Short-term Subjective and Objective Outcomes of Patients Receiving Endoscopic Transcanal Myringoplasty for Repairing Tympanic Perforations

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Abstract

Objective. Endoscopic transcanal myringoplasty (ETM) has been an emerging technique for repairing tympanic perforations since the late 1990s. Objective outcomes (ie, graft success rates and hearing results) of patients who received ETM are well documented; however, subjective outcomes of these patients have rarely been reported. Hence, this study evaluated subjective and objective outcomes of patients who received ETM for repairing tympanic perforations.

Study Design. Prospective study.

Setting. Tertiary care university hospital.

Patients and Methods. Patients who underwent ETM for perforations of the tympanic membrane were included. We evaluated subjective variables of patients receiving ETM as the primary outcome and objective variables as the secondary outcome.

Results. In total, 91 ears that underwent ETM were included. The mean pain scale score was 0.1 (range, 0-2) on postoperative day 3. The mean duration of pain medication was 2.0 (range, 0-3) days. The mean number of days required to resume routine activities was 1.0 (range, 1-2) days. The overall graft success was determined postoperatively at 3 months in 80 of 91 ears (87.9%). Closure of the air-bone gap to within 20 dB was achieved in 79 (86.8%) ears.

Conclusion. In this study, patients who received ETM had mild postoperative pain and resumed routine activities early. These patients also exhibited favorable graft success rates and hearing results at 3 months postoperatively. On the basis of our results, we conclude that patients who receive ETM for the repair of tympanic perforations have favorable short-term subjective and objective outcomes.

Keywords

chronic otitis media, endoscope, tympanic perforation, tympanoplasty

Since the 1950s, microscopic myringoplasty has been the standard surgery for repairing a perforated tympanic membrane.1-5 Despite having a high rate of graft take of more than 90%, this technique frequently requires postauricular incision and general anesthesia.3,4 In addition to conventional microscopic myringoplasty, endoscopic transcanal myringoplasty (ETM) has been an emerging technique since the late 1990s.6-15 The major difference between microscopy and endoscopy is the surgical view. The view during microscopic surgery is defined and limited by the narrowest segment of the ear canal. By contrast, transcanal endoscopy bypasses the narrowest segment of the ear canal and provides a wider view, even when a 0° endoscope is used.7,9 Thus, ETM does not entail canalplasty, postauricular incision, and general anesthesia; thus, it is less invasive than the microscopic technique.6-15

Surgical outcomes for chronic otitis media are assessed using subjective and objective outcome measurements. Subjective outcome measurements evaluate the symptoms reported by patients and the functional results, whereas objective outcome measurements include graft success rates and hearing results.16 These outcomes affect the postoperative quality of life of the patients. Graft success rates and hearing results of patients who received ETM are well documented6-15; however, subjective outcomes of these patients
have rarely been reported. Hence, this study evaluated the short-term subjective and objective outcomes of patients who received ETM for repairing tympanic perforations.

Patients and Methods

The joint institutional review board of the Taipei Medical University approved our study protocol. Informed consent was obtained from each patient. We prospectively included patients who underwent ETM from September 7, 2015, to April 1, 2017, at the Wan Fang Hospital. The indication of myringoplasty was tympanic perforations due to chronic otitis media; these patients were followed for at least 3 months. Final follow-up was completed on July 1, 2017. We excluded patients with ossicular chain disease and cholesteatoma. The same surgeon performed all the procedures.

Preoperatively, we used a video recording system to visualize the status of the tympanic membrane by using an endoscope (Karl Storz, Tuttlingen, Germany; 4.0-mm, 0-degree, 18-cm-long lens). The recorded image was obtained to evaluate the perforation size of the tympanic membrane and condition of the middle ear mucosa. The tympanic membrane was divided into 4 quadrants according to the position of the malleus handle, and each quadrant accounted for 25% of the tympanic membrane. The perforation size was evaluated and divided into 4 groups (<25%, 25%-50%, >51%-75%, and >75%); the perforation location was classified as anterior or posterior to the malleus handle. If an anterior perforation extended posterior to the malleus handle, it was considered central. Perforations were considered inferior if they were inferior to the umbo of the malleus.

