PREVALENCE OF HEARING LOSS AMONG CHILDREN WITH CLEFT PALATE: A CASE STUDY

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DECLARATION

I **ABIBA SUMAILA** do hereby declare that this dissertation which is being submitted in fulfillment of the requirements for the Master of science degree in Audiology is the result of my own research performed under supervision, and that except where otherwise other sources are acknowledged and duly referenced, this work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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DEDICATION

I dedicate this work to my hard-working father Alhaji Sumaila Akilo and my supportive husband Alhaji Iddi Muhayu-Deen.

ACKNOWLEDGEMENT

I owe my very existence to Almighty Allah for his kindness and mercy on me to successfully complete this work.

My sincere gratitude goes to my family especially my mother Hajia Tayiba Amidu, my siblings Zubaida Sumaila (midwife), Nafisah Sumaila (midwife), my brother Mujab Sumaila (immigration Officer), Fuseina and Hassan Sumaila, Ramatu Sumaila and lovely brother Amidu Sumaila (Papa J).

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LIST OF ABBREVIATIONS

ABR	Auditory Brainstem Response
AC	Air Conduction
ACPA	American Cleft Palate-Craniofacial Association
ASHA	American Speech-Language-Hearing Association
BSA	British Society of Audiology
CL	Cleft lip
CP	Cleft palate
dB	Decibel
EAC	External Auditory Canal
ECV	Ear Canal Volume
ENT	Ear, Nose, and Throat
HAC	Hearing Assessment Centre
HL	Hearing Level
Hz	Hertz
KATH	Komfo-Anokye Teaching Hospital
KBTH	Korle Bu Teaching Hospital

OAEs	Otoacoustic Emissions
OC	Orofacial Cleft
OM	Otitis Media
PTA	Pure Tone Average
SNHL	Sensorineural Hearing Loss
TEOAE	Transient Evoked Otoacoustic Emission Test
TM	Tympanic Membrane
WHO	World Health Organization

ABSTRACT

Background: Cleft of the lip, palate, or both remain one of the most common congenital abnormalities. On average, about one in every 500 –750 live births results in a cleft. This disorder can result in feeding problems, speech problems, hearing problems, teeth problems, and frequent ear infections. Studies conducted in Ghana focused on the prevalence rate of cleft lip and palate. Hearing loss as a result of episodes of otitis media among children with cleft palate is well documented around the world. Currently, no such data exist in the country; hence this study was aimed at establishing the prevalence rate of hearing loss among children with cleft palate at a teaching hospital in Ghana.

Aim: This study was aimed at determining the prevalence of hearing loss among children with CP in Ghana.

Method: This cross-sectional research employed audiologic and tympanometric assessment to examine the hearing status of 45 children with CP between the ages of 0 and 5 years. Participants undertook otoscopy, tympanometry, TEOAE test, and ASSR test. An estimated hearing threshold greater than 15 dB HL was considered a hearing loss.

Results: The majority (54.44%) of tympanograms indicating middle ear pressure against middle ear compliance were abnormal, which is consistent with otitis media with effusion. Greatest (67.78%) absence of TEOAEs was found for ears with abnormal tympanogram findings. ASSR testing revealed elevated estimated hearing thresholds in most (54.44%) of the ears tested.

Conclusion: The prevalence rate of hearing loss among children with CP was 67.78%. The degrees of hearing loss recorded were between slight and mild. The type of hearing loss presented was

conductive. The increased rate of abnormal middle ear status experienced among children with CP may lead to hearing loss at the speech frequencies.

Keywords: Hearing loss, cleft palate, otitis media with effusion.

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Orofacial clefts (OCs) are part of the most frequent inborn facial anomalies which arise from the unsuccessful merging of the medial, lateral, and maxillary processes, which typically occur between the 6th and 10th weeks of intrauterine life (Agbenorku *et al*., 2013). A cleft palate (CP) occurs if the tissue that forms the roof of the mouth does not completely join (creating a cleft or split) during pregnancy (Centers for Disease Control and Prevention [CDC], 2017). These inborn anomalies are known to be caused by factors such as genetics and environmental factors (Agbenorku *et al*., 2013). Factors that predispose an expectant mother to give birth to a child with CP include; malnutrition, consumption of alcohol, smoking, administration of unprescribed drugs, and deficiencies in vitamins and folic acid (Newman & Agbenorku, 2014).

On average, about one in every 500 –750 live births result in a cleft (Dixon *et al*., 2011; Fadeyibi *et al*., 2012). Cleft of the lip, palate, or both remain one of the most common congenital abnormalities and has a birth prevalence rate ranging from 1/1,000 to 2.69/1,000 in different parts of the world. In the USA, the prevalence of Cleft lip (CL) and/or palate is 2.2 to 11.7 per 10,000 births. Cleft palate (CP) alone results in a prevalence rate of 5.5 to 6.6 per 10,000 births. Prevalence rates reported for live births for cleft lip and palate and cleft palate alone vary within different ethnic groups. The highest prevalence rates for CL and CP are reported for Native Americans (3.74/1,000) and Asians (from 0.82/1,000 to 4.04/1,000) (Fadeyibi *et al*., 2012).

Africans (from 0.18/1,000 to 1.67/1,000) have the lowest prevalence rates (Suleiman *et al*., 2005). The rate of occurrence of cleft palate alone is similar for Caucasians, Africans, North American

natives, Japanese, and Chinese. In Malawi, there is a reported low prevalence rate for Cleft lip and or cleft palate, 0.7 per 1,000 live births (Msamati *et al*., 2000). Suleiman et al (2005) found that the prevalence rate of clefting among a group of Sudanese hospital newborns in the city of Khartoum is 0.9 per 1,000 live births. In Ghana, an earlier survey by Agbenorku *et al*. (2011) revealed a CL/CP prevalence of 6.3 per 1,000 people at Wudoaba communities located in the Ketu South District of the Volta Region. Also, a study carried out by Agbenorku *et al*. (2013) at 11 health facilities in Kumasi in the Ashanti Region of Ghana showed a prevalent rate of 1.31/1000 (1/763) live births.

This disorder can result in feeding problems, speech problems, hearing problems, teeth problems, and frequent ear infections (Corren & Rachelefsky, 2007; Gani *et al*., 2012: Kosowski *et al*., 2012; Goswami, Jangra, & Bhushan, 2016). The link between CP and middle ear infection (otitis media [OM]) has been well reported in literature (Gani *et al*., 2012; Goswami, Jangra, & Bhushan, 2016; Karanth & Whittemore, 2018; Edentanlen & Saheeb, 2019).

Muscles of the soft palate are responsible for correct opening of the Eustachian tubes. However, in children with CP, these muscles do not work properly to open the tubes for ventilation of the middle ear leading to OM with effusion. Nasal regurgitation and choking are common because of the inability of the palate to separate the nasal and oral cavities (Goswami, Jangra, & Bhushan, 2016). Some of the feed may get into the middle ear space through the Eustachian tubes, and it may cause fluid to accumulate in the middle ear cavity which is relatively small compared to that of the adult. This may cause OM. Furthermore, Children with cleft palate are prone to inflammation or swelling of the tissue lining the sinuses (sinusitis) which can cause upper respiratory tract infection (Edentanlen & Saheeb, 2019). This can lead to acute otitis media (AOM)

which is analogous to acute sinusitis in that it is a result of obstruction at the ostium (opening) of the Eustachian tubes (Karanth & Whittemore, 2018).

The prevalence rate of CP in Ghana is well documented (Agbenorku *et al*., 2013); however, currently, no work has been done on the prevalence of hearing loss among children with CP in the country. In view of this, the study was aimed at establishing the prevalence rate of hearing loss among children with CP at a teaching hospital in Ghana.

1.2 STATEMENT OF THE PROBLEM

Research shows that children with CP are more likely to develop OM with Effusion which may cause some degree of conductive hearing loss (Gani *et al*., 2012; Goswami, Jangra, & Bhushan, 2016; Karanth & Whittemore, 2018; Edentanlen & Saheeb, 2019). Presently no data exist on the prevalence of hearing loss among children with cleft palate in Ghana. So, it is imperative to determine the prevalence of hearing loss among children with cleft palate in Ghana, thus justifying this research study.

1.3 SIGNIFICANCE OF THE STUDY

This study is expected to help ascertain the prevalence rate, degree, and type of hearing loss among children with CP in Ghana. This will suggest to physicians to add audiometric assessment to the various test conducted for children with CP.

The findings of the study will make available valuable information which may form the basis for other studies and provide information that can shape policies.

1.4 AIM

This study was aimed at determining the prevalence of hearing loss among children with CP in Ghana.

1.5 OBJECTIVES OF THE STUDY

The objectives of the study were:

i. To ascertain the prevalence of hearing loss among children with CP.

ii. To determine the various types of hearing loss among children with CP.

iii. To determine the degree of the hearing loss.

1.6 HYPOTHESES

H_1: There is a high prevalence of hearing loss among children with CP.

H_2: The type of hearing loss associated with CP will be conductive.

H_3: The degree of hearing loss associated with children with CP will be mild to moderate.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

Middle ear disease is common among children with CP due to the abnormalities of the muscles of the soft palate affecting the proper functioning of the Eustachian tube leading to poor drainage of the middle ear cavity. Also, nasal regurgitation and choking are common among children with CP during feeding resulting in food particles entering the middle ear. This may cause middle ear infection resulting in some degree of conductive hearing loss. Against this background, related literature documented on human ear, hearing loss, overview of CP, and the association between CP and hearing loss were reviewed under this chapter.

2.2 ANATOMY AND PHYSIOLOGY OF THE HEARING MECHANISM

Auditory perception enables us to detect acoustic signals and communicate effectively with others. The major purpose of the hearing mechanism is to convert acoustic energy into neural impulses that can be interpreted by the brain (Oxenham, 2018). The audibility of the human ear ranges from 20 Hz (very low) to 20 000 Hz (very high) and from -10 dB (very soft) to 120 dB (very loud) (Rosen & Howel, 2013). The auditory system can be subdivided into two, namely; the peripheral auditory system (outer, middle, and inner ear) and the central auditory system (the auditory pathway and the auditory cortex in the brain) (Sincero, 2013).

2.2.1 Outer Ear

The outer or external ear can be divided into three parts, namely; the pinna (auricle), the external auditory canal (EAC)/meatus (ear canal), and the tympanic membrane (TM) or eardrum (Burkard, 2017).

