OTOLOGY

Factors affecting the treatment outcomes of myringoplasty in patients with small tympanic membrane perforations

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Abstract

Purpose Factors affecting the outcomes of myringoplasty have been widely discussed but remain controversial. In this study, we retrospectively analyzed the factors associated with the outcomes of myringoplasty treating small tympanic membrane perforations (defined as those involving less than 30% of the whole eardrum area) in patients with a history of chronic otitis media.

Methods The clinical demographic data, preoperative pure tone audiometry, surgical procedures, and surgical outcomes of patients with small tympanic perforations were analyzed statistically. Overlay myringoplasty was performed in 24 ears (45.27%); Gelfoam® plugs were placed in 29 ears (54.73%). Univariate and multivariate tests among demographic, surgical procedure-related, hearing test-related factors were performed.

Results A total of 53 patients (22 males and 31 females) were enrolled (mean age 54.84 ± 15.51 years). Fourteen patients (26.41%) had the habit of cigarette smoking, 8 (15.09%) had diabetes mellitus, 20 (37.73%) had a past history of chronic otitis media, 5 (9.43%) had a history of grommet insertion, 5 (9.43%) had received radiotherapy in the head and neck region, and 1 (1.88%) had microtia. The success rate for overlay myringoplasty using Silastic® sheets was 54.16%; the success rate for Gelfoam® plugs was 54.16%. On univariate analysis, smoking, older age, and the mean air conduction and bone conduction hearing levels significantly affected the surgical outcomes. Cigarette smoking was the only independent (negative) prognostic factor of surgical success on multivariate analysis (OR = 0.1614, 95% CI: 0.0336–0.7762, $p = 0.0228$).

Conclusion As for surgical repair for the small tympanic membrane perforations with a history of chronic otitis media, age, cigarette smoking, mean air conduction threshold, and mean bone conduction threshold were associated with surgical outcomes; cigarette smoking was the independent predictive prognostic factor for the surgical outcomes.

Keywords Prognostic factor · Silastic® sheet · Gelfoam® plug · Myringoplasty · Tympanic membrane perforations · Chronic otitis media

Abbreviations

COM	Chronic otitis media
PTA	Pure tone audiometry
DM	Diabetes mellitus
AC	Air conduction
BC	Bone conduction
ABG	Air–bone gap

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Introduction

Myringoplasty is a means by which tympanic membrane perforations are repaired in the absence of ossicular reconstruction [1, 2]. Several factors were reported to affect healing of a perforated tympanic membrane [3]. Although many such factors have been analyzed; those affecting success remain controversial and have been inconsistent among studies. The success rate of eardrum repair has also been debated [4, 5]. The reason why there has been such a difference could result from patient selection, non-standardization of the surgical procedures, comorbidities, and differences in study design, follow-up duration, and the definition of successful myringoplasty [1].

Regarding the relationship between the size of perforation and perforation closure rate, contradictory results were

seen in different studies. There were no statistical differences between the success rate of perforation closure and different perforation size groups in several studies [1, 6-10]. However, Konstantinidis et al. reported a significant decline in the success rate when the perforation exceeded 30% of the eardrum [11]. A small perforation as a related factor to the success in myringoplasty was also addressed [3]. A systematic review and meta-analysis demonstrated that a larger perforation generally compromised the success rate with a cutoff value of 3–5 mm and 30% of the eardrum [12]. Here, we focus on perforations less than 30% of the eardrum and retrospectively analyzed factors associated with the surgical outcomes of 53 patients with a history of chronic otitis media (COM). We sought to disclose the factors associated with surgical success.

