

# A Prospective Randomized Comparative Study Between Management of Small Perforation of Tympanic Membrane by Chemical Cauterization and Fat Graft Myringoplasty

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## Abstract

**Background:** Loss of hearing is a national health problem. Many literatures has proven the effectiveness of fat graft myringoplasty and chemical cauterization in closure of small tympanic membrane perforation and improvement in hearing . In the present study we have made an attempt to compare the effectiveness of these procedures **Methods:** This is a prospective randomised comparative study conducted in 60 patients from September 2017 to march 2019 who attended ENT OPD of Indira Gandhi government hospital, Puducherry. These patients were subjected to a detailed history taking, examination of ear, nose, and throat and later were subjected to series of investigations and the audiological assessment of the hearing loss was documented. The patients were randomly divided into two groups consisting of 30 members each and the first group underwent fat graft myringoplasty and the second group underwent chemical cauterization under endoscopic guidance. **Results:** There was a successful closure of 90% perforations who underwent fat graft myringoplasty and 83.3% perforations with a mean of 3.6 applications who underwent chemical cauterization. After fat graft myringoplasty there was a hearing improvement of 10.99 decibel and air bone closure of 10.93 decibel. Chemical cauterization showed a hearing improvement of 9.87 db and air bone closure of 9.82 db. Statistical analysis was done and both the procedures were found to be equally effective in terms of closure of small perforation of tympanic membrane and postoperative hearing improvement.

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## Introduction

Tympanic membrane perforation is caused by variety of causes, the most common being trauma and infections. Tympanic membrane perforation leads to conductive hearing loss.<sup>1</sup>The pars tensa perforations or central perforations are morphologically classified arbitrarily by the demarcation with the vertical line passing through the handle of malleus and the horizontal on passing perpendicularly to the first line through umbo into 4 quadrants (a) Anteriosuperior (b) Anteroinferior (c) Posteriosuperior (d) Posterioinferior.<sup>2</sup> **Closure** of tympanic membrane provides the advantage of **isolating the middle ear from exposure of pathogens, restores the vibratory area of the membrane** and affords round window protection, thus improving the hearing.<sup>3</sup>

In chronic perforation of tympanic membrane, squamous epithelium is found adjacent to the middle ear mucosa and creates a perforation edge without raw surface. This is a contributing factor for a perforation to persist. It breaks up fibrosis, promotes granulation and new tissue formation at the margin of the perforation. Chemical cauterization by trichloro acetic acid can achieve the improvement in hearing likely to be achieved by tympanoplasty. Anaesthesia was not found to be necessary as the pain was very less and decreased on repeated applications.<sup>4</sup>

Microscopic study of ear lobule showed that the fat cells are more compact and contain more fibrous tissue. It provides scaffolding for the growth of tympanic membrane epithelium and mucus membrane by bridging the gap. Simple and cost effective procedures like chemical cauterization and fat plug myringoplasty have been found to be effective in healing small central perforations with significant hearing improvement.<sup>5</sup>

In the present study we have made an attempt to compare the effectiveness of fat graft myringoplasty and chemical cauterization in closure of small tympanic membrane perforation and hearing improvement in both cases.

### Methods

This is a prospective randomised comparative study conducted in department of ENT Indira Gandhi government general hospital and postgraduate institute, Puducherry from September 2017 to April 2019. Patients with inactive disease and small perforation (<25% surface area or one quadrant) of tympanic membrane between 18 and 50 years with pure conductive hearing loss less than 50 decibel were included in the study. Patients with active disease, residual perforation, squamous disease, sensorineural hearing loss, active foci of infection, nasal polyposis and systemic disease were excluded from study. As per the study conducted in Guwahati by Debnath M, Khanna S<sup>5</sup> sample size was calculated using epi info software and total sample size was calculated as 60, which consisted of 30 in each group. All the patients were included in the study after taking ethical committee and scientific committee clearance. These patients were subjected to a detailed history taking, examination of ear, nose, and throat and later were subjected to series of investigations and the audiological assessment of the hearing loss was documented. The patients were randomly divided into two groups and the first group underwent endoscopic fat graft myringoplasty with ear lobe fat and the second group underwent chemical cauterization with 30 percent trichloro acetic acid under endoscopic guidance.

