

The Role of Collagen Tympanoplasty for the Management of Traumatic Perforations

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Abstract:

Introduction: Traumatic perforation of the tympanic membrane is common presentation in the ENT out-patient departments. The variety of treatment options ranges from just regular follow up without any intervention to immediate surgical intervention. Collagens are the amplest proteins of the body and are major components of connective tissue. The objective of this study is to compare the closure rates of traumatic perforations larger than 25% of the tympanic membrane with office-based repair with collagen sheets against spontaneous closure of the traumatic perforation.

Materials and Methods: A randomised control trial was done in the department of ENT from a tertiary care hospital, between August 2021 and December 2022. All the patients were examined and diagnosed by the same surgeon to exclude examiner's bias. Demographic data, mechanism of injury, characteristics of the perforation and pure tone audiogram was recorded for each patient at first presentation. Patients aged between 20 and 50 years of age, who were having a traumatic perforation involving more than one quadrant with conductive hearing loss of not more than 45dB were chosen as study participants and were included in the study. Patients selected were randomly divided into two groups – Group A (cases) and Group B (controls) by simple random sampling (using lottery method). The patients in Group A underwent an office based myringoplasty. The patients in Group B were subjected to routine otoscopy and were advised water precautions.

Results: Sixty-eight patients with traumatic perforation of the tympanic membrane who presented to the emergency department and our out-patient department were included. 58 patients (85.3%) had moderate sized perforations involving 2 quadrants of the tympanic membrane and 10 patients (14.7%) had large sized perforations involving 3 quadrants of the tympani membrane. After 6 months the perforation healed in a total 60 patients (88.2%), a higher rate of healing was seen in the cases group (32 patients - 94.1%) than the controls group (28 patients - 82.4%) in the controls group. Among the patients with large perforations in the study all the 5 patients in the cases group had successfully healed perforations while only 2 out of the patients in the controls group had healed perforations.

Conclusion: From the above study we conclude that perforations involving less than 50% of the tympanic membrane were found to have similar closure rates even with conservative management; collagen tympanoplasty in these cases does not show any significant improvement. But in cases with traumatic perforation involving more than 50% of the tympanic membrane, the closure rates are higher with collagen tympanoplasty.

Keywords: Collagen, Traumatic perforation, Office tympanoplasty.

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Introduction

Traumatic perforation of the tympanic membrane is common presentation in the ENT out-patient departments. The incidence of traumatic TM

perforation is reported in previous literature is 6.80/1000 persons.[1] Traumatic perforations are seen to occur due to various causes and the

commonly seen causes are pressure injury due to blunt force trauma, penetrating trauma (commonly ear bud or hairpin injury) and blast injuries due to firecrackers. The traumatic perforations can also be due to slapping, forceful syringing and caloric tests, faulty technique of ear cleaning or extracting FB, probing, accidents, travelling in a non-pressurized air craft or sudden fluid compression while diving.[2]

Traumatic perforations usually result in conductive hearing loss, the extent of which depends on the size and location of the perforation but it rarely exceeds 30dB. Traumatic perforations may also be accompanied by ossicular chain injury, sensorineural hearing loss, vertigo, tinnitus perilymph fistula and facial nerve injury[3] and late cholesteatoma formation. Incomplete healing of the tympanic membrane perforation subjects the patients to suffer from secondary infections of the middle ear leading to continuous ear discharge and hearing loss which in turn affects the quality of life of the patient.[4] There is no consensus over the best management for traumatic perforations. The variety of approaches ranges from just regular follow up without any intervention to immediate surgical intervention. The common recommendation consists of water precautions alone. Previous literature suggests that perforation due to trauma has spontaneous healing rate ranging from 78. % to 90%.⁵ Few studies have shown to have a chance in perforation closure of 95% depending on the size of the perforation and it is also observed that the rate of spontaneous healing of perforations is inversely proportional to the age of the patient and size of the perforation.[6]

If the perforation does not heal spontaneously in 3 to 6 months, then myringoplasty was done in the absence of infection which had a 90% success rate. The main aim of surgically closing a chronic tympanic membrane (TM) perforation is to prevent reappearance of active discharge from middle ear along with improvement in hearing.[7] Even immediate surgical intervention recommendations range from office procedures done under local anaesthesia to tympanoplasties done in the operation theatre under general anaesthesia.

