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Comparison of the medical costs and effects of large traumatic eardrum perforations treatment☆

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ABSTRACT

Objective: We investigated the medical costs and effects of ofloxacin drops (OFLX), gelatin sponge patches, spontaneous healing, and endoscopic myringoplasty on healing in large tympanic membrane perforations (TMPs).

Methods: In total, 100 patients with large traumatic TMPs involving > 50% of the eardrum were randomly assigned to OFLX, gelatin sponge, spontaneous healing, or endoscopic myringoplasty treatment groups. Medical costs, closure times, and closure rates were compared among groups at 6 months.

Results: The closure rates in the OFLX, gelatin sponge, spontaneous healing, and endoscopic myringoplasty groups were 95.7%, 82.6%, 58.3%, and 91.7%, respectively ($P = 0.05$). The mean closure time was 13.73 ± 6.14 days in the OFLX group, 15.89 ± 4.95 days in the gelatin sponge group, 48.36 ± 10.37 days in the spontaneous healing group, and 12 days in the endoscopic myringoplasty group ($P < 0.001$). The mean medical costs in US dollars were \$15.53 ± 3.15, \$103.64 ± 111.58, \$11.17 ± 1.33, and \$715.90 in the OFLX, gelatin sponge, spontaneous healing, and endoscopic myringoplasty groups, respectively ($P < 0.001$).

Conclusion: Although the gelatin sponge and myringoplasty treatments significantly shortened the closure time compared with spontaneous healing, the gelatin sponge patch did not significantly improve the closure rate, and the medical cost of myringoplasty was significantly higher than that of the other treatments. In contrast, OFLX significantly shortened closure time and had a higher closure rate than spontaneous healing, and the medical costs were lower than those of the gelatin sponge and myringoplasty procedures.

1. Introduction

Traumatic tympanic membrane perforation (TMP) is a common problem encountered in otology clinics. Although traumatic TMPs tend to heal spontaneously, larger perforations are less likely to heal spontaneously or require a long healing time [1,2]. Kronenberg et al. [3] reported that only 20% of the TMPs in their study healed spontaneously, and that large and central kidney-shaped perforations were the least likely to heal spontaneously. Several biological materials and medications have been suggested to shorten closure times and improve closure rates in large TMPs [4–6]. Some otologists recommend immediate endoscopic myringoplasty to facilitate eardrum healing, particularly in developing countries and for blast-induced TMPs [7–11]. Ofloxacin drops (0.3% [w/v], OFLX) and gelatin sponge patches, which are used to treat otitis externa and otitis media and as packing material in ear surgery, respectively, are commonly found in otology clinics. In recent years, clinical studies have shown that OFLX and gelatin sponge patches facilitate the healing of large traumatic perforations [5,6]. However, no previous study has compared the medical costs of the OFLX, gelatin sponge, spontaneous healing, and endoscopic myringoplasty treatments. Therefore, we compared the medical costs and effects of OFLX, gelatin sponge patches, spontaneous healing, and endoscopic myringoplasty to facilitate the development of treatment strategy for large traumatic TMPs.

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2. Materials and methods

Our study was reviewed and approved by the Institutional Ethics Review Board of Yiwu Central Hospital. Informed consent was obtained from all participants prior to enrollment.

Consecutive patients diagnosed with a traumatic TMP who visited the Department of Otorhinolaryngology, Head and Neck Surgery at Yiwu Central Hospital between January 2012 and June 2017 were recruited for the study. Cases that met the following criteria were included in the analysis: (i) a traumatic TMP resulting from a slap or punch to the ear, a firecracker blast injury, or a direct penetration injury; (ii) duration of injury < 2 weeks without middle ear infection; and (iii) perforation > 50% of the tympanic membrane.

Patients with severe vertigo or ossicular disruption suspected on physical examination or imaging and those with a history of chronic suppurative otitis media were excluded from the study.

