
**“ENDOSCOPIC ASSESSMENT OF TYMPANIC
MEMBRANE AND AUDIOLOGICAL
EVALUATION OF MIDDLE EAR FUNCTION
IN CHILDREN WITH CLEFT PALATE - A ONE
YEAR CROSS SECTIONAL STUDY”**

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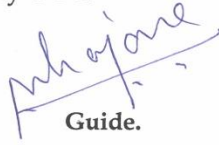
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LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
CLP	Cleft Lip Palate
OME	Otitis Media Effusion
VT	Ventilation tube
CP	Cleft Palate
CL	Cleft Lip
TM	Tympanic Membrane
TVP	Tensor Veli Palatini
LVP	Levator Veli Palatini
ET	Eustachian tube
TT	Tensor Tympani Muscle
SP	Salpingopharyngeal
LP	Lateral Pterygoid
MP	Medial Pterygoid

ABSTRACT

Title:

ENDOSCOPIC ASSESSMENT OF TYMPANIC MEMBRANE AND AUDIOLOGICAL EVALUATION OF MIDDLE EAR FUNCTION IN CHILDREN WITH CLEFT PALATE

Objectives:

1. To assess the functional status of middle ear in children with cleft palate.
2. To assess the grade of retraction of tympanic membrane in children with cleft palate using Sade and Tos classification.

Methods:

- A one-year study was undertaken and Children with cleft palate are clinically assessed, followed by grading of tympanic membrane retraction by otoendoscopy, using Sade and Tos classification.
- Evaluation of middle ear function done by Pure Tone Audiometry and Tympanometry.
- The results are gathered and assessed for grade of tympanic membrane retraction, middle ear pressure and degree of hearing loss.

Results:

Type B was most commonly observed findings of tympanometry in our study. Mean right ear audiometry was 26.79 ± 9.13 . Mean left ear audiometry was 29.73 ± 9.20 .

Distribution according to Sade grading in right ear (Pars Tensa) revealed as follows: Sade 0-41.9%, Sade I-23.3%, Sade II-25.6%, Sade III-7.0% and Sade IV-2.3%.

Distribution according to Sade grading in left ear (Pars Tensa) revealed as follows: Sade 0-32.6%, Sade I-18.6%, Sade II-39.5%, Sade III-9.3% and Sade IV-0%.

Distribution according to Tos grading in right ear (Pars Flaccida) revealed as follows: Tos 0- 88.4%, Tos I-9.3%, Tos II-2.3% and Tos III-0.0%. Distribution according to Tos grading in left ear (Pars Flaccida) revealed as follows: Tos 0- 90.7%, Tos I-7%, Tos II-0% and Tos III-2.3%.

We observed no statistically significant association between cleft type and right as well as left tympanometry type ($p>0.05$).

We found statistically no significant difference in the number cases with different grades of right ear Sade as well as left ear (Pars Tensa) in our study ($p>0.05$).

Conclusion:

This study demonstrates that children with cleft palate are more prone to middle ear diseases in the form of Acute otitis media and Chronic suppurative otitis media compared to normal children without cleft lip palate. Regular otoendoscopic audiological monitoring and early intervention at crucial time is required to prevent long-term auditory deficits in children with cleft palate. A regular evaluation is a must for proper development of speech and academic progression of the child. Our study also emphasizes on the importance of multidisciplinary care, involving otolaryngologists, audiologists, and speech therapists, to optimize hearing outcomes and quality of life of child. Further studies with a larger sample size and longitudinal follow-up is recommended to better understand the progression of middle ear pathology in children with cleft palate.

Keywords: Cleft lip Palate, Otoendoscopy , Tympanometry, Audiometry

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INTRODUCTION

Cleft lip/palate (CLP) is among the most frequent congenital disorders worldwide and is more prevalent among Asians and Native Americans.¹ “Various factors, such as alcohol consumption, smoking, steroids, viral infection, anticonvulsants, and retinoids, can cause CLP.”^{2,3} “Otitis media with effusion (OME) is a common condition among CLP patients that may affect speech, language, and learning development.”⁴ “Abnormal development of the Eustachian tube, abnormal formation of the tensor veli palatini muscle or levator veli palatini muscle, and craniofacial bone abnormalities can cause the development of recurrent or continuous OME in CLP patients. Previous studies have shown that 80% of CLP patients do not have OME at birth, but 90% of infants suffer from OME before their first year, and 97% experience OME within the first two years of their life.”^{5,6,7}

“Recurrent or chronic OME can cause atelectasis, ossicular fixation, tympanosclerosis. These pathologic changes cause conductive and sensorineural hearing loss at critical ages of development which may affect speech and language skills.”⁸ “Different factors, such as age at palatoplasty, the frequency of ventilation tube (VT) insertion, the type of cleft, surgical technique, and ethnicity, were key prognostic factors influencing hearing outcomes in CLP patients”.^{9,10}

“Hearing loss is a well-known complication of cleft palate but the magnitude of this problem is not generally appreciated. A lot of attention has been paid to the development of a competent velopharyngeal port and normal facial development in these children. Unfortunately, this concern with the production of normal speech and the prevention of facial deformity has diverted attention from a common but unfortunately ignored complication of hearing loss. Middle ear disease is common in

childhood. Seventy-one percent of all children have at least one episode of otitis media by the age of three years”.¹¹ “In contrast children with cleft palate have been reported to have higher rate of recurrent acute otitis media or otitis media with effusion.”¹² Dhillon describes, “a 97% incidence of otitis media with effusion in children with cleft palate, less than 24 months of age.”¹³

“India is one of the most populous countries and has a significant prevalence of CLP. The prevalence of CLP in India is monitored by the Indian Birth Defects Registry. Out 1.34 billion Indians, 423,519 suffer from CLP. It was made by an estimated 226,882 males and 196,637 females suffer from CLP with slight male Predominance.”¹⁴

“Cleft lip and/or palate is the one of most common birth defects.”¹⁵ “The incidence varies between 1 and 1.82 among 1000 new-borns, varying with geographic and ethnic background.”¹⁵ “Cleft patients are generally divided into three main categories: those with a cleft palate [CP], a cleft lip [CL] and a cleft lip and palate [CLP], all of which can occur isolated or as part of a craniofacial syndrome.”¹⁶ “Due to the orofacial cleft, multiple problems can arise with feeding, dental development, speech development, appearance and psychological well-being, making cleft children a vulnerable population that requires specialised care.”¹⁷

“Children with a cleft palate are prone to developing middle ear problems, especially otitis media with effusion [OME].”¹⁸ “The most important factor in the pathogenesis of otitis media is the anatomical malformation of the paratubal muscles, which compromise the strength of the tensor veli palatini muscle, causing repetitive failure to open the Eustachian tube and ventilate the middle ear cavity”.¹⁹

“As a result, middle ear pressure declines and local secretions accumulate leading to OME.”^{20,21} “By the age of two, more than 95% of the cleft palate children will experience at least 1 episode of OME”.^{22,23} “Furthermore, the rate of spontaneous clearing of fluid is decreased, and middle ear problems tend to be more severe and persist longer. Where the incidence of OME rapidly declines after the age of six in the general population, cleft palate children show an impaired clearance that may prolong until the age of 12.”²⁴ “This increased incidence and duration of OME consequently enhances the risk of developing OME sequelae. The prolonged presence of fluid in the middle ear combined with negative pressure may damage the structure of the tympanic membrane causing local atrophy and retraction, a situation favourable for the development of cholesteatoma.”^{25,26}

“As many children with cleft palate have persistent OME, a large proportion receive ventilation tubes [VT], the primary goal is to restore hearing in this already at-risk population for speech and language development. However, also the placement of ventilation tubes increases the risk of developing a permanent perforation and possibly chronic otitis media, especially in children undergoing repeated VT insertions and when using long-term tubes.”^{26,27} “As a result, cleft palate patients are advised to have a regular ear examination. Once OME has been detected an active observation period of three months is recommended. If the fluid remains present after three months, ventilation tubes are placed. However, therapy of OME is debatable and depends on the individual context. If the OME causes significant hearing loss and the child already suffers from language and speech delay, earlier intervention may be recommended. Existing data support both an aggressive approach with early - even prophylactic-placement of ventilation tubes as well as a conservative in which the hearing loss is carefully assessed.”²⁸⁻³¹

Endoscopy provides a better visualization of the tympanic membrane and middle ear structures. Otoendoscopy gives a clear idea about progression of the disease by providing an objective assessment. Hence the present study was carried out with the objective to assess the functional status of middle ear in children with cleft palate and also to assess the grade of retraction of tympanic membrane in children with cleft palate using Sade and Tos classification.

OBJECTIVES

1. To assess the functional status of middle ear in children with cleft palate.
2. To assess the grade of retraction of tympanic membrane in children with cleft palate using Sade and Tos classification.

REVIEW OF LITERATURE

A study carried out by **James AL et al³² in 2012** to “assess inter- and intra-observer variability of different staging systems for tympanic membrane (TM) retraction using otoendoscopy in children at risk of retraction from cleft palate, to compare hearing level with stage of retraction, and to propose optimum characteristics for monitoring TM retraction with endoscopy. They included total of 108 ear drums (44%) were rated as having pars tensa and/or flaccida retraction. Intra observer agreement was fair to moderate ($P < 0.001$) for the different staging systems and interobserver agreement slight to moderate ($P < .001$). Conductive hearing loss (pure-tone average air-bone gap >25 dB HL) was present in 11 ears (15%). Study concluded that endoscopic image capture may provide a clear objective record of TM retraction.”³²

Kim E. et al³³ in 2016 conducted the study with the objective to “assess the effect of ventilation tube (VT) placement on long-term hearing outcomes in children with cleft palate. They included children with cleft palate diagnosis who underwent surgery at RCHSD between 1995 and 2002. An increased number of tubes was associated with a greater incidence of hearing loss at age 10, even after adjusting for total number of otologic complications. So, they concluded that while children with worse middle ear disease are more likely to receive more tubes and have long-term conductive hearing loss as a result of ear disease.”³³

A study conducted by **Yanti A. et al³⁴ in 2017** with the objective to “determine the tympanogram findings in Indonesian children aged six months to seven years with cleft palates including 30 patients (17 males and 13 females) with Veau classification of palatal clefts aged six months to seven years (median 26.5

months) who underwent tympanometry. Examinations of 58 ears found that type B tympanograms occurred most frequently (70.7%). The authors found a significant relationship between age and type of tympanogram ($p = 0.0039$) with the risk of type B and C tympanograms in infants (6-60 months) as high as 4.8 times that of children without cleft palates. The type B tympanogram was most frequently seen in patients with cleft palates aged six months to seven years old with the quantitative values of tympanometry lower than the normal values. Therefore, there was a significant difference in the type of tympanogram seen with age.”³⁴

A study by **Parkes W. et al**³⁵ in 2018 to “obtain prognostic information for guiding surveillance and treatment, a cohort of children with retraction from cleft palate were prospectively followed for over 5 years. They included 37 ears that were assessed with oto-endoscopic images and audiometry at a median age of 9 years and reassessed at a median follow-up interval of 6.4 years. Initially, 19/37 retractions (51%) demonstrated contact with the incus and/or promontory. Follow-up images were rated as stable ($n=16$) or better ($n=12$) for 28/37 retractions (76%). Of the nine retractions that became more extensive, two developed cholesteatoma (5% of the total). No ossicular erosion developed in ears without cholesteatoma. Conductive hearing loss was initially present in five ears, worsened in one, and normalized without intervention in others. Clinically significant progression occurred infrequently, justifying the conservative approach taken to manage these retractions. Such data are necessary to weigh the potential benefit of preventive intervention over observation.”³⁵

Kalaiarasi R et al³⁶ in 2012 did a study with the objective to “describe the middle ear findings and audiological profile in children with orofacial clefts by including 96 children with orofacial clefts were identified. Among 96 children with orofacial clefts,

only 24 children (25%) had symptomatic ear problems, whereas on ear examination, 56 children (58.3%) had abnormal ear findings. Middle ear effusion (MEE) was the most common ear condition, and it was seen in 94 ears (48.9%). Cholesteatoma was noted in six children (3.1%). Out of 73 children in the zero to five age group, 58 children (79.5%) did not have any history of ear problem but 55.5% (81 ears) had features of MEE such as a dull tympanic membrane (TM). In the age group of more than five years to 10 years, only four children (28.5%) were symptomatic. Five children (55.5%) out of nine in the age group of more than 10 years had a symptomatic ear problem of which four children (44.4%) had chronic otitis media squamosal disease. The mean air conduction threshold in the age group zero to five years, more than five years to 10 years, and more than 10 years were 33 ± 8.3 decibels (dB), 25 ± 6.2 dB, and 31.5 ± 14 dB, respectively. Out of 144 ears (72 children) in the asymptomatic group, 67 ears (46.5%) had normal hearing. Seventy-seven ears (53.5%) had some degree of hearing loss. Mean air conduction hearing loss in the asymptomatic group was 29.8 ± 7.3 dB. This study highlighted the higher incidence of middle ear diseases compared to the presenting symptoms in children with orofacial clefts.”³⁶

A study by **Dochy F. et al**³⁷ in 2019 to “determine the prevalence of middle ear problems in different age categories of children with cleft palate and to determine factors that may influence the middle ear status by including total 166 children, aged up to 18 years old, were enrolled; 58 had a cleft palate, 108 a cleft lip and palate. After the age of 6 years old, the prevalence of otitis media with effusion and or need for ventilation tubes progressively decreased, but is still present in 13.3% of the 9-18-year-olds. They observed that 22.2% had developed myringosclerosis, an atrophic/retracted/atelectatic tympanic membrane, 5.4% developed tympanic

membrane perforation and 3,6% developed cholesteatoma. A significant number of cleft children develop middle ear sequelae or complications at a later age.”³⁷

Bayoumy AB et al³⁸ in 2020 conducted the study with the objective to “investigate the natural course of retraction pockets in the posterosuperior quadrant of the pars tensa in a large cohort of patients by involving 71 patients with 81 ears and a median age of 23 years were included. The median duration of follow-up was 64 months. The mean air bone gap at first and last visits was 17.9dB (SD 11.3) and 15.5dB (SD 12.9), respectively, with a mean improvement of 2.4dB. In 10 ears (12%) the hearing level (air-bone gap) deteriorated with 10dB or more. Patients who presented with a TMR Sade grade I at first visit had significantly better audiometric outcomes than patients presenting with Sade grade III. Progression to cholesteatoma occurred in one patient (1%), progression to perforation occurred in five patients (6%), and progression to ossicular chain damage occurred in five patients (6%). So, they concluded that otoscopic findings and audiometric results remained stable in most TMRs without treatment. Additionally, audiometry did not worsen during last follow-up.”³⁸

A study by **Mirashrafi F et al³⁹ in 2022** to “evaluate the otologic outcomes in children at least five years post-repair. Based on patients’ charts, their age, gender, cleft type, date of palatoplasty, as well as the date and the frequency of ventilation tube (VT) insertion, were recorded. There was no significant difference in middle ear status between children with complete and incomplete cleft palates. The mean age at the time of study and the mean follow-up duration were significantly higher in the normal middle ear group, compared to the abnormal middle ear group (7.7 ± 1.6 vs. 6.8 ± 0.9 , $P=0.03$ and 6 ± 1.15 vs. 5.42 ± 0.9 , $P=0.04$, respectively). Middle ear status was not significantly different between early or late palatoplasty patients. So, they concluded that middle ear status improved as patients grew older; however, the age of

palatoplasty and the frequency of VT insertion were not significant prognostic factors in patients who underwent intervelar veloplasty under magnification.”³⁹

Anatomy and physiology of Eustachian Tube

“The Eustachian tube is named after the Italian anatomist, Bartolomeo Eustachi, who observed that it is a canal that connected the nasopharynx to the middle ear. The Eustachian tube is also known as the pharyngotympanic tube or the auditory tube.”⁴⁰

Structure and Function

“The Eustachian tube plays a role in equalization, oxygenation, and drainage of the tympanic cavity. The major function of the Eustachian tube is equalization of pressure in the middle ear with respect to ambient pressure. In doing so, the Eustachian tube allows for regulation of the pressure across the tympanic membrane. It thus influences the tension in the middle ear, and indirectly affects the effectiveness of sound wave transmission. It is believed that the Eustachian tube also may be involved in sound transformation through reverberation phenomena. Patency of the tube allows for air exchange in the tympanic cavity to replenish oxygen to the middle ear, in addition to providing an outlet for mucus and other fluid from the middle ear.”

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“The Eustachian tube is normally closed, as its proximal walls are collapsed. These can be actively pulled apart to open the tube with the help of accessory muscles or passively pushed apart by air exiting or entering the middle ear under pressure. The active opening of the Eustachian tube to relieve positive or negative pressure in the middle ear commonly is called “clearing the ear.”⁴⁰

“The Eustachian tube is located in the para-pharyngeal space and is closely linked to the infratemporal fossa. The Eustachian tube continues from the anterior wall of the middle ear to the sidewall of the nasopharynx, progressing along the posterior edge of the medial pterygoid plate. It then proceeds forward, downward, and medially, to form a 45-degree angle to the sagittal plane, and about a 30-degree angle to the horizontal plane.”⁴⁰

“The discontinuous opening of the pharyngeal ostium in the nasopharynx causes peristaltic-like movements that may be due to the visco-elastic features of the tubular structure of the cartilage.”⁴⁰

Embryology

“The Eustachian tube partially originates from the first pharyngeal pouch and extends as tubotympanic recess. After contact with the outer ear canal, mesoderm between 2 canals forms the tympanic membrane; this expands to form the tympanic recess. The stalk of the recess forms the Eustachian tube. The skeletal elements have two parts, the bony lateral portion that arises from the anterior wall of the middle ear cleft and the cartilage portion that covers the dorsal region along the length of the tube.”⁴¹

Blood Supply and Lymphatics

“Blood is supplied to the Eustachian tube by several arteries of the external carotid, including the ascending pharyngeal branch and two branches of the maxillary artery, the middle meningeal artery, and the artery of the pterygoid canal. Venous returns drain into the pterygoid venous plexus, and lymphatics drain into the retropharyngeal lymph nodes.”⁴¹

Nerves

“Motor innervation to the muscle attachments of the Eustachian tube is provided by the pharyngeal plexus of the vagus nerve (cranial nerve X) and the mandibular branch of the trigeminal nerve (cranial nerve V). Specifically, the levator veli palatini and salpingopharyngeus muscles are innervated by cranial nerve X, and the tensor tympani and tensor veli palatini muscles are supplied by the mandibular branch of cranial nerve V. Sensory innervation to the Eustachian tube bony part is by Vagus and glossopharyngeal nerve and the cartilaginous part is by maxillary and mandibular branches of trigeminal nerve.”⁴¹

Muscles

“There are 6 muscles recognized to having an active role in the functions of the Eustachian tube: tensor tympani, salpingopharyngeus; tensor veli palatini; levator veli palatini; lateral and medial pterygoids. The tensor muscle of the soft palate (TVP) not only functions to open up the lumen of the Eustachian tube, but it also contributes to mastication as it is actively involved in the process of phonation, swallowing, chewing. During these motions, the ET is oriented inwards.”⁴¹

“The TVP is a slender, triangular muscle made of an external and medial portion, the external originates from the navicular fossa, the lateral aspect of the sphenoid bone/sulcus, and the tensor tympani muscle.”⁴¹

“The medial segment is derived from the middle third of the posteromedial wall of the tube that is mostly cartilage; the two segments then migrate inferiorly and converge on the pterygoid hamulus forming a strong tendon that curves around the hamulus and anchors directly into the soft palate as the palatine aponeurosis. The TVP

operates in combination with the tensor tympani muscle (TT), and they both share similar nerve innervation. Its lateral surface directly contacts the surface of the anterior superior medial pterygoid muscle. Its strength declines with age and there is a reduction in its range of motion.”⁴¹

“The elevator of the soft palate (LVP) is cylindrical and traverses the space just underneath the ET, entering into the cartilaginous portion. Here it forms a sling with fixed insertion points between the midline of the soft palate and the petrous apex of the temporal bone; it sits posteriorly and medially to TVP. Its actions on the tube are opening and closing of the tube. The vagus nerve innervates it.”⁴¹

“The tensor tympani (TT) is a thin muscle positioned outside the middle ear and along the tube. It is anchored to the sphenoid bone and the bony segment of the ET. Distally, the tendon anchors onto the malleolus. Its contraction assists and occurs in conjunction with the TVP, while at the same time, placing tension on the malleolus to muffle the vibrations in the eardrum during mastication and swallowing.”

