Effect of Middle Ear Gelfoam on Hearing and Healing Process after Tympanoplasty: A Prospective Randomized Case-Control Study

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Abstract

Introduction: This prospective randomized case-control study was performed to compare the surgical outcomes of our swing-door overlay tympanoplasty with or without absorbable gelatine sponge (AGS, gelfoam) packing in the middle ear cavity, according to the surgical procedure. Subjects and Methods: Fifty-seven patients who underwent swing-door overlay tympanoplasty by a single surgeon were enrolled in the study. The data of 30 patients of the gelfoam-packing group (GPG) and 27 patients of the non-gelfoam-packing group (NGPG) were prospectively collected and compared. Results: Closure of the tympanic membrane was found to be successful in all patients at postoperative 3 months evaluation. NGPG showed a statistically better healing process compared to GPG; earlier epithelialization and less fascia edema in NGPG than in GPG (P<0.05). The air-bone gap (ABG) measured at postoperative 1 and 2 months was smaller in NGPG than GPG, although there were no statistical differences. Conclusion: Swing-door overlay tympanoplasty showed good surgical outcomes in terms of graft uptake rate regardless of AGS packing. However, this study revealed earlier healing process and faster recovery of ABG in NGPG, thereby indicating that the gelfoam in the middle ear may interfere with both hearing recovery and the healing process of neodrum. Non-gelfoam packing in the middle ear cavity appeared to be superior to gelfoam packing in swing-door overlay tympanoplasty.

INTRODUCTION

Tympanoplasty is a common and well known surgical procedure in the otologic area. Numerous factors affecting the final surgical outcomes include the graft materials, causes of perforation, and age¹. However, little attention has been paid to middle ear packing material(MEPM)s and their effects on the graft materials, ossicular changes, hearing, etc in the success of tympanoplasty. Absorbable gelatine sponge (AGS, gelfoam) was introduced by Correl and Wise as an absorbable haemostatic agent in 1945, and thas become the most commonly used MEMP in clinical practice. This material established its place as a scaffolding substance to support the grafting material and ossicular chains during tympanoplasty².

Swing-door overlay tympanoplasty, which has been published recently with excellent surgical results, is a modified technique of classic overlay tympanoplasty³. In this surgical technique, clearly visible annulus plays a role as a splint and prevent falling of the graft material. It was conjectured that the tympanoplasty

without gelfoam packing in the middle ear may facilitate the healing process of the neodrum as well as hearing recovery.

This prospective randomized case-control study was performed to compare the surgical outcomes of swingdoor overlay tympanoplasty with or without gelfoam packing in the middle ear in patients with chronic otitis media(COM), according to the surgical procedure.

SUBJECTS AND METHODS

Subjects

Fifty-seven patients who underwent swing-door overlay tympanoplasty by one surgeon (S.N.P) in the department of otorhinolaryngology-head and neck surgery of tertiary referral centre between June 2015 and May 2016 were enrolled in this study. Patients who had cholesteatoma and previous middle ear surgery history were excluded. They were randomly divided into the gelfoam-packing group(GPG) and the non-gelfoampacking group(NGPG). The data of 30 patients of GPG and 27 patients of NGPG were prospectively collected and compared. All patients visited the outpatient department every month for up to postoperative 3 months.

Physical and Audiologic Evaluations

Postoperative healing status of the neodrum with perforation, retraction, lateralization, or anterior wall blunting was considered as surgical failure, whereas complete healing of the neodrum without perforation, free mobile drum without atelectasis, and keeping the anteroinferior tympanomeatal recess angle almost acute without blunting as shown under a microscope were designated as the success of healing. Post-operative edema of the fascia and degree of neodrum epithelization were observed by a 0-degree otoendoscope (Karl Storz, Tuttlingen, Germany). With the group blinded, two otology specialists quantified the degree of edema and epithelization of the neodrum. Out of the total neodrum width, the epithelized area was scored as percent and the edema rate was measured in scores from 0 to 3 points; 0 as none, 1 as mild, 2 as moderate, and 3 as severe edema. Also, changes in the air-bone gap (ABG) were conducted with pure-tone audiometry (PTA) of 0.5, 1, 2, and 4 kHz for evaluating audiologic outcome.

Surgical procedure

All patients underwent swing-door overlay tympanoplasty³. Under general anaesthesia, the temporalis muscle facia harvested as usual. After reaching the meatus via a post-auricular skin incision, the posterior canal skin was incised circumferentially from 12 to 6 o'clock. A superior longitudinal incision was made to join the circumferential cut. The remnant of the tympanic membrane (TM) was excised and pathologic tissue in the middle ear cavity was removed. After irrigation, middle ear gelfoam packing was performed only in GPG.

The fascia graft was placed following the modified overlay technique, involving placing the fascia under the handle of the malleus (umbo)and elevated tympanomeatal flap but over the annulus. Lastly, firm furacin gauze packing over the bony tympanic sulcus and the external auditory canal was performed. At postoperative 1 month, the packing was completely removed.