These procedures are only recommended in patients where middle ear injury is suspected especially in penetrating injuries.[8] Other methods employed include non-surgical interventions like placing a paper patch over the edges of the perforation or application of fibroblast growth factor which enhances the proliferation of fibroblasts and accelerates the closure of the perforation.[9] Collagens are the amplest proteins of the body and are major components of connective tissue. Collagen fibers are of various diameters and are arranged in different patterns in

different tissues. Collagen types I to IV are the most abundant collagens in animals. For example, muscular fascia, which is commonly used to repair perforated tympanic membrane (TM) tissue during myringoplasty, consists primarily of collagen type I. In addition, collagen types I and III have been found at the perforation border and around dilated blood vessels early in the healing phase after myringotomy in rats.[10] The fibrinogen-based collagen fleece (Tachocomb®, Nycomed Austria GmbH, Linz, Austria) is a collagen-bound fibrinogen sealant. It consists of a sponge-like patch composed of equine collagen.[11]

The aim of this study is to compare the closure rates of traumatic perforations larger than 25% of the tympanic membrane with office-based repair with collagen sheets against spontaneous closure of the traumatic perforation.

Materials and Methods:

A randomised control trial was done in the ENT department of a tertiary care hospital of all patients who presented with traumatic perforations in our emergency and outpatient departments from August 2021 to December 2022. All the patients were examined and diagnosed by the same surgeon to exclude examiner's bias. Demographic data, mechanism of injury, characteristics of the perforation and pure tone audiogram was recorded for each patient at first presentation. Patients aged between 20 and 50 years of age, who were having a traumatic perforation involving more than one quadrant with conductive hearing loss of not more than 45dB were chosen as study participants and were included in the study. Patients with perforations involving only one quadrant, with conductive hearing loss more than 45dB and with sensorineural hearing loss were excluded according to the exclusion criteria. Patients selected were randomly divided into two groups – Group A (cases) and Group B (controls) by simple random sampling (using lottery method). The patients in Group A underwent an office based myringoplasty. They were given local infiltration in all quadrants of the external auditory canal, under endoscopic vision the edges of the perforation were repositioned, 3 layers of collagen sheets were placed over the edges of the perforation and the external auditory canal was packed with gel foam. The patients in Group B were subjected to routine otoscopy and were advised water precautions. The patients in both groups were subjected to a pure tone audiogram on diagnosis, after 3 months and after 6 months. The closure of the perforation was also monitored on a monthly basis.

Result

Sixty-eight patients with traumatic perforation of the tympanic membrane who presented to the

emergency department and our out-patient department were included, of whom 23 were male (33.8%) and 45 were female (66.2%).

The total study group had 30 patients in the 20-30 age group (44.1%), 26 patients in the 30-40 age group (38.2%) and 12 patients in the 40-50 age group (17.6%) with a mean age of 32.19 (21 – 48). 48 patients (70.6%) had a perforation on the left

side and 20 patients had a perforation on the right side (29.4%).

58 patients (85.3%) had moderate sized perforations involving 2 quadrants of the tympanic membrane and 10 patients (14.7%) had large sized perforations involving 3 quadrants of the tympani membrane. The mean hearing loss of the total study group was 34.54dB (18.3 – 48.3dB).

Table 1: Distribution of study participants based on socio demography profile

Variable	Criteria	Frequency	Percent
Age group	20-30	30	44.1
	30-40	26	38.2
	40-50	12	17.6
Groups	Case	34	50.0
	Control	34	50.0
Side	Left	48	70.6
	Right	20	29.4
Gender	F	45	66.2
	M	23	33.8
Perforation	26-50	58	85.3
	51-75	10	14.7
Total		68	100.00

Table 2: Outcome of patients after 6 months follow -up

Variable	Status	Case	Control	Total
Sixth month (n=68)	Healed	32 (94.1)	28 (82.4)	60 (88.2)
	Not healed	2 (5.9)	6 (17.6)	8 (11.8)
Sixth month (Patients involving third quadrant) (n= 10)	Healed	5 (71.4)	0 (0)	5 (50)
	Not healed	2 (28.6)	3 (100)	5 (50)

After 6 months the perforation healed in a total 60 patients (88.2%), a higher rate of healing was seen in the cases group (32 patients - 94.1%) than the controls group (28 patients - 82.4%) in the controls group.

