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A Clinical Study Of Myringoplasty Using Temporalis Fascia In KMCH, Katihar

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Abstract:
Background*: Chronic Otitis Media (COM) Is Defined As An Inflammatory Process In The Middle Ear Space That Results In Long-Term Or More Often Permanent Changes In The Tympanic Membrane Including Atelectasis, Tympanosclerosis, Retraction Pocket Development Or Cholesteatoma. In The Developing World, Chronic Otitis Media Is An Important Cause Of Preventable Hearing Loss. Mucosal Chronic Otitis Media (Tubotympanic COM) Encompasses Cases With Central Perforation In The Pars Tensa Of The Tympanic Membrane. Up To 80% Of These Perforations Heal Spontaneously And For The Remaining, Surgical Repair Is Required. The Current Surgical Management Of Tubotympanic COM Is Myringoplasty. The Present Study Aims To Assess The Success Rate Of Myringoplasty Using Temporalis Fascia And To Evaluate Preoperative And Postoperative Hearing Loss In Patients With Mucosal Chronic Otitis Media / Chronic Suppurative Otitis Media, Tubotympanic Disease (CSOM, TTD) Who Presented In Our Hospital.*
Materials And Methods*: In This Prospective Observational Study, 100 Patients With Clinical Features Of CSOM Tubo-Tympanic Disease With Perforation Of The Tympanic Membrane, Decreased Hearing And Long-Term Discharge With Age Limit More Than 11 Years Were Enrolled. Myringoplasty Was Performed By Grafting Temporalis Fascia Using The Underlay Technique. The Patients Were Discharged After 2 Days And Follow Up Was Carried Out Routinely At 7 Days, 2 Weeks, 6 Weeks, 12weeks And 6 Months. The Results Of Change In Hearing Level Were Compared With Preoperative Audiometric Values*
Results*: Ages Of The Subjects Ranged From 11 Years To 50 Years, Males Were 68% And Females Were 32%. X-Ray Mastoids (Law's Lateral Oblique View) Revealed Sclerotic Pattern In 29 Cases (29%) And Cellular Pattern In 71 Cases (71%). Aged 11-20 Years Had 96.3% Successful Closure Of Perforation, 21-30 Years Had 94.7%, 31-40 Years Has 85.7% And 41-50 Years Had 71.4% Successful Closure (P <0.05).*
Conclusion: *Myringoplasty Using Temporalis Fascia Is An Excellent Method For Surgical Closure Of The Perforated Tympanic Membrane. The Results Of Surgery In Terms Of Graft Uptake Were Numerically Better In Myringoplasty Using Temporalis Fascia. Most Successful Closure Of Perforation Was Seen In The Age Group 11 To 20 Years And In Patients With Cellular Mastoids.*
Key Word*: CSOM; Myringoplasty; Temporalis Fascia; Chronic Otitis Media; Hearing Loss.*

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I. Introduction

Chronic otitis media (COM) is defined as an inflammatory process in the middle ear space that results in long-term or more often permanent changes in the tympanic membrane including Atelectasis, Tympanosclerosis, Retraction pocket development or Cholesteatoma. This results from long-term eustachian tube dysfunction with poorly aerated middle ear space, multiple bouts of Acute otitis media or persistent middle ear infection[1]. In the developing world, Chronic Otitis Media is an important cause of preventable hearing loss[2]. Mucosal Chronic Otitis Media (Tubotympanic COM) encompasses cases with central perforation in the pars tensa of the tympanic membrane. Tympanic membrane perforation usually occurs due to middle ear infections, trauma or iatrogenic causes. Up to 80% of these perforations heal spontaneously and for the remaining, surgical repair is required[3]. The current surgical management of tubotympanic COM is myringoplasty. Simple myringoplasty prevents migration of squamous epithelium into the middle ear and thus cholesteatoma formation[4]. Myringoplasty was first performed by Berthold using full thickness skin graft in 1878 and the operation was called "myringoplastik."[5,6] The procedure was further developed by Wullstein & Zollner. Heermann introduced temporalis fascia as a graft in 1958[7,8]. The present study aims to assess the success rate of myringoplasty using temporalis fascia and to evaluate preoperative and postoperative hearing loss in patients with Mucosal Chronic Otitis Media / Chronic Suppurative Otitis Media, Tubotympanic Disease (CSOM, TTD) who presented in our hospital.

