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Endoscopic Type I Tympanoplasty in 70 Patients with Chronic Otitis Media: A Preliminary Report

ABSTRACT

Objective: To evaluate the preliminary surgical results of Endoscopic Type I Tympanoplasty among patients with inactive chronic otitis media without ossicular pathology.

Methods:

Design: Prospective Series

Setting: Tertiary Government Hospital

Participants: Seventy patients with inactive mucosal chronic otitis media (COM) with air bone gap (ABG) of ≤ 40 dB on the preoperative audiogram scheduled to undergo Type I Tympanoplasty between July 2018 and December 2020 were enrolled.

Results: Seventy-three (73) ears were evaluated. The overall rate of graft uptake was 95.9% at 12 weeks. There was a statistically significant ($p < .001$) improvement in hearing on comparison of pre-operative (25.74 ± 7.34 dB) and post-operative (14.82 ± 6.55 dB) air bone gap. The duration of surgery was less than one hour in 76.7% and 77.2 % patients experienced only mild post-operative pain.

Conclusion: Endoscopic tympanoplasty can provide good results with respect to graft uptake and hearing gain with short surgical duration and minimum postoperative morbidity. Longer follow up of at least 6 months (for graft uptake) and preferably not less than 12 months (for hearing results) may confirm our preliminary findings.

Keywords: *Chronic otitis media; Type I tympanoplasty; endoscopic; post-operative pain; tympanic membrane perforation; hearing; morbidity*

Chronic otitis media (COM) is a widespread disease in developing countries characterized by long standing infection of a part or whole of the middle ear cleft.¹ It was defined by the World Health Organization as a stage of ear disease in which there is chronic infection of the middle ear in the presence of a tympanic membrane perforation and ear discharge.² Myringoplasty and tympanoplasty are surgical procedures that are used for repair of the tympanic membrane and

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Disclosure: The authors declare that this presents original material that is not being considered for publication or has not been published or accepted for publication elsewhere or in part, in print or electronic media; that the requirements for authorship have been met by all the authors, and each author believes that the manuscript represents honest work. Approval was initially obtained for the thesis of HSO supervised by ASS and PP, comparing 30 cases each of endoscopic and microscopic tympanoplasty, and extended to 70 cases of endoscopic tympanoplasty with BS as lead author for the study concept, design, analysis, and drafting.

The authors declare that there are no financial or other (including personal) relationships, intellectual passion, political or religious beliefs, and institutional affiliations that might lead to conflict of interest.



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middle ear respectively, with microscope - assisted tympanoplasty being one of the commonest operations performed on the middle ear.

Surgical management of COM aims to eradicate middle ear disease thereby giving the patient a dry ear, and to improve hearing by closure of the tympanic membrane perforation and ossicular reconstruction if required. Despite various advancements in the operating microscope, the perfect surgical outcome has eluded surgeons as the basic optics have remained unchanged over the years. With the advent of rigid endoscopes for sinus surgery, extended applications in other fields have emerged. Mer and Colleagues introduced middle ear endoscopy in 1967, following which endoscopes have been used in various middle ear surgeries.³

The results of tympanoplasty are measured in terms of success or failure of graft-take and hearing improvement. Superior results in terms of 93 – 97% graft uptake rates and 85 – 90% chance for a hearing gain to within 20 dB of bone conduction levels can be expected in patients with mucosal COM with simple ossicular pathology.^{4,5} Hence, to evaluate the surgical outcome, these cases should be separated from those with cholesteatoma, severe mucosal disease, eustachian tube dysfunction, severe ossicular pathology and revision cases.

This study was undertaken to evaluate the surgical results of Endoscopic Type I Tympanoplasty among patients with inactive chronic otitis media without ossicular pathology and present our preliminary findings.

METHODS

This prospective series was conducted at the Department of ENT, Sri Guru Ram Das (SGRD) Institute of Medical Sciences and Research, SGRD University of Health Sciences, Amritsar, Punjab, between July 2018 and December 2020. It was performed in compliance with the Declaration of Helsinki and prior clearance was obtained from the Institutional Ethics Committee.

Patients with inactive mucosal chronic otitis media (COM) were screened for eligibility. Inclusion criteria were adults between 18 - 50 years of age with inactive mucosal COM with a central perforation and a dry ear for 3 months, and an air bone gap (ABG) of ≤ 40 dB on the preoperative audiogram. Excluded were those with cholesteatoma, revision cases, and any indications of ossicular pathology, sensorineural or mixed hearing loss on preoperative audiogram. Suitable candidates were enrolled in the study after obtaining informed consent and were scheduled to undergo Type I Tympanoplasty, involving reconstruction of the tympanic membrane with normal ossicular chain.⁶

For each patient, demographic details were recorded. A detailed history was obtained, and complete evaluation of the ears, nose and throat was done. In addition, preoperative audiological evaluation

was performed on all patients using an Interacoustics Model AD629 (Interacoustics A/S, Middelfart, Denmark) audiometer to assess the degree and nature of hearing loss.

