

ORIGINAL ARTICLE

Comparative Outcomes of Endoscopic and Microscopic Tympanoplasty in Patients with Tympanic Membrane Perforation at HRH Princess Maha Chakri Sirindhorn Medical Center

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KEYWORDS

microscopic tympanoplasty; endoscopic tympanoplasty; graft take rate; complication; satisfaction

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ABSTRACT

Chronic otitis media with perforated eardrum is a common disease. Treatment involves tympanoplasty to heal the perforated eardrum. Traditionally, microscopic tympanoplasty by postauricular approach has been used as the conventional method, but since the 1990s, endoscopic tympanoplasty by transcanal approach have been used in tympanic membrane surgery. However, endoscopic-assisted surgery compels the doctor to use only one hand to perform the procedure since the other hand is used to hold the camera. Also, the operation area is small, and if bleeding occurs, it may easily obscure the surgical site. A total of 20 patients with tympanic membrane perforation were enrolled in this study and divided into two groups: endoscopic tympanoplasty using tragal perichondrium graft (n=10) and microscopic tympanoplasty using temporalis fascia graft (n=10). Graft success rates and patient satisfaction were evaluated. Clinical outcomes and complications were followed for at least 6 months postoperatively. Independent t-test, Mann-Whitney U test were used to analyze the outcomes and repeated measures analysis of variance was used to analyze pain score. The mean operation time and length of hospital stay were significantly longer in the microscopic tympanoplasty group (145 minutes, 70 hours) than the endoscopic tympanoplasty groups (90 minutes, 47 hours; $p<0.001$). Graft success rates, clinical outcomes, and satisfaction scores were not significantly different between the two groups. No major complications were observed in either group.

Introduction

Chronic otitis media is a common disease, in which patients often show symptoms of tinnitus and ear discharge. Physical examination may reveal a perforated eardrum. Treatment involves myringoplasty to correct hearing impairment, heal the ruptured eardrum, and dry it¹. Microscopic-assisted surgery is the conventional method used for tympanic membrane surgery, as it allows the doctor to better visualize the ear's anatomy and physiology during the operation. This surgical method utilizes two surgical approaches: the postauricular approach and the transmeatal approach²⁻⁴. In 1967, Lade et al.⁵ introduced the use of the endoscope for diagnosis and imaging. Later, in the 1990s, the endoscope began to be used in tympanic membrane surgery. By opting for this surgical method, the doctor can bypass the postauricular approach, thereby reducing the risk of complications such as auricular deformity, while improving wound aesthetics, minimizing intraoperative bleeding, and reducing postoperative pain compared to the microscopic method. In addition, this surgery allows the doctor to see the entire tympanic membrane area and, notably, the entire ear anatomy clearly, including the round

window niche, Eustachian tube orifice, facial nerve, and incudostapedial joint. Also, additional canaloplasty is not required in patients with a narrow ear canal^{6,7}. However, endoscopic-assisted surgery compels the doctor to use only one hand to perform the procedure since the other hand is used to hold the camera. In addition, the operation area is small, and if bleeding occurs, it may easily obscure the surgical site. Recent studies⁸⁻¹⁰ have indicated that the operation time, length of hospital stay, and postoperative complications are higher in microscopic-assisted surgery compared to endoscopic-assisted surgery. Besides, patients undergoing endoscopic surgery are usually able to return to their normal daily life faster than those undergoing microscopic surgery. Post-surgery surveys of endoscopic patients have demonstrated a higher level of satisfaction with the aesthetic aspect of the incision than those of microscopic patients. While endoscopic-assisted surgery requires less operation time, the graft take rates for both methods are not significantly different. Although there are some reports from studies conducted in foreign countries comparing the effects of endoscopic tympanoplasty and microscopic tympanoplasty in patients with tympanic

membrane perforation, endoscopy is still considered a novel surgical method in Thailand. Additionally, alternative surgical techniques exist, and there is some uncertainty in current medical knowledge in Thailand regarding the success rates and differences in the quality of life of tympanic membrane perforation patients treated with endoscopic surgery versus microscopic surgery. Consequently, this research project aimed to compare the effects of endoscopic tympanoplasty with microscopic tympanoplasty in patients with tympanic membrane perforation, both in Thailand and around the world.

