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Original Research Article

Non-surgical approach for repairing perforations of pars tensa in tympanic membrane using TCA cauterization

Sushil Gaur*, Monika Patel, Prince Hirdesh, Vandana Singh

Department of ENT and Head and Neck Surgery, Santosh Medical College, Ghaziabad, Uttar Pradesh, India

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***Correspondence:**
Dr. Sushil Gaur,
E-mail: drsushilgaur@gmail.com

ABSTRACT

Background: Tympanic membrane perforations occurring due to mucosal COM usually require surgical interventions for repair (myringoplasty or tympanoplasty) depending on the size and site of the perforation and the ossicular chain continuity. Various studies have shown TCA cautery as an efficacious non surgical method for repairing small and medium sized TM perforations. This technique was successfully used and popularized for repairing small and medium sized perforations by Derlacki in 1953.
Methods: In this study we included dry pars tensa perforations in 100 patients occurring due to trauma or unresolved cases after inflammation/infection of middle ear. 50% w/v trichloro acetic acid was used for a maximum number of 5 applications at the margins of the perforations which were followed up for the next one year.
Results: In this study, involving a total of 125 perforations (75 unilateral and 50 bilateral), success rate was high among the patients with traumatic perforations and small sized perforations while a few number of perforations only reduced in size, which were later corrected with surgical approaches (myringoplasty/tympanoplasty). The overall success rate achieved in this study was 72.16%.
Conclusions: Though there are various materials and methods available for this procedure, the principle remains the same. This technique should be attempted for patients that fit the criteria for undergoing this procedure before being undertaken for surgical approaches to minimize the risks and cost burden associated with surgery and anesthesia.

Keywords: Non-surgical, Perforation, Pars tensa, Tympanic membrane, TCA, Cauterization

INTRODUCTION

Chronic suppurative otitis media is widely found in developing countries like India, Pakistan, Bangladesh and Nepal, mainly occurring in the rural parts of developing countries where healthcare penetration is less. The relative incidence of lesions involving the tympanic membrane has been estimated at 0.4% to 2.3% of all ear diseases.[1] It is attributed as the leading cause for hearing loss in rural India, resulting mainly due to the perforations of the tympanic membrane, as sequelae of untreated acute suppurative otitis media.[2] If treated in time, it is noted that most (88%) of the acute perforations of any size heal without any need for interventions.[3] The unresolved cases lead to development of chronic suppurative otitis media, which result in non-healing chronic perforations in both pars tensa and pars flaccida depending on the type of disease i.e. mucosal or squamosal COM respectively. Perforations occurring due to mucosal COM usually require surgical interventions for repair like myringoplasty or tympanoplasty depending on the size of the central perforation. Perforations occurring in pars flaccida have completely different surgical approaches and were not included in this study. Factors like treatment cost burden and invasiveness of surgical approaches have lead researchers to innovate and investigate simple non-surgical methods to achieve the same results of successful closure of these perforations

without subjecting the patients to risks of surgery and anesthesia. If left untreated, chronic perforations may lead to chronic otorrhea, involvement of pars flaccida, cholesteatoma formation which goes on to involve the mastoid bone as a complication over the natural course of an untreated disease. This also puts a burden on the increased incidence of hearing loss in the community which in turn affects the overall quality of life (QoL). The main objective of repairing TM perforations for an ENT Surgeon is to provide improved hearing and prevent chronic infections of the middle ear thus relieving the two most common problems related to ear in the community. An intact tympanic membrane prevents the middle ear from repeated attacks of pathogens due to environmental contamination and also provides an adequate vibratory area to the hearing apparatus, both of which are compromised by perforations in the same. Majority of the TM perforations occurring due to otitis media heal spontaneously, unless there is a coexisting dysfunction of eustachian tube, which becomes the main reason for a permanent perforation. Perforations occurring due to trauma usually heal on its own and it is advisable to wait for a minimum of three weeks before intervening. Presence of perforation in a tympanic membrane also limits a patient's ability to participate in occupations like military service and motor vehicle driver and prevents them from taking part in water sports.[4,5] Successful closure of TM perforations is gratifying to both the patient and the surgeon. As much as 25 dB of hearing can be restored with tympanic membrane closure. Other symptoms that get relieved include tinnitus, aural fullness and sensitivity to loud sounds and wind. Patients also get satisfied with relief from a constantly discharging ear which otherwise affects their social life.