41

“The TT and TVP are connected via a fascial link that receives innervation by the mandibular branch of the fifth cranial nerve (trigeminal). The salpingopharyngeal (SP) is one of the straight internal pharyngeal muscles that contribute to the process of swallowing mechanism; it receives innervation from a branch of the 10th cranial nerve (vagus). When the SP and the other 2 internal longitudinal muscles (stylopharyngeus and palatopharyngeus) contract, this results in shortening of the pharynx and laryngeal elevation. The SP is thinly spread over the cartilage segment of the ET. The muscle is small and thin so that it can easily cross the pharynx and at the

same time have an anatomical relationship with the palatine tonsil. It only plays a minor role in the opening of the ET.”⁴¹

“The lateral (external) pterygoid muscle (LP) and the medial (internal) pterygoid muscle (MP) are a group of muscles involved in mastication and function of the middle ear. The LP is created by the 2 muscle heads (bellies), lower and upper.”⁴¹

The literature states that, “there is also a contribution from 2 other muscles; the pterygospinous and the pterygoideus proprius. The upper belly starts in the infratemporal surface and the crest of the greater wing of the sphenoid bone, while the inferior belly evolves from the lateral surface of the lateral pterygoid plane; both muscle segments have a horizontal orientation posterolaterally. The muscle bellies are anchored in the pterygoid fovea muscle just underneath the condylar process of the mandible. However, the superior belly of the LP does anchor to the articular disc of the temporomandibular joint and plays a role in jaw movements.”⁴¹

“The MP is found below the LP. The PM is thinner and quadrangular in shape; it traverses the inferior segment of the infratemporal fossa. The PM has 2 muscle bellies, one shallow and one deep. The deep belly starts laterally to the maxillary tuberosity and the palatine pyramidal process, crossing just underneath the inferior belly of the LP, while the shallow belly is wider and arises from the medial surface of the lateral pterygoid plate and the pterygoid fossa. This muscle courses much deeper to the inferior segment of the LP.”⁴¹

“Both segments of the MP travel laterally and inferiorly to anchor to the rear and inferior medial surface of the angle of the mandible. The mandibular branch of the trigeminal nerve innervates the PM. An additional function of these dual masticatory muscles is to enable peristaltic movement of the tube, in cooperative

interaction with the LVPM and TVP, during the process of swallowing, mimicking the same active motions of the LP, even when there is no swallowing, allowing the tube to open. Their intervention changes the shape of the tube, which becomes more convex, allowing the muscles that act directly on the tube to provide a greater force. The MP is also useful, in particular, because it may act as a fulcrum so that the musculature of the tube acts as a more efficient vector.”⁴¹

Physiologic Variants

“Anatomic and physiologic variations within the Eustachian tube may be causative factors in cases of Eustachian tube dysfunction. Manifestations include difficulty in opening the tube and problems with patency. These variations include narrower tube diameter; flaccidity of the cartilaginous portion of the tube or surrounding tissues; and mucosal hypertrophy of the tube lining, which leads to excess mucus production and clogging.”⁴¹

Surgical Considerations

“The structure of the Eustachian tube is made up of 2 anatomically distinct parts covered by the mucous membrane: a bony component and a cartilaginous component. The bony component courses through the petrous part of the temporal bone and represents one-third (12 millimeters) of the tube's length. The Eustachian tube follows a straight course and slopes down posteroanteriorly and lateromedially at an angle of approximately 35 degrees in adults. The tube begins with an aperture on the anterior, or carotid, wall of the middle ear at the junction of the petrous and squamous constituents of the temporal bone and opens into the tympanic cavity, the walls of which are continuous with the middle ear. Its other end opens into the lateral wall of the nasopharynx, roughly at the level of the inferior turbinate. The Eustachian

tube has a diameter of approximately 3 millimeters and is widest at its two ends and narrowest at its isthmus, which typically is found in the cartilaginous portion. It normally is closed due to pressure from adjacent Ostmann fat pads. The Eustachian tube is lined with ciliated epithelium, which sweeps mucus away from the middle ear in the direction of the nasopharynx.”⁴¹

Clinical Significance

In children, “the Eustachian tube’s course is more horizontal than in adults (10 degrees concerning the horizontal versus 35 degrees in adults). This is believed to be a contributing factor in the development of acute otitis media in children due to impaired middle ear drainage and even reflux of nasopharyngeal contents into the middle ear through the Eustachian tube. Mucus cannot drain as readily with the smaller slope.”⁴¹

“As a pathway connecting the middle ear to the pharynx, the Eustachian tube serves a dual purpose as an entrance and an exit to the middle ear. Gas is not the only substance that can be exchanged via this channel. Pharyngeal contents, most notably phlegm from the nasal passages and nasopharyngeal secretions, constitute liquid media that may be drawn or pushed inside the middle ear through the Eustachian tube and constitute a source of infectious organisms. Conversely, the Eustachian tube is also the principal outlet for middle ear effusions. In cases of obstruction, pressure may build up within the middle ear, leading to rupture of the tympanic membrane. This may occur in barotrauma or perforated otitis media.”⁴¹

“Prostheses exist to facilitate Eustachian tube patency. Usually, these only are useful in the short term, as mucus rapidly plugs them.”⁴¹

“Eustachian tube dysfunction is not limited to obstruction. It also can involve intermittent opening or patulousness of the tube. In this case, patients may complain of autophony, which is characterized by hearing their chewing and speaking unusually loudly.”⁴¹

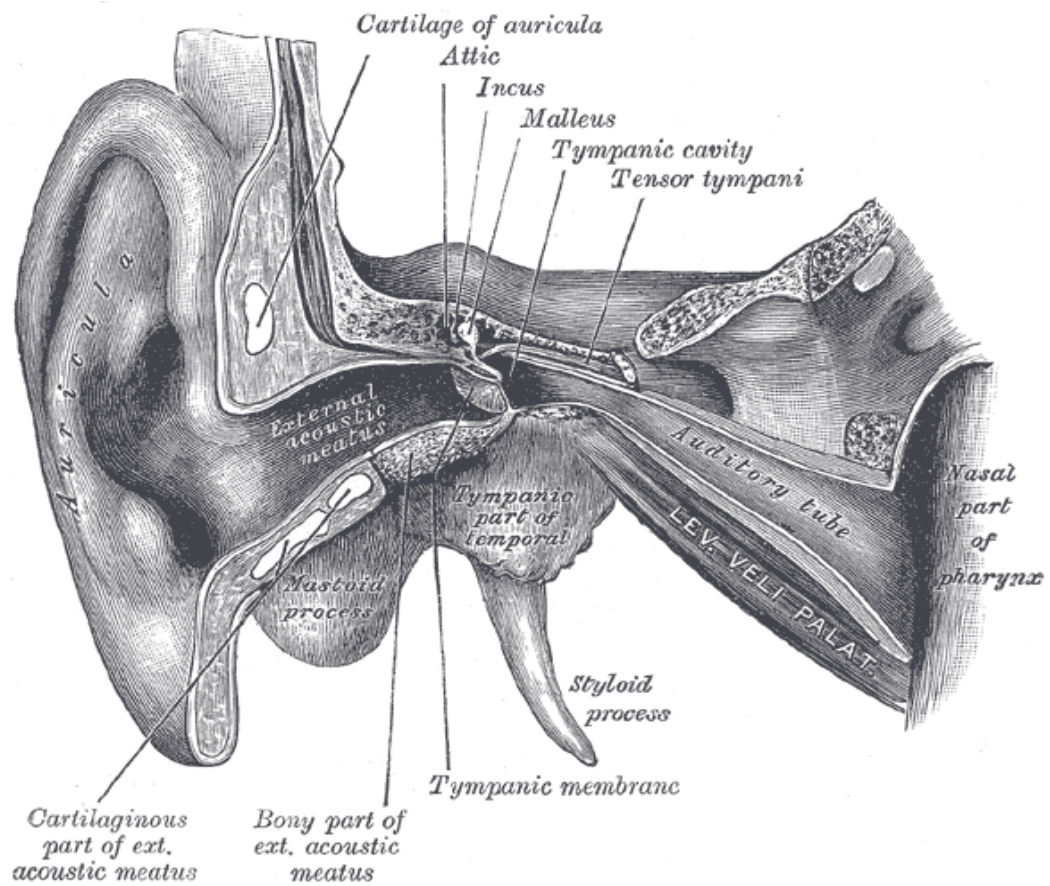


Figure 1: “Anatomy of eustachian tube”⁴¹

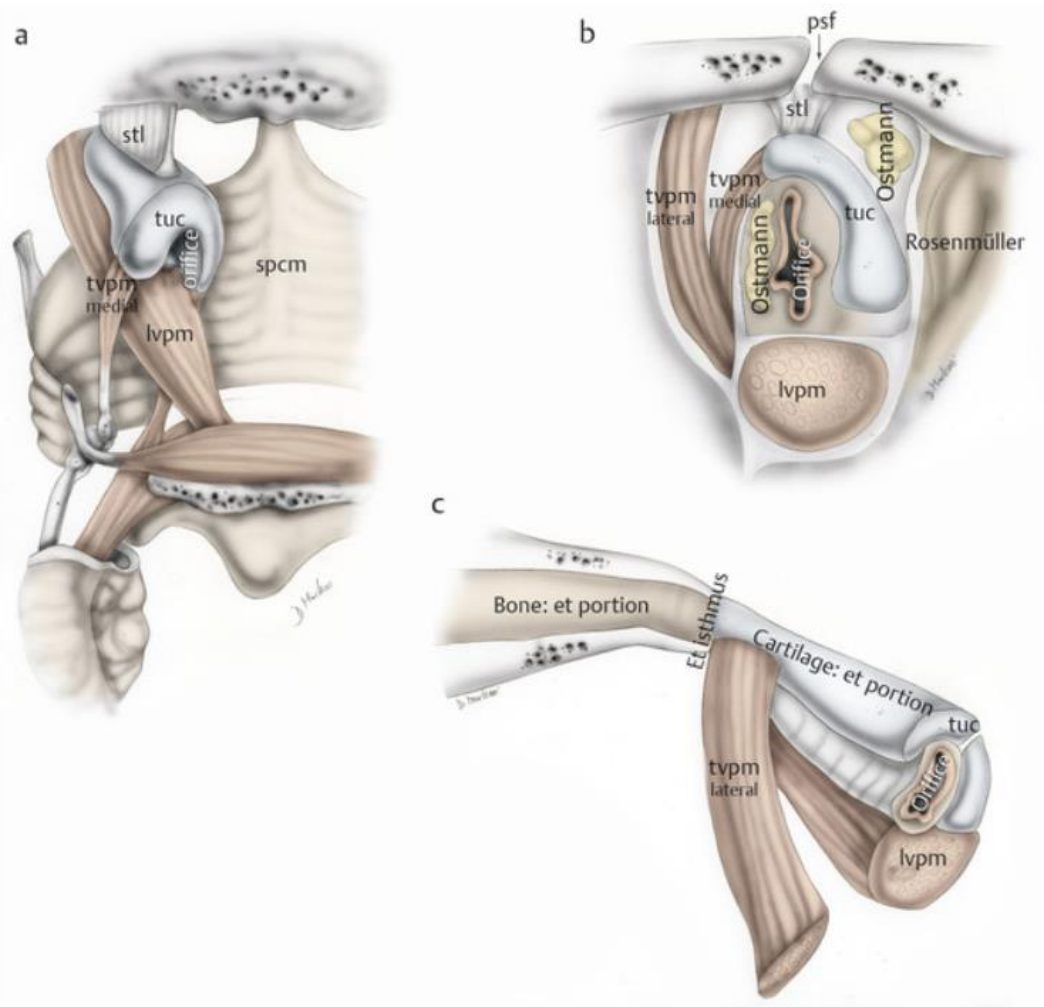


Figure -2 “Right ear. Anatomy of the eustachian tube. The cartilaginous portion and related muscles of the eustachian tube; posterior view (a). The eustachian tube orifice: a view tangential to the eustachian tube lumen at the level of the rhinopharynx (b). Bony and cartilaginous portions of the eustachian tube, coronal view (c). tvpm, tensor veli palatini muscle; lvpm, levator veli palatine muscle; tuc, cartilaginous component of the eustachian tube; psf, petrosphenoidal fissure; spcm, superior pharyngeal constrictor muscle; stl, suspensory tubal ligament.”⁴²

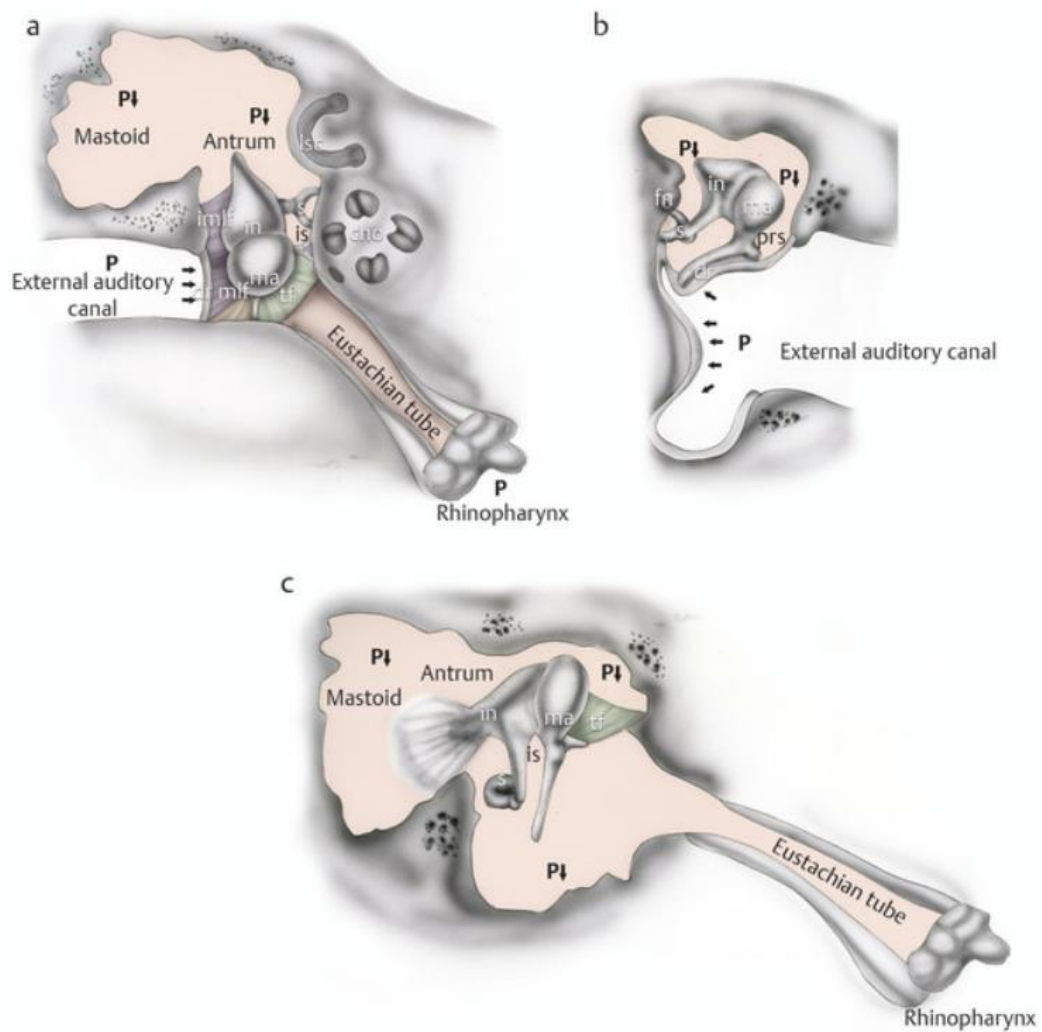


Figure. 3 Right ear. “Total retraction of the eardrum in a patient with failure of eustachian tube function: axial view at the epitympanic level (a), coronal view (b), sagittal view (c). In this case we observe a decrease of the pressure throughout the middle ear and mastoid, with subsequent retraction of the pars flaccida and pars tensa. in, incus; ma, malleus; s, stapes; is, isthmus; tf, tensor fold; fn, facial nerve; dr, eardrum; prs, Prussak space; imlf, lateral incudomalleal fold; mlf, lateral malleal fold; cho, cochlea; lsc, lateral semicircular canal.”⁴²

“TYMPANIC MEMBRANE: It has three layers”⁴⁰: -

- “An outer epithelial layer from the ectoderm of the 1st visceral cleft, which is continuous with the epithelium of the external auditory canal and is made up of two layers of cells. ”⁴⁰
- “A middle fibrous layer from the mesoderm between 1st visceral cleft and tubotympanic recess, which is deficient in pars flaccida. This layer consists of radial and circular fibrous tissue. ”⁴⁰
- “The inner mucosal layer forms a part of tubotympanic recess and is continuous with the mucosal layer of middle ear cleft. ”⁴⁰

Middle Ear Ventilation Routes

In 1946, “Chatellier and Lemoine formulated the concept of the “epitympanic diaphragm.” All epitympanic compartments receive their aeration via the large tympanic isthmus between the medial part of the posterior incudal ligament and the tensor tendon. Obstruction of the tympanic isthmus is common in various types of middle ear disease and causes significant disturbance to air diffusion within the temporal bone pneumatic system, leading to complete or incomplete separation of the tubo tympanic cavity from atticomastoid airspace.”⁴²

“The middle ear is divided into an anteroinferior and a posterosuperior compartment. The anteroinferior compartment corresponds to the middle ear cleft (mesotympanum, protympanum, retrotympanum, and protympanum) and could be compared to the nose, while the posterosuperior compartment corresponds to the epitympanum, antrum, and mastoid cells and could be compared to the lung. These two divisions are separated by the epitympanic diaphragm. There are also some histological differences between these two compartments. The epithelial layer in the

anteroinferior compartment is mainly pseudostratified and ciliated; there are also mucous cells; and the connective tissue is relatively thick and dense. The function of this compartment is mainly mucociliary clearance. In the posterosuperior compartment the epithelial layer is monocellular and contains flat cells; there are no ciliated or mucous cells; the connective tissue is loose and thin; and the function of this compartment is gas exchange. The authors also noted that the factors that caused obstruction of the tympanic isthmus were mucosal fold variations, inflammatory webs and exudate, retracted tympanic membrane, diseased attic mucosa, and cholesteatoma.”⁴²

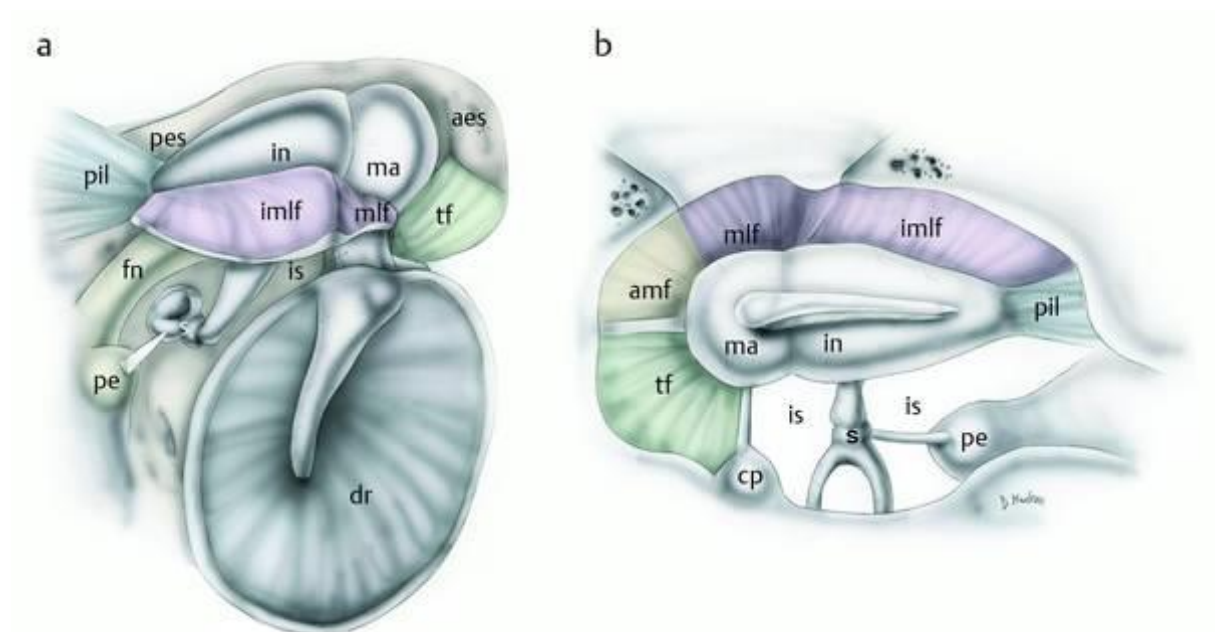


Figure. 4 a, b Right ear. “Drawings representing the “epitympanic diaphragm” in a patient with a complete tensor fold. s, stapes; fn, facial nerve; cp, cochleariform process; ma, malleus; in, incus; aes, anterior epitympanic compartment; amf, anterior malleolar fold; pes, posterior epitympanic compartment; pil, posterior incudal ligaments; tf, tensor fold; mlf, lateral malleal fold; imlf, lateral incudomalleal fold; is, isthmus; pe, pyramidal eminence”⁴²

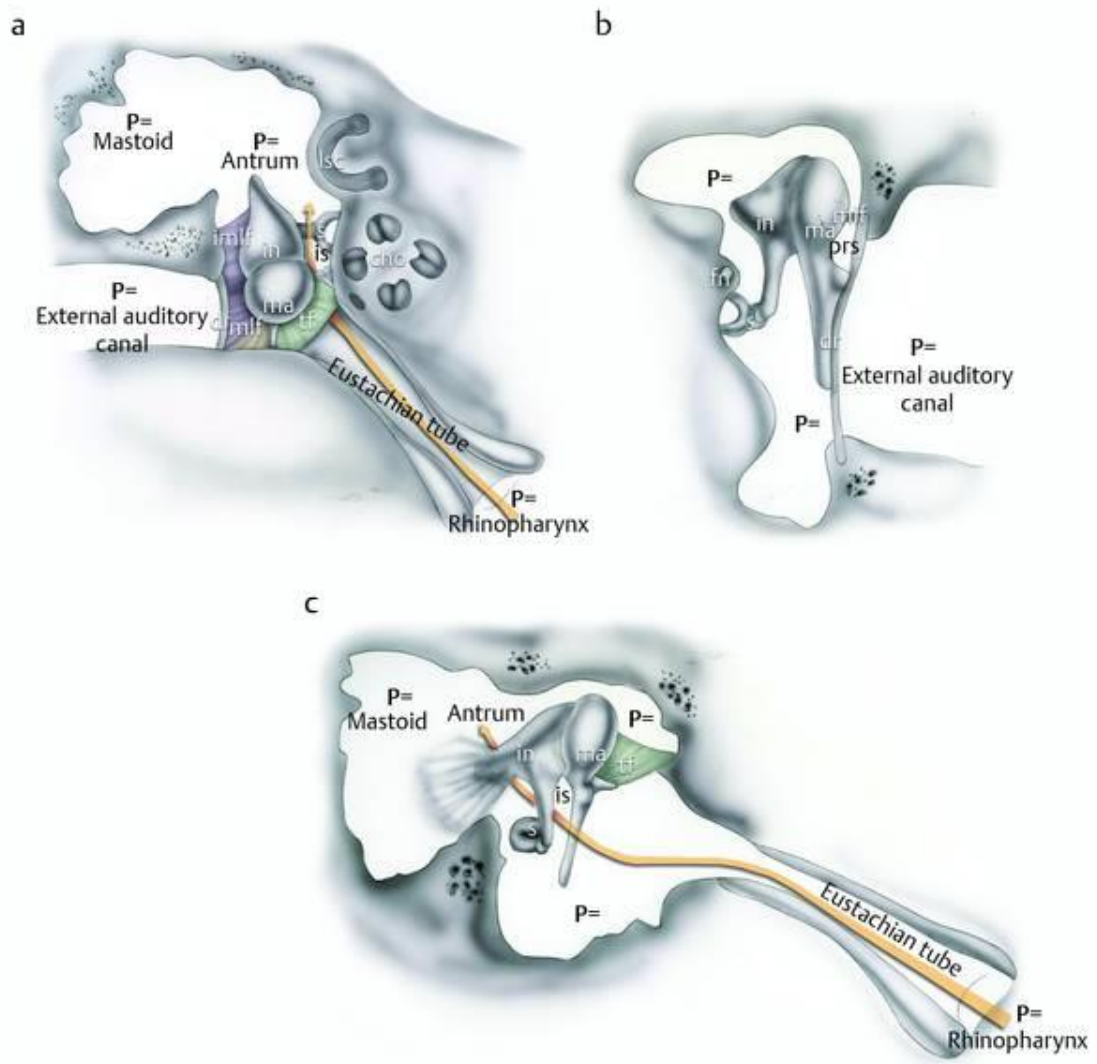


Figure. 5 Right ear. “Middle ear aeration pathway in a patient with normal function of the eustachian tube: axial view at the epitympanic level (a), coronal view (b), sagittal view (c). in, incus; ma, malleus; s, stapes; is, isthmus; tf, tensor fold; fn, facial nerve; dr, eardrum; prs, Prussak space; imlf, lateral incudomalleal fold; mlf, lateral malleal fold; cho, cochlea; lsc, lateral semicircular canal.”⁴²

