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Original Research Article

A study to compare the outcomes of CO_2 laser assisted myringoplasty versus conventional type1 tympanoplasty in small central tympanic perforations

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ABSTRACT

Background: The standard treatment of tympanic membrane perforation is conventional surgical closure using myringoplasty or a tympanoplasty type 1. In this study the role of cabon dioxide (CO_2)-laser-assisted de-epitheliazation of perforation margins and application of bioinert silastic sheet. Success rate was compared with conventional microscopic surgery.
Methods: This was a comparative study containing 60 patients with small dry tympanic membrane perforation (diameter 1-3 mm). The causes of tympanic membrane perforations were mainly traumatic or the eardrum did not heal after spontaneous perforation caused by an acute otitis media or after surgery. The procedure was performed under local anaesthesia. CO_2 (acupulse) applied along the edge of the perforation until complete de-epitheliazation and application of bioinert silastic sheet in small dry perforation. Closure of eardrum perforation was monitored using an otoendoscope. Success rate of the CO_2 laser myringoplasty was compared with conventional type 1 tympanoplasty.
Results: Complete eardrum closure occurred in 24 cases (80%), 06 patients (20%) had a residual perforation. The success rate of this procedure is lower than conventional type 1 tympanoplasty, which is 90-94%. There were no complications during and after the treatment.
Conclusions: A closure rate of 80% (24/30) was achieved with a CO_2-laser-assisted de-epitheliazation. This procedure can be offered carefully to selected cases with perforation size <3 mm, where the CO_2 facility is available before they undergo formal conventional microscopic surgery.

Keywords: Tympanic membrane perforation, Myringoplasty, CO_2 laser, Silastic

INTRODUCTION

Tympanic membrane (TM) perforations are commonly seen in ear, nose and throat outpatient department (ENT OPD). Traumatic perforation incidence has been estimated at 6.8/1000 persons.[1] The causes of acute rupture of TM include direct trauma (69.42%), iatrogenic (13.42%) by using a cotton swabs, pins and sticks.[1] Other study shows infection like acute otitis media (92%) as a common cause of TM perforation.[2] Although the TM has a remarkable ability for regeneration and spontaneous healing, chronic perforations still occur. The most common approach for closure of tympanic membrane perforation is conventional microscopic surgery with underlay temporalis fascia graft technique.[3] Other commonly used graft materials are tragal perichondrium, fat, thin tragal cartilage, fascia lata.[4] Conventional microscopic surgeries are usually invasive and leave a postauricular scar. It also requires general anaesthetic (GA)/local anaesthetic (LA), admissions, suturing, dressing and care of wound with antibiotics (IV/oral). The success rates vary from 90-94%.[5] In some cases, the comorbidity can be a limiting factor due to

general anesthetic complications in conventional microscopic myringoplasty. Minimal invasive techniques are transcanal and otoendoscopic myringoplasties, the grafts placed in this technique are the same as in conventional microscopic myringoplasty. It avoids the post aural scar and its success rate is up to 91.67% and these procedures also requires packing of external auditory canal (EAC) up to 3 weeks.[6]

Noninvasive unconventional myringoplasties are also commonly performed in ENT OPD for small and dry perforations especially post traumatic. Various methods for deepitheliazation of perforation and materials have been used in the past and are still practiced. The common materials used are paper patch (aluminium foil, micropore, adhesive tape) gel foam, silastic sheet.[7] The deepitheliazation of perforation can be done with chemical applications (trichloroacetic acid, 50% silver nitrate) and freshening with a microneedle.[8] However, the effectiveness of such treatment remains controversial.[7,9]

The discovery of carbon dioxide (CO_2) laser has opened a new era. CO_2 laser is used in otorhinolaryngology extensively. The CO_2 laser has a wavelength of 10,600 nm and its properties like absorption by blood/liquids and minimal collateral damage have allowed its safe usage in various ENT procedures. CO_2 laser has been used in ear surgeries for over a decade now. Its application includes stapedotomy, epithelial pearl removal, myringotomy, adhesiolysis.[10] CO_2 laser apart from being accurate and precise also promotes epithelial migration and neovascularization.[11]

CO_2 laser myringoplasty requires no IV access and can be done safely in children, elderly patients with comorbidities, and can be carried out on an out-patient basis with minimal post-operative care. The procedure avoids any manipulations of the chorda tympanic nerve or damage to the middle ear structures and can be done under local anaesthesia except in children.

The purpose of this study was to demonstrate a success rate of deepitheliazation of perforation margins with the CO_2 laser and covering it with bioinert thin silastic sheet in patients with longstanding dry small perforation of the TM (≤3 mm) and comparing it with conventional type 1 tympanoplasty in cases of persistent small central tympanic membrane perforations.

