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Original Research Article

Comparative study of type 1 tympanoplasty with and without gelfoam in the middle ear

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ABSTRACT

Background: Chronic suppurative otitis media is a widespread disease with a significant cause of morbidity with a greater burden in the poor communities of the developing countries for which tympanoplasty is frequently undertaken. Gelfoam may show detrimental effects such as adhesions and fibrosis and improper packing may physically alter the structure of the tympanic membrane leading to failure of tympanoplasty. The graft can be placed without any middle ear supporting agent wherein the graft is held in position by the surface tension between the novel graft placed and the remnant tympanic membrane. This provides the added advantage of facilitating middle ear ventilation through the Eustachian tube. The objectives of the study were to assess the graft uptake and hearing improvement following type 1 tympanoplasty with gelfoam in the middle ear and without gelfoam in the middle ear and to compare and assess results for complications

Methods: This was a randomised control trial done for a period of one year conducted in the department of otorhinolaryngology and head and neck surgery, Karnataka Institute of Medical Sciences, Hubballi which is a tertiary referral hospital. 30 patients underwent type 1 tympanoplasty without gelfoam in the middle ear and 31 patients underwent type 1 tympanoplasty with gelfoam in the middle ear. Post-operative follow up was done to look for graft uptake, hearing assessment by pure tone audiometry and impedance audiometry was done 90 days post-operatively.

Results: Graft uptake was 80% in type 1 tympanoplasty without gelfoam in the middle ear and 80.6% with gelfoam in the middle ear. Both types of surgeries had significant hearing improvement, and complications like retraction and residual perforation were also comparable. Ad type of impedance curve is most common post operatively.

Conclusions: Graft uptake is equally good in cases with gelfoam and without gelfoam. Hearing gain is comparable in both groups of patients. No significant complications occurred in our study. 'Ad' is the most common type of impedance curve after surgery. Long term follow up is important in these patients.

Keywords: Tympanoplasty, Gelfoam, No gelfoam, Graft uptake, Hearing improvement

INTRODUCTION

Chronic suppurative otitis media is a widespread disease with a significant cause of morbidity with a greater burden in the poor communities of the developing countries. Majority of the patients require tympanoplasty. The disease and its sequale produce substantial economic and social costs.[1] It is estimated that 360 million people (5.3% population) suffer from hearing impairment of which about 162-165 million have CSOM. It is of great significance in children as hearing impairment may inhibit their language, communication, development, auditory processing, psychosocial and cognitive development which has a further impact on the child's education with poor academic and social outcomes. In

India the prevalence of CSOM amongst children in rural areas is 6%.[2]

Tympanoplasty involves closure of the tympanic membrane perforation by a graft. By convention GELFOAM is placed in the middle ear ever since its inception in 1950s to provide support to the graft and prevent its medialization as well as for achieving hemostasis. But gelfoam may show detrimental effects such as adhesions and fibrosis and improper packing may physically alter the structure of the tympanic membrane leading to failure of tympanoplasty.[3]

Many surgeons advocate the use of gelfoam either in the dry form or following application of ointment or drops in the middle ear in underlay tympanoplasty to provide a bed for the graft which supports the graft and prevents its medialization. The use of ointment or drops prevents further absorption of blood or tissue fluid into the gelfoam and prevents further lateralization of the graft. However the graft can be placed without any middle ear supporting agent wherein the graft is held in position by the surface tension between the novel graft placed and the remnant tympanic membrane. This provides the added advantage of facilitating middle ear ventilation through the Eustachian tube.

Currently there exists no consensus regarding the use of gelfoam for the middle ear. It is worth noting that not many trials have directly compared the outcomes of packing with gelfoam versus no packing in the middle ear, prompting a study of the same.

The objectives of our study were to assess the graft uptake and hearing improvement following type 1 tympanoplasty with gelfoam in the middle ear. To assess the graft uptake and hearing improvement following type 1 tympanoplasty without gelfoam in the middle ear. To compare and assess the results in terms of graft uptake, hearing improvement and complications like adhesions, fibrosis or granulation tissue leading to graft retraction or failure.