Cleft palate variants

Complete Cleft Palate

“A "complete" cleft involves the entire primary and secondary palates. It extends from the uvula all the way into the alveolar ridge. It involves both the primary palate and secondary palate.”⁴³

Incomplete Cleft Palate

“An incomplete cleft starts at the back of the palate with the uvula and extends forward. It may or may not reach the incisive foramen. In simpler terms, it only involves the secondary palate, since it does not extend all the way forward to include the alveolar ridge. The length to which the cleft can extend forward from the uvula varies in severity of appearance. However, any amount of palate clefting can have an effect on speech development and audiological development. The various types of incomplete cleft palates are as follow.”⁴³

- **Bifid uvula:** “The least severe of the incomplete clefts in appearance, a bifid uvula is the most common palatal cleft. It is also referred to as a “cleft uvula.” A bifid uvula appears as splitting or forking of the uvula. It may be very subtle, evidenced only by a small notch, or the uvula may appear as two distinct entities. A bifid uvula, in and of itself, is not problematic and occurs in about 2 percent of the population. However, usually, a bifid uvula is indicative of a submucosal cleft.”⁴³
- **Submucosal cleft:** “A submucosal cleft is a cleft under the mucosa that lines the roof of the mouth—hence the term “sub.” Because a submucosal cleft is under the mucosa, the only physical indicator of its presence may be a bifid

uvula. Even though they are not seen from the surface, the muscles of the palate are not joined at the midline in a submucosal cleft. This creates an inability to move the palate for some speech sounds. Hence, a submucosal cleft is usually diagnosed when a child has abnormal speech development and a bifid uvula is present. ”⁴³

- **Soft palate cleft:** “A cleft of the soft palate runs from the tip of the uvula and stops before or at the junction of the soft and hard palate. Not only is it more obvious in its appearance than a submucosal cleft, but it also creates the same speech problems as a submucosal cleft. The more severe (longer) soft palate clefts are detected earlier at birth due to feeding difficulties. The cleft of the palate makes it difficult for the infant to create a tight oral seal around the nipple. As a result, the infant may not be able to suckle. A partial or shorter soft palate cleft may not show symptoms at birth or may reveal itself as nasal reflux of liquids or foods. ”⁴³
- **Soft and hard palate cleft:** “A cleft that involves both the hard and soft palate will include the entire soft palate and any part of the hard palate up to the incisive foramen. The most severe form involves the entire secondary palate, seen as a gap in the palate from the tip of the uvula to the incisive foramen. This is the most overt of the incomplete palate clefts. Similar to the isolated soft palate clefts, the combined soft and hard palate cleft is usually detected at birth because of feeding problems. Speech development will be impaired.”⁴³

Veau classification of cleft palate

The clefting of the palate is most usefully described by the Veau classification:”⁴⁵

- “Veau-I cleft palate: A midline cleft of the velum (soft palate), with the intact hard palate. ”⁴⁵
- “Veau-II cleft palate: A midline cleft of the velum (soft palate) and secondary hard palate (posterior to the incisive foramen), with intact primary palate (anterior to the incisive foramen) ”⁴⁵
- “Veau-III cleft palate: A cleft of the velum (soft palate), extending unilaterally through the secondary hard palate, past the incisive foramen, and through the primary hard palate and alveolus. The vomer (the bony part of the nasal septum) remains attached to the palatal shelf on the greater segment (non-cleft side). ”⁴⁵
- “Veau-IV cleft palate: A cleft of the velum (soft palate), extending in the midline through the secondary hard palate up to the incisive foramen and then bilaterally through the primary hard palate and alveolus on each side. The vomer (the bony part of the nasal septum) remains in the midline and is attached to the premaxilla.”⁴⁵

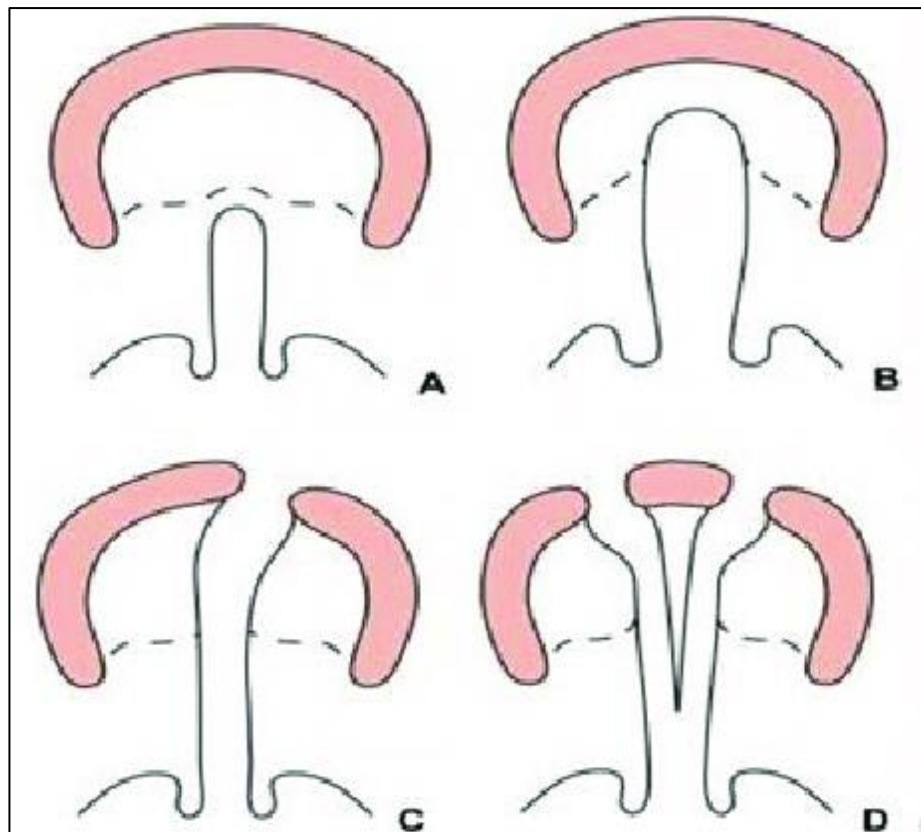


Figure 6: “Veau classification of cleft palate”⁴⁵

A- Class I

B- Class II

C- Class III

D- Class IV

Pathogenesis of middle ear problems in cleft palate

Mechanical

“The abnormal reflux of food and fluid into the nasal cavity can set up chronic inflammatory changes around the Eustachian orifices with oedema, hypertrophy of adenoid pads, low-grade obstruction, and secondary middle ear disease.”⁴⁴

Infection

“The break in the mechanical barrier between the mouth and nasopharynx with its concomitant chronic inflammatory change alters the bacterial flora of the region to permit overgrowth of predominately pathogenic bacteria. This results in otitis media.”⁴⁴

Dynamic

“The dynamic factor in Eustachian tube and middle ear physiology depends upon the intact anatomy of Eustachian apparatus and its extrinsic musculature. In the normal resting phase, the Eustachian orifices are closed, opening widely with yawning and swallowing, and also opening slightly with normal speech. This opening of the Eustachian orifice permits aeration and pressure equalization as well as relief of obstruction in the Eustachian canal, and is dependent upon the action of the intact tensor and levator palatini muscles. The rapid motion of these muscles, particularly in speech, may produce almost a milking action in the cartilaginous portion of the Eustachian tube. Thus, the dilation of the orifices depend upon muscles which are not intact in the child with a congenital cleft of the palate. This dynamic function of the tensor and levator muscles is well known in speech as velopharyngeal closure largely depends upon their contraction, but the secondary opening and closing of the Eustachian orifices may be of equal importance in the prevention of hearing loss.”⁴⁴

“At rest the Eustachian tube is closed. When it is opened it ventilates the middle ear, releases mucus and equalizes pressure differentials that are created by gaseous absorption and environmental pressure changes. In children with an unrepaired cleft palate, the tensor muscle fibres do not have a normal course and midline palatal insertion and, therefore, lack the anchorage to effectively open the

Eustachian tube. In this situation, when gases are absorbed by the mucous membrane of the middle ear they are not replaced, resulting in negative pressure. Sustained negative pressure results in a retracted tympanic membrane and eventual secretion of fluid into the middle ear space from the mucous membrane.”⁴⁴

Evaluation

“After birth, neonates with CL/P will require evaluation and care from an interprofessional healthcare team. The initial assessment is focused on respiratory and feeding issues to ensure the infant can grow and develop appropriately until the definitive surgical repair. Neonates need to be evaluated for sleep apnea, and parents counseled on appropriate management. A trained speech therapist must work with parents to teach appropriate feeding techniques and provide assistive devices to improve intake and reduce infant fatigue during feeds. Various special bottles and nipples are available to protect the nasal passages from reflux during feeds, decrease respiratory distress while feeding, and ensure adequate caloric intake. Many of these require practice for the caregiver feeding the infant and instruction with a specialized speech therapist or lactation consultant. Infants with clefts may nurse more efficiently from a breast than a bottle.”⁴⁵

“A dental and orthodontic evaluation should also be considered for possible oral prosthetics to aid feeding until surgery or to evaluate for nasoalveolar molding if a cleft lip is also present. Appropriate infant weight gain is essential for development and preventing surgical intervention delays. Subsequent and long-term evaluations include:”⁴⁵

- **Audiologic assessment**

- “Evaluation with a newborn hearing screening is essential if it is available. Even if the infant has passed this, subsequent audiometry and tympanometry are required to evaluate for eustachian tube dysfunction and potentially correctable conductive hearing loss.”⁴⁵
- “If the child fails the newborn hearing screen and cannot be evaluated with age-appropriate audiometry, an auditory brainstem response is indicated to confirm the continuity of the neural pathways for hearing. This should be completed in the first months of life to ensure early hearing restoration if indicated.”⁴⁵

- **Speech-language assessment**

- Assessment of feeding and language development is also recommended.
- “Functional assessment should begin in the prelingual years, focusing on feeding but continuing into the school years as the patient adapts to speaking and swallowing with surgically corrected anatomy.”⁴⁵

- **Dental evaluation**

- The first evaluations should occur as primary teeth erupt and continue as permanent dentition erupts from early childhood through adolescence.

- “Dental misalignment is common, as are missing or misshapen teeth if an alveolar cleft is present. The need for braces and possibly orthognathic surgery in the teen and adult years is also high.”⁴⁵

- **Psychosocial and genetic counseling**

- Counseling is recommended for both parents and child
- “For parents, this can form an important part of the early interprofessional team visits and can occur prenatally.”⁴⁵
- “Mental health resources should always be available to children as they progress through the school years to cope with any challenges associated with the social stigma of a cleft.”⁴⁵
- “Family genetic counseling should be offered in addition to future planning as patients with a cleft palate enter adulthood and consider children of their own.”⁴⁵

Endoscopic classification system of pars tensa retractions

“The prevalence of tympanic membrane (TM) retraction in children has been reported to be 8%–10%, with most cases described as mild. While some retractions are reflective of a transient negative pressure state in the middle ear, others become chronic. In paediatric patients, most retractions arise from the pars tensa, as opposed to the pars flaccida. When pars tensa retractions worsen, adherence to the medial tympanic wall and incus may occur. Once a retraction establishes contact with the ossicular chain, concern arises for the development of hearing loss. However, little is known about the incidence of permanent hearing loss in such retraction cases. Similarly, the risk of cholesteatoma formation from a pars tensa retraction remains to

be clarified. As such, our current understanding of when and why to operate on retracted TMs is based more on assumptions than on actual evidence.”⁴²

“Tympanic membrane retractions are an unwanted consequence of sharp variations in middle-ear pressure. This is mainly attributed to the reduced functionality of the Eustachian tube’s pressure equalisation. Retractions of the tympanic membrane follow progressive changes, from simple retractions to retraction pockets, to retraction pockets with cholesteatoma. Tympanic membrane retractions are one of the most significant causes of conductive hearing loss, particularly as a result of ossicular erosion.”⁴⁴

Sadé et al⁴⁶ divided “pars tensa retractions into four grades (grade I to grade IV). However, the significance of ossicular necrosis or association with cholesteatoma was not considered in their study. Little emphasis was given to categorising the pars tensa retractions based on the ossicular status and association with cholesteatoma. Interpretation of the grading system may be prone to variability given subjective differences in terms of the extent of ossicular erosion or depth of tympanic membrane retraction. In addition, there is often a progressive change from simple pars tensa retractions to pars tensa retractions with cholesteatoma.”⁴⁶

“Pars tensa retractions also progress to ossicular necrosis, which is a leading cause for conductive hearing loss. The Sadé grading system does not take into account the ossicular necrosis or the association of cholesteatoma with the retractions. Subjective differences in the interpretation of different grading systems of pars tensa retraction, in terms of the extent of ossicular erosion and depth of tympanic membrane retraction, results in inconsistency. Erosion of the ossicles as a complication of pars tensa retraction is frequently observed, but rarely discussed.”⁴⁶

Sadé Classification of Pars Tensa Retraction⁴⁶

- The **Sadé Classification** (1993) is used to classify **retraction of the pars tensa.**⁴⁶
- It is graded into 5 types.
 - **Grade 1:** Slight retraction of the pars tensa.
 - **Grade 2:** Retraction onto the incus.
 - **Grade 3:** Retraction onto the promontory, but not adherent.
 - **Grade 4:** Adhesion onto the promontory.
 - **Grade 5:** Atelectatic tympanic membrane with perforation.
- “The difference between Sadé Grade 3 and Grade 4 retraction can only be identified intraoperatively by assessing whether the tympanic membrane can be lifted off of the promontory.”⁴⁶
 - “If it is non-adherent, it is a Grade 3 retraction. If it is adherent then it is a Grade 4 retraction.”⁴⁶
- “The corresponding classification system for retraction of the pars flaccida is the Tos and Poulsen Classification.”⁴⁶

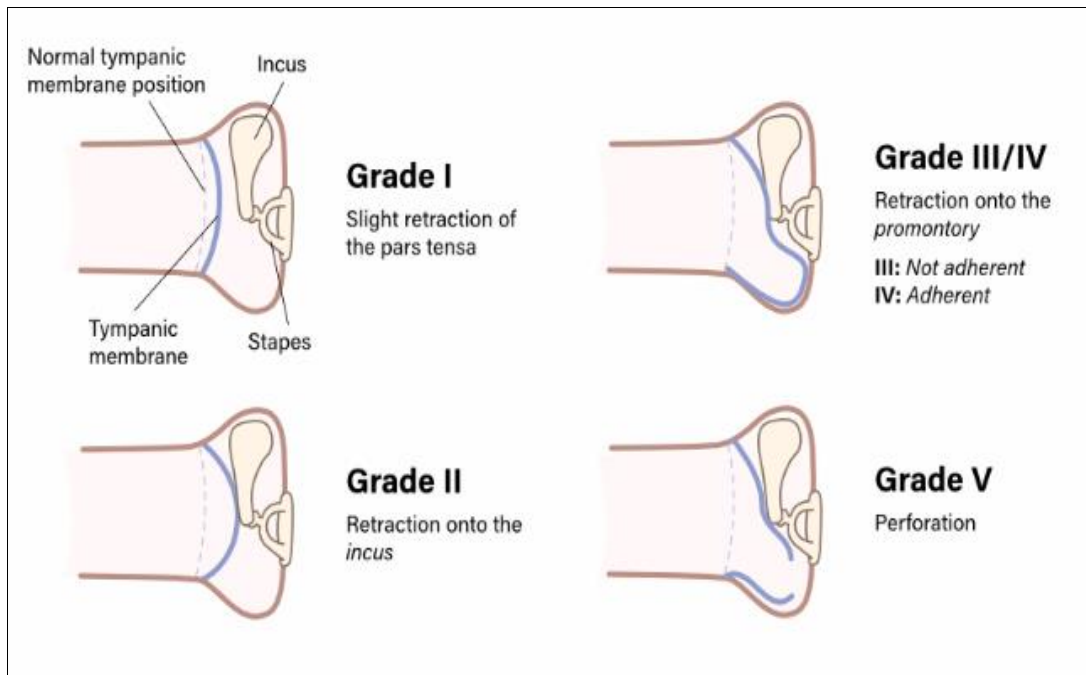


Figure 7: “Sade Classification of Pars Tensa Retraction”⁴⁶

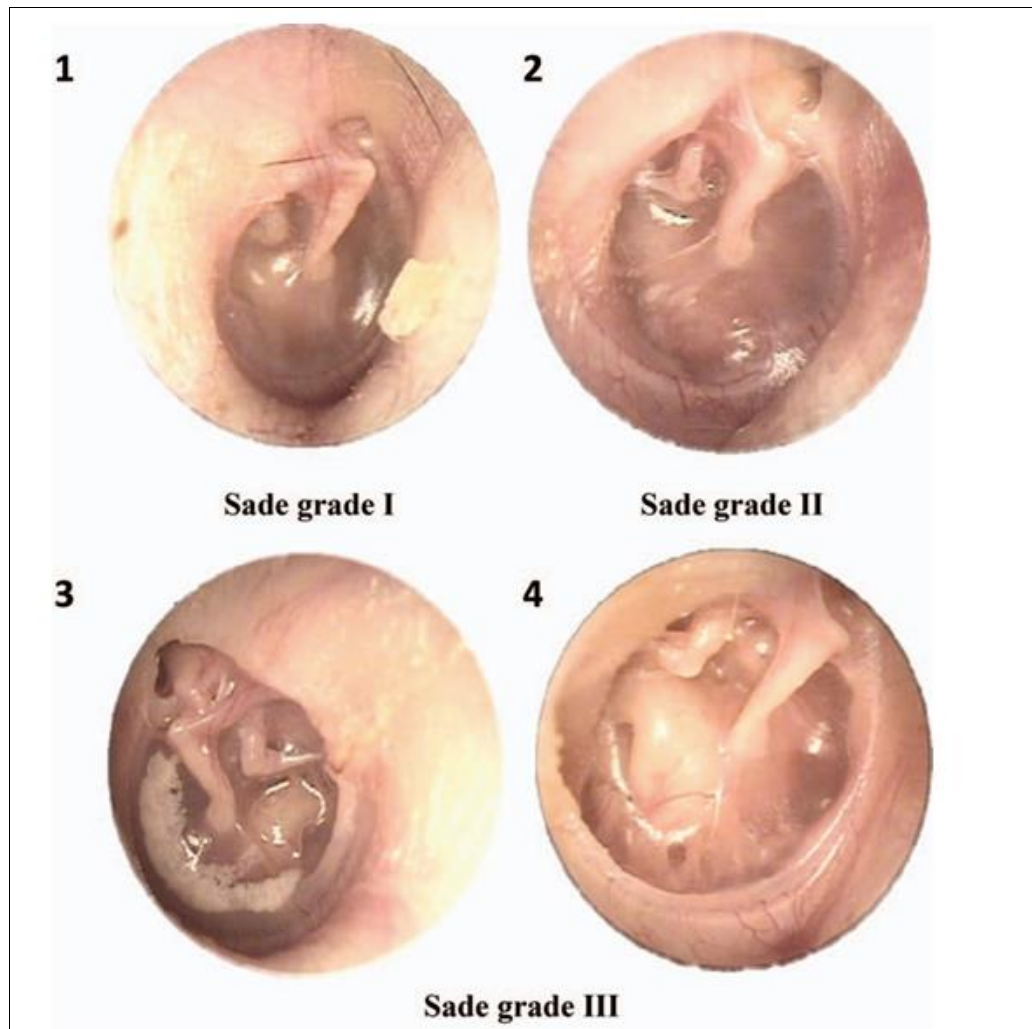


Figure 8: “The Sade classification used in this study. 1: Sade I: mild retraction in the posterosuperior quadrant of the right tympanic membrane. 2: Sade II: retraction in the posterosuperior quadrant of the pars tensa in which the right tympanic membrane touches the incus, with a slight retraction in the pars flaccida. 3: Sade III: retraction in the posterosuperior quadrant of the pars tensa in which the left tympanic membrane touches the incus and the promontory, with as light retraction in pars flaccida and tympanosclerosis of the anterior edge of the pars tensa. 4: Sade III: subtotal atelectasis of the posterosuperior quadrant of the right tympanic membrane in which the incus and the promontory are clearly visible.”⁴⁶

Tos classification⁴⁷

- “The Tos and Poulsen Classification (1980) is used to classify retraction of the pars flaccida.”⁴⁷
- Graded into 5 types:⁴⁷
 - Type 0: Normal pars flaccida.⁴⁷
 - Type I: Retraction towards the neck of the malleus, with a visible air space behind the pocket.⁴⁷
 - Type II: Pars flaccida is retracted and adherent to the neck of the malleus with no visible air space.⁴⁷
 - Type III: Retraction extends beyond the bony annulus, with or without slight bone resorption of the annulus.⁴⁷
 - Type IV: Definite bony erosion of the annulus.⁴⁷