Information related to age, sex, date of injury, perforation size, position of the perforation, presence or absence of otorrhea, and associated clinical findings (e.g., hearing loss, vertigo, and tinnitus) was obtained at the first visit. The tympanic membrane was examined using an endoscope after cleaning cerumen or blood clots from the external auditory canal (EAC) using a cotton bud soaked in a povidone-iodine solution. The tympanic membrane was simultaneously photographed using a digital video camera, and the size of the perforation was assessed using ImageJ software (National Institutes of Health, Bethesda, MD, USA). Pure-tone audiograms were obtained using a GSI 10 audiometer in a quiet room at the initial and final visits or 6 months after treatment. A four-dimensional method was used to determine the pure-tone average at the frequencies of 0.5, 1, 2, and 4 kHz. The principal investigator, assisted by a registered nurse, assigned patients to one of four treatment groups using simple random sampling. Specifically, consecutive subjects who met the inclusion criteria and signed the consent form were assigned random numbers generated by the Statistical Package for the Social Sciences (SPSS) for Windows software (version 19.0; SPSS, Inc., Chicago, IL, USA) that allocated them to the OFLX (n = 25), gelatin sponge (n = 25), spontaneous healing (n = 25), or endoscopic myringoplasty (n = 25) treatment group.

2.1. Technical methods

2.1.1. OFLX group

The EAC was cleaned with a cotton bud soaked in povidone-iodine solution. Approximately 0.2–0.3 mL (2–3 drops) of OFLX (Wanhe, Shenzhen City, China) was applied to the tympanic membrane once daily to ensure that it remained moist. The wound edges were not approximated, and no scaffolding material was applied.

2.1.2. Gelatin sponge group

The EAC was cleaned using a cotton bud soaked in povidone-iodine solution. A modified compressed gelatin sponge sheet larger than the perforation was soaked in 0.5% (w/v) chlortetracycline ointment and placed on the tympanic membrane remnant (i.e., the onlay technique) to completely cover the perforated area with margins of at least 2 mm. No eardrops were prescribed, the EAC was not packed, and the edges were not approximated.

2.1.3. Spontaneous healing group

No intervention was offered; however, all patients underwent regular follow-ups.

2.1.4. Endoscopic myringoplasty group

The periaural area and EAC were infiltrated with 2% lidocaine with 1:100,000 epinephrine. We used the tragal perichondrium as graft material, and the graft was harvested through a 1-cm incision medial to the free border of the tragal cartilage. The edges were approximated by endoscope, and the middle ear cavity was tightly packed with a gelatin sponge through the perforation. The graft was tailored to be 2 mm larger than the perforation size and pushed through the perforation and placed in an underlay manner. The gelatin sponge sheet was placed lateral to the graft in the EAC.

2.1.5. Follow-up

All subjects received oral amoxicillin for 1 week and those in the OFLX, spontaneous healing, and gelatin sponge groups were followed up twice a week until perforation closure or for up to 6 months. Patients in the OFLX group were instructed to apply the drops daily at home. We confirmed that all patients self-administered the drops correctly, and we carefully adjusted the dose to ensure that the surface remained moist (neither dry nor overly wet). Patients were advised to reduce the number of eardrops and to take oral amoxicillin (with or without the application of OFLX drops) if purulent otorrhea developed. The gelatin sponge patch was replaced at each follow-up visit in the gelatin sponge group. The aural dressings were typically removed at postoperative day 12 in the endoscopic myringoplasty group, and the gelatin sponge fragments were aspirated allowing the graft to be visualized. The tympanic membrane was examined endoscopically and color photographs were taken at all follow-up visits by an independent clinician blinded to the group assignments.

2.2. Medical costs

The medical costs are shown in Table 1 according to treatment. Our cost analysis included medication, the cost of materials, medical examination expenses, and surgical fees. All fees were stipulated by the price agency in China. Only the first endoscopic examination fee was included in the cost analysis because the follow-up endoscopic examination fees were subsidized by the Science and Technology Fund.

2.3. Statistical analyses

All statistical tests were performed using SPSS software (SPSS Inc.). The normality of continuous variables was assessed using the Shapiro-Wilk test with P-values > 0.05 deemed to indicate normality. Among-group differences were compared using a one-way analysis of variance (ANOVA), and normally distributed data were expressed as mean ± standard deviation. *Post-hoc* multiple comparisons among groups were performed using the Bonferroni least significant difference test for homoscedasticity and Dunnett's T3 test for heteroscedasticity. Non-normally distributed data were expressed as median and interquartile range. Total differences were estimated using the Kruskal–Wallis one-way ANOVA test. Among-group differences were compared using the Mann–Whitney *U* test. The correlational relationships between two

Table 1
Basic medical costs of OFLX, gelatin sponge patch, spontaneous healing, and myringoplasty groups (USD).