Materials and methods

Records of patients with tympanic membrane perforations and a history of COM who received myringoplasty at the department of Otolaryngology of Chang Gung Memorial Hospital at Keelung, from August 2002 to August 2018, were reviewed retrospectively. COM is defined as repeated chronic inflammation of the middle ear featuring discharge through a perforated tympanic membrane at least 6 weeks in duration [13]. All patients underwent otologic examinations, including otoscopic observation of the tympanic membrane; the area of perforation was calculated by the magnified views with the aid of a microscope or an endoscope (%). Preoperative examination included detailed medical history taking, physical examination, hematological investigations, and routine laboratory tests. Before surgery, all patients underwent pure tone audiometry (PTA) tests from 250 Hz to 8 kHz and speech audiometry. Written informed consent for surgery was obtained from all patients. Overlay myringoplasty was performed to treat 24 patients, and Gelfoam® plugs were done in 29 patients.

Overlay myringoplasty

The surgery was performed under local topical anesthesia induced by packing of pledgets soaked with lidocaine (2%) onto the ear canal. The edges of the perforation were incised and trimmed in an annular manner using a Rosen needle and alligator forceps. The middle ear space was packed with Gelfoam soaked with ofloxacin. A trimmed Silastic® sheet of an area similar to that of the entire eardrum was overlaid on the drum to allow bridging [14]. The external ear canal was then packed with Gelfoam. The silastic sheet was removed 1–1.5 months later after the Gelfoam was absorbed. The silastic sheet patch creates a platform bridge allowing the middle-ear mucosa to heal across the perforation and also serves as a dressing [15].

Gelfoam® plug procedure

Surgery was performed under local topical anesthesia induced by packing of pledgets soaked in lidocaine (2%) onto the ear. The edges of the perforation were incised and trimmed in an annular manner using a Rosen needle and alligator forceps. A Gelfoam® plug of appropriate size was placed across and inserted into the mid-region of the perforation, assuming the shape of an hourglass of area 1.5- to 2-fold the size of the perforated area [16, 17]. We used a Rosen needle and a suction tube to confirm plug stability.

Otoscopic outpatient department follow-up was performed at 1 week, 3, 6 and 12 months postoperatively. The PTA tests were performed 3 months postoperatively. The patient would be instructed to keep their ear dry. If the tympanic membrane was not entirely healed at postoperative 3 months, the myringoplasty was defined as "failure".

We recruited patients with a history of COM and perforations at least 6 weeks in duration. The exclusion criteria were a tympanic membrane perforation extending to over 30% of the eardrum, active eardrum inflammation or myringitis, active infection of the external auditory canal or middle ear space, mastoid pathology, or malignancy of the temporal bone. To minimize bias due to different surgical procedures, Silastic® sheets and Gelfoam® plugs were the only procedures enrolled in this study. We retrospectively analyzed clinical and demographic data retrieved from chart records, PTA test results, and surgical outcomes.

Statistical analysis

All data were analyzed using MedCalc software (ver. 18.6; MedCalc, Ostend, Belgium). The Kolmogorov–Smirnov test showed that the data were not normally distributed; we thus employed Chi-square test for categorical variables, Mann–Whitney U test to compare continuous variables, and logistic regression to analyze the multivariates. A p value < 0.05 was considered to reflect statistical significance.

Ethics statement

This study was approved by the Institutional Review Board of the Chang Gung Medical Foundation (IRB No. 201801655B0). The data were collected retrospectively and all data were anonymized prior to the data analysis.

Results

Fifty-three patients with tympanic membrane perforations who underwent myringoplasty from August 2002 to August 2018 were enrolled [22 males (41.5%) and 31 females (58.5%), aged 20–83 years (mean age 54.84 ± 15.51 years)]. The demographic and clinical data are shown in Table 1, and included gender, surgical procedures, COM history, smoking status, diabetes mellitus (DM) status, opposite ear perforation status, any history of grommet insertion, age, preoperative PTA data, and the extent perforation (%). Fourteen patients (26.41%) had the habit of cigarette smoking, 8 (15.09%) had DM, 8 (15.09%) had opposite ear perforations, and 5 (9.43%) had a history of grommet insertion.