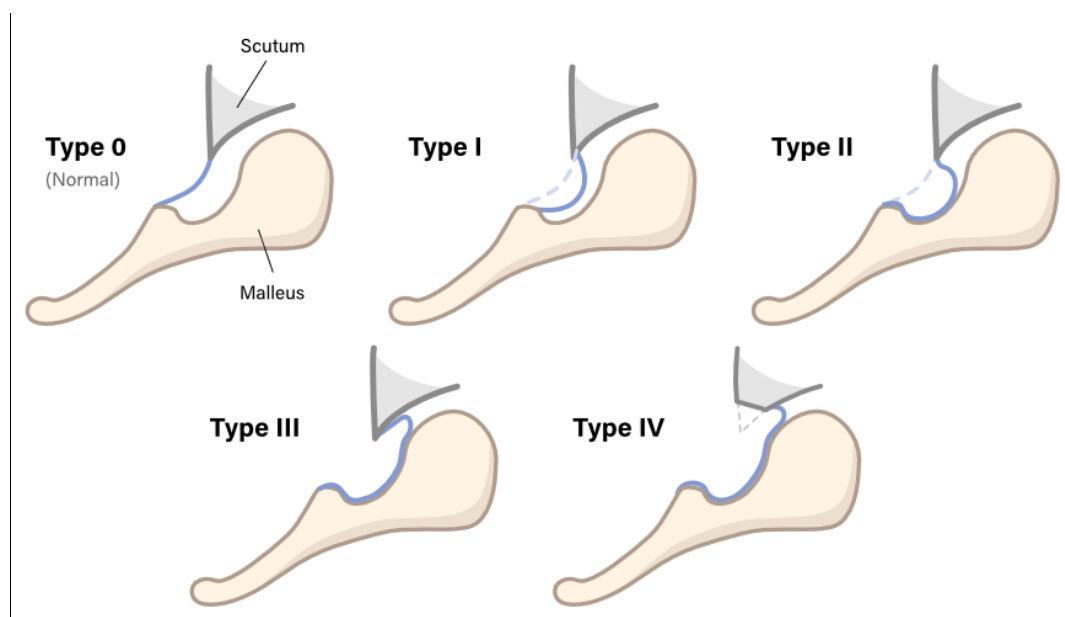


Figure 9: “Tos classification”⁴⁷

Pure tone audiology

“Pure-tone testing assesses the auditory system through two pathways. In air conduction testing, sound waves enter the external auditory canal and pass through the tympanic membrane, ossicular chain, and cochlea to reach the cochlear nerve (part of cranial nerve VIII) and then travel through the brainstem to the auditory cortex. In bone conduction testing, sound waves are introduced directly to the cochlea through the vibration of a bone conduction oscillator on the mastoid process.”⁴⁸

“By utilizing both methods of pure-tone testing, hearing loss is determined to be conductive (involving the pinna through the ossicular chain), sensorineural (involving the cochlea to the auditory cortex), or mixed (both conductive and sensorineural involvement). For some patients, a false "conductive" component may appear in the presence of "third-window" pathologies like semicircular canal dehiscence because of changes in sound transmission from the dehiscence. Third window phenomena are referred to as such because they function as third connections between the inner and middle ears when counted along with the oval and round windows.”⁴⁸

Indications

“Pure-tone evaluation should be performed for patients concerned about abnormal auditory perception, ear trauma, or otologic disease. This includes but is not limited to, subjective hearing loss, tinnitus, hyperacusis, ototoxic monitoring protocols, dizziness or vertigo, middle ear dysfunction, traumatic brain injury or temporal bone fracture, loud noise exposure, blast injury, failed hearing screening, speech delay in children, or conditions with risk factors for hearing loss.”⁴⁸

Contraindications

“A reliable pure-tone evaluation cannot be completed if a patient cannot provide reliable behavioral responses. This is particularly true of children under 6 months of age but is also seen in patients with developmental delays or neurological impairment. Behavioral pure-tone testing may also be contraindicated if unreliable responses are given by patients who are malingering or who have factitious disorders. In these circumstances, objective electrophysiologic or otoacoustic emission testing instead of behavioral responses is necessary to build a complete clinical picture.”⁴⁸

Clinical Significance

“Pure-tone audiometry is the standard gold method of determining the type, degree of hearing loss due to its widespread availability, inter-test reliability, and relative ease of execution. Pure-tone audiometry results provide context for diagnosis, reassurance, monitoring, or further investigation of ear concerns. Repeated assessments track changes in hearing as and indicator of changes in ear health over time.”⁴⁸

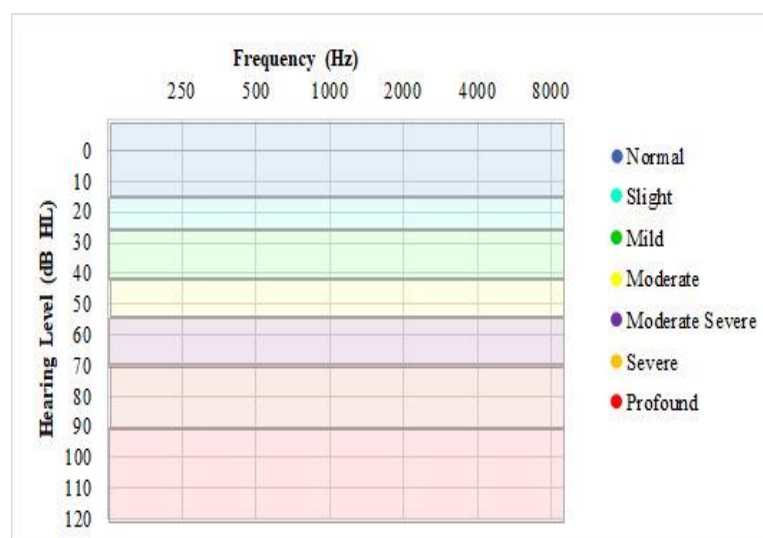


Figure 10: “Normal Hearing Ranges for Audiograms”.⁴⁸

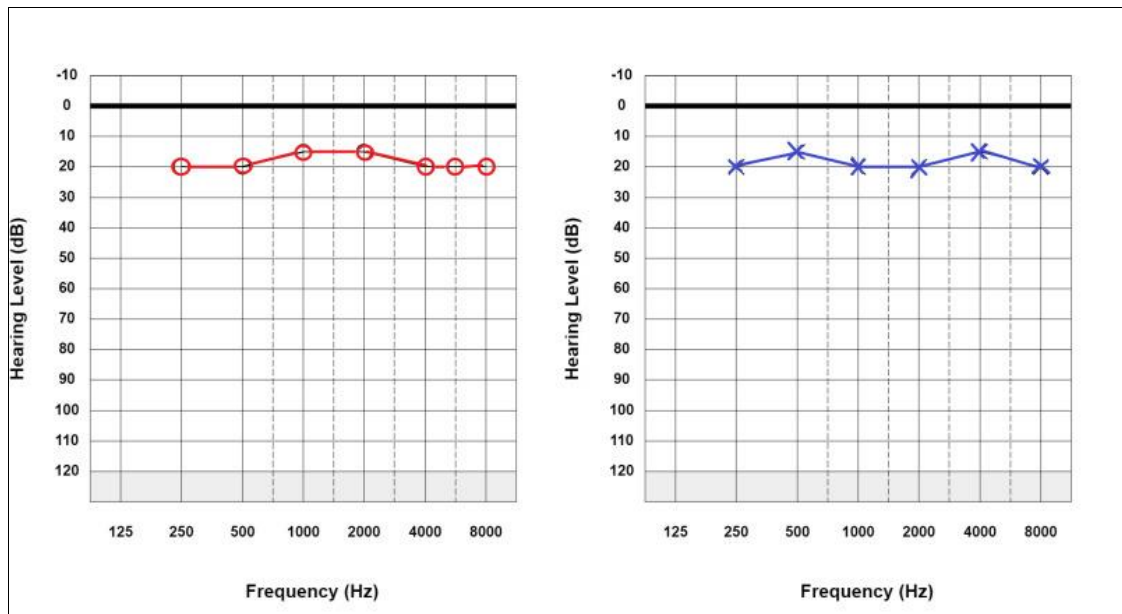


Figure 11: “Normal Hearing Thresholds. Pure tone audiogram showing normal hearing thresholds.”⁴⁸

Tympanometry

Tympanometry, a non-invasive test, evaluates middle ear pressure dynamics by measuring the ear canal’s acoustic impedance. Tympanometry aids in diagnosing middle ear disorders.⁴⁹

Types of Tympanograms: Delving into Middle Ear Pressure Dynamics

“Tympanometry, a crucial tool in diagnosing middle ear disorders, provides a comprehensive analysis of middle ear pressure dynamics. It generates a graph called a tympanogram, revealing valuable insights into the condition of the eardrum and middle ear. Different tympanograms indicate specific pressure conditions, shedding light on underlying ear pathology.”⁴⁹

Type A Tympanogram: The Sign of a Healthy Middle Ear

“Characterized by a distinct peak, the type A tympanogram indicate normal middle ear pressure. The eardrum vibrates freely, creating the characteristic peak in the tympanogram. This healthy middle ear environment ensures optimal hearing and eardrum integrity.”⁴⁹

Type B Tympanogram: Unveiling Negative Middle Ear Pressure

“A type B tympanogram shows a shift of the peak toward negative pressure. This pressure imbalance often stems from Eustachian tube dysfunction or otitis media with effusion. The Eustachian tube, connecting the middle ear to the nasopharynx, fails to ventilate the middle ear, resulting in negative pressure and fluid accumulation.”⁴⁹

Type C Tympanogram:

“**Type C tympanogram** indicates negative pressure in the middle ear and can be indicative of **eustachian tube dysfunction**. It shows a peak, but it occurs when air pressure is more negative than in Type A tympanograms. The curve is skewed towards the left of the graph. Common causes include upper respiratory illnesses, ear infections, or Eustachian tube dysfunction.”⁴⁹

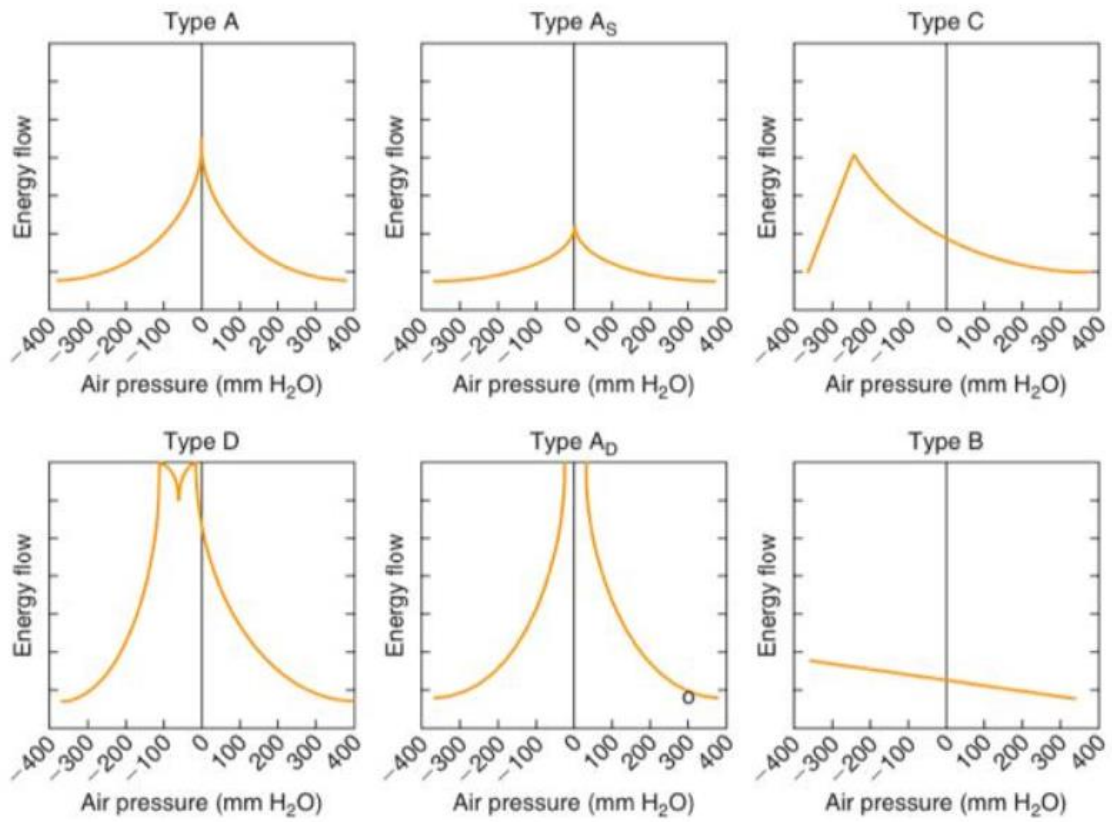


Figure 12: “Classification of tympanogram”⁴⁹

MATERIALS AND METHODS

Study setting: Department of ENT KLES Dr. Prabhakar Kore charitable Hospital, Belagavi

Study population: All patients who come to Plastic Surgery and ENT and HNS OPD in KLES Dr. Prabhakar Kore charitable Hospital, Belagavi and were clinically diagnosed with cleft palate, who has given consent for the study will be taken up.

Study period: One year

Study design: Cross sectional study

Sample Size: 43 Children with cleft palate

Sampling technique:

$$n = Z^2_{1-\alpha/2} P(1-P)/d^2, \text{ where,}$$

n	= sample size
$Z^2_{1-\alpha/2}$	= confidence interval
P	= estimated proportion
d	= desired precision

$$n = \frac{(1.96)^2 \times 90 \times (100-90)}{(10\% \times 90)^2}$$

$$= 42.6$$

$$= 43$$

Required sample size – 43 patients with cleft palate

Sampling technique: Simple Random sampling method

Inclusion criteria:

- Clinically diagnosed all type of cleft palate children between 5-15 years age group, who has given consent for the study has been taken.

Exclusion Criteria:

- Children with history of congenital sensory neural deafness, acquired sensory neural hearing loss, patients with malformed ears, perforated tympanic membrane, submucosal cleft palate.

Methods of data collection:

Study protocol:

- Children with cleft palate are clinically assessed, followed by grading of tympanic membrane retraction by otoendoscopy, using Sade and Tos classification.
- Evaluation of middle ear function done by Pure Tone Audiometry and Tympanometry.
- The results are gathered and assessed for grade of tympanic membrane retraction, middle ear pressure and degree of hearing loss.

Data collection procedure: Patients with cleft palate and who satisfy the inclusion criteria were enrolled in the study. After taking written informed consent, they were instructed to fill questionnaires pertaining to the symptoms of cleft palate. A thorough history were obtained, and complete examination of the ear, nose and throat were performed. Otoendoscopy, Tympanometry, Pure tone audiometry was performed and assessed for grade of tympanic membrane retraction and middle ear pressure and degree of hearing loss.

Statistical analysis:

Data was collected by using a structure proforma. Data entered in MS excel sheet and analysed by using SPSS 24.0 version IBM USA. Qualitative data was expressed in terms of proportions. Quantitative data was expressed in terms of Mean and Standard deviation. Association between two qualitative variables was seen by using Chi square/ Fischer's exact test. Comparison of mean and SD between two groups was done by using unpaired t test to assess whether the mean difference between groups is significant or not.

A p value of <0.05 was considered as statistically significant whereas a p value <0.01 was considered as highly significant.

RESULTS

Table 1: Distribution according to age group

		Frequency	Percent
Age group in years	5 to 10	22	51.2
	11 to 15	21	48.8
	Total	43	100.0

We included total 43 clinically diagnosed all type of cleft palate children between 5-15 years age group. Of these 43 children, majority were from 5-10 years age group i.e. 51.2% and remaining 21 i.e. 48.8% were from 11-15 years age group. Mean age of the study population was 10.06 ± 3.44 years.

Graph 1: Distribution according to age group

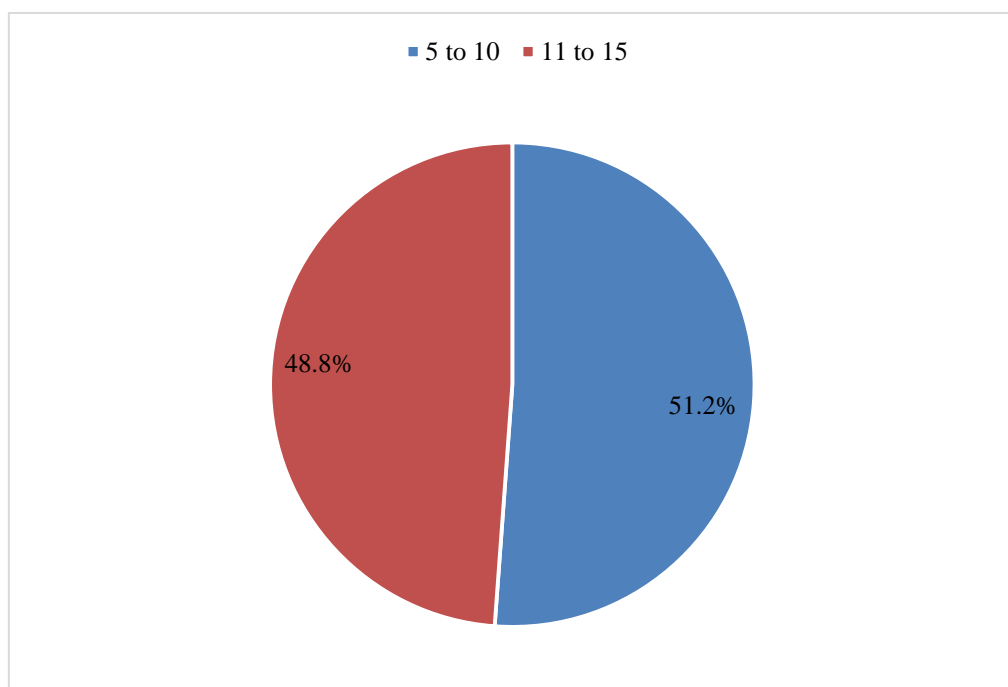


Table 2: Distribution according to gender

		Frequency	Percent
Gender	Male	26	60.5
	Female	17	39.5
	Total	43	100.0

Majority of the cases were males i.e. 26(60.5%) and 39.5% were females.

Graph 2: Distribution according to gender

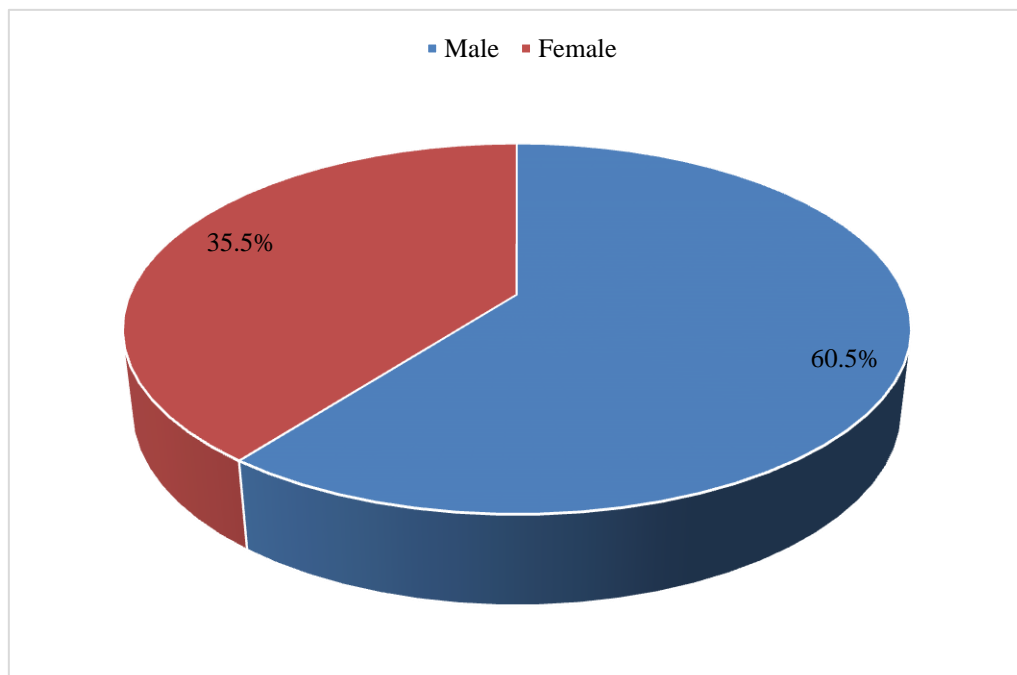


Table 3: Distribution according to cleft type

		Frequency	Percent
Cleft Type	Bilateral complete CLP	4	9.3
	Complete cleft palate	4	9.3
	Left Complete CLP	24	55.8
	Right Complete CLP	11	25.6
	Total	43	100.0

Distribution according to cleft type revealed as follows: Bilateral complete CLP-9.3%, complete cleft palate-9.3%, Left Complete CLP-55.8%, Right Complete CLP-25.6%.

Graph 3: Distribution according to cleft type

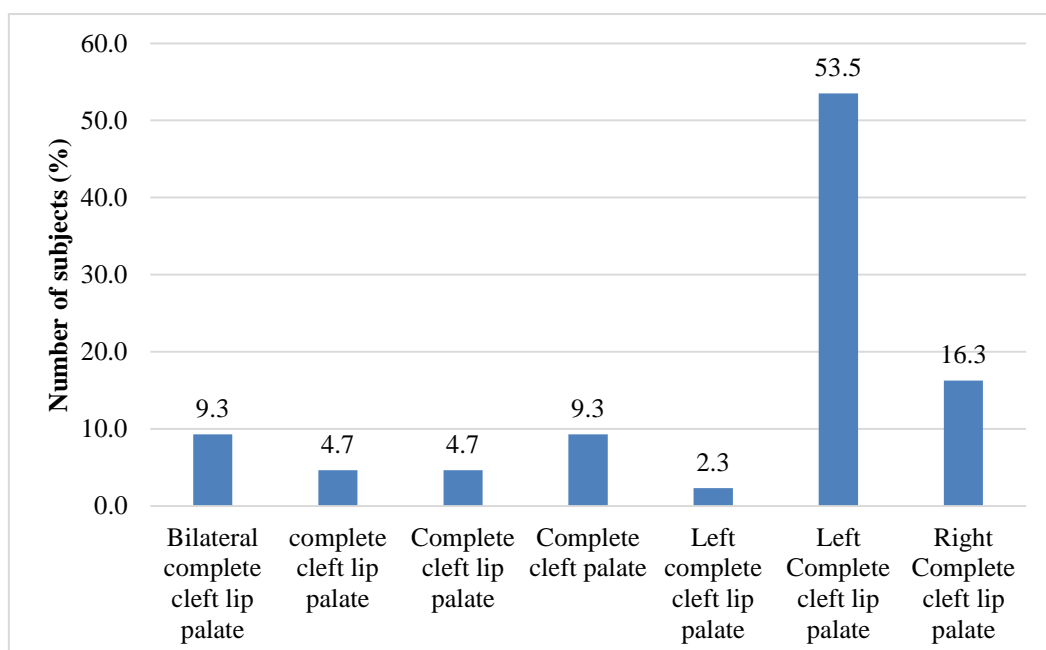


Table 4: Distribution according to type of tympanometry in right ear

		Frequency	Percent
Right Tympanometry	Type A	15	34.9
	Type B	18	41.9
	Type C	10	23.3
	Total	43	100.0

Distribution according to type of tympanometry in right ear showed that majority had type B i.e. 41.9% followed by 34.9% with type A and remaining 23.3% had type C.