The pinna is the part that can be seen from the side of the head and it collects and channels sound into the EAC (Sandell, 2014). This cartilaginous flap-like protrusion is positioned at an angle of 25º to 35º to effectively collect sounds in front of it more than those behind and this is essential to sound localization (Robinson & Kesser, 2013). The concha of the pinna opens into the EAC, which is about 2 – 3 cm long in length (Park et al., 2016). The one-third portion of the S-like shape ear canal is cartilaginous and the inner two-thirds are bony (Chatra, 2011). The ceruminous glands together with the sebaceous glands located at the cartilaginous portion of the EAC produce cerumen (earwax) (Stoeckelhuber *et al*., 2006). The combination of the hair and earwax in the EAC protects the ear canal from physical damage and microbial incursion. The EAC is closed at one side by the TM. Sound waves reaching the pinna travel down the EAC and cause the TM to vibrate setting the ossicles in the middle ear into motion (Szymanski, Toth, & Geiger, 2020).

2.2.2 Middle Ear

Basically, the middle ear consists of the middle ear space (tympanic cavity), ossicles (malleus, incus, and stapes), middle ear muscles (tensor tympani and stapedius muscles), and the Eustachian tube (Sincero, 2013).

The tympanic cavity is an air-filled space located in the temporal bone of the skull (Luers & Hüttenbrink, 2016). The lateral wall of the chamber is formed by the TM and the anterior wall contains the Eustachian tube which equalizes the air pressure in the middle ear cavity and the EAC

(Lass, 2013). The malleus (hammer), incus (anvil), and stapes (stirrup) are the three tiniest bones in the human body. Fused together they form the ossicular chain to conduct vibration of the air in the EAC to the fluid in the inner ear. The stapedius muscle (connected to the neck of the stapes) and the tensor tympani muscle (connected to the handle of the malleus) work together to provide protection to the ear by stiffening the ossicular chain to prevent violent vibration and attenuate louder sound before it gets to the cochlea in the inner ear.

2.2.3 Inner Ear

The inner ear can be divided into the hearing system (cochlea) and the vestibular system (Agrup, Gleeson, & Rudge, 2007). The footplate of the stapes fits nicely into the oval window, which is the passage from the middle ear to the inner ear. The entrance is named vestibule through which access may be gained to the various channels of the inner ear. The vestibular portion of the inner ear houses the organ of balancing, consisting of the utricle, saccule, and the three semicircular canals (superior, posterior, and horizontal) (Lass, 2003).

The cochlea which looks like a snail shell made of twisting bony shell located in the inner ear is responsible for hearing and partakes in the process of auditory transduction (Casale & Murr, 2020). The coil turns two and a half times which narrows to the top. Just after the oval window lies the scala vestibuli (SV) and at the bottom of the cochlea lie the scala tympani (ST), and the scala media (SM) lies in between. Beginning from the round window both SV and ST are filled with a fluid called the perilymph (rich in sodium ions), which continues through a small passage at the apex of the cochlea called helicotroma. However, the SM is filled with endolymph (rich in potassium ions) and it is separated from the SV by the Reissner's membrane and from the ST by the basilar membrane. The SM houses the organ of Corti where true hearing occurs. It contains one row of inner and three rows of outer hair cells (Ciganović, Wolde-Kidan, & Reichenbach, 2017;

Wiwatpanit *et al*., 2018). The hair cells are connected with nerve fibres of the auditory nerve. All these hairs are covered by the tectorial membrane.

Displacement of the perilymph in the SV occurs when the oval window is moved by the stapes. The Reissner's membrane is set into motion causing a disturbance of the endolymph in the SM which in turn displaces the basilar membrane, resulting in the releasing of the round window. When the basilar membrane moves up and down in response to the fluid displacement, the inner hair cells are twisted in a complex manner. The hair cells are stimulated and a chemical (potassium ions) is released at the base of the hair cells which give rise to electric potentials that is conducted along the nerve fibres to the brain (Ciuman, 2017). This pathway formed by the nerve fibres and the auditory cortex of the brain is called the central auditory system.

2.3 HEARING LOSS

The human ear can also be separated into a conductive section (consisting of the outer and middle ear) and a sensorineural section (consisting of the inner and the auditory nerve). Hearing loss occurs as a result of the reduction of sound waves sent to the brain due to a lesion located in the conductive part and/or sensorineural part of the haring mechanism. Some causes of hearing loss include wax buildup in the EAC, perforation of the eardrum, infections, administration of ototoxic medications, damages to the cochlea from excessive noise exposure, genetic factors, and aging.

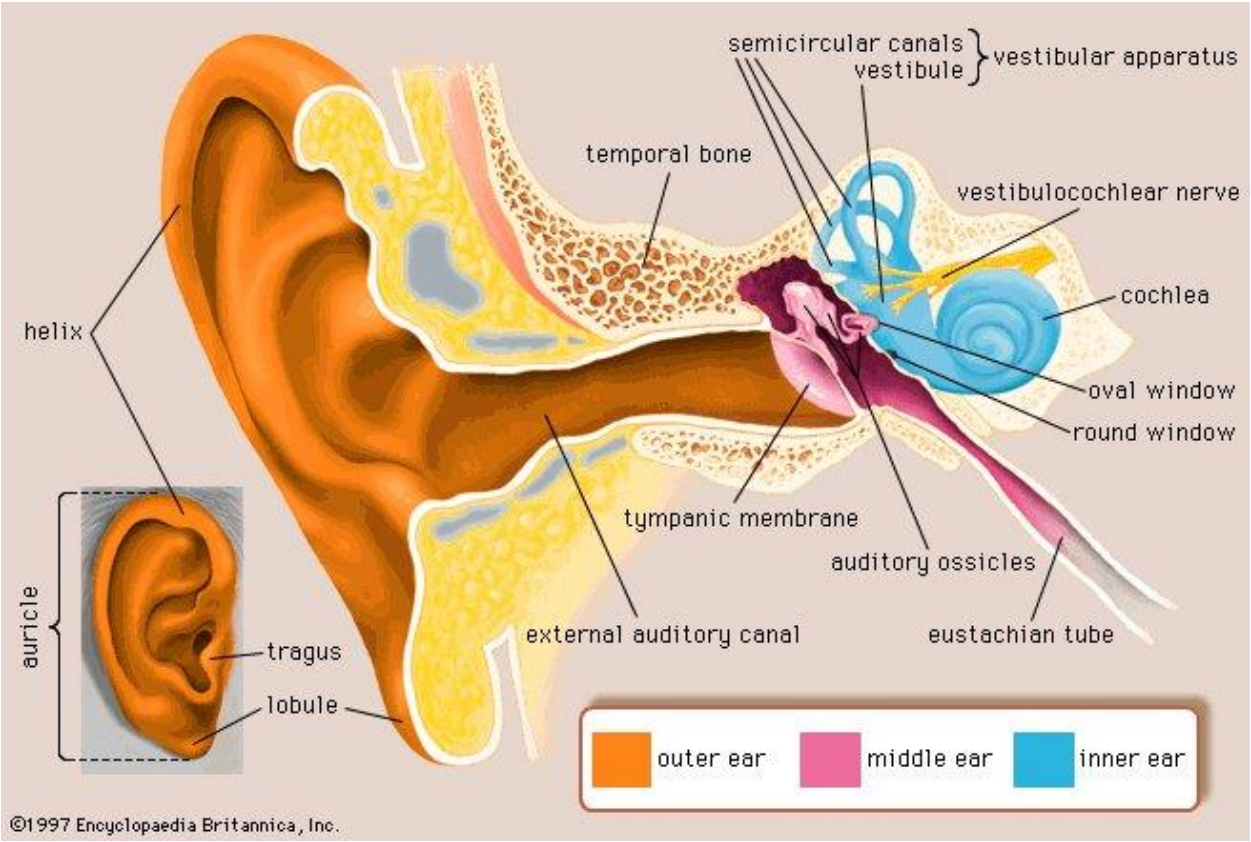

Figure 2.1: Diagram showing the structure of the human ear

Source: Encyclopaedia Britannica, Inc. (1997)

2.3.1 Types of Hearing Loss

The site of lesion along the auditory system determines the type of hearing loss (American Speech-Language-Hearing Association [ASHA], 2015). The main types of hearing loss include conductive hearing loss, sensorineural hearing loss (SNHL), and mixed hearing loss (Duthey, 2013).

2.3.1.1 Conductive Hearing Loss

When hearing loss occurs as a result of an impediment or damage to the outer and/or middle ear that impedes sound conduction to the inner ear it termed conductive hearing loss. Causes of conductive hearing loss include excessive wax impaction, outer ear infection (otitis externa), obstruction of the EAC by foreign bodies, atresia, middle ear infection (otitis media), perforation of the TM, dislocation of the ossicles, otosclerosis, cholesteatoma, to mention a few. This type of hearing loss can normally be corrected medically (Duthey, 2013). Figure 2.2 shows a moderate (41 – 55 dB HL) to moderately severe (56 – 70 dB HL) conductive hearing loss in the left ear (Alshuaib et al., 2015). The bone conduction (BC) hearing thresholds are within normal range (0 – 25 dB HL), whereas the air conduction (AC) shows a hearing loss within moderate to moderately severe.

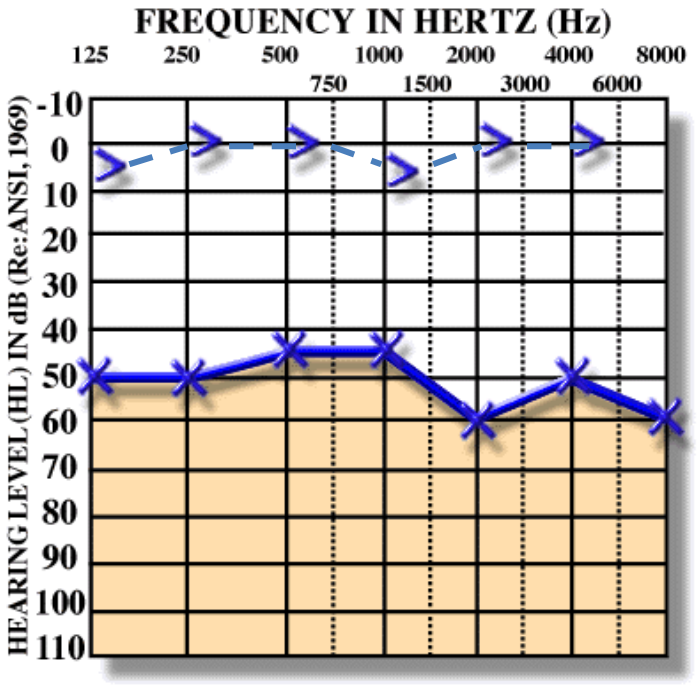

Figure 2.2: An audiogram showing a moderate-moderately severe conductive hearing loss in the left ear. Symbols: ×, left AC; >, left unmasked BC. Source: Fitzakerly (2015)

2.3.1.2 Sensorineural Hearing Loss

This type of hearing occurs as a result of damage to the hair cells in the inner ear or the auditory nerve which prevents or reduces the transfer of acoustic signals to the brain. Some causes include hereditary or genetic factors, aging (presbycusis), ototoxic medications, acoustic trauma, ménière's disease, infections etc. SNHL is permanent and cannot be treated medically, however, sufferers can benefit from aural rehabilitation by means of amplification through hearing aids, cochlear implants, and other assistive listening devices (Hawkins, 2009). Figure 2.3 depicts a mild (26 – 40 dB HL) to moderate (41 – 55 dB HL) sensorineural hearing loss at the high frequencies (typical audiogram for noise-induced hearing loss) in the left ear. Both AC and BC responses at the high frequencies are in the mild to moderate range of hearing loss (Alshuaib *et al.*, 2015).

