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Clinical Report

Myringoplasty Quality Control Is Necessary: Comparison of Surgical Results of Two Consecutive Series in A Single Institution

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OBJECTIVE: The aim of this study was to evaluate and compare myringoplasty results from two different consecutive series conducted at the Kuopio University Hospital during a four-decade period.

MATERIALS and METHODS: We reviewed 315 patients (a total of 338 ears) who underwent myringoplasty at Kuopio University Hospital between the years 1986 and 2012. The results from this series were compared with those form a previously published series of 404 patients who underwent myringoplasty between 1970 and 1985 at the same institution.

RESULTS: Myringoplasty was considered to be successful whenever the tympanic membrane remained closed without atelectasis. The results were analyzed at the 1- and 3-year follow-up. The overall success rate after 1 year was 82.8% compared with 88% in the previous series. The success rate after 3 years was 87.4%. The best closure rate after 1 year (85.7%) was achieved with fascia grafts (n=272) and perichondrium (85.7%, n=14). The closure rate of 61.9% with the perichondrium/cartilage graft (n=21) and 71.0% with the fat graft (n=31) was statistically significantly lower ($p<0.05$) compared with that with the fascia graft. The postoperative air-bone gap (0.5–4 kHz) was <10 $dB_{(HL)}$ in 56.2% and <20 $dB_{(HL)}$ in 79.6% cases compared with 61% and 87%, respectively, in previous series.

CONCLUSION: Myringoplasty is a safe procedure with a reasonably high success rate. We observed a slight deterioration in the overall results compared with the previous series. This study highlights the importance of systematic quality control and the results and the need for follow-up of the learning curve after the introduction of new surgical techniques and materials.

KEYWORDS: Tympanic membrane, myringoplasty, perforation, tympanoplasty type 1

INTRODUCTION

The aim of myringoplasty or tympanoplasty type I is to close a perforation in the tympanic membrane. The success rate, defined as complete closure of the tympanic membrane, is between 64% and 95% [1-25]. The literature describes some prognostic factors that may decrease the success rate, such as a perforation in the contralateral ear [4, 5, 7, 16, 17], large perforation surface area [6, 11-14, 16, 17], perforations caused by welding sparks [17], limited experience of the surgeon [2, 17, 23], and pediatric patients [2, 6].

At our institution, temporalis muscle fascia is most commonly used. The perichondrium and cartilage were introduced more recently for large perforations and for revision surgeries. Fat grafts were exclusively used only for small central perforations.

The purpose of this retrospective study was to review the success rate of myringoplasty from the past 26 years (1986-2012) and to compare the present results to a series (1970-1985) from our institution published earlier by Vartiainen and Nuutinen [23] in 1993. Prognostic factors were evaluated, particularly whether there were any differences between the graft materials.

MATERIALS and METHODS

We collected data from medical reports of 315 patients who underwent myringoplasty at Kuopio University Hospital between 1986 and 2012. Patients with an additional ossicular chain reconstruction or chronic mastoiditis were excluded from the study. It

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was possible to follow-up all patients for at least 1 year. There were 114 children and adolescents whose age was ≤17 years at the time of the surgery. In 23 patients, both ears were operated on during two different sessions. In these cases, the ear with poorer hearing and/or larger perforation was selected for the first surgery. The mean follow-up time was 3 years and 2 months (range, 1 -12 years, 3 months). Each operated ear was analyzed as a separate case; therefore, a total of 338 operated ears were included in this study. All patients were examined by an ear, nose, and throat specialist preoperatively, and otomicroscopy and audiogram were included. A total of 284 surgeries were performed by a senior specialist and 54 surgeries were performed by a resident under supervision.

Three hundred thirty-two surgeries were performed on completely dry ears, in accordance to our clinical protocol. In six cases, however, inflammation of the middle ear mucosa was observed intraoperatively. The etiology of the perforation was recorded as was the size and the location of the perforation. The size of the perforation was classified as small when it was less than half of the tympanic membrane surface. Accordingly, large perforations affected over half of the tympanic membrane. The perforation was considered central if it occupied only the pars tensa. When the perforation reached the fibrous annulus, the perforation was classified as marginal. The status of the opposite ear was also recorded. Classification was performed according to the study by Vartiainen et al. [23] to obtain comparable results.

Two hundred twenty-four procedures were performed under general anesthesia, including those performed on pediatric patients. One hundred fourteen surgeries were performed under local anesthesia and sedation. The mean age of the patients was 33 (range, 4-78 years; median age, 28) years at the time of surgery. Three different graft materials were used. The temporal muscle fascia was most commonly utilized in 272 ears. Fat grafts were used in 31 ears. The perichondrium was used in 35 cases with additional cartilage reinforcement in 21 of these ears. The latter was preoperatively considered with the highest (previous ear surgery, adhesion, large anterior, or marginal perforation) risk for re-perforation, atelectasis, or need of a stronger graft support. The grafts were inserted using the underlay technique, either using the postaural or endaural approach. Gelfoam™ (Pharmacia & Upjohn Company, New York, NY, USA, or Spongostan™ Ferrosan, Copenhagen, Denmark) was used in the tympanum to support the graft. Fat grafts were applied through a transcanal approach with no supportive material intratympanally. In three of the ears, fat grafts were operated on through a retroauricular approach.

