (ET) dysfunction, palatine muscle abnormalities, and middle ear problems may still occur irrespective of the type of cleft palate. Thakur and co-workers found that, majority 72 (68.6%) of abnormal Pure Tone Audiometry was mild conductive hearing loss[17] which also revealed that 10 (9.5%) ears had moderate conductive hearing loss, 1 (1%) had mixed hearing loss and 22 (20.9%) had normal hearing which contradicts the findings of this research.

There was no association between the type of cleft palate and degree of maximum hearing loss. This is similar to findings by Garcia-Vaquero et al[18] which

states that most frequent type of cleft palate was complete unilateral cleft palate (55.37% type III) and the least was type Veau I (8.26%).

Abnormal Tympanogram findings (type B, C1and C2) were common between age 6 to 8 year and improved with the older age groups (9 to 10 and 11 to 12). In this study of 194 ears, 99 ears had type A (normal) and 95 abnormal tympanograms. Out of the 95 abnormal tympanograms, B is 53, C1 is 28, and C2 is 14. Severity of the cleft palate is not statistically related to the severity of the tympanogram ($p>0.05$) for both ears. The overall prevalence rate for the abnormal tympanograms (B, C1, C2) in both ears is 49%. Prevalence rate for the type B Tympanogram is 27.3% in any of the ears which is similar to the findings reports of Wei Zheng and co-workers[14] who found 60% of abnormal tympanogram at the crucial language learning stage. Majority of the abnormal tympanograms found by Thanawirattananit[15] are type B tympanogram (335 out of 461 ears) which is similar to the findings of this study, probably because Eustachian tube dysfunction has progressed for long resulting in secretory otitis media. The negative pressure in the middle ear created by abnormal function of eustachian tube cause middle ear mucosa to secrete serous fluid in to the middle ear. Abnormal tympanogram findings decrease with increasing age and it is similar to the findings by Flynn[22]. All participants in this work had repaired cleft palate by age one year. Prevalence rate for type B Tympanogram is 27.3% in both ears. In the left ear, 20.6% had type B tympanogram whereas in the right ear, 34% had the type B tympanogram in this work. Qun Lou et al[20] found that, middle ear dysfunction was 27.4% of group I participants 48.3% of group II, 40.6% of group III and 75.0% of group IV. They concluded that, the prevalence of middle ear dysfunction and hearing loss increased with advance aging of palatal repair and that early palatoplasty improves middle ear function and not age as found in this work.

Conclusion

There is hearing loss in repaired cleft palate patients in KBTH. The prevalence rate of hearing loss among post repaired cleft palate subjects is 39%. This hearing loss is a conductive hearing loss. There is no SNHL or mixed hearing loss from this study. Moderate, severe, profound and total hearing loss were not recorded in this work. Seventy-six ears (76) out of 194 ears of 97 children with repaired cleft palate suffer from hearing loss in KBTH in Ghana. This hearing loss is mild conductive hearing loss from this study regardless of the type of cleft palate that was repaired. Mild conductive hearing loss and abnormal tympanogram are common between the ages of 6-8 years irrespective of the type of cleft palate. Middle ear function is not related to the type or severity of the cleft palate but the age.

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