II. Material And Methods

This prospective hospital based study was carried out on patients of Department of ENT at Katihar Medical College and Hospital, Bihar from 1st January 2021 to 31st June 2022. A total 100 adult subjects (both male and females) of aged ≥ 11, years were for in this study.

Study Design: A prospective hospital-based study.

Study Location: This was a tertiary care teaching hospital based study done in Department of ENT at Katihar Medical College and Hospital, Bihar.

Study Duration: 1st January 2021 to 31st June 2022.

Sample size: 100 patients.

Source of Data: Patients who presented in the ENT OPD at KMCH, Katihar with CSOM tubo-tympanic disease.

Inclusion criteria:

Patients presenting with clinical features of CSOM tubo-tympanic disease with perforation of the tympanic membrane, decreased hearing and long-term discharge with age limit more than 11 years.

Exclusion criteria:

All patients under the age group of 11 years and patients suffering from ASOM and CSOM, attico-antral disease

Procedure methodology

All the patients were evaluated clinically and investigations were done viz. routine blood investigations, X-ray of mastoids (Law's lateral oblique view), X-ray of paranasal sinuses (Occipito-mental view) and special tests whenever required. Pure tone audiometry was performed in all the subjects. Before the surgical procedure, bilateral TM was inspected under the operating microscope.

In this study, myringoplasty was performed by grafting temporalis fascia using the underlay technique.

The ear drum perforation was quantified as:

1) Small (< 25% area of tympanic membrane)

a) Anterior small perforation (< 25%)

b) Posterior small perforation (< 25%)

2) Moderate (25% to 50% area of tympanic membrane)

a) Anterior moderate perforation (25% to 50%)

b) Posterior moderate perforation (25% to 50%)

3) Large (> 50% area of tympanic membrane).

Operative Procedure:

A post aural Wilde's incision was made starting from the upper attachment of the auricle and continuing in the post-aural fold downward up to the tip of the mastoid process. The incision was then deepened till the periosteum and all the soft tissues were dissected. The pinna along with the elevated posterior meatal skin was then retracted anteriorly with Plester's retractor. Then meatotomy was performed in the posterior meatal skin and mastoid retractor was applied. The margin of the perforated tympanic membrane was trimmed out in all the cases. Then the tympanomeatal flap was elevated. The handle of the malleus was freed from the tympanic membrane. The medial aspect of the perforated tympanic membrane was then inspected for any remaining squamous epithelium, if any, removed meticulously.

Graft Preparation:

Graft preparations were made as follows:

Temporalis fascia was harvested from the same side of operated ear by few millimeters' extension of postauricular incision towards the temporal area. The temporalis fascia was identified and all the adjacent soft tissue was released from the fascia. Hydro-dissection was done with normal saline and a gentle incision was given a few millimeters above the lower border of the temporalis muscle and the fascia was harvested in adequate size. After harvesting, it was spread over the back of the bowl and the remnant temporalis muscle and other soft tissues were removed using a Freer's elevator and allowed to dry for a while.

Graft Placement:

After elevating the posterior tympanomeatal flap, the graft was placed by underlay technique and the tympanomeatal flap was then reflected back over the grafted tissue to its original position and proper tucking was

done without any residual perforations. The middle ear and the EAC was packed with gelfoam. A small piece of ribbon gauze (approximately 1 inch) soaked in soframycin and betadine was placed in the EAC and then the surgical wound was closed in 2 layers i.e.; inner soft tissue layer with 3-0 Catgut and outer skin layer with 3-0 Trusilk. Then mastoid dressing was applied.

The patients were discharged after 2 days and advised as follows:

1. Not to blow, cough or sneeze with mouth and nostril closed.
2. To come for review after 7 days.

Post-auricular suture was removed after 7 days. The light canal pack was removed after 10 days without disturbing the gelfoam layer.

After 2 weeks the ear canal was inspected for the status of external auditory canal, position of the graft and vascular pattern. Follow up was carried out routinely at 7 days, 2 weeks, 6 weeks, 12weeks and 6 months. After 12 weeks, pure tone audiometry was performed. The results of change in hearing level were compared with preoperative audiometric values.

