"EFFICACY AND SAFETY OF MICRODEBRIDER ASSISTED ADENOIDECTOMY OVER CONVENTIONAL ADENOIDECTOMY"- A 1 YEAR RANDOMIZED CONTROL TRIAL IN KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI

BY

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ABSTRACT

Background:

The adenoids are a mass of lymphoid tissues located in the super posterior area of the nasopharynx and affect breathing in the upper airway. 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.

Adenoidectomy forms a valuable treatment option in management of sleep disordered breathing, middle ear pathologies, pediatric chronic rhino-sinusitis and recurrent adeno-tonsillitis. It is conventionally performed using the curettage method which is not only crude but also blind. Damage to Eustachian tube opening is known and the completeness of procedure is difficult to assess but with the advent of endoscopes this area has become more accessible and more procedures are presently performed using nasal endoscopes.

Microdebriders are powered instruments which provide an excellent, safe and thorough surgical clearance in endoscopic nasal surgery. They provide atraumatic dissection with minimal complications and faster postoperative healing.

Objectives:

To study the variation between the safety and efficacy of adenoidectomy done by the conventional curettage method versus the microdebrider assisted method.

Material and methods:

This is a randomised controlled trial and was conducted in the department of Otorhinolaryngology and Head and Neck Surgery of KLE's Dr. Prabhakar Kore Hospital, Belagavi, from January 2018 to December 2018. Patients were allocated into 2 groups i.e. conventional curettage adenoidectomy(group A) and microdebrider assisted adenoidectomy(group B). Preoperatively endoscopic adenoid grading was recorded. Adenoidectomy was done and parameters such as amount of bleeding, operative time and post-operative endoscopic grading of adenoid were recorded.

Results:

45 patients were included in the study, 25 patients in group A and 20 patients in group B. 25 were male and 20 were female. The mean age among the sample was 9.24 years. The most common presenting complaint was mouth breathing and snoring.

Following adenoidectomy operation the percentage of reduction of adenoid grading in microdebrider group was 63.79 % and 30.29% in conventional curettage group, The average time taken by microdebrider assisted surgery was 16.45 mins as compared to 13.28 mins in conventional curettage. The average amount of blood loss in conventional group was 44.76 ml whereas in microdebrider group was 77.30 ml.

Conclusion:

Adenoidectomy is a routine Otolaryngologic surgery done in Paediatric age group for various indications and often after conventional curettage there is remnant adenoid tissue which doesn't alleviate the symptoms. Microdebrider assisted adenoidectomy has proven to deliver completeness of clearance at the expense of slight increase in bleeding and the operative time. Though the cost of surgery is

higher but precise dissection under vision, lesser complications and better disease clearance makes this technique a safe and efficacious alternative over the blind curettage method.

Keywords: Microdebrider, Endoscopic powered adenoidectomy.

LIST OF ABBREVIATIONS

i.e.	id est (Latin; ‘that is’)
et al	Et alii (Latin; ‘and others’)
Etc.	Et cetera
OSA	Obstructive sleep apnoea
OME	Otitis media with effusion
CSOM	Chronic suppurative otitis media

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INTRODUCTION

The adenoids are an aggregate of lymphoid tissues located in the posterosuperiorregion of the nasopharynx and directly affect the breathing in the upper airway. At birth the adenoids are relatively smaller in size and due to the hyperactivity of the immune system they progressively enlarge during the initial years of life and thus can manifest with nasal obstruction.[1]

Adenoidectomy is the mode of treatment employed in managing sleep disordered breathing which is manifested as nasal obstruction, mouth breathing and snoring, middle ear pathologies,chronic rhino-sinusitis and recurrent adenotonsillitis.[2]It is conventionally performed by the curettage method with St. Clair Thompson adenoid curette which is a blind procedure. Damage to Eustachian tube opening leading to middle ear pathologies and also the remnant adenoid tissue postoperatively is a known fact. With the advent of endoscopes, surgeries in the nasal cavities have become safer as they are being performed under vision and hence surgeons now a days are harnessing the power of it even in the anatomically challenging region of nasopharynx.[2]

Microdebriders are electrically powered instruments which have an excellent safety profile. They provide precise atraumatic dissection with lesser complications and faster postoperative healing.

This study is designed to compare the microdebrider assisted adenoidectomy with the conventional curettage adenoidectomy and to study the efficacy and safety of microdebrider at our centre.

OBJECTIVE

To study the variation between the safety and efficacy of adenoidectomy done by the conventional curettage method versus the microdebrider assisted method.

REVIEW OF LITERATURE

The adenoid or nasopharyngeal tonsil are the lymphoid tissues constituting a part of the inner Waldeyer's ring. In childhood adenoid acts as the 1st site for contact of airborne antigens with the lymphoid tissue leading to development of humoral immunity. It was first described by Santorini in 1724 asa nasopharyngeal lymphoid aggregate or 'Luschka's tonsil'. Wilhelm Meyer gave the term 'adenoid' to these 'nasopharyngeal vegetation's in 1870.[3]

The word adenoid is derived from the Greek word *adēn*meaning *gland* and *oid*meaning *resemblance*. Therefore adenoid means a gland like structure.

EMBRYOLOGY

The buccal cavity develops mainly from ventral growth of the upper pharyngeal arches. The rostral growth of the embryo and the formation of the head fold cause the pericardial area and buccopharyngeal membrane to come to lie on the ventral surface of the embryo. Further expansion of the forebrain dorsally, and the bulging of the pericardium ventrally, together with enlargement of the facial processes laterally, means that the buccopharyngeal membrane becomes depressed at the base of a hollow, the stomodeum or primitive buccal cavity. At the end of the fourth week the buccopharyngeal membrane breaks down and a communication is formed between the stomodeum and the cranial end of the foregut which will become the nasopharynx and oropharynx respectively.[4]

The adenoids (nasopharyngeal tonsil) develop in the midline of the nasopharynx poster superiorly at 4 to 6 weeks of gestation by fusion of two endodermal primordia which unite in midline and subsequently get proliferated by

lymphoid tissue at around 16 weeks. It is fully developed by seventh month of gestation.[5] Growth occurs rapidly during infancy and shows a constant growth between 2 and 14 years of age. Adenoids rapidly regress after the age of 15 years in majority of children and are at its relative largest size in relation to the volume of the nasopharynx in the 7-year- old age group.[6]

ANATOMY OF THE ADENOIDS

The pharyngeal tonsil (adenoid) is a midline mass of lymphoid tissue located in the roof of the nasopharynx. It belongs to the group of mucosa associated lymphoid tissue (MALT). It is an inverted pyramid like structure whose apex points towards the posterior end of nasal septum and the base rests on the junction of basisphenoid and basiocciput to the posterior pharyngeal wall.[4]

The adenoids have a paired developmental origin. A median fold sometimes runs from the pharyngeal bursa anteriorly till the nasal septum which divides it into two halves. Sometimes the mucosal fold may be complete representing a fissure and may divide the adenoid into two separate structures i.e. the right and left halves. This pharyngeal bursa (bursa of Luschka) is nothing but the cranial end of the notochord. From this bursa variable number of mucosal folds arise and radiate anteriorly and circumferentially around them the lymphoid tissue will aggregate into follicular and extra follicular structures.[4]

After birth, there is a period of rapid initial growth, but usually the adenoids regress and atrophy in size by around 8–10 years of age (in some instances it may even be seen in adults up to the sixth or seventh decade). The maximum growth of adenoid tissue is seen at around 5-7 years of age, which may be the cause for the

frequent of nasal complaints in this age group and growth retardation, leading to increased incidence of adenoidectomy in this age group.

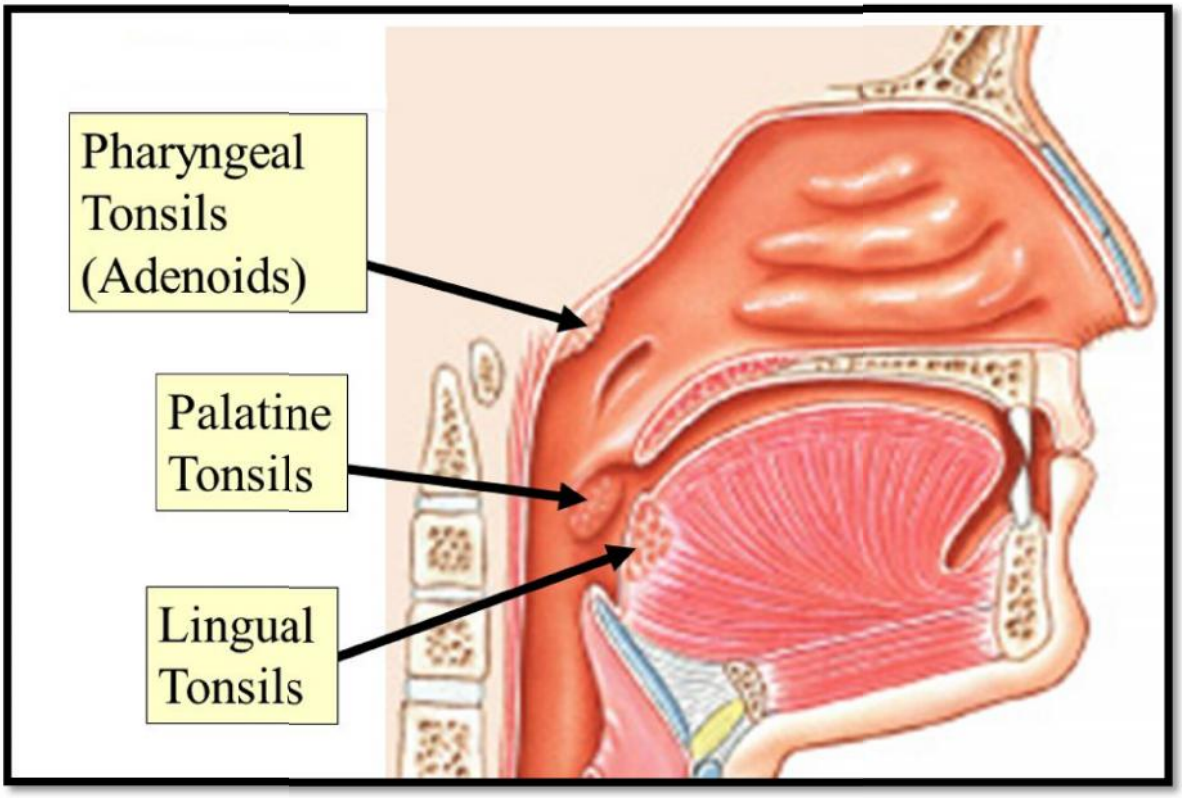


Figure 1:Situation of tonsils in the pharynx

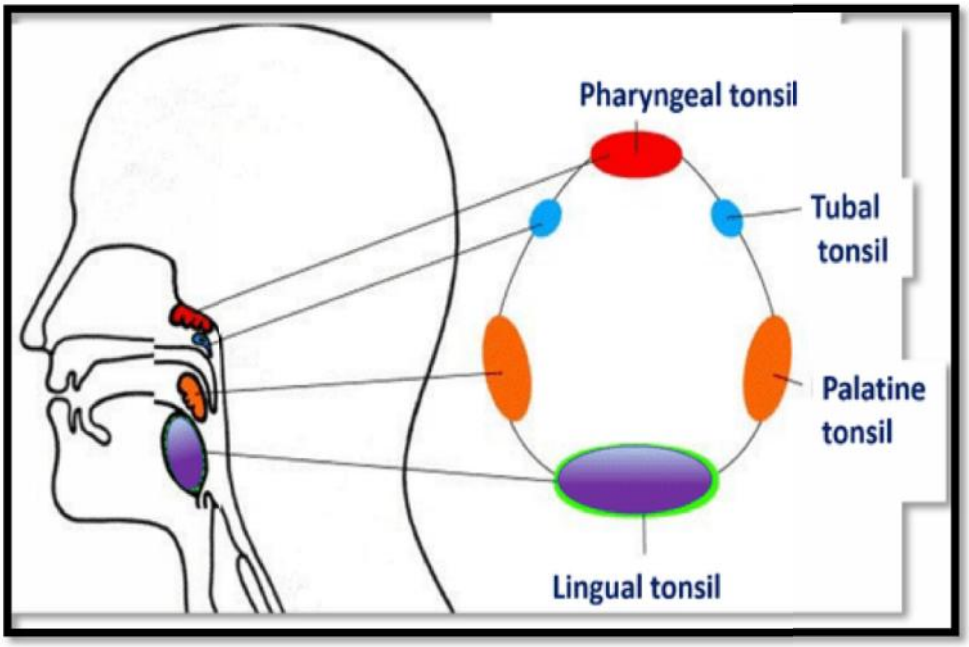


Figure 2:Waldeyer's Ring

BLOOD SUPPLY OF ADENOIDS

The adenoid derives blood supply from-

1. Tonsillar branch of facial artery
2. Ascending pharyngeal artery: It is the 1st branch of external carotid artery.
3. Ascending palatine artery : It's a branch of facial artery.
4. Pharyngeal branch of maxillary artery and
5. Artery of the pterygoid canal
6. Artery from basisphenoid(arising from the inferior hypophyseal artery)