	Endoscopic examination	Amoxicillin	Patch'test	Patching material fee	Eardrops fee	Operation fee	Hospitalization expenses	Total
OFLX	7.3	3.6	0	0	2.9	0	0	13.8
Gelatin sponge patching	7.3	3.6	2.9	3.68	0	1.9	0	19.38
Spontaneous healing	7.3	3.6	0	0	0	0	0	10.9
Myringoplasty	7.3	3.6	0	0	0	191.7	513.3	715.9

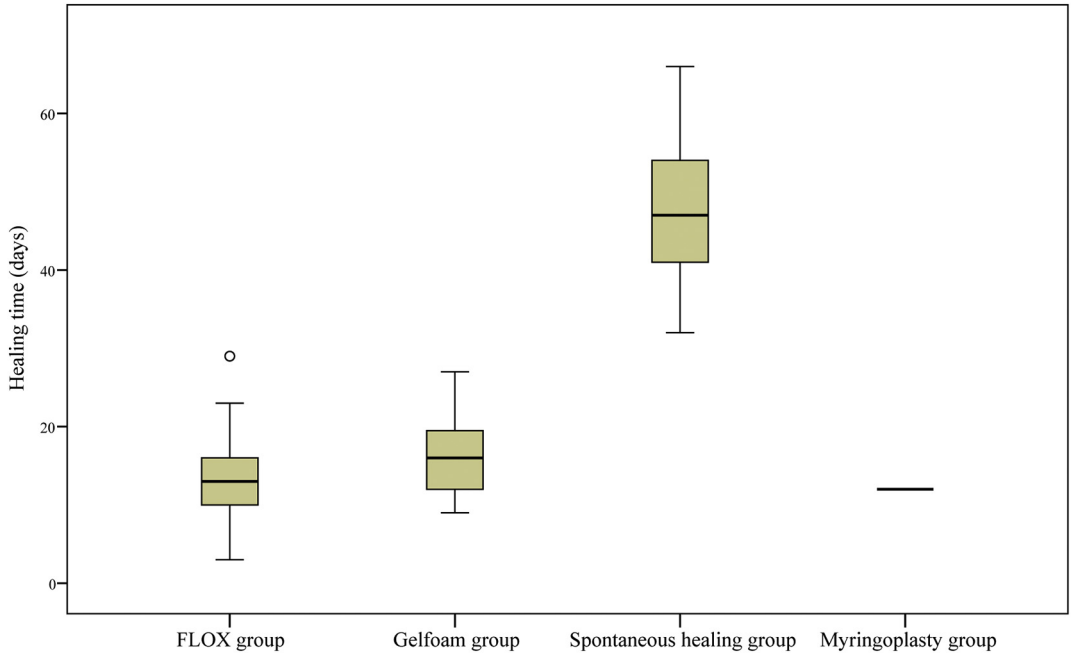

Fig. 1. The mean closure times according to treatment group. The central horizontal lines indicate the median values, and the vertical lines in the closed box show the first and third quartiles. In the ofloxacin group, the median value was 13.0, the 25th percentile was 10.0, and the 75th percentile was 17.0, and the circle indicates a discrete point (29.0). In the gelatin sponge group, the median value was 16.0, the 25th percentile was 12.0, and the 75th percentile was 20.0. In the spontaneous healing group, the median value was 47.0, the 25th percentile was 40.5, and the 75th percentile was 56.25. The closure time was 12.0 for all the patients in the endoscopic myringoplasty group.

continuous variables were determined using Pearson's correlation analysis. The chi-squared test was used to compare certain categorical variables (e.g., closure rates and sex). P-values = 0.05/6 = 0.0083 (Bonferroni correction) were deemed to indicate a significant difference in *post-hoc* multiple comparisons. Otherwise, P-values < 0.05 were deemed to indicate statistical significance.

3. Results

3.1. Patient characteristics

In total, 100 patients met the inclusion criteria; however, two patients in the OFLX group, two in the gelatin sponge group, one in the spontaneous healing group, and one patient in the endoscopic myringoplasty group were lost to follow-up (Fig. 1). Therefore, 94 patients were included in the final analysis (23 patients each in the OFLX and gelatin sponge groups and 24 patients each in the spontaneous healing and endoscopic myringoplasty groups). The groups were matched according to average age, sex, the size, position, duration, cause, and edge of the perforation, and preexisting myringosclerosis (P > 0.05; Table 2).