We used the Middle Ear Risk Index (MERI) 2001 to stratify patients according to known preoperative and intraoperative risk factors for tympanoplasty. The MERI generates a numerical value that correlates with the severity of disease and prognosis. MERI scores of 0 to 3, 4 to 6, and 7 to 12 represent mild, moderate, and severe disease, respectively.

Because there are no validated questionnaires to measure the short-term quality of life for patients who underwent ear surgery, we evaluated subjective and objective variables of these patients. Subjective variables of patients who received ETM were the primary outcome. The subjective variables included pain scale scores on 3 postoperative days, the duration of pain medication, and the number of days required to resume routine activities. Pain was evaluated using an 11-item, patient-reported numerical rating scale (NRS) of pain intensity (NRS-11; range, 0-10). The pain scale was obtained when patients were followed up at postoperative week 1. The pain medication prescribed was 400 mg ibuprofen. Pain medication was taken if the patients felt pain. In this study, routine activities included eating, sleeping, washing hair, and working. Objective variables—namely, graft success rates and hearing results—were the secondary outcome. Graft success was defined as the presence of an intact graft, whereas graft failure was defined as a residual or recurrent perforation at 3 postoperative months. We followed up the recommendations of the American Academy of Otolaryngology—Head and Neck Surgery guideline to report hearing results. These recommendations include the 4-tone pure-tone mean, postoperative air-bone gap mean, word recognition scores, and scattergrams. We performed preoperative and postoperative audiograms at frequencies of 500, 1000, 2000, and 3000 Hz to access the closure of the air-bone gap.

Patients’ data on age, sex, perforation site, the size of perforation, and operative time were also extracted for analysis. We defined the operative time as the duration between the start of local anesthesia and end of wound dressing.

Postoperative complications of residual or recurrent perforations, infections, hemorrhage, and hearing loss were examined.

Surgical Techniques

Two rigid endoscopes (Karl Storz) were used in our surgical techniques (4.0-mm, 0-degree, 18-cm-long lens; 3-mm, 0-degree, 14-cm-long lens). Patient ears were prepared and draped under sterile conditions without hair shaving. Each patient was administered intravenous sedation (50 mg meperidine + 5 mg midazolam) 10 minutes preoperatively by an anesthesiologist. The periaural area and external ear canal were infiltrated with 2% lidocaine with 1:100,000 epinephrine.

We used the tragal perichondrium as graft material. For harvesting the tragal perichondrium graft, a 1-cm incision was made 2 to 3 mm medial to the free border of the tragal cartilage. The perichondrium was freed of the cartilage and prepared as a graft. The incision was sutured with absorbable material. Surgical techniques included ETM without elevation of the tympanomeatal flap and ETM with elevation of the tympanomeatal flap.

**ETM without elevation of the tympanomeatal flap.** When the sizes of perforations were less than 50%, we performed ETM without elevation of the tympanomeatal flap. First, the perforation margin was circumferentially freshened using a pick. The middle ear cavity was tightly packed with Gelfoam (Pfizer, New York, New York) through the perforation. After being prepared 2 mm larger than the perforation size, the graft was pushed through the perforation and placed in an underlay manner. Gelfoam pledges soaked with antibiotic drops (ofloxacin ear solution, 0.3%) were placed lateral to the graft in the external auditory canal.

**ETM with elevation of the tympanomeatal flap.** When the sizes of perforations were larger than 50%, we performed ETM with elevation of the tympanomeatal flap. First, the perforation margin was circumferentially freshened using a pick. The middle ear cavity was tightly packed with Gelfoam (Pfizer, New York, New York) through the perforation. After being prepared 2 mm larger than the perforation size, the graft was pushed through the perforation and placed in an underlay manner. Gelfoam pledges soaked with antibiotic drops (ofloxacin ear solution, 0.3%) were placed lateral to the graft in the external auditory canal.
external auditory canal was packed with Gelfoam pledgets to the level of the isthmus. No mastoid dressing was required.