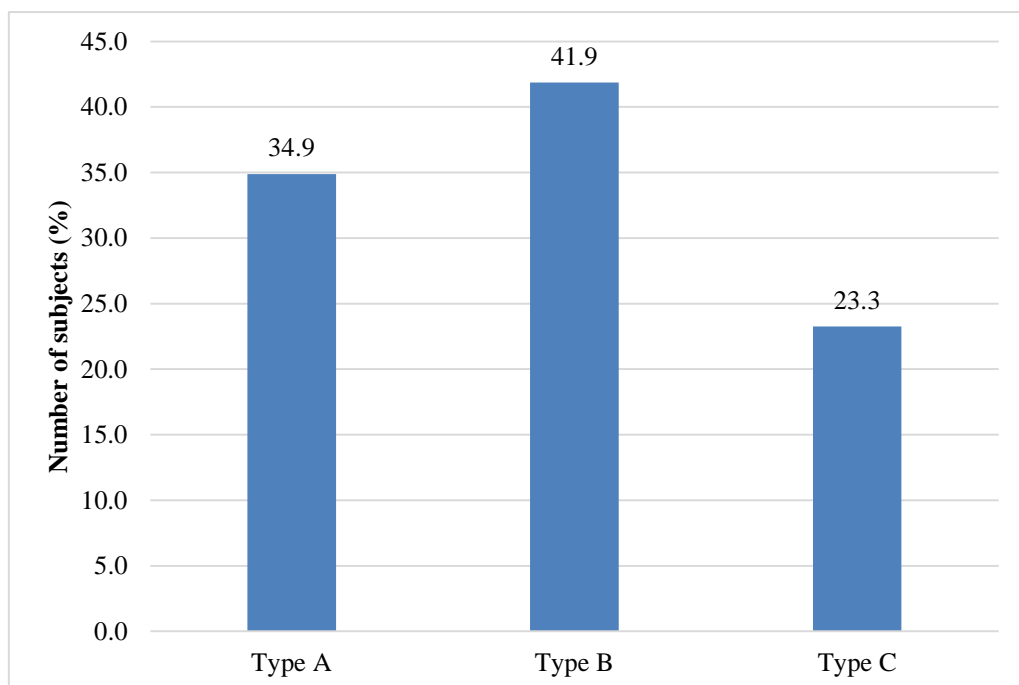
Graph 4: Distribution according to type of tympanometry in right ear

Table 5: Distribution according to type of tympanometry in left ear

		Frequency	Percent
Left Tympanometry	Type A	12	27.9
	Type B	21	48.8
	Type C	10	23.3
	Total	43	100.0

Distribution according to type of tympanometry in left ear showed that majority had type B i.e. 48.8% followed by 27.9% with type A and remaining 23.3% had type C.

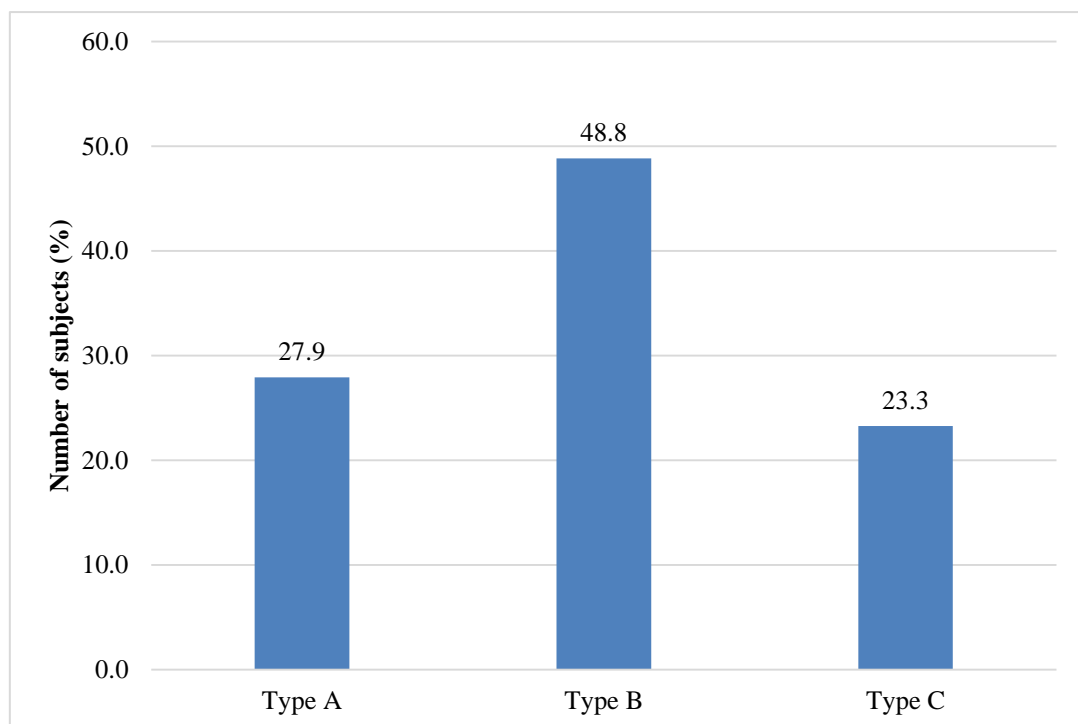
Graph 5: Distribution according to type of tympanometry in left ear

Table 6: Distribution according to Sade grading in right ear

		Frequency	Percent
Right Sade (Pars Tensa)	Sade 0	18	41.9
	Sade I	10	23.3
	Sade II	11	25.6
	Sade III	3	7.0
	Sade IV	1	2.3
	Total	43	100.0

Distribution according to Sade grading in right ear (Pars Tensa) revealed as follows: Sade 0-41.9%, Sade I-23.3%, Sade II-25.6%, Sade III-7.0% and Sade IV-2.3%.

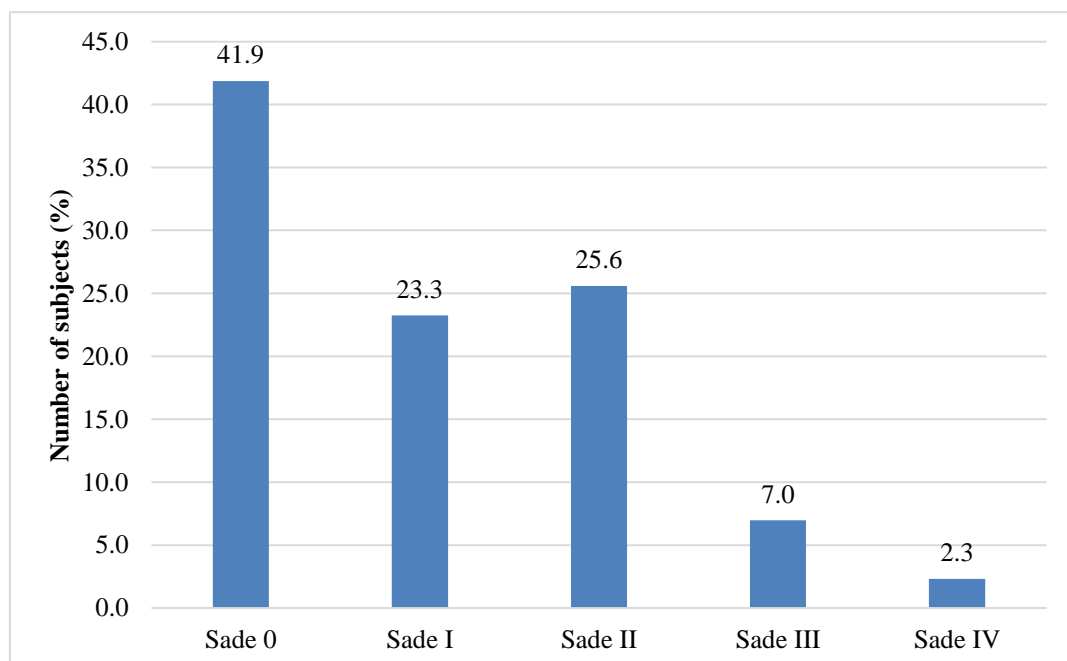
Graph 6: Distribution according to Sade grading in right ear

Table 7: Distribution according to Sade grading in left ear

		Frequency	Percent
Left Sade (Pars Tensa)	Sade 0	14	32.6
	Sade I	8	18.6
	Sade II	17	39.5
	Sade III	4	9.3
	Sade IV	0	0.0
	Total	43	100.0

Distribution according to Sade grading in left ear (Pars Tensa) revealed as follows: Sade 0-32.6%, Sade I-18.6%, Sade II-39.5%, Sade III-9.3% and Sade IV-0%.

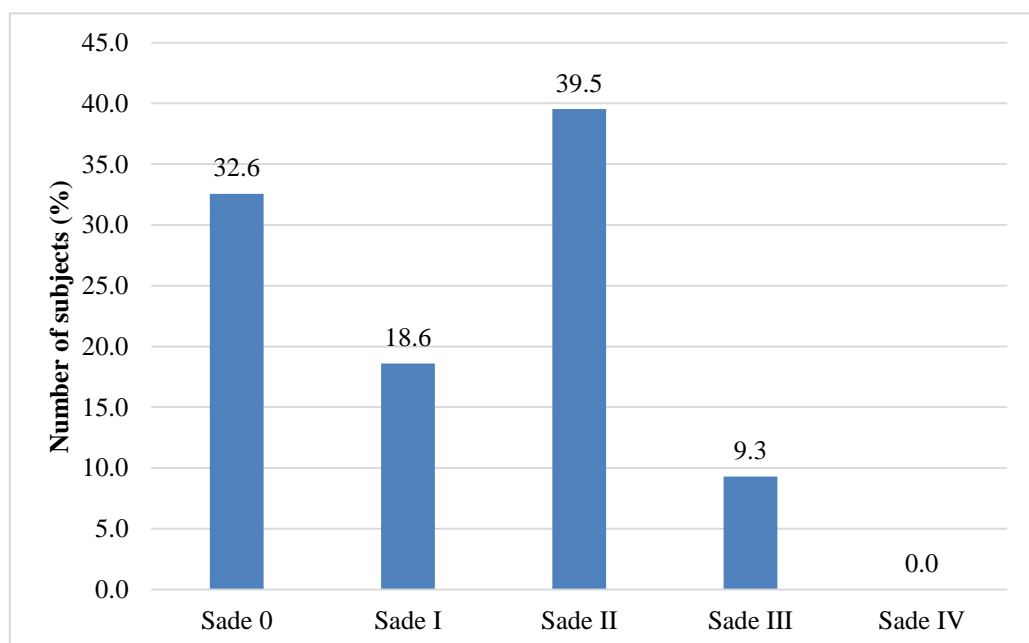
Graph 7: Distribution according to Sade grading in left ear

Table 8: Distribution according to Tos grading in right ear

		Frequency	Percent
Right Tos (Pars Flaccida)	Tos 0	38	88.4
	Tos I	4	9.3
	Tos II	1	2.3
	Tos III	0	0.0
	Total	43	100.0

Distribution according to Tos grading in right ear (Pars Flaccida) revealed as follows: Tos 0- 88.4%, Tos I-9.3%, Tos II-2.3% and Tos III-0.0%.

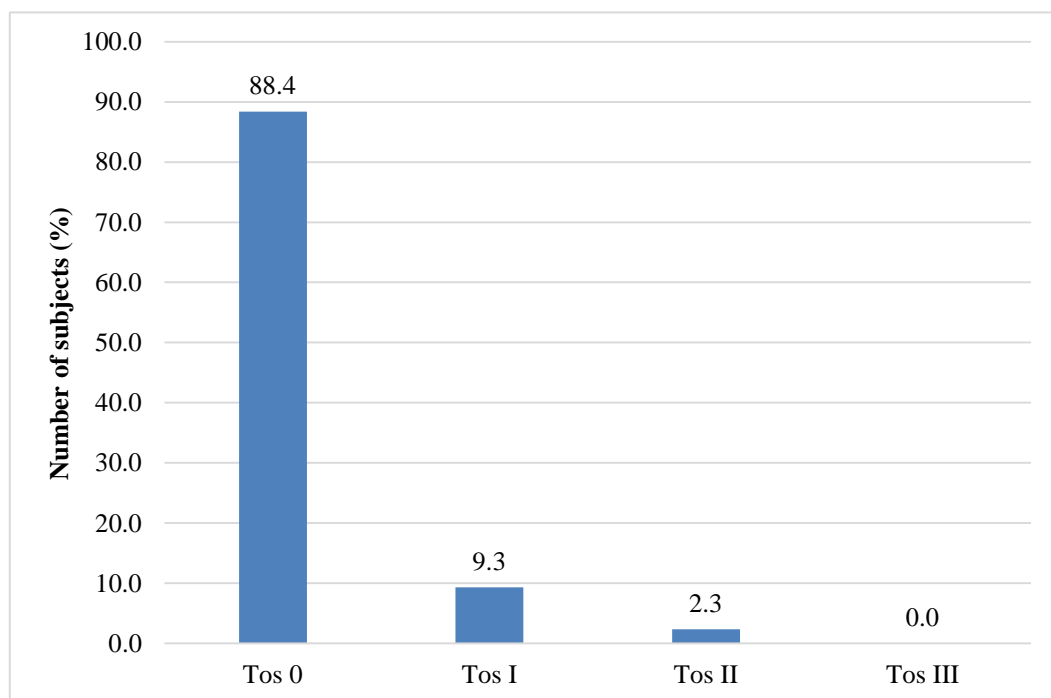
Graph 8: Distribution according to Tos grading in right ear

Table 9: Distribution according to Tos grading in left ear

		Frequency	Percent
Left Tos (Pars Flaccida)	Tos 0	39	90.7
	Tos I	3	7.0
	Tos II	0	0.0
	Tos III	1	2.3
	Total	43	100.0

Distribution according to Tos grading in left ear (Pars Flaccida) revealed as follows:

Tos 0- 90.7%, Tos I-7%, Tos II-0% and Tos III-2.3%.

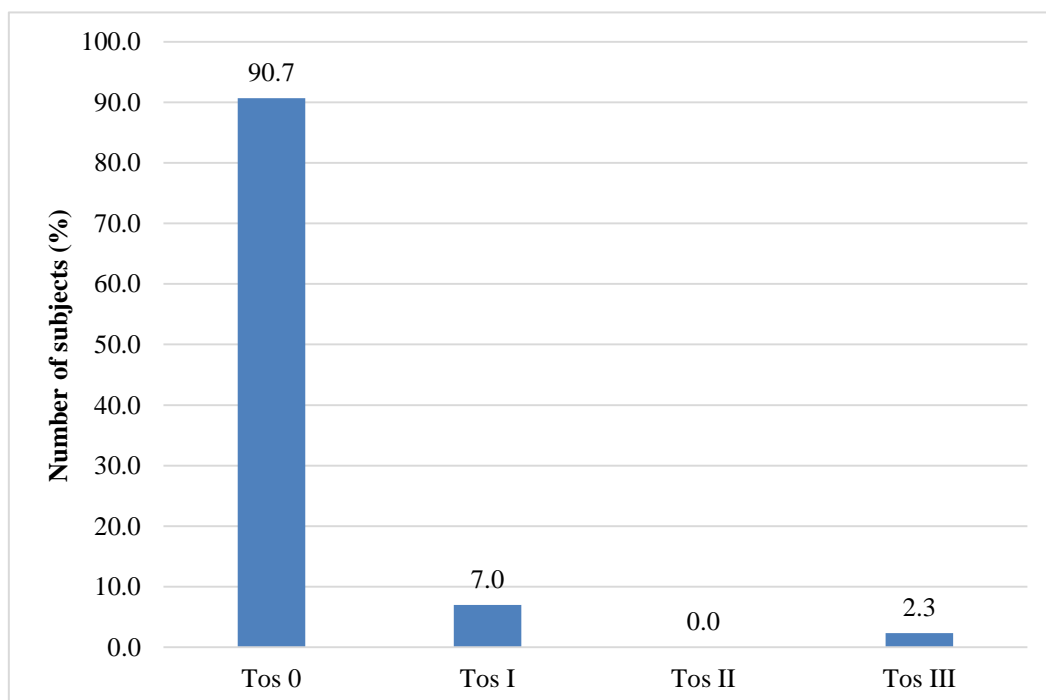
Graph 9: Distribution according to Tos grading in left ear

Table 10: Distribution according to of cleft type and right tympanometry type

Cleft type		Right Tympanometry			Total	p
		Type A	Type B	Type C		
Bilateral complete cleft lip palate	No	2	1	1	4	>0.05
	%	13.3%	5.6%	10.0%	9.3%	
Complete cleft palate	No	4	0	0	4	
	%	26.7%	0.0%	0.0%	9.3%	
Left Complete cleft lip palate	No	6	15	3	24	
	%	40.0%	83.3%	30.0%	55.8%	
Right Complete cleft lip palate	No	3	2	6	11	
	%	20.0%	11.1%	60.0%	25.6%	
Total	No	15	18	10	43	
	%	100.0%	100.0%	100.0%	100.0%	

Distribution according to of cleft type and right tympanometry type showed that out of 15 patients with right tympanometry type A, majority i.e. 40% had left Complete CLP, 26.7% had complete cleft palate, 20% had right complete CLP and 13.3% had bilateral complete CLP. Out of 18 patients with right tympanometry type B, majority i.e. 83.3% had left Complete CLP, 0% had complete cleft palate, 11.1% had right complete CLP and 5.6% had bilateral complete CLP. Out of 10 patients with

right tympanometry type B, majority i.e. 30% had left Complete CLP , 0% had complete cleft palate, 60% had right complete CLP and 10% had bilateral complete CLP. Among all three types of tympanometry, type B is most common and of Left Complete CLP. We observed statistically no significant association between cleft type and right tympanometry type ($p>0.05$).

Graph 10: Distribution according to of cleft type and right tympanometry type

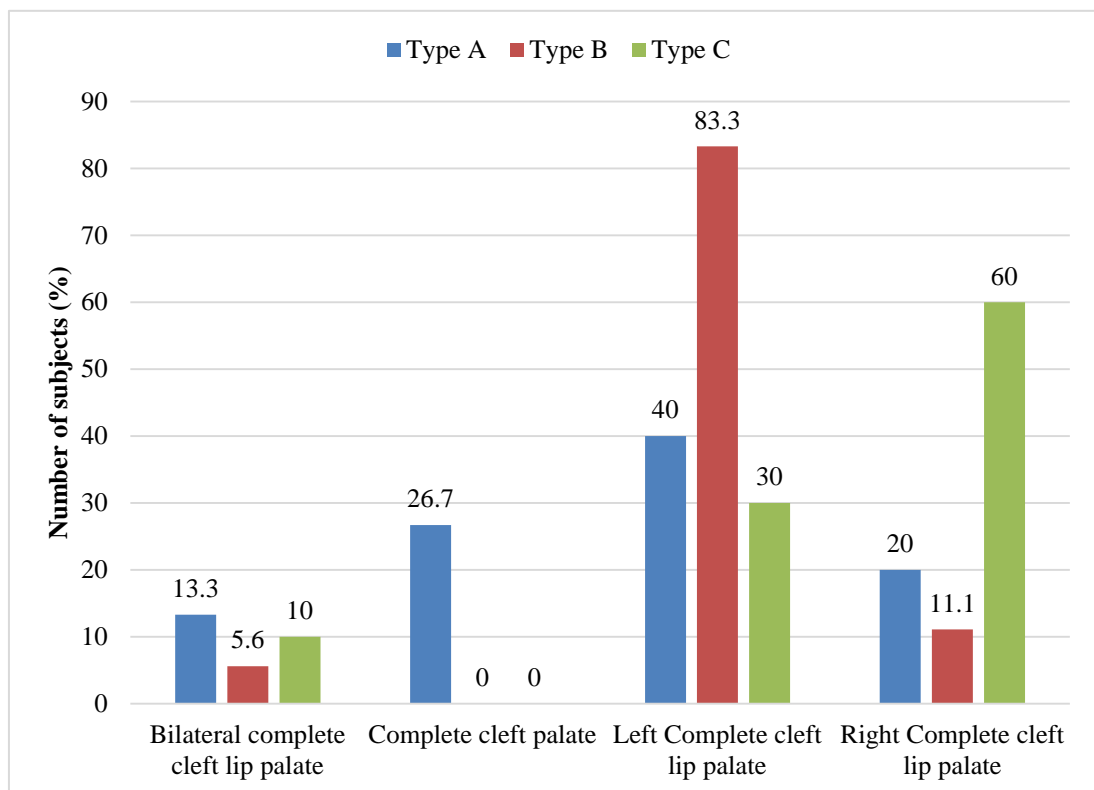


Table 11: Distribution according to of cleft type and left tympanometry type

Cleft type		Left Tympanometry			Total	p
		Type A	Type B	Type C		
Bilateral complete cleft lip palate	No	1	3	0	4	0.189, Not significant
	%	8.3%	14.3%	0.0%	9.3%	
Complete cleft palate	No	3	0	1	4	
	%	25.0%	0.0%	10.0%	9.3%	
Left Complete cleft lip palate	No	5	14	5	24	
	%	41.7%	66.7%	50.0%	55.8%	
Right Complete cleft lip palate	No	3	4	4	11	
	%	25.0%	19.0%	40.0%	25.6%	
Total	No	12	21	10	43	
	%	100.0%	100.0%	100.0%	100.0%	

Distribution according to of cleft type and left tympanometry showed that out of 12 patients with right tympanometry type A, majority i.e. 41.7% had left Complete CLP, 25% each had complete cleft palate and had right complete CLP. 8.3% had bilateral complete CLP. Out of 21 patients with right tympanometry type B, majority i.e. 66.7% had left Complete CLP, 0% had complete cleft palate, 19% had right complete CLP and 14.3% had bilateral complete CLP. Out of 10 patients with right

tympanometry type C, majority i.e. 50% had left Complete CLP, 10% had complete cleft palate, 40% had right complete CLP and 0% had bilateral complete CLP. Among all three types of tympanometry, type B is most common and of Left Complete CLP. We observed statistically no significant association between cleft type and right tympanometry type ($p>0.05$).