Although surgeries like tympanoplasty and myringoplasty still remain the treatment of choice for repairing TM perforations, the non-surgical approach for closure of small and medium sized perforations of TM by TCA cauterization has been found efficacious in this study.

METHODS

A total of 100 patients attending ENT OPD in Santosh Medical College Hospital, Ghaziabad from November 2017 to November 2018, with ages ranging from 18 years to 65 years were included in this study. The inclusion criteria included the following two scenarios: 1) patients having inactive mucosal COM with small to medium sized non healing central perforations in pars tensa and 2) patients with history of traumatic perforations in pars tensa not healing for more than four weeks without intervention. 75 subjects out of n=100 had unilateral tympanic membrane perforations and 25 subjects out of n=100 had bilateral tympanic membrane perforation, thus a total of 125 TM perforations underwent this study.

All the selected patients underwent a complete and thorough otorhinolaryngological evaluation prior to being selected for this study. Patients with active mucosal COM who had wet TM or frank discharge were first treated with oral medications and ear care till tympanic membrane became dry. All the subjects were screened with otoendoscopy for absence of actively discharging middle ear before they were taken up for the study. Examination under microscope (EUM) was also performed to assess the size of perforations and to rule out cholesteatoma, tympanosclerosis, pars flaccida perforations, large/subtotal/marginal perforations. Valsalva was used to assess eustachian tube patency on otoendoscopy. Diagnostic nasopharyngoendoscopy was performed in all the patients to screen for nasal pathology. n=12 patients were diagnosed with allergic rhinitis and were treated with oral medications and local steroidal nasal sprays. These patients were included in the study only after four weeks of therapy with satisfactory disease control (8 subject out of 12 diagnosed with AR had bilateral TM perforations and 4 patients had unilateral TM perforations). n=3 patients were diagnosed with varying degrees of DNS and underwent septal corrections at our facility and were included in this study four weeks later post-operatively. The subjects also underwent hearing assessment with tuning fork tests and pure tone audiometry in OPD with average airbone gap ranging 0-50 dB. The subjects with bilateral perforations underwent sequential cauterization, smaller perforations being cauterized first and larger ones being cauterised four to twelve weeks later, depending on the response of the TM which was cauterized formerly.

Procedure

The patients were taken up for the procedure only in OT under sterile conditions. 2% xylocaine was used for local infiltration by post aural injection to provide adequate local anesthesia. Under the otomicroscopic vision, 50% TCA was applied evenly at the edge of the perforation using a sterile Jobson Horne Probe, until a white cauterised margin, 0.5 mm in width was created. Precaution was exercised to not expose the promontory to TCA while performing the procedure. Excess TCA solution was removed using sterile dry cotton pledgets. Once adequate margin of blanching was seen evenly around the rim of perforation, a custom sized pledget of gelfoam moistened with betadine was placed over the perforation. Patients were kept for 3 hours under observation post-procedure, to observe for pain or vertigo. n=32 patients had varying degrees of transient ear pain post-procedure which lasted for a maximum of thirty minutes and spontaneously relieved without a need for analgesia. Only n=1 patient complained of transient vertigo post procedure which was relieved spontaneously after taking rest for one hour. This procedure was repeated at weekly intervals for a maximum five times. After the first application of TCA, subjects were given oral antibiotics and antihistaminics for one week and called for otoendoscopic examination after 7 days to assess perforation size. Subjects which showed healing of perforation margins underwent PTA to assess hearing improvement (Figure 1 A-C).

