

Original Research Article

A retrospective study comparing treatment outcomes of spontaneous healing, scaffolding with silastic sheet and gelfoam in patients with traumatic tympanic membrane perforations

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ABSTRACT

Background: Objective of the study was to compare the treatment outcome of conservative management, intervention with silastic sheet and gelfoam mixed with autologous blood in traumatic perforations of tympanic membrane.

Methods: A retrospective study was conducted on 69 patients; with traumatic ear perforation were treated by conservative management, silastic sheet placement and gelfoam with autologous blood. Patients data every week and minimum of 4 visits was documented. On follow up data was reassessed in terms of symptom improvement, healing of perforation, duration for healing and development of secondary infection. Statistical analysis was done using Fischer's exact test.

Results: Out of the 69 patients group1 consisted of 38 patients, group2 had 19 and group3 had 12 patients. The age ranged from 02-72 years, with greater incidence in females. In group 1 though the healing rate was very good symptom improvement was gradual. The symptom improvement in both group 2 and 3 were satisfactory and highly significant $p < 0.001$. The difference in healing outcome of three modality of treatments was found significant $p < 0.05$ but the occurrence of infection and local reaction did not affect the healing outcome at the end $p < 0.05$.

Conclusions: Traumatic TM perforations have a high chance of healing. Treatment outcome should not consider only healing status as a sole measure but symptom relief from distressing symptoms like ear buzzing or tinnitus and hearing loss should also be considered. Use of scaffolding method can be useful in such cases. Hence selection of proper treatment modality should be considered based on patient complaints.

Keywords: Retrospective study, Careful consideration, Treatment for traumatic tympanic membrane perforations

INTRODUCTION

One of the commonly faced problems by otolaryngologists is traumatic tympanic membrane (TM) perforations. Various etiologies include attempts of self cleansing of ear, scratching with sharp objects, slap injury, domestic violence, road traffic accidents and barotrauma. Most of the traumatic perforations heal spontaneously. Moreover small perforations are more likely to close spontaneously than larger ones.¹

The symptoms include hearing loss, ear pain, aural fullness, ear buzzing, bleeding from ear and at times can present with vertigo. Most of the studies suggest that 90% of traumatic perforations heal spontaneously within three months of injury.² Many treatment modalities have been proposed like conservative management, everting the edges of perforation and supporting the fragments with gel foam, application of platelet rich plasma.³⁻⁶

In addition to healing of TM, the presenting symptoms of the patients should also be addressed. Ear buzzing is quiet

common and disturbing after traumatic TM perforations. In such cases use of a scaffold can provide symptomatic benefit to the patient. Selection of proper treatment modality is equally important to achieve better results.

METHODS

Ethical considerations

The study was reviewed and approved by Institutional Ethics Committee and is conducted in compliance with the Declaration of Helsinki. All the procedures were performed with prior consent from the patient; under aseptic conditions.

Methodology

A retrospective study on 83 patients presenting with traumatic TM perforation was performed in a tertiary care hospital from May 2016 to September 2017. Out of that 14 patients were excluded from the study some due to lack of complete data and few who presented more than 4 weeks after injury to the OPD. The patients were treated according to their day of visit to the hospital and the consultant in OPD. The patients coming to consultant 1 OPD were treated by conservative approach (group 1), consultant 2 OPD by placement of silastic sheet (group 2) and consultant 3 OPD by gel foam with patients own blood (group 3). All the patients received one systemic antibiotic, one anti histamine. They were all advised to keep ear dry and not wet the ears or instil any ear drops.

Silastic sheet manufactured from high quality medical grade silicone with 0.005mm thickness was used. The sheet was cut in different sizes and sterilised by ethylene oxide gas prior to use. Silastic sheet scaffold of appropriate size and shape was placed over the perforation. The perforation was sealed completely. Gel foam a highly absorbent, nonelastic sponge manufactured

from neutral gelatine of pharmaceutical grade material around 4 mm thick was used in group 3. Gel foam was supplied sterile in its original packaging. Minimal amount of gel foam of appropriate size and shape mixed with patients blood was applied over the perforation and held firmly in place.