Surgical Technique

The surgeries were performed either under general or local anesthesia as per the choice and comfort of the patient by a single surgeon (PP), who had been performing endoscopic ear surgeries as part of routine practice for at least five years before this study. A conventional 0° 18mm Stryker endoscope with 4mm diameter and Stryker 1288 Full HD Endoscopic camera system (Stryker Corp., Kalamazoo, Michigan, USA) were used.

Local anesthesia was infiltrated using 2% xylocaine with 1:2,00,000 adrenaline in all quadrants of the external auditory canal, and at the site of graft harvest. Temporalis fascia graft was harvested via a 1.5 cm supra-auricular incision above the hairline. The perforation was visualized, and margins freshened to remove redundant epithelium. An incision was made in the external auditory canal from the 12 o'clock to 6 o'clock position around 4 mm lateral to the annulus and a tympanomeatal flap was elevated. The middle ear was inspected for any mucosal edema or granulations and ossicular continuity and mobility were confirmed. Gelfoam® absorbable gelatin sponge was placed in the middle ear to form a bed for the graft and temporalis fascia graft was placed by underlay technique. A simple dressing was applied on the site of graft harvest and all patients were discharged the next day.

Evaluation and Follow-up

Post-operative pain was evaluated using the Wong Baker scale on the first post-operative day. The patients were called for follow up at 1 week, 3 weeks and 6 weeks postoperatively. Final assessment for this preliminary series was performed (PP and HSO) at 12 weeks, when graft uptake was assessed with 0° endoscopy and hearing reevaluated with pure tone audiometry. A successful outcome was defined as complete graft uptake and a postoperative ABG of ≤ 20 dB.

Data Analysis

The collated results were analyzed using paired t-test calculated using Statistical Package for the Social Sciences (SPSS) Software version 23 (IBM Corporation, NY, USA). A p value of less than .05 was considered statistically significant.

RESULTS

A total of 88 patients were enrolled in the present study. Of these, 4 were revision cases, 4 had mixed hearing loss, 8 had an air-bone gap more than 40 dB suggesting possible ossicular pathology, and 2 had

retraction pockets on endoscopy and were hence excluded from the study population. Of the 70 patients eligible for the study, 3 underwent bilateral tympanoplasty at the same sitting resulting in 73 operated ears for evaluation. Of these, 47 (67.1%) were done under general anesthesia, while 23 (32.9%) were performed under local anesthesia. The mean age of the patients was 32.4 ± 6.36 years (range 19-44 years). Twenty eight (40%) were males while 42 (60%) were females.

Out of the 73 ears operated, 39 (53.4%) were on the left ear while the right ear was operated in 34 (46.6%) cases. The mean duration of symptoms was 14.6 ± 6.8 months. The most common perforation was the central perforation seen in 31 (42.5%) cases, while 11 (15.1%) had a subtotal perforation. (Figure 1) The mean size of perforation was 18.93 ± 8.61 mm².

Seventy (70) ears showed complete graft uptake at the time of final assessment at 12 weeks resulting in an overall rate of graft uptake of 95.9%. Of the remaining 3 ears, 2 had residual perforation anteriorly, while one developed a perforation inferiorly following a bout of upper respiratory tract infection at 6 weeks postoperatively.