Graph 11: Distribution according to of cleft type and left tympanometry type

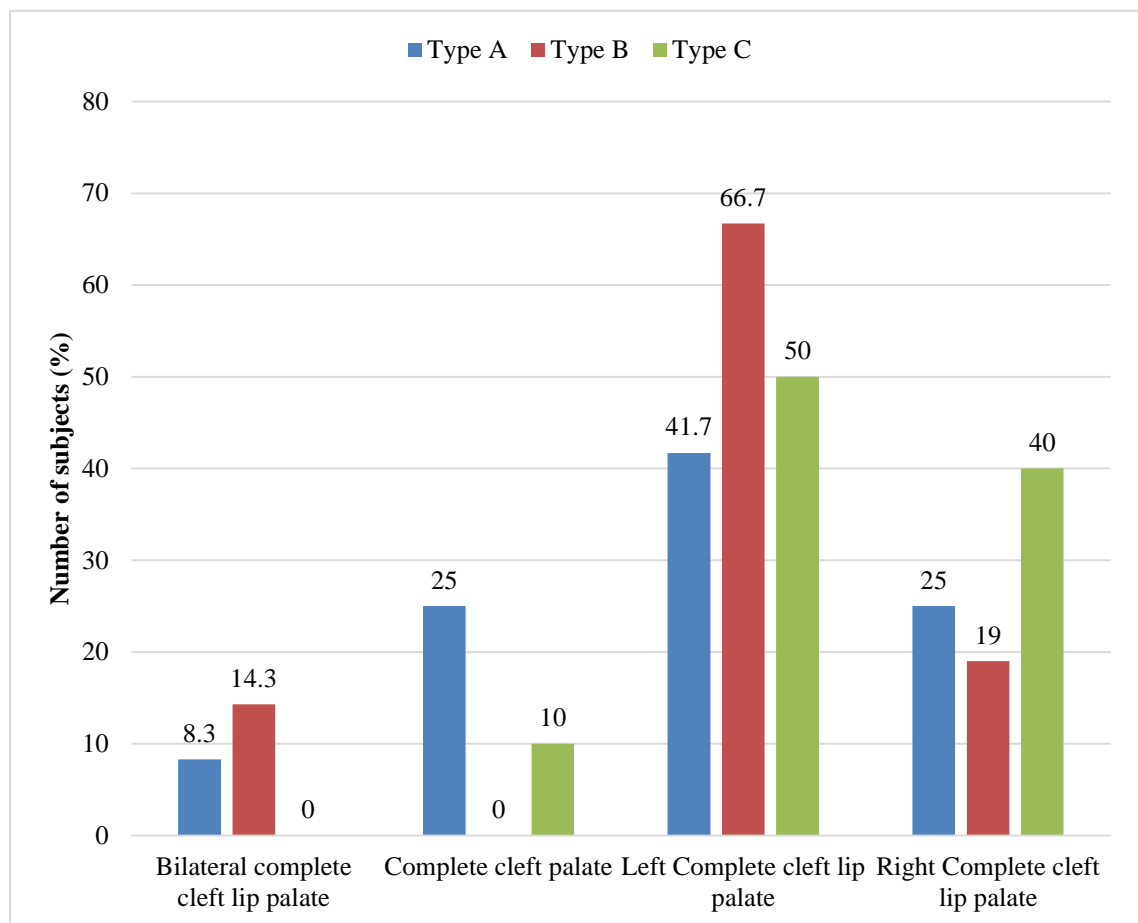


Table 12: Distribution according to of cleft type and right Sade (Pars Tensa)

Cleft type		Right Sade (Pars Tensa)					Total	p
		Sade 0	Sade I	Sade II	Sade III	Sade IV		
Bilateral complete cleft lip palate	No	2	1	1	0	0	4	0.24, Not significant
	%	11.1%	10.0%	9.1%	0.0%	0.0%	9.3%	
Complete cleft palate	No	4	0	0	0	0	4	
	%	22.2%	0.0%	0.0%	0.0%	0.0%	9.3%	
Left Complete cleft lip palate	No	11	5	7	1	0	24	
	%	61.1%	50.0%	63.6%	33.3%	0.0%	55.8%	
Right Complete cleft lip palate	No	1	4	3	2	1	11	
	%	5.6%	40.0%	27.3%	66.7%	100.0%	25.6%	
Total	No	18	10	11	3	1	43	
	%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	

Distribution according to of cleft type and right Sade (Pars Tensa) in our study revealed that majority of the patients in all the grades were having Left complete cleft lip palate i.e. 61.1% had Sade o, 50% with Sade I, 63.6% with Sade II and 33.3% with Sade III. We found statistically no significant difference in the number cases with different grades of right ear Sade (Pars Tensa) in our study ($p>0.05$).

Graph 12: Distribution according to of cleft type and right Sade (Pars Tensa)

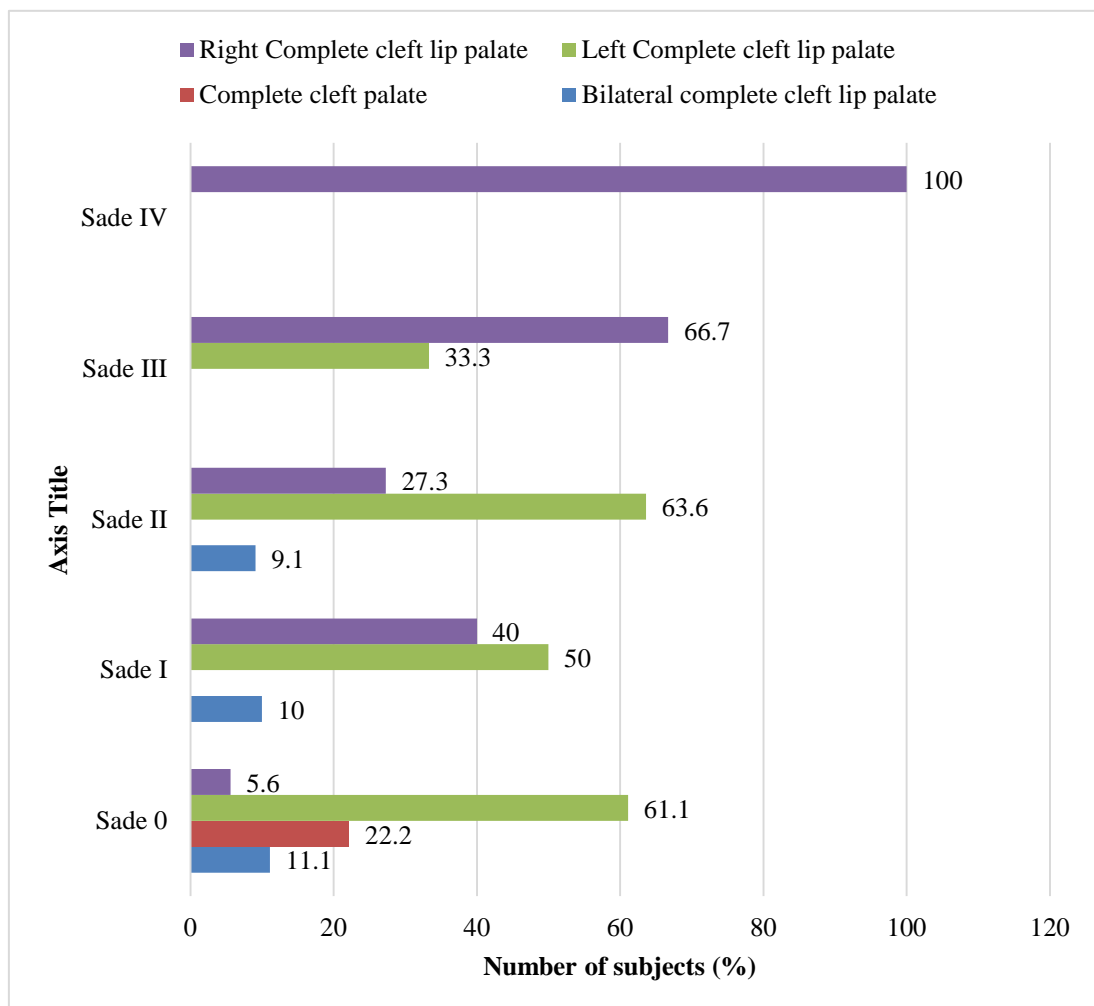


Table 13: Distribution according to of cleft type and left Sade (Pars Tensa)

Cleft type		Left Sade (Pars Tensa)				Total	p
		Sade 0	Sade I	Sade II	Sade III		
Bilateral complete cleft lip palate	No	1	1	2	0	4	0.38, Not significant
	%	7.1%	12.5%	11.8%	0.0%	9.3%	
Complete cleft palate	No	3	0	1	0	4	
	%	21.4%	0.0%	5.9%	0.0%	9.3%	
Left Complete cleft lip palate	No	9	3	10	2	24	
	%	64.3%	37.5%	58.8%	50.0%	55.8%	
Right Complete cleft lip palate	No	1	4	4	2	11	
	%	7.1%	50.0%	23.5%	50.0%	25.6%	
Total	No	14	8	17	4	43	
	%	100.0%	100.0%	100.0%	100.0%	100.0%	

Distribution according to of cleft type and left Sade (Pars Tensa) in our study revealed that majority of the patients in all the grades were having Left complete CLP i.e.64.3% had Sade o, 37.5% with Sade I, 58.8% with Sade II and 50% with Sade III. We found statistically no significant difference in the number cases with different grades of left ear Sade (Pars Tensa) in our study ($p>0.05$).

Graph 13: Distribution according to of cleft type and left Sade (Pars Tensa)

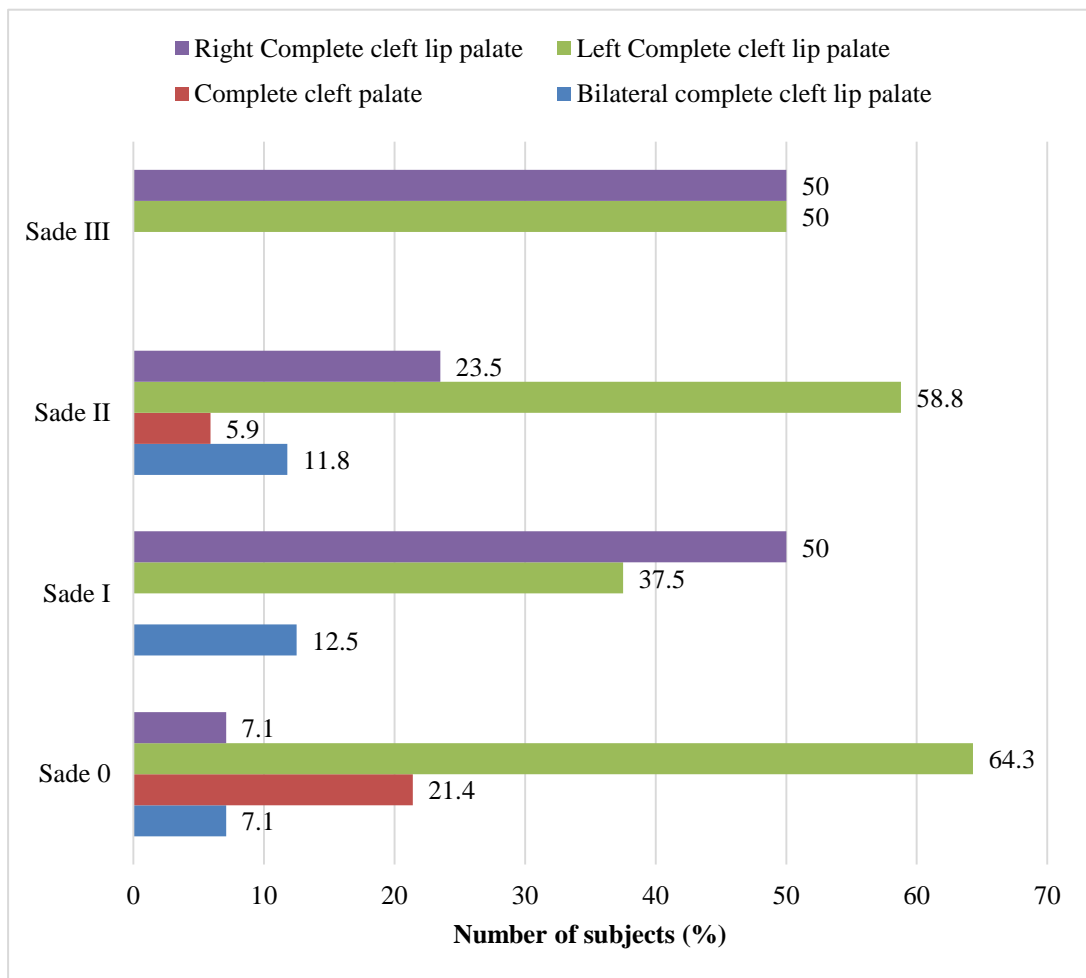


Table 14: Distribution according to of cleft type and Right Tos (Pars Flaccida)

Cleft type		Right Tos (Pars Flaccida)			Total	p
		Tos 0	Tos I	Tos II		
Bilateral complete cleft lip palate	No	4	0	0	4	0.84, Not significant
	%	10.5%	0.0%	0.0%	9.3%	
Complete cleft palate	No	4	0	0	4	
	%	10.5%	0.0%	0.0%	9.3%	
Left Complete cleft lip palate	No	21	2	1	24	
	%	55.3%	50.0%	100.0%	55.8%	
Right Complete cleft lip palate	No	9	2	0	11	
	%	23.7%	50.0%	0.0%	25.6%	
Total	No	38	4	1	43	
	%	100.0%	100.0%	100.0%	100.0%	

Distribution according to of cleft type and right Tos (Pars Flaccida) in our study revealed that majority of the patients in all the grades were having Left complete CLP i.e. 53.3% had Tos 0, 50% with Tos I and 100% with Tos II. We found statistically no significant difference in the number cases with different grades of right ear Tos (Pars Flaccida) in our study ($p>0.05$).

Graph 14: Distribution according to of cleft type and Right Tos (Pars Flaccida)

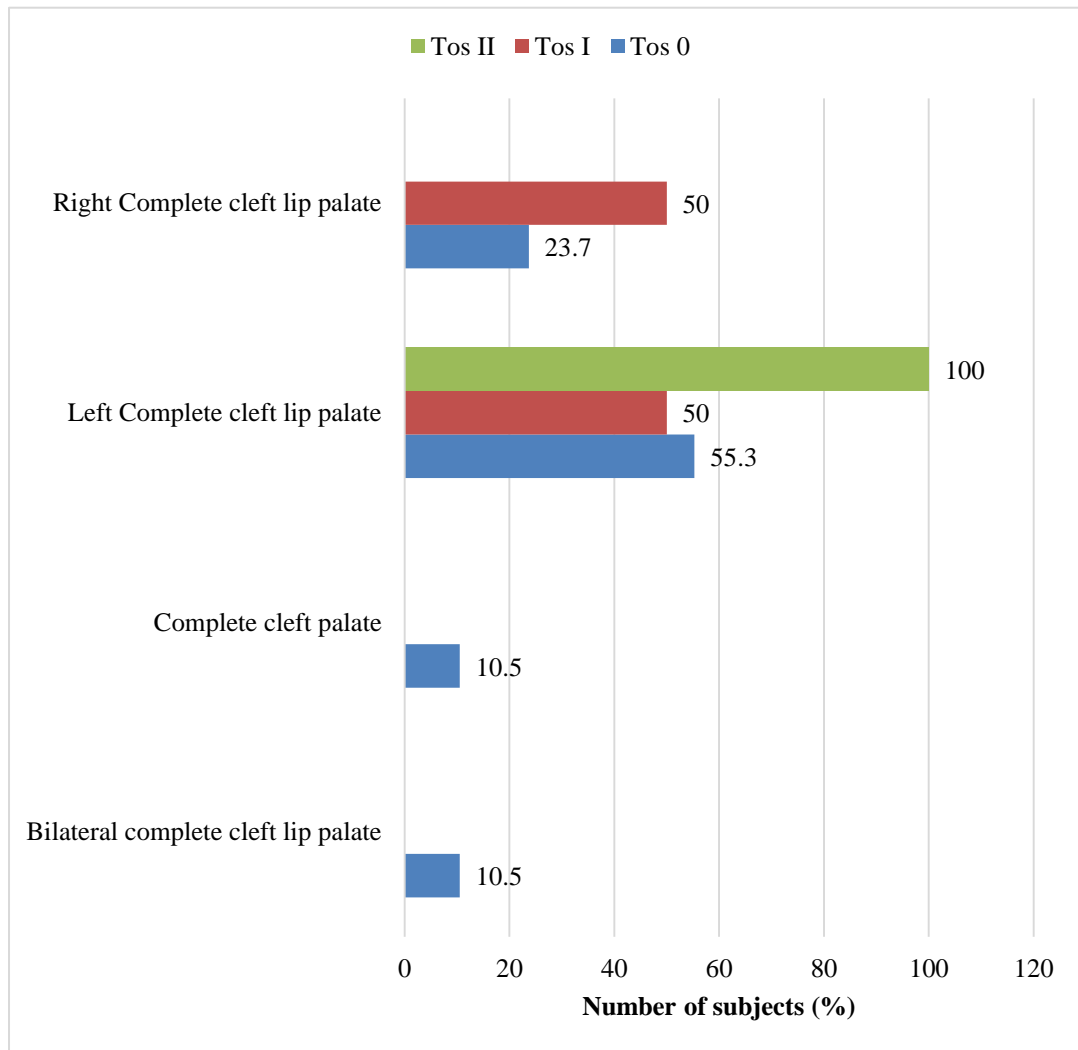


Table 15: Distribution according to cleft type and left Tos (Pars Flaccida)

Cleft type		Left Tos (Pars Flaccida)			Total	p
		Tos 0	Tos I	Tos III		
Bilateral complete cleft lip palate	No	4	0	0	4	0.7, Not significant
	%	10.3%	0.0%	0.0%	9.3%	
Complete cleft palate	No	4	0	0	4	
	%	10.3%	0.0%	0.0%	9.3%	
Left Complete cleft lip palate	No	22	1	1	24	
	%	56.4%	33.3%	100.0%	55.8%	
Right Complete cleft lip palate	No	9	2	0	11	
	%	23.1%	66.7%	0.0%	25.6%	
Total	No	39	3	1	43	
	%	100.0%	100.0%	100.0%	100.0%	

Distribution according to of cleft type and left Tos (Pars Flaccida) in our study revealed that majority of the patients in all the grades were having Left complete CLP i.e. 56.4% had Tos 0, 33.3% with Tos I and 100% with Tos III. We found statistically no significant difference in the number cases with different grades of left ear Tos (Pars Flaccida) in our study ($p>0.05$).

Graph 15: Distribution according to cleft type and left Tos (Pars Flaccida)

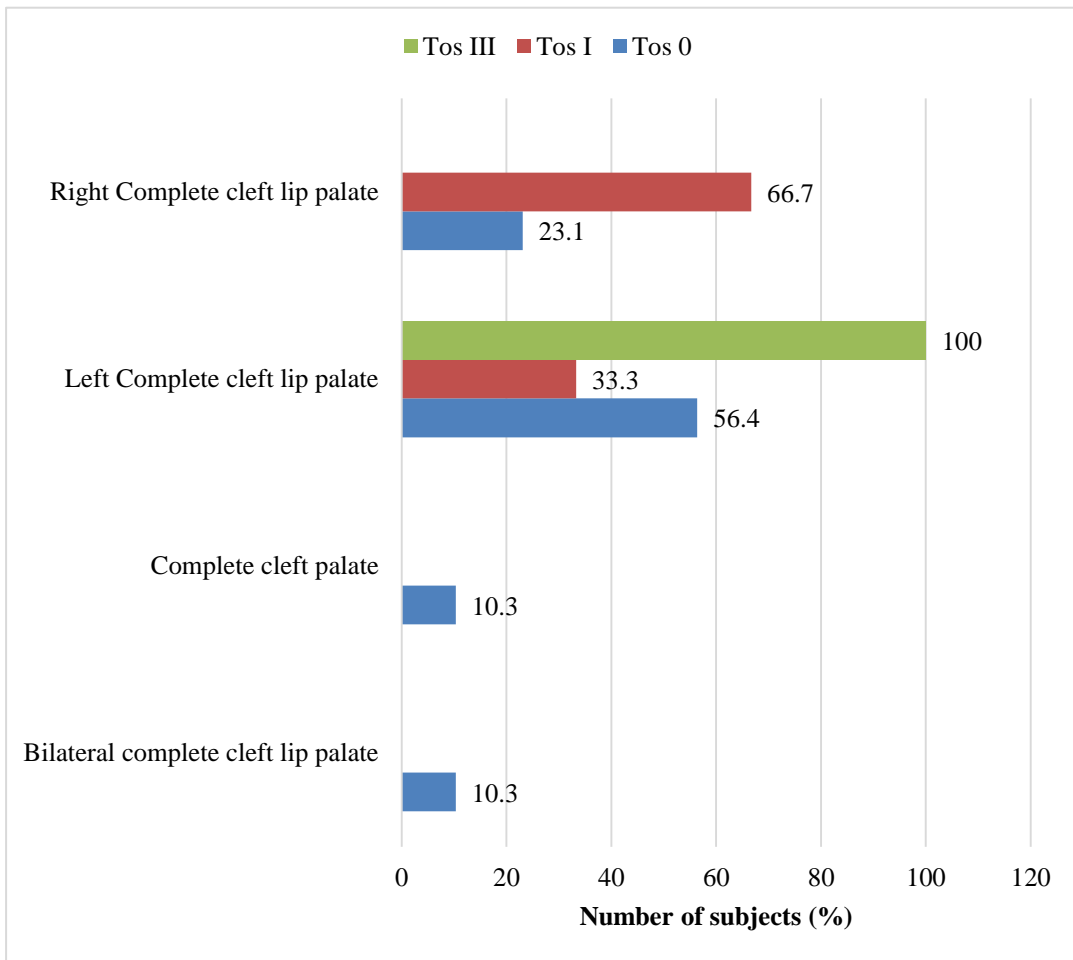


Table 16: Distribution according to right ear audiometry

		N	Mean	Std. Deviation	F	p	Inference
Right Audiometry (dB HL)	Bilateral complete CLP	4	20.50	7.54	2.96	0.093 (>0.05)	Not significant
	Complete cleft palate	4	18.75	2.50			
	Left Complete CLP	24	28.00	8.82			
	Right Complete CLP	11	29.36	9.95			
	Total	43	26.79	9.12			

Distribution according to right ear audiometry assessment showed that in patients with bilateral complete CLP it was 20.50 ± 7.54 , in complete cleft palate 18.75 ± 2.50 , in left complete CLP 28 ± 8.82 and in right complete CLP 29.36 ± 9.95 . We compared the frequency between all the groups and observed that there was no statistically significant difference ($p > 0.05$).