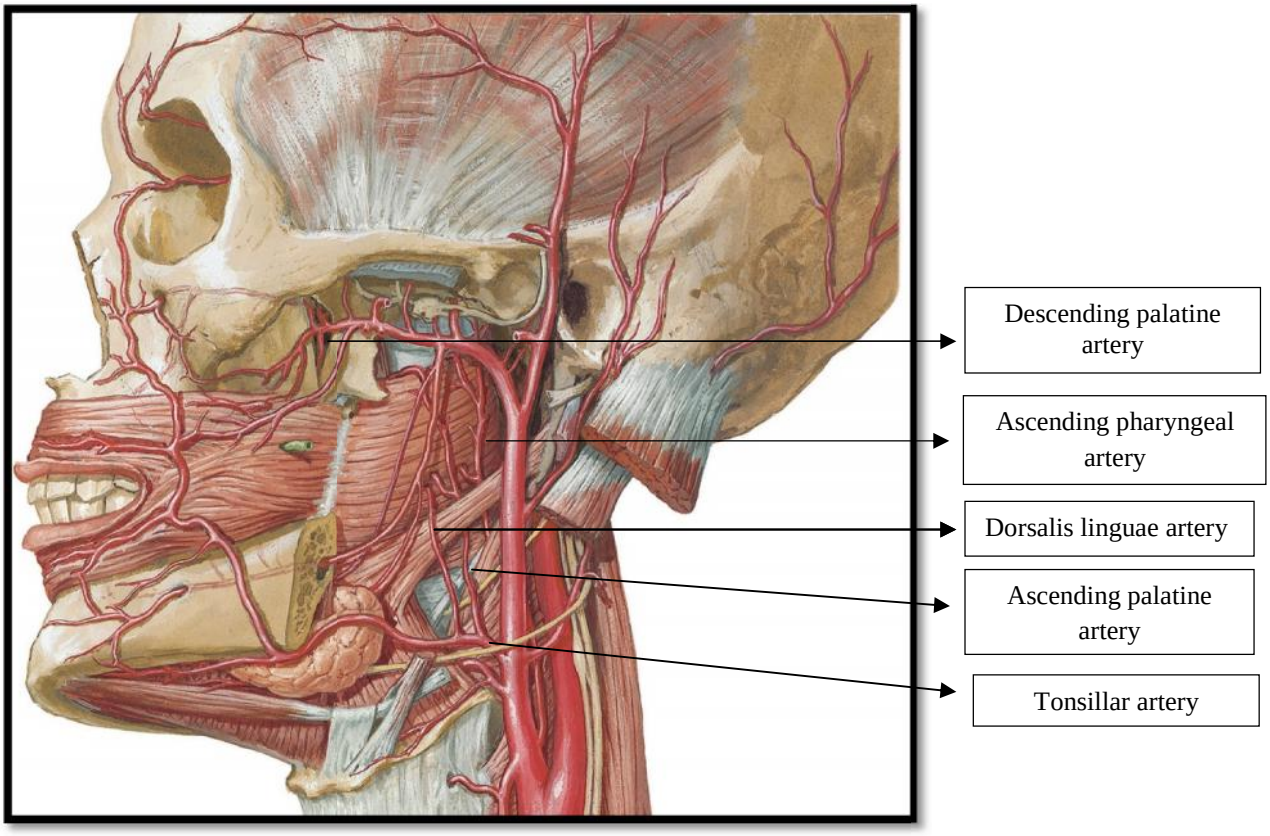


Figure 3:Blood supply of adenoids and tonsil

VENOUS DRAINAGE

Adenoids drain into Internal or external pharyngeal venous plexus via-

- Para tonsillar vein
- Communicating veins
- Direct vein into the facial or internal jugular vein.

Adenoids may also drain into pterygoid venous plexus.

LYMPHATIC DRAINAGE

Adenoids have their drainage into the retropharyngeal group of lymph nodes which drain into upper deep cervical nodes or upper jugulodigastric nodes.

NERVE SUPPLY

It is from pharyngeal nerve plexus formed by glossopharyngeal and vagus nerves.

MICROSTRUCTURE OFADENOIDS

The surface of adenoid is lined by pseudo stratified ciliated columnar epithelium interspersed with small areas of non- keratinized stratified squamous epithelium.

The plane between the superior surface of adenoids and the periosteum of the basisphenoid and basiocciputis created by a connective tissue formed by type III collagen and reticulin forming a hemi capsule like arrangement which anchors the adenoid tissue.

The nasopharyngeal epithelium in thrown into mucosal folds which around which adenoids are aggregated and are organised into follicular and extrafollicular tissue which gives it a characteristic texture of " bag of worms". Adenoid itself is subdivided by septa of connective tissue into multiple parts.

Seromucinous glands lie within the parenchyma and their ducts open up on the nasopharyngeal surface.[4]

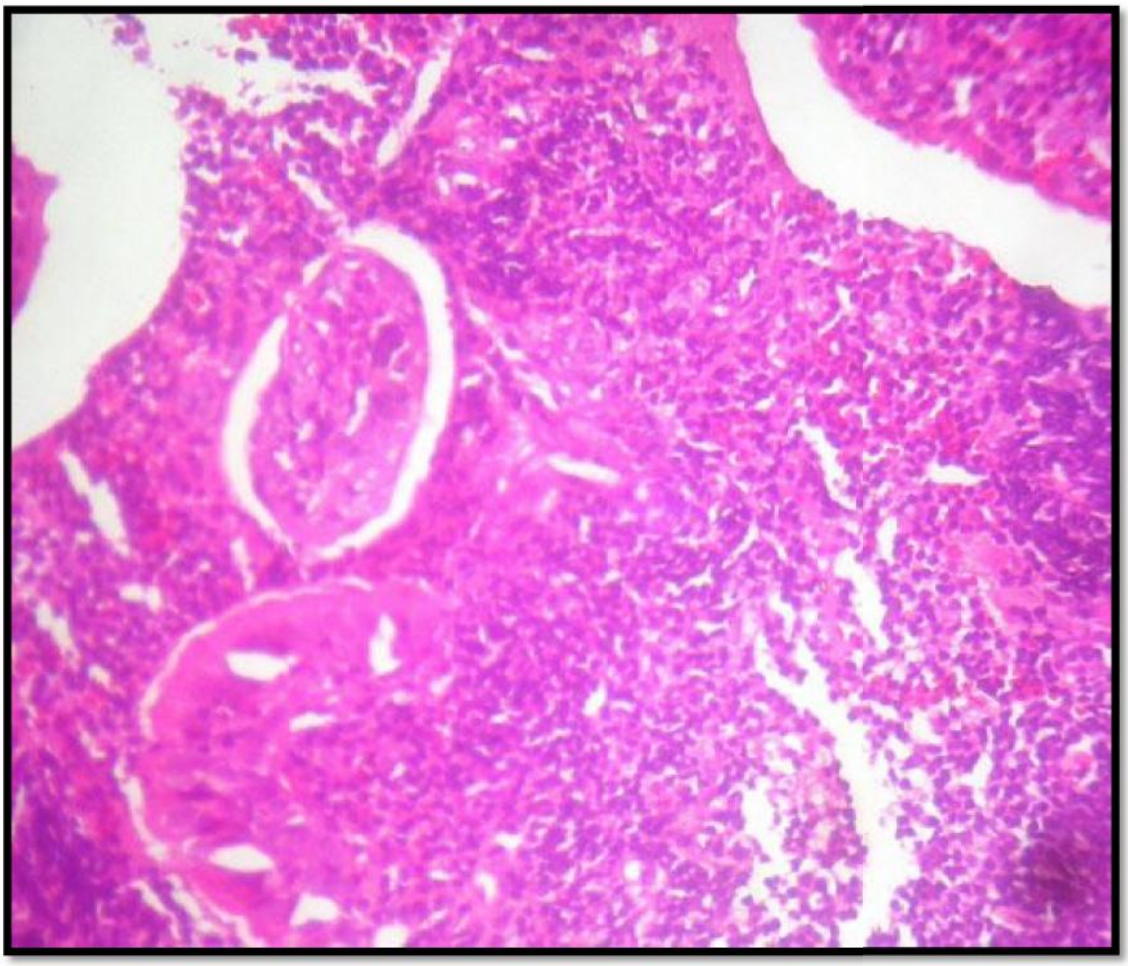


Figure 4:Histology of Adenoid[7]

IMMUNE FUNCTION

The lymphoid tissues of the Waldeyer's ring provides acquired immunity by producing B lymphocytes. Which produce plasma cells giving rise to IgG and IgA immunoglobulins. During childhood " immunological memory" is acquired when the airborne antigens come in contact with the adenoids .[8]

After adenoidectomy though there is a slight decrease in immunoglobulins namely in IgG, IgA and IgM found 4-6 weeks after surgery[9], it should be noted that such a response most likely occurred due to a reduction of antigenic stimulation as there was no lymphoid tissue contact with the airborne antigens. There is no appreciable decrease in IgE after adenoidectomy.[10,11]

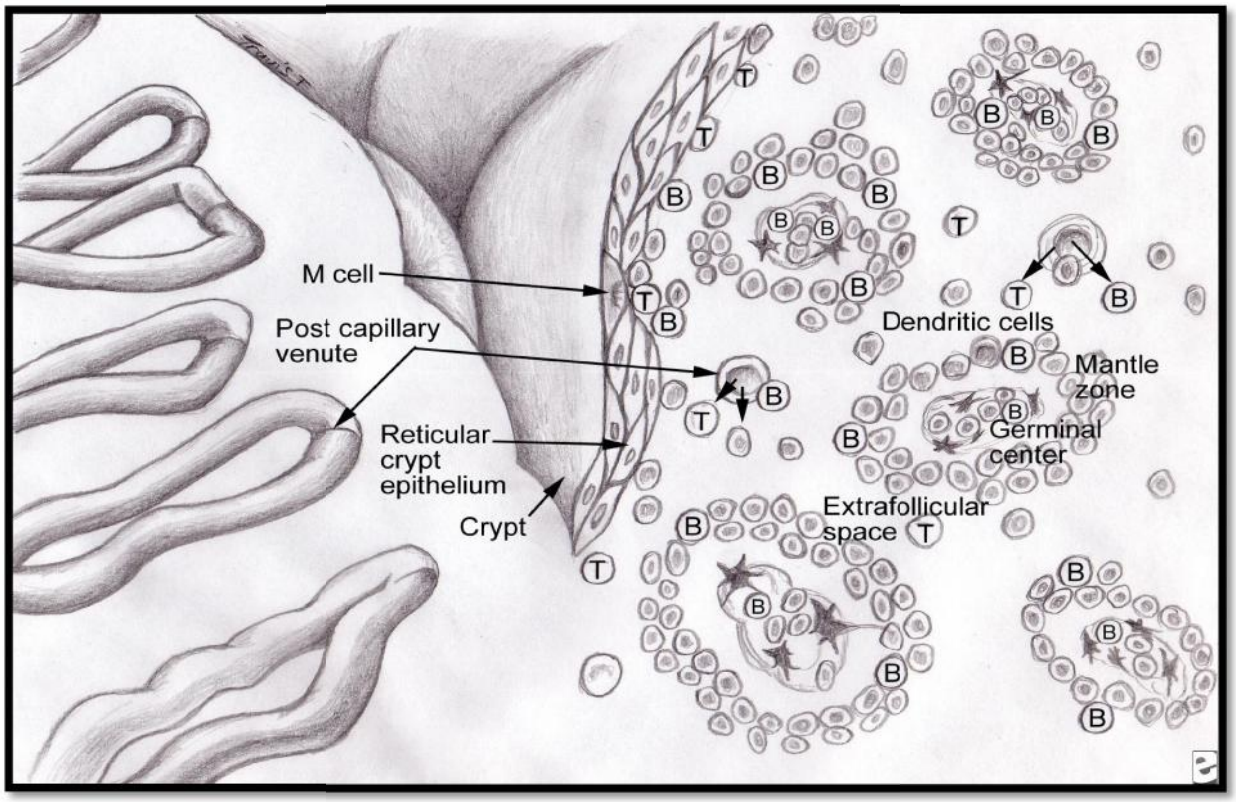


Figure 5:Immunological activity near Adenoid[12]

BACTERIOLOGY

The normal flora in the upper respiratory tract is well established at birth. Actinomyces, Fusobacterium, and Nocardia are acquired by age 6 to 8 months.[13] Subsequently, Bacteroides, Leptotrichia, Propionibacterium, and Candida are also established as part of the oral flora.[14] Fusobacterium populations reach high numbers after dentition and reach maximal numbers at 1 year of age.[14] The ratio of anaerobic to aerobic bacteria in saliva is approximately 10 : 1because of variations in oxygen concentration throughout the oral cavity.[15]

The most common pathogenic bacteria invading the adenoids include haemophilus influenza, streptococcal pneumoniae and group A beta haemolytic streptococci .[16]

PATHOLOGY

Pathological presentation of adenoid hypertrophyare manifested as nasal obstruction , rhinosinusitis, otitis media with effusion etc.[16,17]

Figure 6:Adenoid Facies

OTITIS MEDIA WITH EFFUSION (OME)

As per the study done by Yasan Het al. in 2003 it has been shown that due to recurrent inflammation of adenoids be it of acute or chronic durationalong with increased bacterial load, specially of Haemophilus influenza[16,17], there is squamous cell metaplasia of the adenoid epithelium resulting in reduction of mucociliary

clearance in children of Otitis Media with Effusionover those who do not have OME.[17]

This retained secretions serve as a breeding ground for bacteria and act as a precursor for biofilm production. Chronic gastro oesophageal reflux disorder is also associated with OME due to inflammation of the nasopharynx and adenoids.[18]

BIOFILM

The IUPAC definition of biofilm is an aggregate of micro-orginasms which are embedded within a self-produced matrix of extracellular polymeric substances and adhere to each other and to a surface. These biofilms are very resistant to antibiotics and can complicate the disease process.

OBSTRUCTIVE SLEEP APNOEA

Airway obstruction due to adenoid hypertrophy may lead to reduced tidal volume particularly while sleeping producinglower arterial PaO_2 and elevated $PaCO_2$ levels.[19] It has been seen that such an arrangement leads to poor development of the child. The respiratory improvement following adenoidectomy results in a substantial increase in serum insulin – like growth factor – I (IGF-I) which is directly proportional to clinical growth spurt following surgery as seen in a study done by Bar A et. Al in 1999.[20]

RHINOSINUSITIS

The hypertrophic adenoids impair the drainage of nasal secretions into the nasopharynx which leads to the collection proximal to obstruction. It serves as a breeding ground for bacteria and can lead to rhinosinusitis.

OLFACTION

Adenoidal hyperplasia may reduce olfactory sensitivity and, in particular, retro nasal smell and taste, which improves following adenoidectomy.[21]

RECURRENT OTITIS MEDIA

It has been noted that in children with selective IgA deficiency there is a tendency to develop recurrent otitis media and thus adenoidectomy alone will not help much in these children , they should receive prophylactic antibiotic therapy till immune system maturity over time takes place.

NEOPLASIA

Only reported variant is Non-Hodgkin lymphoma. It is usually suspected post transplantation lymphoproliferative disorders where nasal obstruction is a symptom.[22,23]Though in childhood neoplasia of adenoid is rare.

EVALUATION OF A CASE OF ADENOIDITIS

HISTORY

History of nasal obstruction, snoring , mouth breathing, ear discharge and recurrent upper respiratory tract infection should be taken.

GENERAL EXAMINATION

Look for 'Adenoid facies'

- Dull looking face and sunken eye balls
- Protruded and crowded upper teeth
- Gingival hypertrophy

- Pinched nose
- High arched palate
- Rhinolalia clausa
- Hypoplasia of maxilla
- Continuous nasal discharge with fissures over vestibule

NASAL EXAMINATION

Anterior rhinoscopy with Thudicum's nasal speculum is done and cold spatula test to see the patency of airway. Posterior rhinoscopy is usually not well tolerated by children.