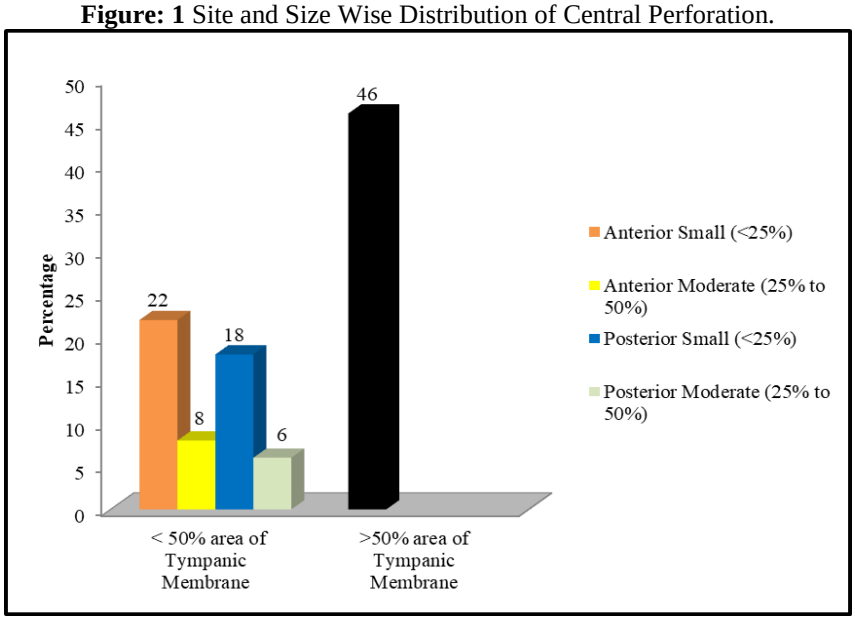
Statistical analysis

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's *t*-test was used to ascertain the significance of differences between mean values of two continuous variables. Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two or more groups. The level $P < 0.05$ was considered as the cutoff value or significance.

III. Result

Maximum number of the patients belonged to the age group 21-30 years i.e., 38(38.0%), followed by 11-20 years 27 (27%), 31-40 years 21 (21%) and 14 (14%) patients were from age group 41-50 years. 68% were male and 32% were female. The male to female ratio was 2.13:1.

Figure: 1 Site and Size Wise Distribution of Central Perforation.



A total of 100 patients were divided according to size of perforation, out of them 40 (40%) had small (<25% area of tympanic membrane) perforations. Of these 40 patients, 22(22%) had small anterior perforations and 18(18%) had small posterior perforations. Further we observed 8(8%) had moderate (25% to 50% area of tympanic membrane) anterior perforations and 6(6%) had moderate posterior perforations. On the other hand, 46(46%) cases had large perforations with involvement of >50% area of tympanic membrane (Figure 1).

In all 100 X-Ray mastoids (Law's lateral oblique view) revealed sclerotic pattern in 29(29%) cases and cellular pattern in 71(71%) cases. X-Ray paranasal sinuses (occipitomental view) revealed Hazy (mucosal thickening) in 27(27%) cases while 73(73%) cases were normal.

Table: 1 Impairment of Hearing in Relation to Age.

Age group	A-B gap range (dB)	Mean A-B gap (dB)
11-20	25.0 to 26.6	26.2
21-30	24.6 to 30.0	26.3
31-40	27.2 to 35.0	28.9

41-50	25.3 to 41.0	35.6

As far as impairment of Hearing in Relation to Age is concerned, we found, in 11-20 years of age group the A-B gap ranged from 25.0 –26.6 dB and mean value was 26.2dB. In the age group 21-30 years, A-B gap ranged from 24.6 – 30.0 dB and mean value was 26.3dB. In the age group 31-40 years the A-B gap range was 27.2 – 35.0 dB and mean value was 28.9dB. In the age group 41-50 years the A-B gap range was 25.3 –41.0 dB and mean value was 35.6 dB respectively (Table 1).

Table:2 Audiometric Assessment with Respect to Site and size of Perforation.