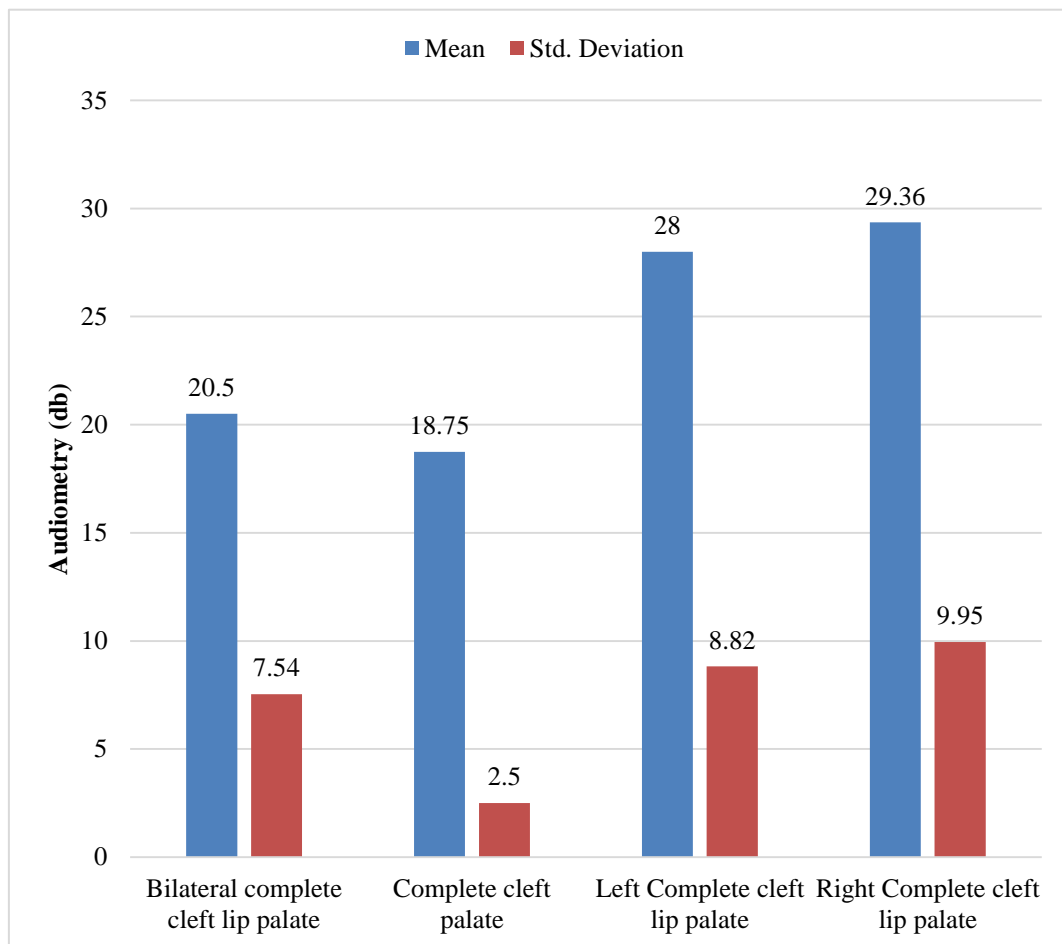
Graph 16: Distribution according to right ear audiometry

Table 17: Distribution according to left ear audiometry

		N	Mean	Std. Deviation	F	p	Inference
Left Audiometry (dB HL)	Bilateral complete cleft lip palate	4	30.25	7.58	1.53	0.22 (>0.05)	Not significant
	Complete cleft palate	4	20.75	9.42			
	Left Complete cleft lip palate	24	30.17	8.63			
	Right Complete cleft lip palate	11	31.81	10.13			
	Total	43	29.72	9.20			

Distribution according to left ear audiometry assessment showed that in patients with bilateral complete CLP it was 30.25 ± 7.58 , in complete cleft palate 20.75 ± 9.42 , in left complete CLP 30.17 ± 8.63 and in right complete CLP 31.81 ± 10.13 . We compared the frequency between all the groups and observed that there was no statistically significant difference ($p > 0.05$).

Graph 17: Distribution according to left ear audiometry

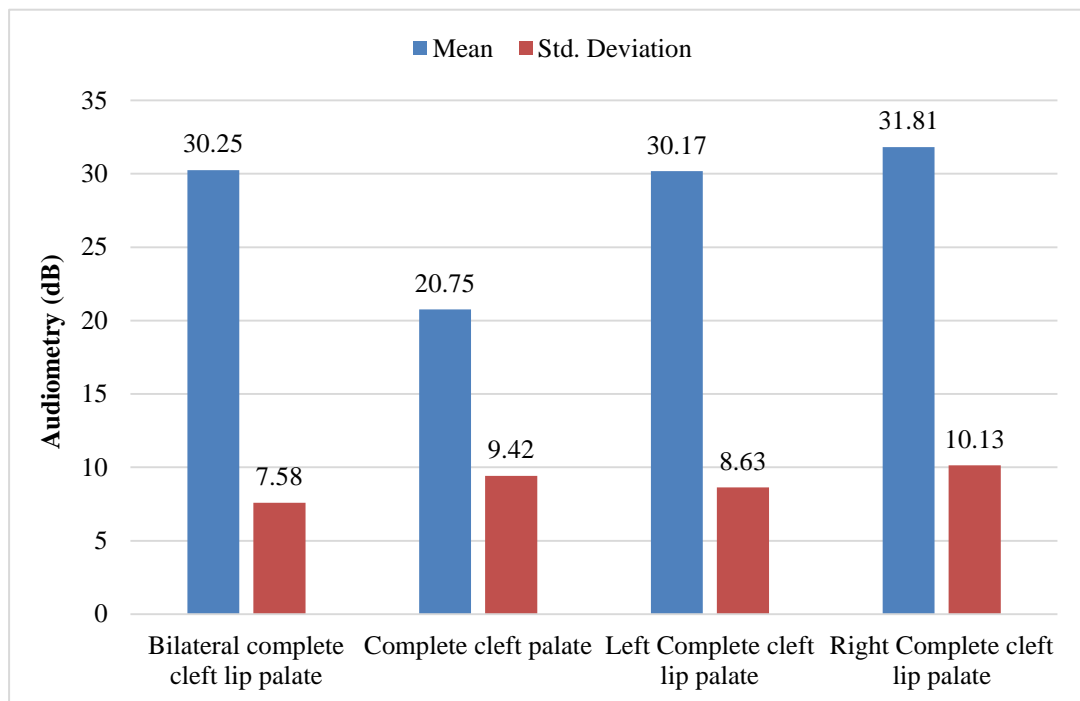


Table 18: Descriptive statistics of the audiometry

	N	Mean	Std. Deviation	Std. Error	Range	Minimum	Maximum
Right Audiometry (dB HL)	43	26.79	9.13	1.39	38.5	10.0	48.5
Left Audiometry (dB HL)	43	29.73	9.20	1.40	40.00	10.00	50.00

Mean right ear audiometry was 26.79 ± 9.13 .

Mean left ear audiometry was 29.73 ± 9.20 .

DISCUSSION

“Children with orofacial clefts often report to the plastic surgery OPD for intervention due to the visible deformity. However, the ear symptoms, are tend to be overlooked in comparison with the noticeable orofacial cleft. Surgical repair of orofacial clefts can produce satisfactory cosmetic results but the problem of otitis media with effusion (OME) persists, causing long-standing hearing loss and can affect linguistic, academic, and personal development.”^{51,52} Abrams et al⁵¹ “found a high prevalence rate of middle ear pathologies (65%) even in adults with orofacial clefts. A poor Eustachian tube (ET) function, leading to reduced middle ear pressure and TM retraction, can also contribute to the increased incidence of acquired cholesteatoma in these children.”⁵¹

Sociodemographic variables

We included total 43 clinically diagnosed all type of cleft palate children between 5-15 years age group. Of these 43 children, majority were from 5-10 years age group i.e. 51.2% and remaining 21 i.e. 48.8% were from 11-15 years age group. Mean age of the study population was 10.06±3.44 years. Majority of the cases were males i.e. 26(60.5%) and 39.5% were females. These findings align with previous studies that suggest a higher incidence of cleft palate among males compared to females (Yanti A. et al³⁴ 2017 ,Agrawal & Panda 2011; Flynn et al 2009).

Cleft types

Distribution according to cleft type revealed as follows: Bilateral complete CLP-9.3%, complete cleft palate-9.3%, Left Complete CLP-55.8% , Right Complete CLP-25.6%. Left Complete CLP is the most common type we encountered in our

study which corroborates with earlier research indicating that left-sided cleft palate is more common than right-sided cleft palate (Sharma et al., 2016). Additionally, bilateral cleft lip and palate were found in 9.3% of participants, consistent with global prevalence rates (Mossey et al., 2009).

Distribution according to type of tympanometry

Distribution according to type of tympanometry in right ear showed that majority had type B i.e. 41.9% followed by 34.9% with type A and remaining 23.3% had type C. Distribution according to type of tympanometry in left ear showed that majority had type B i.e. 48.8% followed by 27.9% with type A and remaining 23.3% had type C. These results are in consistent with previous studies

Yanti A. et al³⁴ reported that, “the proportion of type B and C tympanograms was 85.1% at under five years old and 54.5% above five years.”³⁴

Kalaiarasi R et al³⁶ reported that, “tympanogram was done in 90 children (180 ears), type A curve was seen in 81 ears (45%) followed by type B curve in 65 ears (36.1%).”³⁶

“Handzik et al. showed similar results with tympanogram curves in cleft children. This high rate of the B type curve may be explained due to the presence of MEE. A thorough evaluation by an otolaryngologist should be the standard of care in the management of all children with orofacial clefts. A hearing problem in children with orofacial clefts can subsequently cause speech disorders and further disrupt the learning and development of the child.”⁵⁴

Distribution according to Sade grading

Distribution according to Sade grading in right ear (Pars Tensa) revealed as follows: Sade 0-41.9%, Sade I-23.3%, Sade II-25.6%, Sade III-7.0% and Sade IV-2.3%. Distribution according to Sade grading in left ear (Pars Tensa) revealed as follows: Sade 0-32.6%, Sade I-18.6%, Sade II-39.5%, Sade III-9.3% and Sade IV-0%. The above results are in consistent with the previous studies

Bayoumy AB et al³⁸ reported that, “twenty-two patients (27%) presented with Sade grade I; 29 patients (36%) with Sade grade II, and 30 patients (37%) with Sade grade III.”³⁸

Bayoumy AB et al³⁸ also reported that, “at last visit, 8 patients (10%) had complete resolution of the pars tensa retraction, 16 patients with Sade grade I (20%), and 32 patients (40%) with Sade grade II;25 patients (30%) with Sade grade III.”³⁸

Distribution according to Tos grading

Distribution according to Tos grading in right ear (Pars Flaccida) revealed as follows: Tos 0- 88.4%, Tos I-9.3%, Tos II-2.3% and Tos III-0.0%. Distribution according to Tos grading in left ear (Pars Flaccida) revealed as follows: Tos 0- 90.7%, Tos I-7%, Tos II-0% and Tos III-2.3%.

Parkes W. et al³⁵ in their study of “children at risk for persistent eustachian tube dysfunction from cleft palate showed, most TM retractions remained stable or improved over time. The overall incidence of cholesteatoma development in children with cleft palate with TM retraction was 2.6% over the 8.5-year period, which was predominantly during the teenage years.”³⁵

Bayoumy AB et al³⁸ reported that, “78 out of 81 (96%) ears had either improved or stable retractions (80%) based on otoendoscopy. Thirteen ears (16%) had complete resolution (10%) or improvement of the staging of retraction on otoendoscopy (6%). Three patients (4%) had worsened outcomes on otoendoscopy.”³⁸

Sade et al⁴⁶ described, “308 ears (215 patients) with different types of tympanic membrane retractions who were followed up for average 37 months (range: 12–108 mo). Sixty-eight retractions were found in pars tensa, of which 50 were described as large. Only 1 of the 50 large retractions (2%) progressed into cholesteatoma (average follow-up 34 mo). This is in comparison with our study results; progression to cholesteatoma occurred in one patient (1%).”⁴⁶

Distribution according to of cleft type and tympanometry

In our study distribution according to type of cleft and right tympanometry type, showed that out of 15 patients with right tympanometry type A, majority i.e. 40% had left Complete CLP, 26.7% had complete cleft palate, 20% had right complete CLP and 13.3% had bilateral complete CLP. Out of 18 patients with right tympanometry type B, majority i.e. 83.3% had left Complete CLP, 0% had complete cleft palate, 11.1% had right complete CLP and 5.6% had bilateral complete CLP. Out of 10 patients with right tympanometry type c, majority i.e. 30% had left Complete CLP, 0% had complete cleft palate, 60% had right complete CLP and 10% had bilateral complete CLP. Among all three types of tympanometry, type B is most common and of Left Complete CLP. We observed no statistically significant association between cleft type and right tympanometry type ($p>0.05$).

In our study distribution according to of cleft type and left tympanometry showed that out of 12 patients with right tympanometry type A, majority i.e. 41.7% had left Complete CLP, 25% each had complete cleft palate and had right complete CLP. 8.3% had bilateral complete CLP. Out of 21 patients with right tympanometry type B, majority i.e. 66.7% had left Complete CLP, 0% had complete cleft palate, 19% had right complete CLP and 14.3% had bilateral complete CLP. Out of 10 patients with right tympanometry type C, majority i.e. 50% had left Complete CLP, 10% had complete cleft palate, 40% had right complete CLP and 0% had bilateral complete CLP. Among all three types of tympanometry, type B is most common and of Left Complete CLP. We observed statistically no significant association between cleft type and right tympanometry type ($p>0.05$).

Yanti A. et al³⁴ reported that, “there was no association between initial retraction severity and worsening appearance or hearing loss. There were no significant associations between the presence of clinically relevant features assessed (promontory contact, incus contact, stapes contact, depth of retraction out of sight, and accumulation of keratin medial to the annulus) and deterioration of the overall tensa appearance or hearing.”³⁴

Kalaiarasi R et al³⁶ in their study reported that, “the most common ear finding noted was a dull TM that was seen in 48.95%. Normal ear findings were seen in 51%. Out of 73 children in the zero to five age group, 79.5% children did not have any history of ear problem but 55.5% had features of Middle Ear Effusion like a dull TM. In the age group more than five years to 10 years, 28.5% children were symptomatic. 55.5% children out of nine in the age group more than 10 years had symptomatic ear problem of which 44.4% children had chronic otitis media squamosal disease.”³⁶

Audiometry findings

In our study audiometry findings revealed that mean right ear audiometry was 26.79 ± 9.13 . Also, the mean left ear audiometry was 29.73 ± 9.20 .

Kalaiarasi R et al³⁶ in their study reported that, “out of 144 ears (72 children) in the asymptomatic group, 67 ears (46.5%) had normal hearing. A total of 77 ears (53.5%) had some degree of hearing loss. The mean air conduction hearing loss in the asymptomatic group was 29.8 ± 7.3 dB.”³⁶

Bayoumy AB et al³⁸ reported that, “the mean air bone gap at first and last visits in all patients was respectively 17.9dB (SD 11.3) and 15.5dB (SD 12.1). The difference between the air bone gap at first and last visits was ± 2.4 dB (SD 12.1). This difference was not considered statistically significant ($p > 0.08$, paired T test).”³⁸

Zanzi M et al⁵⁵ study on 18 children with cleft palates; “it also showed that the impedance tympanogram and PTA results were normal in only in 22% and 27.8% of patients, respectively.”⁵⁵

“Children with cleft palates may suffer recurrent or continuous OME, causing atelectasis, ossicular fixation, and tympanosclerosis, which can result in conductive hearing loss of up to 30 dB.”^{56,57} **Luthra et al**⁵⁸ found that, “the air conduction thresholds ranged from 20.37 dB to 28.89 dB in orofacial cleft children. The associated hearing loss was mild and did not show much variation between the different age groups.”⁵⁸

Distribution according to of cleft type and Side (Pars Tensa)

Distribution according to of cleft type and right Side (Pars Tensa) in our study revealed that majority of the patients in all the grades were having Left complete CLP

i.e. 61.1% had Sade 0, 50% with Sade I, 63.6% with Sade II and 33.3% with Sade III. We found statistically no significant difference in the number cases with different grades of right ear Sade (Pars Tensa) in our study ($p>0.05$).

Distribution according to of cleft type and left Sade (Pars Tensa) in our study revealed that majority of the patients in all the grades were having Left complete CLP i.e. 64.3% had Sade 0, 37.5% with Sade I, 58.8% with Sade II and 50% with Sade III. We found statistically no significant difference in the number cases with different grades of left ear Sade (Pars Tensa) in our study ($p>0.05$).

Distribution according to of cleft type and right Tos (Pars Flaccida) in our study revealed that majority of the patients in all the grades were having Left complete CLP i.e. 53.3% had Tos 0, 50% with Tos I and 100% with Tos II. We found statistically no significant difference in the number cases with different grades of right ear Tos (Pars Flaccida) in our study ($p>0.05$).

Distribution according to of cleft type and left Tos (Pars Flaccida) in our study revealed that majority of the patients in all the grades were having Left complete CLP i.e. 56.4% had Tos 0, 33.3% with Tos I and 100% with Tos III. We found statistically no significant difference in the number cases with different grades of left ear Tos (Pars Flaccida) in our study ($p>0.05$).

Distribution according to right ear audiometry assessment showed that in patients with bilateral complete CLP it was 20.50 ± 7.54 , in complete cleft palate 18.75 ± 2.50 , in left complete CLP 28 ± 8.82 and in right complete CLP 29.36 ± 9.95 . We compared the frequency between all the groups and observed that there was no statistically significant difference ($p>0.05$).

Distribution according to left ear audiometry assessment showed that in patients with bilateral complete CLP it was 30.25 ± 7.58 , in complete cleft palate 20.75 ± 9.42 , in left complete CLP 30.17 ± 8.63 and in right complete CLP 31.81 ± 10.13 . We compared the frequency between all the groups and observed that there was no statistically significant difference ($p > 0.05$).

Kalaiarasi R et al³⁶ in their study found that, “children with an isolated cleft palate and a cleft lip with palate had a higher incidence of ear problems in comparison to children with an isolated cleft lip. A higher incidence and an increase in the severity of middle ear disease may be anticipated in children with more overt palatal malformations. In our study, symptomatic ear problems were seen in only the cleft of the palate alone (group II orofacial cleft) and the cleft lip and palate (group III cleft). The more severe the orofacial cleft, the more the children have symptomatic ear problems and abnormal ear findings on examination.”³⁶

Similarly, **Sheahan et al**⁶⁰ reported “the high prevalence (60%) of middle ear problems in subjects with different types of cleft palates with or without cleft lips compared with just 8% in patients with isolated cleft lips/alveoli.”⁶⁰ This assumption is supported by the study of Schwartz et al. “who reported that children with only minimal notching or a terminal slit were at a lower risk of developing otitis media than those with a severe cleft during the first year of life, emphasizing the importance of cleft severity.”⁶¹ “However, some studies show no obvious relationship between the degree of clefting and otologic outcomes, including the incidence of hearing loss, the prevalence of otitis media, and the incidence of TM retraction and perforation.”^{61,62}

CONCLUSION

Type B was most commonly observed findings of tympanometry in our study. Mean right ear audiometry was 26.79 ± 9.13 . Mean left ear audiometry was 29.73 ± 9.20 . Distribution according to Sade grading in right ear (Pars Tensa) revealed as follows: Sade 0-41.9%, Sade I-23.3%, Sade II-25.6%, Sade III-7.0% and Sade IV-2.3%. Distribution according to Sade grading in left ear (Pars Tensa) revealed as follows: Sade 0-32.6%, Sade I-18.6%, Sade II-39.5%, Sade III-9.3% and Sade IV-0%. Distribution according to Tos grading in right ear (Pars Flaccida) revealed as follows: Tos 0- 88.4%, Tos I-9.3%, Tos II-2.3% and Tos III-0.0%. Distribution according to Tos grading in left ear (Pars Flaccida) revealed as follows: Tos 0- 90.7%, Tos I-7%, Tos II-0% and Tos III-2.3%. We observed no statistically significant association between cleft type and right as well as left tympanometry type ($p > 0.05$). We found statistically no significant difference in the number cases with different grades of right ear Sade as well as left ear (Pars Tensa) in our study ($p > 0.05$).

Regular endoscopic and audiological monitoring and early intervention at crucial time is required to prevent long-term auditory deficits in children with cleft palate. Thus a regular evaluation is a must for proper development of speech and academic progression of the child. Thus our study also emphasizes on the importance of multidisciplinary care, involving otolaryngologists, audiologists, and speech therapists, to optimize hearing outcomes and quality of life of child. Further studies with a larger sample size and longitudinal follow-up is recommended to better understand the progression of middle ear pathology in children with cleft palate.

SUMMARY

The present study done in 43 children with cleft palate who approached to Plastic Surgery and ENT and HNS OPD. The objective of our study was to assess the functional status of middle ear in children with cleft palate and also to assess the grade of retraction of tympanic membrane in children with cleft palate using Sade and Tos classification.

The results of our study are summarized as follows:

We included total 43 clinically diagnosed all type of cleft palate children between 5-15 years age group. Of these 43 children, majority were from 5-10 years age group i.e. 51.2% and remaining 21 i.e. 48.8% were from 11-15 years age group. Mean age of the study population was 10.06 ± 3.44 years. Majority of the cases were males i.e. 26(60.5%) and 39.5% were females. Distribution according to cleft type revealed as follows: bilateral complete cleft lip palate-9.3%, complete cleft palate-9.3%, left Complete cleft lip palate-55.8%, right Complete cleft lip palate-25.6%.

Distribution according to type of tympanometry in right ear showed that majority had type B i.e. 41.9% followed by 34.9% with type A and remaining 23.3% had type C. Distribution according to type of tympanometry in left ear showed that majority had type B i.e. 48.8% followed by 27.9% with type A and remaining 23.3% had type C.

Distribution according to Sade grading in right ear (Pars Tensa) revealed as follows: Sade 0-41.9%, Sade I-23.3%, Sade II-25.6%, Sade III-7.0% and Sade IV-2.3%. Distribution according to Sade grading in left ear (Pars Tensa) revealed as follows: Sade 0-32.6%, Sade I-18.6%, Sade II-39.5%, Sade III-9.3% and Sade IV-

0%. Distribution according to Tos grading in right ear (Pars Flaccida) revealed as follows: Tos 0- 88.4%, Tos I-9.3%, Tos II-2.3% and Tos III-0.0%. Distribution according to Tos grading in left ear (Pars Flaccida) revealed as follows: Tos 0- 90.7%, Tos I-7%, Tos II-0% and Tos III-2.3%.

Distribution according to of cleft type and right tympanometry type showed that out of 15 patients with right tympanometry type A, majority i.e. 40% had left Complete cleft lip palate, 26.7% had complete cleft palate, 20% had right complete cleft lip palate and 13.3% had bilateral complete cleft lip palate. Out of 18 patients with right tympanometry type B, majority i.e. 83.3% had left Complete cleft lip palate, 0% had complete cleft palate, 11.1% had right complete cleft lip palate and 5.6% had bilateral complete cleft lip palate. Out of 10 patients with right tympanometry type B, majority i.e. 30% had left Complete cleft lip palate, 0% had complete cleft palate, 60% had right complete cleft lip palate and 10% had bilateral complete cleft lip palate. Among all three types of tympanometry, type B is most common and of Left Complete cleft lip palate. We observed no statistically significant association between cleft type and right tympanometry type ($p > 0.05$).