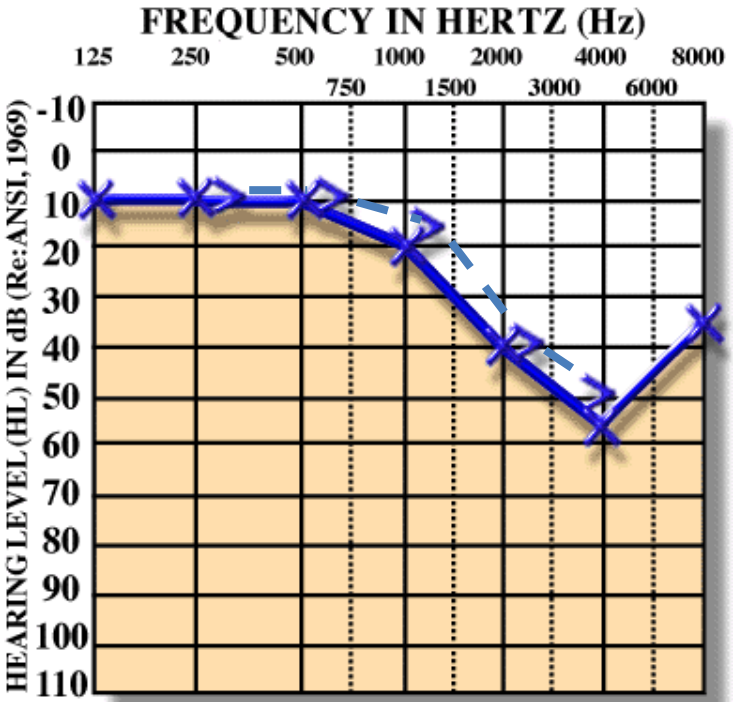

Figure 2.3: An audiogram showing SNHL at the high frequencies.

Source: Fitzakerly (2015)

2.3.1.3 Mixed Hearing loss

Mixed hearing loss is as a result of lesion in the conductive and sensorineural portions of the auditory system. This means that there is damage in the outer or middle ear and in the inner ear. It could be caused by a combination of noise-induced hearing and otitis media (Gelfand, 2016). Figure 2.4 shows a mixed hearing loss, with both AC and BC threshold deviating from the normal range and with an air-bone gap basically greater than 10 dB (Alshuaib *et al*., 2015).

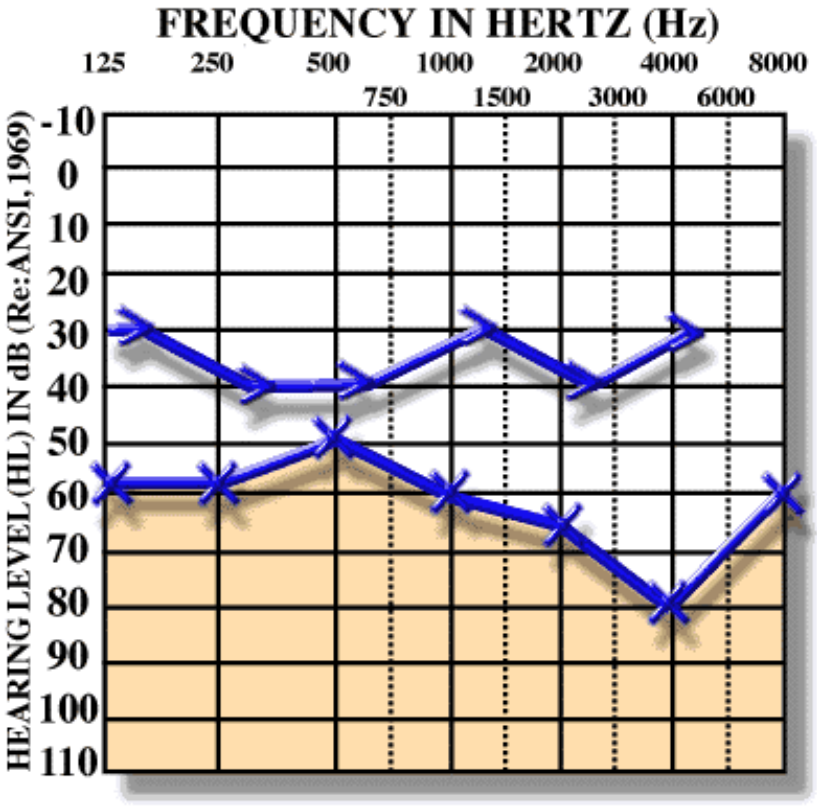

Figure 2.4: An audiogram showing a mixed hearing loss.

Source: Fitzakerly (2015)

2.3.2 Degrees of Hearing loss

Hearing loss can be categorized based on a hearing threshold of intensities and frequencies associated with speech as slight (16 – 25 dB HL), mild (26 – 40 dB HL), moderate (41 – 55 dB HL), moderately severe (56 – 70 dB HL), severe (71 – 90 dB HL) or profound (greater than 91 dB HL) (Alshuaib et al., 2015)**.** Table 2.1 below shows the categorization of the degree of hearing loss by Clark (1981).

Table 2.1: categorization of the degree of hearing loss

Degree Of Hearing Loss	**Hearing Loss Range dB HL**
Normal	0 to 15
Slight	16 to 25
Mild	26 to 40
Moderate	41 to 55
Moderately Severe	56 to 70
Severe	71 to 90
Profound	>91

Source: Clark (1981)

2.3.3 Prevalence of Hearing Loss

Available data show that globally about 466 million (representing over 5% of the world's population) individual have disabling hearing loss (hearing loss greater than 40 dB in adults, and hearing loss greater than 30 dB in children) (Schmucker et al., 2019; World Health Organization [WHO] 2020). Out of this estimation, 432 million are adults and 34 million are children. It is noteworthy that 60% of childhood hearing loss is due to causes that are avoidable (WHO, 2020).

Unaddressed hearing loss can have adverse consequences especially on children. The ability to hear is crucial to the development of speech and language, communication, and learning (Packer, 2018). Hearing loss even mild to moderate among children can adversely affect their speech and language development, communication, and learning, leading to poor performance at school and ability to participate in age-appropriate activities (ASHA, 2015).

Children with hearing loss lag behind in terms of development of receptive and expressive communication skills, thus their vocabulary is under developed compared to their hearing peers (ASHA, 2015; Fitzpatrick *et al*., 2016). This causes learning difficulties that lead to poor academic performance. Hearing loss may cause communication problems which may lead social isolation and poor self-esteem. This may have an impact on the choice of vocation in later life (ASHA, 2015). Early identification coupled with proper intervention can curb effect of hearing loss on speech and language, communication, and learning.

2.4 OVERVIEW OF CLEFT PALATE

Cleft palate (CP) is a birth defect that occurs when the tissues that forms the roof of the mouth does not fuse completely (CDC, 2017; Karanth & Whittmore, 2018). By the sixth week of gestation, the inter-maxillary segment is formed from the fusion of the paired medial nasal prominences and the maxillary prominences (Ansari & Bordoni, 2020). This epithelium tissue will form the core of the primary palate, and posteriorly the nasal epithelium will touch the oral epithelium forming the oro-nasal membrane. In the posterior area, the membrane will make an opening termed the primitive choana (Kwong, 2015) that joins the oral cavity to the nasal cavity. Also, the primary palate will form the anterior triangular one-third from the incisive foramen and the four upper incisors.

The remaining hard palate and all of the soft palate are formed by the secondary palate around the 7^{th} and 8^{th} weeks of pregnancy. It comes out from two palatal shelves (medial outgrowths and the maxillary processes) that grow downward and parallel to the tongue. By the end of the 8^{th} week, the two secondary palatal processes fuse with the primary palate to make the definitive palate. Around this same period, the nasal septum grows to separate the left and right nostrils, and its inferior part combine with the definitive palate. The appropriate formation and fusion of the palates are essential for healthy development of a child and disorder or malformation may cause a cleft palate (Ansari & Bordoni, 2020). Figure 2.5 shows a drawing of a normal formation of the roof of the mouth.

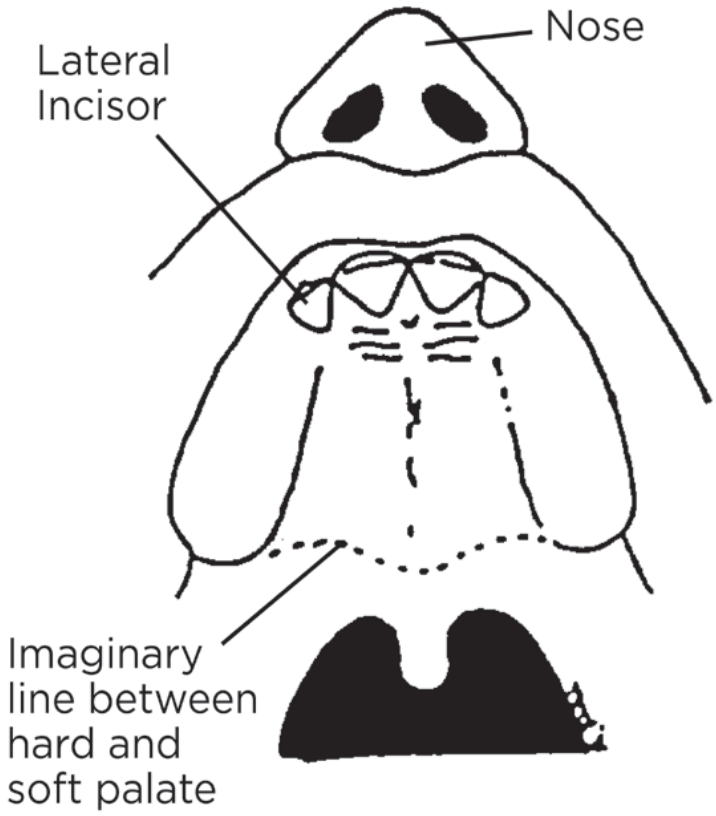

Figure 2.5: A drawing of a normal roof of the mouth

Source: Seattle Children's Hospital (2018)

2.4.1 Causes of Cleft Palate

The precise cause of this defect is usually not known (Mandal, 2019). Some experts hold the view that lack of nutrients or side effects of some drugs can increase the risk of cleft lip and palate. Some children can inherit a gene or genes that cause cleft lip and palate from their parents. Scientists have found some genes responsible for cleft lip and palate (Leslie & Marazita, 2013). A child of a parent with a cleft has a 4% to 6% possibility of inheriting it (Mandal, 2019). Families with no history of clefts have a low risk (0.14%) of being delivered with cleft lips and/or palate.

