

Type 1 Tympanoplasty in the Middle Ear with and without Gelfoam: A Comparative Assessment of the Outcome

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Conflict of interest: Nil

Abstract

Aim: The aim of this study is to compare the type 1 tympanoplasty with and without gelfoam in the middle ear. **Methods:** The present study was conducted in the Department of ENT, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India from January 2020 to January 2021. 100 patients admitted for type 1 tympanoplasty for chronic suppurative otitis media (quiescent and inactive) were considered for the study. Patients were age group of 10-60 years. All cases of CSOM (quiescent and dry) undergoing type 1 tympanoplasty without any contraindication, all cases of traumatic perforation undergoing type 1 tympanoplasty were included in this study. Patients with age group <10 years and >60 years, CSOM with active disease, patients with comorbidities were not included in the studies. **Results:** In our study, 60 patients were male of which 27 were in group 1 and 33 were in group 2. 40 patients were female of which 23 were in group 1 and 17 in group 2. There was no significant difference between the two groups in sex distribution as p value was more than 0.05. In our study, in group 1, 41 (82%) patients had complete graft uptake and 9 (18%) patients had failure of complete graft uptake following surgery. In group 2, 42 (84%) patients had complete graft uptake and 8 (16%) patients had failure of complete graft uptake following surgery. Thus, according to our study, graft uptake is comparable and good in surgical technique with gelfoam and without gelfoam. The T value based on paired t test was 11.6 in group 1 and 7.3 in group 2 with a p value of <0.001 in both groups which is statistically significant. Significant postoperative hearing gain was present in both the study groups (Table 3) In our study, median of hearing gain in group 1 was 13.63 with an interquartile range of 11 and median of hearing gain in group 2 was 14.25 with an interquartile range of 20. The p value based on Mann Whitney u test was 0.77 which is not statistically significant. **Conclusion:** 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: Gelfoam, Middle Ear, Tympanoplasty.

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Introduction

Absorbable gelatin sponge (Gelfoam) has been used for many years in middle ear surgeries. It is used routinely as a support structure in the middle ear cleft when ossicular reconstruction and tympanic membrane grafts are performed. It also helps to maintain the aeration of the middle ear and promote hemostasis. Although the gelfoam is generally well tolerated, fibrosis occasionally forms in the mesotympanum. Some of the studies indicate that absorbable gelatin sponge may be responsible for this fibrosis. A prospective study was conducted by Leining and Silberberg using three absorbable haemostatic agents in the middle ear of adult male Sprague–Dawley rats (middle and inner ear very similar to humans) to determine which promotes fibrosis to the greatest degree: absorbable gelatin sponge (gelfoam), absorbable gelatin film (gelfilm), or absorbable gelatin sheet (Instabovine dermal collagen). It was concluded that absorbable gelatin sponge promotes fibrosis more frequently than absorbable gelatin sheet and absorbable gelatin film in this model[1]. In an experimental histopathological study conducted by Joseph RB, the effect of absorbable gelatin sponge on scar formation in the middle ear of dogs was studied. It showed the presence of gel foam in an area denuded of mucosa produced a significant fibrosis. There was no benefit in using gel foam soaked with hydrocortisone and antibiotics. Fibrosis was localized to denuded area on the promontory. Even though the gel foam disappeared in 2 weeks, the gelfoam induced fibrosis persisted (gelfoam as scaffold and granulation tissue formed). About 3 months later, mature connective tissue, dense fibrous tissue was formed[2]. Middle ear packing agents are used in otologic surgery to provide support to the middle ear structures, maintain aeration of the middle ear, and promote haemostasis. However, there is currently a lack of standardization regarding the use of different types of packing agents. The choice of materials and

how they are used remain controversial. In fact, some have recently advocated for no packing[3]. Tympanoplasty is a common and well-known surgical procedure in otology. Numerous factors affecting the final surgical outcomes include the graft materials, causes of perforation and age[4]. However, little attention has been paid to middle ear packing material(MEPM)s and their effects on the graft materials, ossicular changes, hearing etc in the success of tympanoplasty. Absorbable gelatine sponge (AGS, gelfoam) was introduced by Correl and Wise as an absorbable haemostatic agent in 1945, and it has become the most commonly used MEMP in clinical practice. This material established its place as a scaffolding substance to support the grafting material and ossicular chains during tympanoplasty[5].

Material and methods

The present study was conducted in the Department of ENT, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India from January 2020 to January 2021, after taking the approval of the protocol review committee and institutional ethics committee.

Methodology

After taking informed consent detailed history was taken from the patient or the relatives if the patient was not in good condition. 100 Patients admitted for type 1 tympanoplasty for chronic suppurative otitis media (quiescent and inactive) were considered for the study. Patients were in age group of 10-60 years. All cases of CSOM (quiescent and dry) undergoing type 1 tympanoplasty without any contraindication, all cases of traumatic perforation undergoing type 1 tympanoplasty were included in this study. Patients with age <10 years and >60 years, CSOM with active disease and patients with comorbidities were excluded.