METHODS

Source of data

The study was conducted in the department of otorhinolaryngology and head and neck surgery, Karnataka Institute of Medical Sciences, Hubballi. 65 patients admitted for type 1 tympanoplasty for chronic suppurative otitis media (quiescent and inactive) were considered for the study.

***Setting*:** Tertiary referral hospital.

***Period of study*:** December 2014 to November 2015.

***Study design*:** Randomised control trial.

Arms of study

1. Cases of CSOM undergoing type 1 tympanoplasty with gelfoam in the middle ear.
2. Cases of CSOM undergoing type 1 tympanoplasty without gelfoam in the middle ear.

Inclusion criteria

Inclusion criteria were age group 10-65 years; all cases of CSOM (quiescent and dry) undergoing type 1 tympanoplasty without any contraindication; all cases of traumatic perforation undergoing type 1 tympanoplasty.

Exclusion criteria

Exclusion criteria were age group <10 years and >65 years; CSOM active disease; patients with co-morbidities.

Statistical analysis

Statistical analysis was done using SPSS version 21.0. Chi square test was used for non-parametric data analysis. Paired T test was used to analyse the hearing gain after surgery.

This was a longitudinal study conducted in a period of 1 year from December 2014 to November 2015. Patients were randomly selected for either tympanoplasty with gelfoam or for tympanoplasty without gelfoam after meeting the inclusion and exclusion criteria. Detailed history, general examination and systemic examination of the patient were done. Otological examination including otoscopy and tuning fork tests was done followed by examination of nose and throat. Patients were subjected to clinical, audiological and laboratory investigations. All patients underwent a pre-operative pure tone audiogram. Informed written consent was taken from all patients. And patients were subjected to type 1 tympanoplasty using underlay technique.

Operative technique

The operating ear was painted using povidone iodine, methylated spirit and then draped ensuring complete asepsis. Local anaesthesia (xylocaine 2% with 1:100000 adrenaline) were administered in the post aural region and 4 quadrants of the EAC. Through the post aural William Wildes incision, temporalis fascia graft harvested and preserved. Under the microscope tympanic membrane perforation visualized and edges freshened. Incision taken in the canal 5-6 mm lateral to annulus from 6 o'clock to 12 o'clock. Tympanomeatal flap elevated and middle ear entered and inspected for ossicles, mobility of ossicles, round window reflex and middle ear mucosa. Middle ear filled with adequate gelfoam in cases selected for tympanoplasty with gelfoam. Middle ear left as it is in cases selected for tympanoplasty without gelfoam temporalis fascia graft placed using underlay

technique. Tympanomeatal flap repositioned and EAC filled with medicated gelfoam. Post aural incision closed in 2 layers, mastoid dressing was put for a duration of 1 week.

Patients were given intravenous antibiotics for one week based on culture and sensitivity report. Suture removal was done one week post operatively. Patients were followed up on day 15, day 30, day 60 and day 90. Pure tone audiogram and impedance audiometry was done on day 90 to assess the graft uptake, hearing improvement and complications if any.

RESULTS

65 Patients, 32 in group 1 (tympanoplasty without gelfoam) and 33 in group 2 (tympanoplasty with gelfoam) who fulfilled the inclusion and exclusion criteria were recruited in to the study during the period from December 2014 to November 2015. Out of the 65 patients 4 patients, 2 from each group were lost during the follow up period.

The various observations made in this study are listed below.

Age and gender (socio-demographic) distribution of study participants

The two study groups were comparable as far as age was concerned. And we noted that in our study the most common age of presentation was 11-19 and 20-29.

In our study, 36 patients were male of which 16 were in group 1 and 20 were in group 2. 25 patients were female of which 14 were in group 1 and 11 in group 2. There was no significant difference between the two groups in sex distribution as p value was more than 0.05. Hence the two groups were similar and comparable as far as gender was concerned.

Table 1: Socio-demographic details of study participants (group-1 type 1 tympanoplasty without gelfoam, group-2- type 1 tympanoplasty with gelfoam).

Sl. No	Study parameters	Group-1 N (%)	Group-2 N (%)	X^2 value, df	P value#
1	Age category in years			1.01, 2	0.60
	11–19	11 (36.7)	12 (38.7)		
	20–29	13 (43.3)	10 (32.2)		
	≥30	6 (20)	9 (29)		
	Total	30 (100)	31 (100)		
2	Gender			0.78, 1	0.44
	Male	16 (53.3)	20 (64.5)		
	Female	14 (46.7)	11 (35.5)		
	Total	30 (100)	31 (100)		

NOTE: # the p values given here are based on Chi-square (X^2) test, df- degrees of freedom.