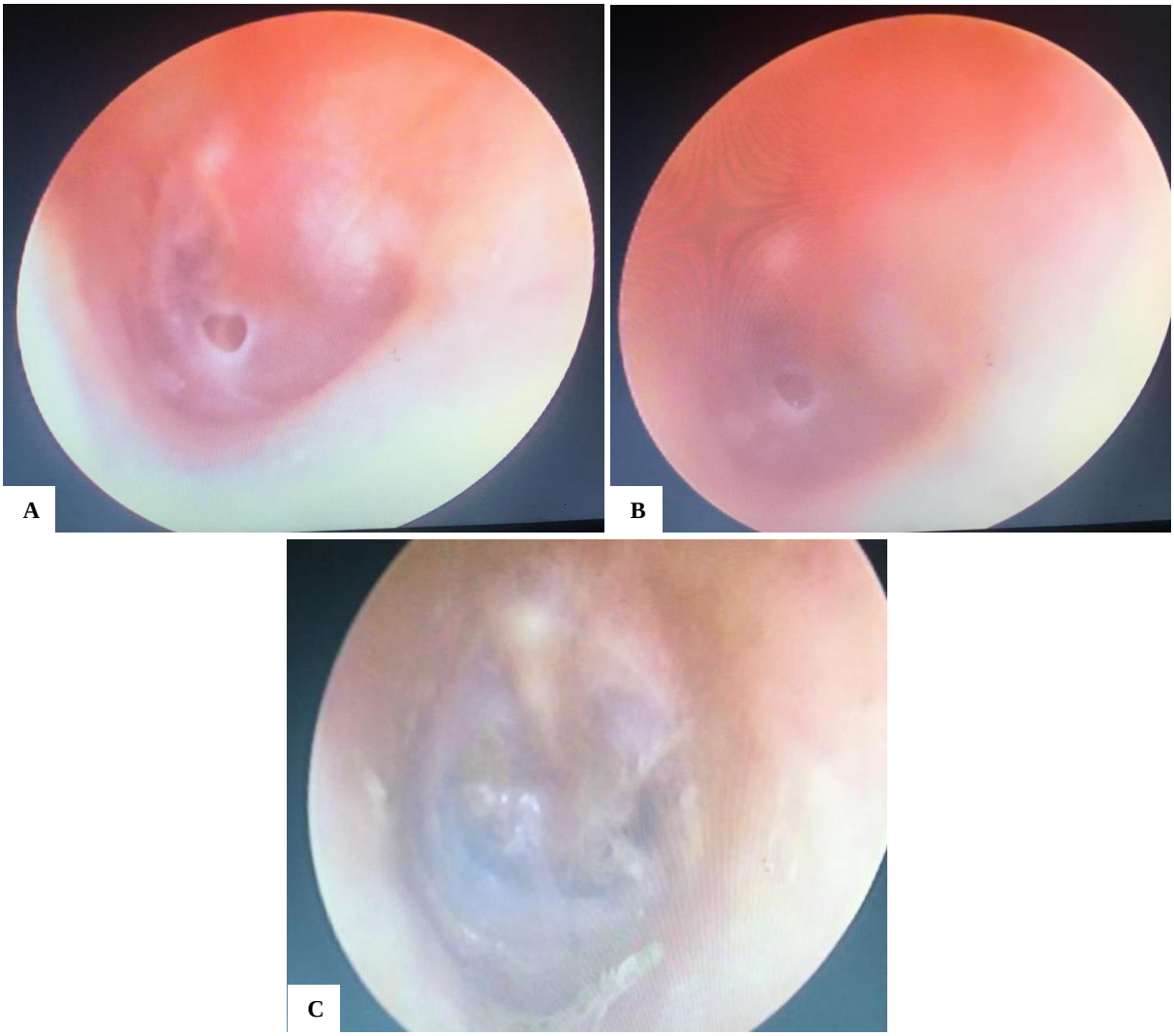

Figure 1: (A) Otoendoscopic picture of TM showing small central perforation after first sitting of TCA application. Note the white margins of perforation after being freshly cauterized with 50% w/v TCA using a Jobson Horne probe under microscope at 25X magnification; (B) Otoendoscopic picture of same TM at 1 week follow-up, after second application of TCA; note the slight (~1 mm) decrease in size compared to the time of presentation; (C) Otoendoscopy of the same TM @ 4 weeks follow up. This patient took a total of 4 sittings to reach this stage. Note the complete closure of TM perforation.

RESULTS

Out of total subjects n=100 who underwent this study, n=75 had unilateral central perforation and n=25 had bilateral central perforations (Figure 2). Etiologically following data was recorded: a total of n=67 patients had inactive mucosal COM, out of which 42 had unilateral disease and 25 had bilateral disease. n=8 patients had history of undergoing myringoplasty/tympanoplasty. Also a total of 33% subjects (n=33) had history of trauma leading to central perforation, out of which n=26 complained of slap injury which were found to be left sided in all 26 cases and 7 patients had history of acoustic barotrauma (due to firecrackers at the time of diwali celebrations) (Figure 3).