The main outcome measure was closure of the tympanic membrane; the surgery was considered successful if the tympanic membrane was intact and mobile at the 12-month follow-up. A closed but atelectatic tympanic membrane was considered as a failure. Audiometry was performed preoperatively and 12 months postoperatively. The hearing results were analyzed as mean air-bone gaps (ABG) in the 0.5-1-2-4 kHz range. The same measures were evaluated in patients who could be followed for up to ≥3 years.

Data were analyzed with Statistical Packages for the Social Sciences (SPSS) for Windows version 17.0 (SPSS Inc., Chicago, IL, USA). Chi-squared test, t-test, and the Mann-Whitney U-test were used for statistical analysis to compare results from the different groups. Institutional permission was granted, and because of the retrospective nature of this study, no ethical committee statement was required.

RESULTS

In 280 (82.8%) ears, the tympanic membrane remained closed and mobile at the 12-month follow-up assessment. The success rate in pediatric (<18 years, n=114) patients was slightly better than that in adults (85.1% vs. 81.7%), but the difference was statistically insignificant (p>0.05).

Evaluation regarding different graft materials indicated that the best success rate (85.7%) was achieved with fascia. This was also the largest group comprising 272 of the ears (Table 1). The success rate with perichondrium was also 85.7%, although this was the smallest group including only 14 ears. The closure rate with the perichondrium/cartilage graft (n=21) and with the fat graft (n=31) was 61.9% and 71.0%, respectively. Lower success rates for both alternative grafts were statistically significant (Table 1). Within the perichondrium group, grafts with cartilage reinforcement had a success rate of 61.9% (n=21) and perichondrium without reinforcement had a success rate of 85.7% (n=14). This difference, however, was not statistically significant.

Chronic otitis media (43%) and post ventilation tube complication (29.5%) were the most common etiologies. Trauma, welding spark, myringotomy, and unknown etiology accounted for 27.5% cases (Table 2). There were no statistically significant differences in success rates between perforations with different etiologies. Two hundred eighty-three ears had small perforations, and in 55 ears, perforation was large. The success rate for small perforations was 83%, and for large perforations, it was 82% (p=0.479). In 18 (78%) out of the 23 cases with bilateral perforation, at 12 months, the surgery had been successful (two cases were operated on the unilateral side only). Compared with patients with a normal contralateral tympanic membrane, the difference was not statistically significant (p=0.059).

Table 1. Different graft materials and a success rate for closing the perforation during myringoplasty (n=338 ears)

Graft	Cases	Success Rate (%)	Statistical Significance
Fascia	272	233 (85.7)	
Pericondrium	35	25 (71.4)	p<0.03
Fat	31	22 (71.0)	p<0.034
Total	338	280 (82.8)	

The p-value shows a statistically significant difference when the success rate of pericondrium or fat grafts is compared with fascia grafts.

Table 2. Etiology of perforation and a success rate to close the perforation using myringoplasty (n=338 ears)

Etiology of perforation	Cases	Success rate (%)
Infection	145	120 (82.8)
Ventilation tube	100	83 (83.0)
Trauma	27	22 (81.5)
Paracentesis	9	7 (77.8)
Welding spark	13	10 (76.9)
Unknown	44	38 (86.4)
Total	338	280 (82.8)

Table 3. Mean preoperative and 1-year postoperative air-bone gaps in myringoplasty (n=338 ears)

	Mean PreOp ABG (dB)	Mean PostOp ABG* (dB)	ABG<10 dB	ABG <20dB	ABG <30dB	ABG>30 dB
All cases	14.8	9.2	190	79	23	10
Intact tympanic membrane	14.6	8.1	170	55	17	6
Re-perforation	15.4	14.1	20	24	6	4
Small perforation	13.5	8.6	172	58	16	9
Large perforation	21.0	12.2	18	21	7	1

*ABG at the 1-year follow-up
In 36 cases, there were audiograms missing at the 1-year follow-up

Most of the surgeries were performed by senior surgeons, who achieved slightly better results in closure of tympanic membrane than resident surgeons (success rate of 83.5% in the senior group and 79.6% in the resident group). The difference, however, was not statistically significant (p=0.495).

In our series, there were six ears that were moist at the time of the surgery, and in five cases, the closure was successful. There were 49 dry re-perforations and two moist re-perforations 12 months postoperatively. Those two ears had been dry for at least 2 years preoperatively. An atelectatic tympanic membrane developed in five ears.

