Original Article

J Adv Med Biomed Res. 2024; 32(150): 1-8

Comparing Success Rate of Two Surgical Approaches of Tympanoplasty in Patients with Chronic Otitis Media

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Article Info

10.22034/jambr.32.150.1

Received: 2023/07/17
Accepted: 2023/12/06
Published Online: 17 May 2024

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How to Cite This Article:
Samarei R, Roushani A , Yousefnezhad A. Comparing Success Rate of Two Surgical Approaches of Tympanoplasty in Patients with Chronic Otitis Media, J Adv Med Biomed Res. 2024; 32(150): 1-8.

ABSTRACT

Background & Objective: Tympanoplasty is a widely performed surgical procedure for chronic otitis media (COM), and efforts are being made globally to establish standardized surgical techniques. This study sought to compare the postoperative outcomes of endoscopic and microscopic approaches in COM patients.

Materials & Methods: This randomized clinical trial of an open-label design was performed on 34 patients who were candidates for tympanoplasty surgery due to chronic otitis media in Urmia Imam Khomeini hospital from April to December 2022. Patient allocation was performed by grouping participants according to odd or even numbers, with half assigned to the endoscopic group and the remaining half assigned to the microscopic group. Demographic data, pain severity, operation duration, and graft success rate preoperatively and 3 and 6 months postoperatively were evaluated. Independent samples t-test, Chi-square test, and SPSS version 21were used to analyze data. A P-value <0.05 was considered statistically significant.

Results: No significant difference was reported in terms of pre and postoperative pure tone audiometry conditions between the two groups. Significantly lower operation time (65.83 ± 11.6 minutes) was reported in the endoscopic group compared to the microscopic group (P=0.001). The graft success rate in the microscopic and endoscopic groups was 77.8% and 75%, respectively, which was not statistically significantly different (P = 0.84). A significant difference was observed between microscopic and endoscopic groups in the pain score of patients immediately after surgery (5.66 ±18.1 and 3.75 ± 1, retrospectively) and one day after surgery (5.50 ± 1.9 and 3.62 ± 0.95, respectively) (P < 0.001).

Conclusion: Endoscopic tympanoplasty technique has demonstrated comparable efficacy in improving hearing loss as the conventional method. However, its advantages in terms of reduced operating time and postoperative pain suggest that it may emerge as the preferred approach for tympanoplasty surgery.

Keywords: Tympanoplasty, Otitis media, Endoscopy, Microscopy

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1. Introduction

Chronic Otitis media (COM) is a medical condition that affects the middle ear and characterized by the potential for tympanic membrane perforation (1). Despite the decrease in the incidence of COM due to the widespread use of antibiotics, surgical intervention remains a crucial treatment strategy for COM, particularly in patients presenting with cholesteatoma (2). Tympanoplasty or myringoplasty is a highly effective surgical technique used to repair the tympanic membrane, restore hearing loss, and establish proper ventilation of the cavity in cases of chronic otitis media (3). Therefore, there is a need to focus on techniques that can improve tympanic membrane repair, leading to overall improvement in surgical outcomes and prevention of disease recurrence (4). A diverse array of alternative surgical approaches, grafting techniques, and graft materials, including fat, vein, cartilage, fascia, and skin, have been explored and utilized in the context of tympanoplasty surgery (5). Endoscopic and microscopic approaches are two widely adopted methods used to visualize the internal components of the ear during these procedures (6).

In the 1950s, The advent of the surgical microscopeled to a significant improvement in visualizing the middle ear structures and tympanic membrane (7). Microscopic tympanoplasty (MT) provides an excellent binocular view with stereoscopic vision, enabling the use of both hands during surgery. However, it is constrained by a linear field of view, which poses challenges for visualizing the middle ear through the ear canal (8). Thus, various approaches have been developed to address this limitation and

improve visualization and access to the middle ear cleft and attic areas when using a microscope (9). In contrast, the conventional approach results in surgical scars and causes significant pain for patients (10).

Endoscopic ear surgery (EES) has become increasingly popular over recent years due to its ability to overcome the limitations of the microscope's straight line of vision (11). Angled endoscopes facilitate direct visualization and access to previously obscured areas, including the anterior epitympanum, retrotympanum, and hypotympanum, which cannot be completely visualized using conventional microscopic approaches without bone curettage (12). Moreover, the endoscopic approach provides several compelling advantages, including: expansive visualization, high-resolution imaging, effortless zoom and exposure adjustments (13).

