

Original Research Article

A comparative study between endoscopic and microscopic type 1 tympanoplasty

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ABSTRACT

Background: The current study aims to compare type 1 microscopic tympanoplasty and endoscopic tympanoplasty and draws an evidence-based conclusion regarding the outcome.

Methods: This randomized controlled clinical study consists of 60 patients, in which 30 cases allocated as group 1 underwent endoscopic myringoplasty, and 30 cases allocated as group 2 underwent conventional myringoplasty. Tympanic membrane (TM), pure tone audiometry (PTA) evaluated preoperatively and at 3 months postoperative follow-up.

Results: Demographic distribution between the groups does not show a significant difference ($\chi^2=6.67$, $p=0.16$). There was no significant difference observed between TM perforation size between the groups ($\chi^2=2.32$, $p=0.51$). For the preoperative AB gap in group 1, the mean ABG was 28.20 ± 2.67 and in group 2 was 28.20 ± 0.80 . The postoperative AB gap in group 1, the mean ABG was 17.40 ± 3.01 , and in group 2, the mean ABG was 19.67 ± 2.93 . The mean difference is 9.13, and it shows a statistically significant difference ($p=0.001$). The mean duration of surgery in group 1 was 130.83 ± 34.84 and in group 2 was 168.33 ± 16.88 min ($p=0.001$). In both groups, 90% have intact graft, and in 10% of patients' residual perforation is present. The mean duration of hospitalization in group 1 is 4.10 ± 0.09 days and in group 2 is 4.97 ± 0.18 days.

Conclusions: By using the endoscopic addition, minimal invasive tympanoplasty can made possible the similar graft success rate with minimal pain. Endoscopic tympanoplasty uses very less operative time than microscopic surgery.

Keywords: Chronic suppurative otitis media, Tympanoplasty, Myringoplasty

INTRODUCTION

In India, chronic suppurative otitis media (CSOM) is a common otological condition. According to a WHO study, the CSOM global prevalence rate estimates between 1% to 46%; it estimates 65-330 million people.¹ In India, 90-700 per million population suffer from CSOM. In Andhra Pradesh, 3.4% population is suffering from CSOM.¹

Early detection and treatment of CSOM can prevent further complications. Myringoplasty and tympanoplasty are defined as surgical procedures used to repair TM and

middle ear. Myringoplasty is the repair of TM perforation when middle ear mucosa and ear ossicles are free of disease. Myringoplasty, known as type 1 tympanoplasty. Tympanoplasty repairs the TM and eradication of middle ear cleft and middle ear ossicles reconstruction. There can be no single best technique for tympanoplasty. Traditionally surgeons perform tympanoplasty with the help of a microscope. Recently endoscopy replaces the usage of the microscope.²

The surgical microscope usage brought revolutionary advances into otological surgery because its new technology expanded the ability of surgeons to see in

limited confines of the temporal bone. Various deep recesses of the temporal bone are not possible to view directly without the otorhinolaryngologist taking measures to expand surgical exposure. Various angulations views can be accompanied by inserting the prism at the end. The advantage of an endoscope is its direct, and quick access to the least accessible nook/corners of the middle ear cavity, hidden from the otorhinolaryngologist's view even with the use of microscope.³ Middle ear endoscopic technique helps in ossicular chain preservation in cholesteatoma surgeries.^{4,5}

The current study attempts to know the efficacy of endoscopic myringoplasty compared to conventional microscopic type1 tympanoplasty. The findings of such a comparison study may help in decision-making while choosing between these two techniques for any particular patient. It would help to tailor the method used and thus individualize the decision.

METHODS

A randomized controlled clinical study was undertaken at the government general hospital, during the period from Jan 2019 to June 2020. Informed consent was obtained before inclusion in the study. The current study granted ethical approval by the institutional ethics committee at RIMS government medical college, Kadapa, Andhra Pradesh, India.

Sampling technique

Random selection of subjects meeting the inclusion and exclusion criteria. Randomization done by the computer randomly assigns the patients into two groups.

Group 1: endoscopic tympanoplasty (n=30), and group 2: microscopic tympanoplasty, (n=30).

Tuning fork tests were carried out by 256 Hz, 512 Hz, and 1024 Hz forks to all the patients.

Inclusion criteria include small, medium, large, and subtotal perforation of the TM. Unilateral CSOM, age between 15 to 65 years, discharge free ear for at least two weeks before surgery.