Environmental factors that predispose a pregnant woman to have a baby with CP may include; malnutrition, consumption of alcohol, exposure to tobacco, exposure to toxins and poor prenatal health (Newman & Agbenorku, 2014; Mandal, 2019). Expectant mothers administering medications such as phenytoin, phenobarbital, sodium valproate, and benzodiazepines for epilepsy management are at a greater risk of having babies with cleft lip and/or palate (Mandal, 2019).

Other risk factors may include deficiency of some vitamins and folic acid, viral infection, and parents who become pregnant when they are older than usual.

2.4.2 Types of Cleft Palate

In 1931 Victor Veau (1871 - 1949) a French surgeon classified cleft lip and palate into 4 major types (Rani & Chickmagalur, 2011; Allori et al., 2017). Figure 2.6 shows illustrarions of the types of clefts.

- **Type 1:** only the soft palate has a cleft (Figure 2.6A)
- **Type 2:** in this type there is a cleft in the hard and soft palate covering to the incisive foramen (Figure 2.6B).
- **Type 3:** includes a cleft of the soft palate and hard palate covering unilaterally from the uvula to the incisive foramen (Figure 2.6C).
- **Type 4:** consists of a cleft of the soft and hard palate covering bilaterally from the uvula through the incisive foramen (Figure 2.6D).

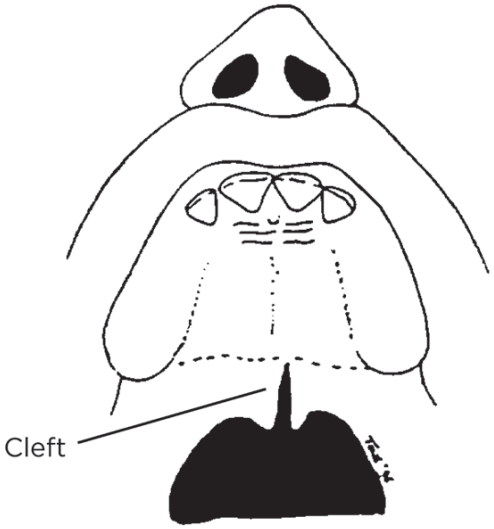

Figure 2.6A: cleft of the soft palate only

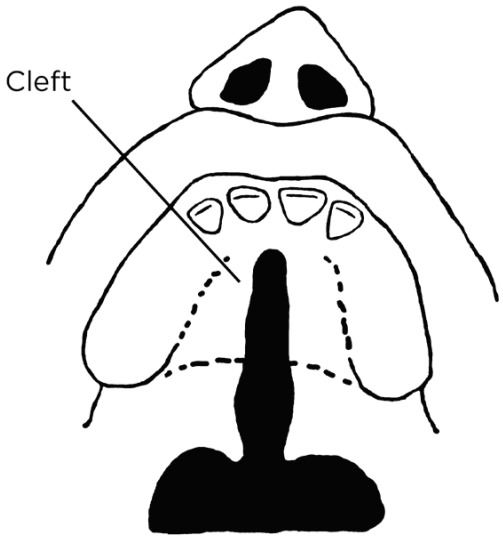

Figure 2.6B: Cleft of both hard and soft palate

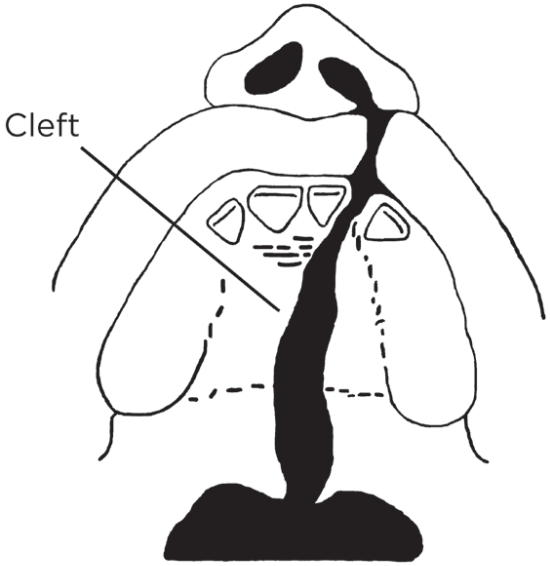

Figure 2.6C: Unilateral cleft of the lip and palate

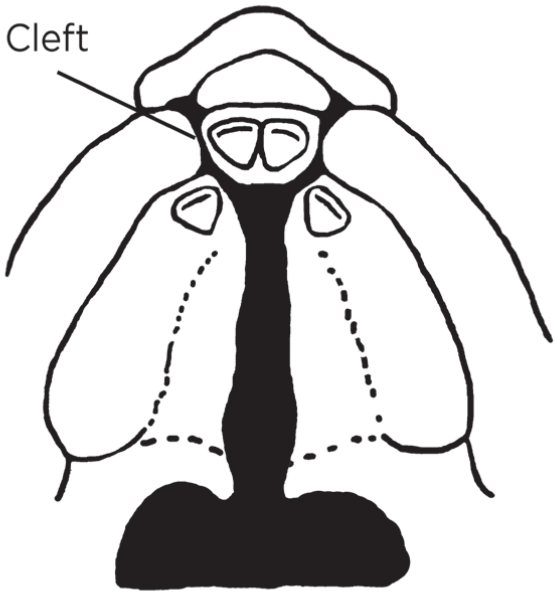

Figure 2.6D: Bilateral cleft of the lip and palate

Figure 2.6: Illustration showing types of clefts

Source: Seattle Children's Hospital (2018)

2.4.3 Prevalence of Cleft Palate

The global prevalence rate of an orofacial cleft in any form occurs in about 1 in 700 live births (Chigurupati, 2010; Dixon *et al*., 2011; Fadeyibi *et al*., 2012; American Cleft Palate-Craniofacial Association [ACPA], 2018; Yilmaz, 2018). Prevalence rates reported for live births for cleft lip and palate and cleft palate alone vary within different ethnic groups. More males are affected with cleft lip and palate, while cleft palate alone is generally more often in females (Hopper et al., 2007).

In the USA, roughly 1 of every 1600 babies is delivered with cleft lip and cleft palate and 1 of every 1700 babies is delivered with cleft palate alone (Mai *et al*., 2019). The highest prevalence rates for Cleft lip and cleft palate are reported for Native Americans (3.74/1,000) and Asians (from 0.82/1,000 to 4.04/1,000) (Fadeyibi *et al*., 2012). Studies conducted in Asia showed that the incidence of oral cleft in every 1000 live births is reported as follows: 1.91 in Pakistan, 1.39 in Jordan, 1.76 in North China, 1.81 in Korea, 1.34 in Japan and 1.5 in Oman (Al Omari & Al-Omari, 2004; Elahi et al., 2004; Kianifar et al., 2015; Noorollahian et al., 2015; Wang et al., 2009).

Africans (from 0.18/1,000 to 1.67/1,000) have the lowest prevalence rates (Suleiman *et al*., 2005). Suleiman et al (2005) reported that only 1/2500 African American is born with a cleft. The rate of occurrence of cleft palate alone is similar for Caucasians, Africans, North American natives, Japanese, and Chinese.

A survey by Agbenorku *et al*. (2011) revealed a CL/CP prevalence of 6.3 per 1,000 people at Wudoaba communities located in the Ketu South District of the Volta Region, Ghana. This high prevalence rate could mean that the Wodoaba communities could be an endemic area for CL/CP in the Volta Region of Ghana. Also, a study carried out by Agbenorku et al. (2013) at 11 health facilities in Kumasi in the Ashanti Region of Ghana showed a prevalence of 1.31/1000 (1/763)

live births. Currently, there is no available database for orofacial cleft (Newman & Agbonorku, 2014). Hence, more studies need to be conducted to establish such a database.

According Mirfazeli et al. (2012), this variance observed in the incidence of oral cleft can be attributed to social influences and racial/ethnic factors in different parts of the world, which is more commonly defined as genetic disorders.

2.4.4 Association between Cleft Palate and Middle Ear Disease

The middle ear is part of a functional system composed of the nasopharynx and the Eustachian tube. The tensor veli palatini muscle opens the Eustachian tube, which promotes ventilation of the middle ear. The tendon of the tensor veli palatini hooks around the hamulus of the pterygoid plate and the aponeurosis of the muscle inserts along the posterior border of the hard palate. The muscle originates partially on the cartilaginous border of the auditory tubes. The function of the tensor veli palatini, similar to tensor tympani with which it shares similar innervation, is to improve the ventilation and drainage of the auditory tubes (Sharma & Nanda, 2009).

In a cleft of the palate, the aponeurosis of the tensor veli palatini, instead of attaching along the posterior border of the hard palate, is attached along the bony cleft edges. This abnormality in the tensor veli palatini decreases its effectiveness as a Eustachian tube ‘opener’ and increases the incidence of middle ear effusion and middle ear infection.

When the Eustachian tube opens, it allows outside air into the middle ear. This equalizes the pressure in the middle ear cavity with the outside air pressure or effectively ventilates the middle ear space (Lass, 2013). When the middle ear space is not adequately ventilated, fluid can accumulate, which can lead to an ear infection. Muscles of the soft palate are responsible for the correct opening of the Eustachian tubes. However, in children with cleft palate, these muscles do

not work properly to open the tubes for ventilation of the middle ear. In some cases, their palate muscles don't even reach the Eustachian tubes. Because cleft palate interferes with how the Eustachian tubes work, children born with cleft palate are more likely to accumulate ear fluid and get an ear infection (otitis media).

One of the immediate problems to be addressed in children with cleft palate is difficulty in feeding. Nasal regurgitation and choking are common because of the inability of the palate to separate the nasal and oral cavities (Goswami, Jangra, & Bhushan, 2016). Some of the feed may get into the middle ear space through the Eustachian tubes, and it may cause fluid to accumulate in the middle ear cavity which is relatively small compared to that of the adult. This may cause middle ear infection (otitis media).