The mean ABG 1 year postoperatively was 9.2 $dB_{(HL)}$ compared with the mean ABG preoperatively of 14.8 dB, and the difference was statistically significant (p<0.001). Closure of ABG within 10 dB and 20 dB was observed in 56.2% and 79.6%, respectively. In 10 ears, postoperative ABG was ≥30 dB, and the mean preoperative ABG was 36 dB. In these 10 ears, the mean ABG postoperatively was 39.2 dB. Myringoplasty with temporal muscle fascia resulted in a closure of ABG ≤10 dB and ≤20 dB in 54.4% and 79.8% of the ears, respectively. In cases with intact tympanic membrane, the mean ABG postoperatively was 8.1 dB, and in cases with postoperative re-perforation, it was 14.1 dB (p<0.001). The mean postoperative ABG in large perforations was 12.2 dB and for small perforations was 8.6 dB. Hearing results with fat grafts were similar to those with fascia grafts, and there was no statistical difference between these groups. Surgery-related deterioration of hearing was not observed in this study (Table 3).

Thirty-two ears with postoperative dry perforation required re-operation. Twenty-one of these re-operations were successful (65.6%). In the remaining 11 cases, 10 ears developed a dry and 1 ear developed a moist perforation postoperatively. Twenty of these re-operated ears had a follow-up of >3 years, and 15 of these ears had an intact tympanic membrane (75%).

We did not observe any severe surgery-related complications, such as facial nerve palsy or sensorineural hearing impairment. In 41 ears (12.1%), minor complications were noted. The most common minor complication was granulation tissue on the tympanic membrane or on the adjacent ear canal skin. Minor wound infection occurred in 15 cases. All of these complications were successfully treated with topical or systemic antibiotics or even by mechanical removal of the granulations.

In patients who had a minimum 3-year follow-up, the success rate was 87.4% (153/175). There were 77.7% central perforations, and 85.7% of the perforations were small. Statistic tests were performed concerning etiology, perforation size, and whether the perforation was central or marginal, but no statistically significant difference was found (p>0.05). In this group, there were two surgeries conducted with fat grafts and one with perichondrium. There was one surgery conducted with perichondrium/cartilage graft. One fat graft surgery had dry perforation at the 1-year follow-up.

There were four perforations at the 1-year follow-up. In one ear, the tympanostomy tube was inserted postoperatively because of serous effusion. One ear had an intact and mobile tympanic membrane at the 1-year follow-up, but was observed to be atelectatic 2 years after surgery.

The mean ABG in the >3-year-follow-up group was 9.0 dB at the end of the follow-up. In this group, the mean ABG was 9.5 dB at the 1-year follow-up audiogram. Changes in ABG were not statistically significant (p=0.487) between the 1- and 3-year follow-up groups.

DISCUSSION

We compared results of myringoplasty (tympanoplasty type I) from 1986 to 2012 with those from a previously published series from our institution and found a slight but statistically significant deterioration of the overall myringoplasty success rate over the past four decades (p=0.044).

The success rate with fascia grafts, however, was equal in the present and previous [23] study (85.7% and 88.7%, respectively; p=0.256). The overall lower results were related to fat and cartilage grafts. The results with fat grafts were significantly poorer than those with fascia grafts (71% vs. 85.7%). The poor results with the fat plug technique were surprising because it was applied only to cases with small and uncomplicated perforations in which a favorable outcome was expected. A significantly better fat graft uptake (between 76% and 91%) was reported in the literature [1, 8, 11, 15, 18, 19, 22]. According to our own results, the fat plug technique is not used anymore at our institution.

The cartilage graft has been gradually introduced at our institution after 2005 for patients with expected poor prognosis (i.e., large perforations, suspected middle ear pathology, and impaired middle ear ventilation). Results with cartilage grafts were also significantly poorer than those with the fascia graft (71.4% vs. 85.7%). The results with perichondrium and cartilage reinforcement succeeded in 13 out of 21 (61.9%) cases. Possible explanations for the lower-than-average results with the cartilage and perichondrium/cartilage graft may be that this technique was used in perforation with lower prognosis and

Table 4. Success rate (%) of perforation closure and hearing result (air-bone gaps) in the present study compared with those in previous studies using the same classification

	Present study	Vartiainen et al. (1993)	Nardone et al. (2011)	Denoylle et al. (1999)	Tek et al. (2012)
Number of cases	338	404	1040	231	77
Perforation closure rate (%)	82.8%	88%	78%	93.5%	76.6%
Air-bone gap<10 dB	56%	61%	68.5%	67.5%	50.8%

because of the novelty of the graft material to the surgeons. The perichondrium graft was also applied to high-risk cases but showed identical results to the fascia graft. Nardone et al. [16] reported that the use of the plain perichondrium as a graft material had a significant negative impact on tympanic membrane closure, but the cartilage had positive correlation to closure rates. Tek et al. [21] had better outcome with cartilage reinforcement vs. fascia (86.5% vs. 67.5%) in high-risk perforations. In a prospective study, Young et al. [25] compared fascia and cartilage myringoplasty and found no significant difference. The closure rate with the fascia and cartilage was 84.2% and 80%, respectively. Altogether, the most recent literature suggests at least comparable results for cartilage myringoplasty as for fascia grafts. Therefore, other aspects must have influenced our results.

