HEARING IMPROVEMENT AFTER ADENOIDECTOMY V/S ADENOIDECTOMY WITH GROMMET INSERTION IN CASES OF OTITIS MEDIA WITH EFFUSION-RANDOMIZED CONTROL TRIAL IN KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI

BY

REG. NO: BE0119004

Dissertation

Submitted to the

KLE Academy of Higher Education and Research, Belagavi, Karnataka

In partial fulfilment

Of the requirements of the degree of

MASTER OF SURGERY
IN
OTORHINOLARYNGOLOGY AND
HEAD AND NECK SURGERY

JAWAHARLAL NEHRU MEDICAL COLLEGE,

BELAGAVI, KARNATAKA

APRIL 2022

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
BELAGAVI, KARNATAKA

ENDORSEMENT BY THE HOD, PRINCIPAL/HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **"HEARING IMPROVEMENT AFTER ADENOIDECTOMY V/S ADENOIDECTOMY WITH GROMMET INSERTION IN CASES OF OTITIS MEDIA WITH EFFUSION-RANDOMIZED CONTROL TRIAL IN KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI"** is a bonafide and genuine research work carried out by **REG. NO: BE0119004.**

Dr. A. S. HARUGOP M.S., Ph.D.
Professor & Head of department
Department of Otorhinolaryngology
and Head & Neck Surgery,
J.N.Medical College,
Nehru Nagar,
Belagavi -590010
Date:
Place: Belagavi

Dr. (Mrs)N.S.MAHANTSHETTI M.D.
Principal
J.N.Medical College,
Nehru Nagar,
Belagavi -590010
Date:
Place: Belagavi

PLAGIARISM ACCEPTANCE LETTER

KLE

JAWAHARLAL NEHRU MEDICAL COLLEGE

(Recognized by Medical Council of India, New Delhi)

Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)

Nehru Nagar, Belagavi- 590 010, Karnataka, INDIA

0831 - 2471350 0831 - 2470759 www.jnmc.edu principal@jnmc.edu

Ref No: MDC/PG/ Date: 17-11-2021

ACCEPTANCE LETTER

The softcopy of thesis entitled: **"HEARING IMPROVEMENT AFTER ADENOIDECTOMY V/S ADENOIDECTOMY WITH GROMMET INSERTION IN CASES OF OTITIS MEDIA WITH EFFUSION RANDOMIZED CONTROL TRAIL IN KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI"** has been submitted for Anti-Plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of **09%** which is within the acceptable limits of **10%** as per the guidelines given by UGC.

Guide.

KAHER BELAGAVI

Dr. (Mrs.) N.S. Mahantashetti.
Chairperson-Antiplagiarism Committee &
Principal,
J. N. Medical College, Belagavi.

To,
Reg. No. BE0119004.
Postgraduate Student,
2019-20 Batch,
Department of ENT,
J. N. Medical College, Belagavi.

ABBREVIATIONS

TM	Tympannic membrane
OME	Otitis media with Effusion
OM	Otitis Media
ME	Middle ear
HL	Hearing Loss
EAM	External Accoustic Meatus
TB	Temporal Bone
EAC	External Auditory Canal
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgE	Immunoglobulin E
IgM	Immunoglobulin M
PTA	Pure Tone Audiometry
RWN	Round Window Niche
ET	Eustachian tube
SCC	Semi Circular Canal
AOM	Acute Otitis Media
URTI	Upper respiratory tract infection

ABSTRACT

BACKGROUND

Adenoids are a lymphoid tissue mass lying within the mucous membrane of the roof and posterior wall of the nasopharynx and may affect breathing in the upper airway. Eustachian tube maintains middle ear ventilation and is lined by ciliated, pseudo stratified columnar epithelium same as that of respiratory tract lining which extend as far as anterior part of middle ear cavity. Upper respiratory tract infection (URTI) disrupts the mucocilliary action of ET due to oedema as well as loss of cilia which can lead to Otitis Media with Effusion (OME). OME is the chronic accumulation of mucus within the middle ear and sometimes the mastoid air cell system. Despite a majority of cases resolving spontaneously some may have persistent hearing loss causing delay in development of language, social behavior, learning difficulties which will affect the academic performance of a child. Surgical treatment options include grommet (ventilation or tympanostomy tube) insertion, adenoidectomy or both. Grommet insertion relieves the symptoms of the effusion such as the conducting hearing loss and episodes of otitis media as well as improving the ventilation of the middle ear.Adenoidectomy is thought to improve middle ear function by removal of mechanical obstruction as well as removing or reducing the reservoir of opportunistic pathogens.In our study, we used pure tone audiometry and tympanometry to meaure the post operative hearing improvement in patients of otitis media with effusion having undergone either adenoidectomy or adenoidectomy with grommet insertion.

OBJECTIVE

To compare hearing improvement after adenoidectomy v/s adenoidectomy with grommet insertion in cases of otitis media with effusion

MATERIALS AND METHODS

Our study was a randomized control study that included 40 patients with OME. Pre and post operative PTA & Tympanometry were used to determine the degree of hearing improvement after undergoing either adenoidectomy or adenoidectomy with grommet insertion.

RESULT

We found that both arms of the intervention showed a successful improvement in hearing loss on comparing pre op and post op pure tone audiometry values after a 6 week interval Adenoidectomy group having an improvement of 3.32 db hearing loss Adenoidectomy with B/L grommet insertion having an improvement of 7.45 db hearing loss With respect to impedence audiometry in both study arms the type b graph moved to a type c graph post intervention

CONCLUSION

The hearing improvement was greater in the adenoidectomy with grommet insertion group as compared to the adenoidectomy group. This finding highlights the added benefit of tympanostomy tube insertion in cases of OME.

KEYWORDS

Otitis Media with Effusion, Adenoidectomy, Grommet, Hearing improvement.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF GRAPHS

LIST OF PHOTOGRAPHS

INTRODUCTION

- The adenoids are a mass of lymphoid tissues which lies within the mucous membrane of the roof and posterior wall of the nasopharynx which may extend to the fossa of Rosenmüller and to the Eustachian tube (ET) orifice as Gerlach's tonsil and affect breathing in the upper airway.[1] It is known that, in general, the adenoids are tiny in size at birth and consistently grow during several years' after birth due to the hyperactivity of the immune system.[2]

- Eustachian tube which maintains the middle ear ventilation is lined by ciliated, pseudo stratified columnar epithelium which is same as that of respiratory tract lining which extend as far as anterior part of middle ear cavity. Upper respiratory tract infection (URTI) disrupts the mucocilliary action of ET due to oedema as well as loss of cilia which can lead to Otitis Media with Effusion (OME). OME is the chronic accumulation of mucus within the middle ear and sometimes the mastoid air cell system .[3]

- Approximately 50% of OME resolves spontaneously within 2-3months, but 5% may result in persistent hearing loss for about a year. This might cause subsequent delay in development of language, social behavior, learning difficulties which will affect the academic performance of a child.[4]

- The most common medical treatment options include the use of decongestants, mucolytics, steroids, antihistamines and antibiotics. The effectiveness of these therapies has not been established. Surgical treatment options include grommet (ventilation or tympanostomy tube) insertion, adenoidectomy or both.[5]

- The use of tympanostomy tubes as a treatment for OME was first introduced by Armstrong in 1954 and has become one of the most common procedures performed on children. The tube insertion relieves the symptoms of the effusion such as the conducting hearing loss and episodes of otitis media as well as improving the ventilation of the middle ear [5]

- Adenoidectomy forms a valuable treatment option in management of middle ear pathologies.Adenoidectomy is thought to improve middle ear function by removing or reducing the reservoir of opportunistic pathogens.[6]

- Opinions regarding the risks and benefits of grommet insertion vary greatly. The management of OME therefore remains controversial.

- Hence a well-controlled study would help in determining the effect of hearing improvement after adenoidectomy with or without grommet insertion in cases of otitis media with effusion

OBJECTIVE

- To compare hearing improvement after adenoidectomy v/s adenoidectomy with grommet insertion in cases of otitis media with effusion

REVIEW OF LITERATURE

- Study by Sinha V et al 2005 [7]: A prospective study conducted between February 1998 to January 2000 included 100 patients between 2-12 years of age, who underwent adenotonsillectomy to remove septic foci as a cause of middle ear infection. Pre operatively they were evaluated for clinical evidence of OME. Thirty-three percentages of patients showed signs of OME and underwent grommet insertion at the same time of surgery to ventilate the middle ear. They were followed up post operatively. The study concluded that there was correlation between tonsillitis, adenoiditis and URTI with OME and its adequate treatment restores the hearing loss.
- Study by Farhad Jalil Khayat et al 2013 [8]: a cross sectional study done from the period from mid October 2009 to mid May 2010 included screening of 1,035 students for any signs and symptoms suggestive of OME. The diagnosis was confirmed using tympanometry and assessment of the hearing threshold was done using pure tone audiometry. X-ray of nasopharynx lateral view was used to measure the size of adenoid. It was found that 48 students had OME, with type B tympanogram being the most common tympanometric finding. Unilateral OME was found to be 16% whereas 37% of the cases had bilateral presentation. The study concluded that there is an association between AH and OME, which is directly proportional to size of AH.
- Study by Chibuike Nwosu et al 2016 [9]: A prospective case control study conducted between November 2014 to June 2015, tympanometry was done on 68 cases of AH within the ages of 1-10 years. 136 ears were studied of which 40 ears (29.4%) had type B tympanogram, while 36 ears (26.5%) had type C. The

incidence of OME was 55.9%; there were 12 (17.6%) unilateral OME, while bilateral OME was 32 (47.1%).

This study concluded that AH is significant risk factor and hence there is need for audiological evaluation for its management.

- Study by Chaudhuri R.G et al 2006 [10]: A Prospective randomized controlled study done on 100 patients of paediatric age group (0-12 years) selected from ENT outpatient department concluded Radial myringotomy in the antero-inferior quadrant of tympanic membrane with insertion of grommet with or without adenoidectomy offers an effective and reliable option in the treatment of patients suffering from otitis media with effusion.
- Study by Upadhya I et al 2014 [11] : A prospective, randomized study done on patients presenting to ENT outpatient department between July 2007 and October 2009 concluded that otitis media with effusion is most common between 7 and 10 years of age. Most of the patients around 51.66% in U/L ears and 20% in B/L ears were manageable with medical treatment, reverting back to normal hearing. Patients with adenoids gave 100% result after surgical removal of the same. Only very few patients required grommet insertion about 5% in U/L and B/L ears each.
- Study by Bandyopadhyay T et al 2018 [12]: A prospective comparative study was done in 100 children taken 50 as cases and 50 as controls for a period of 2 years(children between ages 1 and 10). In this study outcomes of various treatment modalities, were divided into surgical (22) and medical (non surgical) group (28) and outcomes at the end of 3 and 6 months were calculated. The difference in treatment modalities showed statistical significance at the end of 3 months but there was no significant difference in treatment groups after 6 months.

- According to a study by Tuli S.B et al 2001 [13] carried out in 100 patients of otitis media with effusion ,pre operative and postoperative pure tone audiometry and tympanometry was done. Post operative air bone gap was narrowed by 10 – 20 dB in 52 % cases and above 20 dB in 40 % cases. Thus resolution of disease and improvement in hearing was achieved between 3 months and more after grommet insertion.
- According to a study by Maw R et al 1993 [14] a randomised controlled study carried out in 228 children aged 2-9 years with pronounced hearing loss from glue ear and persistent bilateral middle ear effusions confirmed on three occasions over three months. Children were randomly allocated to adenotonsillectomy, adenoidectomy, or neither procedure. The study concluded that treatment of glue ear considerably shortened the time to fluid resolution, combined adenoidectomy and tube insertion being better than either procedure alone.
- Vlastos M I et al 2011 [15] wanted to determine whether tympanostomy tube insertion has benefit, compared with simple myringotomy, in children with otitis media with effusion who receive concurrent adenoidectomy as treatment for obstructive sleep apnoea syndrome caused by adenoid hypertrophy. They concluded that tympanostomy tube insertion confers a short term benefit, compared with simple myringotomy, in children older than three years with otitis media with effusion. They suggested further studies are necessary to identify which of these children will receive long-lasting benefit from tympanostomy tube.
- Coyte PC et al 2001 [16] examined the results of surgery for all 37,316 children (defined as persons 19 years of age or younger) in Ontario, Canada, who received tympanostomy tubes as their first surgical treatment for otitis media. They determined the time to the first readmission for conditions related to otitis media

and the time to the first reinsertion of tympanostomytubes. They concluded that Performing adenoidectomy or adenotonsillectomy at the time of the initial insertion of tympanostomy tubes substantially reduces the likelihood of additional hospitalizations and operations related to otitis media among children two years of age.

The ability to communicate is a crucial aspect of human life as auditory sense is very important for communication of any kind. It is indispensable for normal mental development of a child. Hearing impairment acquires a special significance as a large percentage of population affected are children.[17]The most striking effect of profound hearing loss is the lack of development of spoken language, with its impact on daily communication; this, in turn, restricts learning and literacy, substantially compromising educational achievement and later employment opportunities. There is a high prevalence of psychosocial problems among deaf children.[18] Hearing impairment or loss is an important medical problem worldwide. According World Health Organization (WHO) 2017 report, over 5% of the world's population (360 million people) has disabling hearing loss (328 million adults and 32 million children).[20] The majority of people with disabling hearing loss live in low- and middle-income countries.[20]

In India, 63 million people (6.3%) suffer from significant auditory loss. Four in every 1000 children suffer from severe to profound hearing loss. With over 100,000 babies that are born with hearing deficiency every year. The estimated prevalence of adult-onset deafness in India was found to be 7.6% and childhood onset deafness to be 2%. The National Sample Survey 58th round (2002) surveyed disability in Indian households and found that hearing disability was the 2nd most

common cause of disability and top most cause of sensory deficit. In urban areas, loss was 9% of all disability and in rural areas, it was 10%. It was estimated that the number of person with hearing disability per 100,000 persons was 291; it was higher in rural (310) compared with urban regions (236). In the same survey, about 32% of the people had profound (person could not hear at all or could hear only loud sounds), and 39% had a severe hearing disability (person could hear only shouted words). The survey results revealed that about 7% of people were born with a hearing disability. About 56% and 62% reported the onset of hearing disability at ≥60 years of age in the rural and urban areas, respectively.

The incidence of hearing disability during that year was reported to be 7/100,000 population. The magnitude of milder degrees of hearing loss and unilateral hearing loss would be larger than these estimates for bilateral hearing loss.[21,25] Unlike Sensorineural hearing impairment, conductive impairment is more common and easy to manage and has better prognosis. Hence early screening, timely intervention and well programmed follow up of children with hearing impairment is very crucial in preventing major life disability. To achieve this, there is a need to understand the prevalence and distribution of hearing impairment among children. This study was undertaken as there is scarcity of literature especially in India on the exact magnitude of conductive hearing impairment among children. Inadequate primary ear care programme, poor environmental condition and neglect of upper respiratory tract infection are common predisposing factors for development of conductive hearing loss.[19] WHO defines disabling hearing loss as hearing loss greater than 40 decibels (dB) in the better hearing ear in adults and a hearing loss greater than 30 dB in the better hearing ear in children.[20] Hearing loss is divided into conductive, sensorineural, mixed, and central types.

Conductive hearing loss (CHL) is far more common in children and results from interference with the mechanical transmission of sound through the external and middle ear. Sensorineural hearing loss (SNHL) results from a failure to transduce vibrations to neural impulses effectively within the cochlea or transmit these impulses down the vestibulocochlear nerve. Mixed hearing loss involves a combination of these two types, usually due to damage throughout the middle ear and the inner ear. Finally, central hearing loss refers to defects in the brainstem or higher processing centres of the brain. Both CHL and SNHL may be caused by a wide variety of congenital and acquired factors.[28]

1. Conductive hearing loss
2. Sensorineural hearing loss
3. Mixed hearing loss

IMPACT OF HL

Hearing impairment cannot be seen and hence its effects are not visible to others, so deaf suffers in silence. Unlike blindness, deafness often provokes ridicules rather than sympathy. A deaf person is so isolated from family and friends and greeted by unsympathetic attitude he/she is often depressed and needs psychological counselling. The consequences for a child born with hearing loss are quite severe. It is well established that a child with hearing loss cannot develop speech and language abilities. This puts the child at a disadvantage in school, higher education, and limits future professional opportunities. The problem of the child deaf from the birth is quite different from that of the adult who has become completely deafened after school age or in adult life.

The hard of hearing person whose deafness has developed slowly over the years is different again. But, for all of them, the handicap is the same – the handicap of the silent world, the difficulties of communicating with the hearing and speaking world.[21]

A. Functional impact[20]

One of the main impacts of hearing loss is on the individual ‟s capability for Communication. Development of speech is commonly delayed in such children. Hence significantly impacting academic performance resulting in higher percentage of grade failure and a more pressing requirement for educational support.

B. Communal and emotive impact[20]

A substantial effect on daily life occurs due to the lack of clear communication causing feelings of seclusion, separation, and defeat, predominantly within the elder age group having loss of hearing.

C. Fiscal impact[20]

The WHO estimated that hearing loss which has been unaddressed causes an global annual fee of 750 international billion dollars. It is inclusive of the cost to healthcare (not including the price of assistive devices to improve hearing), scholastic support costs, reduction in output, and communal costs.