Exclusion criteria were age <15 years and >65 years, bilateral ear pathology, active infection in ear, nose, and throat, Ossicular chain abnormality in preoperatively patient with attic antral type CSOM, history of previous surgery for CSOM, and cholesteatoma.

Data collection

Patients with central perforation of TM those attending ENT OPD were selected for endoscopic assisted myringoplasty and conventional myringoplasty using a random number method.

Preoperatively, PTA done by audiologist. All patients were followed for a period of 3 months. PTA and TM status was assessed at each visit.

Classification of perforation

Based on site, we have classified the perforation based on site in TM into anterior, posterior, superior, and inferior.

Based on the size, we have classified the perforation into small-occupying only one quadrant. Medium-occupying more than one quadrant/or/2 quadrants. Large-occupying more than 2 quadrants/or/3 quadrants. Subtotal-occupying more than 3 quadrants but sparing the annulus. Total-all quadrants, including annulus, is destroyed.

Instruments

The surgical instrument consists of 0 degrees, 30 degrees, and 45 degrees, 4 mm rigid nasal endoscopes. All the procedures were performed directly, seeing the monitor. Routine microscopic ear. Instruments (micro-scissors, alligator forceps, sickle knife, plasters knife, smooth and sharpcurved picks) were used.

Infiltration

The postauricular infiltration with 2% xylocaine with 1:100,000 adrenaline. The canal wall infiltration was done under endoscopic guidance using a 2 ml syringe with a 26-gauge lever lock needle with the terminal 1 cm angulated towards the bevel.

Approach

All the cases of microscope-assisted myringoplasty were done through post aural approach. All cases of endoscopic myringoplasty were done through a permeal approach.

Harvesting of graft

For the closure of the TM perforation, temporalis fascia autograft was used.

Inspection

The endoscope introduced into external auditory canal, any obstruction to the vision was noted. The TM with its perforation was visualized. The middle ear was examined through the perforation.

Freshening of perforation margins

Freshening of perforation margins was done using a wide curved pick.

Incision and flap elevation

A 11 O'clock to 1 o'clock incision taken at posterior canal

wall skin of 5 mm away from annulus and tympanomeatal flap was elevated.

Middle ear inspection

The middle ear findings were noted regarding the following state of the ossicles, i.e., malleus, incus and the stapes, state of the incudomalleal and the incudostapedial joints. The Eustachian tube opening, the oval and the round windows, the facial recess, and the sinus tympani were also visualized. The round window reflex visualized to confirm the continuity of ossicular chain.

Graft placement

In underlay technique, the graft was placed below the fibrous layer hugging the malleus's handle.

Repositioning the tympanomeatal flap

The flap was repositioned to its original position, and the margins were placed in approximation circumferentially.

Gelfoam pieces soaked in the ointment were placed over the skin flap to keep the skin in approximation to graft. After the procedures, only a small dressing was given to cover external auditory canal. All patient were prescribed on oral analgesics, and antibiotics for one week. The postauricular sutures were removed on the seventh postoperative day (Figure 1).

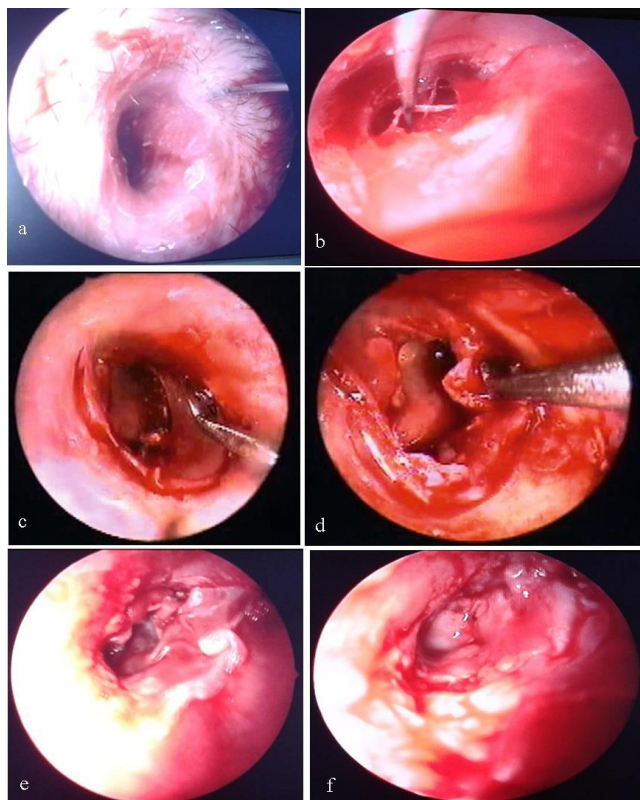


Figure 1 (A-F): Procedure.

