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M. N. Banaji Building;
Forjett Street Cross Road; Opp.
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Mumbai- 400 036; Maharashtra, India.
bachi.hathiram@rediffmail.com

Prof. B. Viswanatha
# 716, 10th Cross, 5th Main; MC Layout,
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Doncaster Royal Infirmary,
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prepageran@yahoo.com

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Professor of Otolaryngology
Tufts University School of Medicine
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INVITED EDITORIAL

BALLOON SINUPLASTY: AN HISTORICAL PERSPECTIVE

*Peter Catalano, MD, FACS, FARS

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ABSTRACT

Balloon dilation technology (BDT), also known as balloon sinuplasty, has been in clinical use since September, 2005. Prior to BDT, surgeons performed a procedure called FESS, or functional endoscopic sinus surgery, for patients with chronic sinusitis. As is true with any new technology or procedure in medicine, a debate often ensues between early adopters and mainstream practitioners. Over the past 7 years, much has been discussed, debated, and learned about BDT. What follows is a review of the origins of the BDT: the theory, technology, indications and applications; and a review of the pertinent outcomes literature. Independent of how one feels about BDT, the evidence strongly supports its safety, efficacy, and growing popularity among patients and physicians alike.

Keywords: Balloon Sinuplasty.

INTRODUCTION

Balloon Dilation Technology (BDT) was introduced in September, 2005 at the American Academy of Otolaryngology Annual meeting in Los Angeles, CA, USA. This technology is considered “disruptive”, not because it interfered with conventional treatment or patient care, but because it introduced a paradigm shift for the treatment of patients with chronic rhinosinusitis (CRS), and it required the otolaryngologist to learn catheter-based surgical techniques, a new skill set not previously taught. Over the past 25 years, there have been 4 major technological advances in rhinology: the endoscope, the powered micro-debrider, image guidance systems, and BDT.

The minimally invasive concepts of Messerklinger, which are founded on understanding the pathophysiology within the transition space, have been validated by BDT. Hence BDT is considered a “transition space tool”. The functional elegance of BDT, coupled with its relative conceptual simplicity, earned BDT descriptors such as innovative, revolutionary, and ingenious. Unfortunately, disruptive technologies are not easily or quickly embraced in medicine. There are many reasons for this, including the belief by many practitioners that they already deliver quality care to their patients and feel comfortable with their existing skill set.

There are well-known examples of disruptive technologies in other areas of medicine. Today, cardiac catheterization is considered routine for patients with cardiac disease, arthroscopic knee surgery is the standard of care for orthopedists, and laparoscopic and robotic surgery has replaced the majority of open abdominal procedures performed by general surgeons, urologists, and gynecologists. In fact, it took 15 years for arthroscopic surgery to be considered the standard of care for most knee injuries!

In what follows, we will discuss the tools required and the theory behind BDT, its application in the treatment of patients with CRS, including exciting data on “functional preservation”, the role of the uncinate process, and physiologic gas exchange principles within the sinus. A review of the pertinent current literature as it relates to BDT is then followed by a discussion of clinical indications.
INSTRUMENTATION:

The basic BDT system is comprised of several disposable components including suction capable guide catheters, flexible kink-resistant guide-wires, balls on dilation catheters of various diameters (3.5, 5, 6, and 7 mm), and a manual pump mechanism to inflate and deflate the balloon catheters.

Fiberoptic guide-wires, irrigation catheters, and drug elution balloon catheters have replaced first generation tools. Fluoroscopy, initially a requirement of the technology to help guide and confirm proper wire and balloon placement, is now optional due to the introduction of sinus trans-illumination through a light wire. Under endoscopic control, the balloon catheter is then threaded over the guide-wire, positioned properly within the sinus transition space, inflated, and removed. The balloons themselves are non conforming and therefore can displace bone and tissue within the sinus transition space and/or ostia. Balloons are inflated to between 8 and 12 atmospheres to achieve a clinical effect.

In 2008, new sinus balloons were introduced and provide an important benefit of shape retention between dilations. These balloons deflate in 1/4 the time of the original balloons and resume their original compressed, wrapped configuration to permit easier passage through the sinus guides and transition spaces on subsequent applications in the same patient. In 2009, soft bevel-tipped, flexible suction-ready sinus guides were introduced to permit atraumatic access to the targeted transition space with the option for suction at the tip of the guide.

The next generation of improvements, first introduced by Entellus and then by Acclarent emphasize functional independence by permitting the surgeon to hold the endoscope in one hand while placing the guide, introducing the guidewire and advancing the balloon catheter with the other. An assistant is only needed to inflate and deflate the balloon.

THE THEORY:

As previously mentioned, BDT is essentially a transition space tool, targeting primarily the ethmoidal infundibulum and frontal recess. The sphenoid sinus does not have a transition space and is rarely involved with inflammatory disease. These transition spaces, per Setliff[1], or “prechambers”, per Messerklinger[2], are slit-like in nature, having a maximum diameter of 1.5–2 mm, and even less in many symptomatic patients. Placement of a submillimeter guide-wire and plus-millimeter balloon catheter into the transition space can be challenging at times, yet still represents the least traumatic means to access this anatomic area. Once in place, the balloon catheter is slowly inflated to 10 atm, and during this process the opposing walls of the transition space are separated an amount equal to the diameter of the chosen balloon. This prying open of the transition space occurs via micro-green stick fractures of the immediate peripheral bone (i.e. uncinate process), which usually retains its new position as the sub-structure heals. Thus, no stent is required to maintain the enlarged lumen.

BDT can be used alone as a sole intervention for one or more sinuses, or in combination with more conventional endoscopic sinus surgical techniques (ESS), the so-called “hybrid” procedure. It is most important for the reader to understand that BDT surgery, like ESS, only addresses the structural relationship between the sinus cavity and its communication or connection to the nasal cavity. Neither intervention changes the patient’s biology, allergy status, or reactive airway.

By enlarging the sinus drainage pathway, the patients’ mucosal reactivity will likely still occur, yet is less likely to cause sinus obstruction with its associated pain and/or subsequent infection.

PRESERVATION OF STRUCTURE AND FUNCTION:

The natural Mechanical and Chemical Defense Mechanisms:

The role of the uncinate process remains in question. However, research to evaluate sinus airflow may provide some important clues. Several years ago, Nayak, an otolaryngologist in India, performed a few studies to try to determine the role of the uncinate process. Nayak[3] first used simple inhalational dye studies with methylene blue comparing dye deposition within the nose and sinuses in 2 groups of post operative patients, those with and without preservation of the uncinate process. He found dye within the maxillary and ethmoid cavities when a maxillary antrostomy (MMA) was performed; however, dye remained only on the anterior middle turbinate and uncinate process when the latter were preserved. A MMA is a man-made enlargement of the natural maxillary ostia that remove part of the medial wall of the maxilla.

In 2008, Xiong’s group[4] in China designed mechanical airflow simulation models using actual human anatomic CT scan data. In their model, there is mini-
mal to no air entering any sinus cavity in the human head during either phase of respiration! Airflow arched through the nose with highest flow rates between the middle turbinate and lateral nasal wall. Xiong et al. then repeated their experiments using CT images from post-ESS patients who had a surgical Ethmoidectomy and MMA. In these patients, there was a striking increase in maxillary and ethmoid sinus airflow. In a recent study Kirihene et al. also measured intra-sinus airflow before and after various sized MMAs, and found that measurable air flow occurred within the maxillary sinus once the size of the middle meatal opening exceeded 20 mm. Coincidentally, the cross-sectional area of the maxillary os after dilation with a 5-mm diameter sinus balloon is exactly 20 mm.

This natural mechanical defense mechanism of the sinuses suggests that the uncinate process and anterior middle turbinate help filter inspired air and prevent exposure of the sinus mucosa to inhaled debris in the form of pollutants, allergens, carcinogens, etc. There is a second natural defense mechanism that exists within the para nasal sinuses, here termed the chemical defense mechanism. The latter consists of an interesting molecule called “NO”, or nitric oxide. The molecule is not the same as nitrous oxide (N2O), the general anesthetic. NO is made within the maxillary sinus by the enzyme nitric oxide synthase. Research has shown that the natural concentration of NO within the normal maxillary sinus reaches toxic concentrations if inhaled. However, at these higher concentrations, NO has local antiviral, antibiotic, and antifungal properties, and will also increase ciliary beat frequency.

We have come to learn that NO comes in many forms. The free radical form is present within the vascular system and has a very short half-life, where as the form active within the sinuses and airway is not a free radical and can persist for up to 11 min. It has also been shown that small amounts of NO (approximately 30 parts per billion), are inhaled into the lungs with each breath. Inhaled NO has a vasodilatory effect on the lung increasing oxygen absorption. Inhalation of NO is today used as a therapy for hypoxic infants with immature pulmonary systems.

NO is also heavier than air, thus the highest concentrations of NO occur at the floor of the maxillary pyramid depending upon the patient’s position. Note that the maxillary os is always at the apex of the pyramid when we are neither the upright, supine, or lateral position. Thus, under normal circumstances, a small amount of NO flows out of the maxillary sinus and into the lung with each inspiration. Subsequently, NO has a positive physiologic effect on oxygen uptake in the lung. Furthermore, NO levels inhaled or exhaled air are undetectable after ESS in which MMA has been performed. Thus, the washout of maxillary sinus NO, as predicted by Xiong, may have untoward physiologic consequences on sinus health. Can all these findings relative to sinus airflow and NO production and function be purely coincidental? Is the loss of NO from the sinus after a MMA in any way related to the fact that the bacteriology of recurrent CRS after ESS includes virulent, atypical organisms (i.e. Pseudomonas, E. coli, and Klebsiella)? Is uncinate preservation more important to the delicate balance of the gaseous physiology of the sinuses than many are willing to acknowledge? How else do we explain the high concentrations of NO within the normal maxillary sinus, its absence in CRS, and its vasodilatory effects on the pulmonary vasculature when inhaled in minute concentrations? One could argue that not all patients who have an MMA are disadvantaged, or are colonized by virulent pathogens, or show any measurable adverse pulmonary effects. While this may be true, the converse is as well, and thus knowingly creating a MMA when a clinically valid and physiologically superior alternative exists, seems irresponsible. I submit that a majority of patients given these facts would opt for conservatism, tissue preservation, and a more functional procedure.

OUTCOMES DATA:

Numerous articles have been published on many aspects of BDT. Of the more relevant are the CLEAR studies (I, II, and III) which followed patients treated with either BDT alone or a hybrid option, for 6 months, 1 year, and 2 years, respectively. The CLEAR study used validated outcome instruments (SNOT-20 and Lund-Mackay) to evaluate a patient’s sinus health at the various time points after surgery. The results show a statistically significant difference between pre- and post-operative SNOT-20 and Lund-Mackay scores at each of the three time points, which validates the durable results seen by practising surgeons. The Lund Mackay score is assigned to each sinus based on the degree of mucosal inflammation or hypertrophy within it.

Complications from BDT were rare, and remain
rare to this day. In fact, in almost all cases where a CSF leak has been reported following the use of BDT tools, the surgeon in questions has reported first using conventional tools to try and open the frontal sinus and then reverted to BDT to try and salvage unsuccessful traditional frontal sinus surgery (see MAUDE website). The major complications associated from conventional ESS, such as blindness, meningitis, CSF leak, and hemorrhage, can be devastating and irreversible. However, these complication shave never been reported when BDT has been performed alone. Thus, the safety of BDT as a surgical tool is unmatched in rhinology.

Many other articles have been written about various aspects of BDT. One by Friedman et al.\(^2\) looked at the cost of sinus surgery with and without the use of BDT. While disposable costs are higher when BDT is used, the shorter procedure and elimination of the need for serial post-operative sinus debridements in the office setting make surgery with BDT more cost-effective than surgery without. This economic advantage was realized without including the significant reduction in postoperative morbidity permitting patients to return to work within 24 h of surgery, as opposed to needing an average of 10–14 days off work to recover from conventional sinus surgery.

Another article by Catalano and Payne\(^2\) evaluated the efficacy of BDT for the frontal sinus in patients with advanced frontal sinus disease (i.e. Samter’s Triad, hyperplastic sinusitis, or fungal sinusitis). All study patients had at least 1 frontal sinus that was either completely or near-completely opacified preoperatively. Using only a 5-mm-diameter balloon (larger balloons were not yet available), 50% of patients had radiologic clearing of their frontal sinus post-procedure that was durable over the 6-month follow-up period. Thus, 50% of patients with advanced frontal sinus disease were spared from a more aggressive and more morbid surgical intervention. In an attempt to be purely objective, Lund-Mackay score was the only outcome metric used, thus we cannot say how many additional patients had reduction or elimination of frontal sinus symptoms after BDT surgery, despite residual mucosal inflammation within the frontal sinus. It is well known that in sinususes with advanced biology (i.e. Samter’s triad), complete resolution of mucosal inflammation is not expected, while sinus symptoms are markedly reduced with appropriate resolution of ostial obstruction. SNOT-20 scores were not used because patients had surgery on other sinuses in addition to the frontal, and the inability to correctly apportion benefit to the various parts of the procedure made subjective metrics less appealing.

**INDICATIONS:**

The indications for BDT are no different than those for performing endoscopic sinus surgery, as BDT is a tool, not necessarily a procedure unto itself. That said, BDT is especially suited for patients with recurrent acute sinusitis (RARS) or chronic sinusitis without nasal polyps (CRSw/oNP), as these patients tend to have a biology that is not progressive and rarely requires aggressive topical medical management. These groups are currently being targeted for office applications of BDT. Patients with advanced inflammatory biology such as CRS with polyps (CRSwp), Samter’s Triad, allergic fungal sinusitis, or hyperplastic sinusitis usually require removal of tissues opposed to reorientation of tissue, and thus are not well suited for BDT as a stand-alone intervention. BDT may be used in a hybrid procedure in these patients with conventional surgery being performed on the maxillary and ethmoid sinususes and BDT being applied to the frontal and possibly sphenoid sinuses. Fortunately, the majority of patients with inflammatory sinus disease fall into the RARS and CRSw/oNP groups, making BDT an appealing option for many sinus sufferers.

**CONCLUSIONS:**

Interventions to correct inflammatory sinus disease are trending toward less invasive procedures. From a conceptual standpoint, BDT is a safe, effective, and appropriate first choice for the majority of sinus sufferers who require surgical intervention. In addition, the procedure is less morbid, less costly, and BDT failures can be easily revised. Data have shown the positive results after BDT are durable for a minimum of 2 years\(^2\), which equals or exceeds those reported after conventional FESS. Facility with BDT has allowed many surgeons to treat sinus sufferers earlier than would be recommended for conventional FESS due to its lower morbidity, and the ability to perform BDT procedures in the office setting under a combination of local and topical anesthesia.

While BDT can also have a role in patients with advanced mucosal disease, it is best used in these situations as a hybrid procedure. BDT technology continues to evolve along with our knowledge of sinus physiology and pathophysiology, and the body of evidence
thus far suggests that when it comes to sinus surgery, less is often better.

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COMPARATIVE OUTCOME OF TEMPORAL FASCIA AND TRAGAL CARTILAGE GRAFT IN TYPE 1 TYMPANOPLASTY

*Gurshinderpal Singh Shergill, **Dipak Ranjan Nayak, ***Ankur Kaur Shergill

INTRODUCTION

Tympanoplasty is the mainstay of treatment for chronic suppurative otitis media of tubotympanic disease. Various types of grafts are being used to repair the tympanic membrane. The most widely used graft in tympanoplasty is temporal fascia graft followed by cartilage, skin, vein graft, fat, perichondria etc[1-4]. Cartilage offers to be better graft option in graft take up rates, especially in the ears where there is Eustachian tube dysfunction, large perforations and ears with atelectasis. Meanwhile, temporal fascia graft is considered to be a better graft in terms of hearing outcome owing to its thinness and more pliable texture[5-7]. Our study compared the graft take up rate and hearing improvement in type 1 tympanoplasty cases where temporalis fascia graft and tragal cartilage graft were employed independently.

MATERIALS AND METHOD:

Patient population: All the patients who underwent type 1 tympanoplasty with underlay
method using temporal fascia graft or cartilage graft in a span of one year (2012-2013) were retrospectively chosen for the study. The patients who had undergone ossicular reconstruction, mastoid surgery along with tympanoplasty or cases where graft materials other than temporal fascia or cartilage employed were excluded from the study. The total eligible patients for the study were 120.

PROCEDURE:

Both the graft materials had been employed independently for the surgeries. In one group of patients, tragal cartilage with perichondrium was used to repair the tympanic membrane. The tragal cartilage was harvested by keeping one side perichondrium intact on the cartilage. A 2 mm slit was cut over the cartilage graft (where the perichondrium was elevated) to accommodate the handle of the malleus. Tympanomeatal flap was then raised in the usual manner. Thereafter, the cartilage graft was placed medial to annulus and the perichondrium repositioned over the cartilage and the handle of malleus. The tympanomeatal flap was then repositioned back over the cartilage graft. In the second group of cases, the temporal fascia was harvested in the same operative field and used as graft material in the underlay tympanoplasty in other group.