In developing nations, those children suffering from hearing loss and deafness are not able to receive the benefit of education. Adults with hearing loss are often not preferred for most employment facilities. Within the employed, a greater percentile of people having hearing deficit are shunted into a lesser rank of service in comparison to the general personnel.

Increasing accessibility to educative and professional rehabilitative amenities , as well as improving consciousness mainly within the employers regarding the requirements of those people ailing from hearing deficits, will reduce the redundancy rates for those individuals having hearing loss.

THE MECHANICAL BASIS OF HEARING

Pressure influences, which are responsible for basis of sound, are seized by pinna and focused via EAM. Waves of sound impact TM which is a barrier between outer and middle ear. Since operational vibration of TM necessitates pressure on both sides be equal, ventilation of the middle ear is via the Eustachian tube, whose course is from middle ear anterior wall to nasopharynx.

Vibrations hence produced are conducted by ossicular chain to oval window where these ossicular mechanical vibrations are transformed to fluid pressure waves which cause the movement of the hair cells along basilar membrane & within the organ of Corti. The action is then converted into neural signals.

The intensity of the sound is governed by sum of hair cells firing, hence louder noises trigger a larger number of neurons. The frequency is determined by incidence of the neurons discharging as well as their activation pattern along basilar membrane. The vestibulocochlear nerve carries these neural impulses to the brainstem from where it is directed to the various brain regions for further processing. Any flaw in a part of this network could lead to hearing deficit.

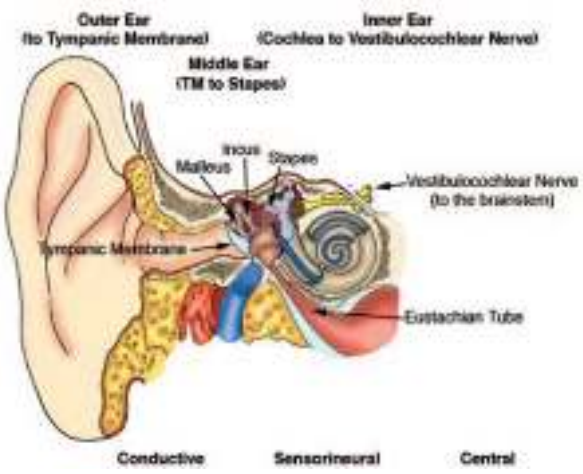


Figure 1: Anatomy of ear

Structures concerned with conduction of sound are:

1. EXTERNAL EAR

a. PINNA

b. EAC

2. MIDDLE EAR

a. AUDITORY OSSICLES

b. EUSTACHIAN TUBE

A. The External Ear

Region of ear lateral to TM comprising of EAC, auricle & cartilaginous region of ear. Auricle is a hemispherical elastic cartilage plate distinguished by a number of ridges/grooves. Majority including helix antihelix, tragus, antitragus, surrounding the scaphoid depression located posterior to EAM termed concha. There exists a continuity between the cartilage of EAM, outer region of ear canal & auricle.[30]

EAC has an outer half consisting of a cartilaginous extension of auricle and a medial half consisting of mastoid and tympanic region of Temporal Bone. Medially bounded by TM and lined by thin skin that is having medially minimal subcutaneous tissue however containing many hair follicles, sebaceous and ceruminous glands laterally. Length of bony EAC measures 24mm.

The tympanic membrane comprises three layers

1) Outer squamous cell epithelial layer

2) Middle ear facing medial mucosal layer facing, and

3) Tunica propria or Fibrous layer, forming tympanic membrane substance[31]

It is this layer which imparts shape and consistency to the membrane. The tunica proprias radial fibres insert into manubrium, circumferential fibers afford power without interrupting the vibration, and the tangential fibers bolster the tympanic membrane architecture.

The malleus manubrium is an important landmark in identifying the tympanic membrane, it is superiorly limited by the lateral/short process and inferiorly by umbo. TM is superiorly incomplete, the fibrous layer deficient superior to manubrium short process termed pars flaccida (Shrapnell‟s membrane). Majority or inferior portion of TM is termed pars tensa.[32]

B. Middle Ear

Area between labyrinths bony capsule and the tympanic membrane in petrous portion of the TB includes ossicular chain and allied musculature, ET orifice, & vascular system. Divisions of tympanic cavity are epitympanic, mesotympanic, and hypotympanic areas.

Hypotympanum lies inferior to Eustachian tube orifice and Round window niche (RWN). It contains various bony trabeculae and jugular bulbs bony covering, if it is dehiscent the jugular bulb is exposed. An inferior channel (inferior tympanic canaliculus) conveys the Jacobson nerve.

Mesotympanic portion is superiorly limited by horizontal section of facial canal and by Round window niche inferiorly. containing round and oval windows, stapes with stapedius muscle posteriorly, and anteriorly canal for tensor tympani muscle. Oval window has a superior convex rim and an inferior concave rim.

In oval window, stapes footplate is secured by annular ligament. The fibrous round window membrane is covered by a mucosal layer roughly kidney bean shaped, with a greater component anterior and inferior and a smaller component located posteriorly and horizontally in the Round window niche.

Posteriorly, in the mesotympanum lie 2 clinically significant bony recesses. Facial recess lies lateral to vertical segment of facial canal. Medial to facial canal is sinus tympani. Chronic infections of the middle ear often lurk hidden in these spaces. Access to middle ear space and Round window niche in canal wall intact practices is via facial recess (ie, intact canal wall mastoidectomy, cochlear implantation).[33]

The pyramidal eminence, a projection of bone from facial canal houses stapedius tendon prior to its insertion into the stapes neck. The protympanum is the anterior most region and is superiorly bordered by the eustachian tube aperture and the canal for the inernal carotid artery anteriorly [33]

Epitympanum superiorly bordered by the tegmen tympani which continues posteriorly as tegmen mastoidea. Medial wall formation by bony prominence of lateral and superior SCC ampullae and the epitympanic region of facial (fallopian) canal. Malleus & incus articulate and fill majority of epitympannic space.

The ossicles are fixed in place by anterior and posterior ligaments hence providing a rotatory axis for the ossicular chain. The space has a posterior communication via a slim opening i.e aditus ad antrum to mastoid cavity.[33]

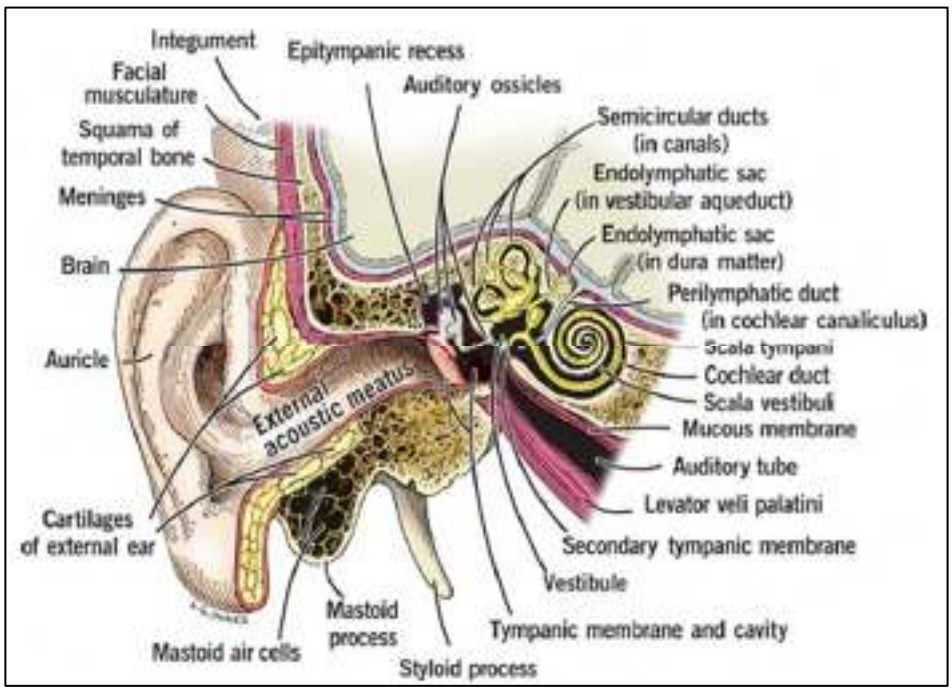


Figure 2: Relations of ear

C. Ossicles.

Sound waves are conducted by ossicular chain of malleus, incus and stapes from tympanic membrane across middle ear space.[34] The malleus head and incus body act as a single element appended by epitympanic ligaments. Articulation of tip of long process of incus is at a right tilt with stapes head such that sound waves originating from the tympanic membrane movement is carried by ossicular chain to Stapes footplate. The surface area of TM to stapes footplate is in a 25 to 1 ratio , pressure density of oval window & inner ear fluids is analogously increased. Stapes acts as a piston at the oval window.[33]

Stapes is stirrup shaped. it consists of a head, neck, and footplate or base. Crura are bent, with the posterior being larger than the anterior, and merge with the footplate, which is made up of both the otic capsule and the periosteal bone. Tensor tympani and stapedius muscles in middle ear control ossicles.

In anterior mesotympanum, superior to ET opening, tensor tympani muscle is located in a bony semicanal. Muscle converging posteriorly into a tendinous segment anchored at cochleariform process before turning to intrude on malleus neck laterally. A branch of the fifth cranial nerve supplies innervation. Their motor neurons are situated in parvocellular division of trigeminal motor nucleus, and its activity pulls drumhead medially, boosting sound conduction system's resonance frequency.[33]

Facial nerve motor part of stapedius muscle comes from either its own or fallopian canal. Stapedius tendon, which arises via pyramidal eminence and inserts at stapes neck, converges superiorly and anteriorly. Motor neurons are situated in brainstem at interface of facial nucleus and lateral superior olivary nucleus, and it is innervated by a seventh nerve branch. Stapedius muscle contracts, pushing stapes backwards and dampening ossicular chain sound transmission, functioning as a protective aspect for the cochlea.[33]

Figure 3: Ear ossicles

D. The Eustachian Tube.

ET is commonly found to be dysfunctional in children with OME. ET plays a crucial role in middle ear cavity's ventilation and secretion clearing. It serves as a sound barrier in the middle ear, preventing sound reflux and material from nasopharynx. Its proper operation is necessary for optimal sound transmission through middle ear chamber. [35]

Osseous section of tube is funnel-shaped, with wide end extending from the middle ear cavity's anterior side.Funnel's thin end, also known as isthmus, is the narrowest point of ET and is located close to bony cartilaginous junction.

Osseous part is generally open and closes slowly compared to cartilaginous section.[36]

Otitis media with effusion (OME)

Otitis media with effusion (OME) is incidence of a middle ear effusion behind an intact TM minus the symptomatology of acute manifestation. Synonyms comprise glue ear, secretory OM, tympanic hydrops, serous OM.[37]

Children are more likely to develop otitis media with effusion, which accounts for the bulk of hearing loss in this age range.[38] Majority of OME cases are asymptomatic with the disease being an incidental finding in 25% of the cases. In spite of the deceptive lack of symptoms, the possible effect on hearing, spoken word, linguistic abilities and understanding focuses the requirement for judicious action.

Mucus builds up in middle ear and, in some circumstances, mastoid air cell system, causing otitis media with effusion (OME). Chronicity of an illness is determined if it lasts for three months or more. OME can cause not just hearing loss in children, but also delayed speech and language development, poor social performance, and balance issues. A definite history of earlier respiratory tract infection and earache with an episode of acute otitis media is occasionally present.

The condition is popularly termed as 'glue ear'. Approximately 80% of children in general population will have had a single episode of OME before age of three and 40% cases will be having three or more episodes like this. Acute OM is the precursor of childhood OME, however it usually occurs after a viral upper respiratory tract illness, associated inflammation/infection of adenoid, secondary bacterial infection with a cascade of inflammatory mediators, upregulation of mucin genes and effusion from middle ear mucosa. In many of the youngsters presenting with OME there is no clear history of acute OM. Research currently in progress indicates a genetic inheritance of susceptibility to OME, causing impaired middle ear oxygen metabolism. It is likely that ventilating the middle ear establishes a higher oxygen tension in part, inhibiting bacterial biofilm activity.[33]

The tympanomastoid compartment and the Eustachian tube originate from the tubotympanic recess, which is an extension of the first pharyngeal pouch. Medial part of tubotympanic recess gets extended hence forming the pharyngotympanic (eustachian) tube. Posterior expansion of the tympanic cavity gives rise to mastoid antrum and its consequent air cell system. Pneumatization progresses as mesenchyme is resorbed.[39]

THE ROLE OF EUSTACHIAN TUBE[33,39]

The role of the eustachian tube is trifectal: (1) middle ear protection against pressure variations in nasopharynx and secretions, (2) middle ear secretion outflow into nasopharynx, and (3) middle ear ventilation to equalise pressure with ambient air pressure and replace absorbed oxygen.

At rest, ET is normally closed. Its recurrent opening is crucial for keeping middle ear pressure close to ambient. As a result, the principal regulator of middle ear

pressure is gaseous exchange between the middle ear and the nasopharynx, which occurs when the eustachian tube opens. The middle ear pressure is regulated by a gradient-mediated transmucosal gaseous exchange between the middle ear and the blood. As a result, poor eustachian tube function puts you at risk for middle ear irritation. Children's Eustachian tubes are smaller in diameter and more horizontally orientated than adults', resulting in much less ventilation. As a result, youngsters are more likely to experience negative middle ear pressure, which adds to a higher risk of middle ear illness. Inflammatory oedema of Eustachian tube epithelial lining is particularly susceptible to middle ear ventilation in infants. With age, middle ear's penchant for negative pressure improves. Because of horizontal angulation and reduced length of eustachian tubes, nasopharyngeal contents might reflux into middle ear, causing irritation and infection. As people age, they take a more upright stance, which reduces their penchant for inflammation.

Figure 4: Eustachian tube dysfunction. This endoscopic image demonstrates moderate inflammation of the right eustachian tube orifice in the resting position

Figure 5: Eustachian tube dysfunction. This endoscopic image demonstrates moderate inflammation of the right eustachian tube orifice in the dilated position

EPITHELIUM[33,39]

It's a modified respiratory epithelium that's comparable to one found in the nasal cavity and sinuses. ET mucosa and the bulk of middle ear's epithelium is ciliated, with a connective tissue subepithelial layer. Goblet cells and mucus glands can be found throughout middle ear, although they are concentrated towards ET's aperture. Mucus generated is mostly glycoproteins with lysozymes, forming a "mucociliary blanket." Film of mucus and its contents are propelled from tympanic cavity to nasopharynx by continuous ciliary motion, cleaning the middle ear space. As it approaches the base of the tympanum, the epithelium becomes more cuboidal and the number of cilia decreases. In epitympanum, antrum, and mastoid air cells, it then transforms to a flat pavement epithelium. From cartilaginous to bony region of ET, as well as from the tympanic cavity to the mastoid antrum and air cells, subepithelial connective tissue gets thinner.

OME is caused by epithelial irritation and formation of a serous or mucus effusion. Flat cuboidal middle ear mastoid mucosa may be replaced by a denser pseudostratified mucus-secreting epithelium with varying degrees of specialisation,

such as ciliary development, in an established illness. Goblet cells are prevalent, and creation of mucus-secreting glands can occur in some cases. Ciliary lining's ability to transfer secretions into nasopharynx is diminished. There is submucosal oedema, as well as inflamed and dilated blood vessels, as well as an increase in macrophages, plasma cells, and lymphocytes.

EFFUSION[39]

It mainly comprises the glycoprotein mucin. Also secretory immunoglobulin A (IgA), lysozyme, interleukins and other inflammatory cytokines are found . Characteristically the effusion is of a sticky gluey nature and has grossly decreased mucociliary transport ability. The changes in the mucosa predisposing to the tenacity of the effusion validates the need for surgical intervention and improvement of ventilation of the middle ear.

MICROBIOLOGY[33,39]

Positive culture swabs of middle ear effusion in OME cases in paediatric population (greater than 2 months' period) produced the expected quartet of respiratory bacteria, inclusive of *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Branhamella* (*Moraxella*) *catarrhalis*. Sixty-six percent of the samples were negative using classic culture techniques, and no harmful organisms could be cultivated from fluid that had been present for six months.However,on polymerase chain reaction techniques (PCR), of middle ear mucosal biopsy specimens 36 % of samples demonstrated intracellular *Streptococcus pneumoniae*.

So it can be extrapolated that this is a result of bacterial persistence such as Biofilms. These are societies of sessile bacteria, resistant to disruption having a low metabolic rate, which are entrenched in an extracellular polymeric substance matrix of

their own synthesis. They may cling to a foreign body or a mucosal surface having compromised host defences. They are increasingly implicated in chronic inflammatory conditions such as OME.

It is likely that the biofilm is a secondary bacterial outcome after a viral URTI, contributory to inflammation and production of mucus film. It is possible that those with a genetic defect of middle ear oxygen metabolism are predisposed to persistent OME with all its clinical manifestations.

Risk factors for OME include males, feeding by bottle, passive smoke inhalation, respiratory inhaled allergies, dietary allergens, recurrentepisodes of acute OM, viral URTI infection,dysfunction of the eustachian tube and a juvenile immune system.[40]

Classification of OME

Acute OME - Lesser than 3weeks timespan.

Subacute OME - 3weeks to 3months timespan.

Chronic OME - More than 3 months timespan.

Two broad categories of OME .

1) Persistent middle ear effusion after an acute attack

2) Secretory OM.

