

Original Research Article

Comparative study of type 1 tympanoplasty with and without gel-foam in the middle ear

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ABSTRACT

Background: Chronic suppurative otitis media is a widespread disease for which tympanoplasty is frequently undertaken. Gel-foam may cause 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. The objectives of this study were to assess the graft uptake and hearing improvement following type 1 tympanoplasty with gel-foam in the middle ear and without gel-foam in the middle ear and to compare and assess results.

Methods: This was a randomized control trial done for a period of one year conducted in the department of ENT, at a tertiary referral hospital. 40 patients with dry perforation underwent type 1 tympanoplasty without gel-foam in the middle ear and 40 patients with dry perforation underwent type 1 tympanoplasty with gel-foam in the middle ear. Post-operative follow-up was done to look for graft uptake. Hearing assessment by pure tone audiometry was done 90 days post-operatively.

Results: Graft uptake was 82.5% in type 1 tympanoplasty without gel-foam in the middle ear and 85% with gel-foam in the middle ear. Both types of surgeries had significant hearing improvement.

Conclusions: Graft uptake is equally good in cases with gel-foam and without gel-foam. Hearing gain is comparable in both groups of patients.

Keywords: Tympanoplasty, Gel-foam, Middle ear, Graft, Surgery

INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) 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 sequelae 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 gel-foam 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 gel-foam 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 gel-foam 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 gel-foam 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 gel-foam for the middle ear. It is worth noting that not many trials have directly compared the outcomes of packing with gel-foam versus no packing in the middle ear.

The objectives of this study was to assess the graft uptake and hearing improvement following type 1 tympanoplasty with gel-foam in the middle ear; to assess the graft uptake and hearing improvement following type 1 tympanoplasty without gel-foam in the middle ear and to compare and assess the results in terms of graft uptake and hearing improvement.

METHODS

Source of data

The study was conducted in the department of otorhinolaryngology and head and neck surgery, Malla Reddy Institute of Medical Sciences, Hyderabad. 80 patients with dry perforation admitted for type 1 tympanoplasty by underlay technique for chronic suppurative otitis media (quiescent and inactive) were considered for the study

Setting

The study was carried out at tertiary referral hospital.

Period of study

The study period was from December 2019 to November 2020.

Study design

The study design was randomized control trial.

Aims

The aim of the study were- (a) to investigate cases of CSOM undergoing type 1 tympanoplasty by underlay technique with gel-foam in the middle ear; (b) to investigate cases of CSOM undergoing type 1 tympanoplasty by underlay technique without gel-foam 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 comorbidities.

Institution Ethics Committee permission was obtained. This was a longitudinal study conducted in a period of 1 year from December 2019 to November 2020. Patients were randomly selected for either tympanoplasty with gel-foam or for tympanoplasty without gel-foam after meeting the inclusion and exclusion criteria.

Detailed history, general examination and systemic examination of the patient were done. Otolological 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 prepared aseptically. Local anesthesia (xylocaine 2% with 1:100000 adrenaline) were administered in the post aural region and 4 quadrants of the EAC. Through the post aural Wildes incision, temporalis fascia graft harvested and preserved. Under the microscope tympanic membrane perforation visualized and edges freshened. Incision was 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 gel-foam in cases selected for tympanoplasty with gel-foam. Middle ear left as it is in cases selected for tympanoplasty without gel-foam temporalis fascia graft placed using underlay technique.

Tympanomeatal flap repositioned and EAC filled with medicated gel-foam. Post aural incision closed in 2 layers; mastoid dressing was put for duration of 1 week. (Figure 1 and 2). Patients were given intravenous antibiotics for one week. 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.

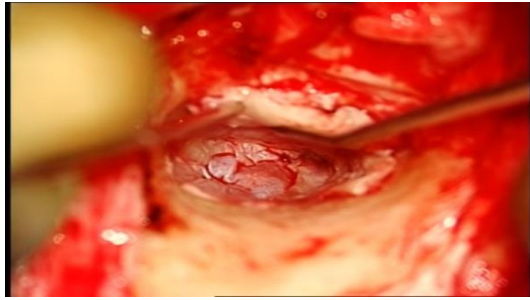


Figure 1: Tympanoplasty without gel-foam.