The parameters under which the data was retrieved are age, sex, laterality, mode of injury, symptoms (ear pain, hearing loss, ear buzzing, ear bleeding), site of perforation, size of perforation, degree of hearing loss. The ear drum appearance was assessed by recorded otoendoscopic picture. Estimation of the size of perforation was done as small (less than 1/4th of TM), moderate (less than half of TM) and large (more than half of TM). Pure tone audiometry was done in all patients >3 yrs age.

Patients data every week and minimum of 4 visits were documented. On follow up data was reassessed in terms of symptom improvement, healing of perforation, duration for healing and development of secondary infection. Patients developing secondary infection was treated with dry ear toileting, removal of scaffold and continued on systemic antibiotics. Further follow up was continued on weekly basis.

Statistical analysis

Statistical analysis was done using Fischer’s exact test.

RESULTS

A total of 69 patients with traumatic TM perforation were included in the study. Group 1 (n=38) included patients who were treated conservatively, group 2 (n=19) included those treated with silastic sheet and group 3 (n=12) were the patients treated with gel foam and autologous blood.

Table 1: Demographic data.

		Conservative (n=38)	Silastic sheet (n=19)	Gel foam with autologous blood (n=12)	P value
Age	Min- Max Age	02-70 yrs	18-47 yrs	18-42 yrs	
Sex	Male	14	9	8	0.188
	Female	24	10	4	
Laterality	Right	13	5	4	0.828
	Left	25	14	8	
Total		69			

Table 2: Etiology for traumatic ear drum perforation.

Etiology	Number of patients (%)
Slap injury	42 (60.86)
Self cleaning	17 (24.63)
RTA/ Fall	4 (5.7)
Blow	5 (7.24)
Iatrogenic	1 (1.4)

Table 3: Healing outcome of traumatic TM perforations.

Method	Total no. of patients	No. of patients with healed TM perforation	P value
Conservative	38	38	0.005
Silastic sheet	19	15	
Gel foam and autologous blood	12	12	

Table 4: Occurrence of infection.

Method	No. of patients	No. of patients with healed TM perforation after control of infection	P value
Conservative	2	2	0.148
Silastic sheet	3	2	
Gel foam with autologous blood	0	0	

Demographic data of the 69 subjects is summarized in Table 1. No significant differences in patient age, sex, duration of injury or cause of injury were observed among the three groups. Youngest patient was 2 year old female child who sustained traumatic perforation as a result of injury due to insertion of pencil. Majority of the patients had traumatic TM perforation caused by overpressure due to slap as a part of domestic violence and blow injuries; details of etiology are given in Table 2.

62.31% of them had small, 24.63% moderate and 13.04% had large central perforations. Hearing loss was mostly of mild conductive type (79.71%). Nine out of 69; 13.04% of patients reported no hearing loss. Apart from pain and hearing loss; ear buzzing is one of the most distressing symptoms which were noticed by 42 patients on D1. Treatment outcome was measured in terms of healing of the perforation, duration for healing and improvement in symptoms.

number of patients presenting with various symptoms on day one and improvement in symptoms on subsequent follow up weekly visits.

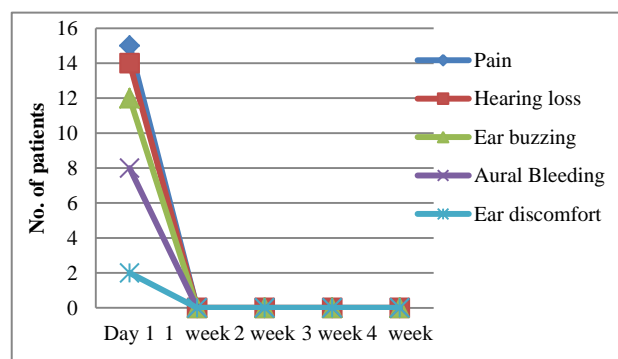


Figure 2: Symptom improvement in group 2.