It is generally impossible to distinguish them on clinical grounds. Symptomatology in chronic OME may be limited to hearing deficit.[41] In some children, hearing impairment may be associated with nasal or postnasal obstruction. Certain aspects of language development appear to be vulnerable to the intermittent, fluctuating hearing loss caused by OME like articulation development, receptive vocabulary development and phonologic awareness.[41] Conductive hearing loss within paediatric OME cases ranges from 25-30 dB. Theses chronic OME cases are at a

greater threat for occurrence of focal retraction pockets, generalized atelectasis and cholesteotoma as the effusion containing leukotriens, prostaglandins and metabolites of arachidonic acid arouse a local inflammatory response.[42] Despite OME becoming less rife with age, serious consequences such as severe atrophy, severe TM retraction, hearing loss, cholesteotoma, & non-healing perforation can develop in chronic OME children.[43] Colour of TM might be pale grey, ochre, black, or so christened blue drum. TM can be thick and dull or thin and translucent. It's possible to see fluid levels or air bubbles. level of splitting of the light reflex, rotation and displacement of malleus handle, and prominence of malleus lateral process can all be used to determine degree of tympanic membrane retraction.

A thorough history and examination are performed on individuals with suspected ET dysfunction. Focus being on any disorders which predispose to edema or inflammation of eustachian tube, such as laryngopharyngeal reflux, allergies, Samter triad (asthma, nasal polyposis, and aspirin sensitivity) or sinusitis. Disorders affecting ciliary motility such as cystic fibrosis and Kartagener syndrome should be diagnosed. Prior operations, particularly a history of adenoidectomy, should be elicited.

In children, otitis media is associated with cigarette smoke exposure, wood burning stoves, and participation in group day care facilities.[45] Inquiry should be made about excessive respiratory tract infections, immune deficiency, food or environmental allergies, or a family history of Eustachian tube problems. Social history should include questions about smoking and secondhand exposures to smoke which have a detrimental effect on mucosal ciliary clearance.

A detailed list of medications is important and should focus on any nasal preparations including topical corticosteroids and oxymetazoline (Afrin), allergy medication, and hormonal replacement therapies.[39] Examination is comprehensive and is inclusive of a thorough evaluation with particular focus on otoscopy as well as nasopharyngoscopy. Otoscopy is best performed using the binocular microscope and the tympanic membrane should be inspected for any retraction, retraction pockets, cholesteatoma, perforations, atelectasis, tympanosclerosis, or effusions. Pneumatic otoscopy is particularly important, looking for evidence of tympanic membrane retractions and the degree of retraction and negative middle ear pressure.[39]

Insufflation of a retraction helps to determine if there is active negative middle ear pressure that may indicate compromise of eustachian tube function. If the retraction has become adherent but the surrounding tympanic membrane moves equally well with positive or negative insufflation, the adhesion may be a remnant of past tubal dysfunction, a factor that could be important in deciding whether surgical intervention is indicated for the retraction. Audiologic assessment is indicated and begins with pure-tone audiometry to assess for conductive or sensorineural hearing loss. Tympanograms are also done to ascertain the middle ear pressure at rest.[39] Endoscopy of the ET is key to determine nature of tubal dysfunction. It is best performed with an endoscope positioned close to nasopharyngeal slit of the ET with view directed down its longitudinal axis, approximately 45° superiorly to nasal cavity's floor. Examination during swallows and yawns reveals the mucosal folds within the valve of cartilaginous bit of ET unfolding in full view during dilation and closing processes.[39]

Anatomical obstructions must be excluded, particularly in cases having unilateral presentation including malignant masses such as masopharyngeal carcinoma Benign causes of mechanical obstruction such as adenoid hypertrophy, retention cysts, Thornwaldt cysts, or as a result of iatrogenic surgical trauma. Physiologic blockage of the eustachian tube being more common than anatomical obstruction which results from mucosal inflammation, from either due to allergies or laryngopharyngeal reflux.[46]

ET can no longer open correctly in ET malfunction, resulting in a build-up of negative pressure inside middle ear space, causing a sense of auditory fullness and conductive hearing deficit in varying degrees. Retraction pocket development, tympanic membrane perforation, atelectasis, cholesteatoma, serous otitis media, and chronic otitis media are some complications.[46]

Medical management of OME:[39]

The remedy of ET malfunction depends upon identification of the underlying causality. Dietary changes, such as avoiding meals that relax the lower esophageal sphincter and enhance acid production, should be used to treat laryngopharyngeal reflux. Proton pump inhibitors (PPIs) and H2 blockers (H2 blockers) are acid-reducing medications that should be taken daily or twice daily.

Sleeping on an inclined bed can help refractory instances, and fundoplication may be considered in the end.

Any allergic aetiology should be looked into. Avoiding the problematic allergen can help, but it isn't always practical. Reduced allergy symptoms may be achieved with oral second-generation antihistamines, nasal corticosteroid sprays, or a

combination of the two. Immunotherapy may be required in refractory patients. Management of anatomical obstructions is tailored to the causality. Nasopharyngeal carcinoma is often treated with radiation therapy, and benign masses such as hypertrophic adenoid tissue can be excised. Infections are treated with the appropriate antibiotics.

Recurrent nasal or sinus disease, immunosuppression or immunodeficiency, or primary mucosal abnormalities are all signs of underlying nasal or sinus disease (eg, Samter triad, Wegener granulomatosis). Immunosuppressants are commonly used to treat granulomatous illness.

Surgical Management of the ET impotence:

Surgery is required if a comprehensive assessment of underlying medical issues and maximum medicinal treatment fail to cure otitis media or atelectasis. Tympanostomy tubes are useful in the treatment of serous otitis media and may help to avoid tympanic membrane retraction, atelectasis, and other eustachian tube dysfunction complications.

If the effusion or inflammation persists despite the presence of a tube, it suggests a fundamental mucosal illness rather than an ET issue. Thick proteinaceous "gluelike" effusions that occlude ventilation tube lumen repeatedly commonly react to oral or topical corticosteroids and may indicate a fundamental mucosal issue. Repeated implantation of ventilation tubes may be required in situations of long-term chronic ET dysfunction.[39] Larger flanged tubes, such as "T" tubes or subannular semipermanent tubes, may be recommended in such instances. Longer duration tubes put tympanic membrane at danger of permanent perforation.[39]

DIAGNOSIS OF OTITIS MEDIA

A. History

The diagnosis of OM is frequently not as straightforward as might be thought. The history is generally obtained, not from the patient, but from the caregiver, the symptoms of fever and irritcapability are neither sensitive nor specific, the physical examination can be hampered by cerumen occluding the external auditory canal, and the patient is often uncooperative. An upper respiratory infection may precede the onset of OM. Signs and symptoms include fever, ear pain, irritcapability, inconsolable crying, changes in eating or sleeping habits, malaise, vomiting and diarrhea, and occasionally tugging at the ear. A recent metaanalysis demonstrated that ear pain is the most useful symptom, while fever, upper respiratory tract symptoms, and irritcapability were less specific. The older child may note fullness in the ear as well as hearing in the affected ear. Children with OME are generally asymptomatic except for hearing loss or problems with balance.[33,39]

B. Physical Examination

It is time well spent to gain the trust of the child before proceeding with the examination. Cerumen can be cleaned from the external canal by use of a curette, or by lavage, if you are certain that the TM is intact. Most cerumen impactions are the result of misguided parental efforts to clean the external auditory canal with cotton swabs, displacing the wax medially.[33,39]

C. Examination of the TM

The most common method for diagnosing OM is examination of the TM with an otoscope. A normal TM is translucent, with the observer able to distinguish the short and long processes of the malleus and occasionally the incus. The TM is concave medially, pearly gray in color, and will readily move with insufflation. To

diagnose OM, the observer should look for abnormalities of color, translucency, contour, and mobility. Thus, the TM may appear erythematous, whitish, or yellow. The drumhead may be opaque or bulging. Purulent otorrhea is indicative of a TM that ruptured as the result of AOM. In OME, the observer may note either air-fluid levels or air bubbles deep to the TM. The TM may be retracted, and the TM will be dull grey or amber, and non-erythematous, unless the child is crying. [33,39]

Common sources of error in diagnosis include mistaking an erythematous TM due to the child‟s crying for an infection, failure to perform insufflation, failure to perform insufflation correctly, and failure to restrain the uncooperative patient adequately. [33,39] An assessment of the TM mobility by pneumatic otoscopy will greatly enhance the accuracy of diagnosis.[47] A normal TM will readily move medially in response to positive pressure, and laterally in response to negative pressure.

If an effusion is present, the TM movement will be dampened. While complete immobility almost guarantees the diagnosis of otitis, in the absence of a TM perforation, decreased mobility is a more common finding. Unfortunately the technique is operator dependent and is often not used by paediatricians or general practitioners.[48] Diagnostic accuracy is improved with a structured approach to teaching otoscopy and by validating clinicians either with myringotomy or videotaped otoendoscopic examinations.

FACTORS RESPONSIBLE FOR NON-RECOVERY OF OTITIS MEDIA

A. Recurring nasopharyngeal infection:

Acute URTI can spread from nasopharynx to ME cleft via ET.

In an intact tympanic membrane, pharyngeal end inflammation of ET may obstruct gaseous exchange, resulting in a diffusion effect that favours physiology of

the middle ear mucosa. As a result, ME pressure is reduced, which increases risk of nasopharyngeal germ aspiration into the middle ear cleft when the tube is opened.

B. Repeated external infection:

Microorganisms can be conveyed by fluid media from ear canal into ME through a punctured tympanic membrane, allowing infective agents to be transferred from external ear to the mesotympannum.

C. Bacterial biofilm colonisation:

The ability of bacteria to change their shape to form non-motile societies adhering to mucosa and protected by polysaccharide matrix is responsible for the bulk of chronic infections. These biofilms are resistant to antibiotics, host resistance, and are undetectable in microbiological testing.

They frequently contain a large number of microbial strains and have the capacity to revert to more traditional planktonic bacterial communities. In persistent infections, biofilms have long been known.[49] The role of biofilms in the maintenance of chronic ear infections has been highlighted by recent microscopic evidence of biofilms in otitis media.[50]

SURGICAL PROPHYLAXIS: [39]

- **Ventilation tubes:**

According to a recent five-trial meta-analysis, having ventilation tubes vs not having tubes resulted in a 56 percent reduction in AOM episodes, or an absolute reduction of 1.0 event per kid per year.[53]

The greatest benefit was shown during the first year of follow-up. Improved quality of life was seen in 79 percent of cases. Negative connotations include greater incidence of tympanosclerosis and membrane atrophy in isolated samples.

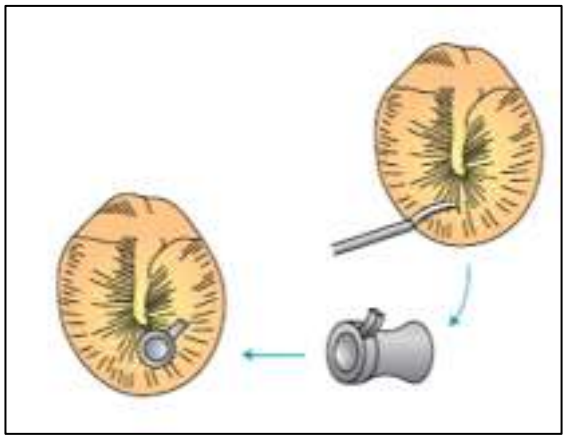


Figure 6: Myringotomy with Grommet insertion

- **Adenoidectomy and Adeno-Tonsillectomy:**

When it comes to adenoidectomy, the lack of evidence for optimum practise is particularly apparent. According to some research, adenoidectomy may be useful in children who have previously had a breathing tube inserted and then developed AOM. In a two-year follow-up, AOM was decreased by 31% compared to the control group (or 0.32 incidents per child-year), and participants spent 42% less time with OME. In addition, the requirement for additional tubes was cut in half.[54]

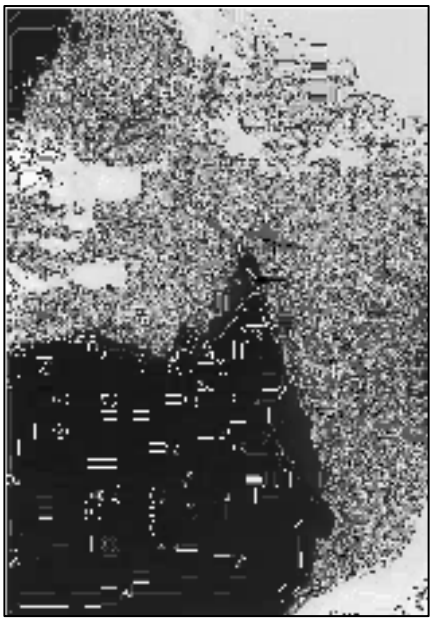


Figure 7: X ray Nasopharynx "A" shows the Adenoid hypertrophy

PURE TONE AUDIOMETRY

- Pure tone audiometry measures the **auditory threshold** of an individual.
- The instrument used is known as the pure tone audiometer.

Hugson and Westlake's descending/ rising approach utilising 10/5 dB increments is the recommended strategy for PTA, and it should be used with flexibility. In children, there is no standard for interpreting data, and normalcy limits range from 15 to 30 dB HL.[39]

Nielsen and Olsen claimed that about 75% of three-year-olds could provide at least six ear-specific air conduction thresholds. The use of acceptable conventional masking techniques will be dependent on the kid's cognitive development and cooperation, and may not be dependable until the youngster is seven years old.[55] PTA is a standard hearing test that uses sinusoid stimuli at octave frequencies ranging from 250 to 8,000 Hz and generally two inter-octave frequencies to determine hearing sensitivity (3,000 and 6,000 Hz). The ear reacts to frequencies between 20 and 20,000 Hz in normal hearing. On an audiogram, the test results are graphed.

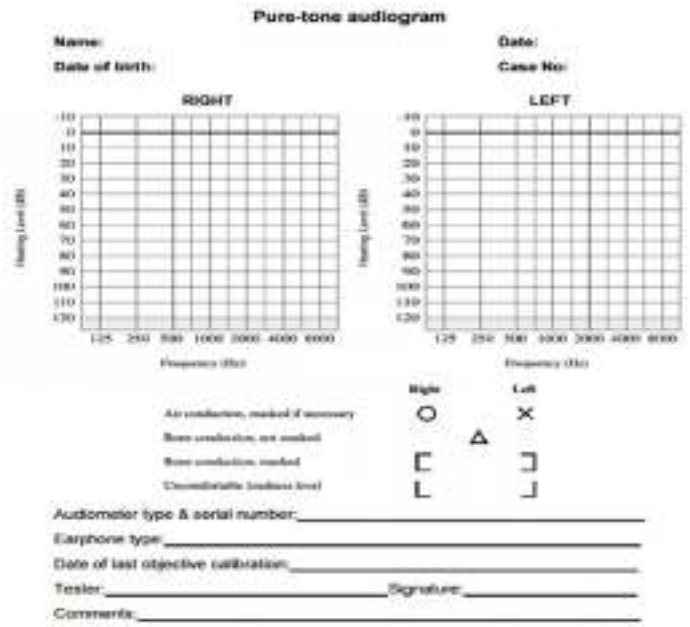


Figure 8: Pure Tone Audiogram

IMPEDANCE AUDIOMETRY (TYMPANOMETRY)

Tympanometry is a method of objectively measuring TM compliance, similar to TM mobility during pneumatic otoscopy. Tympanometry can help with otitis diagnosis, however it can't tell the difference between AOM and OME.

Tympanometry is a simple, rapid, noninvasive test that provides information about TM compliance in electroacoustic terms, using a tympanometer. When an 85-dB sound pressure level (SPL) low-frequency (226-Hz) probe tone is introduced into a sealed ear canal and the pressure in the ear canal is changed, tympanometry is based on the quantity of sound reflected back from the tympanic membrane.

The tympanic membrane is most acquiescent and absorbs, rather than reflecting, sound when pressure in the ear canal coincides to middle ear pressures. When the pressures are equal, the tympanometric peak occurs. Peak pressure comes at 0 da Pa in proper Eustachian tube function. Negative pressure (>100 daPa) is caused by an improperly aerated middle ear. As a result, ear canal pressure that conforms to the tympanometric peak can be used to estimate middle ear pressure. To accommodate for resonance variations in tiny ear canals, a higher-frequency probing tone (660 or 1000 Hz) is employed in babies and newborns.

Classification of tympanogram:[33,39,56]

Generally, tympanograms have been classified as Type A, B, or C.

A. Type A:

"Type A tympanograms have normal peak height (reflecting compliance) and pressure." Variations include

Type AS – normal pressure but shallow seen in otosclerosis or middle ear effusion

Type AD –high peak seen in "ossicular discontinuity or monomeric eardrum"

B. Type B:

"The Type B tympanogram is flat, representing lack of compliance. Measurement of volume simultaneously performed with tympanometry helps in differentiating between a flat tympanogram suggesting an intact drum with middle ear effusion as compared to a perforated drum or ear with a patent ventilating tube."

C. Type C:

"The Type C tympanogram has negative peak pressure suggestive of inadequate aeration of middle ear space."