Despite the high prevalence of Chronic Otitis media (COM) in developing countries, there is limited data comparing the success rates and hearing improvement between endoscopic and microscopic tympanoplasty. Therefore, this study aims to study the clinical benefits and success rates of these two surgical approaches in patients with COM.

2. Materials and Methods

This randomized clinical trial of an open-label design was done on patients who were candidates for tympanoplasty surgery due to chronic otitis media in Urmia Imam Khomeini Hospital, Urmia, Iran from April to December 2022. The study was approved by the Ethics Committee of Urmia University of Medical Sciences with the code: IR.UMSU.REC.1398.266. This research was conducted according to CONSORT reporting guidelines (14).

Sample size was calculated using STATA 17 software to test two independent samples with a significance level of 0.05, power of 0.65, and allocation ratio of 1:1. A two-sided test was used and the minimum sample size was 18 in each group.

Prior to enrolment in the research study, all patients were required to provide informed written consent during their follow-up visit. Participants were randomly allocated to two groups based on the surgical technique employed A blinded nurse randomly assigned patients into two groups (intervention and control group) using odd/even numbers, with equal allocation ratio. Intervention group was operated with microscopic method and control group underwent standard and common endoscopic method. The two groups were then compared to determine which surgical method was more effective. A single experienced otologist performed either microscopic or endoscopic tympanoplasty. The study evaluated various parameters including demographic characteristics, pain severity, operation duration, and graft success rate. The length of the surgical procedure was measeured in minutes using a chronometer. Participants eligible for this study were patients referred to Imam Khomeini Hospital in Urmia who required tympanoplasty surgery due to chronic otitis media.

Patients meeting the following inclusion criteria were enrolled in the study:

Mucoid type of chronic suppurative otitis media

Conductive hearing loss without sensorineural involvement Satisfactory general health status Absence of active infection in the nose, throat, or paranasal sinuses Undergoing primary tympanoplasty for the affected ear Exclusion criteria included individuals younger than14 years of age and older than 55 years, smokers, participants with contralateral ear disease, cholesteatoma, otosclerosis, tympanosclerotic plaque or granulation tissue in the middle ear, those undergoing simultaneous mastoid surgery, revision cases and associated poor general condition, and those with preoperative medical issues such as asthma, diabetes, cardiovascular disease, and chronic liver or renal diseases. Additionally, subjects requiring endoscopic assistance during microscopic surgery were also excluded. Graft success rate was defined as a dry ear with an intact tympanic membrane (TM) in a well-aerated mesotympanum and the absence of retraction in the TM. Follow-up assessments were conducted between 3-6 months postoperatively.

A thorough otoscopic examination was conducted, encompassing various parameters to meticulously assess the tympanic membrane and middle ear structures. The size of the perforation, expressed as a percentage of the overall tympanic membrane area, was meticulously documented. The perforation's location was precisely categorized based on quadrants: antero-inferior, antero-superior, postero-inferior, and postero-superior. Additionally, the presence or absence of tympanosclerosis, a pathological alteration of the tympanic membrane characterized by increased density and stiffness, was noted. The visibility of all perforation borders was carefully evaluated to ensure a complete assessment of the perforation's extent. Furthermore, the presence or absence of inflammatory mucosa within the middle ear cavity was meticulously documented to gauge the overall health of the middle ear structures.

2.1 Pure tone audiometry

An audiologist conducted pure tone audiometry in a soundproof room to gauge the auditory sensitivity of each ear across various frequencies using an audiometer. The results of the assessment were documented on an audiogram or ear print, which separately depicted the findings for each ear. The auditory threshold reflects the minimum level of sound intensity that a person can hear at distinct frequencies. The two key components of pure tone audiometry are air conduction (AC) audiometry and bone conduction (BC) audiometry, respectively.

During AC testing, the subject is seated within an acoustic enclosure and provided with specialized headphones that cover both ears. The audiologist then administers "beep" like sounds via the

headphones at varying frequencies of 250, 500, 1000, 2000, 4000, and 8000 Hz, and at different intensities. The individual signals to the audiologist by raising their hand or pressing a button each time they perceive a sound. The audiologist generates the sounds using an audiometer and notes the minimum intensity level at which the person can detect the sound as their auditory threshold for that specific frequency.

In BC testing, a vibrating device is positioned on the mastoid bone located behind the ear, eliciting mechanical vibrations in response to pure tones presented at frequencies of 250, 500, 1000, 2000, and 4000 Hz. These vibrations are then conveyed to the inner ear via the skull. In this current investigation, both air and bone conduction tests, along with their discrepancy (BAG), were conducted preoperatively, as well as three and six months post-surgery for each participant.