Comparison of graft uptake in the study groups

In our study, in group 1, 24 (80%) patients had complete graft uptake and 6 (20%) patients had failure of complete graft uptake following surgery. In group 2, 25 (80.6%) patients had complete graft uptake and 6 (19.4%) patients had failure of complete graft uptake following surgery. The results were analysed using Chi-square test and the p value was found to be 0.94 which is not statistically significant. Thus according to our study, graft uptake is comparable and good in surgical technique with gelfoam and without gelfoam (Table 2).

Comparison of pure tone audiometry (PTA) in both study groups

The T value based on paired t test was 10.6 in group 1 and 6.3 in group 2 with a p value of <0.001 in both groups which is statistically significant. Significant post-operative hearing gain was present in both the study groups (Table 3).

Table 2: Comparison of graft uptake after surgery in both groups (group-1 type 1 tympanoplasty without gelfoam, group-2- type 1 tympanoplasty with gelfoam).

Sl. No	Graft uptake	Group-1 N (%)	Group-2 N (%)	X^2 value, df	P value#
1	Complete	24 (80)	25 (80.6)	0.004, 1	0.94
2	Incomplete	6 (20)	6 (19.4)		
3	Total	30 (100)	31 (100)		

NOTE: # the p values given here are based on chi-square (X^2) test, df- degrees of freedom.

Table 3: Comparison of pure tone audiometry (PTA), before and after surgery in both groups (group-1 type 1 tympanoplasty without gelfoam, group-2- type 1 tympanoplasty with gelfoam).

Sl. No	Group	Pre- PTA mean (SD)	Post-PTA mean (SD)	T value, df	P value#
1	No gelfoam	32.6 (7.6)	18.5 (6.7)	10.6, 29	<0.001*
2	Gelfoam	37.5 (7.7)	23.5 (10.8)	6.3, 29	<0.001*

NOTE: df-degrees of freedom, # p value based on paired t test. * Statistically significant.

Table 4: Comparison of hearing gain after surgery in both groups (group-1 type 1 tympanoplasty without gelfoam, group-2- type 1 tympanoplasty with gelfoam).

Sl. No	Feature	Group-1 Median (IQR)	Group-2 Median (IQR)	Z value	P value#
1	Hearing gain	12.63 (10)	13.25 (19)	-0.16	0.87

NOTE: #p value is based on Mann Whitney U test.

Table 5: Comparison of type of impedance audiometry after surgery in both study groups (group-1- type 1 tympanoplasty without gelfoam, group-2- type 1 tympanoplasty with gelfoam).

Sl. No	Impedance	Group-1 N (%)	Group-2 N (%)	X^2 value, df	P value#
1	A	7 (23.3)	4 (12.9)	2.59, 5	0.76
2	Ad	10 (33.3)	11(35.5)		
3	As	5 (16.7)	7(22.6)		
4	B	7 (23.3)	6(19.4)		
5	C	0	1(3.2)		
6	Cs	1 (3.3)	2(6.5)		
7	Total	30 (100)	31 (100)		

NOTE: # The p values given here are based on chi-square (X^2) test, df- degrees of freedom.

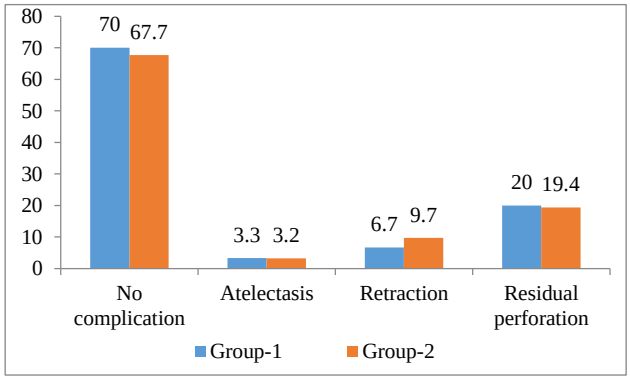

Figure 1: Type of complications in study participants between two groups (group-1 type 1 tympanoplasty without gelfoam, group-2 type 1 tympanoplasty with gelfoam).