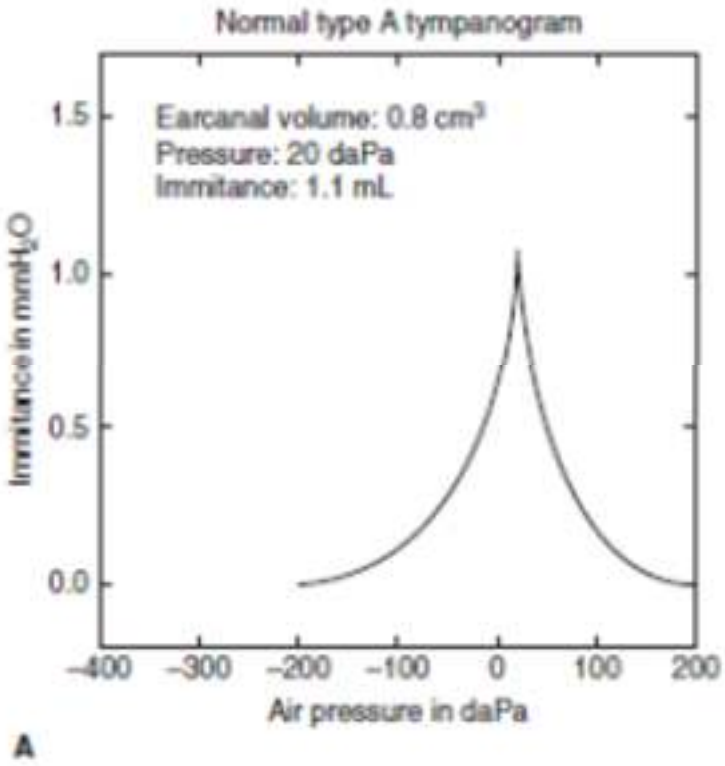


Fig 9: Type A Tympanogram

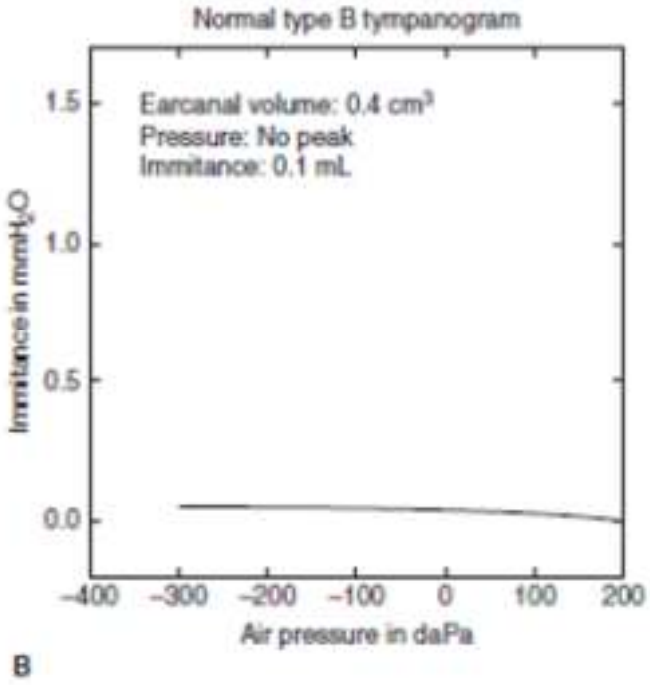


Fig 10: Type B Tympanogram

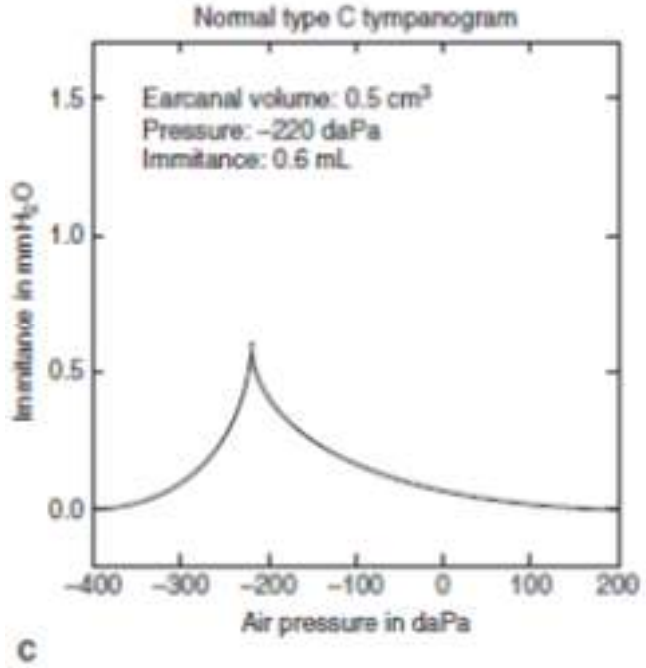


Fig 11: Type C Tympanogram

MATERIALS AND METHODS

Study design: A Randomised Controlled Trial.

Study period: January 2020 to March 2021

Sample size (n): 40 (20 each belonging to adenoidectomy group and adenoidectomy with grommet insertion group respectively).

Sample size formula:

The minimum sample size formula based on two proportions is

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

Where p_1 and p_2 are the proportions of the two groups.

$$p = \frac{p_1 + p_2}{2} \text{ and } d = p_1 - p_2$$

Zα is linked with the level of significance and z_β is linked with the power of the test. For 5% level of the significance zα = 1.96 and z_β = 0.84 for 80% power of the test. By taking proportion of percentage of complete removal, p_1 = 46% and p_2 = 93%, in the two procedures, the sample size obtained is 15 (in each group).[2]

Note: This is the minimum sample size. If possible one can take cases little more than the number so that the results become more confirmative. There is no condition that there should be equal number cases in the two groups both should exceed the minimum sample size.

Statistical Analysis:

The study is focused on comparison of two groups. For the continuous quantitative variables mean and standard deviation will be calculated. The inter group continuous variables will be compared using suitable tools of statistics like normal test, unpaired student's t test. Two quantitative variables, within a group, will be compared using student's paired t test.

Discrete variables will be represented by median. Suitable graphs will be used to depict the comparison.

Rates, ratios, and percentages were used to convey categorical data. The Chi-square test or Fisher's exact test will be used to assess the relationship between the result, clinical, and demographic factors.

All tests will be considered significant if the p value is less than 5% (0.05).

INCLUSION CRITERIA:

All cases of Adenoid hypertrophy with OME done in ENT&HNS department in KLE Dr.Prabhakar Kore charitable hospital.

- Patients with OME between the ages of 3 and 18 years.
- Adenoid facies
- Mouth breathing and snoring
- Treatment with antibiotics prior to surgery
- Patients' guardians/parents who are willing to grant signed, informed permission

EXCLUSION CRITERIA:

- Patients having craniofacial syndrome(cleft lip and cleft palate)
- Acute Adenotonsillitis
- Patients of acute suppurative OM & chronic suppurative OM
- Congenital deformities of ear
- Previous adenoidectomy history
- Allergic rhinitis history

METHODOLOGY:

- Patients who meet the inclusion criteria will be enrolled in the research after receiving clearance and permission from the institutional ethics committee, as well as written informed consent from parents/guardians and an informed assent form from the children..
- Demographic information, a full history of adenotonsillitis-related problems such as mouth breathing, difficulty breathing through the nose, snoring, throat pain, throat discomfort, any parental concern of hearing loss, and other pertinent information will be collected. Following that, a clinical and ENT examination will be performed. In a research proforma, all of the findings will be documented.
- During the ear examination, any ear wax will be carefully removed and otoscopy will be used to analyse the ear. The state and appearance of the tympanic membrane will be recorded.
- If adenotonsillitis is suspected, a digital x-ray of nasopharynx soft tissue neck will be requested, and hypertrophy will be graded using the Fujioka scale. Patients will next undergo pure tone audiometry and a tympanometric examination, both of which will be performed by an audiologist.

- Patient will be subjected to either adenoidectomy or to adenoidectomy with grommet insertion. In order to do so, the patients will be randomly assigned into 2 groups, odd number patients in “group A” and even number in “group B”. Where group A patients will undergo adenoidectomy and group B will undergo adenoidectomy with grommet insertion
- Patients will be given general anesthesia with orotracheal intubation.
- Adenoidectomy will be done using the adenoid curette
- A myringotomy will be performed in anterior-inferior quadrant of eardrum, followed by aspiration of middle ear effusion and insertion of grommet.
- An audiologist will conduct a repeat pure tone audiometry and tympanometric assessment at 6-week follow-up to check for hearing improvement.
- Patients will be subjected to routine investigations for anesthetic assessment and for fitness of surgery.
- “X-ray Nasopharynx lateral view” for “soft tissue visualization” will be taken.
- “Pre operative and post operative” Pure Tone Audiometry
- “Pre operative and post operative” Tympanometry

RESULTS

The following study was carried out as a randomized control trial in "KLES Dr. Prabhakar Kore Hospital, Belagavi" from January 2020 to March 2021.

The study included 40 children who presented to the ENT OPD with symptomatology suggestive of OME which was confirmed on examination and investigation.

After which they were randomly assigned into either the adenoidectomy or adenoidectomy with grommet insertion wings of the study.

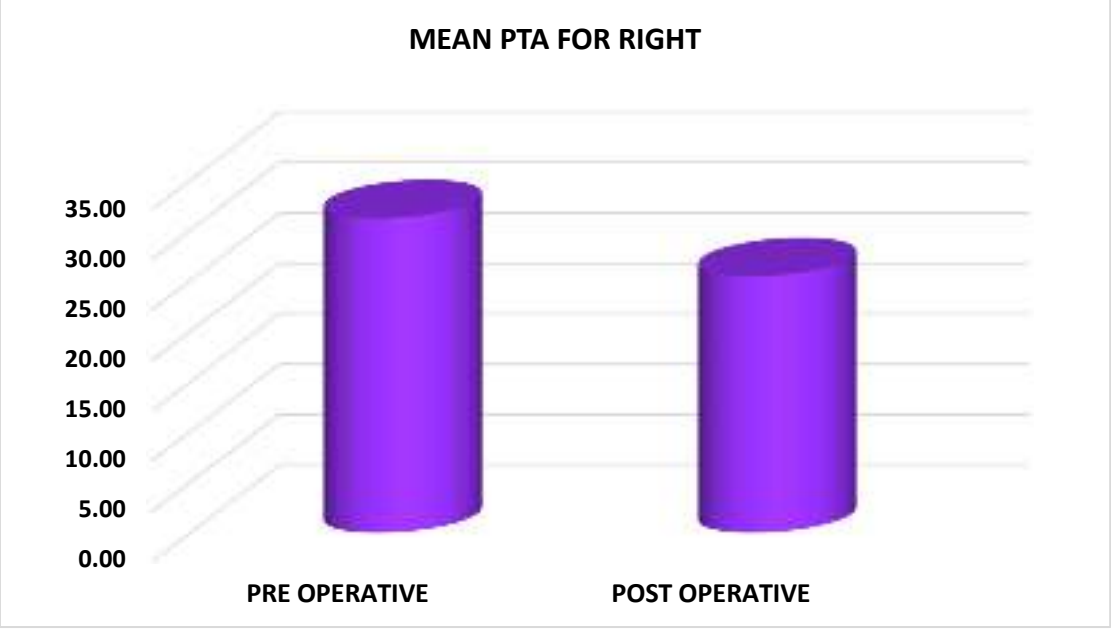
FOR RIGHT				
POST OP TYMPANOMETRY				
PRE OP TYMPANOMETRY	**A**	**B**	**C**	**TOTAL**
A	2	0	0	2
B	0	12	15	27
C	0	0	11	11
TOTAL	2	12	26	40

Table 1. Demonstrates the comparison between the pre op and post op tympanometry graphs for the right ear

FOR LEFT				
	POST OP TYMPANOMETRY			
PRE OP TYMPANOMETRY	**A**	**B**	**C**	**TOTAL**
A	5	0	0	5
B	0	17	17	34
C	0	0	1	1
TOTAL	2	12	26	40

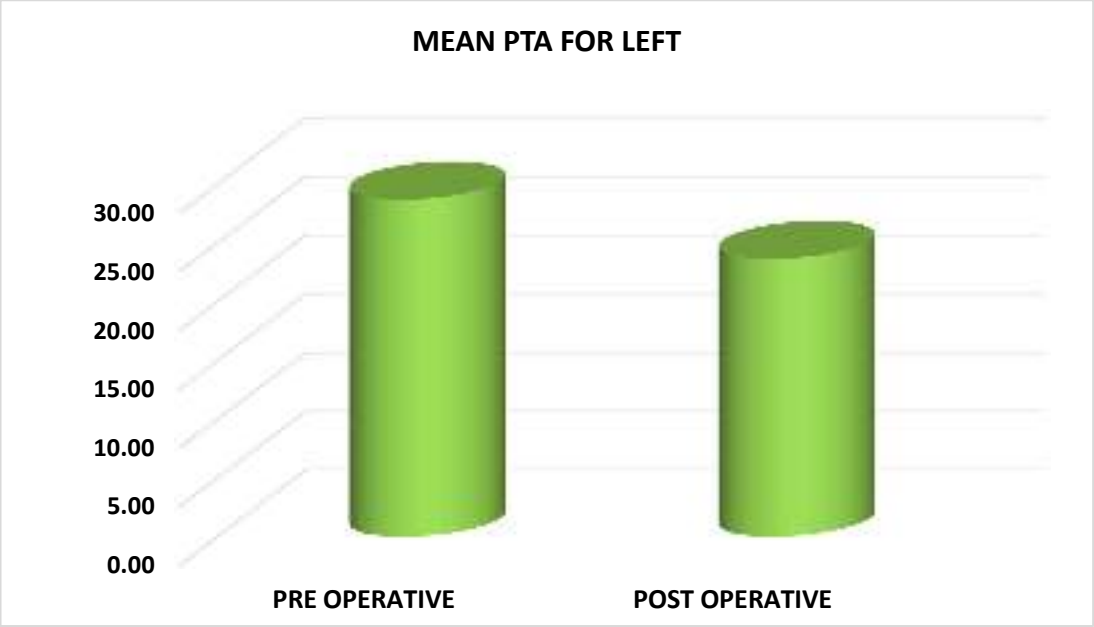
Table 2. Demonstrates the comparison between the pre op and post op tympanometry graphs for the left ear

IN THE FOLLOWING TABLES p VALUE IS CALCULATED USING STUDENT'S PAIRED t TEST									
abbreviations:	**ns -not significant**			**s - significant**		**vs - very significant**			**hs - highly significant**
PRE OP PTA FOR RIGHT				**POST OP PTA FOR RIGHT**					
MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
31.21	8.42	13	46.6	25.46	7.08	13	40.6	0.0007	HS



Graph 1: Compares the outcome of surgery on the sample size of the right ear being measured by the preoperative and the postoperative differences of the pure tone audiometry

PRE OP PTA FOR LEFT				POST OP PTA FOR LEFT					
MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
28.71	9.94	11	46.6	23.67	8.10	10	37.6	0.0076	VS



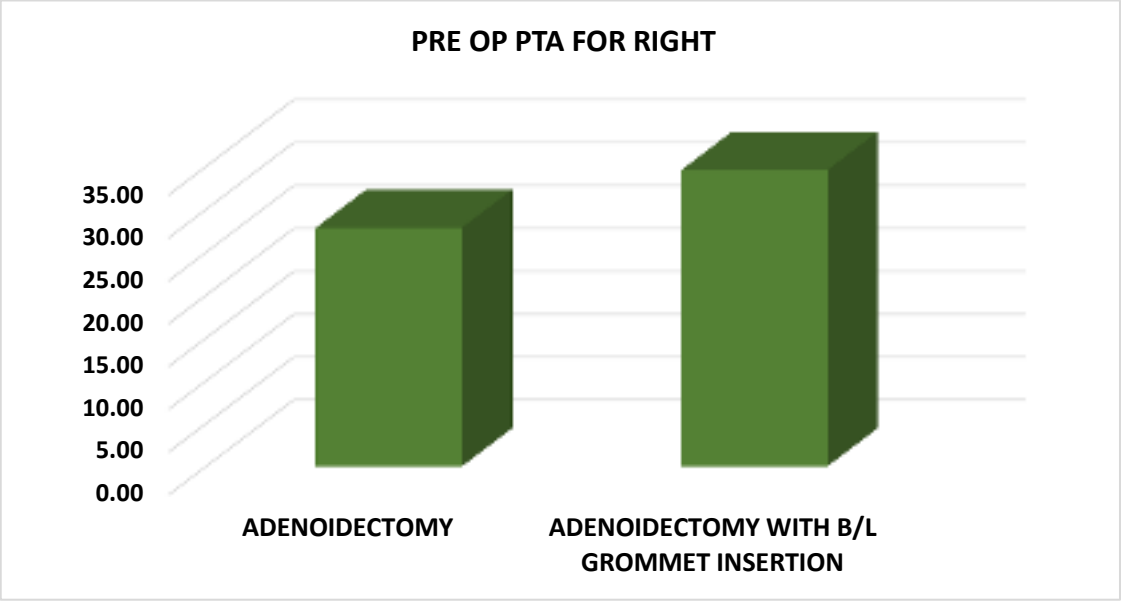
Graph 2: Compares the outcome of surgery on the sample size of the left ear being measured by preoperative and the postoperative differences of the pure tone audiometry

