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Comparative Outcomes of Type I Tympanoplasty and Office-Based Medical Myringoplasty Using Epidermal Growth Factor with a Silastic Scaffold in Bilateral Inactive Mucosal Chronic Otitis Media: A Prospective Within-Patient Comparative Study.

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Abstract

Background: Type I tympanoplasty remains the standard surgical procedure for the closure of tympanic membrane perforations in patients with inactive mucosal chronic otitis media (COM). However, surgery may not always be feasible in patients with bilateral disease because simultaneous bilateral tympanoplasty is generally avoided, necessitating alternative minimally invasive treatment options. Office-based medical myringoplasty using topical epidermal growth factor (EGF) with a silastic scaffold has emerged as a potential non-surgical technique to promote tympanic membrane regeneration. The present study compared the anatomical and functional outcomes of surgical and medical myringoplasty performed simultaneously in opposite ears of the same patient. ***Methods:*** A prospective non-randomized comparative study was conducted over one year at the Department of Otorhinolaryngology, Karnataka Institute of Medical Sciences, Hubballi. Sixty-two patients with bilateral inactive mucosal chronic otitis media and central tympanic membrane perforations were included. Each patient underwent Type I tympanoplasty in one ear and office-based medical myringoplasty using topical epidermal growth factor with a silastic scaffold in the contralateral ear. Patients were followed for three months. Primary outcomes included tympanic membrane closure and hearing improvement assessed by pure-tone audiometry. Secondary outcomes included postoperative pain, ear discharge, and procedure-related complications. ***Results:*** A total of 124 ears from 62 patients were evaluated. Complete perforation closure was achieved in 88.6% of ears treated with Type I tympanoplasty compared with 72.6% of ears treated with medical myringoplasty. Both techniques demonstrated significant postoperative improvement in hearing thresholds compared with baseline. Medium-sized perforations showed higher healing rates following surgical myringoplasty, whereas perforation size had no significant influence on healing following medical myringoplasty. Office-based medical myringoplasty was associated with shorter procedural duration, avoidance of postauricular incision, and acceptable anatomical and audiological outcomes. ***Conclusions:*** Type I tympanoplasty demonstrated superior anatomical closure rates; however, office-based medical myringoplasty using topical epidermal growth factor with a silastic scaffold produced satisfactory healing and hearing improvement in carefully selected patients. Medical myringoplasty represents a practical alternative in bilateral disease, patients unsuitable for surgery, or those declining operative intervention.

Keywords: Chronic Otitis Media; Tympanic Membrane Perforation; Type I Tympanoplasty; Medical Myringoplasty; Epidermal Growth Factor; Silastic Scaffold; Hearing Outcome.

INTRODUCTION

Chronic otitis media (COM) is one of the most prevalent chronic ear diseases worldwide and continues to represent a major public health problem, particularly in low- and middle-income countries.[1,2] Persistent tympanic membrane perforation resulting from chronic middle ear inflammation predisposes patients to recurrent otorrhoea, conductive hearing loss, reduced quality of life, and, if left untreated, potentially serious extracranial and intracranial complications.[3,4,5] Despite advances in antimicrobial therapy and surgical techniques, restoration of an intact tympanic membrane remains the cornerstone of management for inactive mucosal COM.[4,5]

Type I tympanoplasty (myringoplasty) is widely accepted as the standard treatment for chronic tympanic membrane perforations and consistently achieves graft uptake rates exceeding 80–90% in experienced hands.[4,6,7] Besides providing anatomical closure, successful tympanoplasty restores middle-ear mechanics, improves conductive hearing loss, reduces recurrent infections, and permits unrestricted water exposure.[7,8] Nevertheless, the procedure requires an operating theatre, anaesthesia, graft harvesting, postoperative wound care, and healthcare resources that may not always be readily available.[9,10,11]

Patients presenting with bilateral inactive mucosal COM constitute a unique therapeutic challenge. Simultaneous bilateral tympanoplasty is generally avoided because of concerns regarding postoperative discomfort, temporary bilateral conductive hearing impairment, and the rare but serious possibility of bilateral complications. Consequently, treatment is frequently staged, prolonging the period during which one ear remains perforated and symptomatic.[5,6]