ENDOSCOPIC EXAMINATION OF ADENOID

Under local or general anaesthesia nasal endoscopy is performed. Nasal cavity is decongested with 4% xylocaine and adrenaline (1:1000). The size of the adenoid has been graded using **Clemens-McMurray grading** system.

CLEMENS-McMURRAYGRADING

Grade	Description
I	Adenoids occupying one-third of the vertical portion of the choana.
II	Adenoids occupying one-third to two-thirds of the choana .
III	Adenoids occupying two-thirds to nearly complete obstruction of the choana.
IV	Complete obstruction of choana .

Table 1: Clemens and McMurray endoscopic adenoid grading[24]

RADIOGRAPHY

X ray nasopharynx lateral view to assess the obstruction to nasopharyngeal airway.

INVESTIGATIONS

Routine haematological and urine investigations are done. And fitness for general anaesthesia is taken.

ADENOIDECTOMY

Wilhelm Meyer, a Danish otolaryngologist identified the adenoids and their implication in sleep disordered breathing more than a century ago. Since then adenoidectomy is being practiced and many variations have been developed over the course of time.[25]

The first adenoidectomy operation was performed by Wilhelm Meyer in 1876. he recommended curettage through the nose, assisted by the finger in the nasopharynx.

ADENOIDECTOMY INDICATIONS

Adenoid hypertrophy or chronic adenoiditis may cause significant problems requiring adenoidectomy in situations in which the tonsils themselves are not diseased and are not contributing to symptomatology. Adenoidectomy is indicated in craniofacial maldevelopment (adenoid facies) , obstructive sleep apnoea and poor growth of child.

Children with a history of chronic recurrent sinusitis may also benefit from adenoidectomy as it will relieve the obstruction to the drainage of secretions. It is

shown that in patients with chronic rhinosinusitis along with significant adenoid hypertrophy performing adenoidectomy may be beneficial . It is also of significance in children who failed to respond to medical therapy.

Patients with hypo nasal speech (rhinolalia clausa) are also candidates for adenoidectomy. Although surgical intervention should be considered in cases of severe nasal obstruction related to adenoid hypertrophy, there is evidence that alternative medical therapy exists to manage adenoid hypertrophy.[26]

In one of the study it was demonstrated that aqueous nasal beclomethasone therapy led to significant improvement of nasal obstruction secondary to adenoid hypertrophy, which was confirmed by pre and post management flexible nasopharyngoscopy. In addition, patients with underlying inhalant allergies may benefit from antihistamine therapy and possibly from allergic immunologic desensitization therapy.[26]

Conservative adenoidectomy should be performed in patients with a cleft palate or submucous cleft palate, leaving the lower portion of the adenoid pad intact to decrease the risk of post-operative velopharyngeal insufficiency.

Surgical extirpation of the adenoids may remove a nasopharyngeal nidus of contaminated tissue that secondarily acts as a source of infection in the middle ear, or adenoidectomy may simply remove an anatomic obstruction of the Eustachian tube. The actual size of the adenoid pad has not necessarily been implicated in the aetiology of OME.[13]

PREOPERATIVE ASSESSMENT

Preoperative assessment in patients undergoing adenoidectomy is important and coagulation profile is must to be checked . It is apparent that patients who have an obvious family or clinical history of excessive bleeding or an underlying hematologic disorder require close monitoring of their coagulation profiles and consultation with a haematologist.

Patients with obvious severe airway obstruction secondary to adenotonsillar hypertrophy may require polysomnography, chest radiography, electrocardiography, and possible cardiology consultation as per the need.

ANAESTHESIA FOR ADENOIDECTOMY

General anaesthesia is the anaesthetic method of choice for children undergoing adenoid surgery.

PREMEDICATION

In adenoidectomy it is important to maintain a balance between the premedication and the intended anaesthesia technique bearing in mind that patients who have significant upper airway obstruction usually have a disturbed sleeping pattern. It has been suggested that premedication with atropine is sufficient. In children younger than 5 years of age a safer alternative is a combination of atropine with trimeparazine. This has a good antiemetic as well as a sedative profile.Adenoidal curettage may cause bradycardia and it is wise to give intravenous glycopyrrolate or atropine at induction if a vagal blocking agent has not been given.[27]

INDUCTION

The oral route is preferred for endotracheal intubation. The most common problem encountered during placement of Boyle Davis mouth gag is the kinking of the plastic tubes. For this drawback Doughty split tongue blade should be usedalong withnon-compressible tracheal tube connectors to provide safer access for the surgeon and anaesthetist.

Endotracheal anaesthesia provides better control of the patients airway and allows the anaesthetist to assists spontaneous respirations when required. The endotracheal tube (cuffed) also prevents aspiration of blood or debris during the surgical procedure and allows ready suctioning of secretions from the pharynx as needed. A wide choice of anaesthetics is available, and patients can also be managed in lighter planes of anaesthesia to allow for more rapid recovery.[27]

During termination of the anaesthesia one can opt for awakeor deep extubation.In awake extubation there is coughing, straining and increased bleeding before patient comes out of anaesthesia whereas in deep extubation there is a possibility of aspiration and laryngospasm while patient is coming out of anaesthesia. Patients in whom trimeprazine and halothane were used can be extubated deeply without much risk of laryngospasm but where opiate premedication were used high incidence of serious laryngospasm with thiopentone and halothane was noted.It is therefore advised that these patients should undergo awake extubation.

Before extubation nasal and oral bleeding should be checked and thorough suctioning to be done. Once patient develops a good cough reflex and responds to oral commands they can be shifted out of the operating room. Post-operatively close monitoring should be done .[27]

TECHNIQUE OF CONVENTIONAL ADENOIDECTOMY

When general anaesthesia is employed for surgery orotracheal intubation is done and the tube is stabilized in a Doughty tongue blade with Boyle-Davie's mouth gag supported on Draffin's bipod stand. The patient is given Rose's position. A Blair type of head drape can then be used, particularly to protect the patients eyes, and sterile drapes are placed over the patient's chest. The actual surgery is not sterile, but it should be performed with sterile instruments and ancillary equipment to prevent needless exogenous contamination or infection.[28]

The Rose's position (position for tonsillectomy) increases the curvature of the cervical spine and makes adenoidectomy difficult. Hencea more neutral position of the neck, neither flexed nor extended is preferred, or while curetting the adenoids , the head is slightly flexed to achieve better removal of adenoids.[29]

The adenoids are digitally palpated and brought in midline with the index finger. A St. Clair Thomson adenoid curette is introduced into the nasopharynx, taking care not to stretch the soft palate or injure the uvula. A correct sized curette should be used . The curette should be lowered in the nasopharynx along the posterior pharyngeal wall till the posterior end of nasal septum is touched. The curette should be held like a dagger. After engaging the adenoid mass a smooth sweeping motion should be carried out in forward and upward direction taking care not to scrape off the posterior pharyngeal wall. One should not go too laterally while engaging the adenoids as this might cause eustachian tube injury. The nasopharynx again is palpated for any remnants and the same procedure is carried out for them. A nasopharyngeal pack is then placed to attain haemostasis.

There must be absolutely no bleeding from the nasopharynx before extubation. The nasopharyngeal pack is removed with a Naegus forceps . If bleeding continues then a second pack can be placed in situ or an adrenaline(1:1000) soaked pack can be placed. Some surgeons prefer the use of bipolar cautery which can be used either endoscopically or by using a St. Clair Thompson posterior rhinoscopy mirror. If any remnant adenoid tag is oozing blood then it should be removed. Keeping a posterior nasal pack is no longer advocated in todays practice.

Other techniques employed are removal of the adenoid by LaForce adenotome and curetting the remnant of adenoid by Barnhill curette.[29]

In a study done by Kornblut A et. al.a different approach of direct adenoidectomy in employed in which the soft palate is retracted by metal palatal retractor or by insertion of French rubber catheters through the nostrils and brought through the mouth. Here the adenoids were removed under direct vision using punch forceps and scissors.[28]

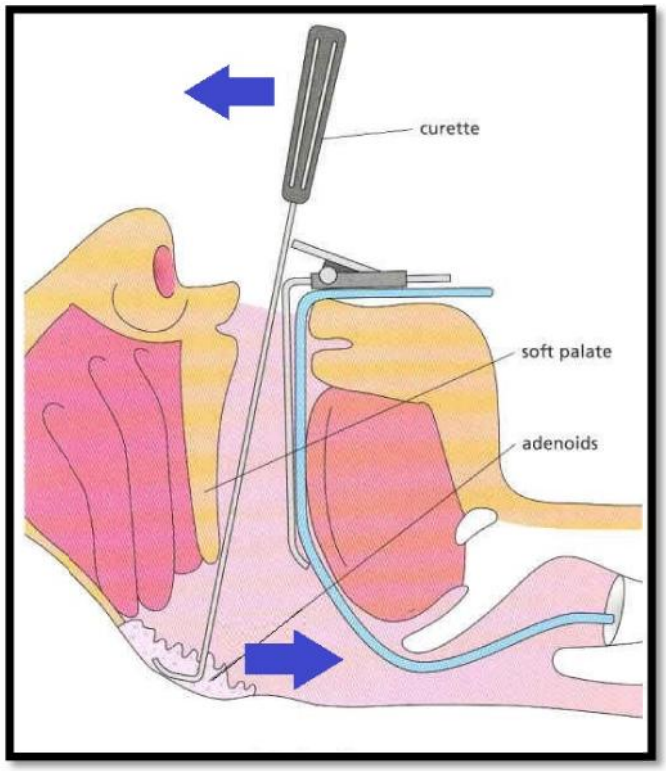


Figure 7:Adenoid curettage by conventional St. Clair Thompson adenoid curette

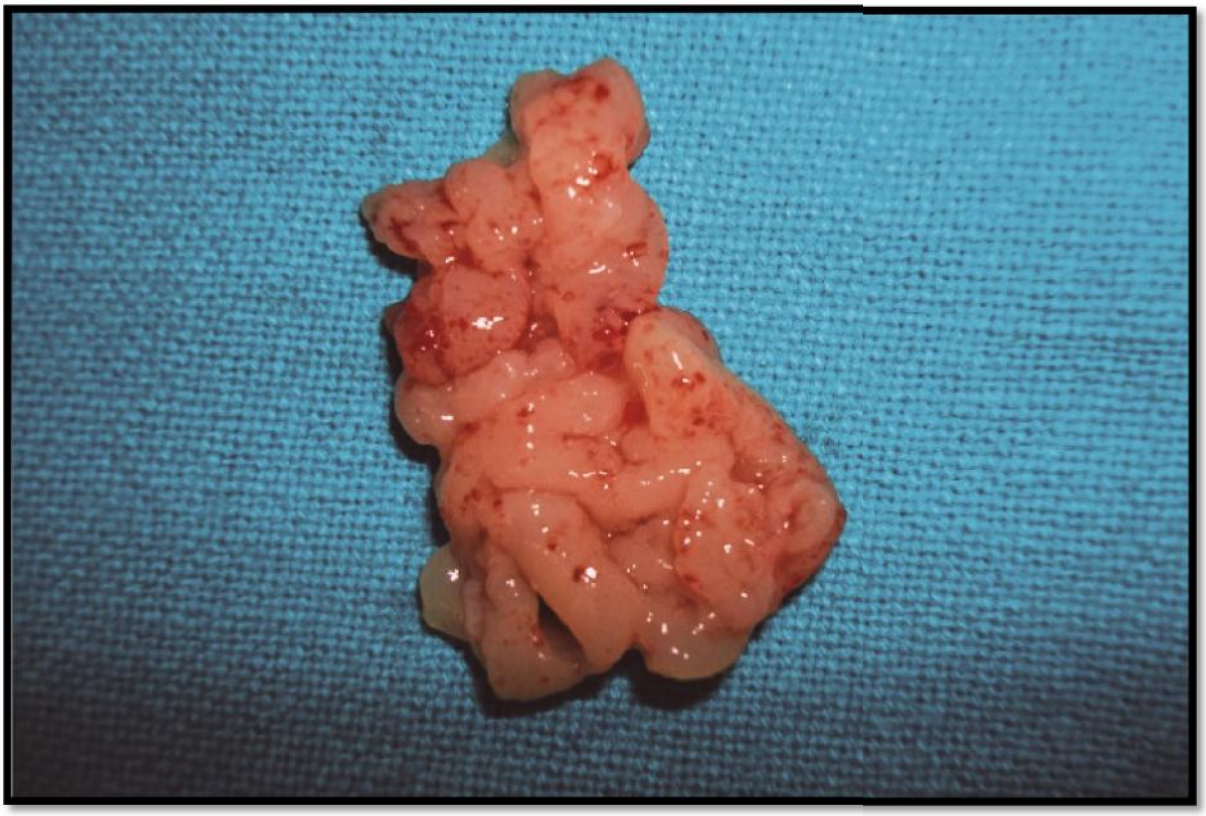


Figure 8:Adenoid mass after removal with curette

COMPLICATIONS OF ADENOIDECTOMY

a) Haemorrhage :

Occasionally there will be excessive haemorrhage at adenoidectomy. It is imperative that preoperative coagulation profile must be normal. Sometimes aberrant vessels may be encountered during surgery and haemostasis should be achieved with either post nasal packing or coagulation cautery.

Insertion of a postnasal pack – A small soft rubber or plastic catheter is passed through each nostril via the nasopharynx into the oropharynx, the catheters are drawn out through the mouth. A piece of strong thread attached to each side of the pack is tied to the distal end of each catheter. The catheters are then withdrawn through the anterior nares and the pack firmly settled into the post nasal space. The threads are tied across the columella and a third piece of thread, previously sutured to the centre of the lower edge of the pack is loosely secured on the check with the adhesive tape. The pack is removed 24 hours later through the open mouth.[30]

b) Trauma to adjacent structures:

Injury to the soft palate, uvula posterior pharyngeal wall and eustachian tube have been described in literature. Post-operative scarring and stenosis of eustachian tube has been associated with ontological implications .

c) Velopharyngeal dysfunction :

Children with large obstructive adenoids may have rhinolalia clausa andis expected to improveafter adenoidectomy. As found out in a study by Alan B et. Al. in 1968 hyper nasal speech following adenoidectomy has incidence of about one in every 1450 operations.[30]

Normally the soft palate closes against Passavant's ridge during phonation. In some children where there is congenitally short soft palate or defective musculature in a patient with a submucosal cleft palate, the adenoid acts as a bridging structure for soft palate to close off the nasopharynx. Here the removal of adenoids in turn leads to production of hyper nasal speech or rhinolalia aperta. If the above obvious examples of palatal abnormality are excluded only a small number of children develop hyper nasality following surgery which is usually temporary and responds to speech therapy

d) Cervical spine complications :

A rare complication of adenoidectomy is atlantoaxial subluxation (Grisel's syndrome). Although unto 10% of patients may report neck pain after adenoidectomy, patients with Grisel's syndrome will have deep calcification of the anterior arch of atlas vertebrae and laxity of anterior transverse ligament between the atlas and the axis. Most cases of atlantoaxial subluxation are related to infection or trauma and only rarely are secondary to adenoidectomy.

