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# Effectiveness of trichloroacetic acid and trichloroacetic acid with gel foam for closure in patients with central perforation of tympanic membrane—a randomized controlled trial

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## Abstract

**Background** The tympanic membrane (TM) forms the partition between the external auditory canal and the middle ear. Perforations occur as a result of acute otitis media or traumatic causes which undergoes healing spontaneously over 3 to 4 weeks. Non-surgical methods are successful in the closure of small to medium-sized perforations. Chemicals used for the cauterization of the margins of perforation are trichloroacetic acid and silver nitrate. This study was performed in a total of 90 patients. External auditory canal, tympanic membrane, site and size of perforation, and middle ear mucosa status were assessed followed by pure tone audiometry. One group constituting 45 subjects underwent TCA cauterization under sterile precautions. Another group of 45 subjects underwent the same procedure with TCA cautery and gel foam application for perforation closure. The procedure was repeated once a week for about 6 weeks. The effectiveness of these two procedures was compared between the two groups after a waiting period of 2 weeks.

**Results** The mean age of the study population is  $41.84 \pm 16.71$ . Of the 90 study participants, 54.4% ( $N=49$ ) were less than 40 years of age, gender, cause, and laterality of perforation were not associated with the outcome whereas the size of the perforation was significantly associated with the closure of TM perforation with chi-square value of 7.028 and  $P$  value of 0.008 ( $< 0.05$ ). Overall, TM closure was achieved in 3.56 applications in TCA with gel foam patching whereas in 6.02 applications with TCA alone.

**Conclusion** TCA cauterization with or without gel foam patching can be performed as a first-line treatment in adults with small to medium-sized perforations.

**Keywords** Tympanic membrane, Trichloroacetic acid, Gel foam, Cauterization

## Background

The tympanic membrane (TM) forms the partition between the external auditory canal and the middle ear. Its posteriosuperior part is more laterally attached than its anteroinferior part because of its oblique alignment. It is 9–10-mm tall, 8–9-mm wide, and 0.1-mm thick. Parts of tympanic membrane are Pars Tensa and Pars Flaccida [1].

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TM perforation is observed frequently and constitutes 0.4 to 2.3% of all disorders of the ear [2]. Perforations occur as a result of acute otitis media or traumatic causes which undergo healing spontaneously over 3 to 4 weeks. Ninety percent of the perforations heal in a 6-week period. In some cases, persistent perforation serves as a window between the middle ear and external ear and leads to chronic otitis media with hearing loss depending on the site and size of the perforation. This further leads to cholesteatoma, mastoiditis, meningitis, or brain abscess [3].

The most common tympanic membrane perforation is medium-sized central perforation constituting 55% of the total perforations. Non-surgical methods are successful in the closure of small to medium-sized perforations [4]. The most common cause of hearing loss in patients with inactive mucosal chronic otitis media is conductive hearing loss (67%) where hearing can be restored by closure of perforation [5]. Non-healing perforations of the TM were taken up for surgical closure by myringoplasty. It is still practiced under endoscopic guidance as the success rate is as high as a cent per cent but carries the risk of complications due to anesthesia, failure of the graft, risk of re-perforation, and discharging ear postoperatively [6]. Enormous research into the subject has proven non-surgical procedures to be successful in the closure of tympanic membrane perforation. The advantages of these procedures are as follows:

1. Day care procedures
2. Simple and time-saving
3. Less expensive
4. Avoids stress due to hospitalization and loss of pay
5. No need for special care which is required post-surgery
6. No post-surgical pain [7]

Chemicals used for the cauterization of the margins of perforation are trichloroacetic acid, silver nitrate, etc. The application of autografts like platelet-rich plasma matrix, fat plug or button graft, and synthetic patching materials like gel foam or silastic sheet are some of the newer methods for patching the perforation following cauterization [8–10]. Gel foam is a denatured porous gelatin sponge that is non-toxic and non-allergic which is also used widely in conventional ear surgeries [11].

#### TCA cauterization

Cauterization helps in achieving healing by establishing the natural pattern of migration of epithelium of the perforated TM. Repeated cauterization is required at the rim of the perforation, thereby resulting in a very thin atrophic scar due to the thinning of the lamina propria

from its normal thickness of 100  $\mu\text{m}$  to approximately 2–3  $\mu\text{m}$  [10]. TCA cauterizations and patching with gel foam is an effective method for closure of the TM perforation. The aim of our study was to compare the efficacy of trichloroacetic acid (TCA) and TCA with gel foam in the closure of TM perforation.