3.2. Healing outcomes

The healing outcomes at 6 months are shown in Table 3 and Fig. 1. The closure rates in the OFLX, gelatin sponge, spontaneous healing, and endoscopic myringoplasty groups were 95.7%, 82.6%, 58.3%, and 91.7%, respectively (P = 0.05). Pairwise comparisons revealed that the closure rates differed significantly between the OFLX and spontaneous healing groups (P = 0.003) and between the endoscopic myringoplasty and spontaneous healing groups (P = 0.008). However, we found no significant differences in closure rates among the other groups (OFLX vs. gelatin sponge, P = 0.343; OFLX vs. endoscopic myringoplasty, P = 1.000; gelatin sponge vs. spontaneous healing, P = 0.069; and gelatin sponge vs. endoscopic myringoplasty, P = 0.622).

The mean closure time was 13.73 ± 6.14 days in the OFLX group,

Table 2
The demographics data of OFLX, gelatin sponge patch, spontaneous healing, and myringoplasty groups.

	OFLX group	Gelatin sponge patch group	Spontaneous healing group	Myringoplasty group	P value
No.	23	23	24	24	
Sex (M:F)	6:17	13:10	7:17	9:15	0.135[a]
Side (L:R)	15:8	17:6	22:2	21:3	0.084[a]
Position(anterior:posterior:kidney-shaped)	15:6:2	8:5:10	18:3:3	9:3:12	0.088[a]
Cause of injury(Slap:Blast)	21:2	21:2	21:3	23:1	0.767[a]
preexisting myringosclerosis (Y:N)	17:6	20:3	18:6	23:1	0.100[a]
Inverted edge (Y:N)	8:15	7:16	6:18	8:16	0.891[a]
Age, years	38.78 ± 10.46	34.48 ± 11.73	33.88 ± 10.21	36.79 ± 13.04	0.441[b]
The duration of injury, days	2.43 ± 1.83	3.35 ± 3.08	5.13 ± 6.92	3.58 ± 4.03	0.322[c]
Hearing level, dB	20.83 ± 2.23	20.17 ± 1.67	19.54 ± 1.25	19.50 ± 1.77	0.091

Continuous variables was expressed using mean ± SD, categorical variable was expressed using n or n(%).
[a] chi-square test/$\chi 2$ test.
[b] One-way Analysis of Variance, ANOVA.
[c] Kruskal-Wallis One-way ANOVA.

Table 3
The healing outcome of FLOX, gelatin sponge patch, spontaneous healing, and myringoplasty groups.

	OFLX group	Gelatin sponge group	Spontaneous healing group	Myringoplasty group	P value
No.	23	23	24	24	
Closure rate, (%)	95.7[a]	82.6	58.3	91.7 a	0.005
Mean closure time, days	13.73 ± 6.14**	15.89 ± 4.95**	48.36 ± 10.37	12.00** # $	< 0.001[b]

The difference was statistically significant between Gelatin sponge and Myringoplasty groups (P = 0.017) (a P value < 0.05 was taken to reflect significance). $ The closure time was 12 days without standard deviation for all the patients in the Myringoplasty group.

[a] The closure rate was significantly different (OFLX vs spontaneous healing, P = 0.003; Myringoplasty vs spontaneous healing, P = 0.008).

[b] Homogeneity test of variance P < 0.05, heterogeneity of variance.

** The mean closure time was significantly different between OFLX, Gelfoam, Myringoplasty group and Spontaneous healing group (P < 0.001).

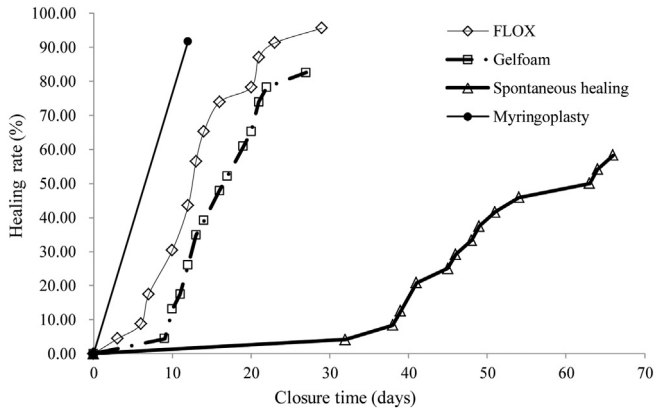

Fig. 2. A Kaplan–Meier curve for tympanic membrane perforation closure times in the treatment groups.