Comparison of hearing gain in both study groups

In our study, median of hearing gain in group 1 was 12.63 with an interquartile range of 10 and median of hearing gain in group 2 was 13.25 with an interquartile range of 19. The p value based on Mann Whitney u test was 0.87 which is not statistically significant. The hearing gain is good and comparable in both the study groups (Table 4).

Comparison of various complications in both the study groups

In our study, residual perforation was seen to be the most common complication following type 1 tympanoplasty in both study groups (Figure 1).

Comparison of post-operative impedance audiometry in both study groups

In both our study groups, 'Ad' type was the most common type of impedance curve after surgery (Table 5).

DISCUSSION

Chronic suppurative otitis media is a leading cause of preventable deafness in the younger age groups. We find a number of patients coming to our OPD with ear discharge and hearing loss who are subjected to tympanoplasty. Although most patients have good graft uptake and hearing gain post operatively, we noticed that some patients had complications like failure of uptake of the graft, inadequate hearing gain or retraction of the graft post operatively. This could be attributed to several reasons one of which is inadequate ventilation of the middle ear. On reviewing the available literature, we did not find enough material directly comparing the results of

underlay type 1 tympanoplasty with gelfoam and without gelfoam in the middle ear as a packing agent, hence this study was undertaken.

We conducted our study on 65 patients having chronic suppurative otitis media with dry perforation in our department of otorhinolaryngology and head and neck surgery, KIMS, Hubbali.

Although 24.5% of our study population had bilateral perforations we studied only one ear in each case because the variables are considered to be independent of each other for study purposes.

In many patients with CSOM we found that there was some predisposing focus in the nose or nasopharynx like sinusitis, deviated nasal septum, adenoid hypertrophy or turbinate hypertrophy. All these predisposing factors were treated either medically or surgically before recruiting into the study. The patients were included in the study only after confirming that there was no predisposing focus in the nose or throat at the time of performing the trial.

In our study, we selected the age group of 10-65 years because in this age group there is less chance of upper respiratory tract infections and presbyacusis.

Table 6: Peak age group of CSOM in various studies.

Studies	Our study	Ettehad et al[4]	Harugop et al[5]	Nawabusi et al[6]	Jha et al[7]	Poorey et al[8]	Mansoor et al[9]	Khanna et al[10]
Peak age	11-19 & 20-29	21-31	15-35	<10	<10	1-10	<10	<10

Table 7: Gender ratio of CSOM in various studies (males: females).

Studies	Our study	Ettehad et al[4]	Harugop et al[5]	Nawabusi et al[6]	Jha et al[7]	Poorey et al[8]
M:F	1.43:1	1.6:1	1.5:1	1.35:1	1.5:1	1.4:1

Table 8: Graft uptake rate in our study versus other study.

Study	Our study (%)	Ghiasi et al[12] (%)
Graft uptake without gelfoam	80	62.2
Graft uptake with gelfoam	80.6	71.1

In our study it was found that the most common age group was 10-19 and 20-29 years which is in comparable with study conducted by Harugop et al and Ettehad et al (Table 6).[4,5]

In our study, we had 36 males (59%) and 25 (41%) females. In our study males were more than females which was comparable to most other studies we reviewed (Table 7).

In our study we found that graft uptake rate was 80%in patients in group 1, where we did not use gelfoam and graft uptake was 80.6% in group 2 where we used gelfoam as a packing agent in the middle ear. In a Study conducted by Ghiasi et al showed graft uptake rate of 71.1% in tympanoplasty with gelfoam and 62.2% in tympanoplasty without gelfoam.[12] Although larger perforations are supposedly difficult to repair there are studies which state that in properly performed procedures by experienced surgeons, the size of the perforation does not matter. Adkins and White proposed that the two factors which adversely influenced the success rate were the presence of a near total or total perforation and the presence of bilateral perforations (Table 8).[11]

The merits of our study was, it is one of the first comparative study of underlay type 1 tympanoplasty with gelfoam and no gelfoam in middle ear and the results being analysed based on graft uptake, hearing gain and analyses of complications.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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