Recent advances in regenerative medicine have renewed interest in minimally invasive methods for tympanic membrane repair. Epidermal growth factor (EGF)4,5,[12,13] an endogenous peptide involved in epithelial proliferation, fibroblast activation, angiogenesis, and tissue regeneration,[14-18] has demonstrated promising effects on tympanic membrane healing in experimental and clinical studies. When combined with a biocompatible silastic scaffold[14,19] that provides temporary mechanical support, topical EGF may facilitate closure of chronic perforations without the need for formal surgery.

Office-based medical myringoplasty offers several potential advantages, including avoidance of general anaesthesia, reduced procedural morbidity, shorter treatment time, lower cost, and greater patient acceptance.[14,17] Such an approach may be particularly valuable in elderly individuals, patients with significant medical comorbidities, individuals unwilling to undergo surgery, and patients requiring bilateral treatment.

Although several investigators have evaluated biological agents or scaffold-assisted tympanic membrane regeneration independently, direct comparisons with conventional surgical myringoplasty remain limited. Furthermore, inter-patient variability in age, Eustachian tube function, perforation characteristics, and healing potential often confounds comparative analyses.[14-18,20-23]

he present study minimizes these confounding factors by adopting a unique within-patient paired-ear design, in which each participant underwent conventional Type I tympanoplasty in one ear and office-based medical myringoplasty using topical epidermal growth factor with a silastic scaffold in the contralateral ear. This design permits direct comparison of two treatment modalities under nearly identical biological conditions while reducing inter-individual variability.

The objective of this study was to compare anatomical closure rates, hearing outcomes, and postoperative complications between surgical and office-based medical myringoplasty in patients with bilateral inactive mucosal chronic otitis media and to evaluate the feasibility of medical myringoplasty as a clinically useful alternative in selected patients.

MATERIALS AND METHODS

Study Design and Setting

This prospective, non-randomized, within-patient comparative study was conducted in the Department of Otorhinolaryngology at Karnataka Institute of Medical Sciences (KIMS), Hubballi, Karnataka, India, over a period of one year following approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrolment.

The study was designed to compare the anatomical and functional outcomes of conventional Type I tympanoplasty with office-based medical myringoplasty using topical epidermal growth factor (EGF) and a silastic scaffold. To minimize inter-individual variability, each patient served as their own control, with one ear allocated to surgical treatment and the contralateral ear receiving medical myringoplasty.

Study Population

Patients presenting to the otorhinolaryngology outpatient department with bilateral inactive mucosal chronic otitis media were screened for eligibility. A total of 62 consecutive patients (124 ears) fulfilling the inclusion criteria were recruited using consecutive sampling.

Inclusion and Exclusion Criteria

Patients were eligible for inclusion in the study if they were aged 12 years or older, had bilateral inactive mucosal chronic otitis media with central perforations involving the pars tensa in both ears, and had remained free of ear discharge for an

adequate preoperative period. All participants were required to provide written informed consent before enrolment in the study.

Patients were excluded if they had marginal or attic perforations, active ear discharge at the time of presentation, external auditory canal stenosis, tympanosclerosis involving the perforation margins, cholesteatoma or squamosal disease, or complicated chronic otitis media. Patients with a history of previous middle ear surgery, those who were positive for human immunodeficiency virus infection or hepatitis B surface antigen, and those who were unable or unwilling to comply with the scheduled postoperative follow-up were also excluded from the study.

Study Groups

Each participant underwent both treatment modalities:

Group A (Surgical Ear)

The selected ear underwent conventional Type I tympanoplasty using temporalis fascia through a postauricular underlay technique.

Group B (Medical Ear)

The contralateral ear underwent office-based medical myringoplasty using freshening of perforation margins followed by topical application of epidermal growth factor over a silastic scaffold.

The allocation of ears was predetermined according to the study protocol, ensuring that each participant contributed one ear to each intervention arm.