15.89 ± 4.95 days in the gelatin sponge group, 48.36 ± 10.37 days in the spontaneous healing group, and 12 days in the endoscopic myringoplasty group (P < 0.001). The pairwise comparisons revealed significant differences in mean closure times between the OFLX and spontaneous healing groups (P < 0.001), the gelatin sponge and spontaneous healing groups (P < 0.001), the endoscopic myringoplasty and spontaneous healing groups (P < 0.001), and the gelatin sponge and endoscopic myringoplasty groups (P = 0.017). No significant differences in mean closure time were found in the other group comparisons (OFLX vs. gelatin sponge, P = 0.758 and OFLX vs. endoscopic myringoplasty, P = 0.712). A Kaplan-Meier curve for closure time is shown in Fig. 2 according to treatment group. Fig. 3 shows the healing process in patients in the OFLX group. Fig. 4 shows the healing process in patients in the gelatin sponge group.

3.3. Complications and medical costs

The infection rates, hearing gain, and medical costs are shown in Table 4. The infection rates were 8.7% in the OFLX group, 4.3% in the gelatin sponge group, 4.2% in the spontaneous healing group, and 4.2% in the endoscopic myringoplasty group (P = 0.891). Furthermore, the pairwise comparisons between groups revealed no significant differences in infection rates (OFLX vs. gelatin sponge, P = 1.000; OFLX vs. spontaneous healing, P = 0.970; OFLX vs. endoscopic myringoplasty, P = 0.970; gelatin sponge vs. spontaneous healing, P = 1.000; gelatin sponge vs. endoscopic myringoplasty, P = 1.000; and spontaneous healing vs. endoscopic myringoplasty, P = 1.000). With the exception of postoperative ear pain in the endoscopic myringoplasty group, no groups had treatment-related complications (e.g., otomycosis, severe vertigo, or EAC hyperkeratosis). The treatments did not differentially affect the hearing gain. The hearing gains in the OFLX, gelatin sponge, spontaneous healing, and endoscopic myringoplasty groups were 9.30 ± 3.35, 9.35 ± 2.87, 5.58 ± 4.67, and 8.29 ± 3.10 dBs, respectively (P = 0.788). Furthermore, the pairwise comparisons revealed no significant differences in hearing gain between groups (OFLX vs. gelatin sponge, P = 1.000; OFLX vs. spontaneous healing, P = 0.120; OFLX vs. endoscopic myringoplasty, P = 1.000; gelatin sponge vs. spontaneous healing, P = 0.066; gelatin sponge vs. endoscopic myringoplasty, P = 1.000; and spontaneous healing vs. endoscopic myringoplasty, P = 0.648).

The mean medical costs in US dollars were $15.53 ± 3.15 for the OFLX group, $103.64 ± 111.58 for the gelatin sponge group, $11.17 ± 1.33 for the spontaneous healing group, and $715.90 for the endoscopic myringoplasty group (P < 0.001). The pairwise comparisons revealed that the mean closure time was significantly different between groups (OFLX vs. gelatin sponge, P = 0.015; OFLX vs. spontaneous healing, P = 0.030; OFLX vs. endoscopic myringoplasty, P < 0.001; gelatin sponge vs. spontaneous healing, P < 0.001; gelatin sponge vs. endoscopic myringoplasty, P = 0.016; spontaneous healing vs. endoscopic myringoplasty, P < 0.001). The comparison of the four treatments revealed that OFLX had the highest closure rate, a short closure time, and low medical costs.