**Postoperative Follow-up**

The patients were discharged on the day of the surgery. If patients had draining ears preoperatively, they were prescribed oral antibiotics postoperatively (first-line cephalosporins or antibiotics according to preoperative culture results). Pain medications were taken if patients felt pain. The packing and stitches were removed 1 week postoperatively. Each patient was scheduled regular follow-up visits at 1 and 3 weeks as well as 2 and 3 months and underwent endoscopy and audiometry at 3 months postoperatively. Theaudiograms at 3 months postoperatively were extracted for analysis.

**Statistical Analysis**

Statistical analysis was performed using Statistical Package for Social Sciences version 16 for Windows (SPSS, Inc, an IBM Company, Chicago). The study results were expressed as mean and 95% confidence intervals (CIs) or range for continuous variables and as percentages for categorical variables. We compared the study data through sample t-tests and Mann-Whitney U tests. The differences between groups were considered significant at \( P < .05 \).

**Results**

A total of 111 ears had undergone ETM during the study period. Of these patients, 20 were excluded because of an inadequate follow-up period of less than 3 months, and the remaining 91 were included in the analysis.

Preoperative demographic data are presented in Table 1. The subjective and objective variables of patients who received ETM are listed in Table 2. The mean duration of pain medication was 2.0 (range, 0-3) days. The mean number of days required to resume routine activities was 1.0 (range, 1-2) days. The overall graft success was determined postoperatively at 3 months in 80 of 91 ears (87.9%), and the mean follow-up period was 5.9 (range, 3-15) months. The graft success rates, preoperative air-bone gaps, postoperative air-bone gaps, and postoperative word recognition scores were significantly associated with the MERI scores. The graft success rates for ETM with elevation of the tympanomeatal flap and ETM without elevation of the tympanomeatal flap were 89.7% and 84.8%, respectively. No significant difference was found between these groups \( (P = .50, \chi^2 \text{ test}) \).

Figure 1 shows that the mean pain scale score decreased from 3.2 (range, 0-7) on postoperative day 1 to 0.1 (range, 0-2) on postoperative day 3. The mean preoperative air conduction threshold was 41.3 (95% CI, 6.8-75.8) dB, the mean preoperative air-bone gap was 20.8 (95% CI, 1.4-40.2) dB, and the mean preoperative word recognition score was 95.8% (95% CI, 81.9-100). Figure 2 depicts the postoperative scattergram of changes in air conduction thresholds and word recognition scores. In total, 77 of 91 (84.6%) ears exhibited an improvement of more than 10 dB in air conduction thresholds. Closure of the air-bone gap to within 20 dB was achieved in 79 (86.8%) ears.

Of the 91 ears, 7 had recurrent perforations; this result may be related to postoperative infections. Two ears had residual perforations; this may have resulted from persistent sniffing habit. The causes of graft failures in the remaining 2 patients were unclear. No patients with deterioration of bone conduction were examined postoperatively.

**Discussion**

Surgical outcomes for chronic ear diseases are evaluated using subjective or objective outcome measurements. Subjective outcome measurements evaluate symptoms, emotions, social functions, and satisfaction with care, whereas objective outcome measurements, which have been reported in most studies, include complete eradication of the disease, creation of a dry and safe ear, and restoration of hearing. A comprehensive health-related quality-of-life outcome assessment should include both the aforementioned outcome measurements.