Preoperative Evaluation

All patients underwent a standardized preoperative assessment, including: Detailed clinical history, Otomicroscopic examination, Diagnostic nasal endoscopy, Pure-tone audiometry (PTA) and Routine pre-anaesthetic investigations where indicated. Perforation size and location were documented during microscopic examination. Pure-tone audiometry was performed in a sound-treated room using a calibrated audiometer. Air- and bone-conduction thresholds were recorded at 0.5, 1, 2, and 4 kHz, and the pure-tone average (PTA) was calculated according to standard audiological protocols2.

Surgical Technique

Type I tympanoplasty was performed under general anaesthesia using a postauricular approach. After infiltration with 2% lignocaine containing 1:100,000 adrenaline, temporalis fascia was harvested and allowed to dry. The perforation margins were freshened, and a tympanomeatal flap was elevated carefully. Following inspection of the middle ear cavity and confirmation of ossicular continuity, the temporalis fascia graft was placed using the underlay technique medial to the tympanic membrane remnant and handle of malleus. The tympanomeatal flap was repositioned, absorbable gelatin sponge was placed for graft support, and the wound was closed in layers. Patients received routine postoperative care according to departmental protocol16,20.

Medical Myringoplasty Technique

Medical myringoplasty was performed under microscopic visualization. The margins of the tympanic membrane perforation were chemically and mechanically refreshed to remove epithelialized tissue. A sterile silastic sheet appropriately trimmed to the size of the perforation was positioned to provide structural support. Topical epidermal growth factor was then applied over the prepared perforation and scaffold. Patients underwent repeated applications according to the study protocol until satisfactory epithelialization or complete closure was achieved. All procedures were performed in the outpatient setting without the need for general anaesthesia.

Outcome Measures

Primary Outcome

The primary outcome was complete anatomical closure of the tympanic membrane at three months following intervention. Successful closure was defined as complete epithelialization without residual perforation on otomicroscopic examination.

Secondary Outcomes

The secondary outcome measures included improvement in hearing thresholds, graft closure rates according to the size of the tympanic membrane perforation, postoperative improvement in the air–bone gap, procedure-related complications, the occurrence of postoperative ear discharge, and the need for any additional surgical or medical intervention.

Follow-up

All patients were followed up at regular postoperative intervals according to the departmental protocol. During each follow-up visit, a comprehensive clinical evaluation was performed, including otomicroscopic examination to assess graft integrity or residual perforation status, evidence of infection or persistent ear discharge, and the presence of any postoperative

complications. Pure-tone audiometry was repeated at one month and three months after the intervention using the same standardized audiological protocol that had been employed during the preoperative assessment, enabling comparison of hearing outcomes over time.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation or median (interquartile range), depending on data distribution. Categorical variables were summarized as frequencies and percentages. Normality of continuous variables was assessed using the Shapiro–Wilk test. Comparisons between treatment groups were performed using the Chi-square test or Fisher's exact test for categorical variables and paired Student's t-test or Wilcoxon signed-rank test for continuous variables, as appropriate. Because each participant contributed paired observations, paired analyses were performed wherever applicable. A two-sided p-value <0.05 was considered statistically significant. Effect estimates were reported with corresponding 95% confidence intervals wherever appropriate.

Ethical Considerations

The study was approved by the Institutional Ethics Committee of Karnataka Institute of Medical Sciences, Hubballi, prior to commencement. All procedures conformed to the ethical principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants before enrolment, and confidentiality of patient information was maintained throughout the study.

RESULTS

Study Population

A total of 62 patients with bilateral inactive mucosal chronic otitis media were enrolled during the study period. Each participant contributed one ear to each intervention arm, resulting in 62 ears undergoing Type I tympanoplasty (Group A) and 62 ears undergoing office-based medical myringoplasty using epidermal growth factor (EGF) with a silastic scaffold (Group B). All participants completed the scheduled follow-up assessments at one and three months.

Baseline Characteristics

The demographic characteristics of the study population were comparable between treatment groups because each patient served as their own control. Patients ranged from 12 to 65 years of age. The distribution of perforation size differed between the treatment ears, with larger perforations more frequently represented in the surgical group, whereas medium-sized perforations predominated in the medical myringoplasty group.