Children with cleft palate are prone to inflammation or swelling of the tissue lining the sinuses (sinusitis) which can cause upper respiratory tract infection. This can lead to acute otitis media (AOM) which is analogous to acute sinusitis in that it is a result of obstruction at the ostium (opening) of the Eustachian tubes. The bacteria responsible for AOM are similar to that responsible for acute sinusitis (Corren & Rachelefsky, 2007).

Studies show that children with cleft palate are more likely to develop otitis media with effusion (Chen *et al*, 2012; Edentalen & Saheeb, 2019). About 90% of children with cleft palate develop otitis media with effusion within the first 2 years of birth, which may lead to speech and language, intellectual, or emotional problems (Gani *et al*., 2012; Karanth & Whittemore, 2018). Children with cleft palate are likely to suffer at least an episode of otitis media or otitis media with effusion by the time they turn age 7 (Goh *et al*., 2019).

2.5 PREVALENCE OF HEARING PROBLEMS AMONG CHILDREN WITH CLEFT

Hearing loss among patients with cleft is well documented complication, but generally gets ignored. Middle ear disease is common among children (Sharma & Nanda, 2009). According to Teele et al. (1989) about 71% of all children have at least one episode of otitis media by the age of three years. On the contrary, children with cleft palate have been reported to have recurrent acute otitis media or otitis media with effusion (Sharma & Nanda, 2009). The problem of recurring otitis media among children with cleft palate could lead to mild to moderate conductive hearing loss among these children (Karanth & Whittemore, 2018; Edentalen & Saheeb, 2019; Werker *et al*., 2018; Goh *et al*., 2019; Paepe *et al*., 2019; Werker *et al*., 2019). When otitis media is not properly treated, it may lead to a permanent hearing loss (Rosenfeld & Kay, 2003). An untreated infection can travel from the middle ear to the inner ear and nearby parts of the head, including the brain causing more permanent damages to the hearing system.

A 90% of incidence of hearing loss was reported among Caucasian patients whereas in Chinese patients the incidence has been reported to be only 23% (Lau et al., 1988). In the Japanese population also, an incidence of 69% has been found (Yabe et al., 1989). More recent studies observed that children born with a cleft lip and palate have higher prevalence of ear infections than children without cleft (Edentalen & Saheeb, 2019). For children who have both types of cleft, studies show that 90 to 93% with middle ear infections will also have temporary or conductive hearing loss (Narayanan *et al*., 2013). Handzic (2018) reported hearing loss incidence 80% among children 1 – 3 years. Audiologic and tympanometric findings of a study among children with CLP in Turkey showed 20% with slight hearing loss and 17% with mild hearing loss (Tunçbilek, Özgür, & Belgin, 2003). A cross-sectional study conducted by the Ghana College of Physicians and Surgeons (2020) at the Korle Bu Teaching Hospital to assess the hearing threshold of patients with

repaired cleft palate showed a prevalence rate of 33%. The hearing loss was 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.

The level of hearing-impaired children with clefts is more severe than normal children who also have an ear infection. The hearing loss may continue into adulthood in about 20 – 30% of children with cleft palate (Sharma & Nanda, 2009). Mild to moderate hearing loss among children has an adverse impact on speech and language development, learning, and how the brain process sound (University of Cambridge, 2019).

2.6 RESEARCH GAP

Studies conducted in Ghana focused on the prevalence rate of cleft lip and palate. Also, hearing loss as a result of episodes of otitis media among children with cleft palate is well documented around the world. Currently, no such data exist in the country; hence this study was aimed at establishing the prevalence rate of hearing loss among children with cleft palate at a teaching hospital in Ghana.

CHAPTER THREE

METHODOLOGY

3.1 INTRODUCTION

This chapter describes the methods and procedures adopted in carrying out the study. They consist of the research design adopted, the study site, sample population and size, samplings technique, audiological test procedure, research instruments, data collection, and data analysis. Data management and ethical issues associated with the study were also captured.

3.2 STUDY DESIGN

To estimate the prevalence of hearing loss among children with cleft palate, this study employed a cross-sectional study design. Cross-sectional study design is a type of observational study that involves the analysis of data from a population or a representative subset at a specific point in time (Setia, 2016). This study was conducted on the consent of the parent and/or guardian of the patients with a clinical diagnosis of cleft palate, who were seen at the plastic and reconstructive surgery unit at the Korle Bu Teaching Hospital (KBTH) between 2019 and 2020.

According to Creswell and Poth (2016), this type of quantitative design, simultaneously allows for measurement of outcome and the exposures in the study participants. In this design, participants are selected based on the inclusion and exclusion criteria set for the study. Using a cross-sectional design is preferred in studies assessing the prevalence of a condition or a phenomenon. Scholars have said it is relatively faster and less expensive to use. Thus, the prevalence of these data may have limited generalizability. Nonetheless, this type of study design will be classified as a cross-sectional study.

3.3 STUDY SITE

This study was conducted at the Panel clinic which is under the Plastic and Reconstructive Surgery Centre (PRSC) of the Korle–Bu Teaching Hospital (KBTH) where children with orofacial clefts (OCs) are managed was selected. The KBTH also houses the Hearing Assessment Centre (HAC) where the hearing assessment was conducted.

3.4 STUDY POPULATION

A study population is the group of individuals taken from the general population who share a common characteristic, such as age, sex, or health condition. The population in this study is the total number of 208 cleft children obtaining treatment at the Panel Clinic-KBTH.

3.5 SAMPLE SIZE AND SAMPLING TECHNIQUE

Yamane's formula for calculating sample size for a finite population was used to compute the sample size (Yamane, 1967). The formula is given as:

$n = N/(1+Ne^2)$ where n= corrected sample size, N= population size, and e= margin of error (MOE) = 0.05

Population=208 $n=208/(1+208(0.05))^2 = 137$ children

Due to the COVID-19 pandemic and the mandatory safety protocols, only 45 children between the ages of 0 and 5 years with cleft palate who were readily available were selected for this study and also the research was time bound. Battaglia (2008) postulated that convenient sampling is useful because it allows researchers to select sites that can easily get data.

3.6 INCLUSION AND EXCLUSION CRITERIA

The inclusion criteria that were used for this study include all children with cleft palate alone who report to the Panel Clinic in Korle-Bu between the ages of 0 – 5 years, between July and August 2020. Most children who are yet to undergo surgery for cleft palate repair are in the age bracket of 0 – 5 years. Due to COVID-19 protocols the hospital was attending to the patients in cohorts depending on the classifications. As at the time of data collection only children with Types 1 and 2 of cleft palate alone were available for selection.

On the exclusion criteria, the following criteria were used to exclude participants: All children with cleft palate aged outside the 0-5 year's bracket; all children with cleft lip alone, as well as all children with both cleft lip and palate would all be excluded from the study.

3.7 EQUIPMENT USED

All tests were conducted by the researcher, except the Auditory Steady-State Response (ASSR) test which was conducted by a Senior Audiologist at the Hearing Assessment Centre of the Korle Bu Teaching Hospital.

3.7.1 Otoscope

The HS-OT10C otoscope (Figure 3.1) was used to examine the outer ear of the participants to rule out any abnormalities of the pinna, external auditory canal, and the tympanic membrane.

Figure 3.1: HS-OT10C Otoscope

Source: http://sunimports.in/product-category/other-products/otoscope/

3.7.2 Tympanometer

Granson-Stadler GSI® Tymstar Version 2 Middle ear Analyzer (Figure 3.3) was used to determine the middle ear pressure (MEP), peak compliance, and the ear canal volume (ECV). A probe tone of 226 Hz was used. Normal MEP was set between $^{-}150$ — $^{+}100$ daPa, peak compliance was set between 0.2 — 2.0 ml, and ECV was set between 0.2 — 2.0 ml. The tympanograms were classified based on the classification system described by Jerger (1970) which is commonly used in Ghana. The tympanograms were classified into Types A, B, and C (Figure 3.2).

Type A tympanogram suggests normal MEP against normal tympanic membrane mobility. Type A can be further classified into Type A_D and A_S. Type A_D represents abnormally high static admittance and Type A_S indicates abnormally low statics admittance. Type B shows no peak MEP with little or no static admittance. This is also known as a flattened tympanogram and mostly indicates otitis media with effusion (OME) which is common among children with CP. Type C represents normal static admittance, but with negative MEP. A type C tympanogram showing simple negative MEP is consistent with early otitis media. High negative MEP with a retracted tympanic membrane indicates acute otitis media (AOM).

3.7.3 Interacoustics OtoAccess Eclipse EP15

Interacoustics OtoAccess Eclipse EP15 (Figure 3.4) was used to conduct Auditory Steady-State Response (ASSR) test. ASSR is a scalp-recorded electro-physiological test where responses are evoked by a periodically repeated (rapid) auditory stimulus (Aimoni et al., 2018). In this study, ASSR responses were recorded at 500 Hz, 1000 Hz, 2000Hz, and 4000 Hz using pure tones. Estimated hearing thresholds were recorded on audiograms.

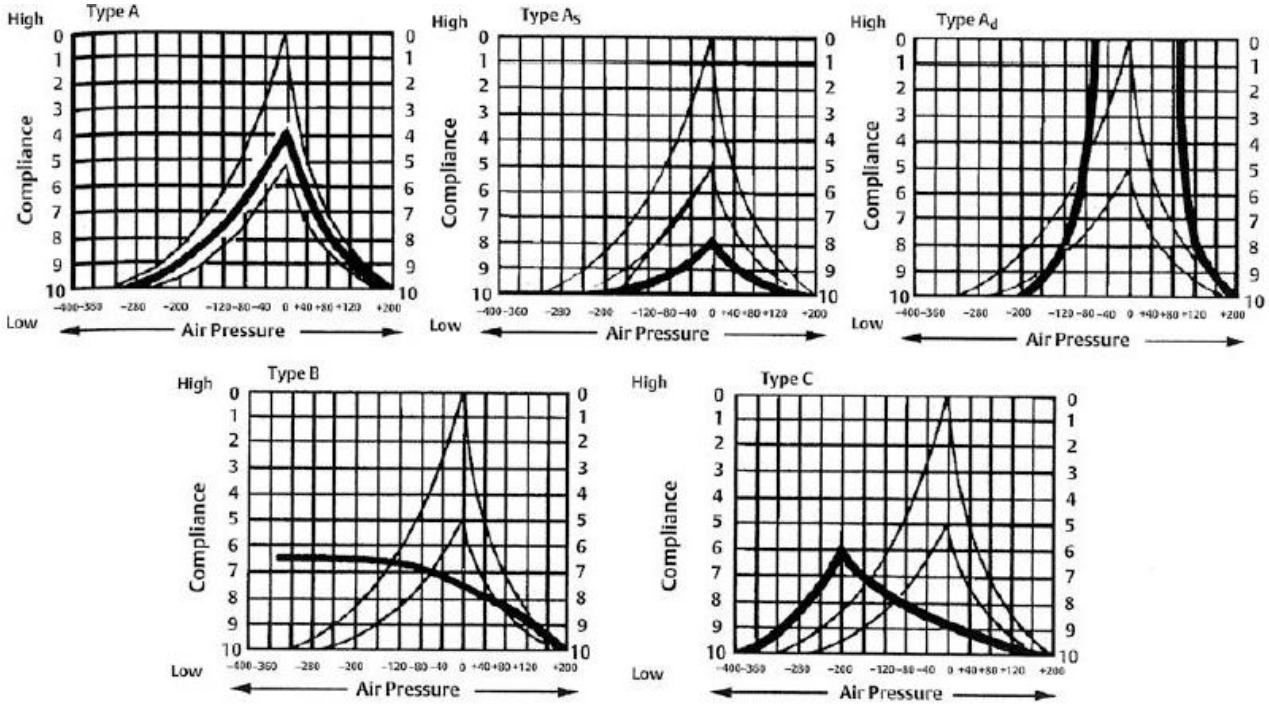

Figure3.2: Tympanograms

Source: Jerger (1970)