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all three types of tympanometry, type B is most common and of Left Complete cleft lip palate. We observed statistically no significant association between cleft type and left tympanometry type ($p>0.05$).

Distribution according to of cleft type and right Sade (Pars Tensa) in our study revealed that majority of the patients in all the grades were having Left complete cleft lip palate i.e. 61.1% had Sade 0, 50% with Sade I, 63.6% with Sade II and 33.3% with Sade III. We found statistically no significant difference in the number cases with different grades of right ear Sade (Pars Tensa) in our study ($p>0.05$).

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Distribution according to of cleft type and right Tos (Pars Flaccida) in our study revealed that majority of the patients in all the grades were having Left complete cleft lip palate i.e. 53.3% had Tos 0, 50% with Tos I and 100% with Tos II. We found statistically no significant difference in the number cases with different grades of right ear Tos (Pars Flaccida) in our study ($p>0.05$).

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Distribution according to right ear audiometry assessment showed that in patients with bilateral complete cleft lip palate it was 20.50 ± 7.54 , in complete cleft palate 18.75 ± 2.50 , in left complete cleft lip palate 28 ± 8.82 and in right complete cleft lip palate 29.36 ± 9.95 . We compared the frequency between all the groups and observed that there was no statistically significant difference ($p > 0.05$).

Distribution according to left ear audiometry assessment showed that in patients with bilateral complete cleft lip palate it was 30.25 ± 7.58 , in complete cleft palate 20.75 ± 9.42 , in left complete cleft lip palate 30.17 ± 8.63 and in right complete cleft lip palate 31.81 ± 10.13 . We compared the frequency between all the groups and observed that there was no statistically significant difference ($p > 0.05$). Mean right ear audiometry was 26.79 ± 9.13 . Mean left ear audiometry was 29.73 ± 9.20 .

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ANNEXURES

ANNEXURE – I - INFORMED CONSENT FORM

Endoscopic assessment of tympanic membrane and Audiological evaluation of Middle ear function in children with Cleft palate - A one year cross sectional study.

Name of Student/Principal Investigator: -----

Name of Guide/Co Investigators: -----

Introduction: The present study will be done among patient with cleft palate, attending outpatient department of Plastic Surgery and ENT and HNS department in KLES Dr. Prabhakar Kore charitable Hospital, Belagavi and they will be investigated for Otoendoscopy, Puretone Audiometry and tympanometry. You're requested to participate in the study and your participation is completely Voluntary.

Explanation of procedure: If you agree to participate in this study, the relevant data will be collected as per proforma, and final diagnosis will be confirmed. After getting inducted in the study, you will be evaluated for retraction of tympanic membrane and middle ear function with Otoendoscopy, Pure tone Audiometry and tympanometry.

Withdrawal from participation in the study: Participation in this study in voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not get any benefits by participating in this study. The data gathered will help population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person to identify you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Cost of investigations done during study will be paid by the **principal investigator / Participant.**

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purpose and or presented to scientific groups. However, your identity will never be revealed.

Questions: If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waiving any of your legal rights.

ASSENT FORM (ENGLISH)

Endoscopic assessment of tympanic membrane and Audiological evaluation of Middle ear function in children with Cleft palate -A one year cross sectional study.

Name of Student/Principal Investigator: -

Name of Guide/Co Investigators: -

Objective - To assess the functional status of middle ear in children with cleft palate.

To assess the grade of retraction of tympanic membrane in children with cleft palate using Sade and Tos classification

I have been told that my parents (mom or dad) have said it's okay (or, have given permission) for me to participate, if I want to, in a project about _____.

I know that I can stop at any time I want to and it will be okay if I want to stop.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the guardian:

Signature or left thumb impression of the guardian:

Name of the investigator:

Signature of the investigator:

ANNEXURE II

PROFORMA

Endoscopic assessment of tympanic membrane and Audiological evaluation of Middle ear function in children with Cleft palate - A one year cross sectional study in KLES Dr. Prabhakar Kore Hospital, Belagavi.

Date:

Name of participant:

Age:

OP/IP no:

Sex:

Date of assessment:

Address:

Date of discharge:

Name of Parent/Guardian:

Relation:

CLINICAL PROFILE:

Chief Complaints:

History of Presenting Illness:

Past History:

Personal History:

Family History:

Treatment history:

I) General Physical Examination -

Built:

Nourishment:

Vitals:

Temperature:

Pulse rate:

Blood Pressure:

Respiratory Rate:

Pallor/Icterus/Clubbing/Cyanosis/Lymphadenopathy/Oedema

ENT Examination

1) NOSE EXAMINATION

External appearance:

Cold spatula test:

On tip elevation:

Anterior Rhinoscopy:

ANTERIOR RHINOSCOPY



Posterior Rhinoscopy:

POSTERIOR RHINOSCOPY

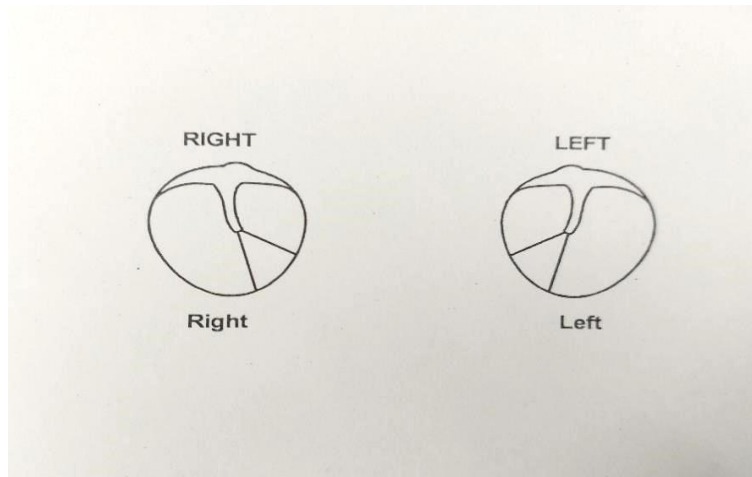


Paranasal Sinus Examination:

2) EAR EXAMINATION

External ear -

Tympanic membrane



TUNING FORK TESTS:

		RIGHT	LEFT
Rinne's test	256 Hz		
	512 Hz		
	1024 Hz		
Weber's test:			
Absolute Bone Conduction test:			

FACIAL NERVE EXAMINATION:

VESTIBULAR FUNCTION:

3) THROAT EXAMINATION:

Oral cavity:

Oropharynx: -

NECK EXAMINATION:

DIAGNOSIS:

Otoendoscopic pictures -	Right	Left
Tympanometry -	Right	Left
Audiometry -	Right	Left

ANNEXURE III PHOTOGRAPHS

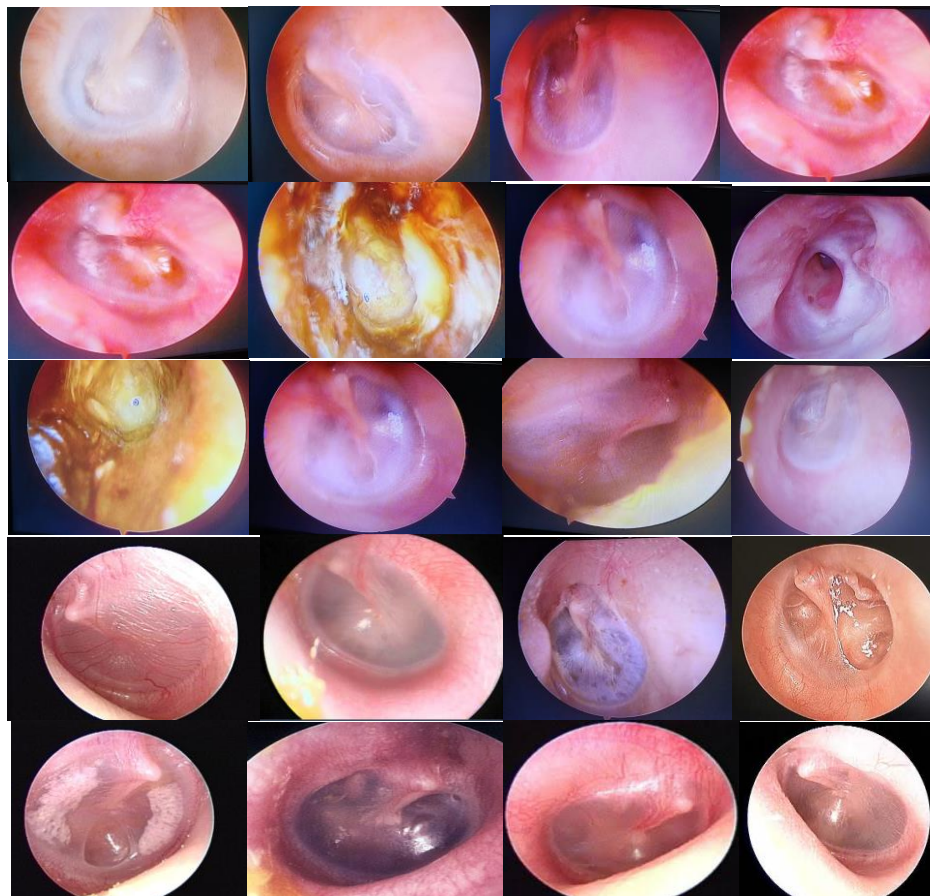


Photo 1 – Otoendoscopic images of Tympanic Membrane

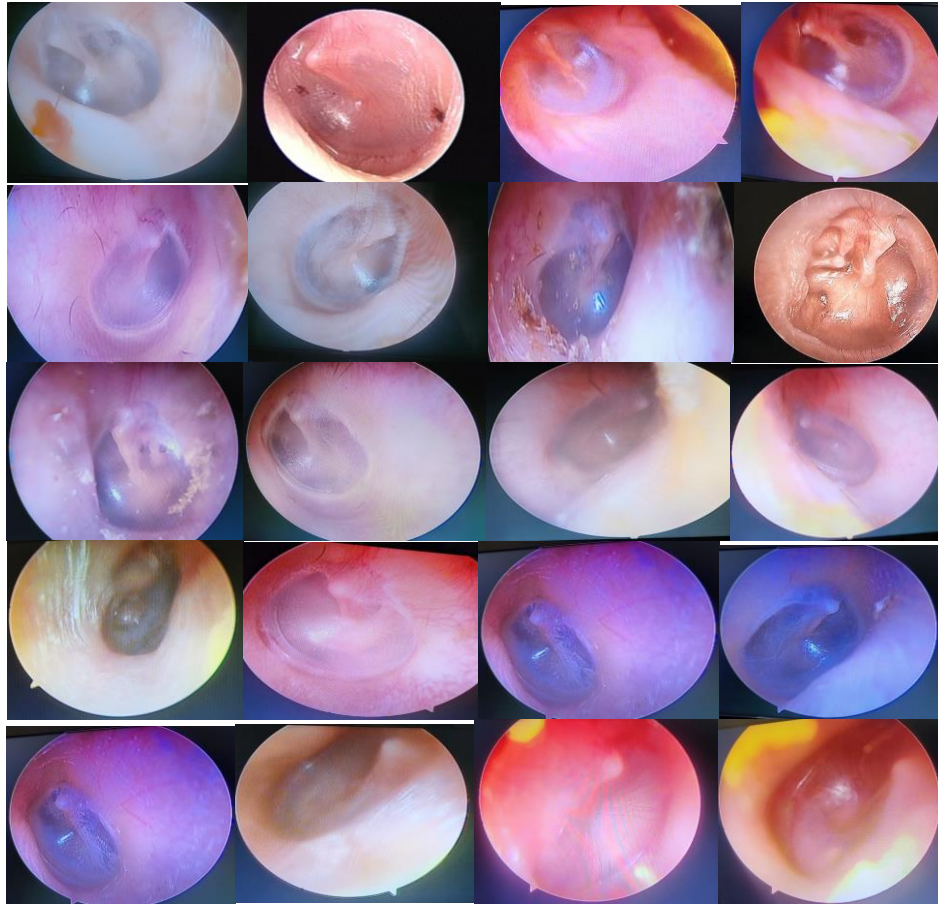


Photo 2 – Otoendoscopic images of Tympanic Membrane

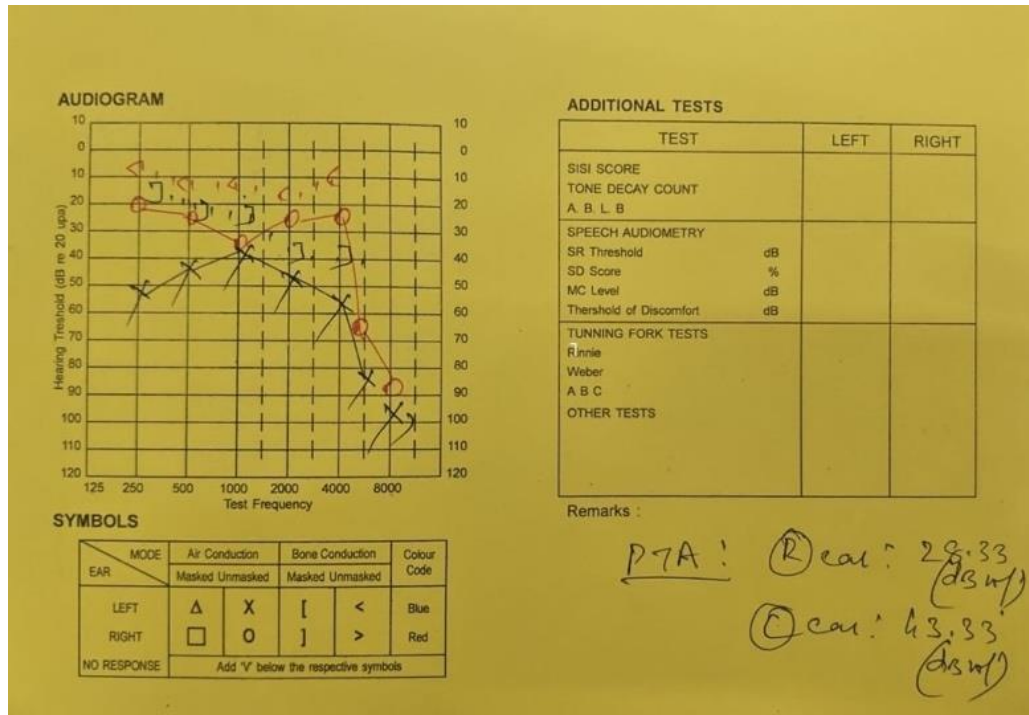


Photo 3 – Pure Tone Audiometry Image

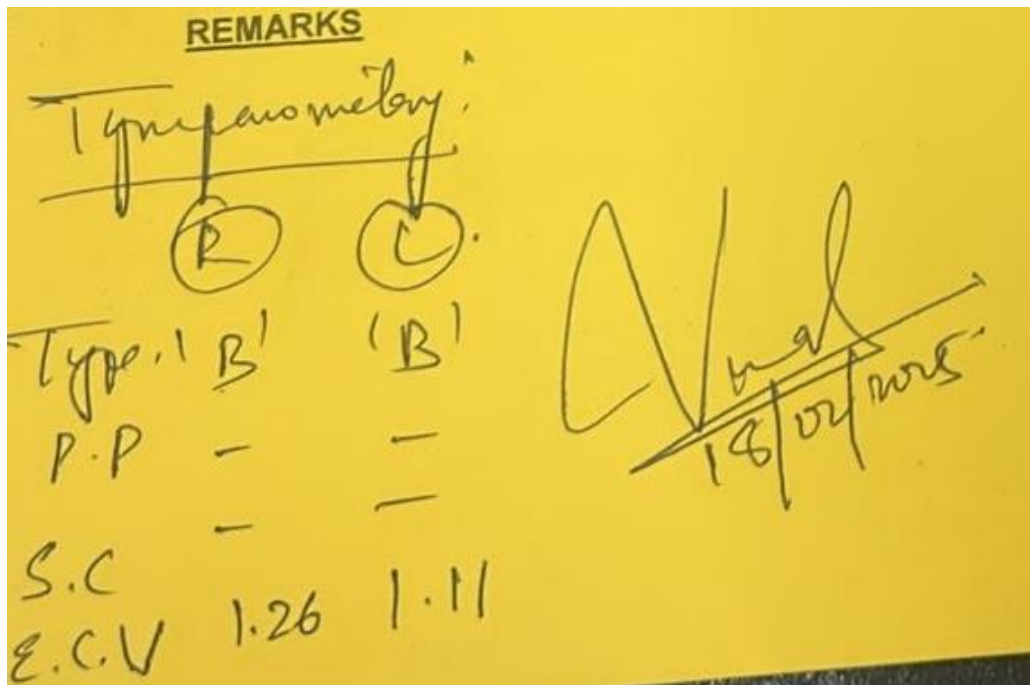


Photo 4 – Tympanometry image

ANNEXURE IV MASTER CHART

Patient ID	Age	Gender	Cleft Type	Right Audiometry (dB HL)	Left Audiometry (dB HL)	Right Tympanometry	Left Tympanometry	Right Sade (Pars Tensa)	Left Sade (Pars Tensa)	Right Tos (Pars Flaccida)	Left Tos (Pars Flaccida)
7165840	15	Female	Right Complete cleft lip palate	25	30	Type B	Type B	Sade I	Sade I	Tos 0	Tos 0
1206192	7	Male	Right Complete cleft lip palate	45	40	Type C	Type C	Sade III	Sade III	Tos I	Tos I
1204152	13	Female	Right Complete cleft lip palate	20	20	Type A	Type A	Sade I	Sade II	Tos 0	Tos 0
1204157	13	Male	Right Complete cleft lip palate	20	25	Type B	Type B	Sade I	Sade II	Tos 0	Tos 0
7131056	15	Male	Left Complete cleft lip palate	48.5	26.66	Type B	Type C	Sade II	Sade III	Tos I	Tos I
10009684	12	Female	Right Complete cleft lip palate	20	50	Type A	Type B	Sade I	Sade I	Tos 0	Tos 0
10009422	12	Male	Right Complete cleft lip palate	45	42	Type C	Type C	Sade Iv	Sade III	Tos I	Tos I
10009642	5	Male	Left Complete cleft lip palate	25	30	Type B	Type B	Sade I	Sade 0	Tos 0	Tos 0
10009514	6	Female	Left Complete cleft lip palate	30	33.3	Type B	Type B	Sade I	Sade II	Tos 0	Tos 0
10009513	15	Female	Left Complete cleft lip palate	25	32	Type B	Type C	Sade 0	Sade II	Tos 0	Tos 0
10009735	14	Female	Left Complete cleft lip palate	20	20	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
10009370	6	Female	Bilateral complete cleft lip palate	26	36	Type C	Type B	Sade II	Sade I	Tos 0	Tos 0
4293508	6	Male	Left Complete cleft lip palate	33	38	Type B	Type B	Sade 0	Sade 0	Tos 0	Tos 0
772744	8	Male	Left Complete cleft lip palate	35	35	Type B	Type B	Sade II	Sade II	Tos 0	Tos 0
10036285	8	Male	Bilateral complete cleft lip palate	20	20	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
10036315	12	Female	Bilateral complete cleft lip palate	26	29	Type B	Type B	Sade I	Sade II	Tos 0	Tos 0
10036828	15	Male	Left Complete cleft lip palate	20	20	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
10038660	14	Male	Left Complete cleft lip palate	33	30	Type B	Type B	Sade 0	Sade I	Tos 0	Tos 0
1161957	5	Male	Left complete cleft lip palate	26	20	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
1200959	12	Male	Left Complete cleft lip palate	26	36	Type B	Type B	Sade I	Sade I	Tos 0	Tos 0
1172835	13	Male	Right Complete cleft palate	20	20	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
1177668	8	Male	Right Complete cleft palate	20	33	Type A	Type C	Sade 0	Sade II	Tos 0	Tos 0
1179625	7	Male	Left Complete cleft lip palate	20	10	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
1181284	9	Female	Left Complete cleft lip palate	33	33	Type B	Type B	Sade 0	Sade 0	Tos 0	Tos 0
1181150	7	Male	Left Complete cleft lip palate	42	36	Type B	Type B	Sade II	Sade II	Tos 0	Tos 0
10024847	13	Male	Complete cleft lip palate	38	29	Type C	Type B	Sade II	Sade I	Tos 0	Tos 0
10021002	12	Female	Left Complete cleft lip palate	26.6	26	Type B	Type B	Sade I	Sade I	Tos 0	Tos 0
10020799	11	Female	Right Complete cleft lip palate	28	23	Type C	Type A	Sade II	Sade I	Tos 0	Tos 0
1195214	7	Female	complete cleft lip palate	20	20	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
793248	15	Female	Bilateral complete cleft lip palate	10	36	Type A	Type B	Sade 0	Sade II	Tos 0	Tos 0
5190434	5	Female	Right Complete cleft lip palate	26	29	Type C	Type C	Sade II	Sade II	Tos 0	Tos 0
1164941	5	Female	Complete cleft palate	15	10	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
1200960	15	Male	Complete cleft palate	20	20	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
747217	7	Male	Right Complete cleft lip palate	36	42	Type c	Type c	Sade III	Sade II	Tos 0	Tos 0
7434078	10	Male	Left Complete cleft lip palate	33	39	Type B	Type B	Sade II	Sade II	Tos 0	Tos 0
10006081	13	Male	Left Complete cleft lip palate	10	29	Type A	Type B	Sade 0	Sade II	Tos 0	Tos 0
10005260	10	Male	Left Complete cleft lip palate	36	39	Type B	Type B	Sade 0	Sade 0	Tos 0	Tos 0
10024847	12	Male	Left Complete cleft lip palate	25	35	Type B	Type B	Sade II	Sade II	Tos I	Tos 0
1036285	8	Male	Left Complete cleft lip palate	36	42	Type C	Type C	Sade II	Sade II	Tos II	Tos III
10036315	12	Female	Left Complete cleft lip palate	10	10	Type A	Type A	Sade 0	Sade 0	Tos 0	Tos 0
1159269	5	Male	Left Complete cleft lip palate	25	36	Type B	Type B	Sade I	Sade II	Tos 0	Tos 0
1156320	8	Male	Left Complete cleft lip palate	25	35	Type C	Type C	Sade III	Sade III	Tos 0	Tos 0
1152716	8	Female	Left Complete cleft lip palate	29	33.3	Type C	Type C	Sade II	Sade II	Tos 0	Tos 0