Statistics

Continuous measures presented as Mean \pm SD, and categorical measures expressed as percentage. Student's two-tailed, independent t-test applied to identify significance between the two intergroups on metric parameters. Student's two-tailed, dependent t-test applied to find the significance on each group's continuous scale. Chi-square/Fisher exact test used to identify significance of a categorical scale between 2 or more groups. $P < 0.05$ set as significant. Analysis carried out by statistical softwares, SPSS 15.0, MedCalc 9.0.1, and Systat 12.0.

RESULTS

Demographics

A total number of 50 subjects were recruited in the study during Jan 2019 to June 2020. Twenty-five patients underwent conventional myringoplasty (group 2), while 25 patients underwent endoscopic myringoplasty (group 1). Considering the endoscopic tympanoplasty group, 16.67% of the patients are ≤ 20 years, 46.67% of the patients are between 21-30 years, 33.33% of the patients are between 31-40 years, none of the patients are between 41-50 years, and 3.33% are between 51-60 years. Considering the microscopic tympanoplasty group, 20% of the patients are ≤ 20 years, 46.67% of the patients are between 21-30 years, 13.33% of the patients are between 31-40 years, 10% of the patients are between 41-50 years, and 10% of the patients are between 51-60 years. There was no significant difference observed between the age distribution of the endoscopic tympanoplasty group and microscopic tympanoplasty group ($\chi^2=6.67$ $p=0.16$).

The endoscopic tympanoplasty group patient's mean age was 28.27 ± 7.81 years, and the microscopic tympanoplasty group was 29.53 ± 11.03 years. There was no significant difference observed between age distribution of both groups (student independent t test.) There was no significant difference observed between sex distribution of both groups ($\chi^2=2.0$, $p=1.00$). The microscopic tympanoplasty group, male patients' mean age was 29.27 ± 10.67 years, and female patients were 29.80 ± 11.76 years ($t=0.66$ $p=0.90$).

Comparison of TM perforation size

Considering the Endoscopic tympanoplasty group, 20% of the patients have a large size, 33.33% of the patients have a medium size, 40.00% of the patients have a small size, 6.67% of patients have subtotal size. Considering the microscopic tympanoplasty group, 33.33% of the patients have a large size, 33.33% of the patients have a medium size, 26.67% of the patients have a small size, 6.67% of the patients have subtotal size. There is no significant difference between TM perforation size of endoscopic and microscopic tympanoplasty groups ($\chi^2=2.32$ $p=0.51$).

Comparison of AB gap between ET and MT group

Considering the preoperative AB gap, in the ET group, the mean ABG was 28.20±2.67, and in the MT group, the mean ABG was 28.80±3.03. The mean difference was 0.81, and not statistically significant. So, in the pretest, there was no significant difference observed between both groups in ABG distribution (Table 1). Considering postoperative AB gap, in the ET group, the mean ABG was 17.40±3.01, and in the MT group, the mean ABG was 19.67±2.93. The mean difference is 2.27, and it has statistically significant. So, in the post test, there was significant difference observed between the groups on ABG distribution.

Comparison of AB gap between pre- and post-op

Considering the ET group, pre op means ABG was 28.20±2.67, and post op mean ABG was 17.40±3.01. The mean difference is 10.80, and it has statistically significant (t=17.90 p=0.001). Considering MT group, pre op mean ABG was 28.80±3.03, and post op mean ABG was 19.67±2.93. The mean difference is 9.13, and it has statistically significant difference (t=13.06, p=0.001). So, in the MT group, there is a significant reduction of ABG. Reduction of AB gap is more in MT group than ET group (student paired t test) (Table 1).