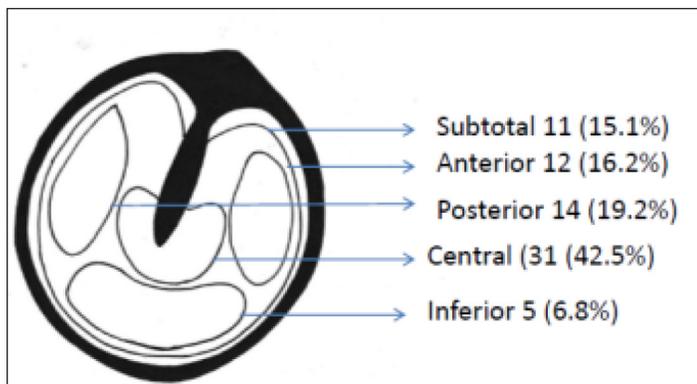


Figure 1. Site-wise distribution of tympanic membrane perforations

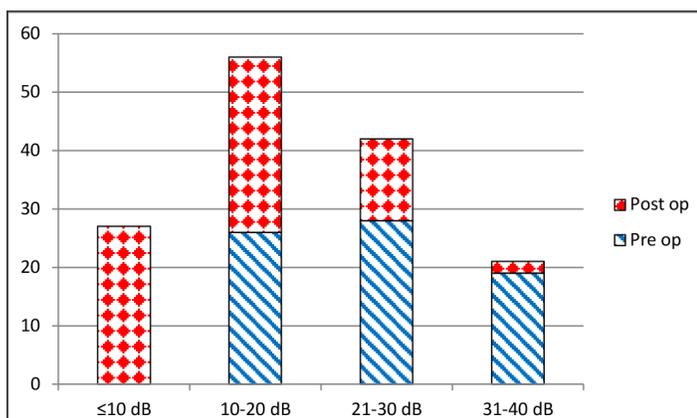


Figure 2. Distribution of patients according to ABG categories before (diagonal lines) and after (stippled) surgery

The hearing gain was evaluated by comparing the pre- and post-operative ABG. On pre-operative evaluation, 26 (35.6%) had an ABG between 10 -20 dB, 28 (38.4%) between 21 – 30 dB and 19 (26%) between 31 – 40 dB, with a mean ABG of 25.74 ± 7.34 dB. At the time of final assessment at 12 weeks, the mean ABG improved to 14.82 ± 6.55 dB, with 27 (37%) with an ABG of ≤ 10 dB, 30 (41.1%) with an ABG of 10-20 dB, 14 (19.2%) with an ABG of 21-30 dB and only 2 (2.7%) patients with an ABG of 31-40 dB. Comparison of the pre- and post-operative mean ABG by dependent t-test indicated a significant improvement; paired t (69) = 22.938, $p < .001$. (Figure 2)

The mean duration of surgery was 53.83 ± 7.86 minutes, with 56 cases (76.7%) being completed within one hour. The mean Wong Baker scale pain score was 2.46 ± 1.26 , with a majority (54; 77.2%) of patients reporting only mild pain, while 16 (22.8%) patients had moderate pain. None of the patients reported severe pain.

DISCUSSION

Since the introduction of tympanoplasty in the treatment of chronic otitis media, a variety of modifications and alternatives in the choice of approach and graft materials have been used in an effort to improve outcomes with minimum morbidity. Even though conventional microscopic tympanoplasty with a post aurial incision is the most commonly used procedure, it may result in significant morbidity namely surgical scar and post-operative pain.⁷ In addition, in our clinical practice we encounter several patients suffering from chronic otitis media who do not opt for tympanoplasty via post aurial incision, stressing the need for an alternative approach. Hence, we undertook the present study to evaluate our results with endoscopic tympanoplasty with regards to surgical results and postoperative morbidity.

Since the introduction of endoscopic ear surgeries in the late 1950's, its application in otologic surgery has expanded from myringoplasty, tympanoplasty, cholesteatoma surgery, ossiculoplasty and cochlear implantation.^{8,9} In the surgical management of COM, the advent of the endoscope aims to facilitate equivalent or superior results to the microscope with regards to the closure of tympanic membrane perforation and hearing gain, while minimizing morbidity.

In the present study, graft uptake with complete closure of tympanic membrane perforation was seen in 70 (95.9%) patients at 12 weeks. Similar results with uptake rates of over 90% have also been observed by various authors in their respective studies.¹⁰⁻¹² On evaluating the success in terms of hearing improvement following surgery, a statistically significant improvement in the air bone gap on comparing the pre- and post-operative hearing thresholds and ABG was found, with 27 (37%) patients achieving a post-operative ABG of ≤ 10 dB. Saini *et al.* their study in 42 patients subjected to endoscopic

tyimpanoplasty also found a significant improvement in the mean ABG following surgery, while in his study on 36 cases of chronic otitis media, el Guindy achieved an air bone gap of less than 10dB in 83.3%, with a graft uptake rate of 91.7%.^{11,13}

One of the main advantages of the endoscope is that it places the surgeon's view at the tip of the scope, facilitating close-up and wide-angle views by simply advancing or withdrawing the endoscope. There is no need to frequently adjust the patients head or to do canaloplasty thereby saving operating time. Also, using angled scopes can further widen the field of vision to evaluate the anterior margin of the perforation, hypotympanum and attic, obviating the need for any bony work.¹⁴

In our study, none of the 73 cases required any canaloplasty or chordal crest curettage for visualization of the tympanic membrane or evaluation of the ossicular chain, even in the present of tortuous external auditory canal or bony overhang. This translated into a shorter duration of surgery, with a mean duration of 53.83 minutes and 56 cases (76.7%) being completed within an hour. Similar observations were also made by Tseng *et al.*¹⁵ and Huang *et al.*¹⁶ in their respective studies. Dundar *et al.*¹⁷ compared endoscopic and microscopic approaches in paediatric patients undergoing type 1 tympanoplasty and found a shorter operative time in the endoscopic tympanoplasty group. However, it is pertinent to state that endoscopic tympanoplasty, like any surgery, has a learning curve, with initial cases requiring a longer operative time.