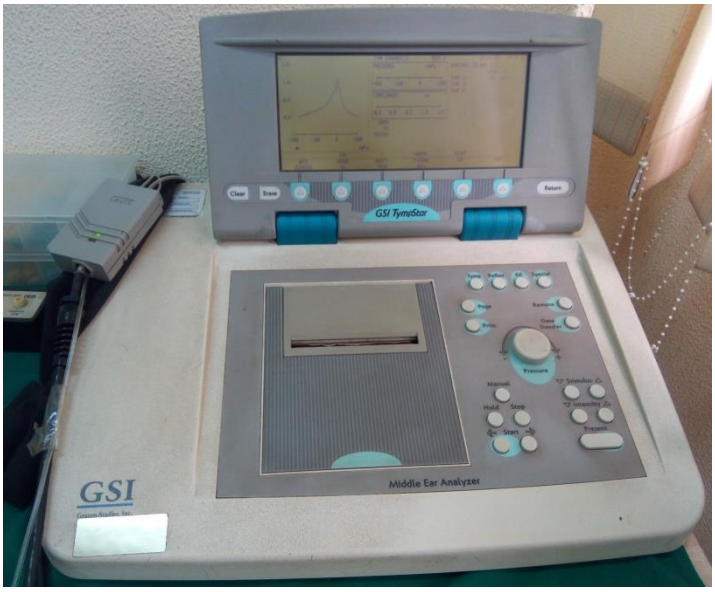

Figure 3.3: Granson-Stadler GSI® Tymstar Version 2 Middle Ear Analyzer

Source: Hearing Assessment Centre-KBTH

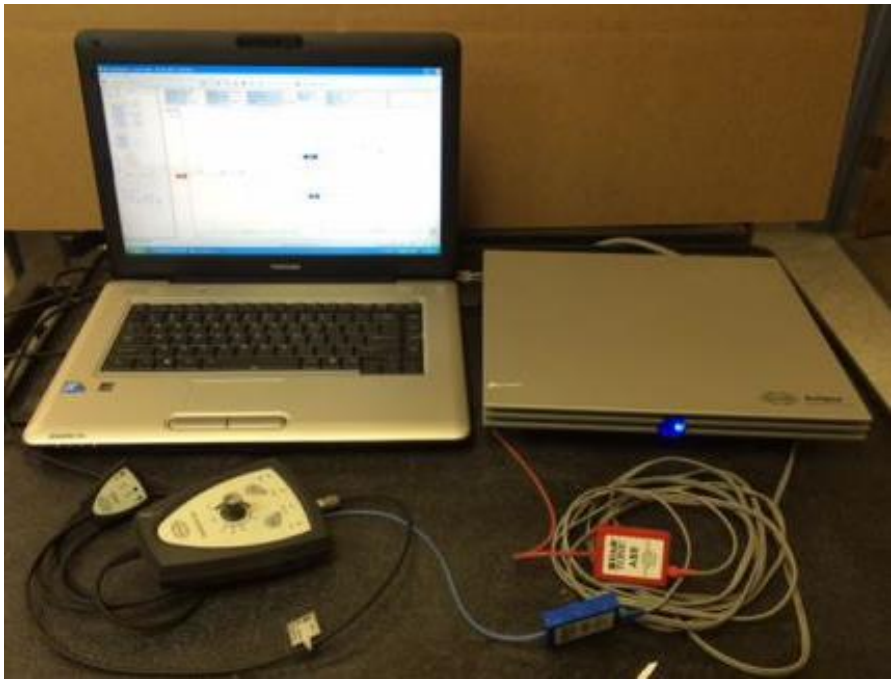

Figure 3.4: Interacoustics OtoAccess Eclipse EP15

Source: KBTH

3.7.4 Interacoustics OtoRead Handheld OAE Device

Interacoustics OtoRead Handheld OAE Device was used to perform the transient evoked otoacoustic emissions (TEOAEs) test to measure the outer hair cells function in the cochlea.

Figure 3.5: Interacoustics OtoRead Handheld OAE Device

Source: https://www.interacoustics.com/templates/yootheme/cache/otoread-185ff853.png

3.8 PROCEDURE FOR DATA COLLECTION

The 45 children were available at the cleft and Panel clinics under the Reconstructive and Plastics Surgery Centre (RPSC). A preliminary assessment was done by the research assistant to obtain the demographic data of participants as well as their medical history. The preliminary assessment was imperative to determine the inclusion and exclusion criteria.

The external auditory canals of the participants were visualized using the HS-OT10C otoscope to rule out wax impaction, signs of infections, foreign bodies or debris, tympanic membrane perforation and obstructive mechanisms of the external auditory canal.

Tympanometry was conducted to assess the integrity of the middle ear of subjects by inserting the probe tip of the Granson-Stadler GSI® Tymstar Version 2 Middle ear Analyzer into the auditory canals to measure the MEP, compliance, and ECV using a probe tone of 226 Hz.

Interacoustics OtoRead Handheld OAE Device was used to perform the transient evoked otoacoustic emissions (TEOAEs) test to measure the outer hair cells function of the inner ear. A repeated broadband click stimulus was used. The results were displayed on the screen of the OAE device as either “PASS” or “REFER” and recorded. To pass the test it was required that 3 out of 4 frequencies (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz) are detected by the OAE device. When a participant passes the test, it showed that there is a significantly low chance that they have a hearing loss.

The Interacoustics OtoAccess Eclipse EP15 with insert earphones was used to conduct the ASSR test in an acoustically treated room with an ambient noise less than 35 dB SPL. Each participant was put to sleep with oral syrup chloral hydrate which was administered by a licensed anesthetist

and monitored throughout the test period. ASSRs were evoked at single carrier frequencies of 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz using 100% amplitude modulation.

3.9 ANALYSIS

The quantitative data generated were coded and entered into the International Business Machines (IBM) Statistical Package for Social Scientist (SPSS) version 22 software and analyzed. General overviews of the data were given by standard descriptive statistics (i.e., mean, standard deviation, and percentages). A student's *t*-test was used to determine the significance between the ages of male and female participants. Data was analyzed based on the number of ears tested.

3.10 ETHICAL CONSIDERATIONS

Ethical clearance was obtained from the Ethics and Protocol Review Committee (EPRC) of the School of Biomedical and Allied Health Sciences (SBAHS) [SBAHS/AA/AUD/10702293/2019-2020] and the KBTH. Also, permission was obtained from the Panel Clinic in KBTH through a written notice. Again, informed consent was obtained from the parents and/or guardians of the participants. Participants were identified with reference codes. Due to confidentiality, only the researcher and her supervisors had direct access to the data.

Finally, the findings of clinical importance will be shared with the patients' doctor for management.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

The demographic data of patients, tympanometry (middle ear test) results, the transient evoked otoacoustic emission (TEOAE) test results, auditory steady-state response (ASSR) test results, and the prevalence of hearing loss in terms of the number of ears assessed, are presented in this chapter.

4.2 DEMOGRAPHIC DISTRIBUTION

The study comprised of 25 (55.6%) males and 20 (44.4%) females with age range 0 – 60 months (0 – 5 years). The mean age was 36.93 ± 14.67 months with a minimum age of 4 months and a maximum of 60 months. A majority of the participants were in the age range 25 – 36 months (n=17, 37.78%). Statistically, the study did not show a significant difference in the ages of male and female participants with *t*-value of -0.47 and *p*-value of 0.64. The significance level of 5% ($p<.05$) was adopted. Demographic data of participants are shown in Table 4.1.

4.3 OTOSCOPIC EXAMINATIONS

There were no abnormalities of the pinna, external auditory canal, and the tympanic membrane of 85 ears, except 5 ears with earwax. They were referred to the ear, nose, and throat (ENT) nurse for aural irrigation before they underwent the other tests.

4.4 TYMPANOMETRY RESULTS

From Table 4.2, type-A tympanograms indicating normal middle ear function were recorded in 32.22% (29 ears), whiles 13.33% (12 ears) presented type-A_s tympanograms indicating reduced peak compliance seen in middle ears with some fluid or ossicular fixation due to the excess fluid

in the middle ear which results in reduced mobility of the tympanic membrane. A majority representing 54.44% (49 ears) recorded type-B tympanograms (flat) which is consistent with otitis media with effusion (OME).

Table 4.1: Demographic data of children with CP

Subjects (*n*=45)	**Number**	**Percentage (%)**
Gender		
Male	25	55.6
Female	20	44.4
Age (Months)		
0 – 12	5	11.11
13 – 24	2	4.44
25 – 36	17	37.78
37 – 48	11	24.44
49 – 60	10	22.22
Maximum	60	
Minimum	4	
Mean ± SD	36.93 ± 14.67	
T-Value	-0.47	
P-Value	0.64	

SD=Standard deviation

Table 4.2: Tympanometry results of participants

Types	**Number**	**Percentage (%)**
A	29	32.22
A_s	12	13.33
B	49	54.44
Total	90	100

4.5 TRANSIENT EVOKED OTOACOUSTIC EMISSIONS TEST RESULTS

Out of the 90 ears tested, 29 (32.22%) passed and 61 (67.78%) referred in the TEOAE test (Table 4.3). As TEOAEs are objectively measured sounds that exit in the ear, it is significant to note that TEOAEs were absent in ears with Type As and Type B tympanograms.