The duration of surgery

The mean duration of surgery of endoscopic tympanoplasty group patients was 130.83±34.84 minutes, and the microscopic tympanoplasty group was 168.33±16.88 minutes. ET groups have 37.50 minutes less duration of surgery than the MT group. There is a significant difference between the mean duration of surgery of the endoscopic tympanoplasty group and the Microscopic tympanoplasty group patients (Table 1). In ET group, males are having statistically significant less duration of surgery minutes than Females (Student independent t test) (Table 2).

In endoscopic and microscopic tympanoplasty groups, 90% of the patients are intact, and 10% are residual perforation. There is no significant difference between the endoscopic tympanoplasty group's TM status and the microscopic tympanoplasty group patients (Table 3).

The mean duration of hospitalization of endoscopic tympanoplasty group patients was 4.10±0.09 days, and the microscopic tympanoplasty group was 4.97±0.18 days. ET groups had a mean of 0.87-day lesser duration of hospitalization stay than MT group. There is a significant difference between the mean duration of hospitalization days of endoscopic tympanoplasty and microscopic tympanoplasty group patients. Duration hospitalization days wise there is no significant difference between gender (Table 4).

Table 1: Comparison of AB gap between ET and MT group, comparison of duration for surgery, and duration hospitalization days.

Variables	Groups				Mean-difference	Student-independent t test	
	Endoscopic tympanoplasty group		Microscopic tympanoplasty group				
	Mean	SD	Mean	SD			
Comparison of AB gap	Pre-op Ab gap	28.20	2.67	28.80	3.03	0.60	t=0.81; p=0.42 (NS)
	Post-op Ab gap	17.40	3.01	19.67	2.93	2.27	t=2.96; p=0.01** (S)
Duration for surgery (min)	130.83	34.84	168.33	16.88	37.50	t=5.30; p=0.001***	
Duration hospitalization days	4.10	0.09	4.97	0.18	0.87	t=9.23; p=0.001***	

**p<0.01 highly significant, S=significant.

Table 2: Comparison of duration for surgery (minutes) gender basis (n=15).

Groups	Male		Female		Mean difference	Student independent t-test
	Mean	SD	Mean	SD		
ET group	111.33	30.03	150.33	28.25	39.00	t=3.66 (NS), p=0.001***
MT group	170.67	10.83	166.00	21.48	4.67	t=0.75 (NS), p=0.46

**p<0.001 very high significant S= significant.

Table 3: Comparison of TM status.

TM status	Endoscopic- tympanoplasty group		Microscopic tympanoplasty group		Chi-square test
	N	%	N	%	
Intact	27	90	27	90	χ ² =0.00, p=1.00 (NS)
Residual perforation	3	10	3	10	
Total	30	100	30	100	

P>0.05 not significant NS=not significant.

Table 4: Comparison of duration hospitalization days gender basis (n=15).

Groups	Male		Female		Mean difference	Student independent t test
	Mean	SD	Mean	SD		
ET group	4.00	0.78	4.20	0.56	0.20	t=1.14 (NS), p=0.26
MT group	5.00	0.00	4.93	0.26	0.07	t=1.00 (NS), p=0.32

p>0.05 not significant (NS).

DISCUSSION

In our study, comparing the surgical outcome of conventional microscopic type 1 tympanoplasty with endoscopic type 1 tympanoplasty in CSOM patients. Thirty subjects with chronic suppurative otitis media were recruited randomly into each of these groups with 30 subjects each and outcome variables were assessed 12 weeks after surgery.

In our study, the endoscopic tympanoplasty group had less operation time than microscopic tympanoplasty group. The endoscopic technique offered clean surgical view with minimal canal incision, and reduced pain.

In both groups, age distribution was comparable. The majority of patients in both groups were between 18 and 40, similar to previous study by Harugop et al.⁶ Considering the endoscopic tympanoplasty group, 16.67% of the patients are ≤20 years, 46.67% of the patients are between 21-30 years, 33.33% of the patients are between 31-40 years, none of the patients are between 41-50 years, and 3.33% are between 51-60 years.

Considering the microscopic tympanoplasty group, 20% of the patients are ≤20 years, 46.67% of the patients are between 21-30 years, 13.33% of the patients are between 31-40 years, 10% of the patients are between 41-50 years, and 10% of the patients are between 51-60 years.