The present study used the postoperative pain score, the duration of pain medication, and the number of days required to resume routine activities as subjective outcome

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**Table 1. Preoperative Demographic Data.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of ears</td>
<td>91</td>
</tr>
<tr>
<td>Number of patients</td>
<td>87</td>
</tr>
<tr>
<td>Age at surgery, y</td>
<td>51.1 ± 15.5</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>41 (45)</td>
</tr>
<tr>
<td>Female</td>
<td>50 (55)</td>
</tr>
<tr>
<td>Site</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>40 (44)</td>
</tr>
<tr>
<td>Left</td>
<td>51 (56)</td>
</tr>
<tr>
<td>Perforation size, %</td>
<td></td>
</tr>
<tr>
<td>&lt;25%</td>
<td>3 (3)</td>
</tr>
<tr>
<td>25%-50%</td>
<td>55 (61)</td>
</tr>
<tr>
<td>51%-75%</td>
<td>23 (25)</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>10 (11)</td>
</tr>
<tr>
<td>Perforation location</td>
<td></td>
</tr>
<tr>
<td>Anterior</td>
<td>25 (48)</td>
</tr>
<tr>
<td>Inferior</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Posterior</td>
<td>5 (6)</td>
</tr>
<tr>
<td>Central</td>
<td>58 (63)</td>
</tr>
<tr>
<td>Middle Ear Risk Index</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>71 (78)</td>
</tr>
<tr>
<td>Moderate</td>
<td>20 (22)</td>
</tr>
<tr>
<td>Elevation of the tympanomeatal flap</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>58 (64)</td>
</tr>
<tr>
<td>Yes</td>
<td>33 (36)</td>
</tr>
</tbody>
</table>

*Values are presented as number (%) or mean ± standard deviation unless otherwise indicated.*
measurements. Patients are typically concerned about these subjective outcomes because they affect their postoperative symptoms, emotions, and social functions. In this study, we used the NRS to measure postoperative pain. The NRS is a segmented numeric version of the visual analog scale and can be administered verbally or graphically for self-completion. When completing this scale, a respondent selects a whole number (0-10 integers) that best reflects the intensity of his or her pain. Moreover, this scale has high test-retest reliability, and construct validity correlated the visual analog scale. Through a literature survey, we found that most studies related to ETM have reported objective and not subjective outcomes. Only a few studies related to ETM have evaluated subjective outcomes. Choi et al reported that the pain score was 0.8 on postoperative day 1, whereas in our study, the score was 3.2. Harugop et al reported that patients who received ETM resumed routine activities in 2.4 days on average, whereas in our study, the patients resumed their routine activities in 1.0 day on average. Nassif et al reported that 77% of the patients who received ETM were discharged on the operative day, whereas in our study, all the patients were discharged on the operative day. Accordingly, we conclude that regarding short-term postoperative recovery, patients who received ETM had favorable subjective outcomes.

In this study, we used graft success rates and hearing results as objective outcome measurements. The graft success rate and hearing results are shown in Table 2. The table shows the subjective and objective variables stratified by the Middle Ear Risk Index (MERI). The continuous variables are expressed as mean (standard deviation) unless otherwise indicated. The P value is calculated using Mann-Whitney U tests for the pain scale and the numbers of days, x² tests for graft success rate, and sample t tests for hearing results. The abbreviations used in the table are as follows: ABG, air-bone gap; MERI, Middle Ear Risk Index; WRS, word recognition score.

Figure 1. Pain scale scores on 3 postoperative days. Pain was evaluated using an 11-item, patient-reported numerical rating scale of pain intensity (range, 0-10). Pain scale scores significantly decreased according to postoperative days (P < .01, paired t test).

Figure 2. Postoperative scattergram of changes in air conduction thresholds and word recognition scores.
success rate in this study (87%) is comparable with those reported in the literature (82%-97%).\textsuperscript{6-15} Moreover, our study extended the work of previous studies because we used the MERI, proposed by Becvarovski and Kartush in 2001,\textsuperscript{17} to stratify the study patients. MERI scores have been used to investigate graft success rates and hearing results.\textsuperscript{21} In this study, approximately three-fourths (78%) of our patients had low MERI scores (<3). These patients typically had dry ears. Approximately one-fourth (22%) of the patients had moderate MERI scores (4-6). These patients frequently had wet ears (ie, persistently wet, middle ear effusion). Although these patients were treated, the status of dry ears could not be achieved. In this condition, the aim of surgical treatment was not only to restore hearing but also to eradicate infections. In the present study, graft success rates, postoperative reduction in air-bone gaps, and postoperative word recognition scores of patients with low MERI scores were higher than were those of patients with moderate MERI scores. This result indicates that the MERI can predict graft success rates and hearing results.

