



## A COMPARATIVE STUDY OF MYRINGOPLASTY USING TEMPORALIS FASCIA VERSUS TRAGAL PERICHONDRIMUM- OUR EXPERIENCE

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**ABSTRACT** Myringoplasty is the operation performed to close the tympanic membrane defects using graft materials. The aim of this procedure is successful closure of perforation and also to improve the hearing. This study is prospective and the aim is to compare the results of myringoplasty using temporalis fascia and tragal perichondrium.

**Results of study include** A total of 60 (30 in each group) patients were included in this study. All the patients were presented dry central perforation with significant deafness. Out of 60 cases, 30 underwent myringoplasty with temporalis fascia, 30 underwent with tragal perichondrium.

26 (86.7%) patients out of 30 had successful closure with temporalis fascia and 25 (83.3%) patients had success with tragal perichondrium.

Considering the hearing improvement, the mean post op A-B gap was 16.9 db compared to mean pre op A-B gap 32.93 db with temporalis fascia and the mean post op A-B gap was 18.26 db compared to mean pre op A-B gap db with tragal perichondrium.

**KEYWORDS :** Myringoplasty, Temporalis Fascia, Tragal Perichondrium, Pure Tone Audiogram

### INTRODUCTION

Perforations of the tympanic membrane result from middle ear infections, trauma or iatrogenic causes. Myringoplasty is described as the surgical repair of tympanic membrane perforation. The three principal indications are (1) to close the perforation (2) to correct the conductive hearing loss (3) to prevent recurrent ear discharge.

A perforation in the tympanic membrane decreases the vibrating area of the membrane in contact with the sound wave.

The repaired TM restores the vibratory area and affords round window protection, and thus improves hearing. It also prevents exposure of the middle ear to external infection and allergens.

The tympanic membranes are repaired using autologous graft materials like vein, fat, fascialata, temporalis fascia, perichondrium and cartilage. Biological graft materials act as a scaffold when applied to close the perforation.

There is a significant relation between the size and site of perforation and hearing loss. The pre-requisite for myringoplasty are (a) dry central perforation

(b) Functioning Eustachian tube (c) no focal sepsis and

(d) Adequate cochlear reserve. The present study aims to evaluate and compare the outcome of myringoplasty using temporalis fascia and tragal perichondrium as graft materials, especially the graft uptake rate and the hearing improvement after myringoplasty.

In the surgical repair of tympanic membrane perforations several factors come into play such as size of perforation, overhang, Eustachian tube function, state of the middle ear mucosa, wound healing, degree of pneumatisation etc.

### AIMS AND OBJECTIVES

The present study was undertaken to compare the outcome of myringoplasty using temporalis fascia and tragal perichondrium for the repair of the tympanic membrane defect. In this study underlay technique was followed in all small to medium size perforations through transcanal route.

The primary objectives of this study are to evaluate

1. Graft uptake
2. Hearing gain of the patients.
3. Failures
4. Complications

### MATERIALS AND METHODS

#### Sample selection

Patients presenting to Dept. of E.N.T, Tirunelveli Medical College Hospital, with dry central perforation. Sometime the size of the tragal perichondrium may not be enough to close large size perforation, so we have chosen only small and medium size perforations for our study.

#### Sample size

30 patients in each group

#### Study design

Randomized controlled trial study design.

#### Methodology

Inclusion criteria

- 1) Age range from 16-45 years
- 2) Dry central perforation small to medium size
- 3) Adequate cochlear reserve
- 4) Patients willing for surgery.

#### Exclusion criteria

- 1) Patients with active ear discharge
- 2) Active infection in nose or sinuses, nasopharynx, oropharynx.
- 3) Sensori-neural hearing loss
- 4) Eustachian tube dysfunction.
- 5) Patients not willing for surgery.

#### PRE-OPERATION EVALUATION:

1. TFT – Rinne's test with 256, 512, 1024 Hertz; Weber's test, ABC test.
2. Otoscopy and Otoendoscopy.
3. PTA to evaluate and document:
  - Degree of hearing loss
  - Type of hearing loss
  - Air Bone Gap
4. Radiological Assessment: To rule out infection in mastoid.

Patients with the above mentioned inclusion criteria are included in the study after proper investigations to rule out any sepsis in nose or throat. Pre-operative pure tone audiogram done for all patients.

