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Original Research Article

Evaluation of audiological profile and graft uptake by endoscopic composite cartilage graft tympanoplasty in chronic otitis media patients

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ABSTRACT

Background: Transcanal endoscopic ear surgery (TEES) permits wide-angle vision, high resolution, and magnification as well as the direct visualization of hidden areas of the middle ear cavity. The aim of the study was to determine the anatomic and functional results of endoscopic composite cartilage tympanoplasty in chronic otitis media cases with safe central perforation.
Methods: This prospective study was conducted on 50 chronic otitis media cases with safe central perforation (small/medium) between February 2020 to July 2021 in a tertiary care center. All the patients were selected as per the described inclusion and exclusion criteria. All cases underwent endoscopic composite cartilage graft tympanoplasty (type-I) under general anesthesia. Audiological outcomes were assessed by comparing mean pure tone average pre-and post-operatively and morphological results (successful graft uptake) were evaluated at 6 months.
Results: The result of this study showed that out of 50 cases 47 had successful graft uptake (94%) while 3 cases were found to have a residual perforation. The pre-operative air conduction threshold (ACT) was 42.82±7.33 dB whereas postoperative ACT was 31.26±7.48 dB, and the difference between the preoperative and postoperative values was found to be statistically significant.
Conclusions: This study concluded that endoscopic composite cartilage tympanoplasty in chronic otitis media cases with dry central perforations is an effective surgical modality with good audiological and morphological outcomes and negligible post-operative complications.

Keywords: Cartilage, Endoscopic ear surgery, Tympanoplasty type I

INTRODUCTION

Chronic otitis media is the chronic inflammation of the mucoperiosteal lining of the middle ear and mastoid cavity. It causes numerous pathological changes in the tympanic membrane and middle ear including perforation, ossicular destruction, myringosclerosis, and conductive hearing loss. The surgical treatment of chronic otitis media primarily aims to eradicate the disease process, reconstruct conductive hearing mechanism, and establish middle ear cleft ventilation.

Since the 1950s, microscopic tympanoplasty has been the standard treatment for the reconstruction of a perforated tympanic membrane.[1]

Transgressing from classical microscopic tympanoplasty techniques to endoscopic tympanoplasty techniques has been evolving gradually with the introduction of better instrumentation and surgical techniques. The reasons for the slow acceptance of this technique appear to be the lack of familiarity with instrumentation and the inability to use both hands.

Using the endoscopic transcanal approach, many ear operations can be performed through a relatively narrow corridor without a large post-auricular incision. The tragal cartilage is an excellent graft, especially in the endoscopic tympanoplasties. The cartilage being relatively rigid is easier to place single-handedly with precision, and its fewer chances of graft rejection or failure prove it a perfect graft transplant while performing endoscopic tympanoplasty.[2] The transanal endoscopic approach is scarless and provides a bloodless field. The graft success rates in the endoscopic tympanoplasty and microscopic tympanoplasty groups have been reported at 100% and 95.8% respectively.[3]

The aim of the study was to determine the morphological and anatomical results of endoscopic composite cartilage tympanoplasty in patients having chronic otitis media with safe central perforation (small or medium).

METHODS

This prospective interventional study included 50 patients of chronic otitis media with dry and safe central perforation (small/medium), who underwent endoscopic composite cartilage tympanoplasty (type I) in the Otolaryngology Department of Sri Guru Ram Rai Institute of Medical and Health Sciences between February 2020 to July 2021. The sample size was decided according to the estimated availability of the surgical cases over the next 18 months of study duration. This study was approved by the institutional ethics committee. The inclusion criteria were: (a) patients aging above 12 years; (b) with chronic otitis media with dry and safe central perforation (small or medium) for at least one and a half months; (c) having conductive hearing loss (air conduction threshold <45 dB in the affected ear); and (d) good tubal function and dry middle ear mucosa. The exclusion criteria were: (a) large subtotal/total perforation; (b) with active squamosal/adhesive disease (unsafe ear); (c) with persistently discharging ear not responding to medication; (d) pure sensorineural and mixed hearing loss in the affected ear; and (e) revision cases.

Informed consent was taken from all patients after proper counseling. All selected patients were subjected to a thorough history regarding presenting complaints, any chronic illness, any long-duration medication, or any systemic disorder. Clinical examination, otoscopy, oto-endoscopy, tuning fork tests, and X-ray (bilateral) mastoid (Schuller's view) were done in all patients. Hearing assessment by pure tone audiometry (PTA) was performed on all patients. The air conduction (ACT) and bone conduction (BCT) pure-tone average were calculated by averaging the thresholds at 0.5, 1, 2, and 4 kHz.