PROCEDURE	NUMBER	%
ADENOIDECTOMY	20	50.00
ADENOIDECTOMY WITH B/L GROMMET INSERTION	20	50.00
TOTAL	40	100.00

Table 3 .Division of patients into surgical arms

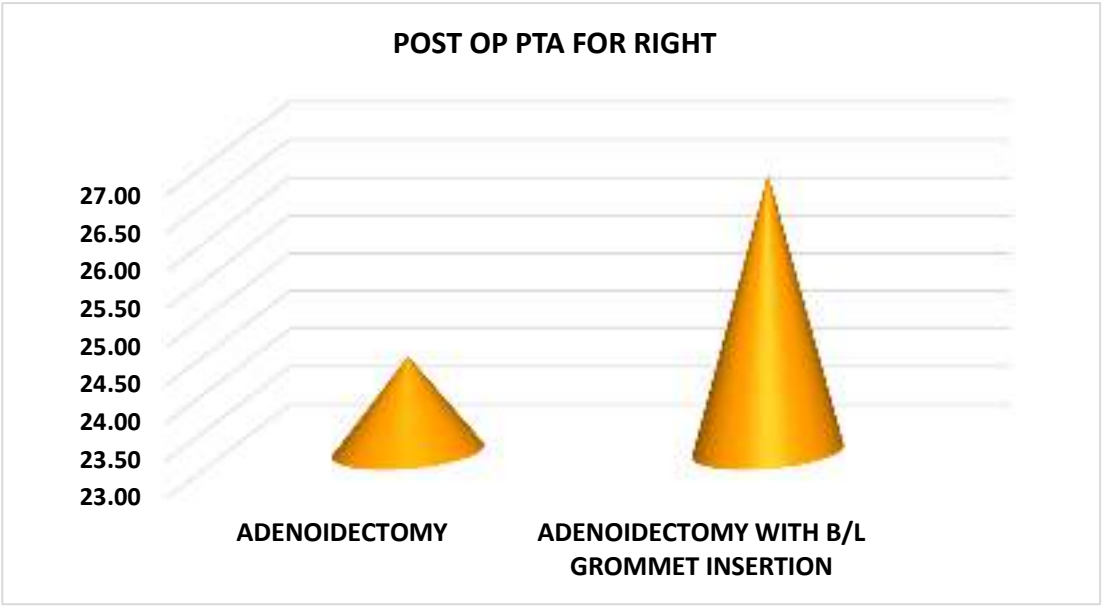
The total number of patients included in the study was 40 of which by random allocation they were divided into 2 groups that is the adenoidectomy and adenoidectomy with grommet insertion wings of the study

FOR PRE OP PTA FOR RIGHT									
ADENOIDECTOMY				ADENOIDECTOMY WITH B/L GROMMET INSERTION					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
27.85	8.71	13	44.6	34.57	6.77	24.4	46.6	0.0096	VS



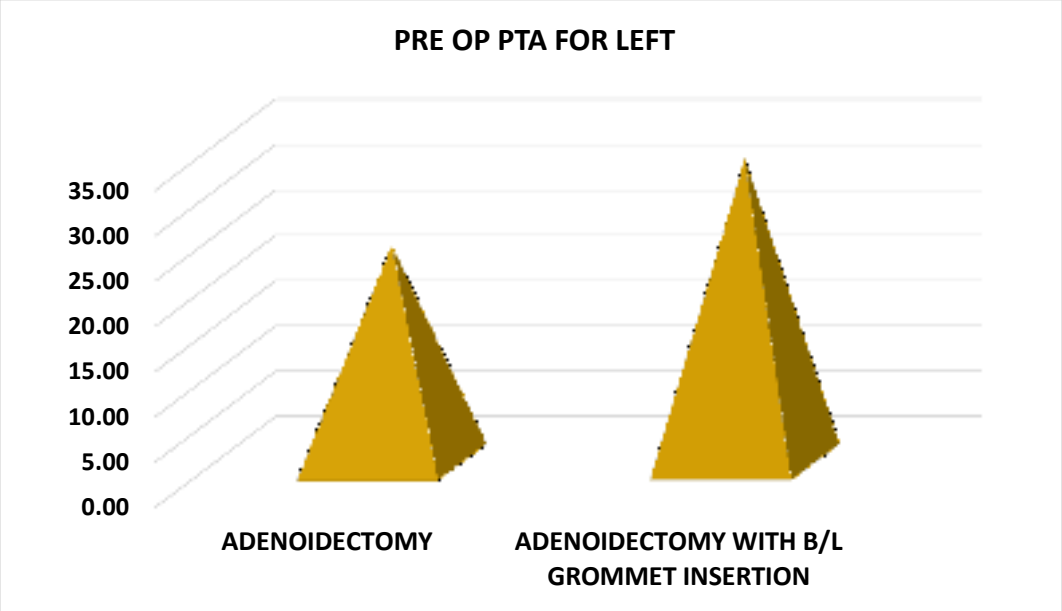
Graph 3. Compares the pre op values of the pure tone audiometry for the right ear between adenoidectomy v/s adenoidectomy with grommet insertion

FOR POST OP PTA FOR RIGHT									
ADENOIDECTOMY				ADENOIDECTOMY WITH B/L GROMMET INSERTION					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
24.26	7.40	13	40.6	26.67	6.71	18	38.6	0.2874	NS



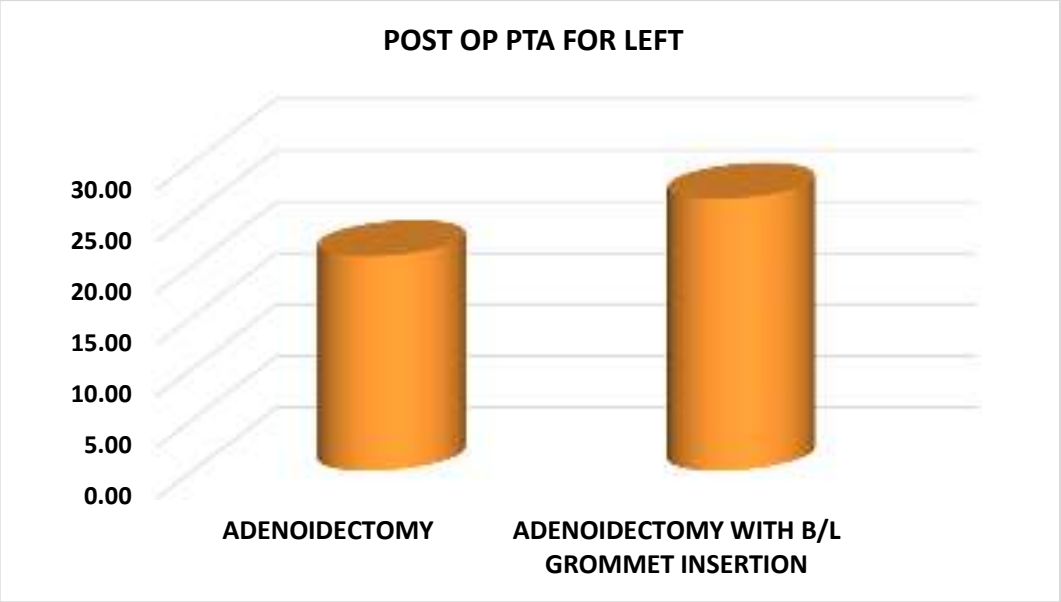
Graph 4. Compares the post op values of the pure tone audiometry for the right ear between adenoidectomy v/s adenoidectomy with grommet insertion

FOR PRE OP PTA FOR LEFT									
ADENOIDECTOMY				ADENOIDECTOMY WITH B/L GROMMET INSERTION					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
23.93	9.91	11	44.6	33.48	7.53	24	46.6	0.0015	VS



Graph 5. Compares the pre op values of the pure tone audiometry for the left ear between adenoidectomy v/s adenoidectomy with grommet insertion

FOR POST OP PTA FOR LEFT									
ADENOIDECTOMY				ADENOIDECTOMY WITH B/L GROMMET INSERTION					
MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
20.88	8.46	10	37.6	26.47	6.83	17	37.3	0.0271	S



Graph 6. Compares the post op values of the pure tone audiometry for the left ear between adenoidectomy v/s adenoidectomy with grommet insertion

Both the arms of the intervention showed a successful improvement in hearing loss on comparing pre op and post op pure tone audiometry values after a 6 week interval

Adenoidectomy group having an improvement of 3.32 db hearing loss

Adenoidectomy with B/L grommet insertion having an improvement of 7.45 db hearing loss

With respect to impedence audiometry in both study arms the type b graph moved to a type c graph post intervention

DISCUSSION

The study title "Hearing improvement after adenoidectomy v/s adenoidectomy with grommet insertion in cases of otitis media with effusion" was a randomized control trial in KLES Dr. Prabhakar Kore hospital, Belagavi conducted from Jan 2020 to March 2021. We verified the long-term results of earlier research on audio logical outcomes in 40 children having otitis media with effusion who received adenoidectomy with grommet insertion vs adenoidectomy in this randomised investigation. The results of our research also revealed pre- and post-operative health-related quality of life knowledge.

Age and Sex Distribution

In our study majority of the children were between the ages of 7 to 10 years of age with the mean age being 9.8 yrs. In the present study of 40 subjects, 24 males (60%) and 16 females (40%) were included. Male-Female ratio was 1.5:1. As per Khayat FJ 2013 [8] The mean age was 9.7± 2.5 years, and most cases with OME were among children in their 7th and 12th year of age. OME was found in 26 (54.2%) females compare to 22 (45.8%) males with a female to male ratio of 1.18 to 1.

As per Upadhya Ila 2014[11] 75% were 07–10 years of age, 5% were 10–13 years of age. Male to female ratio was 1.85:1. According to Tuli.S.B 2001[13] majority of the patients were children between 6-13 years (56%), 14-24 years (22%) 25-34 years (16%), 35 years and above (6%)., Male-female ratio was 2 : 1.

Symptomatology

In our study, out of total 40 patients, decreased hearing was reported by all the patients (100%). As per Upadhya I 2014[11] The most common presenting symptom was decreased hearing 36.67% unilateral, 13.33% bilateral followed by earache

36.67% unilateral, 6.67% bilateral. The less common were nasal discharge, throat pain, vertigo and tinnitus. Farida Khan et al who quoted 52% hearing impairment, 18% earache and 16% ear blockage. Din et al. found hearing loss in 90% patients. According to Tuli.S.B 2001[13] Nasal allergy (72%) and deafness (100%) were the pronouncing symptoms.

Otoscopic findings

In our study, out of total 40 patients, on otoscopy, retraction of the TM was seen in 36 patients (90%), normal TM in 3 (7.5%) & bulged TM in 1 (2.5%) of cases. As per Sinha V 2005 [7]The result of otoscopic examination were retracted drum in 45%, dull appearance in 13%, opaque appearance in 4%, oil drop appearance in 1%, air bubbles behind TM 6%, and normal drum in 31% of cases. As per Upadhya I 2014[11] The most common otoscopic findings were retracted drum in 35% unilateral and 11.67% bilateral ears, congested in 33.33% unilateral, 3.33% in bilateral ears followed by bulged drum in 8.33% unilateral, 3.33% bilateral and normal drum in 0% unilateral, 5% bilateral cases.

As per Bandyopadhyay. T 2018 [12] The commonest appearance of tympanic membrane was dull in both sides on Otoscopy (60 and 74% in right and left ear respectively). According to Tuli.S.B 2001[13] otoscopy of tympanic membrane showed Retraction (52%), Bulge (44%) and normal (4%), Restricted mobility (96%), Dull grey appearance (84%).

Functional examination

In our study tuning fork tests showed conductive hearing loss in 100% patients. Pure tone audiometry showed minimal hearing loss in 31 (77.5%) cases & moderate hearing loss in 9 (22.5%) cases with a mean air bone gap of 29.96 dB. Impedance audiometry showed B-type Tympanogram in 34 (85%) cases, C-type in 5

(12.5%) cases and A-type in 1 (2.5%) cases. As per Khayat FJ 2013 [8] The mean pure tone audiometry gap was 23.5 ±10.6 decibels, ranging between 5 to 50 decibels. Meanwhile, 30 (62.5%) of cases showed mild hearing loss (62.5% of right ears; 58.3% of left ears). Moderate hearing loss was found in 18 (37.5%) of cases (25% of right ears, and in 33% of left ears). Type B tympanogram were seen in 87.5% of right ears and 79.2% of left ears.

As per Nwosu C 2016 [9] incidence of type B tympanogram was 29.4%, while type C was 26.5% with type a accounting for 44.1%.In a study by Upadhya I 2014[11] B type Tympanograms was found in 66.67% in unilateral ears and 33.33% in bilateral ears. Khan found B type to be the commonest finding. Bhatta and Adhikari found 90.2% of children with OME having B type Tympanograms.As per Bandyopadhyay. T 2018 [12] B type tympanograms were obtained in most ears (82 and 88% for right and left ear respectively).According to Tuli.S.B 2001[13] Pure tone audiometry showed average air-bone gap of 15-30 dB in 64% cases while 31-45 dB in 36% cases.Impedance audiometry showed B-type Tympanogram in 60% cases and C-type in 40% cases.

Adenoid hypertrophy

It is apparent that adenoids are usually enlarged in children who have OME. As visualised on x ray lateral view nasopharynx all cases had adenoid hypertrophy which conforms to theory that enlarged adenoids plug Eustachian tube aperture, thereby averting replacement of air which is absorbed from middle ear.

Outcome

In OME, myringotomy and grommet insertion combined with adenoidectomy results in effusion clearance and a return to normal hearing status.[7]

Myringotomy with grommet insertion in antero-inferior quadrant of TM, is a successful procedure with or without adenoidectomy and consistent therapy alternative for individuals with OME.[10]

In a randomised controlled prospective study effected by Chaudhuri R.G et al in 2006 on 100 paediatric age group (0-12 years) patients chosen from the ENT OPD, 92 percent of surgical remediated patients showed statistically significant improvement after 2 months on clinical, otomicroscopic, and PTA findings.[10] In a prospective, randomised research by Upadhya I et al in 2014. Otitis media with effusion is most prevalent between the ages of 7 and 10 years old. After surgical excision of adenoids, patients had a 100 percent success rate with respect to hearing improvement.[11]

Bandyopadhyay T et al 2018 conducted a two-year prospective comparison research with 100 youngsters, 50 as cases and 50 as controls (children between ages 1 and 10). The results of various treatment techniques were separated into surgical (22) and medical (non surgical) groups (28) in this investigation, results were calculated after 3 and 6 months. After three months, the difference in treatment methods was statistically significant.[12]

Preoperative and postoperative tympanometry & PTA were performed in 100 patients with OME in a research by Tuli S.B et al 2001. In 52 percent of cases, the postoperative air bone gap lowered by 10–20 dB, while 40 percent of cases, the gap was more than 20 dB.[13] Thus, between 3 months and longer after grommet implantation, the sickness was resolved and hearing improved.[13]

Maw et al. (1993) studied 228 children aged 2 to 9 years who had severe hearing loss due to glue ear and chronic bilateral ME effusions that were verified 3 times over 3 months. Compared to no surgery, ventilation tubes alone &

adenoidectomy alone exhibited significant otoscopic and tympanometric clearance of fluid. The combination of both therapies resulted in much more improvement. With fluid resolution, mean audiometric hearing thresholds improved. The efficacy of adenoidectomy was sustained throughout follow-up, whereas a Shepard tube singular insertion resolved adhesive for a mean (SD) duration of 9.5 (5.2) months. Combination adenoidectomy and tube insertion method was superior than either operation alone in reducing the time to fluid clearance in glue ear.[14]

In a study performed by Vlastos M I et al. in 2011 to see if insertion of tympanostomy tube is beneficial over myringotomy in children with OME older than 3 years who receive concurrent adenoidectomy as treatment, they found it beneficial.[15] In a study by, Coyte PC et al in 2001 outcomes of surgery for all 37,316 children (classified as those aged 19 and under) in Ontario, Canada, who had tympanostomy tubes as their initial surgical therapy for otitis media were evaluated. They calculated the period between the first readmission for otitis media-related disorders and the first reinsertion of tympanostomy tubes & concluded that doing an adenoidectomy or adenotonsillectomy at the time of the initial insertion of tympanostomy tubes significantly reduced the chance of subsequent otitis media hospitalizations and surgeries in children under the age of two.[16]

Despite the fact that adenoidectomy and adenoidectomy with grommet insertion have been shown to improve hearing in OME children, treatment is not risk free. As a result, large, well-controlled trials that evaluate acute OM recurrence, functional results, measures of life quality, and long-term outcomes might help resolve the “risk–benefit ratio”. Furthermore, those with craniofacial anomalies and other co-morbidities would undoubtedly require additional sub-grouping in order to make more informed treatment decisions.

CONCLUSION

Conclusions of our study include following:

- Between the ages of 7 and 10, OME is the most prevalent.
- Males are more likely to have OME.
- Hearing loss was the most prevalent complaint.
- The otoscopic findings in OME patients were normal, bulged, or retracted TM. The frequency of retracted TM is higher than average.
- Majority had mild conductive hearing deficit on PTA.
- SNHL was not present in any of them.
- The majority of our patients had pre-op B type Tympanograms on impedance audiometry.
- Adenoid hypertrophy was noted in all cases presenting with OME
- Both the arms of the intervention showed a successful improvement in hearing loss on comparing pre op and post op pure tone audiometry values after a 6 week interval
- Adenoidectomy group having an improvement of 3.32 db hearing loss
- Adenoidectomy with B/L grommet insertion having an improvement of 7.45 db hearing loss
- With respect to impedence audiometry in both study arms the type b graph moved to a type c graph post intervention

Hence we can conclude that hearing improvement after adenoidectomy with b/l grommet insertion is greater as compared to adenoidectomy alone though both interventions are responsible for the improvement in cases of OME.