We changed the follow-up routine at our institution in the beginning of the year 2000 to 1 year postoperatively from a formerly much longer follow-up. Thus, 157 cases had a follow-up at 1 year and no further.

In the longer follow-up group, there were 3% cases with non-satisfactory results that occurred after the 1-year follow-up. This is quite a small number (n=6) and does not implicate that a follow-up for >1 year is necessary.

Perforation of the opposite ear has been reported as an impairing prognostic factor in the literature [4, 5, 7, 16, 17]. In our series too, the presence of a perforation in the contralateral ear decreased the success rate (72% vs. 85%). The difference, however, was not statistically significant (p=0.093). It appears that perforation of the opposite ear may be an indirect sign of possible systemic issues, such as mucosal disease/inflammation or an impaired middle ear aeration function, which may affect the healing process after myringoplasty.

Other previously reported prognostic factors were not found to be statistically significant in the present study. The success rate with perforations caused by welding sparks was 76.9% (10/13), which is slightly lower than the overall success rate. Vartiainen and Nuutinen [23] had a success rate of 55.6% (5/9) with welding spark perforations and they were found to impair the prognosis. The number of these cases is rather small in both studies, and they are, therefore, inconclusive. According to a study by Westerberg et al. [24], perforation caused by a welding spark was not found to be of significance for successful myringoplasty (although the number of cases was also relatively small). The hearing results in this group were slightly better than those in perforations caused by other reasons. In the previous series, the hearing results were slightly poorer in the welding spark group.

The difference between senior and resident surgeons was not significant in the present study in contrast to the previous study in which senior surgeons achieved significantly better outcomes. Two hundred eighty-four surgeries were performed by senior surgeons and 54 were performed by residents. A lower number of surgeries performed by residents might explain the difference in results.

In children and adolescents (age, <18 years), the results were slightly better than those in adult patients. Generally, young age is considered to be a poor prognostic factor [2, 5, 6], but this could not be substantiated by our study.

Postoperative ABG improvement was statistically significant. Similar findings have also been reported in the literature [2, 4, 6, 16, 26]. The results (the closure rate and the hearing results) of the present study are compared with those of the previous studies in Table 4. In addition, it seems that hearing remains quite stable at a longer follow-up postoperatively.

Pfammatter et al. [26] found that myringoplasty in large perforations yielded lower postoperative hearing results; accordingly, in our study, postoperative ABG was worse in large perforations compared with that in small perforations; the difference, however, was not statistically significant. In our study, cases with re-perforation had a poorer postoperative ABG. Long-term hearing results remained unchanged, although many patients were not followed up after 1 year.

The limitations of this study are due to its retrospective and descriptive nature. As all ear surgeries in our hospital district are performed at our clinic, the present study describes long-term results from a single institution without bias for selection of patients. Because the annual number of ear surgical procedures is limited, otologic procedures are mainly conducted by two senior surgeons at any given time. In this way, the surgical quality can be maintained as well as surgical training can be performed. Another strength of our study is that there were no dropouts at the 1-year follow-up. The fascia graft technique is still the standard procedure for myringoplasty at our institution, and accordingly, it has maintained consistently favorable outcomes for the past four decades. With the introduction of new techniques, however, the results are lower at the beginning as there is a learning curve to overcome, which is well highlighted in this study with respect to the cartilage graft technique.

CONCLUSION

Myringoplasty is a safe procedure with a considerably high healing rate. Results of the traditional fascia graft myringoplasty remain consistent within the four-decade period at our institution. A significantly lower success rate was observed for the cartilage and fat plug techniques. Perichondrium and perichondrium/cartilage grafts were introduced more recently for high-risk perforations. The results with the perichondrium graft in these high-risk perforations were equal to those with fascia grafts. However, with respect to perichondrium/cartilage grafts, the closure rate was much lower than that reported in the literature. Because of the novelty of the graft material, there

was a learning curve associated with different cartilage myringoplasty techniques, which most probably impaired postoperative results. This study denotes importance of systematic quality control in evaluating traditional and new surgical techniques.

Ethics Committee Approval: Institutional approval was received for this study from Kuopio University Hospital (Approval No: 335/2015).

Informed Consent: Informed consent is not necessary due to the retrospective nature of this study.

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