Patients were informed about the study and after getting consent patients were allotted to either of the treatment group by random. In the treatment group 1 patients underwent myringoplasty using temporalis fascia. In treatment group 2 patients underwent myringoplasty using tragal perichondrium.

All the pts were operated by endomeatal route using 0 degree endoscope under local anaesthesia using 2% lignocaine and 1:100000 adrenaline. Younger patients were operated under general anaesthesia. Patients were followed in post op period for every 2 weeks in the first month and monthly once for 6 months.

All patients underwent post op audiogram on 2<sup>nd</sup> and 6<sup>th</sup> months. Patients were also assessed for other complications like post op wound infection, ear discharge, pain, granulation in the EAC, graft position, graft failure and residual perforation etc.,

**RESULTS and ANALYSIS**

The randomized clinical trials for the study were classified into two groups. In group 1, temporalis fascia was used as graft material and in group 2, tragal perichondrium was used.

Analysis of 60 cases (30 cases from each group) of myringoplasty is under the following headings.

1. Age distribution.
2. Sex ratio
3. Graft uptake in both treatment groups, comparing the (a) age group (b) sex and (c) size of perforation
4. Improvement in hearing.
5. Complications

**1. Age**

In our study all patients (n=60) belonged to the age group 16 to 45. The mean is 28.27 and standard deviation (SD) is 7.856 in all operated group. The age of the youngest patient was 16 year and the eldest patient was 45 years.

The distribution of patients in various age groups in both the treatment groups is almost similar.

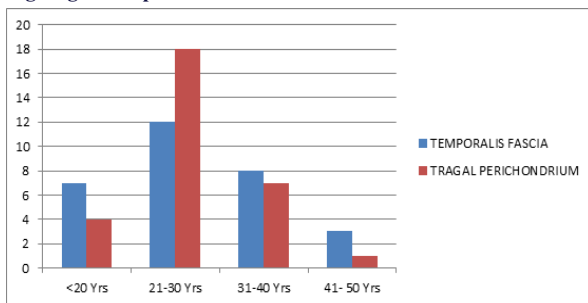
**Table I Age distribution of the patients in this study (n=60)**

AGE GROUP	TREATMENT GROUP		Total
	GROUP 1	GROUP 2	
16- 20 Yrs	7(11.7%)	4(6.7%)	11(18.3%)
21 - 30	12(20.0%)	18(30.0%)	30(50.0%)
31 - 40	8(13.3%)	7(11.7%)	15(25.0%)
41 -45	3(5.0%)	1(1.7%)	4(6.7%)
Total	30(50.0%)	30(50.0%)	60(100%)

Chi<sup>2</sup>: 3.085 df: 3 p-Value: 0.379

As seen in table I and fig 1 majority of the patients (50%) fall within the age group of 20-30 years in both treatment groups. 4 patients are in the age group 41-45 which is the least group in our study.

**Fig 1 Age-Group Distribution**



**2. Sex Distribution**

31 out of 60 (51.7%) are female patients and 29 (48.3%) are male patients.

The sex distribution is similar in both the treatment groups.

**Table II. Sex distribution in both groups.**

SEX	TEATMENT GROUP		Total
	1	2	
FEMALE	16(26.7%)	15(25.0%)	31(51.7%)
MALE	14(23.3%)	15(25.0%)	29(48.3%)
Total	30(50.0%)	30(50.0%)	60(100%)

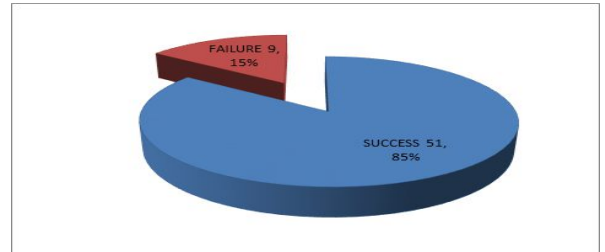
In Table II Chi<sup>2</sup>: 0.067 df: 1 p- Value: 0.796

Distribution of males are slightly higher than females in group 1 but it is statistically not significant (p-Value: 0.796) .In group 2 both sexes are equally distributed

**3. Graft uptake**

Successful closure of tympanic membrane in both groups was seen in 51 patients out of 60 (85%) and failure occurred in 9 patients (15%).