The overall myringoplasty success rate was 52.83% (28/53). In Table 2, overlay myringoplasty with Silastic® sheets was performed in 24 ears (45.27%) and Gelfoam® plugs were placed in 29 (54.73%). In the univariate analysis, smoking, older age, mean air conduction (AC) and bone conduction (BC) hearing levels were significantly associated with surgical outcomes. The average age of patients in whom repair was successful was 50.53 ± 15.53 years; the average age of patients with failed myringoplasty was 59.68 ± 14.29 years; the difference was significant (OR = 0.9589, 95% CI: 0.9219–0.9974, $p = 0.0256$, Table 2). Patients whose perforations were successfully repaired had an average mean AC of 23.88 ± 17.01 dBnHL. However, the figure for those in whom surgical repair failed was 39.20 ± 22.96 dB (OR = 0.9614, 95% CI: 0.9316–0.9922, $p = 0.0065$, Table 2). Similarly, the average mean BC values for those in whom surgery was successful and unsuccessful were 16.61 ± 12.31 and 28.00 ± 19.48 dBnHL, respectively; the difference was significant (OR = 0.9570, 95% CI: 0.9226–0.9927, $p = 0.0119$, Table 2).

In Table 3, we compared the two surgical procedures. In the overlay myringoplasty group, the success rate was 54.16% (13/24); the figure for the Gelfoam® plug group was 51.72% (15/29). The operation time of overlay myringoplasty was 52.33 ± 22.29 min, and that of Gelfoam® plug was 49.00 ± 17.55 min. The comparison of the clinical and demographic data between these two surgical procedures showed no statistical significance.

In terms of smoking status, among the 28 patients whose perforation successfully repaired, 3 had the habit of smoking (10.71%). However, 11 out of the 25 patients who failed myringoplasty had the habit of smoking (44%). Patients who did not smoke had a better surgical outcome (OR = 0.1527, 95% CI: 0.0364–0.6411, $p = 0.0051$, Table 2). In this study, the amount of cigarettes smoked ranged from 0.5 to 2 packs per day (20 cigarettes in a pack) and the patients had smoked for at least 6 months. All factors significant on univariate analysis were entered into a multivariate logistic regression model. Cigarette smoking was the only factor independently (negatively) prognostic of surgical success (OR = 0.1614, 95% CI: 0.0336–0.7762, $p = 0.0228$, Table 4).

Discussion

The success rate of myringoplasty ranged from 35 to 100% [4, 5]. In the present study, the success rate was 52.83% over a postoperative follow-up period of at least 3 months; only the cases whose area of perforation was less than 30% of the whole drum were enrolled. Fat-patch, paper-patch, and fat-plug myringoplasty, as well as Gelfoam® plug insertion, hyaluronic acid fat graft, perichondrial myringoplasty, and chemical cauterization (using silver nitrate or trichloracetic acid), have been described [7, 11, 12, 16-25]. However, as for small tympanic membrane perforations, only a few researchers addressed the issue [16, 18, 24, 26]. Dursun et al. found no significant difference among paper-patch, fat, and perichondrial myringoplasty in terms of the closure rates of perforations smaller than 3 mm [24]. Overlay myringoplasty and Gelfoam® plug [16] were the procedures we used in this study. The success rate of a Silastic® sheet group was 54.16% and that of a Gelfoam® group was 51.72%. On univariate analysis, the two repair methods did not differ significantly in terms of the clinical and demographic data, including surgical outcomes (Table 3).