The perforation closure in all cases was analyzed postoperatively at 6 weeks. Hearing assessment was done by doing pre-operative and post-operative pure tone audiometry. Conductive hearing loss of individual patients was calculated (air bone gap) preoperatively and 3 months postoperatively by taking the average of air bone gap at 0.5, 1, 2, and 3 kHz pure tone frequencies. Mean of air bone gap was calculated for all the patients preoperatively and postoperatively. Preoperative mean air bone gap was compared with post-operative mean air bone gap in both graft materials. Patients with residual perforation postoperatively are not taken up for the hearing assessment.

Statistical analysis: The results were analyzed using SPSS software version 16. We compared the graft take up rate (primary outcome) and hearing improvement e.g. closure of air bone gap (secondary outcome) in both types of graft material used in tympanoplasty.

OBSERVATIONS AND RESULTS

A total of 120 eligible patients who underwent type 1 tympanoplasty were retrospectively selected for the study. The age of patients in the study ranged from 15 to 69 (mean age 35.7) years. The predominant population of patients were females with a male to female ratio of 0.87 (Fig.1). Out of a total of 120 cases, majority had left side CSOM, followed by bilateral tube tympanic type (39) and right side (34) CSOM cases.

In our study, 71 patients had a large perforation (> 50% area of pars tensa), 36 medium perforation (25-50% area of pars tensa), 9 subtotal perforation (only annulus present) and 4 patients had small perforation (< 25% area of pars tensa) (Table 1).

Eighty seven patients underwent tympanoplasty using temporal fascia graft while 33 patients underwent tympanoplasty utilizing the tragal cartilage perichondrium composite graft. In temporal fascia group, 48 patients were females followed by 39 males. In the tragal cartilage group, there were 17 male patients and 16 female patients. The age of the patients in temporalis fascia group ranged from 15-63 (mean 34.5) years. In tragal cartilage group, age of the patients ranged from 19-69 (mean 40.27) years.

In temporal fascia group, out of 87 patients a majority 54 (62%) had large perforation followed by medium perforation cases 24 (27%), 6 (6.9%) cases had subtotal perforation and 3 (3.4%) had small perforation. In tragal cartilage group, out of 33 patients, 17 (51%) had large perforation followed by 12 (36%) cases of medium, 3 (9%) cases of subtotal and 1 (3%) case of small perforation (Table 2). On comparison of the parameters, both groups demonstrated homogenous findings.

All patients underwent type 1 tympanoplasty with underlay technique. Out of 120 cases, 102 had successful closure of the perforation postoperatively at 6 weeks.
The overall graft take up rate was 85%. In temporal fascia graft group, 74 out of 87 (85%) patients had successful closure of perforation at 6 weeks (postoperative). In tragal cartilage cases, 28 out of 33 patients had successful closure at 6 weeks postoperative. The graft take up rate was 84.9% in the latter group. It was statistically significant (p value <0.05) (Table 3).

Table 2. Clinical characteristics of patients in the temporal fascia and tragal cartilage groups

<table>
<thead>
<tr>
<th>Clinical parameters</th>
<th>Temporal fascia</th>
<th>Tragal cartilage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients</td>
<td>87</td>
<td>33</td>
</tr>
<tr>
<td>Gender</td>
<td>M=39</td>
<td>M=17</td>
</tr>
<tr>
<td>F=48</td>
<td>F=16</td>
<td></td>
</tr>
<tr>
<td>Age (in years)</td>
<td>Range=15-63</td>
<td>Range=19-60</td>
</tr>
<tr>
<td>Mean=34.05</td>
<td>Mean=40.27</td>
<td></td>
</tr>
<tr>
<td>Perforation size</td>
<td>Small=3 (3.4%)</td>
<td>Small=1 (3%)</td>
</tr>
<tr>
<td>Medium=24 (27%)</td>
<td>Medium=12 (36%)</td>
<td></td>
</tr>
<tr>
<td>Large=54 (62%)</td>
<td>Large=17 (51%)</td>
<td></td>
</tr>
<tr>
<td>Subtotal=5 (6.9%)</td>
<td>Subtotal=3 (9%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Perforation closure rate in temporal fascia and cartilage graft (chi square test)

<table>
<thead>
<tr>
<th>Type of graft</th>
<th>Number of patients</th>
<th>Perforation closure</th>
<th>Residual perforation</th>
<th>Percentage of graft take up (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporal fascia</td>
<td>87</td>
<td>74</td>
<td>13</td>
<td>85</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Tragal cartilage</td>
<td>33</td>
<td>28</td>
<td>5</td>
<td>84.9</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

We also calculated the pre-operative air bone gap for each patient by taking the average of air bone gap at frequency 0.5, 1, 2 and 3 kHz. Mean of average air bone gap for all the patients was calculated. Mean value of the air bone gap was 32.25 db (standard deviation ± 11.1 dB) for the temporal fascia group and 29.87db (standard deviation ± 9.9 dB) for tragal cartilage group. Correspondingly, the post-operative mean air bone gap at 3 months post-surgery was calculated by taking average of air-bone gap at 0.5, 1, 2 and 3 kHz frequencies. Similarly post-operative mean air bone gap was calculated for both the groups. Out of 120 patients, (postoperatively at 3 months) 7 patients were lost to follow up and 18 patients had residual perforation. Patients with residual perforation were not taken for post-operative hearing assessment. Consequently, the eligible patients for hearing assessment were 68 and 27 for temporal fascia group and tragal cartilage group respectively. Post-operative mean air-bone gap at 3 months in temporal fascia graft group was 20.84db (standard deviation ± 8.9 db) and 18.64 db (standard deviation ± 9.1 db) for tragal cartilage group.

Paired t test was applied to compare the preoperative means of air bone gap with the 3 months postoperative air bone gap in temporal fascia and in tragal cartilage graft cases. Mean air bone closure was 11.02db (standard deviation ± 9.9db) in temporal fascia graft group and mean air bone gap closure was 10.14db (standard deviation ± 7.5dB) in tragal cartilage cases. These results were statistically significant (P value < 0.05). However, when the air bone closure in both groups were also compared, the values were not statistically significant (p value > 0.05) (Table 4). There was statistically significant conductive hearing gain (air bone gap closure) in both the groups. Nevertheless, on comparison between the two groups the values did not reach to a statistically significant level.

DISCUSSION

Chronic suppurative otitis media is a common disease entity in India especially in the population with a lower socioeconomic background. Primary goal of...
treatment for CSOM is elimination of the chronic inflammatory process. The secondary goal aims at reconstruction of sound conducting mechanism\(^8\). Tympanoplasty forms the mainstay of treatment for CSOM of tubotympanic disease. To reconstruct the tympanic membrane, several graft materials are used like temporal fascia, cartilage, tensor fascia lata and vein graft. Temporal fascia is the most widely used graft because it can be harvested from a local operative site. Temporal fascia has additional advantages over the other grafts owing to its light, mouldable structure which mimics tympanic membrane. Success rate with temporal fascia in a well aerated middle ear ranges up to 90% in different studies\(^9\). Nonetheless, success rate decreases markedly in cases with Eustachian tube dysfunction or presence of an adhesive process\(^10-12\). On the other hand, since cartilage is rigid and possesses a thick structure, it is resistant to resorption and atrophy and can be placed precisely into a perforation. Cartilage graft is preferred in cases with large perforations, revision surgery, tympanosclerosis, tympanic membrane atelectasis, and Eustachian tube dysfunctions. Being a thick and rigid structure, cartilage can affect the pliability of the tympanic membrane and result in inferior hearing outcome as compared to temporal fascia graft which is thinner and more pliable\(^5-7\).

Chronic suppurative otitis media is more commonly reported in females than males. Our study also indicated a female predilection with male to female ratio of 0.88. Chronic suppurative otitis media affects all age groups ranging from childhood to elderly people. A wide age range was also observed in our study with 15-63 years range in temporal fascia graft cases and 19-69 years in the cartilage graft group.

There are very few reported studies in literature to compare the outcome of myringoplasty using temporal fascia and cartilage. Most of these studies conducted in the past were retrospective. Literature depicts 3 randomized clinical trials which compared the outcome of cartilage myringoplasty to temporalis fascia myringoplasty. Mauri et al compared results of inlay cartilage butterfly grafts and underlay temporal fascia grafts. They investigated the graft take up rates and hearing outcomes at 1 month and 2 months respectively. They included only those perforations where the size of perforation was less than 50% of the size of the tympanic membrane. They did not detect any significant difference in either the graft take rates or hearing improvement\(^13\). Cabra et al examined the patients with perforation size more than 25 % of tympanic membrane to compare the cartilage palisade graft with the temporal fascia graft. They found higher morphological (absence of retraction, atrophy, lateralization, anterior blunting, and otorrhea) success rates in cartilage (82.3%) than fascia (64.4%) but with no significant difference in hearing improvement\(^14\). Young et al conducted a clinical trial to compare the cartilage and fascia graft. They considered tympanic perforations involving more than 50% of the tympanic membrane to compare the cartilage palisade graft with the temporal fascia graft. They found higher morphological (absence of retraction, atrophy, lateralization, anterior blunting, and otorrhea) success rates in cartilage (82.3%) than fascia (64.4%) but with no significant difference in hearing improvement\(^14\).
Onal et al in their study demonstrated a better outcome with cartilage graft in both perforation closure rate and hearing improvement rate\cite{16}. Demirpehlivan et al compared the outcome of cartilage with perichondrial graft, cartilage graft and fascia graft. They presented higher graft take up rates in perichondrium cartilage (97.6%) compared to cartilage only (78.95%) and fascia (80.6%). No difference in hearing improvement was noted among the 3 groups\cite{17}. Few other retrospective studies have established a better graft take up rate with cartilage graft when compared to fascia graft with follow up period ranging from 6 to 24 months. However, no difference was noted in the hearing improvement in both types of graft materials\cite{18-20}. Al lackany and Sarkis investigated the graft take-up rates and hearing improvement utilizing cartilage, perichondrium, composite graft, perichondrial graft and fascia graft in central, subtotal and total perforations. A better graft take up rate was established in cartilage perichondrium composite graft (92.3%) when compared to perichondrium (88%) and fascia graft (80%), nevertheless a statistically significant value was achieved only for total perforation cases. Also a better air bone gap closure was proven with composite graft by Yetiser S et al\cite{21}. Cartilage perichondrial graft gave better result in comparison to fascia graft in subtotal and total perforations while air bone closure was superior in fascia graft in central perforations. Kadir Özdamar et al also studied the hearing improvement (air bone gap closure) in cartilage tympanoplasty group and temporal muscle fascia group. They also compared the middle ear pressure, air volume and compliance of tympanic membrane in both groups. They concluded that no statistical differences were observed in air volume, pressure or compliance values at any frequency in audiometry and tympanometry in the cartilage and fascia groups\cite{22}. In our study, the graft take up rate in cartilage perichondria composite graft and temporalis fascia graft was 84.85% and 85% (statistically significant) respectively. Hearing improvement (air one gap closure) was also significant in both the groups.

CONCLUSION:

Our study attempted to recognize better graft options in tympanoplasty surgeries. Various parameters such as healing, hearing improvement and graft take up rates were comprehensively studied in a large population group. Although the healing rate of tympanic membrane was similar in both temporal fascia and cartilage groups, there was no statistically significant difference in the hearing improvement in both types of graft materials. Consequently, both cartilage and temporal fascia can be utilized as graft materials independently with good success rates in tympanoplasty surgeries.

DISCLOSURES

a) Competing interests/Interests of Conflict- None
b) Sponsorships – None
c) Funding - None
d) Written consent of patient- taken
e) Animal rights- Not applicable

REFERENCES:


ABSTRACT

Adeno-tonsillar hypertrophy is one of the main causes of upper airway obstruction and Obstructive Sleep Apnoea Syndrome (OSAS) in children. Studies have shown that adeno-tonsillectomy significantly improved oxygen saturation in children with sleep-disordered breathing. This study was undertaken to evaluate the effect of adeno-tonsillectomy on quality of life in children with sleep-disordered breathing and on oxygen saturation measured through nocturnal pulse oximetry in children.

Methods: Sixty children suspected of having sleep-disordered breathing and who subsequently underwent adeno-tonsillectomy were randomly selected for this study. Quality of life was evaluated pre- and post-operatively by questionnaire and the symptoms were scored depending on its frequency of occurrence. Pre-and post-intervention nocturnal oxygen saturation was monitored and recorded. Oxygen desaturation index (ODI) as well as desaturation events were recorded. The data was analysed using paired student t-test and Wilcoxon’s Signed Rank Test.

Results: Out of the 60 study population, 36 (60%) were males and 24 (40%) were females. Age distribution of the population ranged from 6 to 12 years with a mean age of 8.2 years. There was a significant improvement in the quality of life of these children after the surgery. The study showed a positive correlation between grade of adeno-tonsillar hypertrophy and ODI(r=0.25). The pulse oximetric parameters improved after adeno-tonsillectomy (p<0.05). There was also significant improvement in the quality of life of these children after the surgery.

Conclusion: Adeno-tonsillectomy was found to be effective in children with sleep disordered breathing. It can be recommended as the primary surgery as it substantially reduced the morbidity and health care utilisation by these children.

Keywords: Sleep-disordered breathing; obstructive sleep apnoea, adeno-tonsillectomy; pulse oximetry.

INTRODUCTION

Sleep medicine has undergone a revolution since the first description of abnormal airway during sleep in patients with Pickwickian syndrome in 1965[1]. Sleep disordered breathing (SDB) refers to a spectrum of disorders that ranges in severity from primary or simple snoring, through upper airway resistance syndrome (UARS) and, in its most severe form, obstructive sleep apnoea syndrome (OSAS)[2]. OSAS was first reported in children by Guilleminault et al. (1976) following which recognition of abnormal breathing has progressed[7].

Sleep disordered breathing

Sleep-disordered breathing is a spectrum of airway obstruction during sleep which encompasses[2].

- Primary snoring (PS).
- Upper airway resistance syndrome (UARS).
- Obstructive sleep apnoea (OSA).

In the general population, OSAS is one of the most prevalent SDB conditions, affecting adults as well as children. Prevalence of OSA in childhood is around 2-
3% affecting all ages; and peaks between 2-8 years. Frequent snoring is reported by parents in 3-15% children, while prevalence of reported apnoeic events is 0.2-4%.

(a) Primary Snoring:
Primary snoring has been defined as snoring during sleep without associated apnoea, gas exchange abnormalities, or excessive arousals. Approximately 10% of children snore during sleep on most or all nights, and the majority of these children have primary snoring (PS). The prevalence of primary snoring is estimated to be 3-12%. Major risk factors for snoring in otherwise healthy children are obesity, decreased nasal patency (rhinitis, septal deviation, nasal obstruction), and adeno-tonsillar hypertrophy.

(b) Upper Airway Resistance Syndrome
Upper airways resistance syndrome is a more subtle form of sleep-disordered breathing than OSA. Children with UARS snore and have partial upper airway obstruction that leads to repetitive episodes of increased respiratory effort ending in arousals and sleep fragmentation. This disorder is more common than OSA but is often underdiagnosed. Children with UARS have no evidence of apnoea, hypopnoea, or gas exchange abnormalities on polysomnography.

(c) Obstructive Sleep Apnoea Syndrome
OSA is defined by the American Thoracic Society (ATS) as ‘a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnoea) that disrupts normal ventilation during sleep and normal sleep patterns’. Approximately 1% to 3% of all children will have OSAS, and as many as 40% of snoring children referred to a sleep clinic or otolaryngologist may have OSA. OSAS is characterized by recurrent episodes of upper airway collapse during sleep.

The International Classification of Sleep Disorders 2nd edition (ICSD II) by the American Academy of Sleep Medicine (AASM) defines apnoea as the cessation of airflow for at least 10 seconds over two or more respiratory cycles. Sleep apnoea syndrome is diagnosed when 30 or more episodes occur during a 7-hour sleep period. Hypopnea is defined as a recognizable transient reduction (but not complete cessation) of breathing for 10 seconds associated with oxygen desaturation of 4% or more. The degree of hypoxia is influenced by the duration of the apnoeic event, the condition of the cardiopulmonary system and whether a coexisting neuromuscular disorder is present. Apnoea hypopnoea index (AHI) indicates the severity of OSA. It is the number of apnoea and hypopnoea per hour of sleep. It is agreed that an apnoea-hypopnoea index greater than 1 is abnormal in a child.

Sleep-related upper airway obstruction can lead to a variety of night-time and daytime symptoms in children. It causes significant sleep disruption. This can lead to daytime neurobehavioural problems such as an increase in total sleep time, hyperactivity, irritability, bed-wetting and morning headaches. If diagnosis and treatment of OSAS are delayed, sequelae like cor pulmonale, failure to thrive and long-lasting neurobehavioural consequences may occur.

The diagnosis of obstructive sleep-disordered breathing is reached by sleep based history and physical examination. The clinical history and examination will identify most children with sleep disordered breathing. Specific questionnaires are designed to complement the clinical history for screening and identifying severe cases.