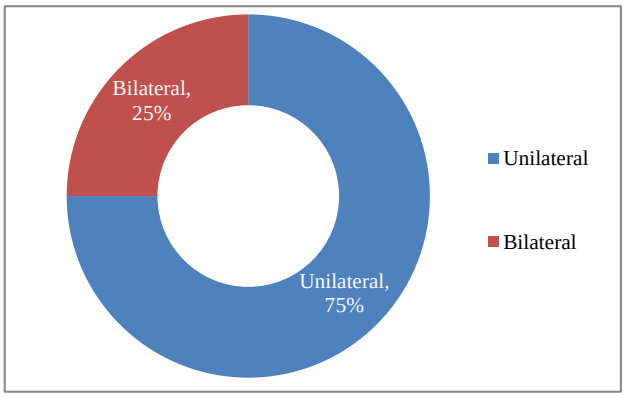

Figure 2: Out of n=100 subjects, 75 had unilateral perforations and 25 had bilateral perforations.

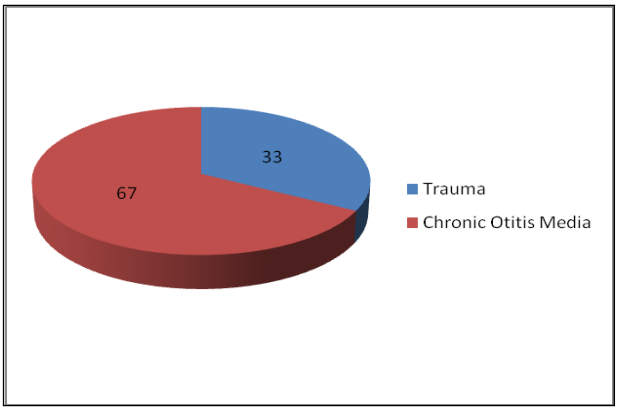

Figure 3: Etiological classification of subjects.

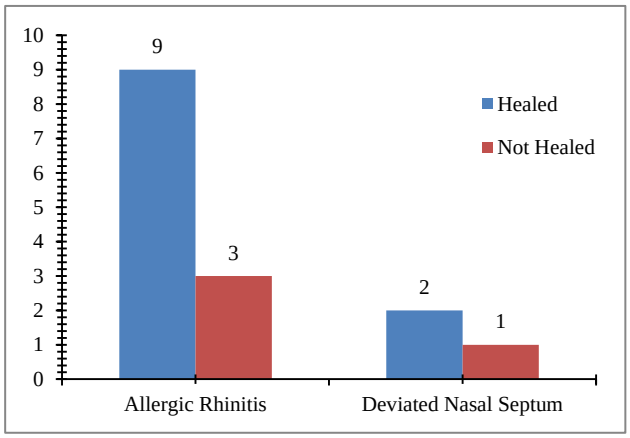

Figure 4: Results showing the outcomes in patients with co-morbidities (allergic rhinitis and deviated nasal septum).

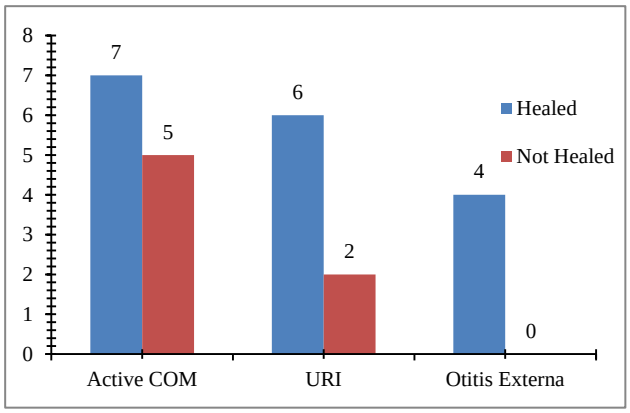

Figure 5: Results in subjects with active diseases (active mucosal COM, URI and otitis externa) while undergoing this study.