Figure 2: Tympanoplasty with gel-foam.

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 analyze the hearing gain after surgery. P value<0.05 was taken as statistically significant.

RESULTS

80 Patients, 40 in group 1 (tympanoplasty without gel-foam) and 40 in group 2 (tympanoplasty with gel-foam) who fulfilled the inclusion and exclusion criteria were recruited in to the study.

Table 1: Sex distribution in group 1 and 2.

Sex	Group 1	Group 2
Female	23	26
Male	27	24

Note: Chi square=0.3607; p=0.5484.

Table 2: Age distribution in group 1 and 2.

Age (years)	Group 1 (%)	Group 2 (%)
10-20	03 (7.5)	04 (10)
20-30	18 (45)	20 (50)
30-40	08 (20)	09 (22.5)
40-50	06 (15)	04 (10)
50-65	05 (12.5)	03 (7.5)
Total	40 (100)	40 (100)

Note: Chi square=1.2069; p=0.8769.

Table 3: Comparison of graft uptake and failure of graft uptake in two groups.

Variables	Group		Chi square	P value
	1 (%)	2 (%)		
Graft uptake	34 (85)	33 (82.5)	0.0907	0.7633
Failure of graft uptake	6 (15)	7 (17.5)		
Total	40 (100)	40 (100)		

Table 4: Comparison of pure tone audiometry results pre-operatively and post-operatively in two groups.

Pure tone audiometry mean±SD	Pre-operative	Post-operative
Group 1	33±3.5	19.5±2.1
Group 2	36.5±4.2	23.5±2.6
T value	4.0488	7.569
P value	<0.001	<0.001

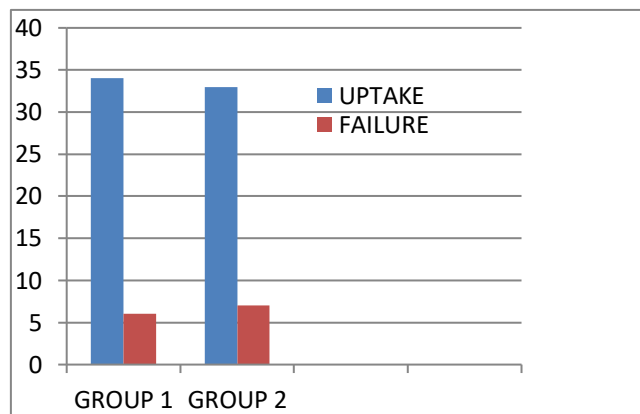


Figure 3: Diagrammatic representation of graft uptake and failure in group 1 and group 2.

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. We wanted to review the literature on comparison of type 1 tympanoplasty with and without middle ear gel foam and see if we could reproduce similar results or otherwise in our institute.

We conducted our study on 80 patients having chronic suppurative otitis media with dry perforation in our

department of otorhinolaryngology and head and neck surgery, MRIMS, Hyderabad.

All predisposing factors related to nose, nasopharynx and throat were treated either medically or surgically before recruiting the patients into the study as these factors could interfere with proper interpretation of results because of higher chances of failure of graft uptake.

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 presbycusis.

In our study we found that graft uptake rate was 82.5% in patients in group 1, where we did not use gel-foam and graft uptake was 85% in group 2 where we used gel-foam 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 gel-foam and 62.2% in tympanoplasty without gel-foam.⁴ 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. In another study by Malick et al graft uptake for type 1 tympanoplasty with gel-foam was 80.6% and for type 1 tympanoplasty without gel-foam was 80%.⁵

CONCLUSION

Based on these results we can conclude that type 1 tympanoplasty with and without gel-foam have similar outcomes and type 1 tympanoplasty without gel foam can be done with similar results without the complications associated with type 1 tympanoplasty with gel-foam.

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Conflict of interest: None declared

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

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