All patients were followed up postoperatively at one month, three months, and six-month intervals and underwent audiometry and otoscopy. The final audiological and morphological outcome considered during this study was done at 6 months. Anatomical success was defined as the presence of an intact graft, as evaluated by a zero-degree endoscope, without perforation, atelectasis, or lateralization at the follow-up of 6 months. Functional results were evaluated by comparing the change in air conduction thresholds preoperatively and post-operatively. All data were collected and analyzed using appropriate statistical methods.

Data were described in terms of range, preoperative ACT, and postoperative ACT (mean±SD), frequencies (number of cases), and relative frequencies (percentages) as appropriate. The comparison of quantitative variables was done using paired t-test. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done using (Statistical package for the social science) SPSS, version 21 (SPSS Inc., Chicago, IL, USA).

Surgical technique

All surgical procedures were performed by the same surgeon using 0 and 30-degree Karl Storz rigid endoscope (18 cm, 4 mm) with connected fiberoptic light transmission. The endoscope was connected to Stryker 1588 Camera unit. All surgeries were done under general and hypotensive anesthesia. Trans-canal approach and over-underlay technique was employed in all the patients to maintain uniformity. The full-thickness tragal chondro-perichondrial graft was used in all cases.

A pick or sharp needle was used to freshen the perforation margins. A lateral circumferential incision using Rosen's knife was made 4-6 mm laterally from the annulus of the tympanic membrane and integrated with radial incisions. The tympanomeatal flap was elevated and the manubrium of the malleus was skeletonized (Figure 1, a-f).

Middle-ear mucosa and ossicular chain mobility were assessed. The cartilage graft with mucoperichondrium (on one side) was then excised and a triangular part of it was removed at a site corresponding to the lateral process and handle of the malleus. The middle ear was then packed with Gelfoam and the harvested graft was placed in position. The over-underlay technique was performed by placing the chondro-perichondrial graft lateral to the handle of the malleus and medial to the tympanic membrane remnant and annulus (Figure 2, a-d). The tympanomeatal flap was repositioned back in the external ear canal. The external ear canal was then packed with Gelfoam and a sterile pack was placed in the external meatus.

All patients during their hospital stay were given intravenous antibiotics, analgesics, proton pump inhibitors, and also oral decongestants. Patients were discharged after 48-72 hrs and were called for follow-up visits. The follow-up protocol involved suture removal on postoperative day seven, followed by ear pack removal and antibiotic ear drop prescription on post-operative day 14.

RESULTS

In this study of 50 cases, there were 27 (54%) females and 23 (46%) males, and a female: male ratio of 1.2: 1 was observed. There was a uniform distribution of the subjects across the age groups. In this study, patients were selected above 12 years of age. There were 10 (20%) cases between 13-20 years of age, 13 (26%) between 21-30 years, 15 (30%) between 31-40 years of age, and 12 (24%) cases above 40 years. The age group with the highest incidence of disease was found to be 31 to 40 years of age (30%). The mean age of patients in this study was 32.14±11.06 years.

In our study, the duration of ear discharge ranged from less than 1 year to more than 5 years. Out of the total 50 cases, 7 (14%) cases had ear discharge for less than 1 year, 25 (50%) for 1-5 years, and 18 (36%) cases for more than 5 years. The maximum number of subjects had a discharge history between 1-5 years (50%). In this study, 4 (8%) cases were found to have decreased hearing for less than 1 year, 31 (62%) cases reported decreased hearing for 1-5 years, and 15 (30%) cases had it for more than 5 years. Maximum cases were found to have a history of decreased hearing between 1-5 years duration. The maximum number of subjects in our study were having medium size perforation (less than 50%) i. e.; 31 (62%) cases, whereas 19 (38%) patients had small perforation (less than 25%). All 50 (100%) cases had patent eustachian tubes in this study as evaluated by the valsalva maneuver. In our study 8 (16%) cases had diploic mastoid, 28 (56%) had pneumatised mastoid and 14 (28%) had sclerosed mastoid as revealed by X-ray mastoid.

In this study of 50 cases, 23 (46%) patients were operated on in the left ear and 27 (54%) patients were operated on in the right ear. The result of this study showed graft uptake success in 47 (94%) cases (Figure 2e) and failure was seen in 3 (6%) cases. The pre-operative ACT was 42.82±7.33 dB whereas postoperatively it was 31.26±7.48 dB and the difference between the pre-operative and post-operative values was found to be statistically significant. Table 1 describes comparison between pre-operative and post-operative air conduction thresholds at 6 months.