METHODS

It was a comparative study conducted from January 2017 to June 2019 in the ENT department of an academic tertiary care hospital. A sample size comprising of 60 patients (30 patients in each group) in the age group of 18-60 years of both sexes consenting to participate in the study were included. Patients with persisted small (≤3 mm) central perforation of TM with dry ear for at least 3 months period before the surgery, single episode of acute otitis media, and healthy TM without any tympanosclerosis around the perforation were included in this study. Patients with cholesteatoma/unsafe ear/chronic discharging ear were excluded from the study. Patients who are smokers, not available for follow-ups and those who underwent any tympanomastoidectomy operations were also excluded from this study.

Sample size

Sample size was calculated assuming the proportion of graft take up as 95% as per the study by Singh et al.[12] The other parameters considered for sample size calculation were 8% absolute precision and 95% confidence level. An infinite population correction was applied. The following formula was used for sample size calculation.

$$n = Z^2P\ (1 - P)/d^2$$

Where n=sample size, Z=Z statistic for a level of confidence, P=expected prevalence of proportion (if the expected prevalence is 95%, then P=0.95), and d=precision (if the precision is 8%, then d=0.08).

The required number of subjects as per the above-mentioned calculation was 29. To account for a non-participation rate of about 3% (1 subjects), it was decided to sample about 30 subjects in each groups of the study.

Sampling method

All the eligible subjects were recruited into the study consecutively by convenient sampling till the sample size is reached.

Selected patients were educated regarding the study and informed written consent was taken. A total of 60 patients with persistent small central TM perforation (≤3 mm), including one case of double perforation of Tympanic membrane post blunt trauma (Figure 1), among them 30 cases were selected for CO_2 laser assisted deepithiliazation of perforation margin and remaining 30 cases for conventional type 1 tympanoplasty included in this comparative study. All patients underwent nasal endoscopy and upper airway examination to rule out allergies, infections, and any underlying pathology during selection for this study. The deepitheliazation of perforation margins was performed under local anaesthesia in the operation theatre (OT), using CO_2 (acupulse) and focused laser single pulse of settings power 10-14 Watts, depth 0.1-0.2 mm, focused 0.1-02 sec, the circular size of the CO_2 laser beam was used to aim the perforation margin around 1mm bigger than the size of perforations (Figure 2). These were applied with acupulse lumenis CO_2 laser. There was no gel foam placed in the middle ear through the perforation. After freshening the perforation, the thin implant grade bioinert silastic sheet (0.05 mm thick) cut in oval shape size of 6-8 mm covering the full defect and resting on the rest of the tympanic membrane was placed (Figure 3) and supported by gel foam over it. The procedure was done on an OPD basis,

short duration (5-10 min) and since all sterile measures were taken, antibiotics were not given. Closure of eardrum perforation was monitored using an otoendoscope in the ENT OPD 2 weekly for 1 month and monthly for the next 6 months.

Figure 1: Otoendoscopic picture of TM shows two perforation with strand in between post trauma.

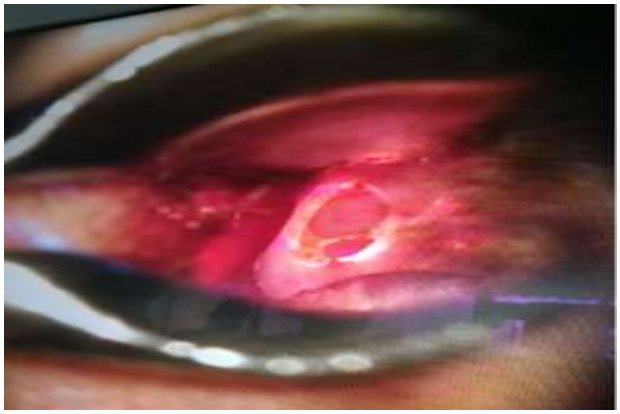

Figure 2: In CO_2 laser assisted myringoplasty- appearance of perforation after laser shot.

Figure 3: In CO_2 laser assisted myringoplasty- thin silastic sheet placed over perforation after laser shot.

The hearing threshold of the patients was measured with pure tone audiometry. Preoperative and postoperative hearing threshold was calculated at 0.5 kHz, 1 kHz, and 2 kHz, and then air–bone gap (ABG) gain was calculated. It was calculated for patients whose hearing has been improved. In the follow-up, patients with residual perforation were excluded from audiological evaluation. The postoperative hearing threshold was measured 3 months after surgery.

A successful anatomical outcome was defined as an intact TM without any residual perforation for at least 3 months after the surgery (Figure 4).

Figure 4: In CO_2 laser assisted myringoplasty- 3 months follow up picture shows complete closure of perforation.