Table 4.3: TEOAE results

TEOAE Results	Number of Ears	Percentage (%)
Pass	29	32.22
Refer	61	67.78

4.6 AUDITORY STEADY-STATE RESPONSE TEST RESULTS

From Table 4.4 the mean estimated hearing threshold at 500 Hz was 21.06 ± 8.04, 1000 Hz was 22.33 ± 8.67, 2000 Hz was 21.33 ± 8.65, and 4000 Hz was 20.67 ± 8.98. The mean 4-frequency pure tone average was 21.35 ± 8.19. Only ears (n=61) with abnormal tympanograms presented either slight or mild hearing loss, which is consistent with conductive hearing loss. From Table 4.5, 29 (32.22%) ears indicated normal hearing, 12 (13.33%) ears indicated slight hearing loss, and 49 (54.44%) ears showed mild hearing loss.

4.7 PREVALENCE OF HEARING LOSS AMONG CHILDREN WITH CLEFT PALATE

Equation 4.1 was used to compute the prevalence of hearing loss among children with CP for all 90 ears tested.

$$\textbf{Prevalence} = \frac{x}{y} \times 100\% \qquad (4.1)$$

Where x = the number of ears with hearing loss, and y is the total number of ears tested.

Prevalence of hearing loss = 61/90 × 100 = 67.78%

Table 4.4: Estimated hearing thresholds of participants tested with ASSR

Subjects	Ear	Tymp. Type	ASSR Thresholds (dB HL)				4-FPTA
			500Hz	1000 Hz	2000 Hz	4000 Hz	
1	Right	B	30	25	30	25	27.5
	Left	As	20	20	25	25	22.5
2	Right	B	25	30	30	25	27.5
	Left	B	30	30	25	30	28.75
3	Right	B	30	30	25	25	27.5
	Left	As	20	20	25	25	22.5
4	Right	B	30	25	30	25	27.5
	Left	B	25	30	30	25	27.5
5	Right	B	30	25	30	30	28.75
	Left	B	30	30	25	25	27.5
6	Right	B	25	30	30	30	28.75
	Left	B	25	30	30	30	28.75
7	Right	B	30	35	30	25	30
	Left	A	15	10	10	5	10
8	Right	B	30	30	25	25	27.5
	Left	As	15	20	20	20	18.75
9	Right	B	25	30	30	30	28.75
	Left	B	20	30	30	30	27.5
10	Right	B	25	30	25	30	27.5
	Left	B	30	30	25	25	27.5
11	Right	A	10	10	5	5	7.5

	Left	A	10	15	5	10	10
12	Right	B	20	30	30	25	26.25
	Left	B	25	30	30	25	27.5
13	Right	B	30	25	30	30	28.75
	Left	B	30	30	25	25	27.5
14	Right	As	20	25	20	20	21.25
	Left	As	20	20	25	25	22.5
15	Right	B	30	30	25	25	27.5
	Left	B	30	30	25	30	28.75
16	Right	A	10	10	10	5	8.75
	Left	B	25	30	30	30	28.75
17	Right	A	10	10	5	5	7.5
	Left	A	15	5	5	10	8.75
18	Right	A	10	15	15	10	12.5
	Left	A	15	10	10	10	11.25
19	Right	As	20	25	25	20	22.5
	Left	As	20	25	25	20	22.5
20	Right	B	30	30	20	25	26.25
	Left	B	30	30	30	25	28.75
21	Right	B	25	30	30	25	27.5
	Left	B	25	30	30	25	27.5
22	Right	A	10	10	5	5	7.5
	Left	A	10	5	5	10	7.5

23	Right	A	15	10	10	5	10
	Left	A	10	15	15	10	12.5
24	Right	A	10	10	10	5	8.75
	Left	A	15	10	10	5	10
25	Right	A	10	10	5	5	7.5
	Left	A	5	10	10	5	7.5
26	Right	B	30	30	20	30	27.5
	Left	B	25	30	30	30	28.75
27	Right	B	20	30	30	30	27.5
	Left	B	30	25	30	30	28.75
28	Right	B	30	30	25	30	28.75
	Left	B	30	30	25	25	27.5
29	Right	As	20	25	20	20	21.25
	Left	As	20	25	20	20	21.25
30	Right	A	15	10	10	10	11.25
	Left	A	10	10	15	15	12.5
31	Right	A	10	15	10	10	11.25
	Left	A	10	15	10	10	11.25
32	Right	A	10	10	15	15	12.5
	Left	A	15	10	10	5	10
33	Right	B	25	30	30	30	28.75
	Left	B	25	30	30	30	28.75
34	Right	B	30	25	30	30	28.75

	Left	B	30	30	25	30	28.75
35	Right	As	20	25	15	15	18.75
	Left	A	10	10	15	5	10
36	Right	B	25	30	30	30	28.75
	Left	B	25	30	30	25	27.5
37	Right	B	25	20	30	30	26.25
	Left	B	25	30	30	25	27.5
38	Right	A	5	5	10	10	7.5
	Left	A	10	15	10	15	12.5
39	Right	B	30	30	25	25	27.5
	Left	B	30	25	30	30	28.75
40	Right	B	30	30	25	25	27.5
	Left	As	20	25	25	20	22.5
41	Right	A	10	10	15	15	12.5
	Left	A	10	15	15	10	12.5
42	Right	A	10	10	15	15	12.5
	Left	A	10	10	5	10	8.75
43	Right	B	30	30	25	25	27.5
	Left	B	30	30	25	30	28.75
44	Right	B	25	30	30	30	28.75
	Left	B	30	30	25	30	28.75
45	Right	B	30	25	30	30	28.75
	Left	As	15	20	20	20	18.75

Maximum	30	35	30	30	30
Minimum	5	5	5	5	7.5
Mean±SD	21.06±8.04	22.33±8.67	21.33±8.65	20.67±8.98	21.35±8.19

4-FPTA=4-Frequency Pure Tone Average dB HL=decibel hearing level Tymp=Tympanogram

Table 4.5: Degrees of hearing loss

Degrees	**Number of ears**	**Percentage (%)**
Normal (¯10 – 15 dB HL)	29	32.22
Slight (16 – 25 dB HL)	12	13.33
Mild (26 – 40 dB HL)	49	54.44

CHAPTER FIVE

DISCUSSION

5.1 INTRODUCTION

Children with cleft palate (CP) are prone to middle ear disorders and associated hearing loss. This study investigated the middle ear and hearing status of 45 children with CP between the ages of 0 and 5 years receiving treatment at the Panel Clinic, Korle Bu Teaching Hospital-Ghana.

5.2 HYPOTHESIS 1

H_1: There is a high prevalence of hearing loss among children with CP.

In this study prevalence of hearing loss among children with CP was 67.78% (61 ears). This is consistent with Thanawirattabanit et al. (2012) who reported a prevalence rate of 79.5% among children with cleft lip and palate (CLP). Also, a study of hearing threshold by Flynn et al. (2009) showed that 83% of patients with CLP presented conductive hearing loss. It should be noted that this study included only those children who had cleft palate, and not those who had cleft lip and cleft palate.

The existence of discharge in the middle ear or eardrum perforation results in sound transmission difficulties (do Amaral et al., 2010). Recurrent otitis media causes perforation or immobility of tympanic membrane and ossicular chain fixation resulting in fluctuation in sound detection and such situation causes lack of auditory stimulation consistency, difficulties in binaural integration and distortions in the perceived message, this impairs hearing, speech and language development. Hearing loss even when mild among children can have an adverse effect on language development, literacy, self-esteem and social skills (Northern & Downs, 2001). When untreated, hearing loss

can result in academic underachievement, and can lead to reduced employment opportunities later in life (Olusanya, 2014). Communication problems among children can have emotional and psychological consequences and may result in feelings of isolation, loneliness and depression (Fellinger et al., 2012). Parents can also be affected by the hearing loss of their children since they lose more workdays, more expenditure, and generally more stress.

5.3 HYPOTHESIS 2

H_2: The degree of hearing loss associated with children with CP will be mild to moderate.

From Table 4.5, 13.33% (12 ears) presented slight hearing loss and 54.44% (49 ears) presented mild hearing loss. The mean 4-frequency pure tone average of the speech frequencies was 21.35 ± 8.19 indicating a mild hearing loss. Most types of clefts lead to moderate to severe conductive hear loss and children with nonsyndromic CLP is mainly moderate hearing loss (Goh et al., 2019). TEOAE was absent in the 61 ears with abnormal tympanograms (types AS and B), and their hearing thresholds in the ASSR tested ranged between slight to mild hearing loss. In this study, the degree of hearing loss ranged from slight to mild, with majority presenting mild hearing loss. It is consistent with a study by Ghana College of Physicians and Surgeons (2020) at the Korle Bu Teaching Hospital where 76 out of 97 participants with cleft palate had mild hearing loss.

5.4 HYPOTHESIS 3

H_3: The type of hearing loss associated with CP will be conductive.

Conductive hearing loss among children with CLP caused by middle ear problems, particularly OME is common and well documented (Karanth & Whittemore, 2018; Edentalen & Saheeb, 2019; Werker *et al*., 2018; Goh *et al*., 2019; Paepe *et al*., 2019; Werker *et al*., 2019). Goh et al. (2019) recorded 33% conductive hearing loss among children with CP, Balatsouras et al. (2012) recorded

67%, and Flynn et al. (2009) recorded 65%. In the current study, 67.78% (61 ears) presented conductive hearing loss. TEOAEs are transmitted from the cochlea through the ossicles and tympanic membrane and measured in the external ear canal. Therefore, any middle-ear or outer-ear disorder can practically interfere with transiently evoked otoacoustic emission transmission (Balatsouras et al., 2012).

The association of cleft palate, middle ear disease, and hearing loss was first reported more than a century ago (Tunçbilek, Özgür, & Belgin, 2003). It has been assumed that otitis media in the patient with cleft palate is almost worldwide, the incidence of permanent hearing loss reported as 0% to 90%, the average being 50% (Lau et al., 1988; Paradise, 1980; Yabe et al., 1989).

Malfunction of the eustachian tube may lead to middle ear effusion, recurrent otitis media affecting the auditory function. The eustachian tube has three physiological functions as it relates to the middle ear cavity: ventilation, protection from nasopharyngeal secretions, and drainage of secretions from the middle ear cavity itself (Bluestone and Doyle, 1988). The main function of the tensor veli palatini is to open the auditory tube rather than to tense the velum (Finkelstein et al., 1990). The tensor veli palatini and tensor tympani muscles are derived from the first branchial arch and share a common innervation. A tendinous link between these muscles and their anatomical relationship suggests their acting together in auditory tube clearance. It has been speculated that the tensor tympani muscle might trigger clearance by increasing middle ear pressure by drawing the tympanic membrane inward (Bluestone and Doyle, 1988). In addition to a dysfunction of the tensor veli palatini muscle in patients with cleft palate, a more collapsible eustachian tube, alterations in skull base, pharyngeal anatomy, and a blocked eustachian tube orifice at the nasopharyngeal end can result to malfunction of the eustachian tube (Carrie et al., 2000).