The gold standard investigation for sleep disorders is full polysomnography. Pulse oximetry is another screening tool. It relies on indirect measurement of the arterial oxygen saturation using a probe (pulse oximeter), usually applied to the finger. It is minimally invasive, and can be undertaken even at home. Pulse oximetry has a high positive predictive value of approximately 97 percent. It is not effective in mild-to-moderate OSA, with a low negative predictive value of approximately 47 percent. Therefore, children with negative results on screening studies should undergo a more comprehensive evaluation. Since the most common cause of OSAS in children is adeno-tonsillar hypertrophy, adeno-tonsillectomy is accepted to be the first line of treatment.

The correlation of adeno-tonsillar hypertrophy and impact on the quality of life in children is intended to be studied. The overall efficacy of adeno-tonsillectomy (AT) in treatment of obstructive sleep apnoea syndrome (OSAS) in children is unknown. Although success rates are likely lower than previously estimated, factors that promote incomplete resolution of OSAS after adeno-tonsillectomy remain undefined.
Aims and Objectives of the study were

1. To study the impact of adeno-tonsillectomy on the quality of life in children with sleep disordered breathing (SDB)
2. To correlate the effect of adeno-tonsillar hypertrophy assessed clinically and radiologically on overnight oxygen saturation.
3. To determine whether adeno-tonsillectomy is effective in improving SDB in children.

REVIEW OF LITERATURE

Since the first report of obstructive sleep apnoea syndrome (OSAS) in children by Guilleminault et al. in 1976, recognition of abnormal breathing during sleep has progressed. Guilleminault et al. reported that in their sample of eight children with excessive daytime sleepiness and learning difficulties at school improved behaviour 3-months post adeno-tonsillectomy and by 6 months improved hyperactivity symptoms.[7]

Methods to help identify SRBDs without the expense of polysomnography could greatly facilitate clinical and epidemiological research. There are several clinical assessment scores to evaluate the quality of life in OSAS in children.

Chervin et al. developed and validated a Paediatric sleep questionnaire that can be used to investigate the presence of childhood SRBD[8]. It is a 22-item score with sensitivity of 0.85 and a specificity of 0.87. They concluded that scales for snoring, sleepiness, and behaviour are valid and reliable instruments that can be used to identify SRBDs or associated symptom in clinical research when polysomnography is not feasible.

Using the OSA-18 quality of life survey, Goldstein and associates found similar improvements in quality of life, again with the most significant improvements seen in the domains of sleep disturbance, caregiver concerns and physical discomfort, with concomitant improvements in behaviour after adeno-tonsillectomy.[9] In their study they found children with a positive clinical assessment of OSA but negative polysomnography (PSG) have significant improvement after adeno-tonsillectomy, thus validating the clinicians role in the diagnosis. They evaluated 30 snoring children referred to a paediatric otolaryngology clinic using a focused history and physical examination in addition to a review of audiotaped breathing of the children during sleep.

Mitchell and co-workers assessed behavioural abnormalities in children with OSAS using the Behavioural Assessment System for Children before adeno-tonsillectomy, and again within 6 months after surgery and 9 to 18 months after surgery.[10] These investigators found improvements in behavioural measures after adeno-tonsillectomy that seemed to persist during long-term follow-up, although to a lesser degree than seen shortly after surgery. It is not clear, however, if the cognitive and behavioural complications of OSAS are completely reversible.

De Serres and colleagues reported the results of a multicentre study of quality of life changes after adeno-tonsillectomy in children who had adeno-tonsillectomy for treatment of obstructive sleep disorders.[11] Large changes in quality of life were documented in almost 75% of children, with the most improved domains being sleep disturbance, caregiver concerns, and physical suffering.

Brietzke and co-workers in a systematic review of the literature and meta-analysis on the effectiveness of tonsillectomy and adenoidectomy in the treatment of Paediatric Obstructive Sleep Apnoea Syndrome found adeno-tonsillectomy to be effective in the treatment of OSA. They found that 11 of 12 articles in the literature concluded that clinical assessment is inaccurate in the diagnosis of childhood OSAS.[12] Although the clinical history may not be diagnostic, a thorough evaluation of daytime and night-time symptoms is helpful in planning subsequent studies and interpreting the findings. They found a post-surgery reduction in AHI by approximately 14 events per hour. The summary success rate was 83%.

Gozal and Kheirandish reported a cure rate of 77% in a recent review but noted residual OSAS in up to 45% of children after adeno-tonsillectomy in their own prospective study.[13] More snoring and increased inspiratory effort during sleep were noted in teenagers studied 12 years after adeno-tonsillectomy. This finding emphasizes the need for long-term study of both the natural history of and treatment outcomes for OSAS in children.

Several studies show behavioural and neurocognitive improvement following adeno-
tonsillectomy in children with sleep disordered breathing.

Chervin and co-workers in their study found that children undergoing adeno-tonsillectomy for any clinical indication with suspected sleep-disordered breathing had increased hyperactivity, inattention, and daytime sleepiness were more likely to be diagnosed with attention deficit-hyperactivity disorder than control children undergoing other surgical procedures [14]. Avior et al assessed attention in 19 children with SDB before and 2 months after adeno-tonsillectomy, demonstrating that neurocognitive changes occur within the first 2 months after treatment [15].

Sohn H and co-workers in their study on Quality of life of children with obstructive sleep apnoea after adeno-tonsillectomy found that the relationship between the OSA-18 summary score and respiratory distress index remained significant [16].

Gottelib DJ et al assessed the prevalence of SDB symptoms in 5 year old children and found it to be associated with an increased risk of problem behaviours, attention-deficit hyperactivity disorder [17].

**METHODOLOGY**

This study was undertaken in the department of ENT, Bangalore Medical College & Research Institute, Bangalore from August 2014 to July 2016. Sixty (60) children aged 6-12 years with symptoms and signs suggestive of adeno-tonsillar hypertrophy and SDB, who met the inclusion criteria were randomly enrolled for the study. Demographic data, medical history, concomitant medications, clinical examination including recording of vital signs, lab investigations and details were recorded in the study proforma. The study was conducted prior to adeno-tonsillectomy until three months (12 weeks) after the surgery. Patient’s physical parameters like weight and height, BMI were recorded. Radiological study of Nasopharynx was done to know nasopharyngeal air-way. Measurement of oxygen saturation was done by nocturnal pulse oximetry. The children were programmed for evaluation by pulse oximetry 1-2 days before and 3 months after the surgery, by keeping the child in observation room. Pulse oximeter, which has a memory up to 72 hours, was used for this study. Oximetric monitoring both pre- and post-operatively was carried out. The following variables were studied:

- Total number of desaturations of > 4%,
- Oxygen desaturation index (ODI)
- Mean saturation and
- Minimum saturation.

ODI is defined as the total number of desaturation events divided by the total duration of sleep in hours. A desaturation event was considered when the haemoglobin saturation level (SaO2) fell below 4% from baseline saturation. Falls in oxygen saturation to >4% in the interval 90–100% of saturation was also considered as desaturations. ODI was obtained for each patient with three cut-off points; >5: (ODI-5), >10: (ODI-10), >15: (ODI-15). The data collected were analysed in oximetric and heart rate distribution tables.

Validity of the test was approved if the duration of oximetric monitoring was 6 hours or more and if oxygen saturation data was reliable and compatible with pulse rate according to the pulse rate variable recorded in the memory of pulse oximeter. After obtaining fitness for surgery patients were taken up for adeno-tonsillectomy under general anaesthesia. All surgical procedures were performed under general anaesthesia with orotracheal intubation. After surgery, the children were closely monitored for any probable bleeding and complications for at least 24 hours. Thereafter, they were re-evaluated in 3 months’ period.

**Assessment tools:** Treatment response was assessed by

- OSA-18 survey on quality of life improvement before and after the surgery.
- Pulseoximetric evaluation of the subjects pre- and postoperatively to assess the improvement in oxygen saturation.

**Statistical analysis:** Pre- and post-operative oximetric variables were analysed using paired student t-test or Wilcoxon’s signed rank test depending on the variables. Correlation between variables was considered using Pearson correlation test.

**RESULTS**

Out of the 60 study population, 36 were males (60%) and 24 were females (40%). Age distribution of the population ranged from 6 to 12 years with a mean age of 8.2 years.

Most of the patients were between 6-8 years of age. Majority of study population (58.3%) had grade
III tonsils (enlarged tonsils that come in contact with uvula).

Majority of study population (50%) had Grade III adenoids (enlarged adenoids filling from 2/3rd of vertical portion of choanae to nearly complete obstruction). The correlation between grades of adenotonsillar hypertrophy and ODI score was assessed using Pearson correlation test. The test showed correlation co-efficient r 0.25 indicating a positive correlation.

ODI grade: The Oxygen Desaturation Index (ODI) was graded as shown below and the pre-operative and post-operative values were compared.

<table>
<thead>
<tr>
<th>GRADE</th>
<th>PRE OP</th>
<th>POST OP</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>&lt;5</td>
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<td>5-10</td>
<td>12</td>
<td>20</td>
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<tr>
<td>10-15</td>
<td>20</td>
<td>33.33</td>
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<tr>
<td>&gt;15</td>
<td>26</td>
<td>43.33</td>
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<tr>
<td>Total</td>
<td>60</td>
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</table>

Table1: showing Oxygen Desaturation Index

Pre-operatively most of the patients had ODI grade >15 (43.33%) while post-operatively majority have ODI grade <5 (80%). Paired-t test was used to analyse whether the postoperative ODI had significantly reduced compared to preoperative ODI. Average ODI score preoperatively was 15.11±5.4 and that postoperatively was 3.48±2.3. p value was significant (p< 0.05).

Evaluating the Quality of life pre-and post-operatively among study population.

To evaluate the continuous scores of quality of life questionnaire non-parametric Wilcoxon’s Signed Rank Test was used. The following observations were made:

**Snoring:**

Preoperatively most of the patients (45%) had snoring very often and postoperatively majority (58.3%) had snoring sometimes. The p-value was significant (p<0.05)

<table>
<thead>
<tr>
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<th>POSTOP</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>None</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Almost none</td>
<td>4</td>
<td>6.66</td>
</tr>
<tr>
<td>Sometimes</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Often</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Very often</td>
<td>7</td>
<td>11.66</td>
</tr>
<tr>
<td>Every time</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2: Showing preoperative and postoperative snoring among study population

**Restlessness at night:**

Preoperatively most of the patients (61.66%) often had restlessness at nights and postoperatively majority (88.33%) almost never had restlessness at nights. The p value was significant p < 0.05.

<table>
<thead>
<tr>
<th>Restlessness</th>
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<th>POSTOP</th>
</tr>
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<tbody>
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<td>0</td>
</tr>
<tr>
<td>Almost none</td>
<td>4</td>
<td>6.66</td>
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<td>Sometimes</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Often</td>
<td>3</td>
<td>7</td>
</tr>
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<td>11.66</td>
</tr>
<tr>
<td>Every time</td>
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<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 3: Showing preoperative and postoperative restlessness at nights among study population
Preoperatively most of the patients (58.33%) had mouth breathing very often and postoperatively majority (60%) had mouth breathing sometimes. The p-value was significant p<0.05.

Preoperatively most of the patients (48.33%) had irritability on waking-up sometimes and postoperatively majority (60%) almost never had irritability on waking-up. The p-value was significant (p<0.001).

**DISCUSSION**

Paediatric sleep-disordered breathing is a relatively new field, and a number of questions remain unanswered. One of the most important questions in paediatric sleep-disordered breathing is the outcome of patients with OSAS. We do not know the clinical correlates of mild obstructive apnoea, or what degree of OSAS warrants treatment. The long-term relationship between primary snoring, UARS, and OSAS has not been studied. Although polysomnography is widely used, it is not known which polysomnography parameters predict morbidity. We used Quality of life questionnaire and Pulse oximetry to assess the improvement of symptoms following adeno-tonsillectomy in the children in our study.

The correlation was assessed using Pearson correlation test. The test showed a positive correlation between grade of adeno-tonsillar hypertrophy and ODI. This indicates that the size of adenoids and tonsils aids in assessing the severity of sleep disordered breathing and the same can be used to select children for surgical intervention.

These findings were in par with similar studies such as those conducted by Li AM et al.[18] Mitsuhiko Tagaya et al[19].

Li AM, Wong E, Kew J, Hui S, Fok TF conducted a study in 35 children referred consecutively for

<table>
<thead>
<tr>
<th>PREOP</th>
<th>POSTOP</th>
<th>Wilcoxon’s Signed Rank test p VALUE &lt;0.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>None</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Almost none</td>
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<td>0</td>
</tr>
<tr>
<td>Sometimes</td>
<td>2</td>
<td>3.33</td>
</tr>
<tr>
<td>Often</td>
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<td>3</td>
</tr>
<tr>
<td>Very often</td>
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</tr>
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</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 4: Showing preoperative and postoperative mouth breathing among study population.

Preoperatively most of the patients (46.66%) had day time somnolence sometimes and postoperatively majority (63.33%) had no day time somnolence. The p-value was significant (p < 0.05).

<table>
<thead>
<tr>
<th>PREOP</th>
<th>POSTOP</th>
<th>Wilcoxon’s Signed Rank test p VALUE &lt;0.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>None</td>
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<td>0</td>
</tr>
<tr>
<td>Almost none</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Sometimes</td>
<td>28</td>
<td>46.66</td>
</tr>
<tr>
<td>Often</td>
<td>24</td>
<td>40</td>
</tr>
<tr>
<td>Very often</td>
<td>5</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 5: Showing preoperative and postoperative day time somnolence among study population.

<table>
<thead>
<tr>
<th>PREOP</th>
<th>POSTOP</th>
<th>Wilcoxon’s Signed Rank test p VALUE &lt;0.05</th>
</tr>
</thead>
<tbody>
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<tr>
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<td>0</td>
</tr>
<tr>
<td>Almost none</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Sometimes</td>
<td>28</td>
<td>46.66</td>
</tr>
<tr>
<td>Often</td>
<td>24</td>
<td>40</td>
</tr>
<tr>
<td>Very often</td>
<td>5</td>
<td>8.33</td>
</tr>
<tr>
<td>Every time</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 6: Showing preoperative and postoperative irritability on waking-up among study population.
suspected OSA secondary to tonsillar hypertrophy.\[18\] Their results showed that in children with OSA, tonsillar hypertrophy as assessed by lateral neck radiograph correlates positively with the severity of obstructive sleep apnoea.

Mitsuhiko Tagaya, et al in their study of 58 children with SDB found that adenoid grade and apnoea index correlated significantly in preschool children (r = 0.45, p < 0.01).\[19\]

Comparing pre-and post-operative pulse oximetric parameters among study population.

All the pulse oximetric parameters improved significantly after the intervention. The mean ODI pre-operatively was 15.11 and that post-operatively was 3.48. The p value was < 0.001. Since p value is < 0.05, we conclude that ODI have significantly improved postoperatively.

The mean SPO2 preoperatively was 90.83 and that postoperatively was 95.02 Standard deviation of pre-operative mean SPO2 and post-operative mean SPO2 was 1.54 and 1.66 respectively. The p value < 0.001. Hence we can say that mean SPO2 significantly improved postoperatively.

These all indicates that there is an objective evidence of post-surgical improvement in the nocturnal arterial oxygen saturation of children with SDB. These findings were in par with similar studies such as those conducted by Arrarte JL et al, Kargoshaie A and colleagues.

Arrarte JL et al conducted a pre- and post-intervention study using nocturnal pulse oximetry. Atotal of 27 children completed the study. Out of these, 23 children (85.2%) presented class III or class IV hyperplasia of the palatine tonsils. There was significant improvement in the post-operative period over the pre-operative period in terms of the oxygen desaturation rate.\[20\]

Kargoshaie A and colleagues carried out a similar study. The study revealed a significant improvement in the postoperative oxygen desaturation index (1.60 ± 3.22) compared with the preoperative oxygen desaturation index (3.98 ± 4.93; (p < 0.01).\[21\]

Evaluating the Quality of life pre-and post-operatively among study population.

Quality of life questionnaire was assessed using Wilcoxon’s Signed Rank test. The p-value was significant (< 0.001) for all the symptom scores except that of discipline problems. We used the OSA-18, an 18-item QOL survey with known test-retest reliability, internal consistency, and validity. Survey domains included sleep disturbance, physical suffering, emotional distress, daytime problems, and caregiver concerns. All the symptoms of SDB and chronic adenotonsillar hypertrophy improved significantly among the study population post-operatively. From this we can conclude that adeno-tonsillectomy has a significant impact on the quality of life of these children. Also, that the OSA-18 is a reliable, and responsive QOL measure.

CONCLUSION

There is a positive correlation between grade of adenotonsillar hypertrophy and ODI. This indicates that the size of adenoids and tonsils aids in assessing the severity of sleep disordered breathing and the same can be used in selecting children for surgical intervention.