In conventional type 1 tympanoplasty underlay technique was used with the postauricular soft tissue approach under local anaesthesia. In type 1 tympanoplasty, temporal muscle fascia was taken as graft and then it was dried and placed with the same technique.

The outcomes of CO_2 laser (acupulse) myringoplasty concerning the post-operative hearing improvement and rate of graft take up which was compared with conventional type 1 tympanoplasty.

Statistics were expressed as mean±standard deviation for quantitative variables, and as a number of cases and percentages for qualitative variables.

Student t-test (independent or paired samples) was used to compare means. P value <0.05 was considered statistically significant.

RESULTS

In this study total of 60 patients were selected. 30 patients who underwent CO_2 laser assisted myringoplasty with thin silastic sheet with a mean age of 35.4±10.4 years ranging from 18 to 60 years were compared with 30 patients who underwent type 1 tympanoplasty (mean age in this group was 35.1±10.2 years ranging from 18 to 55 years). This study showed, no statistically significant difference between the two groups regarding demographic characteristics (Table 1).

Table 1: Percentage distribution of sex of tympanic membrane perforation.

Sex	CO_2 laser myringoplasty (%)	Type 1 tympanoplasty (%)
Male	20 (52.63)	18 (47.36)
Female	10 (45.45)	12 (54.54)

The etiology of the perforations were post-traumatic in 30 cases, post-acute otitis media in 20 cases and post-conventional tympanoplasty surgery residual perforation in 10 cases (Table 2).

Table 2: Percentage distribution of different causes of perforations.

Causes of perforations	No. of ears (%)
Post traumatic	30 (50.00)
Post ASOM	20 (33.33)
Post-surgery	10 (16.66)

In CO_2 laser myringoplasty and type 1 tympanoplasty groups, when preoperative and post-operative AB gaps were compared significant closure was observed in AB gap (P<0.00001) (Table 3).

In both CO_2 laser myringoplasty and type 1 tympanoplasty groups, when preoperative and post-operative AB gaps were compared between operation types, no significant difference was found. As same, when they were compared in terms of gain, no significant difference was found between groups (P=0.38), AB gain was found to be 7.38±1.88 dB in CO_2 laser myringoplasty group, whereas it was 7.08±2.24 dB in type 1 tympanoplasty (Table 4).

In follow up, the displacement and migration of thin silastic sheet were noted in 6 of 30 patients (20%) undergoing CO_2 laser myrignoplasty. Residual perforation occurred in 1 of 30 patients undergoing type 1 tympanoplasty (3.33%) (Table 5).

The displacement and migration of thin silastic sheet were noted in 06 patients and the average time of displacement of sheet was between1-2weeks. In these patients, 03 patients had successful closure of tympanic membrane perforation and 03 patients had a residual perforation despite putting the new silastic sheet. 02 patients ended up in mucoid discharge after 4 weeks and residual perforation. 01 patient had residual perforation without any evident cause. No cholesteatoma/epithelial pearl occurred under the healed TM during the follow-up period. None of the patients had any post-op infections and discharge. Patients were instructed to keep the operated ear dry and not to swim up to 4 weeks.

Table 3: Pre-op and post-op AB gap levels within each group.

Group	Preoperative AB gap (dB)	Post-operative AB gap (dB)	P value
CO_2 laser myringoplasty (n=24)*	20.04±2.49	12.66±2.09	<0.00001
Type 1 tympanoplasty (n=29)**	20.79±2.05	13.55±1.99	<0.0001

AB gap, air-bone gap, *n=24, because 6 patients in CO2 laser myringoplasty group with failed perforation closure was excluded from the audiological evaluation, **n=1, because 1 patients in type 1 tympanoplasty group with residual perforation was excluded from the audiological evaluation

Table 4: Pre-op and post-op AB gap levels and gain according to type of operation.

Pre-op and post-op	CO_2 laser myringoplasty	Type 1 tympanoplasty	P value
Preoperative AB gap (dB)	20.04±2.49 (n=30)	20.79±2.05 (n=30)	0.28
Post-operative AB gap (dB)	12.66±2.09 (n=24)	13.55±1.99 (n=29)	0.16
Gain (dB)	7.38±1.88 (n=24)*	7.08±2.24 (n=29)	0.38

AB gap, air-bone gap, *n=24, because 6 patients in CO2 laser myringoplasty group with failed perforation closure was excluded from the audiological evaluation

Table 5: Graft take up results in our study.

Parameter	CO_2 laser myringoplasty (%)	Type1 tympanoplasty (%)	P value
Graft take up	24 (80)	29 (96.66)	0.1
Failed	6 (20)	1 (3.33)	

Patients were reviewed 2 weekly for 1 month and monthly for the next 6 months as follow up. In cases in which the thin silastic sheet was detached or displaced from the TM perforation, it was replaced with a new one. Repeat application of the silastic sheet was done in 6 patients.