CHAPTER SIX

CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

6.1 INTRODUCTION

This study investigated the hearing status of children with CP receiving treatment at the Panel Clinic, Korle Bu Teaching Hospital. Conclusions, recommendations, and limitations are discussed in this chapter.

6.2 CONCLUSIONS

The prevalence rate of hearing loss among children with CP was higher than normal. The degrees of hearing loss recorded were between slight and mild. The type of hearing loss presented was conductive. The increased rate of abnormal middle ear status experienced among children with CP lead to slight to mild hearing loss at the speech frequencies, which may impact on speech and language development. Audiologic and tympanometric assessment are essential to evaluate the consequences of middle ear disorders especially otitis media with effusion on the hearing status of children with CP.

6.3 RECOMMENDATIONS

In line with the findings of this study, the following recommendations were made:

- Audiologic and tympanometric assessment should be an integral part of the routine test conducted for children with CP.
- Audiologic rehabilitation and treatment of OME is recommended for children with CP presenting hearing loss.

- Hearing assessment and middle ear analysis after the closure of the cleft is highly recommended.
- Further research with the other types of clefts and a larger number of participants should be conducted.

6.4 LIMITATIONS

The sample size is not a true representation of the population of CP receiving treatment at the Panel Clinic, Korle Bu Teaching Hospital.

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APPENDIX A

ETHICAL CLEARANCE

UNIVERSITY OF GHANA

SCHOOL OF BIOMEDICAL AND ALLIED HEALTH SCIENCES

May 16, 2020

Ms. Sumaila, Abiba
Department of Audiology
SBAHS, Korle – Bu

Dear Ms. Sumaila,

ETHICS CLEARANCE

Ethics Identification Number: SBAHS/AA/AUD/10702293/2019-2020

Following a meeting of the Ethics and Protocol Review Committee of the School of Biomedical and Allied Health Sciences held on April 9, 2020, I write on behalf of the Committee to approve your research proposal entitled:

"Prevalence of hearing loss among children with cleft palate: A Case Study".

This approval requires that you submit three-monthly review reports of the protocol to the Committee and a final full review to the Committee on completion of the research. The Committee may observe the procedures and records of the research during and after implementation.

Please note that any significant modification of the research must be submitted to the Committee for review and approval before its implementation.

You are required to report all serious adverse events related to this research to the Committee within seven (7) days verbally and fourteen (14) days in writing.

As part of the review process, it is the Committee's duty to review the ethical aspects of any manuscript that may be produced from this research. You will, therefore, be required to furnish the Committee with any manuscript for publication.

This clearance is valid for three years, with effect from the date issued.

Please always quote the ethical identification number in all future correspondence in relation to this protocol.

Thank you.

Yours sincerely,

Jonathan Quartey (PhD)
Chairman, Ethics and Protocol Review Committee
CC: Dean, SBAHS
Head, Dept. of Audiology, SBAHS
School Administrator, SBAHS

COLLEGE OF HEALTH SCIENCES

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APPENDIX B

PARTICIPANT INFORMATION FORM

UNIVERSITY OF GHANA

DEPARTMENT OF AUDIOLOGY SPEECH AND LANGUAGE

SCHOOL OF BIOMEDICAL AND ALLIED HEALTH

COLLEGE OF HEALTH SCIENCE

TITLE OF RESEARCH: Prevalence of hearing loss among children with cleft palate: The case of children with cleft palate at Korle Bu Teaching Hospital

PRINCIPAL RESEARCHER: ABIBA SUMAILA

Department of Audiology Speech and Language Therapy University of Ghana

Professional: MSc Audiology

Mobile: 0243226397 Email: **abibasumaila39@gmail.com** or **asumaila009@st.ug.edu.gh**

General Information about Research: Under the supervision of Dr. Neal Boafo and Nana Akua Owusu Victoria, University of Ghana, School of Biomedical and Allied Health science, I Abiba Sumaila, a post Graduate student of Department of Audiology Speech and Language Therapy, I'm conducting research on the prevalence of hearing loss among children with cleft palate. The purpose of the study was aimed at determining the prevalence of hearing loss among children with CP in Ghana.

Possible Risk and Discomfort

There are no risks of participation in this study since the testing equipment and procedure is noninvasive and do not give any side effect. Voluntary Participation and right to leave the research.

Participation in this research is voluntary .participant have the right to withdraw from the research at any time and refuse to participate entirely without jeopardy.

Contact for additional information

For any information or questions about the study contact the principal investigator Abiba Sumaila, 0243226397.

Confidentiality

All information provided will remain confidential, and will only be reported as a group data with no identifying information. All data including test result will be kept in safe location and only those directly involved in the research will have access to them.

Possible Benefits

Participants get free hearing test, knowing their hearing status, and any possible of hearing problem.

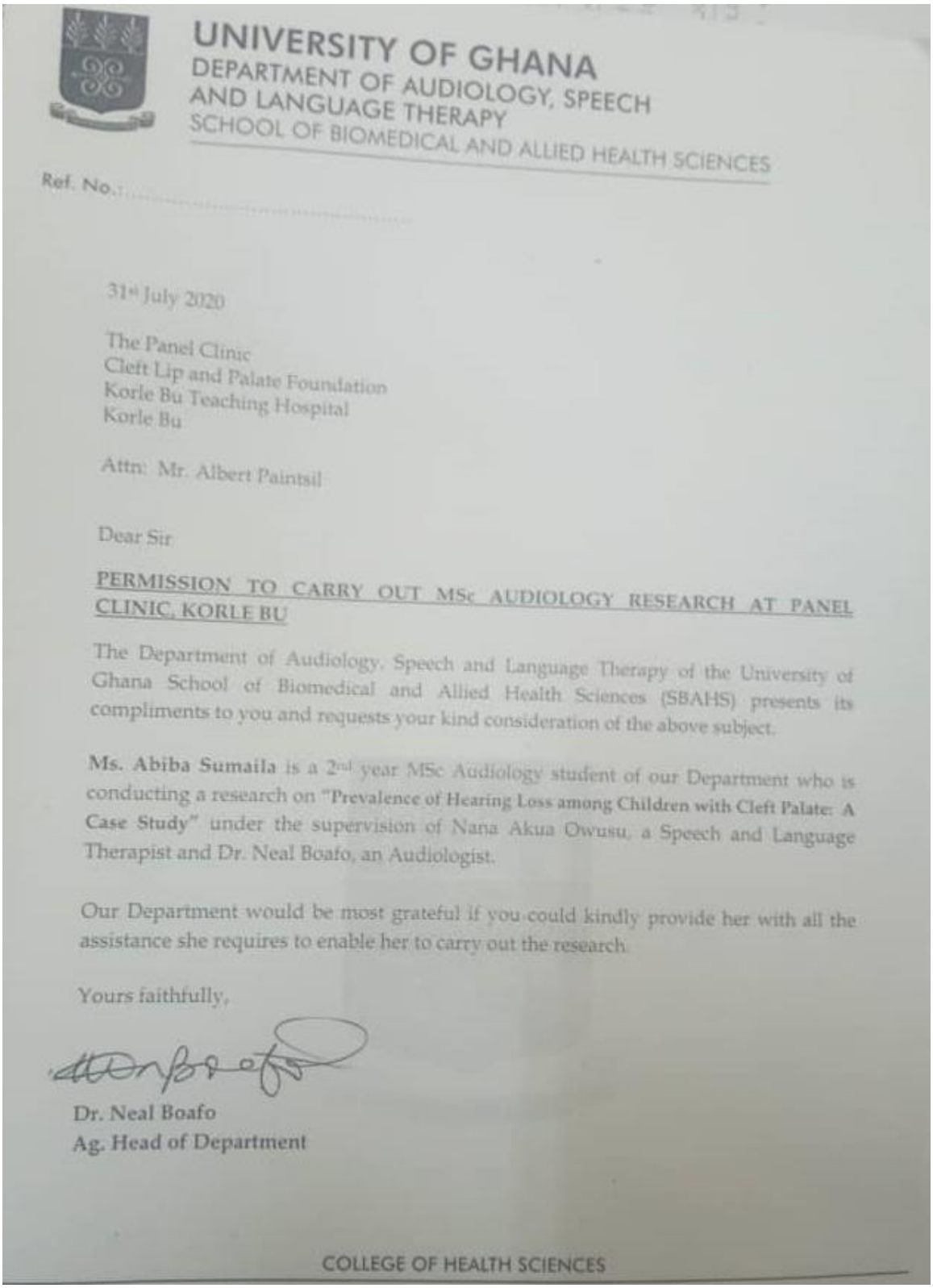
Alternatives to Participation

If the event of noticed problem participant will be referred for further testing and the necessary management needed.

Your right as a participant

This research has been reviewed and approved by Ethics and Protocol Review committee (EPRC) of the school of Biomedical and Allied Health Science, College of Health science University of Ghana. If you have any question about your right as a participant you can contact EPRC office

between the hours of 8am-5:00pm through the landline +223 030 687974/5 or postal address KB 143, Korle BU Ghana.



UNIVERSITY OF GHANA
DEPARTMENT OF AUDIOLOGY, SPEECH AND LANGUAGE THERAPY
SCHOOL OF BIOMEDICAL AND ALLIED HEALTH SCIENCES

Ref. No.:

31st July 2020

The Panel Clinic
Cleft Lip and Palate Foundation
Korle Bu Teaching Hospital
Korle Bu

Attn: Mr. Albert Paintsil

Dear Sir

PERMISSION TO CARRY OUT MSc AUDIOLOGY RESEARCH AT PANEL CLINIC, KORLE BU

The Department of Audiology, Speech and Language Therapy of the University of Ghana School of Biomedical and Allied Health Sciences (SBAHS) presents its compliments to you and requests your kind consideration of the above subject.

Ms. Abiba Sumaila is a 2nd year MSc Audiology student of our Department who is conducting a research on **"Prevalence of Hearing Loss among Children with Cleft Palate: A Case Study"** under the supervision of Nana Akua Owusu, a Speech and Language Therapist and Dr. Neal Boafo, an Audiologist.

Our Department would be most grateful if you could kindly provide her with all the assistance she requires to enable her to carry out the research.

Yours faithfully,

Dr. Neal Boafo
Ag. Head of Department

COLLEGE OF HEALTH SCIENCES