The surgery duration was significantly lower in the group that underwent endoscopic surgery compared to that of conventional myringoplasty. Our study's duration of surgery of endoscopic tympanoplasty group patients was 130.83±34.84 min, and in microscopic tympanoplasty group, it was 168.33±16.88 min. Endoscopic groups are having 37.50 min less duration of surgery than the microscopic tympanoplasty group. None of the subjects had any postoperative complications in the immediate period. In our study, around 40% of patients had a duration of surgery of 2 hours. More than 90% of cases of conventional surgery were completed within 3 hours. This suggests that the duration of surgery and related morbidity can be reduced with endoscopic myringoplasty. In the study conducted by Shakya et al the ET group's operation time is 48.20±10.37 minutes, and it was 52.63±8.68 minutes in MT group. But it was shorter in ET group, without statistically significant (p=1/40.57).⁷

In a study by Huang the mean operation time in group 1 was 75.5±20.4 minutes, compared to 50.4±13.4 minutes of group 2. The operation time in group 2 was

significantly less than group 1, which is based on independent samples t-test (p<0.0001). This study is similar to our study.⁸

In our study, there is significant difference seen between the groups in aspect of duration of hospitalization post-surgery. Subjects who underwent endoscopic myringoplasty had a significantly lesser number of days of hospitalization compared to conventional myringoplasty. The 76% of patients who underwent endoscopic surgery were in the hospital for three days, while around 96% of cases who underwent conventional surgery required four days of hospitalization after surgery. This difference has been observed consistently in other studies also. In a study by Harugop et al patients who underwent endoscopic surgery had mean duration of 2.4 days (5.4 days in conventional) to return to their daily routine. Hence for patients who insist on early mobility, endoscopic myringoplasty is a viable choice.⁶

Regarding graft status in our study, around 90% of both groups had healthy graft status after 3 months. The success rates after myringoplasty are comparable to other studies. In the study done by Shakya, the graft success rates were 91.42% in both groups at 12 weeks postoperative, and does not statistically significant (p=1.00). The graft success rate in both groups is similar.⁷

In the study done by Ojha et al there was no significant difference observed between both groups; this study supports the present study.⁹

Regarding improvement in A-B gap, there was an improvement in the A-B gap from the preoperative condition at 12 weeks in both groups. This suggests that myringoplasty was effective in improving the hearing deficit in these patients. The study revealed no significant difference observed between both groups in the extent of A-B gap improvement. Shakya et al study shows there is statistically significant in hearing outcome before and after the surgery in both groups. In ET group, pre-and postoperative air-bone gap was 18.9±1.6 dB and 9.2±1.4 dB, respectively (p<0.001).⁷ All patients do not show significant difference between pre-and postoperative bone conduction measured (ET, 23.9±16.9 vs. 29.9±19.6 dB, p=0.221; MT, 28.0±15.8 vs. 29.8±18.5 dB, p=0.342).

In the study done by Patel et al at three months follow up in endoscopic group, ten patients (45.45%) had postop A-B gap in the range of 0 to 10 dB while 11 (50%) patients had postop A-B gap in the range of 11 to 20 dB while in microscopic tympanoplasty 10 (45.45%) patients had

postop A-B gap in the range of 0 to 10 dB, while 8 (36.36%) patients had postop A-B gap in range 11-20 dB. There was no significant difference observed in preoperative and postoperative A-B gap rise in both.¹⁰

So, the clinical improvement in hearing is comparable in both conventional and endoscopic myringoplasty at the end of 6 months. Choice of a specific method may depend on other aspects related to the patient and surgery.

The mobility of endoscopic camera better than microscope. The angled scopes may increase the visibility and accessibility to canal wall, anterior recess, anterior perforation, and ossicular chain. There was no need of repeated adjustments. The limitation of endoscopic ear surgery is a one-handed technique. Endoscope provide monocular vision, which leads to loss of depth perception, hence one has to be careful when close to the vital structures and positioning of graft.

CONCLUSIONS

The present study found out that endoscopic type 1 tympanoplasty had a better outcome than microscopic type 1 tympanoplasty. The size of the tympanic perforation has done not affect the surgical outcome in both groups. In terms of duration of surgery and hospital stay duration, endoscopic myringoplasty had an advantage over conventional myringoplasty. In our study. We achieved good access to the least accessible nook and corners of middle ear cavity such as sinus tympani, facial recess, etc. Loss of depth perception and one-handed technique of endoscopic tympanoplasty can easily overcome by practice.

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