Endoscopic ear surgery has its own limitations. Being a one-handed technique, it leaves one hand free for surgery, making it disadvantageous especially in the event of excessive bleeding, requiring halting the surgical procedure to secure hemostasis. This may result in a longer intraoperative duration. Khafagy *et al.*¹⁸ found the duration of surgery in endoscopic tympanoplasty to be longer compared to the use of the transcanal approach for microscope technique. Gadag *et al.*¹⁹ also documented longer duration of surgery in patients of endoscope technique due to difficulty in graft placement and frequent soiling of the tip of the endoscope with blood.

Duration of surgery is an important factor determining post-operative results in terms of duration of anesthesia, the surgeon's concentration and the increased risk of iatrogenic complications¹⁷, with arm fatigue by the weight of the scope, neck strain and backache as some of the other known disadvantages of endoscopic ear surgery. However, proper patient preparation and meticulous attention to hemostasis may help in reducing operative time and preventing these consequences.

Avoiding a post aural incision in endoscopic tympanoplasty results in less dissection of normal tissue, less intra operative bleeding, risk of

auricular displacement and less postoperative pain.¹² Saggu *et al.* found that only 6.6% patients of endoscopic tympanoplasty complained of pain.²⁰ Majority of patients in the present study also experienced only mild to moderate pain in the postoperative period.

In addition to the above-mentioned advantages, we noticed that endoscopic tympanoplasty can be a superior approach for perforations situated anterior to the handle of malleus. Traditionally anterior perforations are considered difficult to treat surgically owing to poor visualization of the perforation, poor vascularity, as well as reduced graft stability due to limited anterior margin requiring anterior tucking of the graft.²¹ We would like to highlight that in 3 patients of ours, endoscopic tympanoplasty was done via an anterior transcanal approach with an incision over the anterior canal and raising an anterior tympanomeatal flap, circumventing these disadvantages. Although this approach will need further prospective studies comparing it with microscope assisted tympanoplasty, we found it quite promising.

Although prospectively conducted on a fairly large number of patients subjected to uniform follow-up, our present study has several limitations. The foremost limitation is that our 6-week period of follow up may have been too short to obtain conclusive results. Our study referenced several articles that reported results after a period of not less than 3 months.^{10-12, 16, 22, 23} However, guidelines have been published with regards to the reporting of hearing results, particularly the AAO-HNSF Committee on Hearing and Equilibrium (1995) that has been frequently cited as a reference for the reporting of hearing results, and it advocates a post-treatment interval of one year or longer when clinical hearing improvement is being addressed.²⁴ Likewise, numerous published articles on tympanoplasty results that date back to 2011, particularly those that discuss graft take rates, all show a minimum follow-up period of 6 months, with most having a minimum of 12 months.²⁵⁻²⁹ A longer follow up period for the reporting of results of at least 6 months (for graft uptake) and preferably not less than 12 months (for hearing results), that is consistent with current publications on the same topic, or that adheres to an internationally accepted guideline may confirm our preliminary results.

Another limitation is that this study only evaluated patients undergoing endoscopic tympanoplasty with no comparative arm, and hence no final conclusion can be made regarding its superiority or inferiority to another approach such as microscopic tympanoplasty. However, microscope assisted tympanoplasty is a well-established procedure, and comparing our results with the extensive literature available on surgical outcomes of microscopic tympanoplasty may give an indication to its probable superiority in decreasing post-operative morbidity with comparable results of graft uptake and hearing gain. The first 30 cases of endoscopic tympanoplasty in this series were



compared with another 30 cases of microscopic tympanoplasty in a separate study that we hope to publish soon.

Meanwhile, for this series, we conclude that endoscopic tympanoplasty performed with the routine endoscope and no additional specialized equipment can provide good results with respect to graft uptake and hearing gain, with short surgical duration and minimum postoperative morbidity. Longer follow up of at least 6 months (for graft uptake) and preferably not less than 12 months (for hearing results) may confirm our preliminary findings.

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