Statistical Analysis

SPSS24.0 program for Windows (SPSS Inc., Chicago, IL) was used for statistical analysis. Data were expressed as mean, standard deviation, and percentage.Student's t-test and chi-square testwere used to compare the clinical characteristics of the patients and student's t-test was used to analyse the surgical outcomes. Differences were considered significant when the p-value was 0.05.

RESULTS

Clinical characteristics

Patients were aged between 10 and 81 years with the mean age of 51.5 years, and there was no statistically significant difference in age (p = 0.480) and sex ratio (p = 0.514) between the two groups. The operation site was on the right in 25 patients (43.9%) and on the left in 32 patients (56.1%). The right side was more common in GPG, while the left side was more common in NGPG, thereby demonstrating a statistically significant difference (p = 0.041).

The locations of perforation in the TMalso showed no significant difference between the two groups (p = 0.725) and the mean preoperative perforation size of TM was 29.5% in GPG and 32.2% in NGPG (p = 0.702). The clinical characteristics of the enrolled patients of the two groups are presented and compared in Table 1.

Physical Evaluations

There was no difference in the graft success rate between GPG and NGPG, since all the patients showed successful graft uptake at postoperative 3 month evaluation (Figure 1). During the follow-up period, none of the patients of this study developed postoperative otorrhea, lateralization of neodrum, anterior wall blunting, facial palsy, profound hearing loss or other problems.

However, NGPG showed the statistically significant faster healing process compared to GPG. The higher neodrum epithelization percent was observed in NPG during the follow up period, with significant differences in postoperative 1-month($68.00\pm16.48\%$ in GPG and $76.30\pm13.34\%$ in NGPG, p = 0.043) and 2-month evaluation($94.67\pm6.87\%$ in GPG and $99.26\pm2.67\%$ in NGPG, p = 0.007). Also, neodrum edemascorewas significantly lower in NGPG at 1-month(1.23 ± 0.91 in GPG 0.74 ± 0.62 in NGPG, p = 0.044) and 2-month(0.19 ± 0.40 in GPG and 0.04 ± 0.21 in NGPG, p = 0.085) evaluations. Complete epithelization and amd loss of edema were observed in both groups at the 3-month visit. (Figure 2)

Audiologic Evaluations

A comparison of the preoperative and final hearing measured at postoperative3 months between GPG and NGPG did not show any differences (p > 0.05). Although there were no statistical differences, the ABG measured at1-month (24.94 ± 11.38 dB in GPG and 20.90 ± 9.99 dB in NGPG, p = 0.161) and 2-months (22.36 ± 14.37 dB in GPG and 15.80 ± 11.43 in NGPG, p = 0.144) after surgery was smaller in NGPG than in GPG, thereby indicating an earlier hearing recovery in NGPG compared with GPG (Figure 3).

DISCUSSION

AGS has been used as a MEMP during otologic surgery for the past 60 years with the introduction of Gelfoam by Zollner and Wullstein⁴. This absorbable material serves to support TM grafts and ossicular chain prosthetic devices during the postoperative healing period. It has been known that AGS plays a role in enhancing epithelialization of the graft material and probably functions as an adherence promoter of the graft to the remnant of the TM². However, there are exists some controversies regarding its use. AGS has been reported to induce an inflammatory reaction, causing fibrosis and adhesions within the middle ear, which leads to conductive hearing impairment due to the adherence of the grafted TM to the promontory or fixation of the reasons for unsuccessful hearing results after tympanoplasty, several materials have been explored to replace AGS^{2,6-10}.

Polyurethane foam(PUF) was marketed as a MEPMand synthetic biodegradable foam. A histologic study by Dogru et al.¹¹ compared short-term and long-term appearances of middle ears packed with either AGS

or PUF in a traumatic model of the rat with middle ear packing. In the reported study, the PUF induced mild inflammation and fibrosis in the middle ear in contrast to the severe inflammatory process and fibrosis associated with AGS packing. However, another study with an animal model of middle ear trauma and PUF or AGS packing showed a similar degree of inflammation and neo-osteogenesis in the middle ear with both the packingmaterials¹². A recent experimental study comparing the effects of AGS and another packing material, OtoporeTM (Stryker, USA; Otopore group) in the middle ear cavity demonstrated less inflammation, adhesion, and new bone formation in OtoporeTM packing group, despite the absence of substantiation about its long-term safety¹³. In a review article investigating 12 middle ear packing unterladed that there exists no perfect agent for middle ear packing unterladed. In addition, they suggested that none of the packing materials would be associated with advantages related to an immediate improvement in hearing, shortening the operating time, reduction in the cost and patients' comfort, although there is a lack of clinical evidence.