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 preoperative 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 such 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 postoperatively. 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.

Statistical analysis

Statistical analysis was done using SPSS version 22.0. Chi square test was used for non-parametric data analysis. Paired T test was used to analyse the hearing gain after surgery.

Results

100 Patients, 50 in group 1 (tympanoplasty without gelfoam) and 50 in group 2 (tympanoplasty with gelfoam) who fulfilled the inclusion and exclusion criteria were included in this study. 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 10-20 years and 20-30 years. In our study, 60 patients were male of which 27 were in group 1 and 33 were in group 2. 40 patients were female of which 23 were in group 1 and 17 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. In our study, in group 1, 41 (82%) patients had complete graft uptake and 9 (18%) patients had failure of complete graft uptake following surgery. In group 2, 42 (84%) patients had complete graft uptake and 8 (16%) 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 0.84 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). The T value based on paired t test was 11.6 in group 1 and 7.3 in group 2 with a p value of <0.001 in both groups which is statistically significant. Significant postoperative hearing gain was present in both the study groups (Table 3) In our study, median of hearing gain in group 1 was 13.63 with an interquartile range of 11 and median of hearing gain in group 2 was 14.25 with an interquartile range of 20. The

p value based on Mann Whitney u test was 0.77 which is not statistically significant. The hearing gain is good and comparable in both the study groups (Table 4). Comparison of various complications showed the residual perforation to be the

most common complication following type 1 tympanoplasty in both study groups. Comparison of postoperative impedance audiometry showed that the 'Ad' type was the most common type of impedance curve after surgery.

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

Study parameters	Group-1 N (%)	Group-2 N (%)	P value#
Age in years			
10-20	18 (36)	20 (40)	0.64
20-30	21 (42)	15 (30)	
Above 30	11 (22)	15(30)	
Total	50 (100)	50 (100)	
Gender			
Male	27 (54)	33 (66)	0.47
Female	23 (46)	17 (34)	
Total	50 (100)	50 (100)	

NOTE: # the p values given here are based on Chi-square (X^2) test

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)

Graft uptake	Group-1 N (%)	Group-2 N (%)	X2 value, df	P value#
Complete	41 (82)	42 (84)	0.003, 1	0.84
Incomplete	9 (18)	8 (16)		
Total	50 (100)	50 (100)		

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)

Group	Pre- PTA mean (SD)	Post-PTA mean (SD)	T value, df	P value#
No gelfoam	33.6 (6.6)	19.5 (5.7)	11.6, 28	<0.001*
Gelfoam	38.5 (6.7)	24.5 (9.8)	7.3, 28	<0.001*

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)

Feature	Group-1 Median (IQR)	Group-2 Median (IQR)	Z value	P value#
Hearing gain	13.63 (11)	14.25 (20)	-0.17	0.77

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).

Impedance	Group-1 N (%)	Group-2 N (%)	P value#
A	11 (22)	6 (12)	0.81
Ad	17 (34)	18(36)	
As	8 (16)	11(22)	
B	11 (22)	9(18)	
C	0	2(4)	
Cs	3 (6)	4(8)	
Total	50 (100)	50 (100)	

Table 6: Peak age group of CSOM in various studies

Studies	Our study	Ettehad et al[6]	Harugop et al[7]	Nawabusi et al[8]	Jha et al[9]	Poorey et al[10]	Mansoor et al[11]	Khanna et al[12]
Peak age	10-20 & 20-30	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[6]	Harugop et al[7]	Nawabusi et al[8]	Jha et al[9]	Poorey et al[10]
M: F	1.5:1	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 ¹⁴ (%)
Graft uptake without gelfoam	82	62.2
Graft uptake with gelfoam	84	71.1

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 postoperatively, we noticed that some patients had complications like failure of uptake of the graft, inadequate hearing gain or retraction of the graft postoperatively. 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 100 patients having chronic suppurative otitis media with dry perforation in our Department of ENT, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar. Although 25% 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 10-60 years because in this age group there is less chance of upper respiratory tract infections and presbycusis. In our study it was found that the most common age group was 10-20 years and 20-30 years which is comparable with study conducted by Harugop et al and Ettehad et al.[6-13] In our study, we had 60 males (60%) and 40 (40%) females. In our study males were more than females which was comparable to most other studies we reviewed[6-10]. In our study we found that graft uptake rate was 82% in patients in group 1, where we did not use gelfoam and graft uptake was 84% 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[14]. 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[14]. The merits of our study were, 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.

Conclusion

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

Reference

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