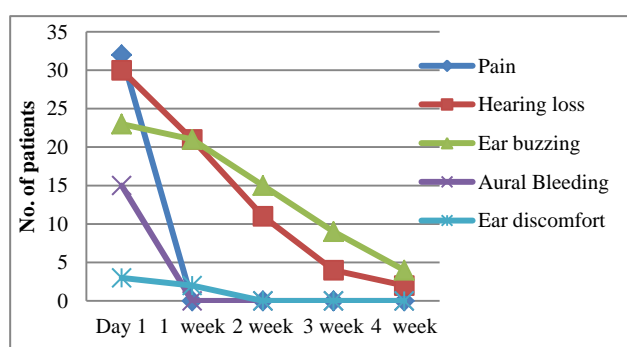


Figure 1: Symptom improvement in group 1.

It was seen that with conservative management though the healing rate was very good symptomatic improvement was gradual. The symptomatic improvement in both group 2 and 3 were satisfactory and highly significant $p < 0.001$. Symptoms which improved immediately following treatment in group 2 and 3 were hearing loss and ear buzzing. Figure 1–3 shows the

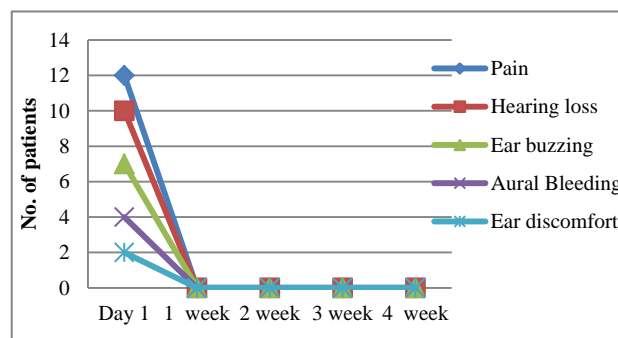


Figure 3: Symptom improvement in group 3.

The perforation healed in 94.73% cases in group 2 and 100% in group 3. Healing outcome of all three groups is given in Table 3. Three patients from group 2 developed infection resulting in removal of silastic sheet during treatment. The healing outcome of three groups when compared was found significant $p < 0.05$.

In group 1; two patients developed ear infection. Ear infection and local reaction to silastic sheet was noticed

in three patients of group 2. Table 4 shows the occurrence of infection. They presented with granulations on tympanic membrane, ear discharge and displacement of the sheet within 2-3 days. They were treated by removal of the silastic sheet, dry toileting of the ear and the ear was left dry without any intervention. On subsequent weekly follow up visits the TM perforation healed completely in four patients and the healing outcome was not much affected by the same $p>0.05$.

The average time required for the perforation to heal was between 3 to 4 weeks for all the three groups.

DISCUSSION

Synopsis of findings

Majority of traumatic ear drum perforations 42 (60.86%) were caused by over pressure due to slap injury or blow to the ear. Few of them 17 (24.63%) were caused by self inflicted trauma by blunt or penetrating injuries. Most of them 55 (79.71%) had mild conductive hearing loss with only two having a mixed hearing loss. Traumatic TM perforations are still common, affects all age groups with females affected more than males as a result of slap injury from domestic violence.

Though the difference in healing outcome of three treatment modalities was significant ($p<0.05$); presence of infection and local reaction did not affect the healing outcome at the end ($p>0.05$). On the contrary parameters like hearing loss and ear buzzing showed significant improvement in group 2 and 3 as compared to group 1 ($p<0.001$) in next week after treatment.

Comparison with other studies

An overview on traumatic TM perforations reported most common complaint was tinnitus followed by aural fullness and reduced hearing.⁷ Whereas some of them noticed hearing loss as the most common complaint followed by tinnitus and otalgia.^{8,9} In our study the most common symptom was hearing loss followed by pain and ear buzzing. The most distressing symptom was ear buzzing.