SUMMARY

Assessment of the hearing improvement is definitive in determining superior surgical modality adoption. Methods of assessement are easy to perform, requiring minimal equipment, expertise and patient cooperation. In our study, we used PTA & Tympanometry to determine the superior surgical procedure based on hearing improvement postoperatively.

Our study was a randomised control trial that included 40 subject with OME that had hearing impairment and were consequently divided randomly into adenoidectomy and adenoidectomy with grommet insertion.

We performed preoperative and postoperative PTA and Tympanometry to determine the degree of hearing improvement.

After analysis of our findings, we found that both arms of the intervention showed a successful improvement in hearing loss on comparing pre op and post op pure tone audiometry values after a 6 week interval

Adenoidectomy group having an improvement of 3.32 db hearing loss

Adenoidectomy with B/L grommet insertion having an improvement of 7.45 db hearing loss

With respect to impedence audiometry in both study arms type b graph moved to a type c graph post intervention

The findings of our study highlight the negative sequelae of a undiagnosed and untreated OME patients with respect to delays in language development, social behavior, learning difficulties hence affecting academic performance. Hence prompt diagnosis and consequent therapy is important in ensuing a positive outcome.

We would like to conclude that, using Pre and postoperative PTA & Tympanometry for assessment was found to be a simple and quick method to analyze the hearing improvement.

We recommend performing corrective surgery of adenoidectomy with b/l Grommet insertion, to correct and restore the ear physiology. This can prevent further complications of the disease and improve the quality of life of patients.

Further studies can also be performed to compare the preoperative and postoperative results at greater intervals, after corrective surgery.

Limitations of this study include

- small sample size , short follow up period , presence of other confounding factors
- dropouts during the observation period as a result of the covid 19 pandemic as well as restricted time period for data collection and assessment
- probability of improper adenoid clearance as traditional method used influencing results

BIBLIOGRAPHY

1. McKerrow WS. Diseases of the tonsil. In: Gleeson M, Browning GG, Burton MJ, Clarke R, Hibbert J, Jones NS, et al., editors. Scott-Brown's Otorhinolaryngology: Head and Neck Surgery. 7th ed. London: Hodder Arnold; 2008 1219-1228
2. Robb PJ. The adenoid and adenoidectomy. In: Gleeson M, Browning GG, Burton MJ, Clarke R, Hibbert J, Jones NS, et al., editors. Scott-Brown's Otorhinolaryngology: Head and Neck Surgery. 7th ed. London: Hodder Arnold; 2008 1094-1101
3. Browning G. Otitis media with effusion. In: Gleeson M, Browning GG, Burton MJ, Clarke R, Hibbert J, Jones NS, et al., editors. Scott-Brown's Otorhinolaryngology: Head and Neck Surgery. 7th ed. London: Hodder Arnold; 2008 877-911
4. Rosenfeld R, Shin J, Schwartz S, Coggins R, Gagnon L, Hackell J et al. Clinical Practice Guideline: Otitis Media with Effusion Executive Summary (Update). Otolaryngology - Head and Neck Surgery. 2016 Feb;154(2): 201-214
5. Osama G, Awad AN.Timing for Removal of Asymptomatic Long-Term Ventilation Tube in Children Indian J Otolaryngol Head Neck Surg. 2016 Dec; 68(4): 406–412.
6. Boonacker CWB, Rovers MM, Browning GG, Hoes AW, Schilder AGM, Burton MJ. Adenoidectomy with or without grommets for children with otitis media: an individual patient data meta-analysis.
   Health Technol Assess 2014;18(5).

7. Sinha V, Patel BH, Sinha S. Incidence of uncomplained secretory otitis media in patients undergoing adenotonsilectomy.Indian J Otolaryngol Head Neck Surg. 2005;57(2):110-111
8. Khayat FJ, Shareef LA. Association Between Size of Adenoid and Otitis Media with Effusion Among a Sample of Primary School Age Children in Erbil City. Diyala Journal of Medicine. 2013;5(2)1-10
9. Nwosu C, UjuIbekwe M, ObukowhoOnotai L. Tympanometric Findings among Children with Adenoid Hypertrophy in Port Harcourt, Nigeria. Int J Otolaryngol. 2016 Aug;1276543.1-4
10. Chaudhuri R.G, Bandyopadhyay N.S, Basu K.S, Role of grommet in otitis media with effusion: a necessity or nuisance? A comparative study. Indian J Otolaryngol Head Neck Surg. 2006 Jul; 58(3): 271–273
11. Upadhya I, Datar .J Treatment Options in Otitis Media with Effusion. Indian J Otolaryngol Head Neck Surg. 2014 Jan; 66(Suppl 1): 191–197
12. Bandyopadhyay. T ; Raman V.E Otitis media with effusion in urban pediatric population in a tertiary care centre :A clinical study.Indian J Otolaryngol Head Neck Surg. 2018 Jun; 70(2): 267–272.
13. Tuli.S.B, Parmar.L.T , Singh.B . Evaluation of tympanostomy tubes in middle ear affections Indian J Otolaryngol Head Neck Surg. 2001 Jul; 53(3): 217–220.
14. Maw .R, Bawden.R Spontaneous resolution of severe chronic glue ear in children and the effect of adenoidectomy, tonsillectomy, and insertion of ventilation tubes (grommets). Bristol medical journal 1993;306:756-60.
15. Vlastos M I, Houlakis M, Kandiloros D, Manolopoulos L, Ferekidis E ,Yiotakis I. Adenoidectomy plus tympanostomy tube insertion versus adenoidectomy plus

myringotomy in children with obstructive sleep apnoea syndrome.The Journal of Laryngology & Otology (2011), 125, 274–278.

16. Coyte PC, Croxford R, McIsaac W, Feldman W, Friedberg J. The role of adjuvant adenoidectomy and tonsillectomy in the outcome of the insertion of tympanostomy tubes. N Engl J Med 2001;344:1188–95
17. Paludetti G, Conti G, Dinardo W, et al. Infant hearing loss; from diagnosis to therapy. ACTA Otorhinolaryngologica Italica 2012;32:347-70.
18. Kral A, O'Donoghue G. Profound deafness in childhood. The New England Journal Of Medicine 2010;363:1438-50.
19. Chaturvedi V. Hearing impairment and deafness magnitude of problem and strategy for prevention. IJO and HNS 1999;51(2):3-6.
20. Deafness and hearing loss [internet]. February2017. Available from: http://www.who.int/mediacentre/factsheets/fs300/en/
21. Varshney S. Deafness in India. Indian J Otol 2016;22:73-6
22. The Rehabilitation Council of India Act, 1992, Ministry of Law, Justice and Company Affairs (1992): (No. 34 of 1992), New Delhi; 1992. Available from: http://www.rehabcouncil.nic.in/engweb/rciact.pdf.
23. The Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995 Ministry of Law, Justice and Company Affairs (1996): (No. 1 of 1996), New Delhi: The Gazette of India; 1996. p .24
24. Garg S, Chadha S, Malhotra S, Agarwal AK. Deafness: Burden, prevention and control in India. Natl Med J India 2009;22:79-81
25. Singh V. Hearing in India: All aspects. Otolaryngol Online J 2015;5.

26. World Health Organization. State of Hearing and Ear Care in the South East Asia Region. WHO Regional Office for South East Asia. WHO-SEARO. SEA/Deaf/9; 2009.

27. http://www.indianjotol.org/viewimage.asp?img=IndianJOtol_2016_22_2_73_182281_t1.jpg

28. Hearing loss in children DOI: 10.1542/pir.30-6-207.Pediatrics in Review 2009;30;207. Kimberly A. Gifford, Michael G. Holmes and Henry H. Bernstein

29. Anson BJ, Donaldson JA. Surgical Anatomy of the Temporal Bone and Ear. Philadelphia, PA: WB Saunders; 1981.

30. Anson BJ, McVay CB. Surgical Anatomy, 5th edition. Philadelphia, PA: WB Saunders; 1981.

31. Lim DJ. Tympanic membrane. Electronmicroscopic observations. Part I. Pars tensa. Acta Otolaryngol (Stockh); 1968;66:181–98.

32. Lim DJ. Tympanic membrane. Part II: Pars flaccida. Acta Otolaryngol (Stockh) 1968;66:515–32.

33. William Lincoln Ballenger MD. Otorhinolaryngology, Head and Neck surgery. 17th edition. Connecticut:People's medical publishing house; 2009.

34. Anson BJ. Morris' Human Anatomy, 12th edition. New York: McGraw-Hill; 1966.

35. Bluestone CD. Introduction. In: Bluestone CD, editor. Eustachian Tube Structure, Function, Role in Otitis Media. London, Ontario: BC Decker Inc; 2005. p. 1–9.

36. Hopf J, Linnarz M, Gundlach P, et al. Microendocopy of the eustachian tube and the middle ear. Indications and clinical application. Laryngorhinootologie 1991;70:391–4.

37. Rosenfeld RM. Comprehensive management of otitis media with effusion. Otolaryngol Clin North Am. 1994; 27: 443-55.

38. Zielhuis GA, Gerritsen AA, Gorissen WH, Dekker LJ, Rovers MM, Vander Wilt GJ, Ingels K. Hearing deficits at school age; the predictive value of otitis media in infants. Int J Pediatr Otorhinolaryngol. 1998; 44: 227-34.

39. Michael Gleeson. Scott Brown's Otorhinolaryngology, Head and Neck surgery. 8th edition. Great Britain:Hodder Arnold;2018.

40. Kraemer MJ, Richardson MA, Weiss NS, Furukawa CT, Shapiro GG, Pierson WE, Bierman CW. Risk factors for persistent middle-ear effusions. Otitis media, catarrh, cigarette smoke exposure, and atopy. JAMA. 1983; 249:1022-5.

41. Gates GA. Acute otitis media and otitis media with effusion. In. Cummings CW, Fredrickson JM, Harker LA, Krause CJ, Richardson MA, Schuller DE editors. Pediatric Otolaryngology: Head and Neck Surgery, 3rd ed, St Loius: Mosby; 1998.. P 461- 477.

42. Sano S, Kamide Y, Schachern PA, Paparella MM. Micropathologic changes of pars tensa in children with otitis media with effusion. Arch Otolaryngol Head Neck Surg 1994; 120:815- 19.

43. Daly KA, Hunter LL, Levine SC, Lindgren BR, Giebink GS. Relationships between otitis media sequelae and age. Laryngoscope. 1998; 108: 1306-10.

44. Maw AR. Otitis media with effusion. In.Adams DA, Cinnamond MJ editors. Scott-Brown`s Otolaryngology. Volume 6, 6th ed: Butterworth-Heineman;1997: p 1-23.

45. Bluestone CD. Epidemiology. In: Bluestone CD, editor. Eustachian Tube Structure, Function, Role in Otitis Media. London, Ontario: BC Decker Inc; 2005. p. 11–24.

46. Proctor B. Anatomy of the eustachian tube. Arch Otolaryngol 1973;97:2–8

47. Kaleida PH, Fireman P. Diagnostic assessment of otitis media. Clin Allergy Immunol 2000;15:247–62.

48. Preston K. Pneumatic otoscopy: A review of the literature. Issues Compr Pediatr Nurs 1998;21:117–28.

49. Bluestone CD, Gates GA, Klein JO, Lim DJ, Mogi G, Ogra PL et al. Definitions, terminology, and classification of otitis media. Annals of Otology, Rhinology and Laryngology. 2002; 188: 8–18. Up-to-date and succinct account of terminology in otitis media.

50. Little P, Gould C, Moore M, Warner G, Dunleavey J, Williamson I. Predictors of poor outcome and benefits from antibiotics in children with acute otitis media: pragmatic randomised trial. British Medical Journal. 2002; 325: 22–5.

51. Lieu JE, Muthappan PG, Uppaluri R. Association of reflux with otitis media in children. Otolaryngol Head Neck Surg 2005;133:357–61.

52. Daly KA, Hunter LL, Giebink GS. Chronic otitis media with effusion. Pediatr Rev 1999;20:85–93

53. Rosenfeld RM. Surgical prevention of otitis media. Vaccine. 2000; 19: S134–9.

54. Paradise JL, Bluestone CD, Rogers KD, Taylor FH, Colborn DK, Bachman RZ et al. Efficacy of adenoidectomy for recurrent otitis media in children previously treated with tympanostomy-tube placement. Journal of the American Medical Association. 1990; 263: 2066–73.

55. Neilsen SE, Olsen SO. Validation of play-conditioned audiometry in a clinical setting. Scandinavian Audiology. 1997; 26: 187–91.

56. Anil K. Lalwani. Current diagnosis and treatment in Otorhinolaryngology, Head and Neck surgery. 3rd edition. McGraw-Hill;2012.

ANNEXURE I

ETHICAL CLEARANCE.

JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI 590010 (KARNATAKA-INDIA)
Website: http://www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+91-0)831 Office : 2472550
Principal: 2471701
Fax No: +91-(0)831 - 2470759

Ref: MDC/DOME/ IEC. **Date: 24/12/2019**

To,

REG. NO: BE0119004
PG student in Otorhinolaryngology and Head & Neck Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"HEARING IMPROVEMENT AFTER ADENOIDECTOMY V/S ADENOIDECTOMY WITH GROMMET INSERTION IN CASES OF OTITIS MEDIA WITH EFFUSION- RANDOMIZED CONTROL TRIAL IN KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI "**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

24

ANNEXURE II

INFORMED CONSENT

"HEARING IMPROVEMENT AFTER ADENOIDECTOMY V/S ADENOIDECTOMY WITH GROMMET INSERTION IN CASES OF OTITIS MEDIA WITH EFFUSION"- A 1 YEAR RANDOMIZED CONTROL TRIAL IN KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI.

PRINCIPAL INVESTIGATOR: REG. NO: BE0119004.

CO-INVESTIGATOR : DR. _____

INTRODUCTION AND PURPOSE:

The present study is conducted among patients who are undergoing adenoidectomy in ENT & HNS department in KLE's Dr.PrabhakarKore Hospital and Medical Research Centre, Belgaum forhearing improvement after adenoidectomy v/s adenoidectomy with grommet insertion in cases of otitis media with effusion. You are requested to participate in the study and your participation is completely voluntary.

PROCEDURE:

If you agree to participate in this study, the relevant data will be collected as per the proforma and the final diagnosis will be confirmed. After getting inducted in the study, your child/ward will be evaluated with X-RAY nasopharynx lateral view and pre operative pure tone audiometry and tympanometry. At the 6 weeks follow up patient will be subjected to post operative pure tone audiometry and tympanometry to assess hearing improvement.

BENEFITS:

Your child/ward will not be eligible for any kind of monetary benefits or free services by virtue of your participation in the study.

RISKS:

Methods applied to do the study are safe. Intra-operative and post-operative bleeding can occur. Post-operative pain though minimal can also occur

COST OF PARTICIPATION:

The cost of the Investigation will be borne by the Study Subject. The other indirect expenses will be borne by the Investigator.

PRIVACY AND CONFIDENTIALITY:

The results of the study may be published in journals for scientific purposes. However, your child's/ward's identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY:

You can withdraw from the study at any time if you wish to do so.

AUTHORIZATION TO PUBLISH THE RESULTS:

The researcher may use the information gathered from this study for presentation in scientific meetings. However, your child's/ward's identity will not be revealed.

QUERIES AND CONTACT:

If you have any queries regarding the study, you can contact **REG. NO: BE0119004.** without any hesitation on Mobile no: _____ and the guide Dr. _____ on Mobile no:_____. If you have any questions about rights as a research participant you can contact Dr.Roopa M Bellad, Professor, Department of Pediatrics and Chairman, Jawaharlal Nehru Medical College Institutional Ethics Committee on human subjects' research on mobile no. 9448113403

CONSENT SUMMARY:

I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom I recognize.

Name and Signature/ left thumb impression of the parent/guardian:

Name and Signature of the interviewer:

Name and Signature/ left thumb impression of the eyewitness (Relative):

Signature of the guide:

Date:

माता-पिता / अभिभावक द्वारा सूचित सहमति / आश्वासन

"सुनवाई के बाद एडेनोइडेक्टोमी की एवं एडेनोइडेक्टोमी के साथ सुनवाई में सुधार ओटिटिस मीडिया के मामलों में उत्तेजना के साथ" - केएलईएस डॉ प्रभाकर कोरे मेमोरियल, बेलगावी में । ज्ञान का यादृच्छिक नियंत्रण परीक्षण

प्रधान अन्वेषक: **REG. NO: BE0119004.**

सह-अन्वेषक: डॉ.

