ORIGINAL RESEARCH

Comparison of the clinical outcomes of type I tympanoplasty done with and without fibrin glue at a tertiary centre

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ABSTRACT
Background: The middle ear cleft's chronic inflammation in the presence of a persistent tympanic membrane perforation is known as chronic otitis media - mucosal type. The present study was conducted to compare the clinical outcomes of type I tympanoplasty done with and without fibrin glue. **Materials & Methods:** 60 patients with tympanic membrane perforation of both genders were divided into 2 groups. In group I, fibrin glue was applied along the edges of the perforation. In group II, fibrin glue was not applied. Parameters such as side, type, hearing improvement, and outcome was recorded on recall visits. **Results:** Out of 60 patients, 32 were males and 28 were females. Side was right in 16 and 13 and left in 14 and 17 in group I and group II respectively. Quadrants were antero-inferior in 9 and 9, antero-superior in 10 and 6, postero-inferior in 6 and 8 and postero- superior in 5 and 7 patients respectively. Pure tone average pre-operative value was 34.6 and 37.4, at 3 months was 25.3 and 24.5 and at 36 months was 23.9 and 22.1 in group I and group II respectively. The difference was significant (P< 0.05). Graft uptake rate in group I was 95% and in group II was 92%. **Conclusion:** Fibrin is safe to use in middle ear procedures and there is no need to worry about negative side effects. Fibrin glue is too expensive to be included in the conventional type I tympanoplasty treatment, but it can be used to secure the graft in patients with extensive perforations, therefore individuals with subtotal perforations may want to consider it.
Keywords: middle ear, graft, tympanoplasty

INTRODUCTION

The middle ear cleft's chronic inflammation in the presence of a persistent tympanic membrane perforation is known as chronic otitis media - mucosal type. Because life-threatening complications are less common than with squamous illness (also known as "unsafe" ear), it is often referred to as "safe" ear.[1]The most common surgical approach for managing tympanic membrane perforation due to chronic otitis media is tympanoplasty with a temporalis fascia graft. The objectives of thisprocedure are to repair the perforated membrane, eradicate infection, and restore hearing loss.[2-4]

A frequent operation is type I tympanoplasty using a post-aural approach with temporalis fascia. Tympanoplasty is a surgical procedure used to repair a perforated (ruptured) eardrum (tympanic membrane) and, in some cases, to reconstruct the middle ear bones (ossicles).[5]

The goal of tympanoplasty is to restore hearing and prevent infections or further damage. Many patients experience significant improvements in hearing and a reduction in ear infectionsfollowingtympanoplasty.[6]Additionally, variouscompounds are employed to guarantee the

graft's adhesion to the remaining tympanic Fibrin glue is being investigated for use in a number of otorhinolaryngology operations, particularly tympanoplasty and other otological surgery.[7]

AIM AND OBJECTIVES

The present study was conducted to compare the clinical outcomes of type I tympanoplasty done with and without fibrin glue.

MATERIALS & METHODS

The present prospective comparative study was conducted on 60 patients with tympanic membrane perforation of both genders at the Department of Otorhinolaryngology (ENT), Narayan Medical College and Hospital, Jamuhar, Sasaram, Bihar, India. All were informed regarding the study and their written consent was obtained. The study was approved by the Institutional Ethics Committee. The duration of the study was from March 2019 to April 2020. A treatment chart and patient data collection form with demographic details such as name, age, gender, etc., complete medical, surgical, and drug histories, laboratory data, and imaging results were recorded.

Inclusion criteria

- Patients who gave written informed consent.
- Patients undergoing type I tympanoplasty forchronic otitis media – mucosal type with a dry ear for at least four were included in the study.
- Patients of either sex aged between 10 and 60 years.
- Available for follow-up.

Exclusion Criteria

- Patients do not give written, informed consent.
- Patients of either sex aged < 10 years or > 60 years
- All patients who had a previous history of ear surgery in the same ear, sensorineural hearing lossor a conductive hearing loss more than 45 dB, congenital ear deformities, and atticoantral variety of CSOM were excluded from the study.
- Not available for follow-up.

Data such as name, age, gender etc. was recorded. Otomicroscopy, pure tone audiometry and posterior rhinoscopy were done preoperatively. The size of the tympanic perforation was recorded and were divided into small, medium, subtotal and total perforations. The surgery was done under general anaesthesia. As a standard, temporalis fascia graft was harvested by postaural route and was used in the repair of the perforation. The procedure was done under the vision of an operating microscope. Patients were divided into 2 groups. In group I, fibrin glue was applied along the edges of the perforation. In group II, fibrin glue was not applied. Parameters such as side, type, hearing improvement, and outcome was recorded on recall visits.

Statistical Analysis

Data thus obtained were subjected to statistical analysis by using Microsoft and SPSS (Statistical Package for The Social Sciences) Version 16.

A P value < 0.05 was considered significant.