The objective of this study is to compare the graft take rates, clinical outcomes, complications, and patient satisfaction between endoscopic tympanoplasty and microscopic tympanoplasty.

Materials and Methods

This randomized controlled trial was conducted in patients aged 18 years old and older who were diagnosed with tympanic membrane perforation of any size by otolaryngologists at the outpatient unit of the Department of Otolaryngology, HRH Princess Maha Chakri Sirindhorn Medical Center, Faculty of Medicine, Srinakharinwirot University, Nakhon Nayok, Thailand. Patients with a history of mastoid infection, middle ear infection within 4 weeks before surgery, persistent otorrhea, cholesteatoma, or tympanic membrane surgery were excluded.

Sample size

The required sample sizes for the two independent study groups were determined based on discrete binary data using the following formula.

$$n2 = \frac{(z1 - \alpha + z1 - \beta)2}{(\epsilon - \delta)2} + \left[\frac{p1(1 - p1)}{k} + p2(1 - p2) \right]$$

$$\epsilon = p1 - p2$$

$$k = \frac{n1}{n2}$$

$$n1 = kn2$$

n1 = number of patients in the experimental group

n2 = number of patients in the control group

p1 = effect size in the experimental group

p2 = effect size in the control group

$Z\alpha/2$ = critical value corresponding to a 95% confidence level ($\alpha = 0.05$)

$Z\beta$ = critical value corresponding to 80% power ($\beta = 0.20$)

Nt (treatment) = 8

The sample size was calculated using the above formula to compare proportions between the two independent populations. The outcome was that each group should comprise at least 8 patients, which would provide sufficient power (80%) to indicate clinically significant differences at a 5% significance level. The researcher followed up with patients for up to 180 days post-surgery. In the study by Plodpai and Paje⁹, the graft take rates of patients undergoing endoscopic surgery and those undergoing microscopic surgery were 96.7% and 91.2%, respectively. However, a 20% sample withdrawal, absence from the trial, or non-compliance with the project protocols was anticipated, and therefore it was considered necessary to include a minimum of 10 patients per group, for a total of 20 patients, in this research project.

Allocation

The eligible patients were assigned into two groups, namely the endoscopic group and the microscopic group, using simple randomization with random number table technique. However, follow-up and evaluation of the treatment plans for the initial 24 identified patients revealed that 4 patients were lost to follow-up. One of those patients had undergone endoscopic tympanoplasty, while 3 had undergone microscopic tympanoplasty. However, this still left 20 patients (10 patients from the endoscopic group and 10 patients from the microscopic group), which met the sample size criterion.

Surgical procedure

A Carl Zeiss microscope (Oberkochen, Germany) was employed for microscopic tympanoplasty by the postauricular approach. A temporalis fascia graft was applied for tympanic membrane repair. Also, 1% xylocaine with 1:100,000 epinephrine was administered into the external ear canal and the postauricular incision.

In endoscopic tympanoplasty, a high-definition monitor and camera (Karl Storz, Germany) were used, and videos were recorded on a computer hard disc. A Xenon light source (Karl Storz Xenon Nova 175, Tuttlingen, Germany) and 3 mm (18 cm length) Hopkins rod lens rigid 0°, 30° endoscope (Karl Storz Endoscopes, Tuttlingen, Germany) were utilized. Additionally, 1% xylocaine with 1:100,000 epinephrine was injected into the external ear canal, and a tragal perichondrium graft was used to repair the tympanic membrane. Tragal cartilage was harvested by making a 1 cm incision along the tragus.

Both tragal cartilage perichondrium and temporal muscle fascia are all eligible for result in safe and successful surgery¹¹ and all cases in this study were operated on by the same senior surgeon.