Management of atlantoaxial subluxation after adenoidectomy should be individualized based on the duration and the symptoms present. Intravenous antimicrobial therapy and possibly cervical traction may be necessary. In the presence of cervical osteomyelitis, long term (4 to 8 weeks) intravenous antimicrobial therapy, coupled with cervical stabilization, will be necessary. Retropharyngeal abscess has also been reported following adenoidectomy.[5]

e) Nasopharyngeal scarring following surgery :

Scarring following adenoidectomy in the nasopharynx is a common entity without much complications. Rarely, adenoidectomy results in total obliteration of the

nasopharynx by scar tissue. However scarring over torus tubaris is associated with ontological complications.

f) Injury to teeth:

Loose teeth should be evaluated prior to surgery. Usually damage occurs due to improper placement of mouth gag.

g) Retained swab:

While the early post-operative risk is of airway obstruction by a retained swab, late presentation months later with infection has also been reported.[31]

h) Persistence of symptoms following surgery :

It is not unusual for symptoms to persists following adenoidectomy. Inthe study done by Yearsley J et. Al in 1969 it has been stated that 70% of children with otitis media with effusion (OME) had previously undergone adenoidectomy.[32]

The reasons for this outcome may be :

1. The adenoid might not be the cause for the OME.
2. Scarring of the eustachian tube orifice or torus tubaris.
3. Remnant adenoid tissue which later hypertrophied and lead to eustachian tube obstruction. Though rare but such a complication may happen in very young children.[33]

i) Regrowth of the adenoid:

In a study done by Buchinsky FJet. Al. in 2000 it was concluded that at least 40% of nasopharynx should be blocked by the hypertrophic adenoids to cause nasal obstruction post-surgery.[33]

MICRODEBRIDER ASSISTED ADENOIDECTOMY

With the advent of endoscopes and powered devices the above mentioned complications occur less frequently as the surgery takes place under direct vision and surgeon can harness the advantage of both the telescopic vision and precise cutting mechanism of microdebrider.[34] The biggest advantage that microdebrider poses is –

- It's safety in patients with instability of cervical spine where it can be used transnasally and there is no need for neck extension as shown in (figure 9) .[35]
- Even in patients with potential to develop velopharyngeal insufficiency post adenoidectomy, a partial adenoidectomy by preserving the adenoid tissue close to Passavant's ridge can help in preventing the complication of rhinolalia aperta and nasopharyngeal reflux.[36]

Disadvantages of microdebrider are-

- The equipment as a whole is expensive and every time the debrider blade has to be changed which adds to the cost of surgery.
- Yanagisawa E, Weaver EM in 1997 encountered difficulty in maneuvering the microdebrider tip into the nasopharynx, especially with endoscope in same nasal cavity.[37] This can be overcome by placing the two instruments in different nostrils or but a transoral approach as done in 1997 byKoltai et al.[38] wherein the shaver blade was bent as per requirement of the nasopharynx as shown in (figure 10).
- The resected tissue goes away in suction and is not available for histopathological examination.

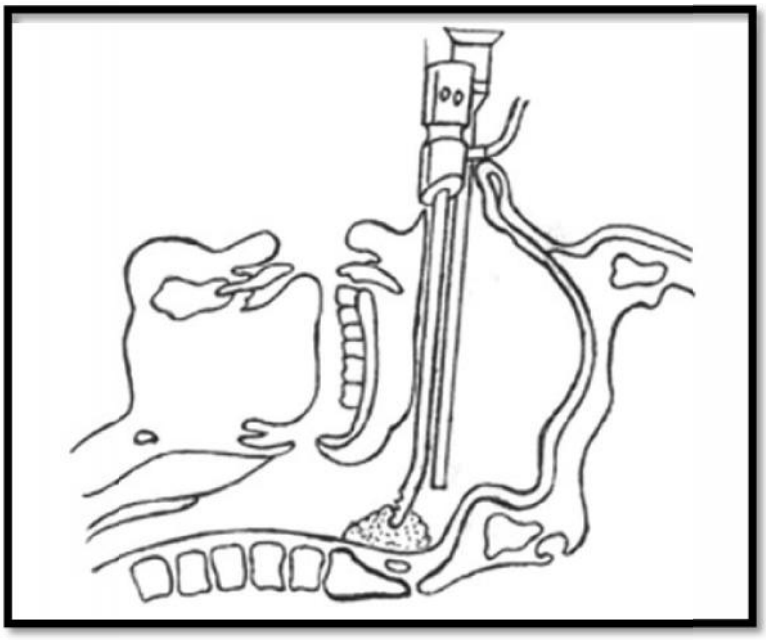


Figure 9: Microdebrider assisted adenoidectomy through nasal cavity with straight blade[35]

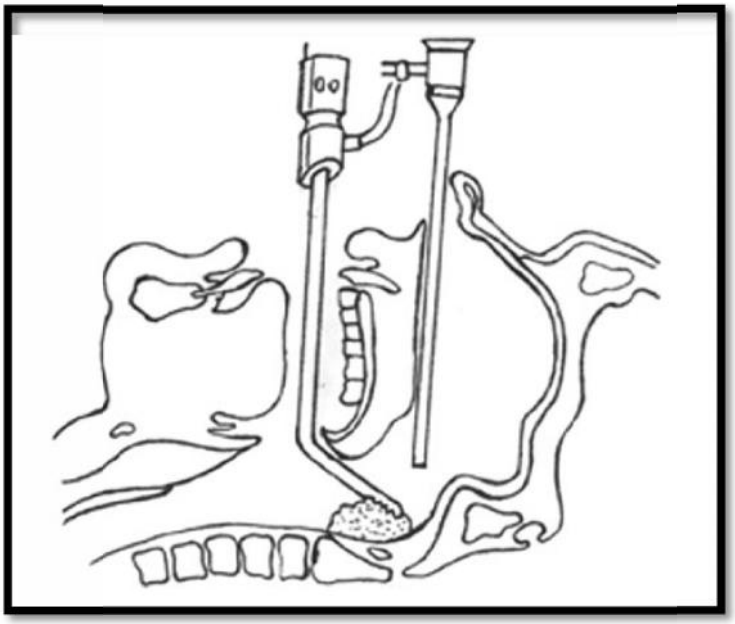


Figure 10:Microdebrider assisted adenoidectomy through oropharynx with 45 degree blade[35]

METHODOLOGY

SOURCE OF DATA

All the cases of adenoidectomy done in ENT & HNS department in KLE'S Dr. Prabhakar Kore Hospital during the study period.

METHOD OF DATA COLLECTION

Study design: A Randomised Controlled Trial. (The patients will be randomly assigned into 2 groups using their hospital ID, odd number patients in group A and even number in group B. Where group A patients will undergo conventional curettage and group B will undergo microdebrider assisted adenoidectomy)

Study period: January 2018 to December 2018

Sample size(n): 40 (20 each belonging to conventional group and microdebrider group respectively).

Formula for sample size calculation:

The formula used for calculating minimum sample size 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.

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

These will be taken as (Equation 1 and Equation 2)

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), this is done in accordance with the parent article(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.).[2]

This is the minimum sample size. If possible one can take cases a little more than this number so that the results becomes more confirmative. There is no condition that there should be equal number of cases in the two groups but 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.

The categorical data was expressed in terms of rates, ratios and percentages. The association between the outcome, clinical and demographic characteristics will be tested using Chi-square test or Fisher's exact test.

For all the tests the value of p less than 5% (0.05) will be considered significant.

INCLUSION CRITERIA

All cases of adenoidectomy done in ENT&HNS department in KLE Dr.Prabhakar Kore charitable hospital.

- Patients between the ages of 3-16 years.
- Obstructive sleep apnea
- Mouth breathing and snoring
- Adenoid facies

EXCLUSION CRITERIA

- Patients having craniofacial syndrome (cleft lip and cleft palate)

METHODOLOGY

- Patient's details and history will be obtained. Clinical examination will be done. Informed consent will be taken.
- Preoperative pictures of the patient will be taken methodically.
- X-RAY nasopharynx lateral view for visualizing soft tissues will be taken.
- Patient will be subjected to either conventional curettage or to endoscopic microdebrider assisted adenoidectomy. 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 conventional curettage and group B will undergo microdebrider assisted adenoidectomy.
- Patients will be given general anesthesia with orotracheal intubation. The nasal cavities will be decongested by using cotton pledges soaked in 4%

lignocaine with 1:100000 dilution adrenaline. Using 0-degree endoscope pre-operative grade of adenoid will be assessed using grading system given in (table 1).[24]

- In the conventional curettagegroup, adenoidectomy will be done using the St. Clair Thompson adenoid curette.
- In the endoscopic group, microdebrider assisted adenoidectomy under endoscopic vision will be done.
- The intraoperative parameters studied will be operative time, blood loss, and completeness of clearance of adenoids.
- Post-operative parameter includes assessment of damage to surrounding structures after 3 weeks with a repeat endoscopy.
- Intra operative time will be taken as the total time from the patient being handed over by the anesthetist to surgeon to the time the patient is handed back to the anesthetist for extubating.
- The amount of bleeding will be assessed by a guide given byAlgadiem EAet.al. in 2009.[39]Where they have calculated that a 10 X 10 sq. cm. gauze used for packing the nasopharynx will correspond to a volume of 12 ml.
- In the microdebridergroup the blood loss will be calculated by subtracting the irrigation solution from the total collected fluid in the suction machine. The amount of irrigation solution will be noted down during surgery to avoid calculation error and prior to the surgery the suction machine will be emptied completely.
- The completeness of clearance of adenoid will be assessed by nasal endoscopy at the end of the procedure in both the groups.

- At 3 weeks follow up a repeat nasal endoscopy will be done under short general anesthesia or IV sedation to assess for any postoperative scarring or collateral damage.

Figure 1:Grade I

Figure 2:Grade II

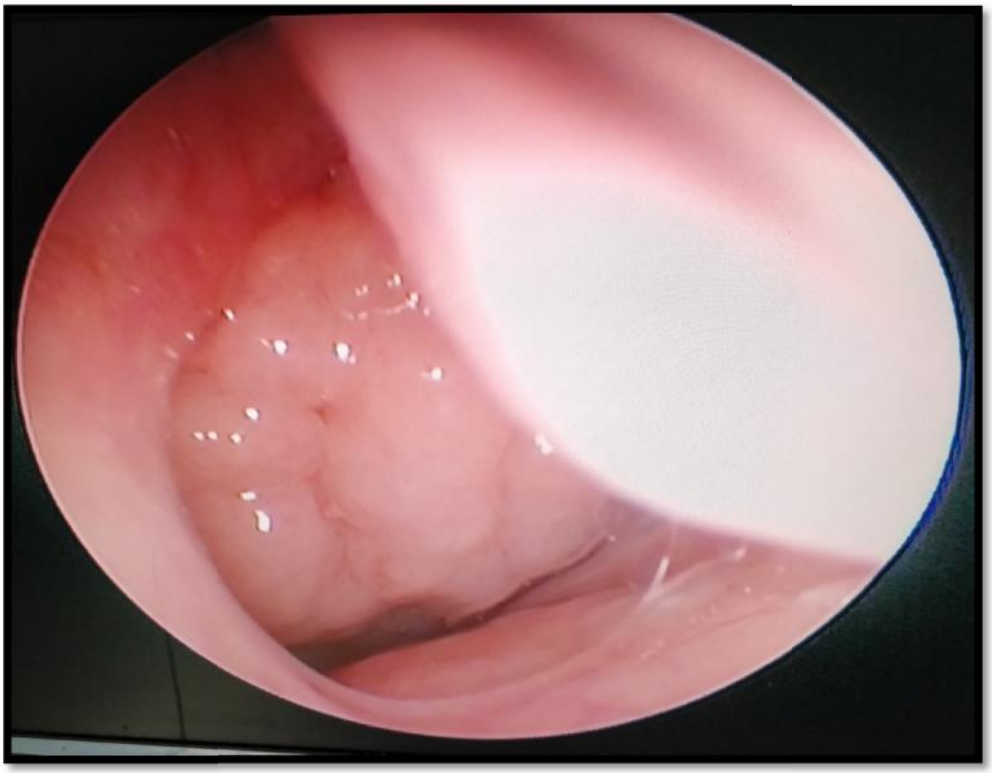


Figure 3:Grade III

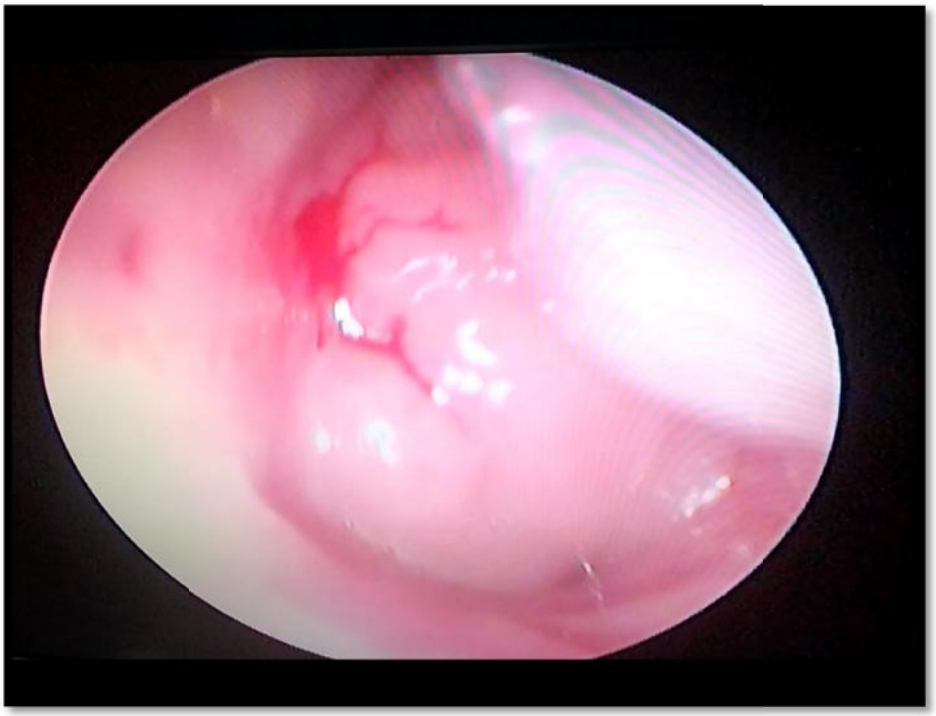


Figure 4:Grade IV

METHOD OFCONVENTIONAL ADENOIDECTOMY

Consent was taken prior to surgery. General anaesthesia employed with orotracheal tube. Patient was placed supine on the operating table. Boyle-Davies's mouth gag with tongue blade applied in the oral cavity which was supported by Draffin's bipods. A more neutral position of the neck was given.