Looking at the preprocedural co-morbidities, n=12 subjects were diagnosed with allergic rhinitis out of which 8 subjects had bilateral central perforation and 4 subjects had unilateral central perforation, out of these 9 had healed and 3 remained perforated. All the above patients underwent treatment before participating in this study as explained in materials and methods. Also, 3 subjects were diagnosed with deviated nasal septum, of varying degrees who underwent septoplasty under GA at our facility and four weeks later were added to this study; out of these, 2 had healed and 1 did not (Figure 4).

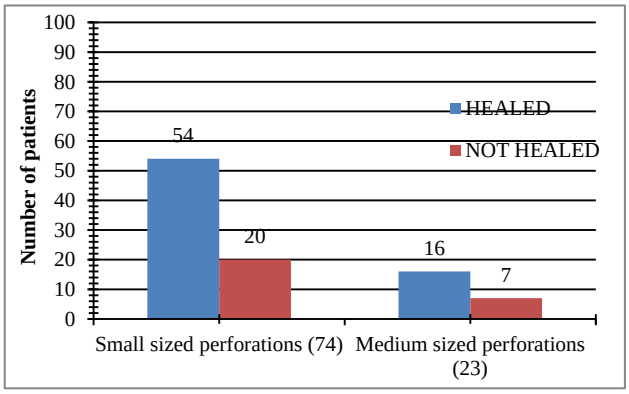

Figure 6: The difference in results among small and medium sized perforations indicated that outcomes were better if the perforation was smaller to begin with during the study.

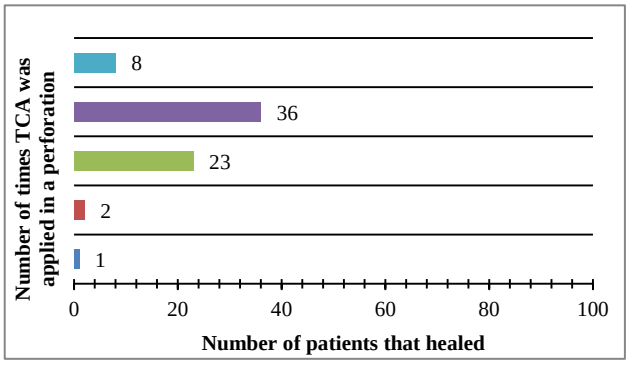

Figure 7: This data shows that maximum number of patients healed after 4 sittings of TCA application while only 1 patient healed after a single application of TCA and 8 patients took 5 repeated attempts to completely heal.

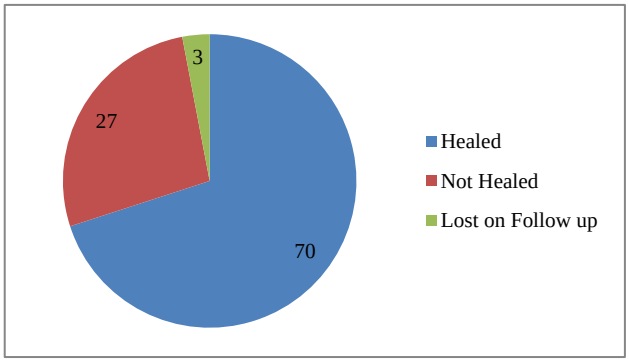

Figure 8: 70 out of 100 patients healed completely, 27 did not heal due to various reasons and 3 were lost on follow up.

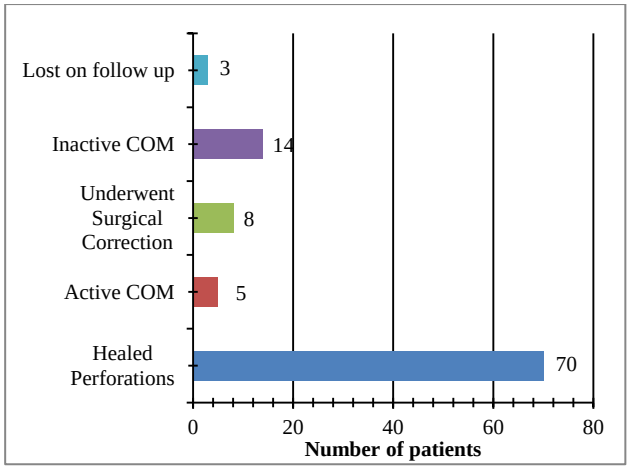

Figure 9: Overall results of all subjects who underwent the study.