Table 1. Baseline characteristics of study ears

Variable	Surgical Myringoplasty (n=62)	Medical Myringoplasty (n=62)
Number of ears	62	62
Study design	Type I Tympanoplasty	EGF + Silastic scaffold
Follow-up	3 months	3 months
Primary outcome	Tympanic membrane closure	Tympanic membrane closure
Secondary outcome	Hearing improvement	Hearing improvement

Tympanic Membrane Healing

At the first postoperative visit, complete closure of the tympanic membrane was observed in 46.8% of surgically treated ears compared with 25.8% of medically treated ears. Failure of closure was significantly less common following surgical myringoplasty (17.7%) than after medical myringoplasty (43.5%) (p = 0.004). By the end of the three-month follow-up, further healing had occurred in both groups. Complete closure was achieved in: 42 of 62 ears (67.7%) after Type I tympanoplasty and 28 of 62 ears (45.2%) after medical myringoplasty. When partially healed perforations were also considered successful, the overall success rate increased to: 88.6% in the surgical group and 72.6% in the medical group. This difference was statistically significant (p = 0.02).

Table 2. Tympanic membrane status at 3 months

Outcome	Surgical (n=62)	Medical (n=62)	p value
Complete closure	42 (67.7%)	28 (45.2%)	
Partial closure	13 (20.9%)	17 (27.4%)	
Persistent perforation	7 (11.3%)	17 (27.4%)	**0.02**

Hearing Outcomes

Both treatment modalities resulted in clinically meaningful improvement in hearing thresholds during follow-up. The surgical group demonstrated improvement in mean pure-tone average from 45.03 ± 15.9 dB preoperatively to 35.7 ± 19.1 dB at three months. The medical myringoplasty group improved from 37.15 ± 14.6 dB preoperatively to 32.6 ± 14.2 dB at three months. Although baseline hearing thresholds differed significantly between groups (p = 0.005), postoperative hearing levels at one month (p = 0.40) and three months (p = 0.304) were comparable, suggesting that both procedures provided similar audiological benefit in successfully healed ears.

Table 3. Comparison of hearing thresholds

Time point	Surgical (Mean ± SD)	Medical (Mean ± SD)	p value
Preoperative	45.03 ± 15.9	37.15 ± 14.6	0.005
1 month	37.6 ± 18.3	35.13 ± 14.5	0.40
3 months	35.7 ± 19.1	32.6 ± 14.2	0.304

Effect of Perforation Size

Healing outcomes varied according to perforation size in the surgical group, with medium-sized perforations demonstrating the highest likelihood of successful closure. In contrast, no statistically significant association between perforation size and healing was observed in the medical myringoplasty group, suggesting that the regenerative approach may be less dependent on the initial perforation size within the range evaluated in this study.

Complications

No major intraoperative or postoperative complications requiring revision surgery occurred during the study period. Minor postoperative complications included transient otorrhoea, otomycosis, and delayed healing in a small number of patients. These events were managed conservatively and resolved with appropriate medical treatment. No serious adverse reactions attributable to topical epidermal growth factor or the silastic scaffold were observed.

Key Findings

The present study demonstrated that surgical myringoplasty achieved a significantly higher anatomical success rate than office-based medical myringoplasty, with successful closure of the tympanic membrane perforation in 88.6% and 72.6% of ears, respectively. Both treatment modalities resulted in statistically significant improvements in hearing thresholds following intervention. Although baseline hearing levels differed between the two groups, the final postoperative hearing outcomes were comparable, indicating that both techniques were effective in improving auditory function. Furthermore, office-based medical myringoplasty using epidermal growth factor (EGF) and a silastic scaffold produced satisfactory anatomical and functional outcomes without the need for general anaesthesia. These findings suggest that medical myringoplasty may serve as a safe and effective alternative in carefully selected patients, particularly in situations where bilateral surgery is undesirable, contraindicated, or when a minimally invasive office-based procedure is preferred.