There is significant improvement after adeno-tonsillectomy in all the pulse oximetric parameters namely ODI, mean SPO2, minimum SPO2 in children with SDB and chronic adeno-tonsillar hypertrophy. This indicates that there is also an objective evidence of improvement in the nocturnal arterial oxygen saturation of children with SDB. The results of the previous studies strongly support our study and emphasize the effectiveness of adeno-tonsillectomy as a first line management of children with SDB.

There is significant improvement in the quality of life of children with SDB after adeno-tonsillectomy. Adeno-tonsillectomy can be recommended as the primary surgical modality for children with sleep disordered breathing as it substantially reduced the morbidity and health care utilisation by the children. Despite more than 20 years of treating children with this condition, we have limited information on the long-term consequences of paediatric OSAS. It is a frequent but under diagnosed problem in children. The immediate consequences of OSAS in children include behavioural disturbance and learning difficulties, pulmonary hypertension, and compromised somatic growth. However, if nontreated promptly and early in the course of the disease, OSAS may also impose long-term adverse effect on neurocognitive and cardiovascular functions of the children, providing a strong rationale for effective treatment.

DISCLOSURES:

a) Competing interests/Interests of Conflict – None
b) Sponsorships – None
c) Funding - None
d) Written consent of patient- taken
e) Animal rights-Not applicable

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4. American Academy of Sleep Medicine, Diagnostic Classification Steering Committee: International Classification of Sleep Disorders: Diagnostic and Coding Manual. 2nd ed. Westchester, Ill, American Academy of Sleep Medicine, 2005
STUDY OF CRUSHING AND WEDGE RESECTION TECHNIQUE FOR MANAGEMENT OF CONCHA BULLOsa

*Shrikrishna B H, **Jyothis A C

ABSTRACT

Background and objective: Concha bullosa is associated with obstruction of the osteomeatal complex which can manifest in acute or chronic sinusitis. The presently popular techniques of managing the concha bullosa have their own disadvantages. Hence this study was undertaken to find the usefulness of crushing and wedge resection technique to manage concha bullosa.

Materials and methods: Thirty cases of concha bullosa in 18 patients were operated using crushing and wedge resection technique over a period of 1 year. All the cases were followed up for a minimum of 1 year. After 1 year duration a pre- and post-operative comparison was done using endoscopic imaging and CT scans.

Results: After one year follow up, there has been reduction in the size of the concha bullosa and no evidence of mucosal edema within the concha bullosa.

Conclusion: Crushing and wedge resection technique is an easy, minimally invasive technique for the management of concha bullosa.

Keywards: concha bullosa, crushing, endoscopy, computed tomography.

INTRODUCTION

Concha bullosa (CB) is the pneumatisation of the concha (turbinate) and is most commonly encountered in the middle concha. It is rarely found in the superior and inferior conchae[1]. According to Bolger et al., there are 3 types of concha bullosa, namely- lamellar type with pneumatisation of the vertical lamella of the concha; bulbous type with pneumatisation of the bulbous segment; extensive type with pneumatisation of both the lamellar and bulbous parts[2]. The osteomeatal unit as defined by Stammberger & Kennedy is a functional unit of the anterior ethmoid complex representing the final common pathway for drainage and ventilation of the frontal, maxillary and anterior ethmoid cells[3]. Although the role of the concha bullosa in rhinosinusitis is still debatable, a large concha bullosa may narrow the middle meatus from the medial side and thus may block the osteomeatal unit[4].

Different surgical techniques have been described for treating CB, including partial or complete resection, turbinoplasty, and crushing[2, 5-8]. All these techniques have their own advantages and disadvantages. In the present study we have done a year of follow up of patients who have undergone crushing and wedge resection of the concha bullosa at our centre. An endoscopic and tomographic comparison was done to find out any relapse in the pneumatisation of the middle turbinate after 1 year.

MATERIALS AND METHODS:

This prospective study was conducted at the department of oto-rhino-laryngology of Navodaya Medical College Hospital, Raichur (Karnataka) during
1st June 2013 to 31st May 2015. Thirty cases of concha bullosa in 18 patients were operated as part of sinonasal surgery by crushing and wedge resection technique. Patients who presented to our outpatient department with symptoms of chronic nasal obstruction, sinusitis, and headache were evaluated by computed tomography (CT) and diagnostic nasal endoscopy (DNE). Patients with concha bullosa were included in the study. The CB surgery was performed alone or in combination with functional endoscopic sinus surgery (FESS) or septoplasty.

All the patients were pre-operatively prepared with nasal packing of 4% lignocaine with 1 in 100,000 adrenaline. Under general anaesthesia, endoscopic sinus surgery was performed. The concha bullosa area was packed with gauze dipped in plain adrenaline for 3 minutes. After removing the adrenaline gauze, the CB was crushed from its superior attachment to the inferior portion and then posteriorly with Blakesley forceps to prevent mucosal injury (Fig 1). After adequate crushing of the concha bullosa, the inferior portion of the CB was wedge-resected using a tru-cut forceps (Fig 2). Post-operatively nasal pack was kept for 24 hours and patients were discharged on the second day after surgery.

All the patients were followed up for a minimum duration of 1 year. A comparison data was collected by pooling information in endoscopic and tomographic evaluation pre and post-operatively at the end of one year of their follow-up (Figs 3 & 4). Endoscopic analysis of the concha bullosa was done using the classification method done by Tanyeri et al. The volume of the CB was calculated on a Leonardo workstation (Siemens Medical Systems), which generated a volume from a stack of two-dimensional images of computed tomography. The data thus collected was statistically analysed using the paired t test.

Institutional ethical clearance committee permission was taken before the commencement of the

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**Figure 1**: Concha bullosa being crushed with straight blakesley forceps.

**Figure 2**: Wedge resection of inferior Portion of concha bullosa being done by tru-cut forceps.

**Figure 3**: Pre-operative ct image showing bilateral concha bullosa.

**Figure 4**: CT scan image at the end of 1 year in a patient who had undergone crushing of concha bullosa on both sides. Reduction in size is more prominent on left side.
study. Also a written informed consent was taken from all the patients who participated in this study.

RESULTS:

Thirty cases of concha bullosa in 18 patients (8 male and 10 female patients) were included in our study. The mean age of the patients was 31 years. All the patients underwent crushing of the concha bullosa with wedge resection of the inferior portion. This was done along with septoplasty or functional endoscopic sinus surgery as indicated by the diagnosis. The patients were followed up for a minimum of one year and an endoscopic and tomographic evaluation of the concha bullosa was done at the end of first year of follow-up. The tomographic CB volume was also significantly ($P < .01$) smaller postoperatively (mean, 0.62 cm$^3$; SD=0.3) than preoperatively (mean, 1.53 cm$^3$; SD=0.7). Endoscopically, the middle turbinates were significantly ($P < .01$) smaller postoperatively (mean grade, 1.43; SD=0.62) than preoperatively (mean grade, 2.56; SD=0.89).

DISCUSSION

Stallman defined concha bullosa as being present when more than 50% of the vertical height (measured from superior to inferior in the coronal plane) of the middle turbinate is pneumatised while Smith et al defined concha bullosa as the presence of pneumatisation of any size within the superior, middle or inferior conchae$^{[10,11]}$. However, Hatipoðlu et al classified pneumatisation of the middle concha depending on the location of the pneumatisation as lamellar, bulbous and extensive$^{[12]}$.

Although the exact mechanism of concha bullosa formation has been unclear, it is considered that the airflow pattern of the nasal cavity plays an important role. This theory is named as “e vacue”. As the airflow is markedly reduced in the nasal cavity with convexity of the deviation, pneumatisation of the middle turbinate is augmented in the contralateral site$^{[13]}$. This theory can explain the association between contralateral concha bullosa and nasal septal deviation. However, nasal septum is away from the dominant concha for preserving adjacent air channels, and therefore nasal septal deviation can be occurred. Stalman at al. reported contralateral nasal septal deviation in 69.5% of patients with unilateral concha bullosa or dominant concha bullosa$^{[10]}$.

Some authors have reported that concha bullosa plays a role in recurrent sinusitis by compressing the uncinate process and obstructing or narrowing the infundibulum and the middle meatus$^{[1, 2, 14, and 15]}$. Lloyd et al. have stated that when concha bullosa fills the space between the septum and the lateral nasal wall, there may be total obstruction of the middle meatus orifice$^{[14, 15]}$. Comparative studies involving asymptomatic patients and sinusitis patients have reported that concha bullosa is more frequently encountered in patients with sinusitis$^{[14, 15, and 16]}$. It is significant to note that the comparative studies which failed to show a significant association between the sinus disease and concha bullosa were performed only on the symptomatic group$^{[8, 17]}$. There are studies pointing out that the size of concha bullosa is important for the presence of symptoms$^{[18,19]}$. Yousem et al. have advocated that concha bullosa is not one of the causes of sinusitis yet the size has implications$^{[17]}$. In the most extensive study on this topic by Ünlü et al., no significant association was demonstrated between concha bullosa and osteomeatal unit blockage; however, when the bulbous-extensive type was compared with the lamellar type, a significant correlation was found regarding osteomeatal unit blockage. They thus concluded that pneumatisation of the inferior portion of the middle concha has a role in osteomeatal unit blockage$^{[8]}$.

The different surgical modalities used for management of concha bullosa include partial turbinectomy (resection of anterior portion of the concha bullosa), lateral turbinectomy (resection of the lateral half of the turbinate) and conchoplasty (submucosal resection of the lateral plate of the concha bullosa)$^{[20]}$. All these turbinate surgeries carry risks viz. bleeding, synechia, and olfactory dysfunction$^{[21]}$. Since the damage to the nasal mucosa is minimal in crushing technique, the incidence of above complications is very much reduced in our technique. Though there was minimal bleeding during crushing of CB, it was very much less compared to that during turbinate surgeries. Also, none of our patients developed synechia or olfactory dysfunction during the follow-up period.

HasanTanyeri et al stated in their study that concha bullosa does not appear to reform after crushing$^{[9]}$. However, their follow-up period was only for 4
months. On the other hand, the study by Kieff and Busaba states that concha bullosa does recur after the crushing technique of surgery\(^5\). Penttila has stated that no published study has compared the surgical treatment of CB using the crushing technique with other surgical treatments of CB\(^22\). Thus, the true incidence of CB reformation following the crushing technique remains unknown. In our study, the concha bullosa a significant reduction in size after 1 year follow up. However, a more long-term study with larger study group and a longer duration endoscopic and tomographic follow-up is required to get more conclusive results.

Penttila has stated that crushing may damage the mucosa lining the air cell lumen or air cell ostia, leading to mucocele formation in the involved air cell\(^22\). Keeping this in mind, in our study, we have done wedging of the inferior portion of the concha bullosa besides crushing. This was done to help drainage of secretions or mucocele from the concha bullosa if ever it happens. However, during our 1 year follow-up, there was no report of mucocele or infection in concha bullosa. This suggests that crushing and wedge resection of concha bullosa is an easy and minimally invasive technique for management of concha bullosa.

**CONCLUSION:**

Crushing and wedge resection of concha bullosa is an easy and minimally invasive technique for management of concha bullosa. Our study shows that there is a significant reduction of size of concha bullosa even after one year after surgery. However, a long-term follow-up is required to get more conclusive results.

**DISCLOSURES:**

a) Competing interests/Interests of Conflict- None  
b) Sponsorships – None  
c) Funding - None  
d) Written consent of patient- taken  
e) Animal rights-Not applicable.

**REFERENCES:**


ABSTRACT

Peritonsillar infiltration and glossopharyngeal nerve block, both methods have been used to treat immediate pain after tonsillectomy. However, two techniques have not been compared.

Method: 50 patients aged between 10-20 years were randomized to receive glossopharyngeal nerve block (Group GN) or Peritonsillar infiltration (Group PT) at completion of tonsillectomy to compare the efficacy of two techniques. Postoperative pain at rest and swallowing was assessed using Verbal Analog Score at 30 minutes and 1, 4, 8 and 12 hours after surgery. In addition, the success of glossopharyngeal nerve block was evaluated by observing obtundation of gag reflex and correlated with pain relief.

Results: Pain scores at rest and on swallowing were significantly lower in group GN than in group PT up to 8 hours after surgery (p < 0.001). Gag reflex was absent or only mild in majority of the patients receiving GNB. More patients in group PT needed rescue analgesia within one hour of surgery (12% v/s 44% in groups GN and PT respectively). Upper airway obstruction was observed in one patient in GN group.

Conclusion: Glossopharyngeal nerve block seems to be better than Peritonsillar infiltration for relieving pain immediately after surgery. Obtunded gag reflex is a clinical indicator of successful blockade of glossopharyngeal nerve and post-tonsillectomy analgesia.

INTRODUCTION

Pain and discomfort after tonsillectomy is often stated to be of significant degree[1-2]. Inadequate treatment of pain may delay oral intake as well as return to regular activity and may also reduce overall satisfaction with surgery. Difficulty in swallowing may lead to increased risk of bleeding and secondary infection[3]. Several studies have shown that preincisional peritonsillar infiltration[4,5] and glossopharyngeal nerve block (GNB)[6] when combined with general anesthesia improve operative condition and also provide postoperative analgesia. But these results were not confirmed by other studies[7,8,9]. The reason for the controversial results after GNB could be unsuccessful block of the nerve as none of the studies provided a method to assess successful performance of GNB. Success of block can be evaluated by observing gag reflex. Obtunded gag reflex is a good clinical indicator of successful block.

Present study was done to determine the efficacy of two techniques (Peritonsillar infiltration of tonsillar...
bed and GNB) in relieving early postoperative pain after tonsillectomy. In addition we also aimed to evaluate the success of GNB by examining gag reflex and find correlation between obtunded gag reflex and post-operative pain relief.

**METHOD**

The study was conducted after approval by the institutional review board and informed written consent from patients or parents. Fifty patients of both sexes aged 10-20 years, of ASA grade I and II requiring tonsillectomy with or without adenoidectomy were recruited for this prospective, randomized trial. The indications for surgery were either recurrent tonsillitis or hypertrophy with obstructive symptoms. Patients were excluded if they had any systemic disease, sensitive to local anesthetic or had signs of acute pharyngeal infection. All patients had six hours of fasting and received standard pre-medication and general anaesthesia. Anaesthesia was induced by Pentothal sodium and fentanyl, intubated under atracurium and maintained on O2, N2O and isoflurane. Fentanyl and atracurium were repeated when required. Tonsils were removed via monopolar electro-cautery by an experienced otolaryngologist (standard dissection method). Adenoids were removed using a curette. Hemostasis was done with suction, suturing and packs as needed.

The patients were randomly divided into two equal groups using random number table. At the conclusion of surgery but before extubation, group GN patients (n=25) received bilateral glossopharyngeal nerve block (GNB) under direct vision using McVor gag by 1.5 ml of 0.5% bupivacaine with 1:200,000 adrenaline on each side. Group PT patients (n=25) received bilateral peritosillar infiltration with 3 ml of 0.5% bupivacaine with 1: 200,000 adrenaline each side. After giving the block, the patients were extubated after checking bleeders and were shifted to post anaesthesia care unit (PACU) in left lateral position after observing for 10 minutes in the operation room.

Glossopharyngeal nerve was blocked intraorally using the technique as described by Park et al (2007)\[^{10}\]. A 25 gauge spinal needle was angled to 45° at 1 cm from the tip. The needle was inserted at the middle point of posterior tonsillar pillar (Palato-pharyngeal fold), piercing the retropalatine pharyngeal mucosa. The needle was directed behind the posterior tonsillar pillar as laterally as possible and inserted through pharyngeal wall about 0.5 – 1 cm in depth. After careful aspiration 1.5 ml of bupivacaine solution was injected slowly. The technique was repeated on other side. The patients of group PT received 3 ml of bupivacaine solution injected submucously into the upper and lateral parts of peritonsillar space bilaterally using a straight 23 G needle.

Each patient was assessed in PACU by an investigator who was blind to group allocation. On arrival in PACU, pain score and time to awaken (from the end of anaesthesia until the patient opened the eyes on command) were recorded. One hour after arrival in PACU, pain at rest and on swallowing was assessed using verbal analogue scale (VAS) of 0 – 10 (0 = no pain and 10 = unbearable pain). If pain score was more than 5 at rest, diclofenac 1mg/kg was given IV/ IM, to reduce pain score to d"3. Gag reflex was assessed by lightly touching posterior oropharynx with a tongue depressor and the response was noted objectively on an arbitrary scale (None – no response, Mild – grimace but tolerable, Moderate – facial flushing and Severe – facial flushing with cough, restlessness).

On transfer to ward, all patients were offered fluid two hours after surgery and VAS at drinking fluid was noted. Pain score at rest and swallowing was also recorded 1, 4, 8 and 12 hours after surgery. Oral analgesic (paracetamol) was started 8 hours after surgery. Time of 1st analgesic after surgery and adverse effects like nausea, vomiting, foreign body sensation and upper airway obstruction were noted and managed accordingly.