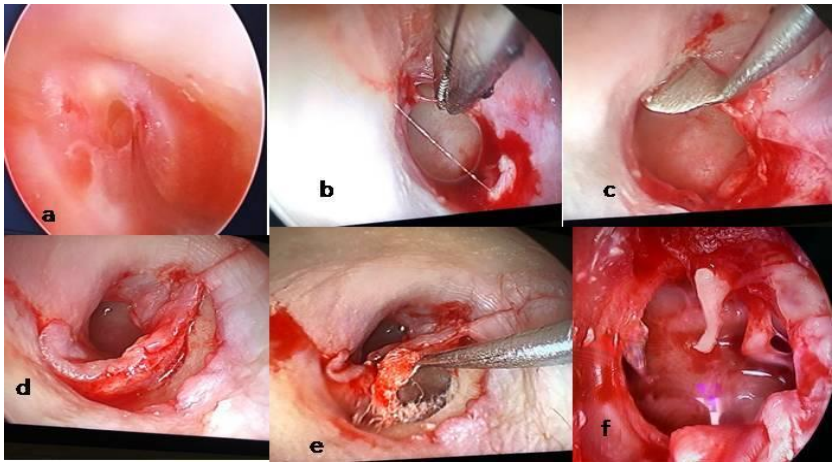

Figure 1: (a) Perforation; (b) freshening of margins; (c) creating raw surface under remnant; (d) a curvilinear incision in the canal; (e) elevation of the tympano-meatal flap; and (f) denuding the handle of malleus.

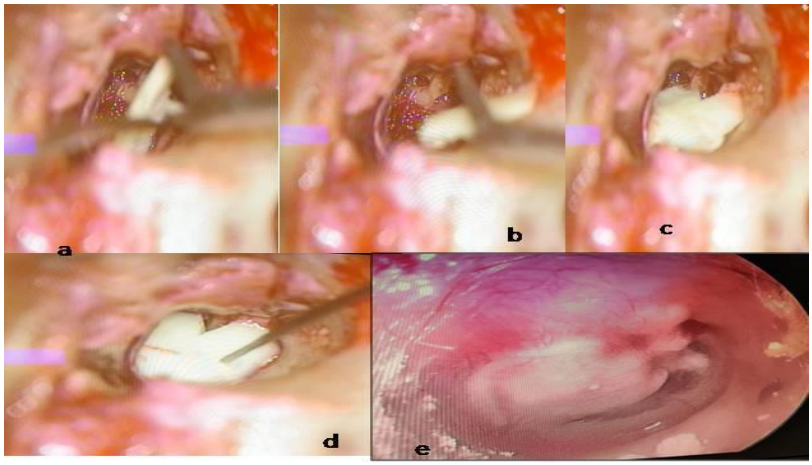

Figure 2: (a and b) Insertion of cartilage graft in the middle ear; (c and d) placement of cartilage graft over the handle of malleus; and (e) intact cartilage graft 8 months post-operatively.

Table 1: Comparison between pre-operative and post-operative air conduction thresholds at 6 months.

Mean Air conduction threshold (ACT)	Pre-operative		Post-operative		T	P value
	Mean	SD	Mean	SD		
	42.82	7.33	31.26	7.48	15.979	0.001

DISCUSSION

The present study was conducted in a tertiary care institute for a period of 18 months. It comprised of total 50 cases which were selected as per the inclusion and exclusion criteria and after taking proper informed consent. All the cases underwent endoscopic composite cartilage graft tympanoplasty (type I) under general anesthesia. Postoperative successful graft uptake was seen in 94% of cases and regarding functional outcomes, a statistically significant difference was observed between pre-and post-operative mean air-conduction thresholds (p=0.001).

Composite cartilage tympanoplasty is a well-established technique. When performed endoscopically, functional and anatomical outcomes are comparable to microscopic surgical techniques. However, advantages in the visualization and access via the EES method have been observed. Cartilage is robust enough to resist middle ear negative pressure and no significant difference has been demonstrated in sound conduction when compared to temporalis fascia.[4-7] Factors that resulted in good graft uptake, involve the exploitation of the natural characteristics of the tragal cartilage, through a specific grafting design that diminishes the possibility of dislodgement and easier one-handed placement. Furthermore, this method reduces the need for middle ear packing, which reduces the likelihood of adhesion formation.[8]