There exist only a few clinical studies regarding middle ear packing materials. Most of the studies have dealt with animal models^{5,7,8,10,11,13,15}, and only one comparative study has reported the effects of MEMP on the outcomes of middle ear surgery in human¹⁴. Smith et al.¹⁶reported better hearingresults of the hydroxylapatite/titanium bell partial ossicularreplacement prosthesis (PORP) without gelfoam compared with the conventional PORP with gelfoam. However, the reported study had a limitation in its rationale on the effect of MEPM as the conditions were not controlled. Previous clinical studies without gelfoam during overlay tympanoplasty or ossiculoplasty demonstrated excellent surgical results, which guided us to perform a more scientific and clinical study to demonstrate the effect of MEPM^{3,17}. Our study is the first prospective randomized case-control study to investigate the effects of middle ear packing using AGS in terms of surgical results and healing processes in humans. While the overall graft success rate was not affected by middle ear packing using AGS, the delayed epithelization of TM and more severe fascia edema were observed in GPG, thereby suggesting that AGS may interrupt the healing process of TM. In addition, larger postoperative ABG was observed in GPG for up to two months, although no significant difference was shown in the third month visit. This result suggests that AGS may remain in the middle ear for more than two months, similar to previous animal studies^{7,18,19}. Therefore, based on our study results, surgical techniques without middle ear packing can be recommended to reduce patient's discomfort caused by delayedhearing improvement and achieve a faster healing process.

Middle ear packing is essential for conventional underlay tympanoplasty to support the graft²⁰. Therefore, even in underlay tympanoplasty, other surgical techniques without MEPM have been suggested. Yuasa et al.²¹ introduced simple underlay myringoplasty with fibrin glue in 1989. They inserted a connective tissue through perforation using the underlay technique and fixed it with fibrin glue without middle ear packing. However, this method exhibited limited visibility into the middle ear and a relatively low overall initial success rate of 77.7%²². Another technique, inlay butterfly cartilage tympanoplastywithout middle ear packingwas introduced by Eavey et al. in 1998²³. Theperforation closure rate was observed between 71 to 100%, but this method has limitationsfor patients with large perforationbecause of the small remaining part of the TM which cannot support the cartilage on its own^{24,25}.Previously, we have introduced the technique and surgical outcomes of a modified method for overlay tympanoplasty; swing-door overlay tympanoplasty. No MEPM was required for this technique and a high success rate of graftuptake(98.4%) with satisfactory hearing results (postoperative ABG was closed to [?]20 dB in 86.9%) was observed in the study. The advantage of this surgical method is that the swing door technique provides a better surgical view and makes it easier to perform surgery than conventional overlay tympanoplasty, and can be applied to all types of chronic otitis media regardless of the size of TM perforation³.

Given that the previous animal studies demonstrated fibrosis or inflammatory reaction in the middle ear cavity by AGS, our clinical study demonstrated the negative effects of AGS in terms of healing processes of neodrum. Also, delayed hearing improvement appeared to be comprehensible.

CONCLUSION

Swing-door overlay tympanoplasty showed good surgical outcomes in terms of graft uptake rate regardless of gelfoam packing. However, our prospective randomized controlled study showed earlier hearing improvement and faster healing process in NGPG, thereby indicating that the gelfoam in the middle ear may interfere with the healing process of neodrum and middle ear cavity. Consequently, it is proposed that surgical technique without AGS during middle ear surgery should be considered based on the advantages of the faster healing process and better hearing results.

DISCLOSURE STATEMENT

All authors have approved this manuscript, and there are no conflicts of interest to report.

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Figure legends

Figure 1. Serial oto-endoscopic findings of pre-and post-operative tympanic membranes.

All included patients showed successful graft uptake at postoperative 3 months. However, NGPG showed statistically significant earlier epithelialization less edematous fascia compared to GPG at postoperative 1-and 2-months (p < 0.05). (GPG; gelfoam-packing group, NGPG; non-gelfoam-packing group.)

Figure 2. Changes in the postoperative graft epithelization and graft edema score.

(A) The percentage of epithelization was measured by two otologic specialists based on the ratio of the epithelized neodrum in the entire grafted eardrum. Significantly higher epithelialization percentages wereobserved in NGPG compared to GPG at1-and 2-months visits (p < 0.05). (B) The severity of edema of the grafted fascia was quantified by two otologic specialists; none=0, mild=1, moderate=2, and severe=3. The edema score of the graft in NGPG was lower in NGPG than in GPG at postoperative 1- and 2-months visits, thereby indicating better healing process in the NGPG(p < 0.05). (GPG; gelfoam-packing group, NGPG; non-gelfoam-packing group. Error bars indicate standard deviations.*P < 0.05. Student's t-test.)

Figure 3. Comparison of the air-bone gaps between GPG and NGPG.

Air-bone gap(ABG)s were measured with average pure tone hearing thresholds at 0.5, 1, 2, and 4 kHz. Although there was no statistical difference (p > 0.05), the mean values showed lower ABG in NGPG at 1- and 2-months visits, thereby indicating faster hearing improvement in NGPG. (dB; decibel, GPG; gelfoampacking group, NGPG; non-gelfoam-packing group. Error bars indicate standard deviations. Student's t-test.)

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Gelfoam_Table.docx available at https://authorea.com/users/321048/articles/450381-effectof-middle-ear-gelfoam-on-hearing-and-healing-process-after-tympanoplasty-a-prospectiverandomized-case-control-study