#### Methodology

The study was conducted in the Department of Otorhinolaryngology, at a tertiary care hospital in Chengalpattu district from June to November 2022. Approval for the study was obtained from the Institutional Human Ethical Committee. The sample size was calculated using the formula  $(z^2pq)/l^2$ . Considering the prevalence of tympanic membrane perforation as 13.4% with 80% power and 10% allowable error, the sample size is calculated to be 90 [12]. Patients fulfilling inclusion criteria were considered as the study population.

#### Inclusion criteria

- Patients above 18 years of age with small to medium-sized central TM perforation of inflammatory or traumatic origin. Patients who had nasal obstruction were first corrected by treating the underlying cause and were then included in the study. Patients with active discharging ears were included after controlling symptoms with appropriate medications.

#### Exclusion criteria

- Known case of tuberculous otitis media with perforation
- Large tympanic membrane perforation with >40 decibel hearing loss which requires tympanoplasty due to a higher chance of ossicular discontinuity.
- Terminally ill patients

#### Procedure

After obtaining written informed consent by explaining the procedure, a detailed history was obtained. A clinical examination was done, and findings were recorded. Ear, nose, and throat examination was done, and patients were subjected to otoendoscopy. External auditory canal, tympanic membrane, site and size of perforation, and middle ear mucosa status were assessed. Otoendoscopic findings were correlated with history and otoscopic examination followed by pure tone audiometry. In patients with bilateral TM perforation, the right side TM was cauterized to eliminate bias. Pure tone audiometry was repeated 8 weeks after the procedure.

**TCA cauterization for closure of TM perforation**

After making necessary exclusions 90 patients were included in the study. One group constituting 45 subjects underwent TCA cauterization under sterile precautions. Under endoscopic guidance, cotton balls soaked in 4% xylocaine were placed snugly in the external auditory canal for about 5 min. Adequacy of anesthesia was checked, and the margin of the perforation was freshened with 50% trichloroacetic acid by using a sterile Jobson's probe until white eschar of 0.5-mm thickness appeared. The procedure was done under utmost precaution so as not to injure the middle ear structures. Patients were observed for 2–3 h for symptoms like pain and vertigo. About 24 patients had pain which resolved spontaneously. The same procedure was repeated at 1-week intervals with anti-histamine and NSAID for 2 days following the procedure. Patients were advised to keep the ear dry. Patients with allergic rhinitis and sinusitis were advised to continue medications as advised. The size of the perforation and development of complications were recorded every week.

**TCA cauterization with gel foam patching for closure of TM perforation**

Another group of 45 subjects underwent the same procedure with TCA cautery and gel foam application for perforation closure. Fifty percent of trichloroacetic acid was used for cauterization. For small-sized perforations, gel foam with a size larger than the perforation was placed so that the cauterized margin was in contact with the gel foam. The procedure was repeated once a week for about 6 weeks with prophylactic anti-histamine and NSAID for a period of 2 days to prevent Eustachian tube catarrh. Patients were advised to keep the ear dry. The effectiveness of these two procedures was compared between the two groups after a waiting period of 2 weeks.

**Statistical analysis**

For the statistical analysis, Statistical Package for Social Sciences (SPSS)-Version 21 was used. Numerical data were expressed in mean and standard deviation, and nominal and ordinal data were expressed in percentage. The chi-square test and Fischer's exact test were performed to test the association between cauterization and closure of TM perforation.

**Results**

The mean age of the study population is  $41.84 \pm 16.71$ . Of the 90 study participants, 54.4% ( $N=49$ ) were less than 40 years of age. Over 50% of them were male population (Table 1). About 75.6% ( $N=68$ ) of them were known cases of CSOM with tympanic membrane perforation. In

**Table 1** Age and gender of the study population,  $N=90$

Characteristics	N	%
<b>Mean age (SD)</b>	$41.84 \pm 16.71$	
<b>Age</b>		
< 40 years	49	54.4
≥ 40 years	41	45.6
<b>Gender</b>		
Male	47	52.2
Female	43	47.8

SD Standard deviation

**Table 2** Characteristics of tympanic membrane perforation,  $N=90$

Characteristics	N	%
<b>Cause</b>		
CSOM	68	75.6
Trauma	22	24.4
<b>Laterality</b>		
Unilateral	67	74.4
Bilateral	23	25.6
<b>Size of perforation</b>		
Small-sized	54	60
Medium-sized	36	40

CSOM Chronic suppurative otitis media

74.4% ( $N=67$ ) of the cases, perforation was confined to the tympanic membrane of one side only. Sixty percent ( $N=54$ ) of the perforations were of small size whereas 40% ( $N=36$ ) were medium-sized perforations (Table 2).