RESULT

Table I:Gender wise distribution of patients

Total- n=60		
Gender	**Male**	**Female**
Number	32	28

Figure 1: Gender wise distribution of patients

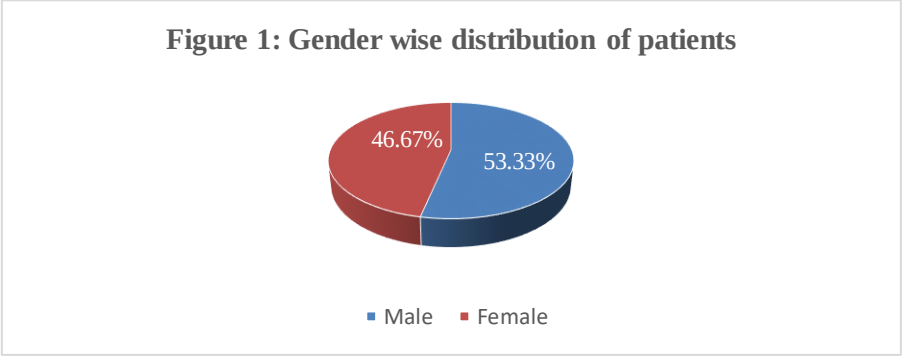


Table I and figure 1, shows that out of 60 patients, 32 were males and 28 were females.

Table II: Assessment of parameters

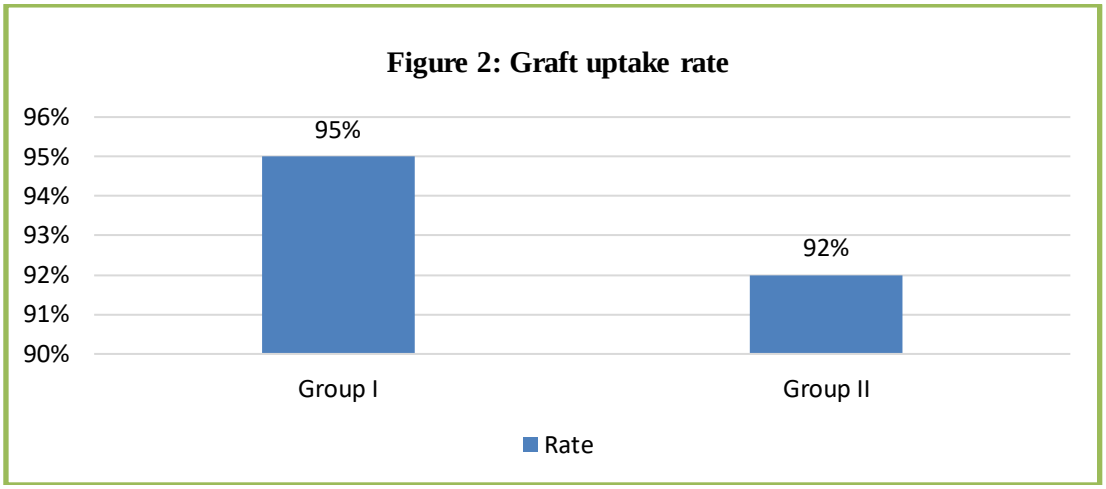
Parameters	Variables	Group I (n=30)	Group II (n=30)	P value
Side	Right	16	13	0.56
	Left	14	17	
Quadrants	Antero-inferior	9	9	0.83
	Antero-superior	10	6	
	Postero-inferior	6	8	
	Postero- superior	5	7	
Pure tone average	Pre-operative	34.6	37.4	0.05
	3 months	25.3	24.5	
	36 months	23.9	22.1	

Table II shows that side was right in 16 and 13 and left in 14 and 17 in group I and group II respectively. Quadrants were antero-inferior in 9 and 9, antero-superior in 10 and 6, postero-inferior in 6 and 8 and postero- superior in 5 and 7 patients respectively. Pure tone average pre-operative value was 34.6 and 37.4, at 3 months was 25.3 and 24.5 and at 36 months was 23.9 and 22.1 in group I and group II respectively. The difference was significant (P< 0.05).

Table III: Graft uptake rate in both groups

Graft uptake	Rate	P value
Group I	95%	0.82
Group II	92%	

Table III andfigure 2, shows that graft uptake rate in group I was 95% and in group II was 92%.



DISCUSSION

Tympanoplasty is usually performed under general anaesthesia, but in some cases, local anaesthesia with sedation may be used.[8] The surgeon will make an incision either in front of the ear or within the ear canal. The eardrum is examined, and any damaged tissue is removed.[9] A graft, often taken from the patient's own tissue (such as from the ear canal or the temporalis muscle), is used to repair the perforation. If the middle ear bones are damaged, the surgeon may reconstruct them using prosthetic materials or the patient's own tissues.[10,11] The present study was conducted to compare the clinical outcomes of type I tympanoplasty done with and without fibrin glue.