2.2 Surgical procedure:

In this study, all patients underwent Tympanoplasty procedure conducted by a specialized medical practitioner. The group utilizing microscopy utilized the Opmi Vario S88 microscope from Carl Zeiss in Oberkochen, Germany for their investigation. In the microscopic approach, an incision was executed behind the ear with subsequent entry into the canal. The Lempert method served as the basis for the lifting of the tympanomeatal flap. When visualization of the perforation margin was inadequate due to anatomical constraints such as a narrow external ear canal, an anteriorly projecting bony overhang, or a large tympanic membrane perforation, a postauricular incision was employed to enhance surgical access and facilitate optimal visualization. The endoscopic group employed an endoscopic system manufactured by Karl Storz in Tuttlingen, Germany. Rigid endoscopes with either 0- or 30-degree angles and diameters of 3.0- or 4.0-mm, and lengths of 11 or 16 cm (also from Karl Storz) were used for the procedure.

In this approach, incisions were made in the posterior aspect of the external auditory canal (EAC), approximately 5 to 6 millimeters lateral to the tympanic annulus, perpendicular to the tympanic membrane (TM) at both the superior and inferior ends of the initial incision. By elevating a tympanomeatal flap, the middle ear cavity was visualized, and any pathological processes present were excised. Gelfoam was utilized to pack the middle ear, and an autologous graft was placed medial to the TM remnant and the manubrium of the malleus.

Typically, the graft was harvested from tragal perichondrium, but in rare cases temporalis fascia was used. Subsequently, the tympanomeatal flap was carefully reposed, and the medial aspect of the external auditory canal was meticulously packed with Gelfoam pledgets to maintain hemostasis and promote healing.

2.3 Pain assessment:

The severity of pain immediately after surgery and one day after surgery was evaluated and recorded by the patient using an 11-point numerical rating scale (NRS-11, range 0 to 10).

2.4 Surgical success assessment:

Surgical success was evaluated by endoscopic assessment at three months and six months post-operation. A dry and clean external auditory canal without any signs of tympanic membrane damage was considered a successful outcome.

2.5 Statistical Analysis

The quantitative variables were analyzed as mean (standard deviation), while the qualitative variables were expressed as frequency (percentage). Independent samples t-test was used to compare the quantitative data (mean), and the Chi-square test was used to compare the frequency between the two groups. Statistical analyses were performed using SPSS version 21. A P-value less than 0.05 was considered statistically significant. To determine the extent of ABG closure, the difference between the preoperative and postoperative ABG values for each patient was calculated individually. This variable was obtained by subtracting the postoperative ABG value from the preoperative one.

3. Results

In this clinical study, 34 patients with COM were enrolled that 18 candidates were in the microscopic tympanoplasty group (9 males, 9 females), and 16 were placed in the endoscopic group (8 males, 8 females).

The mean age of microscopic and endoscopic patients was 42.72 ± 10.86 and 39.62 ± 10.94 years (ranges between 14 to 55), respectively. No significant differences were observed between gender (P=1), mean age of patients, in the tympanoplasty used techniques (P=0.41).

Table 1. Demographic characteristics of studies patients

Variables	MT (n=18)	ET (n=16)	P-value
Gender			
Male	9 (50%)	8 (50%)	1
Female	9 (50%)	8 (50%)	
Age (year)	Mean± Sn	Mean± Sn	0.41
	42.72 ± 10.86	39.62 ± 10.94	

Table 2. Comparing measured clinical features between two groups in three-time sequence

Variables	MT (mean ±SD)	ET (mean ±SD)	P-value
Air conduction audiometry (dB)			
Preoperative	31.77 ± 6.33	29.87 ± 6.98	0.41
Postoperative 3 months	26.02 ± 7.33	26.02 ± 7.29	0.999
Postoperative 6 months	26.50 ± 7.82	25.94 ± 7.07	0.427
Bone conduction audiometry(dB)			
Preoperative	28.0±15.8	23.9±16.9	0.174
Postoperative 3 months	18.11 ± 11.04	17.56 ± 8.10	0.64
Postoperative 6 months	15.05± 10 .49	14.18 ±7.59	0.38
Air–bone gap audiometry(dB)			
Preoperative	18.6±7.1	18.9±7.8	0.995
Postoperative 3 months	7.94 ± 4.26	7.75 ± 4.11	0.681
Postoperative 6 months	8.34 ± 4.84	7.72 ± 4.00	0.201
Operation time (minutes)	65.83 ± 11.6	45.50 ± 5.59	0.001
Graft success rate	14(77.8%)	12(75%)	0.84
Pain score			
Immediately after surgery	5.66 ±18.1	3.75 ± 1	P < 0.001
One day after Surger	5.50 ± 1.9	3.62 ± 0.95	P < 0.001