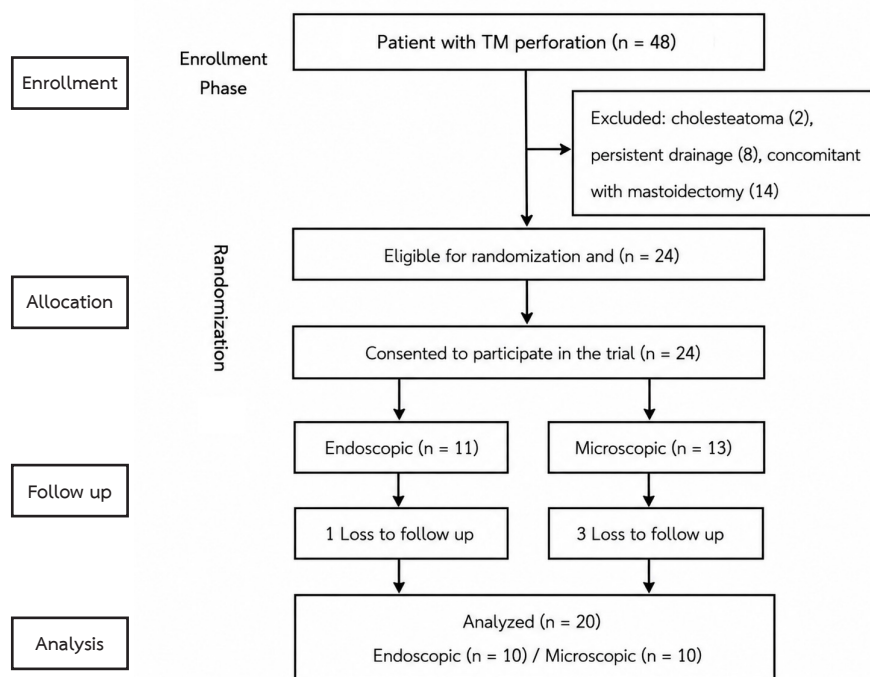


Figure 1 CONSORT flow diagram of this study

Data collection

The researcher conducted a preliminary physical examination and gathered the patient history and general information (gender, age, vital signs, underlying diseases, and drug allergy history). Data on current symptoms, such as length of time before admission, ear itching, earache, ear discharge, and hearing level, were also collected. A questionnaire was used to assess satisfaction at the end of the study (180 days). The visual analogue scale was applied for postoperative pain evaluation at 1 hour, 3 hours, and 1 day after the surgery. The researcher reviewed the patients' medical records to assess the length of stay and operation time, as well as to follow up and evaluate postoperative complications at 30, 90, and 180 days.

Data analysis

Descriptive statistics were used for data analysis. Frequency, percentage, mean, standard deviation, median, and range (minimum and maximum) were calculated. Graft

take rates were compared using Fisher's exact test. Comparative analyses of clinical outcomes, complications, and patient satisfaction between the two groups of patients undergoing endoscopic tympanoplasty and microscopic tympanoplasty were conducted using independent t-test, Mann-Whitney U test, and repeated measures analysis of variance. Data from all patients were analyzed using the above-mentioned statistical methods through the data analysis program STATA version 13.0 (College Station, TX). The statistical significance was set at 5% ($p < 0.05$).

Results

The 10 patients undergoing endoscopic tympanoplasty comprised 7 females (70%) and 3 males (30%), while the 10 patients undergoing microscopic tympanoplasty comprised 7 males (70%) and 3 females (30%). Despite the gender distribution differences, the two groups of patients were similar; most of them underwent left tympanoplasty at the anterior position with a small perforation size (Table 1).

Table 1 Demographic data of the participants between endoscopic and microscopic group

Demographic Categories	Endoscopic (n = 10)		Microscopic (n = 10)		Total (n = 20)		p-value ^a
	n	%	n	%	n	%	
Sex							0.089
Male	3	30	7	70	10	50	
Female	7	70	3	30	10	50	
Affected ear							0.175
Left	8	80	5	50	13	65	
Right	2	20	5	50	7	35	
Perforation size							0.291
Small	9	90	7	70	16	80	
Medium	1	10	3	30	4	20	
Large	0	0	0	0	0	0	
Perforation site							0.175
Anterior	5	50	8	80	13	65	
Posterior	5	50	2	20	7	35	