We found that out of 60 patients, 32 were males and 28 were females. Lakshmanan S et al.[12] compared the clinical outcomes of type I tympanoplasty done with and without fibrin glue. The patients were randomly divided into two groups – Group A and Group B. Patients in group A underwent tympanoplasty with fibrin glue and patients in group B underwent tympanoplasty without fibrin glue. The patients were followed up for 6 months and the postoperative hearing improvement and graft uptake rates were compared. The pre-operative mean pure tone average for group A was 34.33±7.3dB; it improved to 22.14±6.5 Db at the end of 6 months. In group B, it improved from 34.25±8dB to 22.64±7.4dB at the end of 6 months. There was no statistical significance in hearing improvement between both the groups. Though there was no statistically significant difference in the graft uptake rates between group A (94.3%) and group B (91.4%), fibrin glue had better outcomes with larger perforations.

We found that side was right in 16 and 13 and left in 14 and 17 in group I and group II respectively. Quadrants were antero-inferiorin 9 and 9, antero-superior in 10 and 6, postero-inferior in 6 and 8 and postero- superior in 5 and 7 patients respectively. Pure tone average pre-operative value was 34.6 and 37.4, at 3 months was 25.3 and 24.5 and at 36 months was 23.9 and 22.1 in group I and group II respectively. We found that graft uptake rate in group I was 95% and in group II was 92%.

Fibrin glue gives a particular advantage for graft uptake in subtotal perforations and is a safe method of tympanoplasty.[13]

Maeta et al. found that although overall graft uptake was poorer than with traditional myringoplasty, the application of fibrin glue in large perforations resulted in improved rates of graft uptake and better hearing results.[14]

LIMITATION OF THE STUDY

The shortcoming of the study is small sample size.

CONCLUSION

Authors found that fibrin is safe to use in middle ear procedures and there is no need to worry about negative side effects. Fibrin glue is too expensive to be included in the conventional type I tympanoplasty treatment, but it can be used to secure the graft in patients with extensive perforations, therefore individuals with subtotal perforations may want to consider it.

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REFERENCES

1. Acar M, Yazıcı D, San T, Muluk NB and Cingi C. Fat-plug myringoplasty of ear lobule vs. abdominal donor sites. Eur Arch Otorhinolaryngol 2015;272(4): 861–866.
2. Hsu YC, Kuo CL, Huang TC. A retrospective comparative study of endoscopic and microscopic tympanoplasty. J Otolaryngol Head Neck Surg 2018; 47:44
3. Indorewala S, Pagare R, Aboojiwala S, Barpande S. Dimensional stability of the free fascia grafts: a human study. Laryngoscope 2004; 114:543–7
4. Asghari A, Mohseni M, Daneshi A, Nasoori Y, Rostami S, Balali M. Randomized clinical trial comparing bucket handle and cartilage tympanoplasty techniques for the reconstruction of subtotal or anterior tympanic membrane perforation. Int J Otolaryngol 2018; 2018:2431023
5. Gun T, Sozen T, Boztepe OF, Gur OE, Muluk NB and Cingi C: Influence of size and site of perforation on fat graft myringoplasty. Auris Nasus Larynx 41(6): 507-512, 2014. PMID: 25199735.
6. Knutsson J, Kahlin A and von Unge M: Clinical and audiological short-term and long-term outcomes of fat graft myringoplasty. Acta Otolaryngol,137(9): 940-944, 2017. PMID: 28537107.DOI:10.1080/00016489.2017.1326063 .

7. Han JS, Han JJ, Park JM, Seo JH and Park KH: The long-term stability of fat-graft myringoplasty in the closure of tympanic membrane perforations and hearing restoration. ORL J OtorhinolaryngolRelat Spec 83(2): 85-92, 2021. PMID: 33341797. DOI: 10.1159/000512084
8. Khafagy A, El-begermy M, El-begermy M and Afifi P: Comparative study between fat plug and inlay butterfly cartilage grafts for myringoplasty in adults. The Egyptian Journal of Otolaryngology 37(1), 2021. DOI: 10.1186/s43163-021-00076-y 14
9. Saliba I and Woods O: Hyaluronic acid fat graft myringoplasty: a minimally invasive technique. Laryngoscope 121(2): 375-380, 2011. PMID: 21271592. DOI: 10.1002/lary.21365 15
10. Saliba I: Hyaluronic acid fat graft myringoplasty: how we do it. Clin Otolaryngol 33(6): 610-614, 2008. PMID: 19126140. DOI: 10.1111/j.1749-4486.2008.01823.
11. Saliba I: In response to Growth factors expression in hyaluronic acid fat graft myringoplasty. Laryngoscope 127(7): E252, 2017. PMID: 28480556
12. Lakshmanan S, Umamaheswaran P. A Comparative Study of Outcomes of Type I Tympanoplasty with or without Fibrin Glue. Bengal Journal of Otolaryngology and Head Neck Surgery. 2019 Apr 30;27(1):15-8.
13. O'Connor F, Shea JJ. A biologic adhesive for otologic practice. Otolaryngol Head Neck Surg. 1980; 90: 347-8.
14. Maeta M, Saito R, Nakagawa F, Miyahara T et al. A clinical comparison of orthodox myringoplasty and a simple method with fibrin glue. Nippon-Jibiinkoka- Gakkai-Kaiho 1998; 101:1062-8.