But among the patients with large perforations in the study all the 5 patients in the cases group had

successfully healed perforations while only 2 out of the patients in the controls group had healed perforations.

The cases group showed an increase in the mean PTA from 34.37dB to 21.25dB after 6 months and the controls group showed an increase in the mean PTA from 34.71dB to 22.96dB after 6 months.

Table 3: Comparison of the study groups based on Pre-op and six-month post op PTA

		Mean	N	Std. Deviation	Std. Error Mean	P value
Cases	Pre-Op PTA	34.371	34	7.4277	1.2738	<0.00
	Sixth Month PTA	21.253	34	6.0627	1.0397	
Control	Pre-Op PTA	34.718	34	7.6607	1.3138	<0.00
	Sixth Month PTA	22.959	34	7.3783	1.2654	

*Paired t test applied

Discussion: The perfect method of treatment for closure of traumatic perforations remains debatable. Numerous tissues and materials have been used in world literature. The success rates also vary among different methods. Golz et al.[12] testified 55.7% of success rate with conventional paper patching Office tympanoplasty. Whereas Ozgursoy et al.[13] showed 82.4% of success rate when treated with fat graft. Gokce Simsek et al[14] in their study using paper patching technique for closure of traumatic perforation too observed that

there is 100% closure rate for small perforations 80% closure rate for medium and only 54% closure rate for large perforations. Whereas Nathan D. Cass et al[15] had observed higher success rate ranging from 80-92% while grafts infused with collagen tissues (eg. Fascia, perichondrium and cartilage along with collagen). In the present study 66% of the perforations were to be observed in females whereas 33% of them were seen to be found in males. Similar observations were made by Nathan D. Cass et al where most of the study participants

were female (82.5%) in compared to male participants. In the present study 70% of the traumatic perforation were seen to be on the left side. This is similar to observations made by Sagiv et al[16], Lou et al[17] and Kronenberg et al[18] where maximum traumatic perforations involved the left ear.

For perforations involving more than 50% of the tympanic membrane, study groups treated with collagen tympanoplasty resulted in 100% success, whereas the control group showed the success rate of 40%. Like our observation, Nathan D. Cass et al observed success rate of 81.5% among the large perforation treated with collagen tympanoplasty and Nobuhiro Hakuba et al[19] conducted a study to study the effect of basic fibroblast growth factor combined with atelocollagen for closing chronic tympanic membrane perforations. Complete closure of perforation was achieved in 92.0% of the cases. These observations are supported by Seung Hyo Choi et al.[20] in their study they observed 100% success rate for closure of perforations. Above finding of closure rates were far higher than results obtained by Mohammad Farhadi et al[21] where the success rate of tympanic membrane closure with collagen tympanoplasty was found to be nearly 70%. In our study the perforations involving less than 50% healed with the success rate of approximately 93% which is like closure rates of pin hole perforations when treated with collagen noted by Nobuhiro Hakuba et al.

In the current study the improvement in mean air-bone gap when treated with collagen tympanoplasty was 13.11 ± 4.86 dB after 6 months. This is similar to the observations made by Farhadi et al where the improvement was noted to be 15.75 ± 4.29 dB. and Hakuba et al where there was an improvement of 13 dB. These observations were supported by Seung Hyo Choi et al where the improvement in Air-Bone Gap was found to be 12.9dB.

Limitations:

The mode of injury to the tympanic membrane was not assessed in the present study which may have an impact on the closure rates. Further study of traumatic perforations larger than 50% is required to ascertain the higher closure rates of collagen tympanoplasty versus conservative approach.

Conclusion:

From the above study we conclude that though there are various techniques a protocol to treat traumatic perforations of the tympanic membrane the outcome depends on the size of the perforation. Perforations involving less than 50% of the tympanic membrane were found to have similar closure rates even with conservative management; collagen tympanoplasty in these cases does not

show any significant improvement. But in cases with traumatic perforation involving more than 50% of the tympanic membrane, the closure rates are higher with collagen tympanoplasty. The improvement in air bone gap was found to be higher when treated with collagen tympanoplasty.

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