परिचय और उद्देश्य:

वर्तमान अध्ययन उन रोगियों के बीच किया जाता है जो केएलईएस डॉ। प्रभाकर कोरे मेमोरियल हॉस्पिटल एंड मेडिकल रिसर्च सेंटर, बेलगावी में ईएनटी और एचएनएस विभाग में एडेनोएक्टोमी से गुजर रहे हैं, ओटिटिस मीडिया के मामलों में यूस्टेट सम्मिलन के साथ एडेनोएडेक्टोमी वी / एस के एडेनोएक्टोमी के बाद सुधार को सलाही है। आपसे अनुरोध है कि अध्ययन में भाग लें और आपकी भागीदारी पूरी तरह से स्वैच्छिक हो।

प्रक्रिया:

यदि आप इस अध्ययन में भाग लेने के लिए सहमत हैं, तो सांख्यिकी डेटा प्रोफार्मा के अनुसार एकत्र किया जाएगा और अंतिम निदान की पुष्टि की जाएगी।

अध्ययन में शामिल होने के बाद, आपके बच्चे / वार्ड का मूल्यांकन एक्स-रे
नासोफरीनक्स लेटरल व्यू और पी ऑपरेटिव प्योर टोन ऑडियोमेट्री और टाइम्पेनोमेट्री के साथ किया जाएगा। 6 सप्ताह तक चलने वाले रोगी का मूल्यांकन करने के लिए ऑपरेटिव प्योर टोन ऑडियोमेट्री और टाइम्पेनोमेट्री के अधीन किया जाएगा। सुनवाई में सुधार।

लाभ

रोगी अध्ययन में अपनी भागीदारी के आधार पर किसी भी तरह के मौद्रिक लाभ या मुफ्त सेवाओं के लिए पात्र नहीं होंगे।

जोखिम

अध्ययन करने के लिए लगभग सुरक्षित हैं। इंट्रा-ऑपरेटिव और पोस्ट-ऑपरेटिव रक्तस्राव हो सकता है। पोस्ट-ऑपरेटिव दर्द हालांकि न्यूनतम भी हो सकता है

साझेदारी का हिस्सा:

सहमति सारांश:

मुझे अपनी स्थानीय भाषा में इस सहमति पत्रों की सभी सामग्री समझाई गई है और अध्ययन के बारे में अपने सभी प्रश्नों को मेरे सर्वोत्तम ज्ञान के लिए स्पष्ट किया है, मैं इस अध्ययन में भागीदारी के लिए अपनी स्वैच्छिक सहमति देता हूं। मैं एक प्रत्यक्षदर्शी के सामने सूचित सहमति पत्र पर हस्ताक्षर करता हूं जिसको पहचानता हूं।

प्रतिभागी का नाम और हस्ताक्षर / बाएं अंगूठे का निशान:

साक्षात्कारकर्ता का नाम और हस्ताक्षर:

नाम और हस्ताक्षर / प्रत्यक्षदर्शी के बाएं अंगूठे का निशान (सापेक्ष):

गाइड का हस्ताक्षर:

दिनांक:

एक शोध अध्ययन में भाग लेने के लिए सहमति कथन

मैं, श्री / श्रीमती / मिस्र स्वेच्छा से इस अध्ययन में भाग लेने के लिए सहमत हूं. इस सहमति पत्र पर हस्ताक्षर करके मैं अपने कानूनी अधिकारों को नहीं छोड़ रहा हूं। मैं किसी भी समय वापस ले सकता हूं। मैं पढ़ने के बाद हस्ताक्षर कर रहा हूं, या मुझे अंतिम और लाभों सहित मौखिक भाषा में पढ़ा गया है और सभी प्रश्नों को समझ रहा हूं।

अध्ययन रोगी का हस्ताक्षर _____

अध्ययन रोगी का नाम _____

गवाह का नाम और हस्ताक्षर _____

_____

अन्वेषक का नाम और हस्ताक्षर _____

दिनांक: _____

स्थान: _____

पालक / पालकांद्वारे सूचित संमती / संमती

"ओटीटिस मीडियाच्या प्रकरणात कोमेट इन्सर्शन एडिनॉइडक्टॉमी वही / एस एडेनॉइडक्टॉमी यांची सुनावणी सुधारणे" - केएलईएस डॉ. प्रभाकर कोरे हॉस्पिटल बेलगावी मध्ये ए वरीष्ठ सहाय्यक नियंत्रण चाचणी.

प्रधान अन्वेषक: REG. NO: BE0119004.

सह-अन्वेषक: डॉ.

परिचय आणि उद्देश:

केएलईच्या डॉ.प्रभाकर कोरे चॅरिटेबल हॉस्पिटल आणि मेडिकल रिसर्च सेंटर, बेळगाव येथील ई एन टी. आणि एच एन एस विभागात एडिनॉइडक्टॉमी घेतलेल्या रुग्णांमध्ये हा अभ्यास केला जातो. ओफिटिसच्या ओटिटिस मीडियाच्या प्रकरणात कॉमेट इन्सर्टेशनसह एडीनॉइडक्टॉमी वही / एस एडीनॉइडक्टॉमी नंतर बेल्जॉम सुधारणे सुधारते. आम्हाला अभ्यासामध्ये सहभागी होण्याची विनंती आहे आणि आपला सहभाग पूर्णपणे ऐच्छिक आहे.

प्रक्रिया:

आपण या अभ्यासामध्ये भाग घेण्यास सहमती दर्शविल्यास, संबंधित आकडेवारी फॉर्मनुसार गोळा केली जाईल आणि अंतिम निदानाची पुष्टी होईल.
अभ्यासामध्ये सामील झाल्यानंतर, आपल्या मुलाचे / बाळाचे मूल्यांकन एक्स-रे नासोफरीनक्स काजूकडील इथर आणि पी ऑपरेटिव्ह शुद्ध टोन ऑडिओमेट्री आणि टायम्पानोमेट्रीद्वारे केले जाईल. सहा आठवड्यांच्या पाठपुराव्याच्या रुग्णांना ऑपरेटिव्ह शुद्ध टोन ऑडिओमेट्री आणि टायम्पॅनोमेट्रीचे मूल्यांकन केले जाईल सुनावणी सुधारणा.

फायदे:

अभ्यासामध्ये आपल्या सहभागाच्या आधारे रुग्ण कोणत्याही प्रकारच्या आर्थिक लाभांसाठी किंवा विनामूल्य सेवेसाठी पात्र ठरणार नाही.

जोखीम:

अभ्यासासाठी त.ज.केलेल्या पद्धती सुरक्षित आहेत. इंट्रा-ऑपरेटिव आणि पोस्ट-ऑपरेटिव्ह रक्तस्त्राव होऊ शकतो. ऑपरेटिव्ह पोस्ट नंतर कमीतकमी वेदना देखील होऊ शकते

सहभागाची किंमत:

तपासणीचा खर्च अभ्यास विषयाद्वारे केला जाईल. अन्य अप्रत्यक्ष खर्च अन्वेषक तपासेल.

गोपनीयता आणि गोपनीयता:

अभ्यासाचे निकाल वैज्ञानिक उद्देशाने वेगवेगळ्या प्रकारे प्रकाशित केले जाऊ शकतात, तथापि, आपली ओळख उघड केली जाणार नाही. संकलित केलेली सर्व माहिती कोडित केली जाईल जेणेकरून संशोधक व्यतिरिक्त इतर कोणालाही आपली ओळख कळू शकणार नाही.

अभ्यासामधून पैसे काढणे:

आपली इच्छा असल्यास आपण कधीही अभ्यासामधून माघार घेऊ शकता.

विकल्प:

जर तुम्ही अभ्यासाची निवड रद्द केली तर तुम्हाला व्यवस्थित व्यवस्थापनाची ओळ मिळेल आणि केएलईच्या डॉ प्रभाकर कोरे हॉस्पिटलशी तुमचा संबंध प्रभावित होणार नाही.

परिणाम प्रकाशित करण्यासाठी अधिकृतता:

संशोधक या अभ्यासामधून गोळा केलेल्या माहितीचा उपयोग वैज्ञानिक बैठकींमध्ये सादरीकरणासाठी करू शकतात. तथापि, आपली ओळख उघड केली जाणार नाही.

प्रश्न आणि संपर्क:

अभ्यासाशी संबंधित काही प्रश्न असल्यास, भविष्यात किंवा अभ्यासाशी संबंधित दुखापत किंवा आजारपणाच्या बाबतीत, आपण डॉ. REG. NO: BE0119004. ईएनटी आणि हेड अँड नेक शस्त्रक्रिया विभाग, केएलईएस हॉस्पिटल आणि एमआरसी, बेलगावी, फोन नंबर । किंवा डॉ ईएनटी विभागाचे प्राध्यापक, केएलईएस हॉस्पिटल आणि एमआरसी, बेलगावी फोन क्रमांक संपर्क साधू शकता.

अभ्यासाचा सहभागी म्हणून आपल्या हक्कांबद्दल काही शंका असल्यास, जे. एन. मेडिकल कॉलेजच्या संस्थाविषयक नैतिक समितीचे मानवी विषय सचिवालय, फोन नं. चे अध्यक्ष म्हणून बालरोग तज्ज्ञ डॉ रुपा एम. बेल्लद यांच्याशी संपर्क साधू शकता. जे एन. मेडिकल कॉलेज, बेलगावी येथे, फोन क्रमांक 9448113403

संशोधन चाचणीत सहभागासाठी सूचित संमती

मी, श्री. / सुश्री / श्रीमती _____ अभ्यासाचा विषय म्हणून सहभागासाठी स्वेच्छेने सहमत आहे. या संमती फॉर्मवर स्वाक्षरी करून मी माझा कोणताही कायदेशीर हक्क सोडत नाही, मी कधीही अभ्यासातून माघार घेऊ शकतो. मी जोखीम आणि फायदे यासह आणि माझ्या सर्व प्रश्नांची उत्तरे देऊन स्थानिक भाषा वाचून वा वाचल्यानंतर मी संमती फॉर्मवर स्वाक्षरी करीत आहे.

विषयाचे नाव: _____

कायदेशीररीत्या अधिकृत नातेवाईक: _____

स्वाक्षरी किंवा डावा अंगठा प्रिंट
विषय / कायदेशीररीत्या अधिकृत नातेवाईकाचा: _____

तारीख:

साक्षीदाराचे नाव: _____ स्वाक्षरी: _____

अन्वेषकांचे नाव: _____ स्वाक्षरी: _____

तारीख:

ठिकाण: _____.

संमती सारांश:

या संमती फॉर्मची सर्व सामग्री मला माझ्या स्थानिक भाषेत स्पष्ट केली गेली आहे आणि मला माझ्या सर्व प्रश्नांना माझ्या माहितीनुसार समजून घेतल्यावर आणि त्या स्पष्ट केल्यानंतर मी अभ्यासात सहभागासाठी माझी स्वेच्छेने संमती देतो. मी ज्यांना ओळखतो त्या प्रत्यक्ष साक्षीदारासमोर मी माहिती संमती फॉर्मवर सही करतो.

सहभागीचे नाव व स्वाक्षरी / डाव्या अंगठ्याचा ठसा:

नोकरीकर्त्याचे नाव व स्वाक्षरी:

नाव आणि स्वाक्षरी / ठोक्याच्या साक्षीच्या डाव्या हाताच्या अंगठ्याचा ठसा (संबंधित):

मार्गदर्शकाची सही:

तारीख:

ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ/ಪೋಷಕರು / ಗಾರ್ಡಿಯನ್ ಅವರಿಂದ ಒಪ್ಪಿಗೆ

'ಅಡೆನಾಯ್ಡೆಕ್ಟಮಿ ವಿ / ಎಸ್ ಅಡೆನಾಯ್ಡೆಕ್ಟಮಿ ನಂತರ ಶ್ರವಣ ಸುಧಾರಣೆ ಒಟಿಟಿಸ್ ಮೀಡಿಯಾದ ಪ್ರಕರಣಗಳಲ್ಲಿ ಗ್ರೋಮೆಟ್ ಅಳವಡಿಕೆಯೊಂದಿಗೆ ಎಫ್ಯೂಷನ್' - ಕೆಎಲ್ಇಎಸ್ನಲ್ಲಿ 1 ವರ್ಷದ ರಾಂಡೋ ಗಾತ್ರದ ನಿಯಂತ್ರಣ ಪ್ರಯೋಗ ಡಾ. ಪ್ರಭಾಕರ್ ಕೋರೆ ಆಸ್ಪತ್ರೆ, ಬೆಳಗಾವಿ.

ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿ: **REG. NO: BE0119004.**

ಸಹ-ತನಿಖಾಧಿಕಾರಿ: ಡಾ.

ಪ್ರೊಫೆಸರ್ ಒಟೊರಿನೊಲಾರಿಂಗೋಲಜಿ ಇಲಾಖೆ.

ಜೆ.ಎನ್. ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಬೆಳಗಾವಿ

ಪರಿಚಯ ಮತ್ತು ಉದ್ದೇಶ :

ಪ್ರಸ್ತುತ ಅಧ್ಯಯನವನ್ನು ಕೆಎಲ್ಇಎಸ್ ಡಾ. ಪ್ರಭಾಕರ್ ಕೋರೆ ಆಸ್ಪತ್ರೆ ಮತ್ತು ವೈದ್ಯಕೀಯ ಸಂಶೋಧನಾ ಕೇಂದ್ರ, ಬೆಳಗಾವಿಸಲ್ಲಿ ಇಎನ್ಟಿ ಮತ್ತು ಎಚ್ಎನ್ಎಸ್ ವಿಭಾಗದಲ್ಲಿ ಅಡೆನಾಯ್ಡೆಕ್ಟೊಮಿಗೆ ಒಳಪಡುವ ರೋಗಿಗಳಲ್ಲಿ ನಡೆಸಲಾಗುತ್ತದೆ. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು ವಿನಂತಿಸಲಾಗಿದೆ ಮತ್ತು ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದೆ.

ವಿಧಾನ :

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಒಪ್ಪಿದರೆ, ಪ್ರೊಫಾರ್ಮಾದ ಪ್ರಕಾರ ಸಂಬಂಧಿತ ಡೇಟಾವನ್ನು ಸಂಗ್ರಹಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಅಂತಿಮ ರೋಗನಿರ್ಣಯವನ್ನು ಸ್ವೀಕರಿಸಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರ್ಪಡೆಗೊಂಡ ನಂತರ, ನಿಮ್ಮ ಮಗು / ವಾರ್ಡ್ ಅನ್ನು ಎಕ್ಸ್-ರೇ ನಾಸೊಫಾರ್ನೆಕ್ಸ್ ಲ್ಯಾಟರಲ್ ವ್ಯೂ ಮತ್ತು ಪೂರ್ವ ಆಪರೇಟಿವ್ ಪ್ಯೂರ್ ಟೋನ್ ಆಡಿಯೊಮೆಟ್ರಿ ಮತ್ತು ಟೈಂಪನೋಮೆಟ್ರಿಯೊಂದಿಗೆ ಬೇಸ್ಲೈನ್ ಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ. 6 ವಾರಗಳ ನಂತರದ ರೋಗಿಯನ್ನು ಪೋಸ್ಟ್ ಆಪರೇಟಿವ್ ಶುದ್ಧ ಟೋನ್ ಆಡಿಯೊಮೆಟ್ರಿ ಮತ್ತು ಟೈಂಪನೋಮೆಟ್ರಿಗೆ ಒಳಪಡಿಸಲಾಗುತ್ತದೆ. ಶ್ರವಣ ಸುಧಾರಣೆ.

ಪ್ರಯೋಜನಗಳು :

ನಿಮ್ಮ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯಿಂದಾಗಿ ರೋಗಿಯು ಯಾವುದೇ ರೀತಿಯ ಎತ್ತೀಯ ಪ್ರಯೋಜನಗಳು ಅಥವಾ ಉಚಿತ ಸೇವೆಗಳಿಗೆ ಅರ್ಹನಾಗಿರುವುದಿಲ್ಲ.

ಅಪಾಯಗಳು :

ಅಧ್ಯಯನ ಮಾಡಲು ಅನ್ವಯಿಸಲಾದ ವಿಧಾನಗಳು ಸುರಕ್ಷಿತವಾಗಿವೆ. ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ರಕ್ತಸ್ರಾವ ಸಂಭವಿಸಬಹುದು. ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ನೋವು ಕನಿಷ್ಠವಾಗಿದ್ದರೂ ಸಹ ಸಂಭವಿಸಬಹುದು

ಭಾಗವಹಿಸುವಿಕೆಯ ವೆಚ್ಚ :

ತನಿಖೆಯ ವೆಚ್ಚವನ್ನು ಅಧ್ಯಯನ ವಿಷಯದಿಂದ ಭರಿಸಲಾಗುತ್ತದೆ. ಇತರ ಯಾವುದೇ ವೆಚ್ಚಗಳನ್ನು ತನಿಖಾಧಿಕಾರಿ ಭರಿಸುತ್ತಾರೆ.

ಗೌಪ್ಯತೆ :

ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಗಳಿಗಾಗಿ ನಿಯತಕಾಲಿಕೆಗಳಲ್ಲಿ ಪ್ರಕಟಿಸಬಹುದು. ಆದಾಗ್ಯೂ, ನಿಮ್ಮ ಗುರುತು ಬಹಿರಂಗಗೊಳ್ಳುವುದಿಲ್ಲ. ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಕೋಡ್ ಮಾಡಲಾಗುವುದು ಇದರಿಂದ ತನಿಖಾಧಿಕಾರಿಯನ್ನು ಹೊರತುಪಡಿಸಿ ಬೇರೆ ಯಾರಿಗೂ ನಿಮ್ಮ ಗುರುತು ತಿಳಿಯುವುದಿಲ್ಲ.

ಅಧ್ಯಯನದಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವಿಕೆ :

ನೀವು ಬಯಸಿದರೆ ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು.