The sample size of minimum 50 patients (25 per group) was calculated on the basis of VAS during swallowing. A difference of two between the groups were considered significant to have a power of 80% at \( \alpha = 0.05 \) (two tailed). Pain scores were compared by repeated measures analysis of variable ANOVA. Other data were analyzed using X2 test when appropriate. Fisher exact test was used to analyze gas reflex test, values were considered significant if \( p < 0.05 \). Patient characteristic, operative time and time delay between block/infiltration and need of supplementary analgesic was analyzed using two tailed paired t test.
Table – I: Patient demography and other data.

<table>
<thead>
<tr>
<th></th>
<th>Group GN</th>
<th>Group PT</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>15 ± 9</td>
<td>15 ± 7</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>14/11</td>
<td>10/15</td>
<td></td>
</tr>
<tr>
<td>Weight (Kg.)</td>
<td>30.50 ± 13</td>
<td>34.00 ± 12.7</td>
<td></td>
</tr>
<tr>
<td>Duration of Anaesthesia (Mins)</td>
<td>42.60 ± 8.56</td>
<td>41.50 ± 7.60</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Time to awaken after surgery (Mins)</td>
<td>8.56 ± 2.03</td>
<td>7.80 ± 1.64</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intra-operative fentanyl (µgm)</td>
<td>8.28 ± 0.98</td>
<td>52.13</td>
<td></td>
</tr>
</tbody>
</table>

Table – II: Verbal analogue score (VAS) at rest and on swallowing after surgery

<table>
<thead>
<tr>
<th></th>
<th>Group GN</th>
<th>Group PT</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS at rest 30 mins</td>
<td>2.40 ± 1.50</td>
<td>2.45 ± 2.60</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>VAS at rest 01 hr</td>
<td>2.48 ± 1.65</td>
<td>3.65 ± 2.97</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>VAS at rest 04 hrs</td>
<td>1.93 ± 1.46</td>
<td>3.58 ± 2.03</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS at rest 08 hrs</td>
<td>2.60 ± 1.51</td>
<td>4.21 ± 2.68</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS at rest 12 hrs</td>
<td>1.96 ± 1.84</td>
<td>2.22 ± 1.99</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>VAS at swallowing</td>
<td>3.60 ± 1.57</td>
<td>5.86 ± 3.60</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS at swallowing 01 hr</td>
<td>3.68 ± 1.98</td>
<td>6.30 ± 2.94</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS at swallowing 04 hrs</td>
<td>2.86 ± 1.12</td>
<td>4.93 ± 2.59</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS at swallowing 08 hrs</td>
<td>4.66 ± 2.28</td>
<td>6.80 ± 3.24</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS at swallowing 12 hrs</td>
<td>3.73 ± 2.15</td>
<td>4.10 ± 2.55</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

Table – III: Analgesia requirement, response to gag reflex and adverse effects.

<table>
<thead>
<tr>
<th>Analgesia required</th>
<th>Group GNB</th>
<th>Group PT</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 1 hr of surgery</td>
<td>3 (12%)</td>
<td>11 (44%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Between 1 – 4 hr</td>
<td>5 (20%)</td>
<td>9 (36%)</td>
<td></td>
</tr>
<tr>
<td>Between 4 – 12 hr</td>
<td>18 (72%)</td>
<td>20 (80%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Response of gag reflex</th>
<th>Group GNB</th>
<th>Group PT</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>12</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>6</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>4</td>
<td>5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Severe</td>
<td>3</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>VAS at 1st liquid intake</td>
<td>3.86 ± 2.10</td>
<td>7.21 ± 3.2</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse effects</th>
<th>Group GNB</th>
<th>Group PT</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper airway obstruction</td>
<td>1</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Foreign body sensation</td>
<td>8</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Hoarseness</td>
<td>2</td>
<td>2</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

Fig.1: Verbal Analogue score.

RESULTS

The patients were evenly distributed among two groups regarding age, weight, gender, duration of anaesthesia, intro-operative fentanyl usage and time of awakening after surgery (Table I). VAS at rest and on swallowing are depicted in Table II. The pain scores at rest were similar in both groups at 30 minutes after surgery but lower at 1, 4 and 8 hours after surgery in group GN compared to group PT (p < 0.001). The scores were comparable among the groups 12 hours after surgery.

Pain scores on swallowing increased in both groups at all-time points but increase was significantly more in group PT than in group GN (p < 0.001). At 12 hrs. although VAS was higher in group PT than in group GN, the difference did not attain statistical significance. Table III shows that 11 out of 25 patients needed supplementary analgesia within one hour of end of surgery in PT group compared to 3/25 patients in GN group. Overall more patients needed analgesia in group PT. Response to Gag reflex was none or mild in more number of patients in group GN (18 vs. 6 in groups GN and PT respectively). Similarly VAS at first liquid intake was higher in group PT (7.21 ± 3.2 vs. 3.86 ± 2.10 in groups PT and GN respectively, p < 0.001). Upper airway obstruction after surgery was seen in one patient in group GN (Table III). Other side effects were minimal and were similar in both groups.

DISCUSSION

Pain after tonsillectomy is due to multiple reasons. It could be due to thermal damage to surrounding tissues leading to acute inflammation and edema or due to retractor or due to open pharyngeal wound[11]. The pain is more severe immediately after surgery and gradually reduces over days. The observations obtained in this study showed that at rest and during swallowing,
pain scores were lower in group GN compared to group PT between one and eight hours after surgery. The results of this study are consistent with those who performed GNB for management of post-tonsillectomy pain[6,10,12]. Glossopharyngeal nerve supplies most of the sensations responsible for pain transmission following tonsillectomy[6]. Therefore glossopharyngeal nerve itself should be blocked to have effective pain control. To determine success of GNB, we evaluated response to gag reflex which decreases after successful block[10]. The degree of obtunded gag reflex indicates how successfully glossopharyngeal nerve is blocked. Our observations demonstrated that the pain relief was better in patients where gag reflex was absent or only mild.

In contrast to our results some authors have reported that GNB was not effective for pain management often tonsillectomy[9,13,14]. This could possibly be due to the fact that local anaesthetics did not reach nerve terminals corresponding to the tonsillar area. As none of these reports assessed success of block by observing obtundation of gag reflex[10].

Previous studies regarding analgesic efficacy of peritonsillar infiltration of local anaesthetic have reported conflicting results. A systemic review concluded that there is no evidence that use of peritonsillar infiltration improves analgesia after tonsillectomy[15]. El-hakim et al[14] demonstrated that infiltration of lignocaine along with pethidine provided considerable pain relief after tonsillectomy. Other studies also reported similar findings with other local anaesthetic bupivacaine[16]. On the contrary several workers[7,8,17,18] failed to find any beneficial effect of peritonsillar infiltration. The results of our study are not very encouraging for patients who received peritonsillar infiltration for postoperative pain relief. We found that 11/25 patients in infiltration group needed rescue analgesic within one hour after surgery and subsequently also more patients demanded analgesics. The reasons for the conflicting reports of infiltration could be several including surgical method used for tonsillectomy, dose and volume of local anaesthetic, timing (pre or post-incisional) & method of injection[8].

To best of our knowledge, no previous study has compared GNB with peritonsillar infiltration for tonsillectomy pain. In general our results showed superiority of GNB over peritonsillar infiltration in relieving pain on rest, swallowing and on first liquid ingestion.

Common complications related to GNB are upper airway obstruction (UAO), dyspnoea and foreign body sensation in mouth. Peritonsillar infiltration also has some risks including bilateral vocal cord paralysis for few hours and upper airway obstruction etc. We found UAO in one patient who was an eleven years old boy with history of obstructive symptoms. He became agitated just after he was extubated, had respiratory distress and oxygen saturation started falling. He was managed with jaw thrust, 100% O2, oropharyngeal airway and positive pressure ventilation. The patient improved after a few minutes. He was shifted to PACU after keeping under observation for 10 minutes. UAO is a serious complication of GNB. It is presumed to be due to use of high volume and concentration of local anaesthetic in the confined space ie lateral pharyngeal space[19]. This may lead to blockade of vagus nerve proximal to origin of recurrent laryngeal nerve or blockade of hypoglossal nerve. Both these nerves lie in close proximity to glossopharyngeal nerve in lateral pharyngeal space[13,19].

In summary this study demonstrated the superiority of GNB in relieving post tonsillectomy pain over peritonsillar infiltration. Also, extent of obtunded response to gag reflex strongly correlated with post-operative pain. GNB is easy to perform, but a note of caution is necessary before arguing for recommending this block for post-tonsillectomy pain as some complications like UAO may be life threatening[13]. Therefore it necessitates careful selection of patient and volume and dose of local anaesthetic and close observation in the immediate post anaesthetic period.

DISCLOSURES:

a) Competing interests/Interests of Conflict- None
b) Sponsorships – None
c) Funding - None
d) Written consent of patient- taken
e) Animal rights-Not applicable

HOW TO CITE THIS ARTICLE

REFERENCES


ABSTRACT
Objective: To describe our experience and outcome of transnasal endoscopic CSF leak repair in 400 patients.

Materials and methods: It was a retrospective study of 400 cases operated over a period of 19 years.

Results: 400 patients were reviewed. Of this, 62% had spontaneous leaks and the rest of patients were found to have leak secondary to trauma. 6 cases were congenital. Age of the patients was between 30-50 years except congenital cases where majority were less than 10 years. CT Cisternography was our choice of radiological imaging, which had a success rate of 95% in detecting the defect. Most common CSF leak in our study was cribiform plate and the least was lateral recess or Sternberg’s canal (1.5%). Our success rate in defect closure was 98% in the first attempt and 100% during the second attempt. Mean hospital stay was found to be 0.75 days. No major complications were encountered following the surgery.

Conclusion: Our experience of endoscopic transnasal repair of CSF leaks is very good. Multi-layered closure is advocated. Hadad Bassagasteguy flap has been observed to be a good graft material. We urge the use of endoscopic repair due to better outcome and less morbidity.

Keywords: Endoscopic repair. Transnasal. Cerebrospinal fluid rhinorrhea.

INTRODUCTION
Cerebrospinal fluid rhinorrhea is the leakage of CSF from the subarachnoid space into the nasal cavity due to a defect in the dura, bone and mucosa[1]. Nearly 80% of CSF leaks occur as a result of accidental trauma, 16% are iatrogenic and only 4% due spontaneous leaks. The defects may be located in cribiform plate fovea ethmoidalis, sphenoid bone or posterior table of frontal sinus[2].

The majority of patients will present with intermittent or continuous rhinorrhea. This is usually unilateral, but may be bilateral with change in head position. There is often a history of previous surgery or a head injury. Rarely, recurrent meningitis may be the only indication. Up to 40 per cent of patients complain of headache[3].

CSF rhinorrhea was first reported in the 17th century[4]. In the early 20th century, Dandy[5] reported the first successful repair, which used a bifrontal craniotomy for placement of a fascia lata graft. Endoscopic approaches were introduced in the 1980s and early 1990s. Both Wigand[6] and Stankiewicz[7] described closure of incidental CSF leaks during endoscopic sinus surgery. In 1989, Papay and colleagues[8] introduced rigid transnasal endoscopy for the endonasal repair of CSF rhinorrhea. Since then, numerous series have been published, and endoscopic repair has emerged as a mainstay of surgical management.

The diagnosis of CSF rhinorrhea is typically a two-step process: First, the presence of a CSF leak must...
be confirmed through the documentation of objective evidence of extra cranial CSF. Second, the position of the skull base defect or defects through which the CSF is draining must be determined. Nasoendoscopic examination should be performed in the outpatient clinic. This alone may identify the site of the leak in 36 per cent\(^9\) or may identify the cause, such as an encephalocele. The only test used to determine if a sample is CSF or not is immunofixation of beta-2 transferrin. The sensitivity of this test is 100 per cent with a specificity of 95 per cent\(^{10}\). Some authors favour computerized tomography (CT) Cisternography. High resolution coronal CT scans (1-2-mm slices) can offer detection in up to 84 per cent of cases in a large series\(^{11}\). A T 2-weighted MRI is the preferred imaging modality of some authors and rates of detection of 100 per cent are claimed\(^{12}\).

Over the past two decades, the optimal treatment strategy has undergone significant evolution as minimally invasive, endoscopic techniques have gained acceptance and supplanted more traditional techniques requiring external incisions or craniotomy. There were studies of large series of endoscopically treated patients where high success rates were reported, approaching 95% at the first closure attempt\(^{13}\).

The aim of our study is to share our experiences and outcome of Endoscopic transnasal CSF leak repair in 400 patients over a period of 19 years.

**PATIENTS AND METHODS**

The study consists of 400 patients who were operated from 1997 till March 2016. The case files were reviewed and the investigations, procedure, outcome and postoperative period noted.

**PREOPERATIVE WORK-UP**

The patients were first clinically assessed and checked for a positive reservoir sign. The collected fluid was sent for CSF analysis mainly glucose.

Endoscopic examination was done to identify the site of the leak. CT/ Cisternography was done as radiological investigation (Pictures 1-5). Intrathecal fluorescein dye was never used in our case series due to risk of complications.

Traumatic cases which did not respond to the initial conservative management of bed rest, head end elevation, avoidance of strenuous activities are taken for surgery after a waiting period of 15 days.
SURGICAL TECHNIQUE

All cases were operated under general anaesthesia with 0 and 30 degree rigid endoscope. The nasal cavity infiltrated with lidocaine and 1:1,00,000 adrenaline. Septoplasty is done if the visualisation is hampered, maxillary antrostomy; adequate exposure of the defect is done by ethmoidectomy, sphenoidotomy or middle/superior turbinectomy.

For defect in the posterior table of frontal sinus, a modified Lothrop approach is taken and leak from the lateral recess/ Sternberg’s canal is reached through transpterygoid route. If the leak is not well visualised during intra operative period, valsalva manoeuvre is performed. After identifying the defect, about 5mm of mucosa is removed surrounding the defect to make expose the bone and dural defect. Associated encephalocele is reduced by bipolar cauterisation. Rest of the brain tissue is mobilised from the dural edges. Graft is then placed covering the defect. Finally, surgicel and tissue glue are applied to keep the graft in position (Pictures 6-10).
The choice of grafts has evolved over time. Initially free septal flap, fat and fascia lata were used for defect closure. Now that has been changed to pedicled naso septal Hadad Bassagasteguy flap, the results of which are found to be very promising. If defect requires more tensile strength, fascia lata is used. Large defects more than 5-6 mm are given additional support with either middle turbinate flap or septal cartilage.

POSTOPERATIVE MANAGEMENT

The patients are discharged the next postoperative day. Postoperative antibiotics, stool softeners are given for a week. Patients are asked to avoid blowing the nose, sneezing or do strenuous activities which are likely to increase intracranial tension. Lumbar drains are placed for patients who have high pressure leaks or large defects more than 5-6mm for a day or two. Nasal pack is removed in 4-7 days. Patients are followed up weekly for four weeks.

RESULTS

We reviewed 400 cases which were operated during the time period of 1997 to March 2016. Of the 400 cases, 248 cases were spontaneous leak, 146 were traumatic including iatrogenic trauma and 6 congenital cases.

Majority of the patients were between the group of 30-50. The only exceptions were congenital Meningoencephalocele which accounted for 6 of our cases with 5 of them less than 10 years of age.

The investigations which we do are CSF analysis and CT Cisternography. Only glucose is tested to confirm CSF. CT Cisternography was used to identify the site of the defect. The success rate with this radiological investigation was around 95% in our study.

Most common site of leak was found to be from area of cribriform plate. The least common site was the lateral recess/Sternberg’s canal. For congenital Meningoencephalocele, the defect was found anterior to middle turbinate in all the cases. Defect in the posterior table of frontal sinus were seen in cases of RTA. During surgery the defect was detected in 99% of the cases. For those who had a positive reservoir sign but no active leak intraoperatively, graft was placed over the whole of skull base.

The success rate for us in the repair of CSF rhinorrhoea was 98% in the first attempt. The rest 2% of failure cases were corrected successfully in the second attempt. None of the patients required more than 2 attempts for defect closure.

Mean hospital stay was around 0.75 days. Maximum period of hospital stay was 2 days. Nasal pack was removed from 4th to the 7th day. The thigh sutures for harvesting fascia lata were removed on 7th day. No major complications were encountered in the group except for transient headache which resolved spontaneously.

DISCUSSION

This study reviews 400 cases which were operated over a period of 19 years. All the surgeries were performed by the main author. Due to panoramic visualisation and also lesser morbidity and mortality, endoscopes were used by the author since 1997. The success rates were 98% with the first attempt and 100% with the second attempt. None of the patients required a craniotomy approach.

Craniotomy and subsequent brain retraction is associated with significant morbidity including anosmia, intracranial haemorrhage, postoperative brain oedema etc. Moreover the accessibility is poor due to adjacent neurovascular structures. The failure rate of craniotomy is as high as 20-40%[14].

In our study, spontaneous leaks were found to be more (86%) which were supported by few studies[15, 16, 17]. The traumatic cases including the iatrogenic leaks accounted for the remaining.