DISCUSSION

The present prospective within-patient comparative study evaluated the anatomical and functional outcomes of conventional Type I tympanoplasty and office-based medical myringoplasty using topical epidermal growth factor (EGF) with a silastic scaffold in patients with bilateral inactive mucosal chronic otitis media (COM). By treating opposite ears of the same patient with different interventions, the study minimized inter-individual variation in age, genetic predisposition, Eustachian tube function, environmental factors, and healing potential. This paired-ear design represents a major methodological strength, allowing a more direct comparison of the two treatment modalities than conventional parallel-group studies.

The principal finding of this study was that Type I tympanoplasty achieved a significantly higher anatomical closure rate than medical myringoplasty. At the end of three months, the overall healing rate was 88.6% in the surgical group compared with 72.6% in the medical myringoplasty group. Although surgical repair demonstrated superior anatomical success, office-based medical myringoplasty achieved satisfactory closure in nearly three-quarters of treated ears without requiring general anaesthesia or graft harvesting, indicating that it may be an effective alternative in selected patients.[14,19]

The graft uptake observed after Type I tympanoplasty in the present study is consistent with previously published literature, where closure rates generally range from 80% to 95% using the temporalis fascia underlay technique. Variability among published studies reflects differences in patient selection, perforation characteristics, surgical expertise, duration of follow-up, and methods used to define successful healing. Nevertheless, the success rate achieved in the present study lies within the upper range reported in contemporary otologic practice, supporting the continued role of Type I tympanoplasty as the reference standard for chronic tympanic membrane perforation repair.[7,8,24,25]

The favourable outcomes observed with medical myringoplasty support the growing interest in biological approaches for tympanic membrane regeneration. Epidermal growth factor is known to stimulate epithelial migration, fibroblast proliferation, collagen synthesis, angiogenesis, and extracellular matrix remodelling, all of which contribute to tympanic membrane healing.[12,13,14,16] The silastic scaffold used in this study probably served as a temporary structural framework that maintained contact between regenerating tissue and the perforation margins while allowing sustained epithelial migration across the defect. The combination of these biological and mechanical mechanisms may explain the satisfactory healing observed in the majority of patients managed without formal surgery.[14,19]

Although medical myringoplasty achieved lower closure rates than surgery, its clinical advantages should not be underestimated. The procedure was performed in the outpatient clinic without general anaesthesia, required no postauricular incision, avoided donor-site morbidity associated with fascia harvesting, and substantially reduced operative time and healthcare resource utilization. Such characteristics make the technique particularly attractive in elderly individuals, medically unfit patients, those unwilling to undergo surgery, patients awaiting staged bilateral tympanoplasty, and healthcare settings with limited operating theatre availability.[14,22]

An important finding of the present study was that both interventions resulted in meaningful improvement in hearing thresholds. While patients undergoing Type I tympanoplasty demonstrated greater anatomical success, postoperative hearing outcomes were comparable between groups at three months. This observation suggests that complete surgical closure is not the sole determinant of functional hearing improvement. Even partial reduction in perforation size following regenerative therapy may improve middle-ear sound transmission sufficiently to produce clinically relevant audiological benefit. These findings are consistent with previous reports demonstrating that restoration of tympanic membrane integrity, irrespective of the treatment modality, is associated with reduction of the conductive hearing component.[8,10,11]

The influence of perforation size on treatment outcome remains controversial. In the present study, larger perforations demonstrated lower closure rates following surgery, consistent with previous reports suggesting that increasing perforation size is associated with reduced graft uptake because of diminished vascular support and larger areas requiring epithelial regeneration. Interestingly, perforation size showed less influence on healing following medical myringoplasty, although the study may not have been adequately powered to detect subgroup differences. Future studies with larger sample sizes should investigate whether biological regenerative techniques perform differently according to perforation morphology and size.[7,25]

The paired-ear study design deserves particular emphasis because it reduces many important confounding variables that commonly affect comparative surgical studies. Previous investigations comparing surgical and non-surgical interventions have generally evaluated different patient populations, making interpretation difficult because healing is influenced by age, smoking status, nutritional factors, Eustachian tube function, middle-ear mucosal health, and host biological variability. By comparing opposite ears of the same individual, the present study effectively controlled for many of these factors, thereby increasing the internal validity of the findings.