In this study, ETM without elevation of the tympanomeatal flap was used to repair medium-sized tympanic perforations (size <50%). This surgical procedure is based on the results of our earlier study.\textsuperscript{22} We found that for repairing medium-sized tympanic perforations, the graft success rates and hearing results of ETM with and without elevation of the tympanomeatal flap are comparable. However, patients who received ETM without elevation of the tympanomeatal flap had shorter operative times and fewer follow-up visits than did those who received ETM with elevation of the tympanomeatal flap.\textsuperscript{22} In the present study, ETM with elevation of the tympanomeatal flap was used to repair large-sized tympanic perforations (size >50%). The graft success rates for ETM with elevation of the tympanomeatal flap and ETM without elevation of the tympanomeatal flap were not significantly different (89.7% vs 84.8%, \(P = .50, \chi^2\) test). This surgical principle yielded expected results as shown in this study.

Based on our study, ETM has several benefits. First, the operative time for ETM was less than 1 hour, which is appropriate for an operation under local and intravenous anesthesia. If the operative time exceeds 1 hour, patients become uncomfortable because of lying on the operating table. Second, patients receiving ETM had a mild degree of pain and resumed routine activities soon on postoperative day 1. Third, ETM did not entail postauricular incision and canalplasty. Therefore, ETM is a minimally invasive technique.

Compared with microscopy, endoscopy has several disadvantages during ear surgery. First, the endoscope must be held in one hand; therefore, only one hand is available for performing surgery. This procedure is particularly cumbersome when bleeding obscures the view of the operating field. Furthermore, endoscopy provides a monococular view, which causes the loss of depth perception unlike the binocular view provided through microscopy. Moreover, ETM requires more training and experience.\textsuperscript{23}

The strength of this study is its novelty. To our knowledge, this study is the first to describe both subjective and objective outcomes of patients who received ETM. These outcomes provide information regarding the quality of life of patients who received ETM. Moreover, we used the MERI to evaluate our patients preoperatively and to predict surgical outcomes postoperatively.

This study was limited by selection bias because of the patients who were lost to or unavailable for follow-up. Second, the questionnaire for subjective outcomes lacked reliability and validation tests. Third, this study was a descriptive study and lacked a control group, for example, a group of patients who received microscopic postauricular myringoplasty. Fourth, we evaluated only the short-term subjective and objective outcomes of the patients who received ETM. The long-term quality of life of patients who receive ETM should be evaluated in future studies. Therefore, a well-designed prospective controlled study is recommended.

**Conclusion**

In this study, patients who received ETM had mild postoperative pain and resumed routine activities early. These patients also exhibited favorable graft success rates and hearing results at postoperative 3 months. The MERI can predict graft success rates and hearing results. On the basis of our results, we conclude that patients who receive ETM for the repair of tympanic perforations have favorable subjective and objective outcomes.

**Author Contributions**

Chih-Chieh Tseng, collection, analysis, and interpretation of data; drafting, revising, and final approval of manuscript; accountable for the work; Ming-Tang Lai, interpretation of data; drafting, revising, and final approval of manuscript; accountable for the work; Chia-Che Wu, interpretation of data; drafting, revising, and final approval of manuscript; accountable for the work; Yi-Fang Yuan, interpretation of data; drafting, revising, and final approval of manuscript; accountable for the work; Sheng-Po Yuan, interpretation of data; drafting, revising, and final approval of manuscript; accountable for the work.

**Disclosures**

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**References**