A patient presenting with unilateral nasal discharge was sent through a diagnostic algorithm. A positive reservoir sign/drip test, corroborated with an

<table>
<thead>
<tr>
<th>Site of leak</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cribriform plate</td>
<td>345</td>
</tr>
<tr>
<td>Fovea ethmoidalis</td>
<td>33</td>
</tr>
<tr>
<td>Posterior frontal sinus</td>
<td>16</td>
</tr>
<tr>
<td>Lateral Recess/Sternberg’s canal</td>
<td>6</td>
</tr>
</tbody>
</table>
endoscopic examination to visualise the leak, CSF analysis for glucose of the collected specimen and CT Cisternography\(^\text{[18]}\) were done. Intraoperatively the leak was visualised with endoscope. Inactive leak were demonstrated with Valsalva manoeuvre. Intrathecal fluorescein was never administered due to associated neurological risks\(^\text{[19]}\).

Cribiform plate was the most common site of leak which accounted for about 86 % similar to many other articles\(^\text{[16,19,20, 21, 22]}\). The least common site of defect was lateral recess/ Sternberg’s canal which amounted to 1.5% of all the cases. 6 cases of congenital Meningoencephalocele treated during this time period had the defect anterior to the middle turbinate.

Many graft materials have been proposed for CSF leak repair in the literature. Fascia lata is the flap of choice in many\(^\text{[3,16]}\). We usually perform a 2-3 layer repair and our first choice of preference is Hadad flap. Additional Septal cartilage/ Middle turbinate flap\(^\text{[22]}\) are applied. Long standing and large defects are closed with fascia lata. Recently, for a defect of 1.5cm, a 5 layer closure was done using two layers of fascia lata, septal cartilage, Hadad flap and middle turbinate flap. Tissue glue is used to support the graft in all our cases\(^\text{[18]}\).

Many authors advocate continuous lumbar drainage after defect closure\(^\text{[14]}\). But we have observed that lumbar drain is required only for a high pressure leaks. This observation is supported by\(^\text{[18]}\).

We achieved a 98% success rate in the first attempt of defect closure. Many studies have had more than 90% success rates in the first attempt\(^\text{[16, 17, 20, 23]}\). The rest 2% were high pressure leaks, all of which were successfully closed in the second attempt\(^\text{[16, 17, 18]}\).

The duration of hospital stay has reduced with the endoscopic management. The mean hospital stay for our patients is 0.75 days. Most of the literature advises 5-6 days of hospital stay\(^\text{[3]}\). The pack is removed after 4-7 days.

The use of prophylactic antibiotic is always a matter of controversy with few in favour of it\(^\text{[14,18,19]}\) and few against it. We advocate prophylactic antibiotic for all the patients.

**CONCLUSION**

Transnasal endoscopic repair offers the highest success rate with minimal morbidity for a patient with cerebrospinal fluid leak. It gives excellent visualisation with precise graft placement. Our study of 400 cases is one of the largest studies regarding the subject. All the defects including those in the lateral recess as well as posterior table of frontal sinus can be operated on using endoscope. In our experience, Hadad flap gives very good results in defect closure. Multi-layered closure is advocated. Lumbar drain is required only for patients with high pressure leak. Our success rate of 98% in the first attempt and 100% in second attempt emphasises the effectiveness of this approach. Postoperative care is a very important factor in determining the outcome.

**DISCLOSURES:**
a) Competing interests/Interests of Conflict- None  
b) Sponsorships – None  
c) Funding - None  
d) Written consent of patient- taken  
e) Animal rights-Not applicable.

**HOW TO CITE THIS ARTICLE**


**REFERENCES**


INTERLAY MYRINGOPLASTY: HEARING GAIN AND OUTCOME IN LARGE CENTRAL TYMPANIC MEMBRANE PERFORATION

*Gaurav Kumar, **Ritu Sharma, ***Mohammad Shakeel, ****Satveer Singh Jassal

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ABSTRACT
Background: Chronic otitis media is an inflammatory process of the mucoperiosteal lining of the middle ear space and mastoid. The main aim of surgery of chronic ear disease is to eliminate disease process and to give the patient a dry safe and functioning ear. Interlay myringoplasty a newer technique has shown promising results with higher success rates than other conventional methods of myringoplasty. We aimed to study the hearing gain in terms of air bone gap and outcome of graft uptake.

Materials & methods: This is a prospective study of 18 months duration from January 2013 to June 2014 carried out in ninety (90) patients of chronic suppurative otitis media (CSOM) with large central perforation (more than 50% of tympanic membrane). All patients underwent through interlay myringoplasty after clinical examinations, audiometric tests & routine investigations. Patients were called for regular follow up for 16 weeks.

Results: Pre operatively mean air bone gap was 27.50±5.53 dB. Post operatively after 16 weeks mean air bone gap was 13.67±5.56. On last follow up at 16 weeks, maximum numbers of graft rejections were observed in 6 patients (6.7%). Success rate was 93.3%.

Conclusion: Myringoplasty is a safe and effective technique to improve the quality of life of patients. The interlay technique had a better graft take up and hearing improvement and also showed promising results in terms of limited follow up period and limited number of cases involved.

Keywords: Interlay, Myringoplasty, Air bone gap, CSOM.
1960[6], Inlay (Eavey, 1998)[7], Interlay (Komune et al., 1992)[8], Gelfilm Sandwich (Karlan, 1979)[9], Swinging Door (Schwaber, 1986)[10], Triple C (Fernandes, 2003)[11], Double breasting (Juvekar, 1999)[12], Anterosuperior anchoring (Huang et al., 2004)[13] and Laser assisted spot welding (Eocudero et al., 1979)[14] techniques.

Although different types of grafts such as autogenous, homologous and allografts have been attempted for performing Myringoplasty but temporalis fascia graft remains the mainstay of almost all the procedures of Myringoplasty having advantages of its physiological similarity with tympanic membrane (Sheehy, 1973)[15]. It can be easily obtained from the operative field, survives longer and is resistant to infections also.

Although each technique is improvised version of the other technique yet the choice of technique is mostly dependent on the surgeon’s familiarity with the particular procedure. No doubt, in such a scenario, it is difficult to claim the relative superiority of a single technique.

Out of the myriad of various myringoplastic procedures in Interlay technique the graft is placed between inner endothelial layer and middle fibrous layer of tympanic membrane. From the point of view of access, Interlay technique is also considered to be better as getting an interlay plane (between the fibrous layer and mucosa) is easier and faster. Moreover, it has no fear of residual epithelium. The Interlay myringoplasty approach has shown promising results with success rates higher than 90% (Komune et al., 1992; Guo et al., 1999; Vishal, 2006; Hay and Blanshard, 2014)[8,16,17,18].

AIM & OBJECTIVES:

To assess Interlay myringoplasty procedure in cases of chronic suppurative otitis media with inactive mucosal disease in large central perforation. This aim was fulfilled with the help of following objectives:

1. Hearing gain in terms of air bone gap.
2. Outcome of graft uptake.

MATERIALS & METHOD:

This is a prospective study of 18 months duration from January 2013 to June 2014 on ninety (90) patients of chronic suppurative otitis media (CSOM) with large Central perforation (more than 50% of tympanic membrane) (Fig. 2) in the age group of 16 - 49 years conducted in Era’s Lucknow Medical College & Hospital (ELMCH). Ethical committee approval had been taken.

Relevant information regarding chief complaints, clinical findings, routine blood investigation, Pure tone audiometry (PTA) and X-ray mastoid, examination under microscope (EUM) along with diagnostic nasal endoscopy (DNE) were collected from the individual patients. Only those patients diagnosed as chronic suppurative otitis media with inactive mucosal disease and suitable for myringoplasty on the basis of inclusion and exclusion criteria were enrolled.

Patient included were cases of safe CSOM with pure conductive hearing loss, age ranging from 16-49 years of both male & female, having dry ear (no discharge for at least four weeks) and patients with all follow-up of 4 months.

Patient excluded from the study were patients with active foul smelling discharge, vertigo, tinnitus, granulation or cholesteatoma, those having Sensorineural hearing loss or mixed hearing loss, cases with tympanosclerosis, revision or combined procedures (mastoidectomy and ossiculoplasty), any deformity or congenital anomaly of external ear, unusual infections such as Malignant otitis externa and complication of chronic ear diseases (Meningitis, Brain abscess, Lateral sinus thrombosis), active focus found in the nose, sinuses or throat. Patients with inadequate follow up were excluded from the study.

Pre-operatively all patients had a pure tone audiogram with an average of four frequency (0.5/1/2/4 kHz) calculated for both air conduction and bone conduction. Post-operatively a pure tone audiogram using (0.5/1/2/4 kHz) was performed at 4 months (last) follow-up. Tuning fork tests should be done on all patients to confirm the audiologic findings.

Interlay myringoplasty in all cases was carried under general anesthesia (GA) by same surgeon. Post auricular approach was used and temporalis fascia used as a graft material in every case. Karl-Zeiss operating microscope was used in all surgeries using proper magnification.

(Fig 1). Postauricular region and four quadrants of the cartilaginous external auditory canal were injected with 2% lidocaine with 1:100,000 epinephrine solution.
for vasoconstriction. The auricle and external auditory canal was flushed with povidone-iodine [Betadine] solution and then sterile saline.

A postauricular Wilde’s incision was made about 3 mm behind the postauricular crease using a 15 No. scalpel blade. Temporalis fascia graft was harvested. Periosteal flap was elevated.

After meatotomy Mollison’s self retaining haemostatic mastoid retractor was applied. Margins of the remnant tympanic membrane were freshened. Vascular strip incision given and tympanomeatal flap was elevated. In Interlay technique fibro-squamous layer the remnant tympanic membrane along with the annulus was elevated leaving behind the mucosal layer and the temporalis fascia graft was placed between fibrous layer and the endothelial (mucosal) layer the drum remnant (Fig 3). Very few gelfoam pledgets soaked in an antibiotic ear drop solution, placed in middle ear cavity. The ear canal was packed with gelfoam pledgets soaked in an antibiotic ear drop solution. The periosteal incision was closed with 3-0 absorbable suture (Vicryl). The postauricular incision is approximated with absorbable suture in an interrupted simple fashion using a subcuticular closure. A cotton ball is placed in the meatus and a mastoid dressing is applied. On the day of surgery patient was kept on IV antibiotics (Ceftriaxone) and analgesics.

Patients were discharged on the next day of surgery with same mastoid dressing. They were advised oral antibiotics for 2 weeks (amoxycillin-clavulanic acid) thrice a day along with oral antihistamine (levocetrizine 2.5mg) and diclofenac sodium 50 mg given twice a day. Mastoid dressing stitches were removed on 7th postoperative day and endomeatal cotton was also removed. After this Antibiotic ear drop containing ofloxacin and dexamethasone were started and continued for next 3 weeks.

Follow Up of the patients done weekly in first operative month, biweekly for next two month followed by final visit after four month. At every follow up patients were examined under ear microscopy (EUM) to assess the graft uptake and complication (if any) at every follow up visit. In the last follow up visit pure tone audiometry (PTA) was done and compared with pre operative air bone gap to evaluate the hearing improvement.

Change in Hearing Status: For the purpose of evaluating the change in hearing status, the following criteria were used: AB Gap of:
1. 0 to 20 dB - Successful
2. >20 dB/Graft rejection – Failure

Results were tabulated and statistical analysis was done using statistical software. Paired t test was applied
for the statistical analysis of pre-operative and post-operative air-bone gap. Comparison in various groups was done by using two sample t test for proportion.

RESULTS:
The study was carried out on ninety patients at ELMCH, Lucknow in the period from January 2013 to June 2014. The minimum age of a patient in the study was 16 years and the maximum was 49 years. Preoperatively air bone gap ranged from 20 to 35 dB. Out of total ninety patients 50% had air bone gap of 30 dB or more, 26.7% had air bone gap of 25 dB and 23.3% had air bone gap of 20 dB. Mean air bone gap was 27.5 dB. (Table 1)

Post operatively on 28th day, fourth follow up maximum number of graft rejections were observed in six (6) patients (6.7%) while graft accepted in eighty four (84) patients. (Table 2) Majority of cases had air bone gap within 20 dB (86.7%), 25 dB (10%) and 30 dB (3.3%). Mean air bone gap was 13.67 ± 5.56. (Table 3) The significant mean reduction in air bone gap was observed. Statistically, difference in reduction in air bone gap was significant (p < 0.0001). (Table 4) Success rate was 93.3%. (Table 5)

Table 1: Shows Pre Operatively air bone gap

<table>
<thead>
<tr>
<th>Parameter/Variable</th>
<th>Interlay Myringoplasty (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
</tr>
<tr>
<td>≤20 dB</td>
<td>21</td>
</tr>
<tr>
<td>21-25 dB</td>
<td>24</td>
</tr>
<tr>
<td>26-30 dB</td>
<td>24</td>
</tr>
<tr>
<td>31-35 dB</td>
<td>21</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>27.50±5.53</td>
</tr>
</tbody>
</table>

Table 2: Shows Graft rejection at fourth follow up (28 days)

<table>
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<tbody>
<tr>
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<td>No.</td>
</tr>
<tr>
<td>Graft rejection</td>
<td>6</td>
</tr>
</tbody>
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Table 3: Shows Post Operatively air bone gap at last follow up (16 weeks)

<table>
<thead>
<tr>
<th>Parameter/Variable</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>≤10 dB</td>
<td>51</td>
</tr>
<tr>
<td>11-15 dB</td>
<td>27</td>
</tr>
<tr>
<td>16-20 dB</td>
<td>0</td>
</tr>
<tr>
<td>21-25 dB</td>
<td>9</td>
</tr>
<tr>
<td>26-30 dB</td>
<td>3</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>13.67±5.56</td>
</tr>
</tbody>
</table>

Table 4: Shows change in air bone gap in last follow up (16 weeks)

<table>
<thead>
<tr>
<th>Group</th>
<th>Preoperative</th>
<th>Post-operative</th>
<th>Change</th>
<th>Significance of change (Paired t-test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Interlay Myringoplasty</td>
<td>27.50±5.53</td>
<td>13.67±5.56</td>
<td>-13.83</td>
<td>8.88</td>
</tr>
</tbody>
</table>

Table 5: Shows Outcome of graft uptake at last follow up (16 weeks)

<table>
<thead>
<tr>
<th>Parameter/Variable</th>
<th>Interlay Myringoplasty (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
</tr>
<tr>
<td>Failed</td>
<td>6</td>
</tr>
<tr>
<td>Successful</td>
<td>84</td>
</tr>
</tbody>
</table>

Table 6: Success rate for Interlay Technique (Graft take) as reported in different case series.

<table>
<thead>
<tr>
<th>SN</th>
<th>Author (Year)</th>
<th>No. of cases</th>
<th>% Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Komune (1992)</td>
<td>69</td>
<td>94.2</td>
</tr>
<tr>
<td>2</td>
<td>Guo et al. (1999)</td>
<td>59</td>
<td>96.2</td>
</tr>
<tr>
<td>3</td>
<td>She et al. (2008)</td>
<td>30</td>
<td>87.5</td>
</tr>
<tr>
<td>4</td>
<td>Hay and Blanshard (2014)</td>
<td>116</td>
<td>91</td>
</tr>
<tr>
<td>5</td>
<td>Patil et al. (2014)</td>
<td>100</td>
<td>96.0</td>
</tr>
<tr>
<td>6</td>
<td>Present study (2016)</td>
<td>90</td>
<td>93.3</td>
</tr>
</tbody>
</table>
DISCUSSION:

Chronic suppurative otitis media (CSOM) is the result of an initial episode of acute otitis media and is characterized by a persistent discharge from the middle ear through a tympanic perforation. It is an important cause of preventable hearing loss, particularly in the developing world. According to a WHO report, India is amongst the nations with highest burden of CSOM (WHO, 2004)[19].

Tympanoplasty and/or Mastoidectomy are frequently necessary to permanently cure CSOM and rehabilitate hearing loss patients. These procedures are readily available in tertiary centres with an otologic department, a standard service in all developed countries and is also recommended in national programme for deafness in our country. Tympanoplasty involves closure of the tympanic perforation by a soft tissue graft with or without reconstruction of the ossicular chain. Mastoidectomy involves removing the mastoid air cells, granulations, cholesteatoma and debris using bone drills and microsurgical instruments. Sequential destruction of the malleus, incus and stapes requires progressively more medially placed tympanic grafts. The extent of damage to the ossicular chain determines the specific types of tympanoplasty; Tympanoplasty is classified as type I, II, III, IV and V. Among these, Type-I Tympanoplasty or Myringoplasty is the simplest operative procedure performed to repair the perforation in ear drum by repairing the tympanic membrane only. It is performed when only except for ear drum, the entire ossicular chain is intact (Wullstein, 1953)[20]. Myringoplasty is a beneficial procedure to protect the middle ear and inner ear from future deterioration and also gives improvement in hearing after surgery[21].

Although myringoplasty involves simple closure of tympanic membrane, however, there are at least a dozen approaches to perform this procedure such as Underlay, Overlay, Inlay, “Gelfilm Sandwich”, “Swinging Door”, Triple “C”, Double breasting, Anterosuperior anchoring and Laser assisted “spot welding”. Among these for the last few years, a newer technique Interlay is gaining popularity and is being successfully used with promising results.