Different models of presentation of the size of perforations were provided by several authors. Some authors chose

Table 1 Clinical demographics of all patients ($N = 53$)

Characteristic	N (%)
Gender	
Male	22 (41.51)
Female	31 (58.49)
Surgical procedure	
Overlay myringoplasty	24 (45.27)
Gelfoam® plug	29 (54.73)
Chronic otitis media	53 (100.00)
Smokers	14 (26.41)
Diabetes mellitus	8 (15.09)
Opposite ear perforation	8 (15.09)
History of grommet insertion	5 (19.43)
Age, years (SD)	54.84 ± 15.51
Mean air conduction, dB (SD)	28.30 ± 21.30
Mean bone conduction, dB (SD)	21.20 ± 16.77
Perforation, % (SD)	14.81 ± 15.96

Overlay myringoplasty overlay myringoplasty using a Silastic® sheet, *SD* standard deviation, *Mean* average pure tone audiometry (PTA) at 500, 1000, 2000, 4000 Hz, *Air conduction* air conduction on PTA, *Bone conduction* bone conduction on PTA, *dB* decibels of normal hearing level

Table 2 Univariate analysis of surgical outcomes in patients undergoing myringoplasty to treat small tympanic membrane perforations

Variable	Postoperative success		Univariate analysis		
	Yes	No	OR	95% CI	p value
Gender					0.7281
Male	11	11	1.0000		
Female	17	14	0.8235	0.2755–2.4615	
Surgical procedure					0.8592
Overlay myringoplasty	13	11	1.0000		
Gelfoam®plug	15	14	1.1030	0.3731–3.2614	
Smoker					**0.0051***
No	25	14	1.0000		
Yes	03	11	0.1527	0.0364–0.6411	
Diabetes mellitus					0.3449
No	25	20	1.0000		
Yes	03	05	0.4800	0.1021–2.2557	
Opposite ear perforation					0.5498
No	24	21	1.0000		
Yes	04	04	1.5942	0.3397–7.4820	
History of grommet insertion					0.7374
No	25	23	1.0000		
Yes	03	02	1.3800	0.2113–9.0142	
Age, years	50.53 ± 15.53	59.68 ± 14.29	0.9589	0.9219–0.9974	**0.0256***
Mean air conduction, dB	23.88 ± 17.01	39.20 ± 22.96	0.9614	0.9316–0.9922	**0.0065***
Mean bone conduction, dB	16.61 ± 12.31	28.00 ± 19.48	0.9570	0.9226–0.9927	**0.0119***
Perforation, %	14.28 ± 05.56	15.40 ± 06.44	0.9684	0.8829–1.0621	0.3398
Operation time, minutes	49.85 ± 21.63	52.13 ± 12.51	0.9942	0.9630–1.0264	0.7194

Overlay myringoplasty overlay myringoplasty using a Silastic® sheet, *Mean* average pure tone audiometry (PTA) at 500, 1000, 2000, 4000 Hz, *Air conduction* air conduction on PTA, *Bone conduction* bone conduction on PTA, *dB* decibels of normal hearing level, *OR* odds ratio, *CI* confidence intervals

*$p < 0.05$. Significant differences are shown in bold

the actual size of perforations in millimeter or centimeter [12, 16, 18, 21, 26, 27] and some used percentage of the perforations [6, 7, 10, 11, 19, 20, 23, 28, 29]. Although there is usually no more change in the area of tympanic membranes in adults, the area of everyone's ear drums is not the same. We think that the percentage of perforation area which equals to the perforation area divided by the whole drum area can more represent the relative dimensions of perforations than the absolute value. It is difficult to measure the size of the perforation and whole drum, so we measured the size with the magnification images with a microscope or an endoscope, more likely the way Konstatinidis et al. did [11].

The role of the perforation size affecting surgical outcomes remains controversial. Some authors considered that size did not affect the outcome [8, 10, 30]. However, Onal et al. considered that surgical failures might be expected for large perforations associated with difficulties in membrane vascularization and epithelialization, especially for perforations exceeding 50% of the eardrum [3]. The perforations of the above-mentioned studies were not limited to small perforations [3, 8, 10, 30]. Konstantinidis et al. performed fat graft myringoplasty in 82 patients with tympanic membrane perforations of less than 50% of the eardrum; they found the fat graft myringoplasty achieved the highest success rate in perforations smaller than 30% of the pars tensa [11]. Dursun et al. [24] recruited patients with perforations less than 3 mm and they found no significant differences in success rates regarding the perforation size among three different surgical techniques, which was consistent with our findings. In the present study, the ratio of the perforation relative to