4. Discussion

The fundamental principles of treatment for traumatic TMP are to reduce the closure time, improve the closure rate, reduce the medical cost, and achieve healing without complications. Traumatic TMPs tend

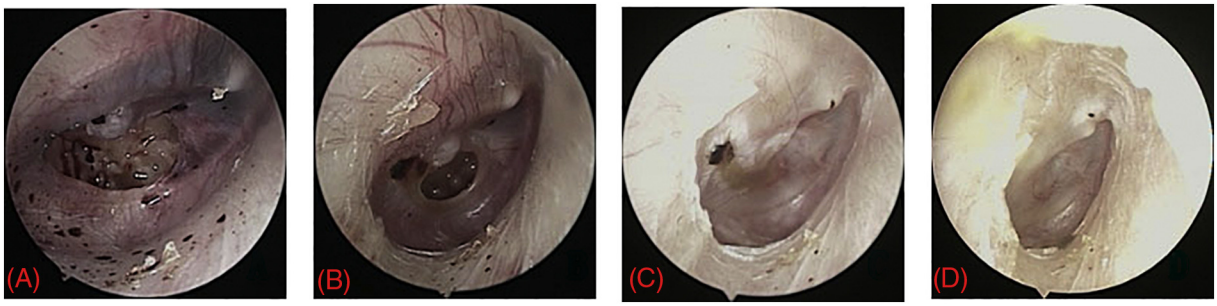

Fig. 3. Extent of tympanic membrane perforation healing at various time points in the OFLX group. (A) Day 4 after perforation, (B–D) Days 5, 12, and 19 after OFLX treatment, respectively.

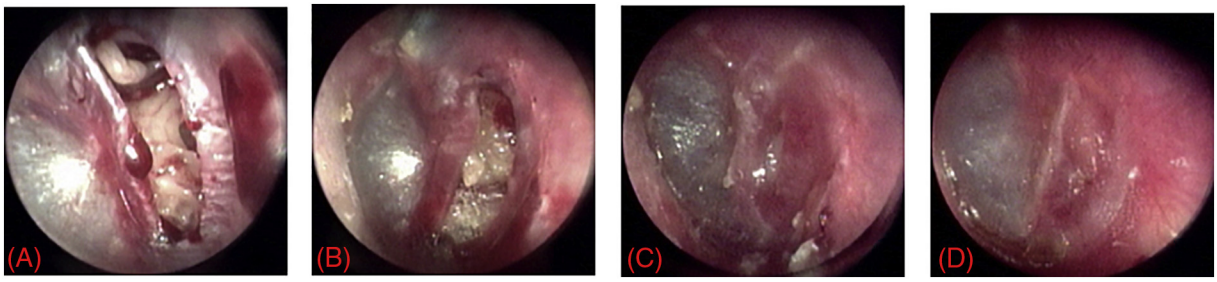

Fig. 4. Extent of tympanic membrane perforation healing at various time points in the gelatin sponge group. (A) Day 2 after perforation (B–D) Days 5, 16, and 22 after gelatin sponge patch, respectively.

to heal spontaneously, and the conservative treatment is to keep the EAC dry until the membrane regenerates spontaneously. However, large and central kidney-shaped perforations are less likely to heal spontaneously [1–3]. Several techniques have been developed to shorten the closure time or improve the closure rate, including patching with biological materials [4,6], topical application of growth factors [12], and myringoplasty and type I tympanoplasty [8–11,13]. OFLX drops and gelatin sponges, which are readily available, simple, and inexpensive (less than $4 USD in China), are commonly used in otology clinics. OFLX drops are used to treat acute and chronic otitis externa and acute and chronic suppurative otitis media, and gelatin sponges are used to pack the EAC and middle ear during surgery. In fact, some otologists report the exclusive use of OFLX or gelatin sponges to repair TMPs [5,6,14,15].

Several studies have shown that gelatin sponge patches facilitate the healing of acute and chronic TMPs and shorten closure time for large perforations [6,14]. A recent series of clinical and experimental studies demonstrated that topical application of OFLX facilitates eardrum healing [5,15,16]. Our finding that a single application of OFLX or a gelatin sponge patch shortened the eardrum healing time compared with that of no treatment (spontaneous healing) is consistent with that of previous studies. Furthermore, the closure rate in the OFLX group was higher than that of the spontaneous healing group and comparable with that of the endoscopic myringoplasty group. In contrast, the closure rate in the gelatin sponge group was not significantly different from that of the spontaneous healing group, which was similar to previous findings showing that biological material patches shortened the closure time, but did not improve the closure rate of large traumatic TMPs [4,6]. Large TMPs may cause tinnitus, aural fullness, and conductive hearing loss and significantly affect quality of life. Some patients require myringoplasty to improve these symptoms; however, given the economic benefits, myringoplasty has been strongly recommended by some otologists in developing countries [7–11]. Thus, although traumatic TMPs tend to heal spontaneously, some otologists continue to perform myringoplasty. The packing material is generally removed from the EAC 10–14 days after myringoplasty. In our study, the EAC packing material was removed 12 days after myringoplasty; thus, the 12-day closure time was relatively fixed in this group. We found that the mean closure times and closure rates did not differ significantly between the OFLX and endoscopic myringoplasty groups, whereas the mean closure time in the myringoplasty group was shorter than those of the gelatin sponge and spontaneous healing groups.