The size of perforation: small perforation, <1 quadrants, middle perforation, >1 quadrants and <2 quadrants; and large perforation, >2 quadrants

^aFisher's exact test

A comparative study of the clinical outcomes between patients undergoing endoscopic tympanoplasty and microscopic tympanoplasty revealed that post-surgery follow-up of graft take rates at all time intervals (30 days, 90 days, and 180 days) showed differences between the two groups, but without statistical significance (Table 2). In addition, no patients in either group required canaloplasty, and intraoperative blood loss was less than 30 ml. Although

pain scores at 1 hour, 3 hours and 24 hours after the operation differed between the two groups, the differences were not statistically significant (Table 3). However, comparison of the pain scores for each time period showed that the 24-hour postoperative pain scores were significantly lower than both the 3-hour postoperative pain scores ($p < 0.001$) and the immediate postoperative pain scores ($p < 0.001$).

Table 2 The comparison of the graft success rate between endoscopic and microscopic group

Timing (days)	Endoscopic (n = 10)		Microscopic (n = 10)		p-value ^a
	Failure	Uptake	Failure	Uptake	
7	0	10	0	10	-
30	0	10	1	9	0.500
90	1	9	3	7	0.291
180	1	9	2	8	0.500

^aFisher's exact test

Table 3 The comparison of the pain scores between endoscopic and microscopic group

Pain scores	Endoscopic (n = 10)	Microscopic (n = 10)	Total (n = 20)	p-value ^a
Timing (hours)				
1	3.5±1.4	4.2±0.8	3.9±1.1	0.175
3	3.5±1.4	4.1±0.8	3.8±1.1	0.234
24	2.3±1.4	2.3±0.5	2.3±1.0	1.000

3h vs. 1h = -0.05, 95%CI -0.39-0.29, p -value = 0.770^b; 24h vs. 1h = -1.55, 95%CI -1.21- -1.89, p -value < 0.001^b; 24h vs. 3h = -1/50, 95%CI -1.16- -1.84, p -value < 0.001^b

^aIndependent test, ^bRepeated Measures Analysis of Variance

The difference in the preoperative and postoperative air-bone gap (Δ ABG) varied between the two patient groups: 15.0 ± 7.9 dB in the group undergoing endoscopic tympanoplasty and 17.8 ± 5.5 dB in the group undergoing microscopic tympanoplasty. However, the difference was not statistically significant ($p=0.366$) (Table 4). Patients undergoing endoscopic tympanoplasty, however, required a shorter operation time and length of stay—90 minutes (range: 50-105) and 47 hours (range: 45-70), respectively—than those undergoing microscopic tympanoplasty, who

required 145 minutes (range: 90-160) and 70 hours (range: 58-72), with statistical significance (Table 4). Neither group experienced major complications requiring intraoperative or postoperative surveillance, such as postauricular numbness, ear bruising, or surgical wound infection. Postoperative satisfaction scores suggested that the endoscopic and microscopic groups differed in overall satisfaction, but the difference was not statistically significant (7.5 vs. 7.0, $p=0.189$).

Table 4 The comparison of clinical outcomes, complications, and patient satisfaction between endoscopic and microscopic group

Categories	Endoscopic (n = 10)	Microscopic (n = 10)	Total (n = 20)	p-value
No required canaloplasty	10	10	20	-
Minimal blood loss < 30 ml	10	10	20	-
Operating times (mins)	90 (50-105)	145 (95-160)	100 (50-160)	<0.001*
Length of stay (hrs)	47 (45-70)	70 (58-72)	59 (45-72)	<0.001*
Air-bone gap (dB)				
Pre-operative	19.2 $\pm$ 10.8	22.1 $\pm$ 8.3	20.2 $\pm$ 9.4	0.664*
Post-operative	4.2 $\pm$ 6.1	3.3 $\pm$ 6.3	3.8 $\pm$ 6.1	0.689*
Δ ABG	15.0 $\pm$ 7.9	17.8 $\pm$ 5.5	16.4 $\pm$ 6.7	0.366*
No complications	10	10	20	-
Patient satisfaction (180 days)	7.5 (5.0-8.0)	7.0 (5.0-8.0)	7.0 (5.0-8.0)	0.189*