While the subjects were undergoing this study, a total of 12 subjects started having actively discharging mucosal COM who were then given treatment for three weeks following which 7 of whose perforations healed and rest 5 did not heal at all. A total of 8 patients also had complains of URI while undergoing this study which affected their outcomes, n=6 of these subjects' perforations eventually healed and rest 2 were lost on follow up. Also, n=4 subjects had complains of otitis externa in the same ear for which they were undergoing the procedure. These patients were treated conservatively with medications and 10% Ichtammol glycerine packing and eventually all four of these cases healed completely. These results indicated that presence of actively discharging middle ear and URI affected the outcomes of TCA cauterization while otitis externa had no effect on the results (Figure 5). Out of n=100 subjects, 76 were found to have small central perforation while 24 subjects had medium sized central perforation. It was noted that small sized perforations healed quicker and with lesser number of applications of TCA (Figure 6). Out of 76 small central perforation which underwent the procedure, n=1 healed after single application, n=2 healed after 2 applications, n=18 healed after 3 applications (2 patients were lost on follow up), n=29 healed after 4 applications while n=4 subjects took 5 attempts to completely heal. Out of the 24 medium sized perforations which underwent the procedure, n=5 healed after 3 applications, n=7 healed after 4 applications (1 subject was lost on follow up) and n=4 subjects took full 5 attempts to completely heal. A total of 20 unilateral CP and 7 bilateral CP did not heal despite 5 repeated attempts. Some of these patients had coexisting ENT diseases as mentioned before which probably hindered in healing the membrane. From this data we gathered 1.07% subjects needed 1 application, 2.06% needed 2 applications, 23.70% needed 3 applications, 37.11% needed 4 applications and 8.24% needed 5 applications of TCA. On an average 3.84 number of applications were required for successful closure of these perforations. In summary we had a success rate of 72.16% in this study. A total of 70 patients healed, 27 patients did not heal and 3 patients were lost on follow up. Out of the 27 subjects that didn't heal, 5 became active COM who were put on conservative treatment and did not become inactive during the tenure of this study. 8 out of these 26 eventually underwent surgical correction by type 1 tympanoplasty under general anesthesia while 14 cases were inactive COM who did not consent for surgery and were kept on ear care and follow up in OPD (Figure 8, 9). This clinical study showed that application of TCA for repairing perforations of pars tensa in TM is an effective and efficacious non-surgical approach for treatment of mucosal COM in selected patients. An overall success rate 72.16% was achieved in this study.

DISCUSSION

The physiological mechanism of hearing and the pathophysiological process of COM employ tympanic membrane as the central organ that is directly involved in both of these. Worldwide, millions of patients suffer a significant decrease in QoL (quality of life) due to perforation of tympanic membrane. Various pathophysiological mechanisms are known to cause a breach in the integrity of the tympanic membrane. Statistical data indicates that direct or indirect trauma to the tympanic membrane leading to perforations is reported at 8.6/1000 persons, [6] which includes penetrating, blunt and iatrogenic injuries, which could also very well affect the inner ear. Since more than 400 years ago, various methods have been adopted to attempt closure of tympanic membrane perforations, which have gradually evolved into complex surgeries, not only repairing the tympanic membrane defects but also attempting to regain the hearing mechanism by repairing few of the smallest bones in our body vis-à-vis Malleus, Incus and Stapes. Materials like pig bladder, silver wired rubber discs, cotton wool coated with glycerin, etc. have been used with varying degrees of success.[5,7] Upon realizing the pathophysiological mechanisms of healing in human tissues, Roosa in 1876, used cauterizing agents (silver nitrate) to freshen up the epithelialised rim of a perforation, which eventually hastened the process of healing and lead to successful closure of tympanic membrane defects by a non-surgical approach.[8] Other noteworthy attempts were made by Kuneff in 1895 who used TCA for the first time for same purpose. A non-surgical approach for any disease process is always more welcome than invasive surgical interventions and anesthesia and their side effects. A specific group of tympanic membrane perforations when carefully selected, show good response to some of these non-surgical approaches. One of these was popularized in 1953 by using 100% saturated TCA on small and medium sized dry central perforation. In this study we re-evaluate the efficacy of TCA cautery to successfully close small and medium sized dry perforations when done under strict asceptic conditions and coupled with a strictly structured follow-up program. When the tympanic membrane has a defect in its structure alone, without any involvement of