**Fig 2**



The above fig 2 shows the result in both groups

TREATMENT GROUP	GRAFT UPTAKE		Total
	YES	NO	
1	26(86.7%)	4(13.3%)	30(100%)
2	25(83.3%)	5(16.7%)	30(100%)
Total	51(85.0%)	9(15.0%)	60(100%)

Chi<sup>2</sup>: 0.131 df: 1 p- Value: 0.718

Successful closure of perforations using temporalis facia (GROUP 1) is higher (86.7%) when comparing the success rate of the tragal perichondrium (GROUP 2) graft (83.3%) , although the success rate of temporalis fascia looks higher, statistically it is not significant (p-Value:0.718)

**Table IV**

Comparison of age groups in both treatment groups.

AGE GROUP	Treatment Group 1		Treatment group 2		Total	
	Graft take up	Graft failure	Graft take up	Graft failure	Graft take up	Graft failure
16-20 Yrs	7 (100%)	0 (0%)	4 (100%)	0 (0%)	11(100%)	0 (0%)
21-30	12 (100%)	0 (0%)	16 (88.8%)	2 (11.1%)	28 (93.3%)	2 (6.7%)
31-40	5 (62.5%)	3 (37.5%)	5 (71.4%)	2 (28.5%)	10 (66.7%)	5 (33.3%)
41-45	2 (66.6%)	1 (33.3%)	0 (0%)	1 (100%)	2 (50.0%)	2 (50.0%)
Total	26 (86.7%)	4 (13.3%)	25 (83.3%)	5 (16.7%)	51 (85.0%)	9 (15.0%)

Chi<sup>2</sup>: 3.371 df:3 p-value: 0.337.

{p- value >0.05 Not significant. So there is no significant difference in the graft uptake between two groups across the age group }

**Comparing both treatment groups**

Success rate was 100% in the age group 16-20 followed by 98.3% in 21-30 age group. In our study success rate is more in younger age groups and less in elders.

**Table V. Comparison of sex with treatment outcome in both groups.**

SEX	GROUP 1		GROUP 2		TOTAL
	SUCCESS	FAILURE	SUCCESS	FAILURE	
MALE	12 (85.7%)	2 (14.3%)	13 (86.7%)	2 (13.3)	29 (48.3%)
FEMALE	14 (87.5%)	2 (12.5%)	12 (80%)	3 (20%)	31 (51.7%)
TOTAL	26 (86.7%)	4 (13.3%)	25 (83.3%)	5 (16.7%)	60 (100%)

Chi<sup>2</sup>: 0.171 df: 1 p-value: 0.672.

{p- value >0.05 Not significant. So there is no significant difference in the success of both groups due to sex. }

Male patients had more success 86.7% than females 80% when comparing both the groups the males had a higher success rate (86.2%) than females (83.9%), but it is not statistically significant.

**4. (A). Preoperative audiometric evaluation**

Preoperatively, A-B gap with 31- 40 db was observed in 39 of the patients and A-B gap of 21- 30 db was observed in 21 of patients.

The mean pre op A-B gap was 31.93 db.

Table VI. Pre op A-B gap in both groups

PRE OP A-B GAP	TREATMENT GROUP		TOTAL
	TEMPORALIS FASCIA	TRAGAL PERICHONDRIMUM	
21-30 db	8	13	21
Percent	13.3%	21.7%	35%
31-40 db	22	17	39
Percent	36.7%	28.3%	65%
Total	30	30	60
	50%	50%	100%

Chi2: 1.831 df:1 p-value: 0.175.

{p- value >0.05 Not significant. So there is no significant difference between two treatment groups in Pre-Op A-B Gap group.}

#### 4. (B.) Postoperative hearing improvement

The hearing statistics were based on the average of the three frequencies 500, 1000 & 2000 Hz and the hearing compared in the 2<sup>nd</sup> & 6<sup>th</sup> month following surgery.

Table VII. Comparison of post op A-B gap in 2<sup>nd</sup> and 6<sup>th</sup> months.