Site and size of perforation	**No of cases**	**A – B gap (d B)**	**Mean A – B gap (d B)**
Anterior perforation	30	18.3 – 31.2	22.7
Posterior perforation	24	19.6 – 32.3	23.3
Large perforation	46	25.9 – 41.1	38.3
Small and moderate size perforation < 50% area	54	18.9 – 31.9	22.9
Large perforation >50% area	46	25.9 – 41.1	38.3

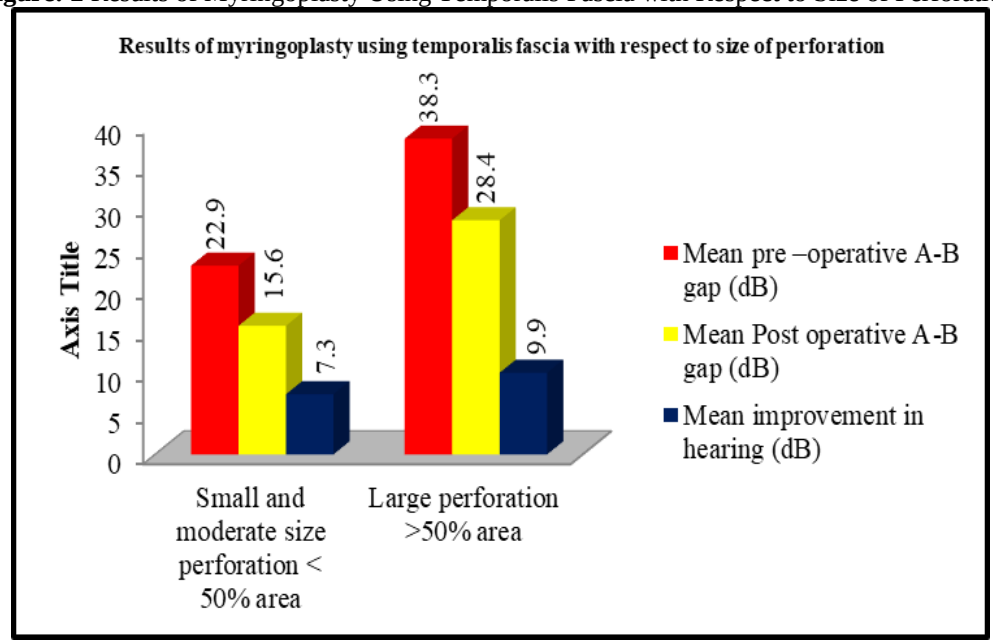
The maximum number of the cases had anterior site perforation i.e., 30% of cases. Those patients had A-B gap range of 18.3 – 31.2 dB and mean value was 22.7dB. Posterior site perforation was seen in 24% of patients with A-B gap range of 19.6 – 32.3 dB and mean value was 23.3dB. Large perforation was seen in 46% of cases with A-B gap range of 25.9 – 41.1 dB and mean value was 38.3dB (Table 2).

Table: 3 Results of Myringoplasty Using Temporalis Fascia with Respect to Age and site

Age/site of perforation	No of cases	**Successful closure of perforation (%)**	**Mean pre –operative A-B gap (dB)**	**Mean Post operative A-B gap (dB)**	**Mean improvement in hearing (dB)**	**P Value**
11-20	27	26(96.3)	26.2	16.9	9.3	<0.0001
21-30	38	36(94.7)	26.3	16.5	9.8	<0.0001
31-40	21	18(85.7)	28.9	20.3	8.6	<0.0001
41-50	14	10(71.4)	35.6	27.3	8.3	<0.0001
Total	100	90(90.0)	29.3	20.3	9.0	<0.0001
Anterior perforation	30	28(93.3)	22.7	15.5	7.2	<0.0001
Posterior perforation	24	22(91.7)	23.3	15.8	7.5	<0.0001
Large perforation	46	40(87.0)	38.3	28.4	9.9	<0.0001
Total	100	90(90.0)	28.1	19.9	8.2	<0.0001

The mean improvement in hearing in all age groups was found to be statistically significant taking mean improvement in hearing as Z score. (p value= <0.0001) Out of 30 anterior site perforation cases 28 (93.3%) cases had successful closure of perforation, the mean improvement in hearing was 7.2dB. In the 24 posterior site perforation cases, 22 (91.7%) cases had successful closure of perforation with a mean improvement in hearing of 7.5dB. Among the 46 large perforation cases, 40 (87.0%) cases had successful closure of perforation, the mean improvement in hearing was 9.9dB. (Table 3).