Table 3 The comparison of clinical data between overlay myringoplasty and Gelfoam® plug

Variables	Overlay myringoplasty	Gelfoam® plug	p value
Gender	24	29	0.9831
Male	10	12	
Female	14	17	
Smoker			0.8317
No	18	21	
Yes	6	8	
Diabetes mellitus			0.7711
No	20	25	
Yes	4	4	
Opposite ear perforation			0.9247
No	21	24	
Yes	3	5	
History of grommet insertion			0.8031
No	22	26	
Yes	2	3	
Age, years	57.29 ± 15.49	52.82 ± 15.51	0.4316
Mean air conduction, dB	29.06 ± 24.13	32.80 ± 18.88	0.1978
Mean bone conduction, dB	21.25 ± 16.91	22.58 ± 17.22	0.9287
Perforation, %	16.25 ± 17.10	13.62 ± 14.60	0.2214
Operation time, minutes	52.33 ± 22.29	49.00 ± 17.55	0.6966
Success rate, %	54.16%	51.72%	

Mean average pure tone audiometry (PTA) at 500, 1000, 2000, 4000 Hz, *dB* decibels of normal hearing level, *Air conduction* air conduction on PTA, *Bone conduction* bone conduction on PTA

Table 4 Multivariate analysis of patients undergoing myringoplasty to treat small tympanic membrane perforations

Variable	Coefficient	Standard error	Wald statistic	Odds ratio	95% CI	p value
Smoking	− 1.8237	0.8012	5.1808	0.1614	0.0336–0.7762	**0.0228***
Age	− 0.0235	0.0292	0.6483	0.9768	0.9224–1.0343	0.4207
Mean air conduction	− 0.0498	0.0423	1.3905	0.9513	0.8756–1.0336	0.2383
Mean bone conduction	− 0.0398	0.0546	0.5314	1.0407	0.9349–1.1583	0.4660
Constant	− 2.5464	1.3736	3.4364			0.0638

Mean average pure tone audiometry (PTA) at 500, 1000, 2000, 4000 Hz, *Air conduction* air conduction on PTA, *Bone conduction* bone conduction on PTA, *CI* confidence intervals

*$*p < 0.05$. Significant differences are shown in bold

the whole drum was $14.81 \pm 5.96\%$ (range 10–30%). In the successful group, mean perforation percentage was $14.28 \pm 5.56\%$, and the failed group was $15.40 \pm 6.44\%$; the size of perforation was found to be not statistically associated with surgical success (Table 2).

In the univariate analysis, cigarette smoking, age, mean air conduction threshold and mean bone conduction threshold significantly affected the success. In previous studies, age was not a significant prognostic factor after stratification [1, 3]. Onal et al. divided patients into < 20, 20–29, 30–39, and ≥ 40 years age groups [3]. Dangol et al. divided patients into those aged < 18 and ≥ 18 years [1]. The classification models of the both studies [1, 3] differed from

ours. In the present study, the average age of the successful and failed groups was 50.25 ± 16.14 and 59.68 ± 14.29 years, respectively; we compared the ages of these 2 groups and the difference was significant (Table 2). Thus, older age may be associated with poorer outcomes but age per se is not a prognostic predictive factor for surgical success.

Postoperative air–bone gap (ABG) improvement was almost demonstrated in the studies of various surgical procedures, including fat myringoplasty, butterfly cartilage myringoplasty, hyaluronic acid fat graft myringoplasty, paper-patch myringoplasty, and so on [1, 3, 4, 6, 11, 18, 20, 24, 27]. As for AC thresholds and ABG improvement among the different size groups, patients with smaller perforations

had significantly better postoperative results ($p < 0.05$) [6]. Concerning the preoperative hearing status, including mean BC and AC thresholds, these factors have not been studied as ones related to the surgical prognosis yet in the literature. In the present study, the mean BC threshold was 28.00 ± 19.48 dBnHL in the failed group and 16.61 ± 12.31 dBnHL in the success group; the mean AC threshold was 39.20 ± 22.96 and 23.88 ± 17.01 dBnHL, respectively. Better preoperative BC and AC hearing status were associated with better surgical outcomes ($p < 0.05$, Table 2). However, the mean BC and AC thresholds were not significantly prognostic in multivariate logistic regression (Table 4).