TREATMENT GROUP	PRE OP A-B GAP MEAN	POST OP A-B GAP MEAN 2 <sup>nd</sup> month	POST OP A-B GAP MEAN 6 <sup>th</sup> month
GROUP 1	32.93 DB	17.56 DB	16.9 DB
GROUP 2	30.93 DB	19.13 DB	18.26 DB

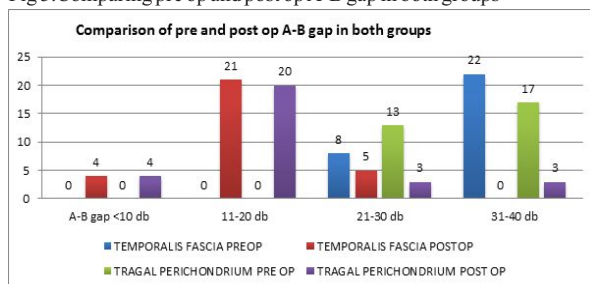
The mean post op A-B gap is better in 6<sup>th</sup> months in both groups that value is taken for analysing post op hearing improvement.

#### Comparing post op A-B gap in both treatment groups

In successful patients, in treatment group 1, the post op mean air-bone gap was 16.03 db compared to the post op mean air-bone gap of 18.26 db in treatment group 2. The improvement in A-B gap was more in group 1 compared to treatment group 2. But it is statistically not significant.

The mean post op A-B gap closure in both groups was 17.58 db when compared to pre op mean A-B gap 31.93db. The improvement in A-B gap was 14.35 db.

Fig 3. Comparing pre op and post op A-B gap in both groups



#### Complications

In the complications aspect 6 patients (3 from each group) had granulations in the EAC which subsided after treatment. 8 patients (3 from group 1 and 5 from group 2) had ear discharge in the early post op period and resolved later on 12 patients (7 from group 1 and 5 from group 2) had pain in the ears. None of the patient had any worsening of hearing.

#### DISCUSSION

Otitis media<sup>1</sup> is a term used to describe inflammatory disease of the mucous membrane lining the middle ear cleft. It is an important disease of children and adults and is caused by multiple factors including infections, Eustachian tube dysfunction, allergy and traumas. Chronic otitis media is classified into tubotympanic disease characterised by the presence of central perforation and atticointral disease characterised by the presence of a cholesteatoma.

Tympanoplasty is the main surgical treatment for tubotympanic disease.

Raine and singh<sup>2</sup> in a retrospective analysis of 114 tympanoplasties in children in the age group of 7 to 16 demonstrated a significant higher rate of failure between 8 and 12 years. The probable explanation is high incidence of failure in younger children is due to increased incidence of upper respiratory infection and immature Eustachian tube function. In our study the youngest patient was 16 years of age.

Ronald strahan<sup>3</sup> documented that the incidence of graft failure and failure to restore hearing were higher in older age group.

Over the years different grafting materials have been introduced right from pig's bladder membrane by Benzer in 1640 to canal wall skin by William house in 1958 to temporalis fascia in 1964 by Net Chalet and cartilage in 1963. Currently temporalis fascia and perichondrium have been the most commonly used grafting materials.

In this we have compared the results of tragal perichondrium and temporalis fascia used to repair the perforated tympanic membrane using underlay technique. Both tragal perichondrium and temporalis fascia are accessible near the operative site, available in adequate amount, have excellent contour, can be thinned down and having excellent survival capacity. In this series the temporalis fascia graft take rate was 86.7% (26 out of 30) and the graft failure was 13.3 % (4 out of 30). In our study maximum graft take rate (100) was in the age group of 16-20 years, followed by 93.3%, 66.7%, 50% in the age group of 21-30 years, 31-40 years and 41-45 years respectively. Vrabec et al<sup>4</sup> found better success with advancing age. This is due to low incidence of upper airway infections and better Eustachian tube function in this age and the relative immaturity of the immune system in younger children.

Fadl A. Fadl<sup>5</sup> in his study in outcome of 97 patients who underwent tympanoplasty type-I surgery, the success rate was 80% in males and 87.7% in females. In our study the success rate was more in males 86.2% when compared to females 83.9%

In the study by Gibb<sup>6</sup> using temporalis fascia as graft material by underlay technique the percentage of take rate was 87.5%. The hearing restoration rate for temporalis fascia was 82% in the study conducted by R.W.Strhan, Paul H. Ward, Mario Acquarelli, Bruce Jafek. The present study achieves a take rate of 85% and satisfactory hearing of 81%.

In our study the successful closure of tympanic membrane using tragal perichondrium was 83.3%.

In our study 13% patients (8 no.) had post op A-B gap <10 db, 68% patients (41 no.) had postoperative air-bone gap between 10- 20 db. There were 8 patients (13%) with A-B gap of between 20-30 db and 3 (5%) patients with A-B gap of between 30-40 db post operatively.