Figure: 2 Results of Myringoplasty Using Temporalis Fascia with Respect to Size of Perforation.



A total 54% cases had small and moderate size perforation (<50% of area of TM) out of which 50 (92.6%) cases had successful closure of perforation, and mean improvement of hearing was 7.3dB, on the other hand 46% cases had large perforation (>50% of area of TM) out of these 40 (87.0%) cases had successful closure of perforation, and mean value of improvement in hearing 9.9dB (Figure 2).

Sclerotic pattern was found in 29 cases out of which 24 (82.7%) cases had successful closure of TM. Cellular pattern was found in 71 cases out of which 66 (93.0%) cases had successful closure of TM. Overall successful closure of perforation in myringoplasty using temporalis fascia was 90%.

IV. Discussion

The present study was carried out to assess the result of myringoplasty in terms of graft uptake and hearing status post operatively in patients with CSOM, TTD in KMCH, Katihar. Myringoplasty using temporalis fascia was carried out in 100 patients attending ENT department of Katihar Medical College hospital. The age of the patients ranged from 11 years to 50 years. Of these, 68 cases were male and 32 cases were female, the male to female ratio being 2.13:1. All the patients attended ENT outpatient department of Katihar Medical College & Hospital, with the chief complaints of discharging ear of varying duration and impairment of hearing of varying degree.

Myringoplasty was performed using temporalis fascia graft. Postoperative pure tone audiometry was performed using the same frequencies as pre-operatively and the air bone gap in dB and the average threshold of hearing was recorded. This test was performed in all the cases after 12 weeks of follow up period, introduced by Boron A in 1980[9].

Various authors used different types of criteria for assessing the results of myringoplasty, like Proctor in 1960[10] advocated a social hearing method; Portman in 1963[11] favoured a hearing gain method. Wiatr M in 1970[12] used the mean air bone gap for each frequency. Booth expressed that subjective improvement of the patient and the air conduction gain was superior to the air bone gap. They mentioned that sometimes there was improvement in bone conduction also after myringoplasty. The successful hearing improvement in this study was considered according to the criteria proposed by Kurtush in Glasscock 5th edition[13]. If post operative air bone gap was 11-20 dB or below, then it was considered to be in a good range according to this criterion. In our study, The temporalis fascia was chosen as graft material because of: (i) its easy availability (ii) adequate size of tissue availability (iii) easy to handle (iv) easier placement of graft (v) requires minimum nutrition for survival. Temporalis fascia is the current gold standard for graft material. The biochemical properties afforded by its cellular matrix enable it to provide an excellent substrate for epithelial migration, which is complemented by ample numbers of fibroblasts and cellular components necessary for proper healing of the perforation.

The findings of various studies and their results could be compared below:

Author	Successful closure
Haegemann M[14](2003)	91%
Cueva RA[15] (1999)	97.5%
Palva and Palva[16](1969)	93%
Strauss et al[17](1975)	82%
Gibb AG[18] (1982)	89.3%
Benecke Je[19] (1995)	90%
Present Study	90%

In our study, healing of the perforation was found to be complete using temporalis fascia in 90 cases in 2-3 months except in 10 cases. Five failures were seen in large perforations. Three of them rejected within 6 weeks of post operative period. In other two cases rejection occurred after 10 weeks due to the super added infection of the graft and presented with ear discharge in the operated ear. So, the early failure might be due to large perforation thereby getting poor blood supply and less attachment with rim of perforation margin or may be due to post operative infection due to poor hygiene and inattentive post operative care at home. Four cases of temporal fascia graft developed small residual perforations after 3-4 months. They responded to trichloroacetic acid cautery and got healed. The causes of failure may have been due to infection despite antibiotic coverage, and due to respiratory tract infection producing cough and sneezing leading to graft displacement or due to bathing in the ponds even after the advice of not to do so. No other complications were seen within this follow up period of 6 months.

V. Conclusion

Myringoplasty using temporalis fascia is an excellent method for surgical closure of the perforated tympanic membrane. The results of surgery in terms of graft uptake were numerically better in myringoplasty using temporalis fascia. Most successful closure of perforation was seen in the age group 11 to 20 years and in patients with cellular mastoids.

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