Hearing outcome and complications are important factors to consider. In our study, all of the patients in the myringoplasty group (n = 23) complained of local ear pain, and 11 patients in the OFLX group complained of ear discomfort without ear pain. No complications were reported in the gelatin sponge or spontaneous healing groups. The pairwise comparisons revealed no significant differences in infection rates between groups ($P > 0.0083$). Moreover, the hearing gain at 6 months did not differ significantly between groups. Several previous studies have reported eardrum healing and improved hearing in traumatic TMP cases with normal ossicular chains [4–6,12,15–17]. Therefore, ossicular chain integrity should be assessed in patients whose eardrum healed without improved hearing.

A second factor to consider is medical cost. While most previous studies have investigated the efficacy of various treatments compared with conservative treatment (waiting for spontaneous healing), few have compared the medical costs associated with various treatments for traumatic TMPs. Our study is the first to compare the medical costs associated with the various treatments for large traumatic TMPs. Our cost analysis was restricted to the fee for the first endoscopic examination and the cost of preventative antibiotics because the follow-up endoscopic examination fees and travelling expenses were subsidized by the Science and Technology Fund. We found that the medical costs for the spontaneous healing group were lower than those for the other groups, and that the cost of OFLX treatment was lower than that of the myringoplasty and gelatin sponge procedures. It is likely that the low medical cost in the spontaneous healing group was due to the fact that fees for subsequent follow-up visits were not included in the analysis. We found that most of the large TMPs required a closure time of at least 6 weeks in the spontaneous healing group, whereas the mean closure time in the OFLX group was 2 weeks. Therefore, given follow-up visits to the otology clinic every 2 weeks, the medical costs (including the endoscopic examination fees, travelling expenses, and registration fees) would be higher for the spontaneous healing group than the OFLX group. This is supported by Park et al. [4] who argued that regular follow-up was likely to be more expensive for spontaneous healing because watchful observation requires longer-term follow-up than other procedures. Moreover, patients are at greater risk of middle ear infection when a TMP remains unhealed.

Table 4
The hearing gain and medical costs of OFLX, gelatin sponge patch, spontaneous healing, and myringoplasty groups.

	OFLX group	Gelfoam group	Spontaneous healing group	Myringoplasty group	P value
No.	23	23	24	24	
Infection, %	8.7	4.3	4.2	4.2	0.891
Hearing gain, dB	9.30 ± 3.35	9.35 ± 2.87	5.58 ± 4.67	8.29 ± 3.10	0.788
Mean medical costs, $	15.53 ± 3.15	103.64 ± 111.58	11.17 ± 1.33	715.9 $	< 0.001[a,b]

$ The medical costs is 715.9 USD without standard deviation for all the patients in the Myringoplasty group.
[a] Post Hoc Multiple Comparisons showed significant differences.
[b] Homogeneity test of variance $P < 0.05$, heterogeneity of variance.

Our study had several limitations. First, our sample size was small. Second, the closure time in the myringoplasty group was based on the time to removal of the EAC packing material when, in fact, a few perforations had healed prior to removal of the packing material. Third, our cost analysis was restricted to the first endoscopic examination fee and the cost of the preventative antibiotics.

5. Conclusions

Although the gelatin sponge and myringoplasty treatments significantly shortened the closure time compared with spontaneous healing, the gelatin sponge did not significantly improve the closure rate, and the medical costs of myringoplasty were significantly higher than those of the other treatments. OFLX significantly shortened closure time and improved the closure rate compared with spontaneous healing; moreover, the medical costs associated with OFLX treatment were lower than those calculated for the gelatin sponge and myringoplasty procedures. Finally, the gelatin sponge patch was easily detached from the eardrum and required repeated placement. Myringoplasty required hospitalization and EAC packing, and involves postoperative pain. In contrast, OFLX is frequently used in outpatient settings and is readily available, simple to use, and inexpensive.

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Conflict of interest

No.

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