Previous studies have noted higher prevalence of traumatic TM perforation in female population consistent with our findings.^{10,11} Traumatic perforations of the tympanic membrane have a very high chance of spontaneous healing. So that early surgical intervention of traumatic perforations is not indicated by few studies.^{4,12-14} In our study the healing outcome with conservative management was very good. But ear buzzing was still present for initial few weeks till the perforation reduced or healed. Though two of them developed a secondary infection later on; their healing outcome was 100%. They were treated by simple dry ear mopping and the infection was controlled. Presence of infection did not affect the healing process.

Various studies have reported different techniques of scaffolding for the non surgical regeneration of traumatic TM perforations. Use of scaffolds aids the migration of epithelial cells, it acts as a splint and given a flat surface, the epithelium grows at the rate of 1mm per day.^{15,16} In the past paper patch was frequently used but due to many disadvantages like inflexibility, non transparency, easy detachment and high chances of infection now a days other materials are used¹⁴. Other materials used are gel foam, collagen, calcium alginate, silk and chitosan.

In our study we used silastic sheet which is manufactured from high quality medical grade silicone as a treatment modality in group 2 and gelfoam in group 3. Silastic sheet has advantages of being inert, has no adherence to the tissue. As the perforation healed the sheet was seen displacing outwards in the canal. After complete healing of the TM was confirmed the sheet was further manually removed from the ear canal. Patient symptoms of ear buzzing and hearing loss improved drastically with sheet placement. The silastic sheet is latex free and hence chances of reaction reduce, but in our study local reaction was seen in 3 cases. Silastic sheet scaffold showed effective healing in traumatic TM perforations in 94.73% of cases. Review of literature revealed no study demonstrating the use of silastic sheet in traumatic TM perforations.

Gelfoam is highly purified neutral gelatine of pharmaceutical grade material. It is non toxic, non allergic, non immunogenic and non pyrogenic. It is usually absorbed completely in 4-6 weeks without inducing excess scar tissue. In a recent study it was also concluded that gelfoam patching helps epithelial migration, promotes edema, granulation tissue formation at the edges and aids in ear drum healing.¹⁷ A natural human blood clot consists of 95% red blood cells, 5% platelets, less than 1% white blood cells, and numerous amounts of fibrin strands.¹⁸ The fibrin strands contain various growth factors and also have molecules that function in cell migration. Keeping the ear drum moist again promotes granulation tissue, hyperplasia of perforation edged, thereby aiding in ear drum healing.¹⁹ Gelfoam with autologous blood will help create moisture and clot formation will further aid in healing. The method is simple, minimally invasive procedure, cost effective and can be prepared in the OPD setting without any specialised machinery for preparation. The effective healing in traumatic TM perforations was seen in all patients of group three. Patient symptoms of ear buzzing and hearing loss improved drastically. Although adverse reactions in the form of infection, foreign body reactions have been reported with gel foam use; there was no such occurrence during the study.²⁰

Saimanohar et al in a comparative study concluded that minimally invasive procedures like everting the edges and supporting with gelfoam definitely reduces the total period of healing.²¹ Various other studies have also reported that early intervention by scaffolds reduces the

healing time. In our study it was seen that there was no significant difference in the healing time.^{22,23}

Strengths of study

In our study it was observed that any intervention does not improve the healing outcome nor does fasten healing process. The major advantage of intervention was to relieve the patients of distressing symptoms. When considering traumatic TM perforations it is well known that they have a high chance of healing. The smaller perforations heal faster as compared to the larger ones. Few previous studies have reported the closure rates for small perforation to be greater than 94% and thus any kind of intervention was not recommended.¹ But the symptoms of ear buzzing or tinnitus can be present with even a small perforation. The role of scaffolding is important here to seal the perforation which reduces ear buzzing and at times improves hearing function also.

CONCLUSION

Traumatic TM perforations are well known to have a high chance of spontaneous healing. Treatment outcome should not consider only healing status as a sole measure but symptomatic relief from distressing symptoms like ear buzzing or tinnitus an hearing loss should also be considered. Use of scaffolding method can be useful in such cases. Hence selection of proper treatment modality should be considered based on patient complaints.

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