The adenoids are digitally palpated and brought in midline with the index finger. A St. Clair Thomson adenoid curette is introduced into the nasopharynx, taking care not to stretch the soft palate or injure the uvula. A correct sized curette should be used . The curette should be lowered in the nasopharynx along the posterior pharyngeal wall till the posterior end of nasal septum is touched. The curette should be held like a dagger. After engaging the adenoid mass a smooth sweeping motion should be carried out in forward and upward direction taking care not to scrape off the posterior pharyngeal wall. One should not go too laterally while engaging the adenoids as this might cause eustachian tube injury. The nasopharynx again is palpated for any remnants and the same procedure is carried out for them. A nasopharyngeal pack is then placed to attain haemostasis.

If the patient has associated chronic tonsillitis, tonsillectomy was performed. After the completion of tonsillectomy, pack in the nasopharynx was removed. Patient was extubated after confirming that there is no bleeding from nasopharynx.

METHOD OF MICRODEBRIDER ASSISTED ADENOIDECTOMY

Consent was taken prior to surgery. General anaesthesia employed with orotracheal tube. Patient was put in supine position on operation table. Nasal cavity was packed with 4% lignocaine with adrenaline soakedpledgets. Nasal cavities were suctioned and using 0-degree endoscope the adenoids were visualised and were graded.

A red rubber catheter was passed from left nostril and one end was brought out through the mouth. This was used to pull gently the soft palate anteriorly during the procedure.

Using the lack's tongue depressor the tongue was depressed and the 45-degree curved blade microdebrider was passed into the nasopharynx via oropharynx. Under direct endoscopic vision the adenoids were debrided and after complete removal the nasopharynx was packed with 10 x 10 cm nasopharyngeal pack to achieve haemostasis.

RESULTS AND ANALYSIS

Total number of cases:

Gender	Conventional group	%	Microdebrider group	%	Total	%
Male	13	52.00	12	60.00	25	55.56
Female	12	48.00	8	40.00	20	44.44
Total	25	100.00	20	100.00	45	100.00
Chi-square=0.2882 P = 0.5921						

Table 1: Total number of cases

Conventional group – 25 cases

Microdebrider group – 20 cases

Male preponderance is 55.56 %

As per the sample size formula used in (Equation 1 & Equation 2) the minimum sample size is 15 patients per group but a little more than that has been included so that the results become more confirmative. There is no condition that there should be equal number of cases in the two groups but both should exceed the minimum sample size to keep the power of study at >80%.

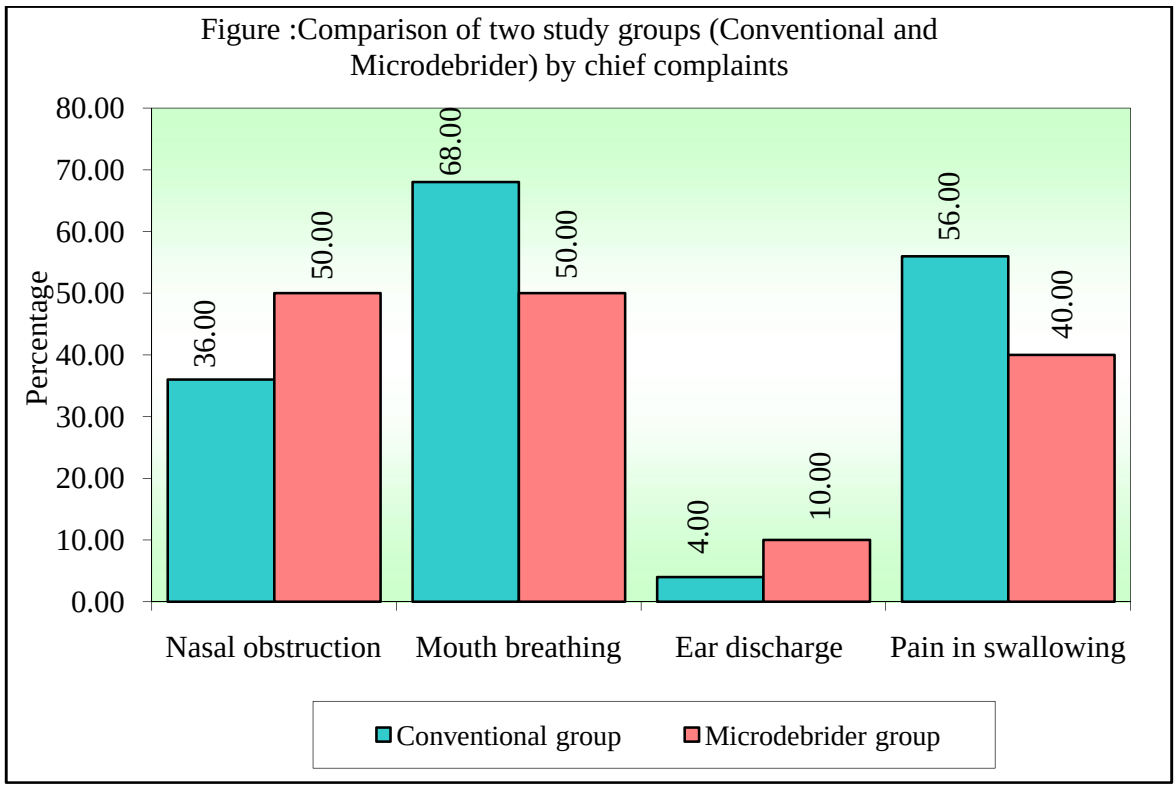
Age distribution in the groups:

Age groups	Conventional group	%	Microdebrider group	%	Total	%
<=5yrs	3	12.00	1	5.00	4	8.89
6-10yrs	14	56.00	11	55.00	25	55.56
11-15yrs	8	32.00	8	40.00	16	35.56
Mean age	8.80		9.80		9.24	
SD age	3.19		2.59		2.95	

Table 2:Age distribution in the groups

The mean age of patients undergoing adenoidectomy was 9.24 yrs. The 2 groups are comparable as the difference between standard deviation is not significant p = 0.26.

Chief complaints:



Graph 1: Chief complaints

The most common presenting complaint was mouth breathing and snoring followed by nasal obstruction and nasal discharge.

Clemens and McMurray adenoid grading before operation:

Adenoid grade	Conventional	Microdebrider	Total
1	0	0	0
2	5	5	10
3	14	12	26
4	6	3	9
Total	25	20	45

Table 3:Clemens and McMurray adenoid grading before operation

Adenoid grading after adenoidectomy:

Adenoid grade	Conventional	Microdebrider	Total
1	3	19	22
2	16	1	17
3	6	0	6
4	0	0	0
Total	25	20	45

Table 4:Clemens and McMurray adenoid grading after adenoidectomy

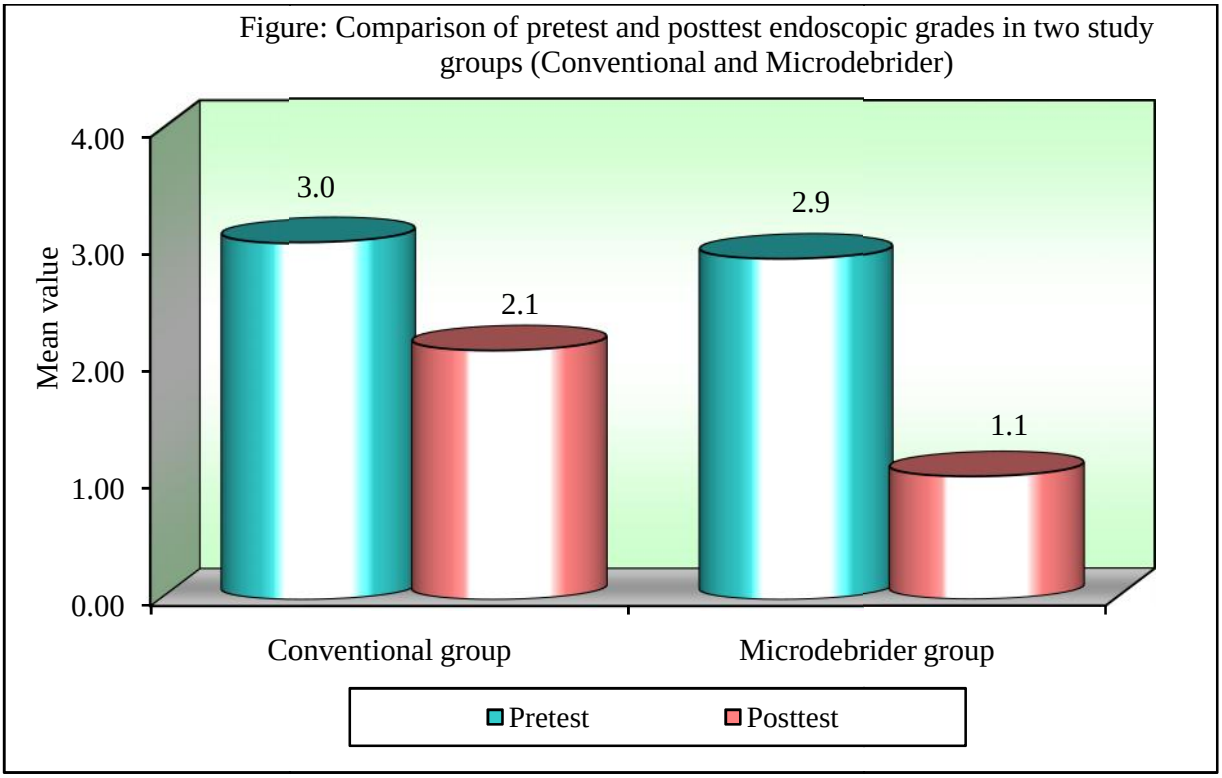
The conversion of patients after adenoidectomy to grade 1 is 12% and grade 2 is 64% in conventional group as compared to 95% patients landing in grade 1 post microdebrider assisted adenoidectomy which is statistically significant ($p<0.05$).

This can also be seen by using Wilcoxon matched pair test:

Groups	Time	Mean	Std.Dv.	Mean Diff.	SD Diff.	% of change	Z-value	p-value
Conventional group	Pre-op	3.04	0.68					
	Post-op	2.12	0.60	0.92	0.57	30.26	3.9199	0.0001*
Microdebrider group	Pre-op	2.90	0.64					
	Post-op	1.05	0.22	1.85	0.59	63.79	3.9399	0.0001*

Table 5:Comparison of completeness of clearance of adenoids in both group

Here it can be clearly seen that pre-op to post-op endoscopic grading of adenoid shows that in both the groups the completeness of clearance is statistically significant but in microdebrider group the percentage of change i.e. the reduction of grading post operatively is 63.79% as compared to 30.29% in conventional group , which indicates the effectiveness of microdebrider.

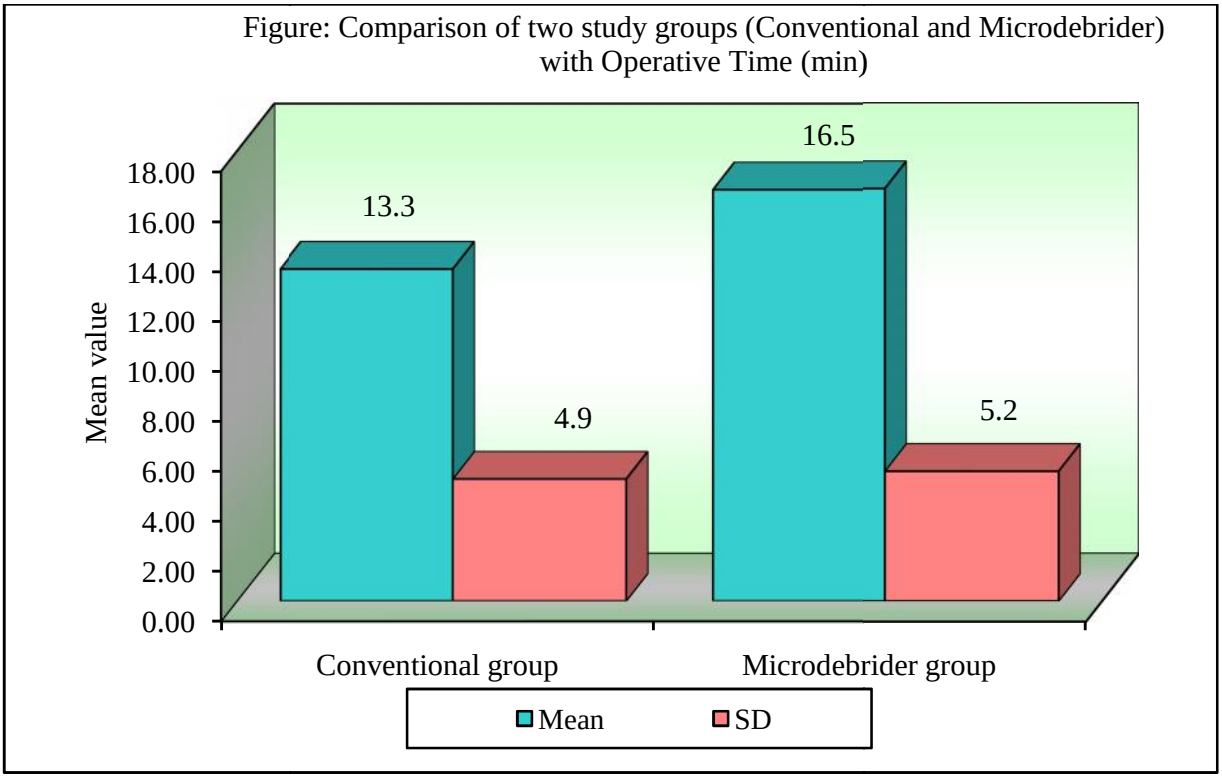


Graph 2:Comparison of pre and post-operative adenoid grade in both groups

Operative time taken:

Groups	Mean	SD	SE	t-value	P-value
Conventional group	13.28	4.88	0.98	-2.1084	0.0409*
Microdebrider group	16.45	5.18	1.16		

Table 6: Operative time taken



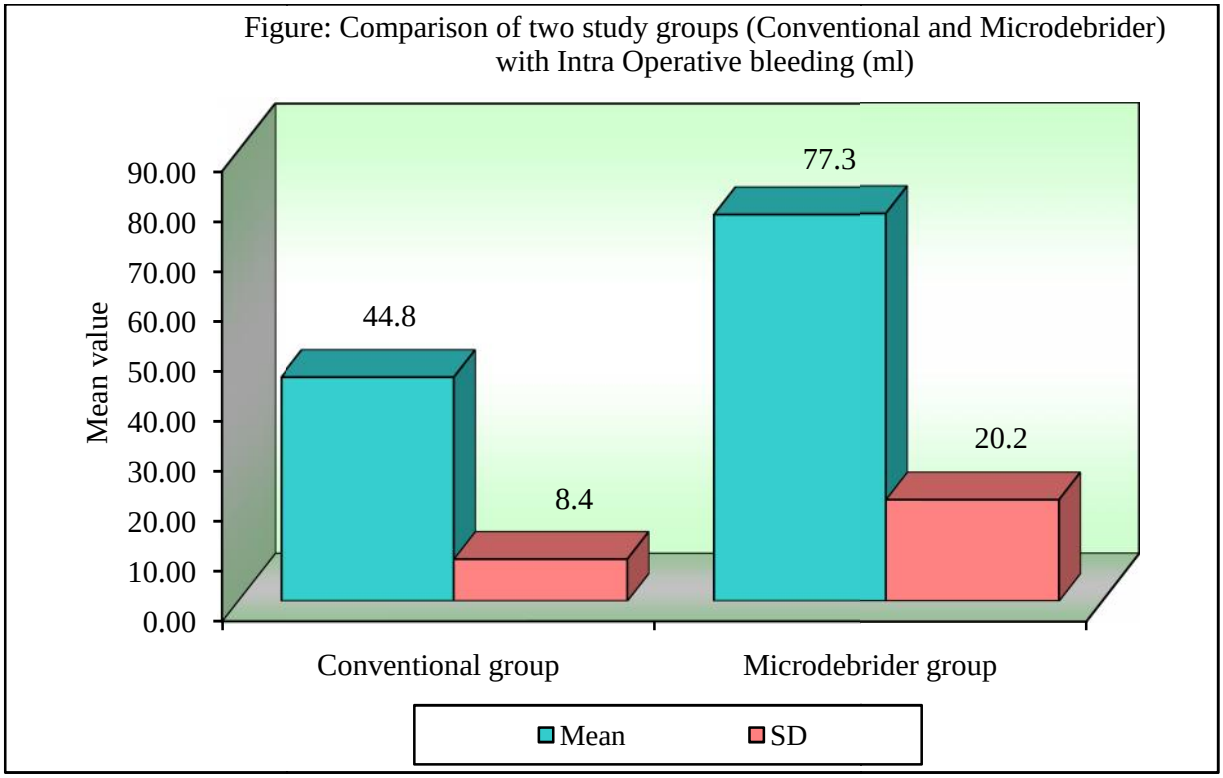
Graph 3:Comparison of operative time taken

The average time taken by microdebrider assisted surgery was 16.45 mins as compared to 13.28 mins taken by conventional method which was significantly higher with a p-value of less than 0.05 and was statistically significant(p=0.041).

Intraoperative blood loss:

Groups	Mean	SD	SE	t-value	P-value
Conventional group	44.76	8.37	1.67	-7.3187	0.0001*
Microdebrider group	77.30	20.21	4.52		

Table 7: Intra-operative blood loss



Graph 4: Intra-operative blood loss

The average amount of blood loss in conventional group was 44.76 ml whereas in microdebrider group was 77.30 ml. The blood loss was higher in microdebrider assisted adenoidectomy and was statistically significant ($p<0.05$).

Post-operative complications:

At 3 weeks follow-up none of the patients in either of the 2 groups showed eustachian tube dysfunction, uvular injury or posterior pharyngeal wall scarring.

DISCUSSION

Conventional curettage adenoidectomy is a blind and crude procedure and as stated by Koltai and Havas in their studies in 1997 and 2002 , there is often residual tissue left behindnear choana and torus tubaris region.[40,38] Our study also showed that residual tissue wasleft behind in children undergoing conventional curettage adenoidectomy specially near the choana. This might be due to the inability of adenoid curette to reach these areas and therefore it can be ascertained that these children may have persistent symptoms post-surgery.

In 1997, Koltai et al., had brought power-assisted adenoidectomy in lightand under the vision of laryngeal mirror they achieved a superior resection of adenoid.[38] Yanagisawa and Weaver in 1997 used an endoscope along with a microdebrider through a transnasal approach and concluded that they had a completeness of clearance of adenoid with significantly lesser complications.[37] Costantini et al. in 2008, had used a 70° endoscope with video attachment introduced and a 40° microdebrider blade through the mouth to remove the adenoid and they realised that the limitation of mobility of instruments through the nasal cavity could be overcome with this approach.[41]Anand V et al. in 2014 suggested that this difficulty of manouvering the instruments can be overcome by passing the endoscope through 1 nostril and straight blade microdebrider through the other.[43]

Pagella et al., in 2009 on the other hand combined conventional curettage method with endoscopic method and concluded that with this method though a longer time is taken for surgery but the need to use angled endoscopes and microdebrider blades can be avoided.[42]same was suggested by Das AT et al. in 2017.[34]

In our study we have tried to compare the efficacy and safety of conventional curettage method versus the endoscopic microdebrider assisted technique. There is an increasing trend towards performing adenoidectomy in isolation rather than combining it with adeno-tonsillectomy.[34]In olden days adenoidectomy and tonsillectomy were performed together but now due to clearly laid down indications for each of the surgery adenoidectomy is gaining popularity as an isolated procedure. In our series only 13% of patients underwent adenoidectomy alone.

In table 9 various presenting complaints have been described. The most common complaint over all was mouth breathing and snoring around 60% (i.e. 27 patients) followed by pain while swallowing and nasal obstruction respectively.It is well established that adeno-tonsillectomy is routinely performed for sleep disordered breathing and rightly so most of the patients in the present study were falling into the same indication.[44]

Chief complaints	Conventional group	%	Microdebrider group	%	Total	%
Nasal obstruction						
No	16	64.00	10	50.00	26	57.78
Yes	9	36.00	10	50.00	19	42.22
Chi-square= 0.8931 P = 0.3452						
Mouth breathing						
No	8	32.00	10	50.00	18	40.00
Yes	17	68.00	10	50.00	27	60.00
Chi-square= 1.5001 P = 0.2212						
Ear discharge						
No	24	96.00	18	90.00	42	93.33
Yes	1	4.00	2	10.00	3	6.67
Chi-square with Yates's correction = 0.0401 P = 0.8410						
Pain in swallowing						
No	11	44.00	12	60.00	23	51.11
Yes	14	56.00	8	40.00	22	48.89
Chi-square= 1.1381 P = 0.2862						
Total	25	100.00	20	100.00	45	100.00

Table 1: chief complaints

Only performing the surgical steps of the adenoidectomy would take about 5-10 minutes, but a properevaluation of the operative time must include all the steps like setting up the instrument trolley, painting and draping, achieving haemostasis and taking pre and post-operative endoscopic pictures of adenoids.In short the time taken from patient being handed over to the surgeon by anaesthetist to the complete haemostasis of nasopharynx . The duration of microdebrider assisted adenoidectomy in our study was approximately 16 minutes 45 seconds which was roughly 3 minutes more than conventional adenoidectomy. This was due to increased time taken while setting up connections for powered instruments as well as repeated defogging of endoscope. In a study by Somani et. al.(2010), their operating time with endoscopic technique was 12 minutes 30 seconds, which was 2 minutes shorter than conventional adenoidectomy.[35]This finding was in contrast to our study.

We have used zero degree endoscope through the nose with a 45° curved blade microdebrider through oropharynx whereby we prevented injury to the soft palate by retracting the soft palate anteriorly by using a red rubber catheter passed through the other nostril and brought out through the mouth and clamped on the head towel. Our findings are opposite to those by Stanislaw et. al.[45]as well ,where powered adenoidectomy has merited to be 20% faster than curettage adenoidectomy. They also used 45 degree microdebrider blade through oropharyngeal route coupled with a laryngeal mirror for visualization. This might be the reason why they took lesser time, as setting up of powered instruments and repeated defogging was not needed in their case. In our opinion microdebrider can be a potentially dangerous instrument if not used under vision therefore we recommend endoscopic visualization.

Since in all the above mentioned studies the operative instruments were not constant and the criterion for defining time taken for operation was not certain, so it won't be correct to compare operative time.

In our study the intra-operative blood loss ismore in microdebrider group. This was statistically significant though the difference was small i.e. 30 ml. Stanislaw et al.[45] however reported a significant reduction in blood loss with endoscopic techniquewhich was in contrast to our study. Also in study by Feng et. al.[46] conventional adenoidectomy group had more bleeding though it was not statistically significant.As the microdebrider cuts the tissueslittle by little in an oscillating fashion the bleeding surface is exposed for a longer time and the continuous suction effect of microdebrider also sucks in more blood.

After conventional adenoidectomy, 64% of patients still had grade II and 24% had grade III remnant adenoid tissue (table 4&5)which might later regrow and cause airway obstruction. Our results are similar to the ones reported by Havas et al. in 2002 and Pagella et al. in 1997, where the remnant adenoid was seen in 39% and 49% cases respectively.[40,42] The possible explanation to such high quantity of remnant adenoids in our understanding is that during conventional adenoidectomy only the tissue that overlies choana fails to get cleared or is pushed towards the nasal cavity, which on endoscopy is perceived as adenoids obstructing the choana. Whereas with the help of endoscope, the nasopharynx can be clearly visualised and any remnant thereof can be removed and a complete clearance of disease can be achieved.

In present study 95% of the patients post microdebrider assisted adenoidectomy landed with grade I adenoid as seen in the (table4&5). Therefore it can be agreed that endoscopic microdebrider-assisted adenoidectomy has the

advantage of improved visualisation and continuous suction of blood from the surgical field, thus one can precisely remove adenoid tissue from the choana and torus tubaris.[45]

With the use of endoscope the need for neck extension is alleviated and hence can be employed in cervical spine instability patients. Usually adenoidectomy is avoided in patients with cleft palate due to the fear of velopharyngeal insuffiency butan accurate removal using endoscope and microdebriderenables the surgeon to carefully excise part of the adenoid under vision without touching the velopharyngeal sphincter i.e. adenoid tissue near Passavant's ridge untouched as suggested byStern Y et al. in 2006.[47]

Collateral damage to adnexa following adenoidectomy is less but there is always a fear of trauma to the eustachian tube opening and subsequent ontological complications. In our study the torus tubaris region was partially injured in two cases of curettage adenoidectomy. In microdebrider group, however there was an increased incidence of nasal mucosal injuries. To summarise, though both techniques have their own peculiar problems, they are usually self-resolving and minor. None of the patients developed any known post-operative complications like otitis media with effusion or damage to soft palate or uvula.

The newer method of microdebrider assisted adenoidectomy was found to be a safe and efficacious tool in terms of completeness of clearance. However the drawbacks were increased time taken for surgery and increased amount of bleeding . The newer procedure still has some contra-indications and can't used for taking a biopsy.

In the Indian scenario the limitation of instrumentation and the cost of surgery are important factors which govern the choice of surgical method. The use of nasal endoscopes is a routine practice now butavailability of powered instruments like microdebriders is still less. Endoscopic microdebrider-assisted adenoidectomy is technically more difficult to perform than conventional adenoidectomy,[38,45]but those surgeons who are routinely performing endoscopic sinus surgery in them the learning curve is smaller,[48]and there was also high degree of surgeon satisfaction due to improved plane of dissection.[45] Now a days documentation is very important and The TV monitor relays the display enabling recording for documentation and teaching purposes.

CONCLUSION

Adenoidectomy is a routine Otolaryngologic surgery done in Paediatric age group for various indications and often after conventional curettage there is remnant adenoid tissue which doesn't alleviate the symptoms. Microdebrider assisted adenoidectomy has proven to deliver completeness of clearance at the expense of slight increase in bleeding and the operative time. Though the cost of surgery is higher but precise dissection under vision, lesser complications and better disease clearance makes this technique a safe and efficacious alternative over the blind curettage method.

SUMMARY

This study was done in the Department of Otorhinolaryngology and Head and Neck Surgery, Jawaharlal Nehru Medical College and KLES Dr Prabhakar Kore Hospital from January 2018 to December 2018.The objective here was to study the variation between the safety and efficacy of adenoidectomy done by the conventional curettage method versus the microdebrider assisted method.

We included 45 cases undergoing adenoidectomy and divided theminto 2 groups i.e. conventional adenoidectomy having 25 patients and microdebrider adenoidectomy having 20 patients. Out of 45 patients 25 were male and 20 were female. The age group of sample was between 4-15 years, with the mean age of 9.24 years. The most common presenting complaint was mouth breathing and snoring.

Following adenoidectomy operation the percentage of reduction of adenoid grading in microdebrider group was 63.79 % compared to only 30.29% in conventional curettage group, which indicates the effectiveness of microdebrider in completeness of clearance.

The operative time taken and the intra-operative bleeding were however more in microdebrider group as compared to the conventional group, where the difference was about 3 minutes and 30 ml respectivelyand was statistically significant.

In either of the two groups on 3 weeks follow-up no significant post-operative complications were observed . The major limitation encountered in present study was the absence of flexible paediatric nasopharyngoscope and the difficulty faced while doing post-operative diagnostic nasal endoscopy with rigid endoscope in paediatric

population for visualizing post-operative complications and scarring under local anaesthesia.

In this era of endoscopes it is becoming very necessary do deliver a superior clearance of disease with minimal or no post-operative complications. Even in our study we have given better clearance of disease with the microdebrider and thus strongly recommend it. With the cost of surgery being a small initial hindrance, parents should be encouraged that a better disease free status eventually pays off in the mental and physical well-being of their children.