the middle ear or the ossicular chain transformer system, it leads to a decrease in the surface area of the membrane which eventually dampens the ossicular chain movement impeding the adequate amplification of the stimulus, thereby leaving the patient with upto 45 dB loss of hearing in the speech frequencies.[10] This amount of hearing disability can affect the QoL of a patient if left untreated. Not only the middle ear transformer mechanism fails with a perforation, there is another pathological pathway leading to deafness, where in the sound reaches both the round and the oval window simultaneously without the dampening and phase changing effect of an intact tympanic membrane which leads to cancellation of the input signal at cochlear level and thus causes an even greater degree of hearing loss. A perforation causes a loss that depends on frequency, perforation size and middle ear space. Perforation induced losses are greatest at lowest frequencies.

The size of perforation is more important in determining the time of healing than its position. Roosa in as early as 1876 noted the tendency of even very large perforations to heal spontaneously.[8] When a large perforation heals spontaneously, it is devoid of the middle fibrous elements and it develops a thin atrophic scar which is adequate for the purpose of sound conduction but it is highly vulnerable to repeated perforation by infection or eustachian tube dysfunction. The principle of closing a perforation by inducing the fibrous layer to grow prior to epithelial closure helps in restoring the normal anatomy of the tympanic membrane. Histopathological study of newly formed tympanic membrane perforation revealed squamous epithelial perforation at the edge within 12 hours, granulation formation within 36 hours, while it takes several days to regenerate the inner mucosal layer of the membrane.[9] On a flat surface, stratified squamous epithelium grows at the rate of 1mm per day.[10] On the edge of a tympanic membrane perforation, this epithelialisation also takes place on its medial surface leaving no raw surface leading to arrest of healing and spontaneous closure of the perforation. Also, cytokines like transforming growth factor beta 1 (TGF Beta 1) are found at the border of chronic perforations and are implicated in the arrest of healing.[11] When a tympanic membrane perforation is chemically cauterized using trichloroacetic acid, the squamous epithelium is destroyed repeatedly at each application, which breaks up the fibrosis and promotes granulation and new tissue formation at the margin, which then grows over the flat surface provided by medicated gelfoam that acts as a splint to support the newly forming membrane. Also it is noted that the closure is more likely to occur when the perforation involves no more than 65% of the pars tensa. In patients with perforations larger than the recommended 65% (of pars tensa), myringoplasty is advised. In our study the overall success rate was 72.16%, which means out of 97 patients which underwent the full tenure of the study, 70 were treated by a non-surgical approach. Out of the 122 perforations that underwent TCA applications in this study, we were able to achieve successful closure in 88 perforations. All these 88 perforations would have otherwise been advised to be undertaken for tympanoplasty under GA, which was avoided as a direct result of attempting closure of perforations by this non-surgical approach. If this non-surgical approach was not offered to these patients, many of them would not have even undergone surgery due to various reasons like financial burden/ being unfit for surgery/ not consenting to undergo surgery etc. and eventually would have been living with chronic perforations in their tympanic membranes which would have had a negative effect on their QOL because of the natural history of this disease which encompasses various bothersome symptoms like chronic ear discharge, chronic ear pain, hearing loss etc. and various extra-cranial and intra-cranial complications, some of which are life threatening. Besides decreasing the financial burden of the surgeries on these patients, the side-effects and morbidities associated with general anesthesia and prolonged hospital stay were also avoided. And the fact that all of this was possibly averted without the patient undergoing any invasive surgical procedure provides a compelling case for popularizing non-surgical approach to attempt closure of perforations in tympanic membrane.

With the results of this study, we can propose that all the patients that fit the selection criteria for undergoing chemical cauterization by TCA application, should be offered and counseled for undergoing this procedure before being advised to undergo surgical correction for treatment of chronic perforation of tympanic membrane.

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