The thin silastic sheet was removed after 4 weeks and PTA was done after 6 weeks. There was one case of double perforation post blunt trauma which was also closed successfully.

DISCUSSION

TM perforation has a natural tendency to heal on its own following trauma of ear drum and ASOM. Even when conditions are favorable the studies have shown that up to 21.3%[13] of such perforations may not heal and can become permanent. Such perforations may result in conductive hearing loss or repeated infections of middle ear.

The mechanisms are not clear that how some cases fail to heal TM perforation but one of the common physical finding is the contact of outer squamous epithelium of TM to inner mucosal layer by growing medially and rounding the edges of perforation.[13] The ear has to be kept dry and ear drops are avoided in dry perforations so that no infection can enter from outer ear.[14]

The unfavorable conditions for natural healing are presence of middle ear infection and upper airway allergies, eustachian tube dysfunction and abnormal middle ear aeration. In our study we excluded smokers as they may have impair healing by altered mucociliary clearance of middle ear cleft.[15]

The conventional tympanoplasty is surgical repair of choice. However, in some selected sets of patient the inconvenience of surgery and its associated risks may cause concerns like scar or being admitted in hospital.[16] In such selected patients this CO_2 laser assisted myringoplasty may be offered using bioinert thin silastic sheet to assist closure of perforation by natural healing process. As the literature suggest that the small perforations can be closed successfully with other unconventional techniques, we used this novel technique which is simple and safe.[13]

In this study where we compared with conventional type 1 myringoplasty though our results were lower but had few advantages. CO_2 laser assisted myringoplasty using thin silastic sheet procedure was quick, safe and repeatable. It was very well tolerated and its failure did not change any outcomes when they underwent conventional type 1 myringoplasty. It avoided scar and it was a painless procedure without any complications.

The only drawback was in some cases the silastic sheet got displaced from the perforation site and needed a repeat application of silastic sheet. The detachment or migration may occur while healing and the exact timing of this event could not be anticipated.

Many people have been using unconventional method for freshening and patching of small TM perforations in OPD with various materials like silver foil paper, micro paper tape, gel foam, collagen dressing materials like alloderm and silastic sheet. The freshening of margins for small dry perforation is done by using micro ear needle, trichloroacetic acid or 50% silver nitrate local applications. Golz et al reported 55.7% success rate using conventional paper patching in perforations of less than 5 mm of size.[17] Santhi et al reported 73% success rate with the trichloroacetic acid cauterization of perforated margins and patching.[8] Ozgursoy et al achieved 82.4% success rate using fat graft myringoplasty.[18]

Conventional underlay myringoplasty procedure using temporalis fascia graft or tragal perichondrial graft in OT achieves success rate above 90%. The approach can be postaural which is commonly used though some surgeons prefer transcanal or endaural approach especially in small posterior based perforations. Role of antibiotics in this procedure is debatable.[19] In this study we could achieve 80% success rate with CO_2 laser myringoplasty as compared to conventional type 1 tympanoplasty which had significantly higher success rate between 90-94%.

CO_2 laser myringoplasty is a sterile technique which is safe and without any side effects. It is a day care surgery and can done be quickly without any pre op preparation or drugs, it requires minimal LA and the post procedure period is pain free and do not require any drugs or antibiotics. CO_2 laser deepitheliazation is accurate and controlled well with its circular size aiming beam. CO_2 laser also known for its wound healing by stimulating neovascularization.[20] Thin bio inert silastic sheet of size 0.05mm can be used safely over the dry perforations.

This procedure also has a role in small dry post-surgery residual perforations. We recommend this technique in selected patients who are willing for this procedure as it offers a fairly good chance of success and its failure also does not change any surgical outcomes subsequently.

Limitations

The limitation is not all ENT centre has a CO_2 laser in their department. The perforation sizes can be tricky and to see middle ear status is not feasible in all cases so it may cause difficulty in appropriate selection of cases. Also study needs large group to get more data to validate this study results.

CONCLUSION

The CO_2 laser assisted deepithelization of perforation margins and application of implant grade bioinert thin silastic (0.05 mm) sheet in our study achieved 80% success rate in closure of the persistent small (≤3 mm) central TM perforation. The success rate of this procedure is lower than conventional type 1 tympanoplasty, which is between 90-94%. However, CO_2 laser assisted procedure can be offered to carefully selected cases of post traumatic perforations as it avoids any scar and any tissue cutting without any complications. The procedure may be good option in an ENT centre where CO_2 laser is available before they undergo formal conventional microscopic surgery and if patients are willing as it does no harm to TM

or middle ear structures and risk of post-operative infection is minimal.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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