In the group who underwent fat graft myringoplasty, suture removal was done at 1 week, regular follow up done, oto-endoscopy and postoperative audiological assessment done at 9 weeks and compared to the preoperative hearing and statistical analysis made.

In the group who underwent chemical cauterization, a maximum of four applications was done at 2 weeks interval between each application. The closure of perforation was assessed endoscopically during each time of application and at the end of ninth week. The hearing was assessed at the end of the ninth week and compared to the preoperative hearing and statistical analysis made.

A comparison between closure of perforation and hearing improvement between the groups who underwent fat graft myringoplasty and chemical cauterization was done

**Results****Table 1: Showing Closure of Perforation in fat Graft Myringoplasty and Chemical Cauterization**

Closure of Perforation	Fat Graft Myringoplasty	Chemical Cauterization
CLOSED	27	25
NOT CLOSED	3	30
TOTAL	30	30
PERCENTAGE	90	83.3

Out of 30 persons who underwent fat graft myringoplasty, 90 percentage of perforation got closed and out of 30 persons who underwent chemical cauterization 83.3 percentage of perforation got closed with an average of 3.6 applications. According to Fisher's Exact Test the difference was not found to be significant as the p value = .706 (>.01). There is no significant difference between closure of perforation in fat graft myringoplasty and chemical cauterization.

**Table 2: Table showing the mean improvement in air conduction threshold and air bone closure postoperatively in fat graft myringoplasty**

Samples Test	Differences					T	Sig. (2-tailed)
	Mean Improvement	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference			
				Lower	Upper		
PreOp Mean ACT - PostOp Mean ACT	10.99000	3.72312	.67975	9.59976	12.38024	16.168	P<0.01 Strongly Sig.
PreOp Mean BCT- Post Op Mean BCT	.05667	.31038	.05667	-.05923	.17256	1.000	P =.326 Non sig
Pre Op – Post Op Mean Air Bone Gap	10.93333	3.72488	.68007	9.54244	12.32423	16.077	P<0.01 Strongly sig.

This above tables shows that the difference between the preoperative and post operative air conduction threshold is 10.99 db which implies that the hearing gain is about 11 db and the t value is 16.168 and P<0.01% which indicates a strong significance. Similarly the difference between the preoperative and postoperative air bone gap is 10.93 db, with t value 16.077 and P< 0.01%, which implies a significant air bone closure.

**Table 3:** Table showing the mean improvement in air conduction threshold and air bone closure postoperatively in chemical cauterization

Samples Test	Mean Improvement	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		T	Sig. (2-tailed)
				Lower	Upper		
				PreOp Mean ACT - PostOp Mean ACT	9.87667		
PreOp Mean BCT- Post Op Mean BCT	.05333	.29212	.05333	-.05575	.16241	1.000	P =.326 Non sig
Pre Op – Post Op Mean Air Bone Gap	9.82333	3.60982	.65906	8.47540	11.17126	14.905	P<0.01 Strongly sig.

This above tables shows that the difference between the preoperative and post operative air conduction threshold is 9.87 db which implies that the hearing gain is about 10 db and the t value is 14.821 and P<0.01% which indicates a strong significance. Similarly the difference between the preoperative and postoperative air bone gap is 9.82db, with t value 14.905 and P< 0.01%, which implies a significant air bone closure.

**Table 4:** Comparison between improvement in air conduction threshold after fat graft myringoplasty and chemical cauterization

Independent Samples T Test for increase in postop air conduction threshold										
		Levene's Test for Equality of								
		Variances		t-test for Equality of Means					95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2tailed)	Mean Difference	Std. Error Difference		
								Lower	Upper	
Hearing improvement	Equal variances assumed	.197	.659	1.170	58	.247	1.11333	1.13262	-.79215	3.01882
	Equal variances not assumed			1.170	57.977	.247	1.11333	1.13262	-.79217	3.01883

The results were analysed using Independent samples T test. The improvement in ACT after fat graft myringoplasty and chemical cauterization were analysed using Independent samples T test. The P value is .247

which is non significant( p value  $>.05$ ).From the results, it is evident that there is no significant difference in hearing improvement after fat graft myringoplasty and chemical cauterization.