Despite these strengths, several limitations should be acknowledged. First, the study was conducted at a single tertiary referral centre, which may limit the generalizability of the findings. Second, the sample size, although adequate for the primary objective, may have been insufficient for detailed subgroup analyses based on perforation characteristics or demographic variables. Third, follow-up was limited to three months; therefore, long-term durability of regenerated tympanic membranes could not be assessed. Fourth, patient-reported outcome measures, quality-of-life assessments, postoperative pain scores, and cost-effectiveness analyses were not formally evaluated. Finally, allocation of treatment was not randomized, although the within-patient design substantially reduced selection bias.

The findings of the present study have important clinical implications. While Type I tympanoplasty should remain the preferred treatment for patients suitable for surgery because of its superior anatomical success, office-based medical myringoplasty using epidermal growth factor with a silastic scaffold appears to be a promising minimally invasive alternative in carefully selected patients. The technique may be particularly useful in bilateral disease, patients with significant medical comorbidities, individuals declining surgery, and healthcare environments where operating room resources are limited. As regenerative medicine continues to evolve, biological tympanic membrane repair may become an increasingly important component of otologic practice.[14,15,17,18]

Future multicentre randomized controlled trials involving larger patient populations, longer follow-up, standardized hearing outcome measures, and formal cost-effectiveness analyses are required to define the precise role of epidermal growth factor-assisted tympanic membrane regeneration within contemporary management algorithms for chronic otiti s media.

Strengths and Limitations

The present study has several important strengths. Its prospective design minimized recall bias and allowed systematic data collection throughout the study period. A unique paired-ear (within-patient) comparison was employed, enabling each participant to serve as their own control, thereby reducing inter-patient variability and potential confounding factors. The study simultaneously evaluated both anatomical and functional outcomes, providing a comprehensive assessment of treatment efficacy. Furthermore, it directly compared the conventional surgical approach with a minimally invasive regenerative technique, generating clinically relevant evidence that is readily applicable to routine otologic practice. Despite these strengths, the study has certain limitations. It was conducted at a single tertiary care centre with a moderate sample size, which may limit the generalizability of the findings. The non-randomized allocation of treatment introduced the possibility of selection bias. In addition, the follow-up period was limited to three months, precluding assessment of long-term graft durability and hearing outcomes. Finally, the study did not include formal evaluation of patient-reported quality of life or cost-effectiveness, both of which are important considerations when comparing conventional surgical and office-based treatment modalities.

CONCLUSION

The present prospective within-patient comparative study demonstrated that Type I tympanoplasty remains the superior treatment for achieving complete anatomical closure of chronic tympanic membrane perforations, with significantly higher graft uptake than office-based medical myringoplasty using topical epidermal growth factor (EGF) and a silastic scaffold. Nevertheless, both treatment modalities resulted in clinically meaningful hearing improvement, and medical myringoplasty achieved satisfactory perforation closure in a substantial proportion of patients.

The paired-ear study design, in which each participant served as their own control, minimized inter-individual confounding and strengthens the validity of these findings. Office-based medical myringoplasty offers several practical advantages, including avoidance of general anaesthesia, elimination of donor-site morbidity, reduced procedural complexity, and lower healthcare resource utilization. These characteristics make it a valuable option for carefully selected patients, particularly those with bilateral disease requiring staged intervention, patients medically unfit for surgery, or individuals unwilling to undergo operative treatment.

Further multicentre randomized controlled trials with larger sample sizes, longer follow-up, cost-effectiveness analyses, and patient-reported outcome measures are required before EGF-assisted regenerative therapy can be recommended as a routine alternative to conventional tympanoplasty.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Ethical Approval

The study was approved by the Institutional Ethics Committee of Karnataka Institute of Medical Sciences, Hubballi. All procedures performed in this study involving human participants were conducted in accordance with the ethical standards of the institutional ethics committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed Consent

Written informed consent was obtained from all individual participants included in the study.

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