At the end of 3 months of follow-up, four patients lost to follow-up and were considered to have TM perforation. Three patients lost to follow-up were in the above 40 years age group. Age, gender, cause, and laterality of perforation were not associated with the outcome whereas the size of the perforation was significantly associated with the closure of TM perforation with a chi-square value of 7.028 and  $P$  value of 0.008 ( $<0.05$ ) (Table 3).

Tympanic membrane closure was achieved in 86.67% of the patients treated with TCA and gel foam whereas closure occurred in 62.2% of the patients treated with TCA alone. The association between cauterization using TCA and gel foam was found to be statistically significant with the closure of TM perforation with a chi-square value of 4.208 and  $P$  value of 0.04 ( $<0.05$ ) (Table 4). The number of attempts was also found to be significantly associated with the closure of TM perforation by Fischer's exact test with a  $P$  value of 0.0001 ( $P<0.05$ ) (Table 5). Overall, TM closure was achieved in 3.56 applications in TCA with gel foam patching whereas 6.02 applications in TCA alone.

**Table 3** Association between characteristics of the study population and closure of tympanic membrane perforation following cauterization, *N* = 86

Characteristics	Closure of perforation		Chi-square value	P value
	Achieved	Not achieved		
<b>Age</b>				
< 40 years	37	11	0.43	0.836
≥ 40 years	30	8		
<b>Gender</b>				
Male	36	9	0.240	0.624
Female	31	10		
<b>Cause of perforation</b>				
CSOM	53	15	0.001	0.988
Trauma	14	4		
<b>Laterality</b>				
Unilateral	53	13	0.947	0.331
Bilateral	14	6		
<b>Size of perforation</b>				
Small-sized	47	7	<b>7.028</b>	<b>0.008</b>
Medium-sized	20	12		

CSOM Chronic suppurative otitis media

**Table 4** Association between cauterization with TCA with gel foam and TCA alone and closure of tympanic membrane perforation by chi-square test, *N* = 86

Characteristics	Closure of perforation		Chi-square value	P value
	Achieved	Not achieved		
<b>Agent used for cauterization</b>				
TCA with gel foam	39	6	4.208	<b>0.04</b>
TCA	28	13		

TCA Trichloroacetic acid

**Table 5** Association between the number of attempts of cauterization and closure of tympanic membrane perforation by Fischer's exact test, *N* = 90

Number of attempts	Closure of perforation		P value
	Achieved	Not achieved	
One	15	1	0.0001
Two	12	2	
Three	14	1	
Four	15	4	
Five	3	2	
Six	8	13	

Lost to follow-up patients were considered to have treatment failure

Table 6 shows the pure tone average and air–bone gap (ABG) before and after both procedures. Treatment with TCA and gel foam shows good improvement in hearing compared to the group treated with TCA alone since closure was achieved in 39 and 28 patients treated with TCA with gel foam and TCA alone, respectively.

### Discussion

Most TM perforations tend to heal spontaneously, though in some cases (large perforations), intervention is essential to protect middle ear structures from repeated infections and entry of foreign substances [13]. Treatment of tympanic membrane perforation varies from time to time. Transcanal endoscopic ear surgeries (TEES) have replaced microscopic surgeries in the past three decades [14]. Recent advancement in research and the advent of newer treatment options have emphasized the role of cauterization which hastens the natural healing of TM perforation by the process of epithelialization. The principle of cauterization lies in the destruction of the outgrown squamous epithelium by repeatedly irritating the edges of Tm by using chemicals, thus enabling the growth of fibroblastic proliferation [15]. The latter sounds simple though advantageous to both the care provider and the patients. Re-perforation following surgical repair ranges from 7 to 27% [3].

Bala et al. found the success rate following TCA cauterization to be 96% in small TM perforations by using 30% TCA [16]. Mourya et al. found TCA cauterization to be successful in 94.54% of the study population with significant improvement in hearing post-procedure. The mean age of the study population was 28.25 years which is much less than our study population of 41.84 years [17]. Makwana et al. found the same procedure to be successful in 75% of the study participants by using 2.5% TCA in two to three applications [15]. Gaur et al. used TCA cauterization to achieve a closure rate of 72.16% in 3.84 applications on average [18].