**Table 5:** Comparison between air bone gap closure between fat graft myringoplasty and chemical cauterization

Independent Samples T Test for closure of air bone gap										
		Levene's Test for Equality of								
		Variances		t-test for Equality of Means					95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Hearing improvement	Equal variances assumed	.138	.712	1.172	58	.246	1.1100	.94702	-.78567	3.00567
	Equal variances not assumed			1.172	57.943	.246	1.1100	.94702	-.78571	3.00571

The results were analysed using Independent samples T test. The AB GAP closure after fat graft myringoplasty and chemical cauterization were analysed using Independent samples T test. The P value is .246

which is non significant(p value  $>.05$ ).From the results, it is evident that there is no significant difference in AB GAP closure after fat graft myringoplasty and chemical cauterization

## Discussion

In our study fat graft myringoplasty showed closure of small perforation of tympanic membrane with a success rate of 90%. There was residual perforation in 3 patients who developed respiratory tract infections followed by ear discharge. The results were comparable to Ringenberg JC<sup>6</sup>, Sinha V et al.<sup>7</sup>, Chalishazar U<sup>8</sup>, SHARMA C et al<sup>9</sup>, Mukherjee M, Paul R<sup>10</sup> with a success rate of 86%,95.8%,90%,80%,92% respectively. In our study chemical cauterization achieved a successful closure of 83.3% with mean of 3.6 applications. Out of 5 patients who had residual perforation 2 patients had respiratory tract infection followed by ear discharge and 1 patient developed otomycosis. There were no other serious complications. The results were comparable to Makwana P et al<sup>11</sup>, Uppal KS et al<sup>12</sup>, Gur OE et al<sup>13</sup>, and AL Bala G, Kannappan, Nahas TK, Khosh A<sup>14</sup> who used chemical cauterization with a success rate of 75, 78%,71.5%,92.5% respectively.

According to the study conducted by Debnath M, Khanna S<sup>5</sup> fat graft myringoplasty was found to be better option for closure for the closure of Tympanic Membrane perforation less than 5 mm with only one surgical sitting. The comparison between closure of perforation using FGM and chemical cauterization was done by chi square test and fishers exact test(p value.706) and was not found to be significant. As per our study both procedures are equally effective in closure of small tympanic membrane perforation

In the study conducted by Debnath M, Khanna S<sup>5</sup> there was a mean hearing gain of about  $16 \pm 4.02$  dB after fat graft myringoplasty and there was a mean hearing gain of about  $8.66 \pm 3.69$  dB after chemical cauterization which was found to be statistically significant .In our study too there is mean improvement of 10.99 decibel in terms of air conduction threshold and mean improvement of 10.93decibel in terms of air bone closure after fat graft myringoplasty.

Statistical analysis done and p value is  $<0.01$  which is strongly significant in case of postop air conduction threshold and postoperative air bone closure. In patients who underwent chemical cauterization there is mean improvement of 9.87 decibel in terms of air conduction threshold and mean improvement of 9.82 decibel in terms of air bone closure after chemical cauterization. Statistical analysis done and p value is  $<0.01$  which is strongly significant in case of postop air conduction threshold and postoperative air bone closure

The mean improvement in air conduction threshold after graft myringoplasty(10.99 db) and chemical cauterization(9.87db) were compared using independent samples T test and p value was found to be .247 which was not found to be statically significant. Similarly The mean improvement in air bone closure after graft myringoplasty(10.93db) and chemical cauterization(9.82db) were compared using independent samples T test and p value was found to be .246 which was not found to be statically significant.

Statistical analysis was done and both the procedures were found to be equally effective in terms of closure of small perforation of tympanic membrane and postoperative hearing improvement

### Conclusion

Fat graft myringoplasty and chemical cauterization is equally effective in closure of small perforation of tympanic membrane and causing postoperative hearing improvement. These two procedures do not require general anaesthesia and they are easy to perform, reliable with a satisfactory outcome, virtually simple and rapid, risk free, less hospital stay and also lessen the financial burden and morbidity on the part of the patient.

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