The mean pre and post-operative A-B gap were 32 dB and 18 dB respectively with a mean audiological improvement of 14 dB. Graft could be seen in the all cases except 9 pts at 6<sup>th</sup> month.

In the audiological evaluation, these 9 patients were found to have less hearing improvement at 6<sup>th</sup> month compared to other patients. Only 3 patients did not have any improvement in hearing level after surgery in all the subsequent follow-ups.

Sheehy and Anderson<sup>7</sup> stated that in most case of chronic suppurative otitis media, even though the ossicular chain may appear normal, there is some factor of scar tissue that prevents total restoration of hearing. However in our series in 8 patients (13%) there was no significant hearing improvement (post op A-B gap was more than 20 db) in spite of successful graft uptake. Jyothi P. Dabholkar, Krishna Vora And Abhik Sikdar<sup>7</sup> in their study used temporalis fascia for myringoplasty and achieved 84% success rate and 80% with tragal perichondrium. They also achieved 76.2% success in closure of post operative A-B gap <10 db with temporalis fascia and 76% with tragal perichondrium respectively.

B.J Singh And A.Sengupta<sup>8</sup> in their study 220 patients, comparing the success rate of tympanic membrane closure with different graft materials, temporalis fascia showed best (95%) closure rate and 9.3 db hearing gain, followed by tragal perichondrium (90% closure rate and 8.5 db hearing improvement) and areolar tissue (80% closure rate and 8.9 db mean hearing improvement).

In our study the success rate for temporalis fascia was 86.7% and 83.3% for tragal perichondrium. Post op A-B gap closure < 20 db was 83.3% in group 1 and 80% in group 2

Sudhangshu Shekhar Biswas et al<sup>9</sup> retrospective study of 60 patients the mean pre and post-operative air conduction threshold in the successful cases were 34 dB and 24 dB respectively with a mean audiological improvement of 10 dB. Improvement of mean air-bone gap was 11 dB. In our study the mean pre op A-B gap was 31.93 db and the post op mean A-B gap was 17.58 db with an improvement of mean A-B gap 14 db which is better than the above study.

Present study achieves 86.7% uptake achieved with temporalis fascia and 83.3% with tragal perichondrium. Good hearing restoration (post op A-B gap < 20 db) 83.3% is achieved with temporalis fascia and 80% with tragal perichondrium.

Regarding the outcome of myringoplasty with temporalis fascia and tragal perichondrium is nearly identical.

## CONCLUSION

This study had been carried out over a limited period of time in a limited number of cases. The results and outcome mentioned here may considerably vary from other series; still as the cases were collected from tertiary referral hospital, this study may be of some value in reflecting certain facts regarding outcome after myringoplasty using various grafts.

Form the present study we conclude that

1. Both tragal perichondrium and temporalis fascia provide viable autograft material.
2. Both materials are mesodermal in origin which excludes the risk of iatrogenic cholesteatoma.
3. Both achieve comparable and excellent graft takes.
4. Both achieve comparable and good hearing restoration.

And we finally conclude that both graft materials are effective in successful closure of tympanic membrane perforations and improvement of hearing and there is no significant statistical difference regarding the outcome between the temporalis fascia and tragal perichondrium in the surgical management of small and medium sized perforation.

## SUMMARY

A total of 60 (30 in each group) patients were included in this study the minimum age was 16 years and maximum age was 45 years, the mean was 28.27 years. In this series the male patients were 29 and female patients were 31. All the patients were presented dry central perforation with significant deafness. Out of 60 cases, 30 (50%) underwent myringoplasty with temporalis fascia, 30(50%) underwent myringoplasty with tragal perichondrium.

26 (86.7) % patients out of 30 had successful closure with temporalis fascia and 25 (83.3%) patients had success with tragal perichondrium.

Considering the pre OP A-B Gap and post OP A-B Gap, six months after surgery, 25 patients showed improvement (post op A-B gap < 20 db) with temporalis fascia and 24 patients showed improvement (post op A-B gap < 20 db) with tragal perichondrium. The mean post op A-B gap was 16.9 db when compared to mean pre op A-B gap 32.93 db with temporalis fascia and the mean post op A-B gap was 18.26 db compared to mean pre op A-B gap db with tragal perichondrium.

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