It is recommended that there is still further scope for analysis on a larger sample size for an even better and robust statistical evaluation and to better appreciate the post-operative complications of endoscopic powered adenoidectomy.

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ANNEXURE-I - INFORMED CONSENT BY PARENT/GUARDIAN

"EFFICACY AND SAFETY OF MICRODEBRIDER ASSISTED ADENOIDECTOMY OVER CONVENTIONAL ADENOIDECTOMY"- A 1 YEAR RANDOMIZED CONTROL TRIAL IN KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI.

PRINCIPAL INVESTIGATOR :DR._____

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. Prabhakar Kore Hospital and Medical Research Centre, Belgaum for complete clearance of adenoids and to compare the variation between the conventional curettage and microdebrider assisted adenoidectomy. 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 intraoperative various assessments will be done regarding the blood loss, intraoperative time and completeness of clearance of

adenoids. At the 3 weeks follow up patient will be subjected to nasal endoscopy to look for any scarring or collateral danage.

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 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:

ANNEXURE-II-PROFORMA

"EFFICACY AND SAFETY OF MICRODEBRIDER ASSISTED ADENOIDECTOMY OVER CONVENTIONAL ADENOIDECTOMY"- 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:

Blood Pressure

Pulse

Respiratory Rate

Pallor

Icterus

Clubbing

Cyanosis

Lymphadenopathy

Oedema

II) ENT Examination

1. NOSE EXAMINATION

External appearance

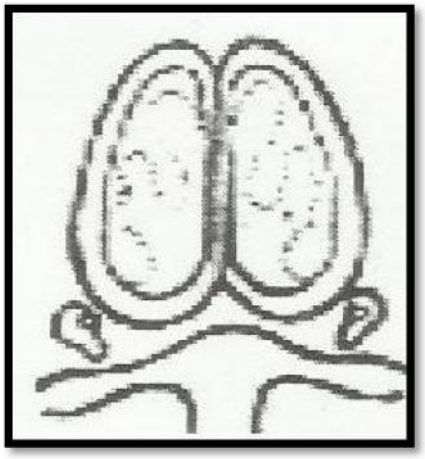
- Root
- Bridge
- Dorsum
- Alae
- Tip
- Columella

Cold spatula test

Cottle's test

Anterior Rhinoscopy

Posterior Rhinoscopy



Paranasal Sinus Examination

2. EAR EXAMINATION

Preauricular area

Pinna

Postauricular area

External auditory canal

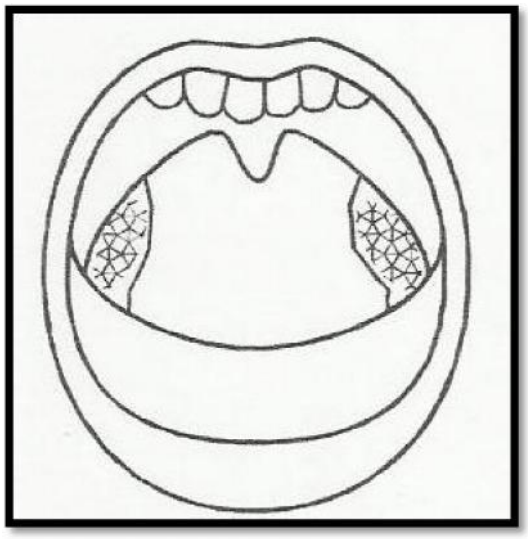
Tympanic membrane

Tuning fork tests

Facial nerve examination

Vestibular examination

3.1 ORAL CAVITY and OROPHARYNX



4. NECK EXAMINATION

Diagnosis:

<u>Preoperative</u>:

Preoperative pictures –

Routine tests:

CBC

Bleeding profile

<u>Conventional curettage or Microdebrider assisted technique-</u>

<u>Intraoperative measurement –</u>

Preoperative Endoscopic Grading of Adenoids-

Operative time-

Intra-operative bleeding: **Blood soaked gauze 10x10-**

Blood soaked gauze 30x30-

Suctioned blood- suction fluid

Post-operative Endoscopic Grading of Adenoids-

Follow up at 3 weeks-

Endoscopic assessment of scarring and trauma-

ANNEXURE-III - ETHICAL CLEARANCE LETTER

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/61 **Date: 22/11/2017**

To,

PG student in ENT&HNS,
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 **"EFFICACY AND SAFETY OF MICRODEBRIDER ASSISTED ADENOIDECTOMY OVER CONVENTIONAL ADENOIDECTOMY – A 1 YEAR 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. Arathi Darshan)
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.

ANNEXURE-IV-PHOTOGRAPHS

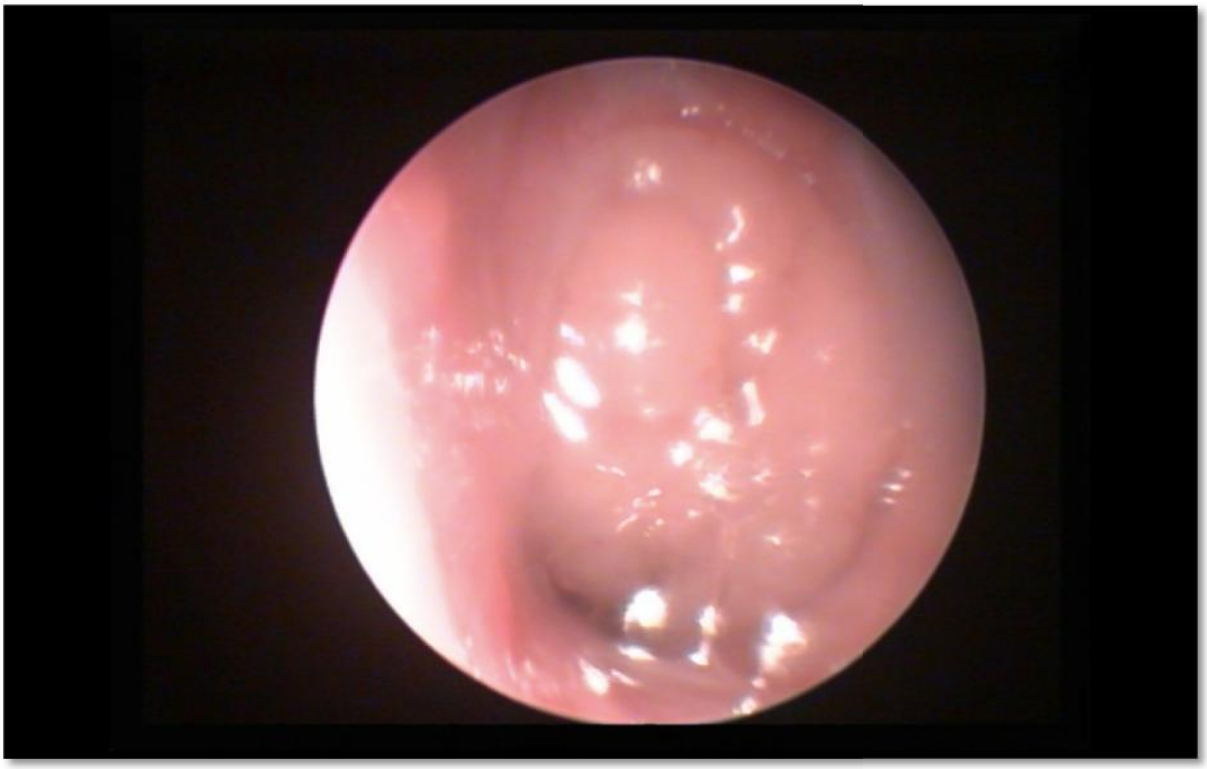


Figure 15:Preoperative grade IV in group A

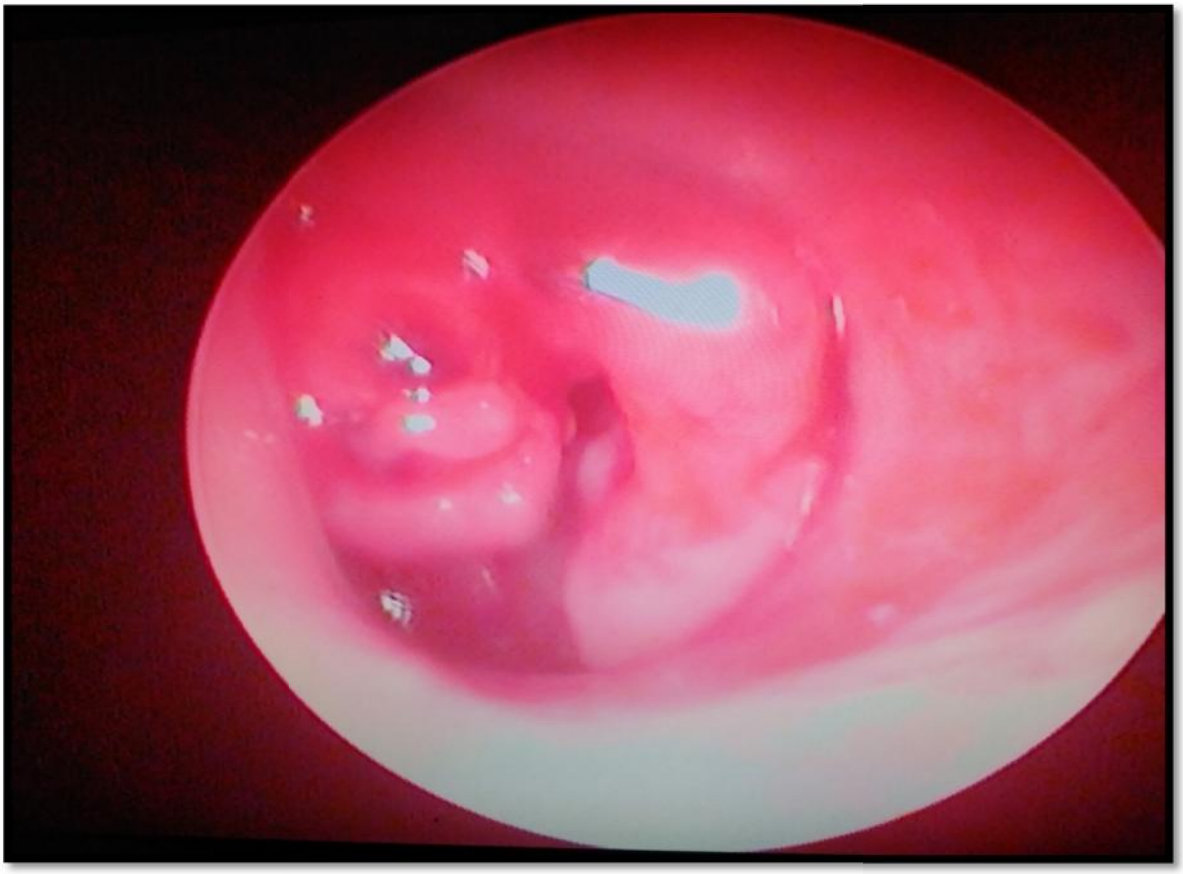


Figure 16:post-operative remnant adenoid tissue in group A

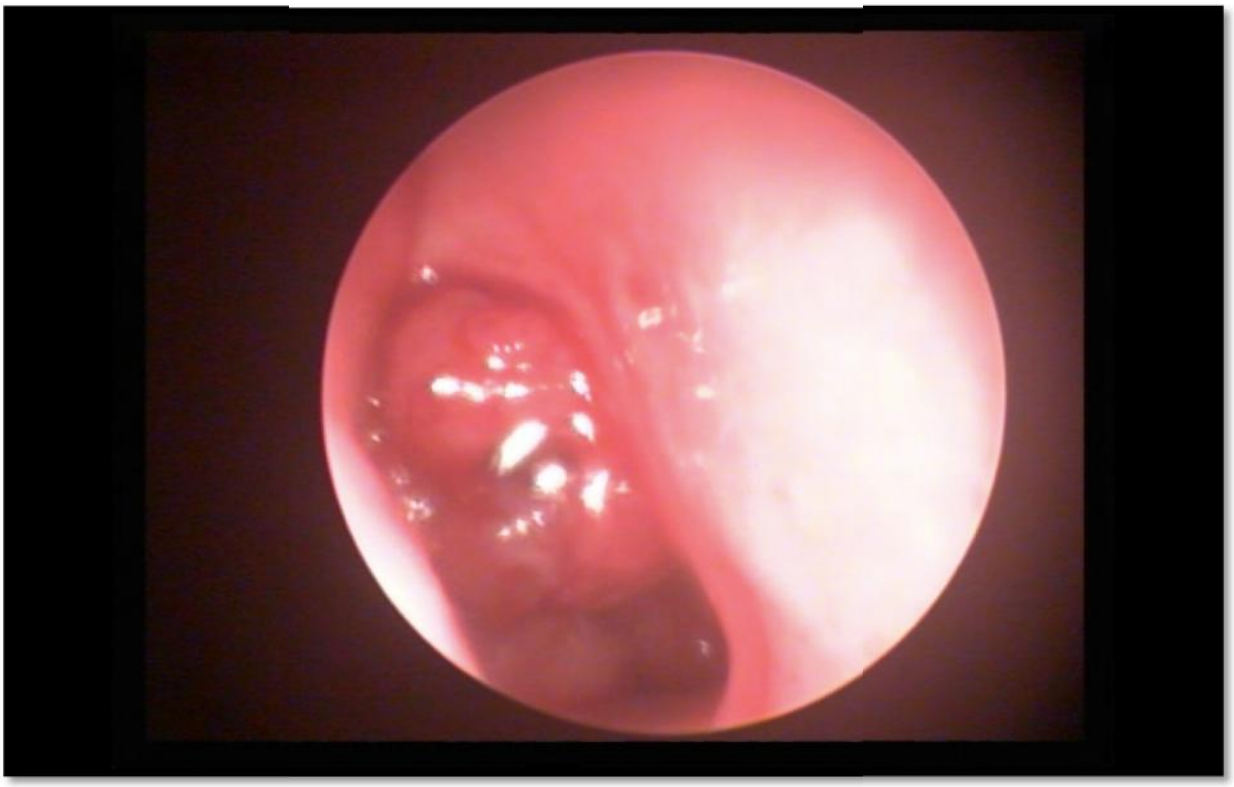


Figure 17:On follow-up remnant adenoid after conventional curettage in same patient