*Mann-Whitney test, **Independent test

Discussion

A comparative study on the effects of endoscopic tympanoplasty and microscopic tympanoplasty in patients with tympanic membrane perforation suggested that the graft take rates at all time intervals (30 days, 90 days, and 180 days) differed between the two groups but without statistical significance. This finding is consistent with a previous study by Plodpai and Paje⁹, who reported that the graft take rates for endoscopic-assisted surgery patients were higher than those for microscopic-assisted surgery patients. The present study also concurs with previous international research that indicated no significant differences between postoperative graft take rates for both methods^{9,12}. In addition, the current study indicated that differences in preoperative and postoperative hearing levels, intraoperative blood loss, and pain scores on the first day after surgery between the two groups were not statistically significant, which was consistent with earlier studies. Both groups of patients showed no significant differences in preoperative and postoperative hearing levels, pain scores, intraoperative blood loss, and pain levels on the first day after surgery^{9,13}. However, both methods of surgery produced only small differences in wound size, which may explain the similar intraoperative blood loss and pain scores recorded 1 day after the surgery.

Patients undergoing endoscopic tympanoplasty required less operation time and had a shorter length of stay than those undergoing microscopic tympanoplasty, with statistical significance. This finding is consistent with recent studies reporting that endoscopic-assisted surgery takes less operating time than microscopic-assisted surgery⁹, due to

the limited visualization of the perforation with the microscope, which requires more time spent examining the entire tympanic membrane¹⁴. Patients undergoing microscopic tympanoplasty had a longer hospital stay than those undergoing endoscopic tympanoplasty, which is consistent with the study conducted by Nassif et al.⁸. It was also found that patients undergoing microscopic-assisted surgery spent more time in the hospital due to the incision being at the back of the ear pinna, which may require pressure to be applied to the wound for at least 24 hours after the surgery in order to stop any bleeding. As a result, this group required a longer hospital stay than the group undergoing endoscopic surgery, which involved only a 1–2 cm surgical incision.

In addition, the current study showed that no serious postoperative complications were reported in either group, i.e., no major issues requiring close observation, such as numbness at the back of the ear, ear bruising, or an infected surgical wound. Postoperative assessment of satisfaction levels in the two groups suggested that patients in both the endoscopic-assisted and microscopic-assisted surgery groups gave similar scores (7.5 [range 0–8] vs. 7.0 [range 0–8] points). This was surprising, since some endoscopic surgery patients were treated with a tragal perichondrium graft, which could result in a visible scar. This finding was also inconsistent with studies by Harugop et al.¹⁵ and Kim et al.¹⁶, who found that patients undergoing endoscopic-assisted surgery reported higher satisfaction with the aesthetic outcome than those undergoing microscopic-assisted surgery, as the latter group often had scars above the hairline.

This study has certain limitations. The sample size was relatively small, which may have limited the statistical power to detect subtle differences between two groups and the study was conducted in a single tertiary center, which may affect the generalizability of the finding to other settings or patient populations. Further multicenter studies with large sample sizes are recommend to validate and extend these results.

Conclusions

The findings from this comparative study on the effectiveness of endoscopic and microscopic surgeries in patients with tympanic membrane perforation indicate that operation time and length of stay were shorter for patients undergoing endoscopic surgery than for those undergoing microscopic surgery. However, the graft take rates, postoperative hearing levels, and intraoperative blood loss showed no significant differences. In addition, there were no reports of serious adverse postoperative events in either surgical group, and no significant differences in patient satisfaction between the two groups. The study results allow us to conclude that the endoscopic method of myringoplasty is not less effective in treating patients with tympanic membrane perforation than the microscopic method. Therefore, endoscopic surgery may serve as an alternative treatment option for patients with a perforated tympanic membrane.

Ethical statement

This study was approved by the Institutional Human Research Ethics Committee of Srinakharinwirot University (protocol code SWUEC-080/61E; approval date: 1 June 2018). Informed consent was obtained from all participants or their legal representatives.

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