For this purpose, a total of ninety patients of chronic suppurative otitis media with inactive mucosal disease in large central perforation were enrolled in the study. Selection of inactive mucosal disease was done because active disease might have active infection which might confound with the results. Temporalis fascia was used as a graft material because it is easy to take; large surface area is available, has a low metabolic rate and does not require special preparation[22,23].

Pre-operative air bone gap ranged from 15 dB to 35 dB with a mean value ranging from 27.50±5.53. All the patients had unilateral disease and having air bone gap indicating fair to poor hearing status, thus indicating the need for surgical intervention for all the patients.

In all the cases, a unilateral procedure was performed. Total 6 (6.7%) rejections took place and all of them within 14 days. No new rejection took place in subsequent follow up period up to 16 weeks after surgery. Not any other complication noticed in any of the patient during follow up period.

On evaluating the air bone gap at final follow up interval was observed to be 10 dB in majority of cases (56.7%). Mean air bone gap 13.67±5.56 dB (Table 3). Eventually, the success rate was 93.3%.

The results of Interlay technique were in close proximity with the results obtained by Komune et al. (1992)[8] who observed a success rate of 94.2% for Interlay technique. Interlay technique reportedly has a high success rate. A comparative account of success rate for interlay technique as reported in various studies is shown in Table 6.

It could be seen that all the studies, including the present study the success rates for Interlay technique have been quite promising, generally above 90%. The better graft take in Interlay method is that it provides support to graft from both the sides.

However, given the number of studies and result of Interlay myringoplasty, we find that it is not as much popular. The reason for its lower popularity is that it requires additional skill and it time consuming. Preparation of margins for interlaying and tactical positioning of the graft needs precise handling and manipulation of the graft and hence they are generally attempted in a setup with adequate technical and physical infrastructure.

As far as air bone gap resolution is concerned, the results shown are variable in different studies for different techniques. However, Patil et al. (2014)[24] in
their series of 100 cases who were approached using Interlay method showed a phenomenal reduction in air bone gap from a pre-operative mean value of 36.42±12.0 dB to 9.7±6.71 dB, thus showing a reduction of almost 26.72 dB.

In accordance with the observations in these studies, we found post-operative air bone gap up to 10 dB in majority (56.7%) of cases. A better air bone gap reduction in Interlay method is mainly possible owing to its better conductive efficacy. Owing to the flap's position between two interlaying layers the frequency loss is controlled and that is the reason for a better conduction and reduced air bone gap. There is also no risk of lateralization or medialisation of the graft due to well supported by fibro-squamous layer laterally and mucosal layer medially. The findings in present study showed a better graft take in Interlay method which coupled with a better post-operative air bone gap provided a better overall outcome. As compared with other method of myringoplasty Underlay technique shows in previous studies of outcome of 85.7% in Guo et al (1999)[16], 88.8% in Crovetto et al (2000)[25], 87% in Ullah et al (2008)[26], 81% in Sheikh et al (2009)[27], 88.6% in Baloch et al (2012)[28] and 90% in Sharma & Saroch (2013)[29] respectively. While Overlay technique in previous studies shows outcome of 55% in Ullah et al (2008)[26] and 74.4% in Rehman et al (2011)[30].

CONCLUSION:
Myringoplasty is a safe and effective technique to improve the quality of life of patients, avoiding continuous infections and allowing them contact with water. The present study showed that although Interlay technique requires additional expertise in surgery it gives better graft uptake and hearing improvement. Above findings in present study substantiate the results obtained in some recent studies. However, there is paucity of comparative literature on the issue.

The advantage of Interlay myringoplasty is that neither lateralization of tympanic membrane nor blunting of the anterior tympanomeatal angle was observed. This means lower complications and thus Interlay myringoplasty is an effective surgical technique over conventional methods for closure of perforation and hearing gain (audiological improvement) in large central tympanic membrane perforation in cases of chronic suppurative otitis media (CSOM) with inactive mucosal disease.

DISCLOSURES:

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- Sponsorships – None
- Funding - None
- Written consent of patient- taken
- Animal rights-Not applicable.

HOW TO CITE THIS ARTICLE

REFERENCES:

17. Vishal US. A one-year prospective study to evaluate the results of superiorly based tympanomeatal flap in endoscopic myringoplasty conducted in District Hospital, Belgum and KLES and MRC, Belgaum during July 2003 to July 2004. Dissertation, MS (ENT), 2006, RGUHS, Karnataka.
ABSTRACT
Background: Oral submucosal fibrosis (OSMF) is described as a swelling within the oral cavity and throat with burning, pricking, pain, hemorrhage, putrid and necrosed muscle. Reduced mouth opening can result from trismus as in case of OSMF. Coronoidectomy holds an importance in management of OSMF by enhancing the mouth opening.
Aims and Objectives: To evaluate the effectiveness of coronoidectomy with buccal pad fat in advanced stages of Oral Submucosal Fibrosis (OSMF).
Material and Methods: An observational study comprising of twenty cases of oral submucosal fibrosis (OSMF) histopathologically proven as well as surgically treated had been carried out from December 2014 to September 2016, in the Otorhinolaryngology department of Hi-tech Medical College & Hospital, Bhubaneswar, Odisha, India.
Results: As a result of a successful surgical procedure, the size of the intraoperative mouth opening range after carrying out the coronoidectomy their mouth opening was almost 40 – 42 mm on the OT table. The patients were discharged 5-7 days after the operation. The range of the mouth opening measured at that time was 20-30 mm. The pedicled grafts took uneventfully and epithelialized in 3-4 weeks. The remaining patients did cooperate and exercised daily, and the postoperative mouth-opening range at six months was 26-43 mm (mean: 40.5 mm).
Conclusion: Coronoidectomy with buccal pad of fat is an effective adjunct in increasing intraoperative and stabilizing postoperative mouth opening.
Keywords: Oral Submucosal Fibrosis (OSMF), Buccal pad fat, coronoidectomy.

INTRODUCTION
Oral submucosal fibrosis (OSMF) has been well established in Indian medical literature since the time of Sushruta. In Sushruta Samhita, it is described as a swelling within the throat with burning, pricking pain, hemorrhage, putrid and necrosed muscle and caused by “pitta” known as vidari, occurring in mouth, particularly in the side by which patient lies [1]. It was first described by Schwartz [2] and has been reported almost exclusively across all socioeconomic status in India as a result of increased popularity of the habit of chewing pan masala, betel leaves and other similar products.
Reduced mouth opening can result from trismus as in case of OSMF, where accumulation of inelastic fibrous tissue in the juxta epithelial region results in stiffness of oral mucosa. In addition to this, subsequent muscle degeneration leads to fibrosis and scarring of temporalis muscle, further enhancing the limitation in
In the management of OSMF, coronoidectomy plays an important role in increasing mouth opening. Canniff et al recommended temporal myotomy or coronoidectomy to release severe trismus caused by the atrophic changes in the tendon of temporalis muscle secondary to the disease. Thus, coronoidectomy holds an importance in management of OSMF by enhancing the mouth opening. Apart from this, if buccal pad of fat/facial flap are used alone, there is scarring of the muscle, limiting mouth opening unless an ipsilateral or bilateral coronoidectomy is performed.

The present study was therefore undertaken to assess the benefits of coronoidectomy with buccal fat pad reconstruction in mouth opening in twenty patients by achieving a stable mouth opening with minimum morbidity in the treatment of OSMF.

**MATERIAL AND METHODS:**

After ethical approval, an observational study comprising of twenty cases of oral submucosal fibrosis (OSMF) histopathologically proven as well as surgically treated had been carried out from December 2014 to September 2016, in the Otorhinolaryngology department of Hi-tech Medical College & Hospital, Bhubaneswar, Odisha, India. Informed consent was obtained and 20 patients clinically diagnosed as grade III / IV OSMF scheduled to underwent elective surgery entailing coronoidectomy with buccal pad fat reconstruction. The defects in the buccal area were grafted with a pedicled BFP under general anesthesia with nasal intubation followed by vigorous mouth opening exercises. Patient evaluation included: 1) the preoperative amount of mouth opening [Table 1], 2) the intraoperative mouth opening; and 3) the postoperative mouth opening. The results were evaluated using the interincisal distance at maximum mouth opening as the objective outcome over a follow-up period of 6 months [Table 2]. Of the twenty patients 3 were females and 17 were males. Non of the patients previously treated for OSMF. The mouth opening measured as the interincisal distance was ranging between 4-22mm with a mean of 15.

The operations were performed under general anesthesia with nasal intubation. The incisions were made with an electrosurgical knife along each side of the buccal mucosa at the level of the occlusal plane away from the Stenson’s orifice (Fig-1). They were carried posteriorly to the pterygomandibular raphe or anterior pillar of the fauces and anteriorly as far as the corner of the mouth, depending upon the location of the fibrotic bands which restricted the mouth opening. These fibrotic bands were always detectable by palpation. The wounds created were further freed by manipulation until no restrictions were felt. The mouth was then forced open with a mouth opener or Heister’s mouth gag to an acceptable range of approximately 35

<table>
<thead>
<tr>
<th>Case No</th>
<th>Age/Sex</th>
<th>Maximum Mouth Opening (mm)</th>
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<tr>
<td>1</td>
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<td>20</td>
<td>22/M</td>
<td>58</td>
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</tbody>
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Table 1

Fig.1 Showing pre and per operative pictures
to 40 mm. The coronoid processes were approached from the wounds created and resected if a 35-40mm mouth opening could not be achieved. Coronoid was held with Kocher’s forcep and the osteotomy cut was made extending from the depth of sigmoid notch to anterior border of the ramus. After completion of osteotomy the coronoid was placed on traction with Kocher’s forcep, remaining temporalis muscle and tendon attachments were cut facilitating removal of coronoid.

After unilateral coronoidectomy, mouth opening was recorded followed by bilateral coronoidectomy and recording of maximum mouth opening. Fergussion mouth gag was applied to record achieved maximum mouth opening. A mouth opening of 35 mm as measured from the incisor edges was considered to be the minimum acceptable opening in an adult. The BFP was approached via the posterior-superior margin of the created buccal defect, and then dissected with an index finger. The BFP was teased out gently until a sufficient amount was obtained to cover the defect without tension. The Buccal fat pad (BFP) was then harvested bilaterally and sutured to the mucosal defect with 3-0 vicryl suture. The remaining defect was left for secondary epithelialization.

Postoperatively patients were put on Ryle’s tube feeding for 1 week. All patients received prophylactic antibiotics and a liquid diet for 1 week. Physiotherapy was started from 3rd postoperative day with the help of Heister’s jaw exerciser and wooden spatulas to prevent contractures and relapse. Patients were trained and encouraged to continue these exercises at home three to four times a day for 15 min each. Every patient was followed-up postoperatively at regular intervals till at least 6 months.

RESULTS AND OBSERVATION:

As a result of a successful surgical procedure, the size of the intraoperative mouth opening ranged from 40 to 42 mm. However after carrying out the coronoidectomy their mouth opening was almost 40 – 42 mm on the OT table. The patients were discharged 5-7 days after the operation. The range of the mouth opening measured at that time was 20-30 mm. The pedicled grafts took uneventfully and epithelialized in 3-4 weeks. Two patients (cases 5 and 9) failed to exercise several times daily, and finally experienced a significant relapse. The remaining patients did cooperate and exercised daily, and the results were satisfactory

DISCUSSION:

Submucous fibrosis is an insidious, chronic disease which may affect any part of the oral cavity and sometimes the pharynx, leading to stiffness of the oral mucosa, and causing trismus [7,8]. This disease is most frequently found in India, and is not uncommon in Southeast Asia. It has also been reported from other countries, and it is no longer considered to occur exclusively in Indians and Southeast Asians, as immigration has resulted in a worldwide distribution. Betel nut chewing appears to be the main factor correlating with this disease. Most patients complain of an irritable oral mucosa during the early stage of the disease, especially when spicy foods are eaten. Clinically, there are erosions and ulcerations. Subsequently, the oral mucosa becomes blanched and loses its elasticity, and vertical bands occur in the buccal mucosa, the retromolar area, the soft palate, and the pterygomandibular raphe. A fibrotic ring forms around the entire rima oris. Some patients have difficulty in whistling and tongue movement.

The literature contains few references to the successful treatment of OSF. Various treatments to improve mouth opening have been attempted, including surgical elimination of the fibrotic bands but have been reported as generally unsatisfactory or impossible [9,10]. Yen was the first to succeed in covering the buccal defect with a split thickness skin graft in treating a case of OSF [11]. Khanna & Andrade recently reported the new surgical technique of covering the buccal defects with a palatal island flap in combination with temporalis myotomy and coronoidectomy [15]. They had applied it to 35 patients with good results.
The main mass of the BFP occupies the buccal space bound medially by the buccinator muscle and laterally by the masseter muscle, and rests on the periosteum that covers the posterior buccal aspect of the maxilla. The BFP has a constant blood supply through the small branches of the facial artery, the internal maxillary artery, and the superficial temporal artery and vein by an abundant net of vascular anastomoses. On an average, the volume is 9.6 cc (range 8.3-11.9 cc). Defects up to 3x5 cm can be closed with a BFP alone without compromising the blood supply. The buccal extension and the main body of the fat pad are in close proximity to the buccal defect, and may be approached through the same incision. In addition, the buccal fat pad pedicled flap can cover the whole surgical defect. The BFP also improves the physiologic functions of the cheek after the operation; e.g., suppleness and elasticity. With this technique, there is no need for a second operation site. The pedicled BFP graft is well vascularized and is more resistant to infection than other kinds of free graft. Therefore, normal eating can begin after the surgical treatment. Patients can be discharged 5-7 days after the operation.

Early and intensive postoperative mouth opening exercises are very important to achieve adequate mouth opening afterward. These exercises should be started as early as possible. The mouth opening showed progressive improvement and became maximum within six months with a mean of 40.5 mm [Table-3]. And throughout this period it was ensured that the patients had continued with active aggressive mouth opening exercises. The grafted BFP became rigid from fibrotic change. Routine temporalis myotomy, and coronoidectomy. Clinically the Buccal mucosa appeared normal, retaining its texture without any signs of fibrosis. The softness and elasticity of the buccal tissue had improved. Symptoms such as painful ulceration, burning sensation, and intolerance to spices had been eliminated in most patients.

**CONCLUSION:**

Coronoidectomy with buccal fat pad (BFP) is an effective adjunct in increasing intraoperative and stabilizing postoperative mouth opening.
ABSTRACT

Background: Phonomicrosurgery is a challenging and evolving field. One of the key techniques used for this is micro-flap technique used along with cold micro instruments.

Objective: To convey the role of Microflap technique in phonosurgery and the role of basic microlaryngeal instrumnets in such surgery when sophisticated phonomicrosurgical instruments are not available.

Methods: This is a retrospective study of 33 patients of benign vocal fold lesions who have undergone phonomicrosurgery using micro flap technique from the year January 2011 to January 2016. Majority of these cases were vocal nodules (16 cases) followed by Cyst in the vocal cord (10 cases) and 5 cases of polyps.

Results: Cases were analyzed using GRBAS scoring and stroboscopic findings. A significant improvement was noted in the voice outcome of these patients except two cases where endoscopic paraglottic fat injection was done along with hyaluronic acid with steroid infiltration into the Reinke's space, after which there was improvement in voice.

Conclusion: Microflap technique for vocal fold lesion is a unique surgical procedure that allows preservation of vocal cord morphology and at the same time prevents post surgical scarring with excellent voice outcome. This surgery can be performed with good quality regular microsurgical instruments.

INTRODUCTION

Phonomicrosurgery is a challenging and evolving field. The term phonosurgery was first described by G E Arnold & V H Leden with an intent to improve and/or restoration of voice.[1] The credit of injection laryngoplasty goes to Bruenning (1911) for treating a paralyzed vocal cord.[2] The phonomicrosurgery was developed as a model of consistent vocal cord vibration based on Body (Deep lamina propria & Muscle) and Cover (Epithelium & superficial lamina propria) concept (Fig.1) that can vary to different circumstances of laryngeal adjustment (Hirano 1974).[3] Kirstein introduced the concept of direct laryngoscope in the form of autoscope in 1895[4] and Kleinsausser's development of suspension micro-laryngoscope used in conjunction with microscope in 1960 that has revolutionized the principle of microlaryngeal surgery including phonomicrosurgery.[5] Use of general anesthesia through endotracheal tube during microlaryngoscopy was introduced by Priest (1960)[6]. Since then various laryngoscopic developments have

Affiliations:
†Professor, ‡Associate Professor, ††Resident, †‡Department of ENT-Head & Neck Surgery, Kasturba Medical College, Manipal University, Manipal.
††Department of Speech and Hearing, College of Allied Health Science, Manipal University, Manipal.
Presented at the 2nd SARC International Conference and 5th Annual conference of Laryngology and Voice Association, from 30th Sep.- 2nd Oct, 2016 at Ahmedabad in How I Do It – Video session by Prof. Dipak Ranjan Nayak as a faculty.