The endoscopic approach to the middle ear and the tympanic cavity is a practical, minimally invasive, and conservative technique. In our study, we found no need to use several flaps/tissue dissection or perform canaloplasty and as a result, there was no disturbance in the external ear blood circulation. Endoscopic tympanoplasty is a time-saving technique and also the anatomy of the middle ear is preserved. Less pain, reduced demand for analgesics and reduced time of operation and a shorter period of follow-up are the other advantages of the endoscopic method. Endoscopic tympanoplasty is possible to be performed with 0 or 30-degree telescopes with complete visualization of the ossicular chain and middle ear and with no need for any bone drilling.[9]

In our study, the majority of patients (30%) belong to the 31-40 years age group, followed by the 21-30 years age group (26%), the above 40 years age group 24%, and only 20% of patients were between 13-20 years of age. The mean age of patients was 32.14±11.06 years. Similar to our study, Daneshi et al included the patients with a mean age of 37.9 years in their study, performed on 9 patients.[9] In our study, the prevalence of disease was more common in females as compared to males. Of the 50 cases, 27 (54%) were females and 23 (46%) were males. The study conducted by Kaya et al on the results of endoscopic cartilage tympanoplasty in 87 cases, also found that 55 cases were females and 32 were males.[10]

In this study, out of a total of 50 subjects, 23 (46%) patients were operated on in the left ear and 27 (54%) patients were operated on in the right ear. In another study of 50 cases, 32 (64%) patients had surgery on the left ear, and 18 (36%) had it on the right.[8]

In this study, 94% successful graft uptake rate was noticed and 3 cases (6%) had a residual perforation. Ayache et al in 2013, reported 30 endoscopic myringoplasties with a success rate of 96%. His study reported two patients who had residual perforation, which healed spontaneously.[11] Our study was found to have a very close resemblance with a study conducted by Gokgoz et al and Tasli et al on the results of endoscopic transcanal tympanoplasty. Similar to our study they also included 50 patients who all underwent endoscopic type I tympanoplasty, using tragal cartilage graft and over-underlay technique. The graft success rate was 94% at 6 months postoperatively. But unlike our study, they included both medium and large-size perforation and had more left side laterality. In their study, as a postoperative complication, three patients had a crescent-shaped perforation in the anterior quadrant.[8]

In our study, a significant improvement was seen in the mean air conduction threshold postoperatively and on comparing with pre-operative thresholds, a statistically significant difference was found. In one study, where 53 cases underwent endoscopic composite cartilage tympanoplasty, available data of 39 patients revealed a mean pre-operative PTA of 42.8 dB (SD±16.7) and mean post-operative PTA of 25.7 dB (SD±15.9) with a statistically significant difference (p<0.001).[12] In another study where endoscopic cartilage tympanoplasty was done using full thickness and partial thickness tragal graft, the average preoperative hearing was 40.80±7.46 dB and 39.40±7.95 dB for full thickness and partial thickness cartilage groups, respectively. The post-operative PTA at 2 months showed an average hearing of 26.72±8.08 dB for full-thickness and 26.40±8.60 dB for the partial thickness group. The hearing improvement in both groups was comparable and statistically significant compared to their respective pre-operative hearing levels (p value=0.012 for full-thickness and p value=0.018 for partial thickness group).[13]

The common factors responsible for failure of tympanoplasty are atelectasis, eustachian tube dysfunction, tympanosclerosis, active suppuration, large perforation, unfavorable middle ear mucosa, and revision

myringoplasty.[14] No post-operative facial nerve weakness or ossicular chain-related complications were observed in our series. No other complications like otitis externa, granulation formation, medialization or lateralization of the graft, and worsening of hearing were observed during the follow-up period. Only 3 cases were found to have residual perforation while the rest 47 cases showed successful graft uptake. The audiological results only partially improved in patients who had graft failure. The postoperative graft failure might have happened due to improper placement of the graft, inadequate blood supply, or infection.

In our opinion lack of sample size calculation, randomization and blinding were one of the limitations of this study. The other limitations of this study were its retrospective nature, small sample size, and shorter follow-up period. This was a single-institution study and the experience of a single surgeon may be a probable confounder. According to us, the strength of this study was its comparable morphological and audiological results with fewer complications in our learning curve phase. We propose that a blinded, randomized study taking into account a bigger sample size, long-term results, complications, and comparison with other surgical techniques will be required to arrive at clinically relevant conclusions.

CONCLUSION

In our study, we conducted an endoscopic composite cartilage graft tympanoplasty (type-I) in 50 cases and observed a graft uptake success rate of 94%. There was good uptake of graft along with improvement in the audiological profile of the patients. Besides the 3 failure cases with residual perforation, no significant postoperative complications were observed during the study. From this study, we can conclude that endoscopic composite cartilage graft type I tympanoplasty is a feasible, safe, minimally invasive, and effective procedure with successful outcomes.

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

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