ಪರ್ಯಾಯಗಳು :

ಒಂದು ವೇಳೆ ನೀವು ಅಧ್ಯಯನದಿಂದ ಹೊರಗುಳಿಯುವುದಾದರೆ, ನೀವು ದಿನನಿತ್ಯದ ನಿರ್ವಹಣೆಯನ್ನು ಪಡೆಯುತ್ತೀರಿ ಮತ್ತು ಇದು ಡಿ ಎಲ್ ಇ ಎಸ್ ಡಾ. ಪ್ರಭಾಕರ್ ಕೋರೆ ಆಸ್ಪತ್ರೆಯೊಂದಿಗಿನ ನಿಮ್ಮ ಸಂಬಂಧದ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.

ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸಲು ಅಧಿಕಾರ :

ಸಂಶೋಧಕರು ಈ ಅಧ್ಯಯನದಿಂದ ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ವೈಜ್ಞಾನಿಕ ಸಭೆಗಳಲ್ಲಿ ಪ್ರಸ್ತುತಪಡಿಸಲು ಬಳಸಬಹುದು. ಆದಾಗ್ಯೂ, ನಿಮ್ಮ ಗುರುತು ಬಹಿರಂಗಗೊಳ್ಳುವುದಿಲ್ಲ.

ಪ್ರಶ್ನೆಗಳು ಮತ್ತು ಸಂಪರ್ಕ:

ನೀವು ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ಭವಿಷ್ಯದಲ್ಲಿ ಅಥವಾ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಗಾಯ ಅಥವಾ ಅನಾರೋಗ್ಯದ ಸಂದರ್ಭದಲ್ಲಿ, ನೀವು ಡಾ. REG. NO: BE0119004. , ಇಎಸ್‌ಐ ಮತ್ತು ಹೆಚ್ & ಸಿಹೆ ಸರ್ಕಾರಿ ವಿಭಾಗ, ಕೆಎಲ್‌ಇಎಸ್ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಂಆರ್‌ಸಿ, ಬೆಳಗಾವಿ, ದೂರವಾಣಿ ಸಂಖ್ಯೆ ಅಥವಾ ಡಾ. , ಇಎಸ್‌ಐ ವಿಭಾಗದ ಪ್ರಾಧ್ಯಾಪಕ, ಹೆಚ್ & ಸಿಹೆ ಸರ್ಕಾರಿ ವಿಭಾಗ, ಕೆಎಲ್‌ಇಎಸ್ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಂಆರ್‌ಸಿ, ಬೆಳಗಾವಿ. ಅವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು ಫೋನ್. ಸಂಖ್ಯೆ

ಚುರುಕಾದ ಪಾಲ್ಗೊಳ್ಳುವವರಾಗಿ ನಿಮ್ಮ ಹಕ್ಕುಗಳ ಬಗ್ಗೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ನೀವು ಜೆ. ಎನ್. ಮೆಡಿಕಲ್ ಕಾಲೇಜ್ ಸಾಂಸ್ಥಿಕ ನೈತಿಕ ಸಮಿತಿಯ ಮಾನವ ವಿಷಯಗಳ ಸಂಶೋಧನೆ, ಅಧ್ಯಕ್ಷರಾಗಿ ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ ಪ್ರಾಧ್ಯಾಪಕ ಡಾ. ರೂಪಾ ಎಂ. ಬೆಳ್ಳದ ಅವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು. 9448113403

ಒಪ್ಪಿಗೆ ಸಾರಾಂಶ :

ಈ ಒಪ್ಪಿಗೆಯ ರೂಪದ ಎಲ್ಲಾ ವಿಷಯಗಳನ್ನು ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ಅಧ್ಯಯನದ ಬಗ್ಗೆ ನನ್ನ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳನ್ನು ನನ್ನ ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮವಾಗಿ ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ಸ್ಪಷ್ಟಪಡಿಸಿದ್ದೇನೆ. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನನ್ನ ಸ್ವಯಂಪ್ರೇರಿತ ಒಪ್ಪಿಗೆಯನ್ನು ನಾನು ಈ ಮೂಲಕ ನೀಡುತ್ತೇನೆ. ನಾನು ಗುರುತಿಸಿದ ಕಣ್ಣಿನ ಸಾಕ್ಷಿಯ ಮುಂದೆ ಮಾಹಿತಿಯುಕ್ತ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಮಾಡುತ್ತೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು ಮತ್ತು ಸಹಿ / ಎಡ ಹೆಬ್ಬೆರಳು ಅನಿಸಿಕೆ:

ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ:

ಕಣ್ಣಿನ ಸಾಕ್ಷಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ / ಎಡ ಹೆಬ್ಬೆರಳು ಅನಿಸಿಕೆ (ಸಾಪೇಕ್ಷ):

ಮಾರ್ಗದರ್ಶಿಯ ಸಹಿ:

ದಿನಾಂಕ:

ಸಂಶೋಧನಾ ಪ್ರಯೋಗದಲ್ಲಿ ಭಾಗವಹಿಸಲು ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ

ನಾನು, ಶ್ರೀ / ಮಿಸ್ / ಶ್ರೀಮತಿ _____ ಅಧ್ಯಯನದ ವಿಷಯವಾಗಿ ಭಾಗವಹಿಸಲು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪುತ್ತೇನೆ. ಈ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಮಾಡುವ ಮೂಲಕ ನಾನು ನನ್ನ ಯಾವುದೇ ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ಬಿಟ್ಟುಕೊಡುತ್ತಿಲ್ಲ. ನಾನು ಯಾವಾಗ ಬೇಕಾದರೂ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು. ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳನ್ನು ಒಳಗೊಂಡಂತೆ ಮತ್ತು ನನ್ನ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಿಸಿದ ನಂತರ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ಓದಿದ ಅಥವಾ ಓದಿದ ನಂತರ ನಾನು ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಹಾಕುತ್ತಿದ್ದೇನೆ.

ವಿಷಯದ ಹೆಸರು: _____

ಕಾನೂನುಬದ್ಧವಾಗಿ ಅಧಿಕೃತ ಸಂಬಂಧಿ: _____

ಸಹಿ ಅಥವಾ ಎಡ ಹೆಬ್ಬೆರಳು ಮುದ್ರಣ

ವಿಷಯ / ಕಾನೂನುಬದ್ಧ ಅಧಿಕೃತ ಸಂಬಂಧಿ: _____

ದಿನಾಂಕ:

ಸಾಕ್ಷಿಯ ಹೆಸರು: _____ ಸಹಿ: _____

ತನಿಖಾಧಿಕಾರಿಗಳ ಹೆಸರು: _____ ಸಹಿ: _____

ದಿನಾಂಕ:

ಸ್ಥಳ:

ANNEXURE III

PROFORMA

"HEARING IMPROVEMENT AFTER ADENOIDECTOMY V/S ADENOIDECTOMY WITH GROMMET INSERTION IN CASES OF OTITIS MEDIA WITH EFFUSION"- A 1 YEAR RANDOMIZED CONTROL TRIAL IN KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI.

Date:

O.P. No: IP No:

Name: Age:

Sex: Occupation:

Address: Phone No:

D.O.A D.O.D:

CLINICAL PROFILE:

Chief Complaint:

History of Present Illness

Past History:

Personal History:

Family History:

Physical Examination:

I) General Physical Examination -

Vital signs:

Pulse

Blood pressure

Respiratory Rate

Pallor

Icterus

Clubbing

Cyanosis

Lymphadenopathy

Oedema

II) ENT Examination

1. NOSE EXAMINATION

External appearance

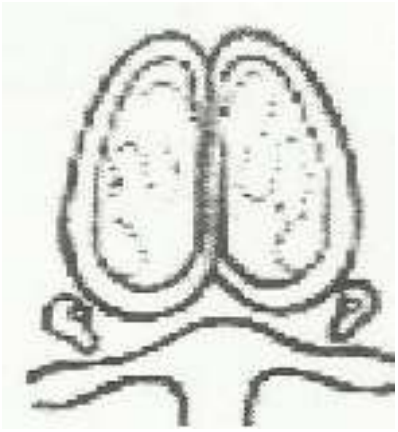
- Root
- Bridge
- Dorsum
- Alae
- Tip
- Columella

Cold spatula test

Cottle's test

Anterior Rhinoscopy

Posterior Rhinoscopy



Paranasal Sinus Examination

2. EAR EXAMINATION- Right ear Left ear

Pinnae

Preauricular area

Post auricular area

External auditory canal

Tympanic membrane

Tuning Fork Test: Right ear Left ear

Rinne's test:

256hz

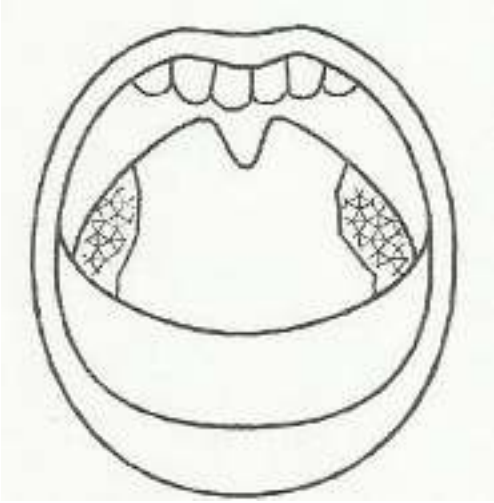
512hz

1024hz

Weber's test:

Absolute Bone Conduction test:

3.1 ORAL CAVITY and OROPHARYNX



4. NECK EXAMINATION

Diagnosis:

<u>Preoperative</u>:

Preoperative pure tone audiometry –

Preoperative tympanometry –

Routine tests:

CBC

Bleeding profile

Serum Urea

Serum Creatinine

HIV

Hbsag

ADENOIDECTOMY OR ADENOIDECTOMY WITH GROMMET INSERTION

Follow up at 6 weeks-

Post operative:

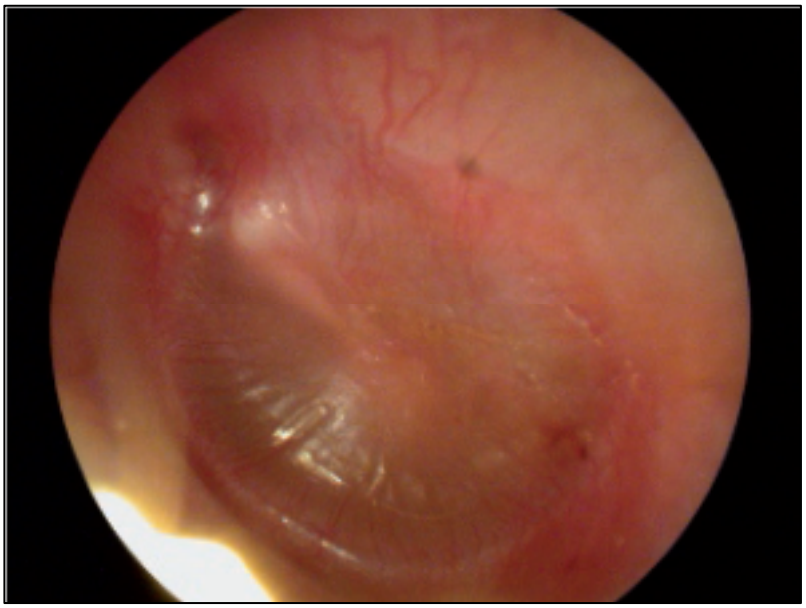
Post-operative pure tone audiometry –

Post operative tympanometry -

ANNEXURE V

PHOTOGRAPHS

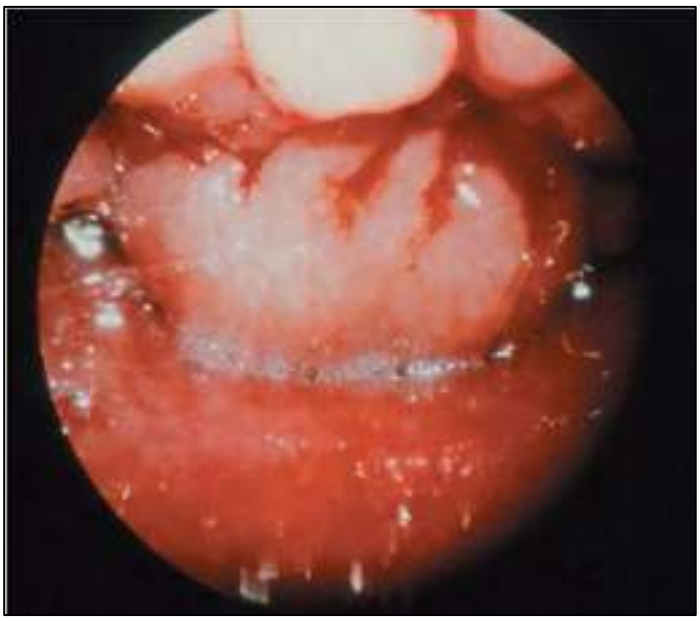
Photograph 1: Otoendoscopic image of Normal right tympanic membrane



Photograph 2: Otoendoscopic image of Right tympanic membrane showing OME fluid & air bubbles

Photograph 3: Otoendoscopic image of Right tympanic membrane with Grommet insitu

Photograph 4 : Saint Claire Thompson Adenoid Curette with cage



Photograph 5: Endoscopic view of Adenoid Hypertrophy

Photograph 6: Tissue sample of Grade 3 Adenoid hypertrophy after adenoidectomy

ANNEXURE V - KEY TO MASTERCHART

A	TYPE A TYMPANOGRAM
B	TYPE B TYMPANOGRAM
C	TYPE C TYMPANOGRAM
PTA	PURE TONE AUDIOMETRY
PRE OP	PRE OPERATIVE
POST OP	POST OPERATIVE
B/L	BILATERAL

ANNEXURE VII - MASTER CHART

SR.NO	PROCEDURE	PRE OP TYMPANOMETRY		PRE OP PTA		POST OP TYMPANOMETRY		POST OP PTA		RESULT
		RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	
1	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	31.6	28.3	C	B	23.3	28.3	IMPROVED
2	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	31.6	25	C	C	22.6	23	IMPROVED
3	ADENOIDECTOMY	C	A	23.3	11	C	A	22	10	IMPROVED
4	ADENOIDECTOMY	A	B	15	28.3	A	B	13	25.4	IMPROVED
5	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	46.6	46.6	B	B	38.6	36.4	IMPROVED
6	ADENOIDECTOMY	C	B	26.2	22.4	C	C	22.4	18.6	IMPROVED
7	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	40	40	B	B	32.4	30.6	IMPROVED
8	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	42	38.6	B	B	34.6	32.4	IMPROVED
9	ADENOIDECTOMY	C	B	22.4	20.6	C	C	20.2	18.4	IMPROVED
10	ADENOIDECTOMY	C	A	25.6	12	C	A	22.4	10	IMPROVED
11	ADENOIDECTOMY	C	B	26.2	22.6	C	C	22.4	20.4	IMPROVED
12	ADENOIDECTOMY	B	C	22.4	26.6	C	C	20.6	22.4	IMPROVED
13	ADENOIDECTOMY	C	A	25.2	11	C	A	22.6	10	IMPROVED
14	ADENOIDECTOMY	C	A	22.6	12	C	A	20.2	12	IMPROVED
15	ADENOIDECTOMY	C	B	20.2	24.6	C	C	18.4	20.6	IMPROVED
16	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	33.4	30.3	C	B	24.3	22.6	IMPROVED
17	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	30.2	24	C	C	22.6	17	IMPROVED
18	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	38.4	40.2	B	B	30.6	32.4	IMPROVED
19	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	28.6	26	C	C	20.4	18	IMPROVED
20	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	44.2	42.6	B	B	36.2	34.6	IMPROVED
21	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	26.4	28	C	C	18.6	20.4	IMPROVED
22	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	24.4	28.6	C	C	18	20.2	IMPROVED
23	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	40.6	42.2	B	B	32.4	33.3	IMPROVED
24	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	26.4	28	C	C	18.6	20.4	IMPROVED
25	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	28.6	26.6	C	C	20	18.6	IMPROVED
26	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	38.4	40.6	B	B	30.6	32.6	IMPROVED
27	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	30.2	32.6	C	C	22.4	26.4	IMPROVED
28	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	44.6	44.2	B	B	36.4	37.3	IMPROVED
29	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	34.6	32.6	C	C	27.3	26.4	IMPROVED
30	ADENOIDECTOMY WITH B/L GROMMET INSERTION	B	B	30.6	24.6	C	C	23.4	18.4	IMPROVED
31	ADENOIDECTOMY	C	A	26.2	11	C	A	23	10	IMPROVED
32	ADENOIDECTOMY	A	B	13	24.3	A	B	13	21.4	IMPROVED
33	ADENOIDECTOMY	C	B	26.2	23.4	C	C	22.6	20.6	IMPROVED
34	ADENOIDECTOMY	C	B	28.2	20.6	C	C	23.4	17.4	IMPROVED
35	ADENOIDECTOMY	B	B	44	36.6	B	B	40.6	32.4	IMPROVED
36	ADENOIDECTOMY	B	B	33.6	22	C	C	24.6	18	IMPROVED
37	ADENOIDECTOMY	B	B	40	40	B	B	35.4	34.6	IMPROVED
38	ADENOIDECTOMY	B	B	38.4	36.4	B	B	33.6	32.4	IMPROVED
39	ADENOIDECTOMY	B	B	44.6	44.6	B	B	38.4	37.6	IMPROVED
40	ADENOIDECTOMY	B	B	33.6	28.6	C	B	26.3	25.3	IMPROVED