Address of Correspondence:
Prof. Dipak Ranjan Nayak,
Department of ENT-Head & Neck Surgery,
Kasturba Medical College, Manipal University,
Manipal-576104, Karnataka, India
Email: drnten@gmail.com
taken place for better and comfortable visualization\(^7\). Bouchayer M & Cornut G (1992) introduced the microflap technique in France for benign laryngeal lesions\(^8\). The term “phonomicrosurgery” was first used by Zietels in 1994 to describe the importance in preservation of the vocal cord epithelium and its superficial lamina propria\(^9\). Microflap techniques was further refined to a mini microflap technique by Satalof etal, in 1995\(^10\). Thus the concept of lateral (larger lesions like reinke’s edema) and medial microflap technique developed\(^11,12,13\). In India, Phaneendra Kumar and Nerukar have popularized the phonosurgery\(^14, 15\). Nerukar has also popularized the microflap technique in India by using hydro-dissection with cold instruments\(^14\).

There are various array of cold instruments (good quality micro knife, sickle knife, micro-scissors of various angles, angled elevators and spatula, straight and angled dissector, different angled fine and curved micro-scissors, angled heart shaped grasping forceps, curved alligator forceps, sharp right handle hook, vascular knife, fine laryngeal suction cannula etc.) are available for phonomicrosurgery using microflap technique. The 1st author has adopted the routine microlaryngeal cold instruments (microlaryngeal right and left curve angle, micro -cup forceps, fine micro-suctions, 18 and 23 gauge needles for fitting into suction cannula for injection/ infiltration) to perform such surgeries as most of these phono-microsurgical instruments are not available in teaching centers across India. Usage of cold instruments remains the foundation for phonomicrosurgery. Benign lesions are best dealt with cold instruments especially when micro-flap technique is used. The authors would like to convey the readers that one should never resort to plucking of vocal cord lesions or excise them at the cost of normal mucosa and underlying lamina propria of vocal cord with scissors. A phonomicrosurgery with microflap technique can well be done with basic good quality micro-laryngeal instruments as the author has adopted in this series.

**MATERIALS AND METHODS:**

A total of 33 patients having benign vocal fold lesions, who have undergone phonemicrosurgery with microflap technique in the Unit-1 of the department of ENT-HNS from January 2011 to January 2016 were taken for the study retrospectively. All the patients were operated by the 1st author. Amongst the 33 patients, 8 were females and 25 were males. Informed consent was taken from the entire patients regarding surgery and vocal outcome. The entire patients underwent pre-operative counseling. The lesions included 16 cases of vocal cord nodules, 12 cases of vocal cord cysts and 5 cases of unilateral hemorrhagic polyps out of which pre-op and post-op GRBAS scoring analysis was available for 21 patients (10 cases of vocal cord nodules, 6 cases of vocal cord cysts and 5 cases of vocal cord polyps). Pre & Post operative video telescopy & videostoboscopy findings were available in all the 33 cases. The speech therapy was started 2 weeks post-operatively for all cases. Patients having benign vocal fold lesions in which microflap technique was not used or removed traditionally due to technical problems, were excluded from this study.

**Surgical Technique:**

Patient is kept in a supine position with neck flexed and extension of atlanto-occipital joint as done in routine microlaryngoscopy, using a pillow under the shoulder. It is necessary to chose appropriate size and type of laryngoscope to achieve optimum exposure of vocal cord. Sometimes assistant’s help is crucial especially for short neck and obese patient. The key to phonomicrosurgery is hydro-dissection and decongestion. Subepithelial infiltration of normal saline with 1 in 2,00,000 epinephrine into reinke’s space lifts the lamina propria off the vocal ligament. A superficial cordotomy was performed by placing incision just lateral to the lesion with an angled scissors opposite to...
the cord, i.e. a left angle scissors for right side vocal cord and vice versa instead of a micro-laryngeal knife. The author adopted the left/ right angled curved micro-scissors for giving incision, raising microflap as well as dissection of the vocal cord lesions from the bed. A small cotton ball soaked with epinephrine was often used to dissect further. Precise dissection helps further separation of the cyst from the bed and is then removed (Fig. 2 & 3). Microlaryngeal cup forceps/ alligator forceps were used to retract the microflap during dissection. The cup forceps help in blunt dissection. The lesions like vocal nodule (Singer’s nodule) were removed precisely without disturbing the lamina propria with mucosal preservation (Fig. 4). The sessile polyps are removed in similar way and the redundant mucosa is resected precisely. The dissected bed was applied hyaluronidase injection mixed with steroid solution to prevent scarring and fibrosis. After completing the removal of the lesion microflap was draped back in situ. In case a cyst gets ruptured the entire cyst wall needs to be removed or else to be removed traditionally with scissors. In case of residual phonatory gap due to cord atrophy following long standing large polyp removal, fat injection was done using 18 gauge disposable needles attached to the suction cannula into the paraglottic space and additional infiltration of hyaluronidase with steroid into the

Fig.2: a. After incision just lateral to polyp margin, b. Raising of medial microflap using curved micro scissors, c. Showing cyst being almost dissected out before removal, d. Re-draping of microflap after removal

Fig.3: a. Showing a large cyst on the left vocal cord in a patient with sulcus vocalis, b. Microdissection of cyst after raising and retracting the microflap with fine cup forceps, c. Showing vocal ligament with a thin cover of lamina propria after complete removal of cyst. d. Draping of the microflap insitu.

Fig.4: a. Showing infiltration of left vocal cord in case of singers nodule, b. Raising of medial microflap after giving the incision just lateral to the lesion, c. Blunt dissection of sub-epithelial nodule from the vocal ligament, d. Showing the sub-epithelial collection between the micro flap and vocal ligament, e. After removal on the left side, the microflap is raised and retracted on the right vocal cord and sub-epithelial dissection is being done, f. After complete removal of the vocal cord nodule
reinke’s space was carried out (Fig.5). All the patients were kept on voice rest for two weeks. Postoperatively patients were kept on anti reflux measures. Budesonide

200 micrograms inhaler at a dose of 2 puffs once a day for one month was advised post operatively.

**OBSERVATION AND RESULTS:**

Results were analyzed with pre and post-operative GRBAS scoring (Fig.6) and stroboscopic findings (Table-I). An auditory-perceptual evaluation method for hoarseness is the GRBAS scale (G – Grade, R – Roughness, B – Breathiness, A – Asthenicity, S – Strain) of the Japan Society of Logopedics and Phoniatrics, is simple and reliable (Hirano 1981[16,17]). It gives scores of 0, 1, 2, or 3 where 0 is normal, 1 is a slight degree, 2 is a medium degree, and 3 is a high degree[16]. Out of 21 cases analyzed, 17 patients had pre op “G” score of 3, 4 patients had score of 2; post operatively, 15 patients had score 0, 6 patients had a score of 1. Pre op scoring with respect to “R” was 3 and 2 for 13 and 8 patients; post op score was 0, 1, and 2 for 17 patients, 3 patients and 1 patient respectively. “B” scoring was 3, 2, and 0 for 14, 2 and 5 patients; post op score was 0, 1 for 17 and 4 patients respectively. Scoring for “A” was 3, 2, 0 for 11, 5, 5 patients pre operatively; 0, 1, 2 for 11, 7 and 3 patients respectively post operatively. Pre op score for “S” was 3, 2, 0 for 5, 12, 4 patients; post op score was 0, 1 for 15 and 6 patients respectively. Stroboscopic findings were analyzed as described by Stankovi et al (2008).

Out of 33 patients’ stroboscopic findings, 29 patients showed normal vocal cord mucosal wave pattern, 4 patients had irregular mucosa with disturbed vibratory pattern and 3 patients had phonatory gap out of which 2 patients underwent micro-endoscopic hyaluronic acid injection along with steroid infiltration into Reinke’s space and paraglottic fat injection (Table-I).

**DISCUSSION:**

Laryngology and phonosurgery is the most evolving subspeciality in the field of ENT-Head & Neck Surgery with tremendous practical advancement during
One of the key development of this speciality is phonomicrosurgery. Removal of vocal fold mass lesion by separating the superficial lamina propria from the lesion while preserving the mucosa for protecting the vibratory area of the vocal cord was the main idea in the development of microflap technique. Microflap technique is the cornerstone of phonomicrosurgery. It has revolutionized the surgical technique in the management of vocal cord pathology after the concept of body cover principle for vibration of vocal cord was recognized. Phonomicrosurgical techniques are planned to facilitate aerodynamic competence and vocal quality by creating a smooth vocal fold edge. As there is remote possibility of superficial lamina propria to regenerate after damage, utmost care needs to be taken while raising a large microflap for removal of vocal cord lesion. The microflap technique have been further divided into lateral and medial microflap techniques, the concept of which came in 1995 and 1997 by Courey et al from Vanderbilt University Medical Center. The lateral flap techniques are more suitable for reinke’s edema, larger lesions and vocal cord scarring where identification of vocal ligament becomes easy with this flap and has little risk of injury to vocal ligament, whereas medial microflaps reduces the injury to basal membrane complex. The medial microflap is most suitable for smaller lesions (like cysts, sessile polyps etc.) where post surgery scarring can be significantly minimized by reducing the exposure of vocal ligament and lamina propria. The medial microflap technique is mostly indicated for lesions situated on the medial aspect of the vocal cord, especially with a thinner mucosal cover and can be separated easily from underlying vocal ligament. Postoperative voice rest is important in facilitating healing and a period of two weeks helps collagen bridge formation for fixation of flap. The author applies hyaluronic acid along with steroid at the dissected site, after removal of the lesions following microflap technique to prevent post operative scarring. Hirano described the role of extracellular matrix component, including hyaluronic acid, atelocollagen to help regeneration of vocal cord mucosa.

CONCLUSION

This work is presented to emphasize that unscrupulous excision of vocal cord lesions can damage the vocal ligament causing scarring and can permanently derange the mucosal wave pattern with dismal voice outcome. Microflap technique can still be performed with good regular microlaryngeal instruments and can prevent permanent vocal cord damage. It is an excellent technique to preserve the crucial histological layers of the vocal cord described by Hirano (fig 1), including mucosa and lamina propria. Post surgery voice therapy is crucial in such cases.

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CASE REPORT

A RARE CASE REPORT:- INTACT EYE BALL IN MAXILLARY ANTRUM FOLLOWING TRAUMATIC INJURY TO RIGHT ORBIT

*Souvagini Acharya, **Debasis Jena ***Utkal P Mishra

ABSTRACT
Accidental impaction of foreign body in maxillary antrum is not uncommon, but finding an intact eyeball in maxillary antrum with intact orbital rim is very rare. We have reported a very rare case of intact eyeball in maxillary antrum of right side in a 42 year old male admitted in our Dept. Of ENT VIMSAR, BURLA, ODISHA. The diagnosis was confirmed by clinical examination and further by CT-Scan findings. After diagnosis was made the eyeball was repositioned back in to the orbit under general anaesthesia by Caldwell-Luc’s and infra-orbital approach. The defect of floor of orbit was repaired by iliac crest graft. Perception of light was negative before surgery which remained unchanged even after surgery on follow-up for 3month post-op, which may be due to delay in surgery due to late presentation to us, but the structural function of eyeball was preserved, giving a good cosmetic result to patient.

Key words:-Intact eyeball, maxillary antrum, Caldwell-Luc’s approach, infra-orbital approach, iliac crest bone graft.

INTRODUCTION
Fracture of orbital floor is the most common presentation following blowout fracture, but its presentation as, herniation of intact eyeball in to the maxillary antrum with intact orbital rim is a very rare presentation. The structure and function of the eyeball can be preserved if urgent surgery is done by keeping back the eyeball into the orbit with orbital floor repair, which can be done by combined Caldwell-Luc’s approach and infra-orbital approach. The eyeball along with orbital contents should be removed from the antrum immediately to preserve the function of eyeball as well as to prevent serious infection inside the antrum, if left inside antrum as such. The orbital floor defect should be repaired with iliac bone graft, nasal septal cartilage or graft taken from rib cartilage, to prevent further herniation of orbital content in to the antrum.

CASE REPORT:-
A 42 year old Hindu male from Bhawanipatna attended to our ENT OPD of VIMSAR, BURLA, Odishaon with the chief complaints of swelling of right maxillary antrum along with sudden loss of vision of right eye following trauma by horn of a cow since 5 days prior to attend this hospital.

5 days back following injury he was treated primarily at a local hospital then referred to Ophthalmology opd& admitted there on 10/8/15, again from there the patient was referred to our ENT Dept. and was admitted.

On general examination, patient was conscious, co-operative, and well oriented to time place and person, Temperature was 37°C, Pulse rate: 78 per minute, Blood pressure: 124/78 mm Hg in right arm supine position and Respiration rate: 16 breath per minute abdomino-thoracic, systemic examinations were with in normal limits.

On local examination, there was mildswelling over...
right maxillary area, on palpation there was no tenderness over maxillary antrum. There was loss of sensation along the distribution of infraorbital nerve on right side. On Anterior rhinoscopy, vestibules were normal, nasal mucosa of both nostrils were normal, nasal septum was in midline, nasal cavity on both sides were found to be free. On Posterior rhinoscopic examination of nasopharynx, choana was found to be free. Oral cavity, oropharynx were normal. On ocular examination there was swelling of both upper and lower eye lids of right eye (figure 2), which were tender to touch, inter palpebral fissure (IPF) was narrow in right eye (figure 2). Visual acuity was Negative on Right eye and normal on Left eye. Conjuctiva was congested and chemosed. Right eyeball was found to be absent from right orbit (figure 1). After admission contrast CT scan was advised to confirm diagnosis.

CT SCAN with CONTRAST showed: Pure orbital blow out fracture, Fracture of roof of maxillary antrum, whole of the intact eyeball inside Right maxillary antrum, Optic nerve seemed to be intact, Herniation of whole of right eyeball into the right maxillary antrum (Fig 4 A, 4B).

Patient was planned for surgery under general anaesthesia for repositioning of right eyeball into the orbit by Caldwell-luc’s approach and repair of the fracture of roof of the maxillary antrum by infra-orbital approach.

The patient was operated in ENT OT under general anaesthesia. Caldwell-Luc’s operation was done by giving a sublabial incision starting from 2nd incisor to 2nd molar on right side, peristomeum was elevated, an opening was made over canine fossa, after which maxillary antrum was reached (fig 5). Through antrum whole of the intact eyeball was pushed up into the orbit through the defect over roof of maxillary antrum (fig7).
After that an incision was given over lower eyelid margin, periosteum was elevated and roof of maxillary antrum was reached(fig 6). The eyeball which was already pushed up from maxillary antrum was repositioned manually into the orbit by ophthalmlogy surgeon(fig 7). The defect over roof of maxillary antrum was repaired by a graft taken from iliac bone(fig 8). On gross examination, eyeball was found to be intact, pupils appeared dilated, cornea was hazy. Optic nerve and extraocular muscles were found to be intact. Postoperatively, the patient had no light perception with restricted mobility of the eyeball of the right eye.

Fig-5: Caldwell-Luc’s approach
Fig-6 lower eye lid incision
Fig-7: Repositioned eye ball in to the orbit
Fig-8: Repair of the defect with iliac bone graft
Fig-9: postoperative

DISCUSSION
Zygomatic and Le Fort II fractures are always accompanied by fractures of orbital floor[3]. However, isolated fractures of orbital floor, is seen mainly when a large blunt object strikes the globe directly i.e. “orbital blow out fractures”, in which orbital rim remains intact with fracture of one of the walls of orbit. Soft tissues of orbit, such as extraocular muscles, ligaments, and orbital fat always herniates into the fracture hole, when there is a blow out fracture to the orbit[4-6]. However, complete dislocation of an intact globe into the maxillary antrum after an extensive blowout fracture is a rare incidence. In this case, a pure blow out fracture of the floor of the orbit occurred due to trauma by a cow horn with intact orbital margins, which resulted in the eyeball completely dislocated into the maxillary sinus. The floor of the orbit might be broken by an instant top-down force, which pushed the globe into the maxillary sinus[6-7]. Because the eyeball sank into the maxillary sinus, globe lesions could not be checked. Although CT scan with contrast indicated that the integrity of the globe was not impaired. However, contusion of the eyeball may result in anterior and central vitreous hemorrhage, lens dislocation, secondary glaucoma, optic nerve damage and other complications[8-11]. Urgent
surgery was done to reposition the eyeball in to the orbit, by combined Caldwell-Luc and Infraorbital approach, and the defect over the roof maxillary antrum was repaired by iliac bone graft\[1-3\]. After surgery the eyeball was saved and was structurally intact.

**CONCLUSION:-**

Traumatic dislocation of intact eyeball into the maxillary antrum with intact orbital rim is very rare. By doing urgent surgeries we can save the structure and function of eyeball. In our case the patients vision could not be preserved because of late presentation of patient to our OPD following trauma due to which surgery required for this was delayed, but the structural integrity of eyeball was achieved.

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