Table 2 reports pre- and post-operative hearing conditions of two groups. Preoperatively, the AC levels of the operation ear were 31.77 ± 6.33 dB in the microscopic group and 29.87 ± 6.98 dB in the endoscopic group. There were no significant differences between the two groups (P=0.41). The BCs were 28.0±15.8 dB and 23.9±16.9 dB, respectively (p = 0.174). The ABGs were 18.6±7.1 dB and 18.9±7.8 dB, respectively. There were no statistically significant differences between the two groups (P = 0.995).

Postoperatively, the improvements in the AC levels between the two groups at 3 months (26.02 ± 7.33 dB and 26.02 ± 7.29 dB, P = 0.999), and 6 months (26.50 ± 7.82 dB and 25.94 ± 7.07 dB; P = 0.427) were not signiicantly diferent. The were no changes in the BC levels between microscopic and the endoscopic groups at 3 months (18.11 ± 11.04 dB and 17.56 ± 8.10 dB, P = 0.64), and 6 months (15.05± 10 .49 dB and 14.18 ±7.59 dB; P = 0.38) which were not statistically significant. The improvements in the postoperative ABGs between the 2 groups were not significantly different at 3 month (7.94 ± 4.26 dB and 7.75 ± 4.11 dB; P = 0.681), 6 months (8.34 ± 4.84 dB and 7.72 ± 4.00 dB, P = 0.201).

The mean operation time in the microscopic group (65.83 ± 11.6 minutes) was significantly longer than endoscopic group (45.50 ± 5.59 minutes), that shows significant difference between two groups (P=0.001). Graft success rate in the microscopic and endoscopic groups was 77.8% and 75%, respectively, which was not statistically significantly different (P = 0.84).

The mean pain score of patients immediately after surgery was 5.66 ±18.1 in the microscopic group and 3.75 ± 1 in the endoscopic group that shows a significant difference between the groups (P < 0.001). One day after surgery, the mean pain score of MT and ET groups was 5.50 ± 1.9 and 3.62 ± 0.95, respectively. According to the t-test, there was a significant difference between the mean pain score one day after surgery between the two tympanoplasty groups (P < 0.001) (Table 2).

4. Discussion

The objectives of tympanoplasty encompass the rehabilitation of a functional and disease-free tympanic cavity, the successful closure of any existing perforations, and the attainment of optimal hearing restoration (15). Although microscopic techniques have traditionally been considered the gold standard for performing this procedure, the use of endoscopic methods has gained popularity in recent years, following the publication of the first article on this approach by El-Guindy in 1992 (16).

The success rates of both microscopic and endoscopic tympanoplasty techniques vary between 75% and 98% (17). Despite the theoretical advantages of the underlay technique, our study did not reveal a statistically significant difference in the success rate of tympanic

membrane healing between the two techniques. In a similar vein, Choi et al. (10) also reported comparable graft success rates between endoscopic and microscopic tympanoplasties (100% and 95.8%, respectively), with no statistically significant difference (p = 0.304). Similarly, Dundar et al. (18) found no statistically significant disparities in graft status 12 months postoperatively between pediatric patients who underwent type 1 tympanoplasty via either the endoscopic or microscopic technique, with graft success rates of 87.5% and 94.3%, respectively. (p > 0.05). These findings suggest that both microscopic and endoscopic tympanoplasty techniques can be equally effective in achieving successful tympanic membrane healing.

In contrast to the present study findings, Jaiswani et al. (19) reported in a literature review that age may influence the success rates of tympanoplasty surgery. However, while their study suggested that age might impact the outcome of the procedure, several other studies have provided evidence to the contrary, indicating that age is not a significant factor affecting tympanoplasty success rates (20, 21, 22). In older patients, preoperative evaluation is an essential step that involves assessing their nutritional profile, cardiovascular health, metabolic health, and psychological well-being, as well as conducting a more thorough anesthetic evaluation (23). For children, the same restrictions apply as for adults, with particular attention paid to psychological assessments and adherence to rest and ear protection guidelines, parental consent, and adequate development of the mastoid bone, Eustachian tube, and immune system (24). The present study included individuals aged 14 to 55 years, with no representation from either the geriatric or pediatric populations, making it impossible to establish age as a significant factor for surgery success.