Of the patching materials, gel foam is a commonly used biological material. Denatured porcine skin is used to make gel foam, an absorbable gelatin sponge that was originally used in neurosurgery as an absorbable hemostatic device. In otology, gel foam is frequently used as TM scaffolds, supportive materials for TM and ossicular grafts, Eustachian tube plugs, and oval window sealant, and to correct defects caused by wounds at the base of the skull. Numerous advantageous characteristics of gel foam include its non-antigenicity, non-toxicity, biocompatibility, and simplicity of handling. Importantly, gel foam is well tolerated and produces adequate hemostasis whether it is dry or wet. Little abnormalities were seen in the ME cavity with intact mucosa. It is shown to be effective in the closure of small to medium tympanic

**Table 6** Comparison of pure tone average and air–bone gap before and after the procedure, *N* = 86

		Small-sized perforation		Medium-sized perforation	
		PTA	ABG	PTA	ABG
TCA with gel foam	Before procedure	28.95 ± 2.33	16.30 ± 2.21	37.47 ± 2.78	22.36 ± 2.53
	After procedure	15.72 ± 1.76	9.63 ± 1.64	17.93 ± 1.97	9.78 ± 1.19
TCA	Before procedure	28.7 ± 2.28	16.46 ± 2.42	37.08 ± 2.94	22.08 ± 2.51
	After procedure	18.59 ± 2.57	11.79 ± 1.79	19.35 ± 2.91	11.21 ± 1.52

TCA Trichloroacetic acid, PTA Pure tone average, ABG Air–bone gap

membrane perforations. Gel foam patching supports the tympanic membrane for the migration of squamous epithelium. Gelfoam, despite being widely used, can cause severe connective tissue hyperplasia, which can lead to adhesion and fibrosis around the TM and ossicular grafts, chain distortion, and TM retraction, particularly in cases of denuded mucosa [19, 20].

Singh et al. proved TCA with gel foam patching to be successful in the closure of tympanic membrane perforation in 76% of the study participants in an average of 4 applications. There was an improvement in hearing and a reduction in symptoms like tinnitus [2]. Jayakumar et al. found a complete closure in 54% of chemical cauterization, and 53% of cases in whom gel film soaked in platelet-rich plasma was used as a plug after freshening the edges of the perforation [21]. Niklasson et al. achieved closure of TM perforation in 83% of the patients using gel foam plug after surgical removal of the edges of perforation which is similar to our study (86.6%) and also found the closure rates were similar to that of fat plug myringoplasty [22]. Furthermore, silver nitrate was also used to freshen the edges of TM. Menon et al. used 50% silver nitrate, and closure of TM was achieved in all traumatic perforation and reperforation after surgery [23]. Similarly, Santhi et al. in addition to silver nitrate cauterization used thin sterile aluminum foil to patch the perforation and achieved closure in 73.75% of the patients with minimal complications [10].

### Conclusion

Cauterization with or without patching of the tympanic membrane with gel foam is a time-saving procedure which requires less expertise, minimal manpower, and comparatively less instrumentation, can be performed in an OPD as the procedure requires local anesthesia in adults making the procedure economical compared to conventional ear surgeries. Hence, TCA cauterization with or without gel foam patching can be performed as a first-line treatment in adults with small to medium-sized perforations.

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### Authors' contributions

NNRB: Conceptualization, validation, investigation, and writing—original draft, review, editing, supervision, and visualization. GK: Conceptualization, validation, investigation, and writing—original draft, review, and editing. BD: Conceptualization, validation, investigation, and writing—original draft, review, and editing. PS: Conceptualization, validation, investigation, supervision, and writing—original draft, review, and editing. RS: Conceptualization, validation, investigation, and writing—review and editing. SKB: Conceptualization, validation, investigation, and writing—review and editing. RSC: Conceptualization, validation, investigation, and writing—review and editing. KSR: Conceptualization, validation, investigation, and writing—original draft, review, and editing. All authors read and approved the final manuscript.

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### Availability of data and materials

Data analyzed during the current study are available from the corresponding author on reasonable request.

### Declarations

#### Ethics approval and consent to participate

Institutional Human Ethical Committee for Faculty Research approved the study (IHEC-II/0198/22). Written consent was obtained from the participants.

#### Consent for publication

Written consent was obtained from all the participants.

#### Competing interests

The authors declare that they have no competing interests.

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