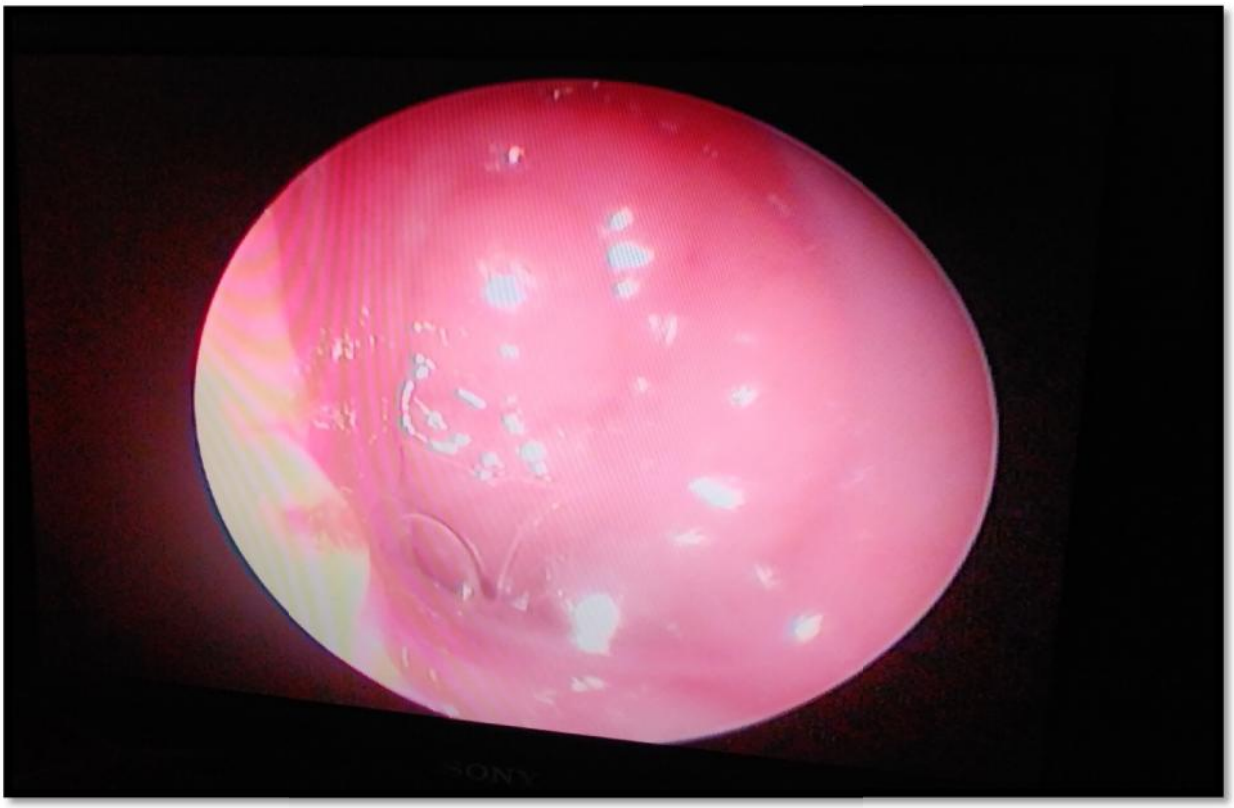


Figure 18: preoperative grade IV adenoid in microdebrider group

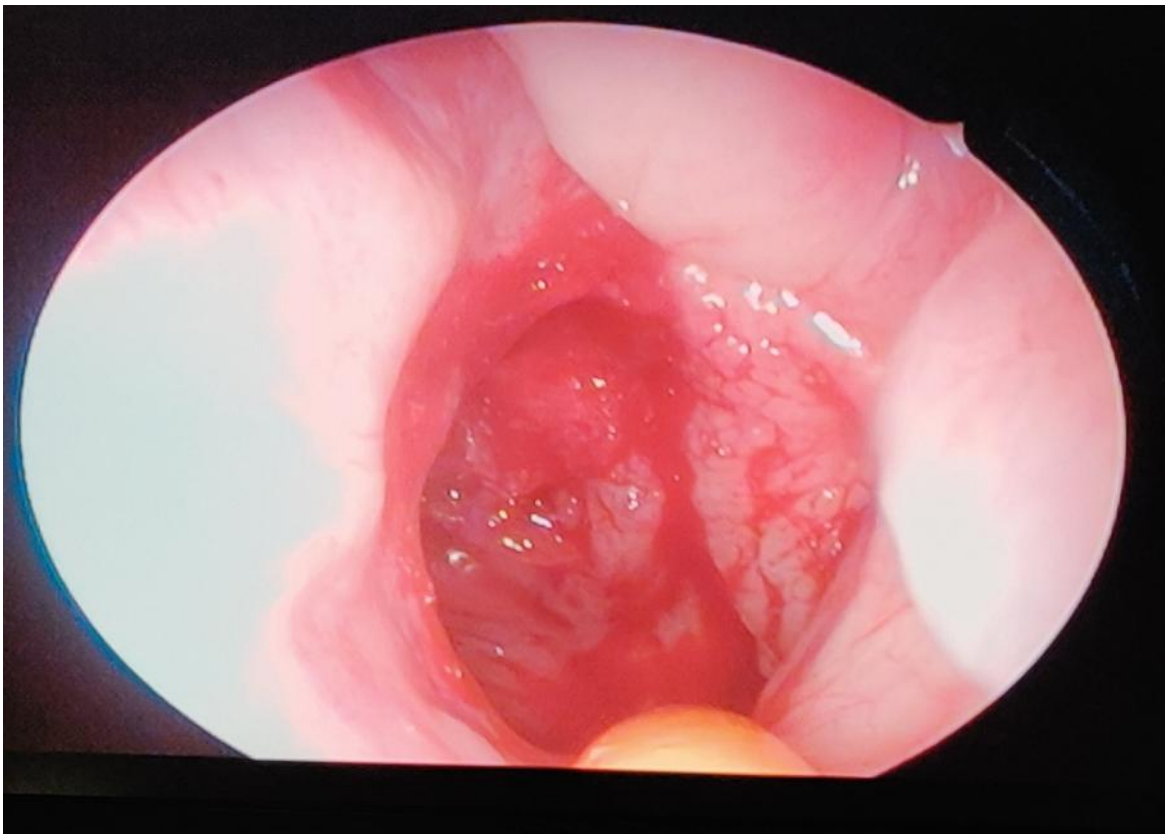


Figure 19:intra operative during microdebrider assisted adenoidectomy

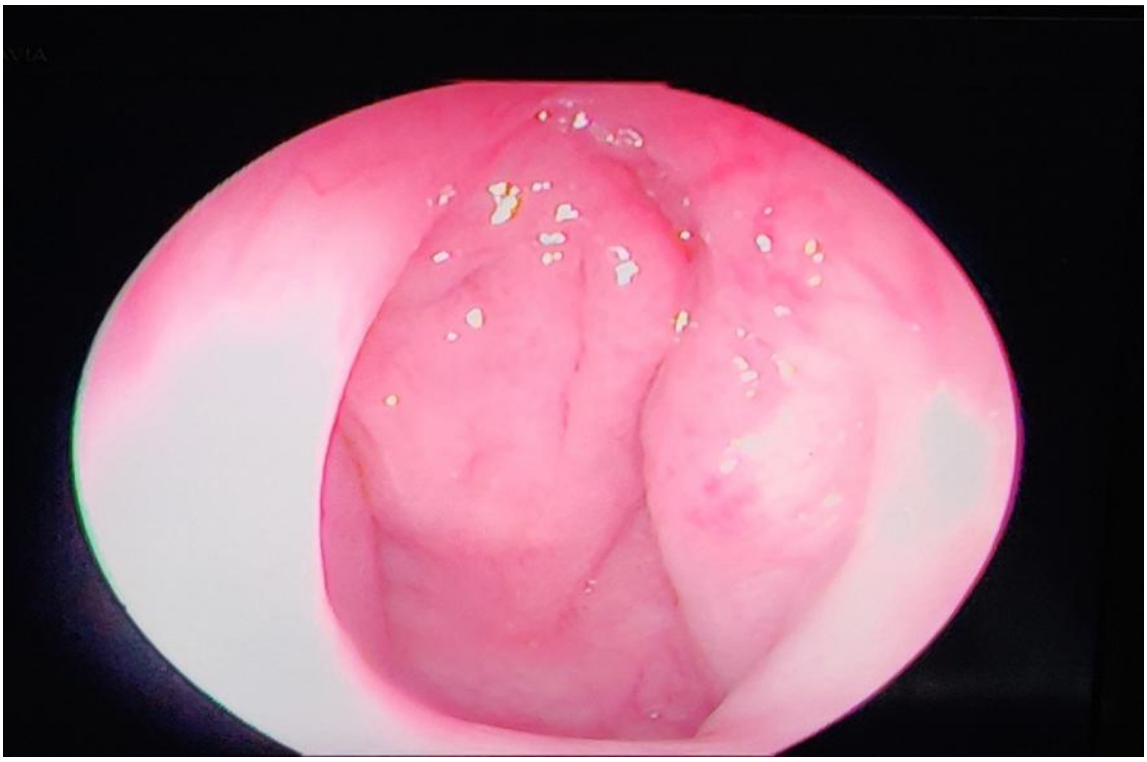


Figure20:On follow up no remnant after microdebrider assisted adenoidectomy

ANNNEXURE – V - KEY TO MASTER CHART

IP. Number	in-patient number
Sex	male/female (M/F)
DNS	Deviated nasal septum
L	left
R	right
C	central
P	present
A	absent
CST	cold spatula test
+	present
-	absent

ANNEXURE - VI - MASTER CHART

S.No.	AGE (yrs)	SEX (M/F)	Surgery Conventional(C)/ Microdebrider(M)	CHIEF	COMPLAINTS			ARS	PRS	CST	X-Ray Nasopharynx adenoid grade(1/2/3)	Pre-Op Endoscopic Grade Adenoid(1/2/3/4)	Operative Time(min)	Intra Operative bleeding(ml)	Post-Op Endoscopic Grade Adenoid	Post-Op Complications (P/A)
				Nasal obstruction	Mouth breathing	Ear discharge	Difficulty/Pain Swallowing	DNS (L/R/C)	Adenoid (P/A)							
1	7	M	C	N	Y	N	N	C	P	—/—	3	4	16	49	3	A
2	11	M	C	Y	Y	N	Y	L	P	+-/+-	2	3	21	62	3	A
3	13	F	C				Y	L	P	++/++	2	2	15	52	2	A
4	11	M	C				Y	C	P	++/++	2	3	20	38	2	A
5	6	M	C		Y		Y	C	P	+-/+-	2	3	9	28	2	A
6	6	M	C		Y		Y	C	P	+-/+-	2	3	16	39	2	A
7	9	F	C		Y		Y	C	P	++/++	3	4	20	44	2	A
8	7	F	C		Y			C	P	++/++	2	3	15	52	3	A
9	4	M	C	Y	Y			C	P	++/++	2	3	15	46	2	A
10	4	F	C				Y	R	P	++/++	1	2	12	46	2	A
11	11	M	C				Y	R	P	+-/++	1	2	7	40	1	A
12	7	F	C	Y	Y			L	P	—/—	3	4	14	36	3	A
13	10	M	C	Y			Y	C	P	++/++	2	3	15	48	2	A
14	8	F	C				Y	L	P	++/+-	3	4	16	42	3	A
15	10	M	C	Y	Y			C	P	++/++	2	3	12	39	2	A
16	9	F	C		Y			L	P	+-/+-	1	3	7	42	2	A
17	6	F	C	Y	Y			R	P	+-/+-	2	3	12	44	2	A
18	15	F	C			Y		R	P	+-/++	1	3	11	36	2	A
19	13	F	C		Y		Y	L	P	++/+-	1	2	5	38	1	A
20	4	M	C	Y	Y			C	P	+-/+-	2	3	5	36	1	A
21	7	M	C		Y			C	P	—/—	3	4	16	47	3	A
22	10	F	C	Y	Y		Y	C	P	—/—	3	4	23	56	2	A
23	12	M	C		Y		Y	C	P	+-/+-	1	2	10	55	2	A
24	6	M	C	Y	Y			L	P	+-/+-	2	3	8	42	2	A

ANNEXURE - VI - MASTER CHART

S.No.	AGE (yrs)	SEX (M/F)	Surgery Conventional(C)/ Microdebrider(M)	CHIEF	COMPLAINTS			ARS	PRS	CST	X-Ray Nasopharynx adenoid grade(1/2/3)	Pre-Op Endoscopic Grade Adenoid(1/2/3/4)	Operative Time(min)	Intra Operative bleeding(ml)	Post-Op Endoscopic Grade Adenoid	Post-Op Complications (P/A)
				Nasal obstruction	Mouth breathing	Ear discharge	Difficulty/Pain Swallowing	DNS (L/R/C)	Adenoid (P/A)							
25	14	F	C				Y	R	P	+-/++	1	3	12	62	2	A
26	7	M	M				Y	C	P	++/++	1	2	30	62	1	A
27	8	F	M	Y	Y			L	P	+-/+-	2	3	20	80	1	A
28	15	F	M		Y		Y	C	P	++/++	2	3	20	88	1	A
29	11	M	M	Y	Y			C	P	—/—	3	4	26	78	2	A
30	10	F	M			Y		C	P	—/—	3	4	14	42	1	A
31	8	M	M		Y		Y	C	P	—/—	3	4	20	94	1	A
32	10	F	M			Y		L	P	++/+-	1	3	16	88	1	A
33	10	M	M	Y			Y	C	P	++/++	1	3	18	116	1	A
34	7	F	M	Y	Y			R	P	+-/++	2	3	17	100	1	A
35	12	F	M				Y	C	P	++/++	2	3	16	124	1	A
36	11	M	M				Y	L	P	++/+-	2	3	12	80	1	A
37	11	M	M	Y				R	P	+-/++	1	2	10	64	1	P
38	8	M	M		Y			C	P	+-/+-	2	3	14	66	1	A
39	7	M	M	Y	Y			C	P	++/++	1	2	12	80	1	A
40	12	M	M	Y	Y			R	P	+-/++	2	3	12	70	1	A
41	11	M	M	Y				L	P	+-/+-	1	2	10	60	1	A
41	5	F	M	Y	Y			R	P	+-/+-	2	3	20	64	1	A
43	9	F	M				Y	C	P	++/++	2	3	16	66	1	A
44	15	M	M				Y	L	P	++/+-	1	2	12	54	1	A
45	9	M	M	Y	Y			C	P	++/++	2	3	14	70	1	A