Hearing restoration following surgery is a crucial criterion for evaluating the success of tympanoplasties. The present study found that both groups had similar improvements in hearing and air-bone gap (ABG), with no significant differences observed in preoperative ABGs. Similarly, Dundar et al. (18) reported no statistically significant difference in preoperative and postoperative ABGs, regardless of the surgical procedure performed. However, in contrast to these findings, Ulku et al. (25) reported in their study that the mean postoperative ABG exhibited significantly greater improvement in the endoscopic group compared to the microscopic group.Furthermore, our findings indicate that the mean operation time in the microscopic group was significantly longer than that in the endoscopic group. The use of an endoscope reduced the operative time and resulted in less exposure to general anesthesia (10). Consistent with our results, a prior investigation demonstrated that endoscopic tympanoplasty was associated with a substantially shorter operative duration compared to microscopic tympanoplasty. (26). Huang et al. (27) found that the mean operative time for endoscopic tympanoplasty was 50.4 minutes compared to 75.5 minutes for the microscopic approach (P < 0.0001) in a sample of 50 patients. Hsu et al. (28) further corroborate the findings, demonstrating a significantly shorter mean surgical duration and operative time in the endoscopic group compared to the microscopic group; additionally, the incidence of postoperative complications, including pain, was substantially lower in the endoscopic group. Choi et al. (10) demonstrated that patients undergoing endoscopic tympanoplasty experienced substantially reduced pain levels on the first postoperative day compared to those undergoing the microscopic technique. In line with these findings, the present study's pain score was lower in the endoscopic group than in the microscopic group on the day of surgery and one day after surgery.

According to the findings of this study, the endoscopic approach is more effective than the conventional microscopic method for reducing postoperative pain severity, even when the same grafting method and materials are used in both groups. The lower incidence of postoperative pain and faster recovery times observed in the endoscopic group may be attributable to aminimally invasive surgical technique for tympanoplasty, performed through the ear canal without detaching the tympano-meatal flap. (, which transforms the external ear canal into an operative area (29. 30), associated with minimal soft-tissue disruption, preserving hair follicles, and leaving a barely noticeable scar at the graft harvest site. (31). These factors could potentially impact the need for hospitalization (32).

Prior research has also demonstrated the benefits of using endoscopes instead of microscopes for tympanoplasty and cholesteatoma surgery (33, 34); however, the underlying reasons for these advantages remain unclear.

The study has several significant limitations that must be taken into account. One of the primary limitations is the type of surgery performed, which was determined by the surgeon's individual preference and patient counseling, and as a result, could have introduced potential bias in the results. Additionally, the analysis utilized a relatively small sample size, which is another limiting factor. Furthermore, the study was conducted at a single hospital, thus constraining the generalizability of the findings. To mitigate these limitations, future research would benefit from employing a larger sample size, a longer follow-up period, or a multi-hospital study design.

5. Conclusion

In conclusion, this study found no considerable variance in the success rate of the operation or enhancement in hearing between endoscopic myringoplasty and microscopic surgery. However, it should be noted that the endoscopic technique resulted in a shorter surgery duration and decreased pain level compared to microscopic tympanoplasty. Therefore, an endoscopic approach may be more desirable when performing tympanoplasty.

6. Declaration

6.1 Acknowledgments

The authors would like to express their gratitude to the clinical research development unit of Imam Khomeini Hospital, Urmia University of Medical Sciences, for English editing.

6.2 Authors' Contribution

Conceptualization, R.S. and A.R.; methodology, A.R.; software, A.Y.; validation, R.S., A.R. and A.Y.; formal analysis, A.R.; investigation, R.S.; resources, R.S.; data curation, R.S.; writing—original draft preparation, A.Y.; writing—review and editing, R.S.; visualization, R.S.; supervision, R.S.; project administration, R.S.; funding acquisition, A.R.".

6.3 Conflict of Interest

The authors declare that they have no conflict of interest.

6.4 Funding

This project did not receive any specific grant from funding agencies in the public and commercial.

6.5 Ethics Approval

The study was approved by the Ethics Committee of Urmia University of Medical Sciences with the code: IR.UMSU.REC.1398.266. The IRCT registration reference is: IRCT20221002056073N2. .

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