Golz et al. found that the myringoplasty success rates for those with perforations less than 3 mm, 3–5 mm, and more than 5 mm were 63.2, 43.5, and 12.5%, respectively. The final closure rate of small- and medium-sized perforations (< 5 mm) was 55.7%. The causes of perforations were postinflammatory in 61 patients, previous unsuccessful myringoplasty in 8, ventilation tube extrusion in 5, and trauma in 3 [31]. The majority of the etiology of the perforations were postinflammatory, which was similar to the postinflammatory nature related to the history of COM of the present study, and the success rate of the cited work was similar to ours (52.83%). The repair rates of tympanic membrane perforations caused by grommet removal or extrusion vary from 0.5 to 3% [32]. In one study, investigating the rate of persistent perforations following grommet extrusion or removal in 210 ears was 0%; multiple grommet insertion did not affect this value [32]. Traumatic tympanic membrane perforations are not rare in primary otolaryngological practice. In a retrospective study analyzing the clinical outcomes of patients with traumatic perforations, 56 of 60 patients recovered spontaneously (93.3%) [33]. Compared with the etiology of postinflammation, the myringoplasty closure rate of perforations caused by grommet extrusion or trauma is higher. The presence of preoperative inflammation of the middle ear mucosa might carry a risk related to the development of postoperative seromucous otitis media, a retraction pocket, or a perforated ear drum [30], explaining why repair of the postinflammatory middle ear mucosa is associated with a lower success rate than perforations of other etiology.

The effect of smoking on the surgical outcomes of myringoplasty remains controversial [8]. We found that smoking was the only significant factor in both univariate and multivariate analyses (Tables 2 and 4); the success rate of myringoplasty in non-smokers was significantly higher than that in smokers, i.e., 64.10% (25/39) and 21.42% (3/14), respectively, in agreement with the findings of Onal et al., albeit that they did not focus on small perforations and performed myringoplasty using the temporalis fascia [3] instead of the procedures in the present study. In the cited study, the success rate was about 78.7% for non-smokers and 47.7% for smokers ($p = 0.008$). However, other studies reported that smoking did not compromise outcomes of myringoplasty [1, 8, 10].

In the previous work, cigarette smoking altered mucus volume and viscosity and damaged the mucociliary function of the middle ear mucosa and Eüstachian tube [34]. Furthermore, nicotine compromises vascularization by triggering cutaneous vasoconstriction and thrombosis development. Inhalation of carbon monoxide during smoking decreases the oxygen-carrying capacity of red blood cells, compromising the oxygenation required for membrane healing [35]. Smoking has been reported as chemically irritating, immunosuppressive, and an adverse factor against infectious agents. Therefore, smoking tended to result in failure of myringoplasty [1, 3].

Limitations

There were some limitations in our study. The retrospective study gave rise to an insufficient data collection and a high attrition rate. Moreover, female patients occupied the majority of this study population, which could be a selection bias but commonly met in a retrospective study. Prospective, randomized controlled studies are warranted to elucidate the factors and diminish such biases.

Conclusion

Myringoplasty is a procedure suitable for repairing the small tympanic membrane perforations. Surgeons should know and pay attention to the factors which affect the surgical outcomes. In this study, age, mean air conduction threshold, and mean bone conduction threshold were significant factors associated with surgical outcomes in the univariate analysis. As for surgical repair for the small tympanic membrane perforations with a history of COM, cigarette smoking was an independent prognostic predictive factor for surgical success.

Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

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