Outcome of Endoscopic Myringoplasty Using Gelfoam Versus no Gelfoam in Tympanic Cavity and External Auditory Canal

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ABSTRACT

Background

Absorbable gelatin sponge (gelfoam) is used routinely during myringoplasty as a scaffold that supports tympanic membrane grafts and ossicular chain and to promote hemostasis. However, gelfoam could cause fibrosis, adhesions, granulations, new bone formation within the middle ear cavity and could obstruct the tympanic ostium of the eustachian tube and affects inner ear function and also interferes with the healing process of neodrum and middle ear cavity.

Objective

To compare the outcome of endoscopic myringoplasty with and without use of gelfoam in external auditory canal and tympanic cavity.

Method

Fifty patients, with 25 patients in each group who underwent endoscopic myringoplasty with and without gelfoam packing in middle ear cavity and external auditory canal were enrolled in the study. The hearing outcome was assessed by comparing pre-operative ABG (Air bone gap) with post-operative air bone gap and air bone gap closure in speech frequencies (0.5kHz,1kHz, 2kHz,4kHz). The status of graft and hearing results was evaluated on 3months of follow-up in both the groups.

Result

Out of total 25 patients enrolled for study in both non gelfoam packing group (NGFPG) and gelfoam packing group (GFPG), 24(96%) had graft uptake in each group. The audiological gain in non gelfoam packing group was 11.15±2.4dB whereas in gelfoam packing group it was 12.45±0.81dB. The audiological gain between the two groups did not show any statistically significant (p= 0.190). However, the pre and postoperative hearing difference was statistically significant(p=0.001) in both non gelfoam packing group and gelfoam packing group.

Conclusion

This study concluded that non gelfoam packing group has similar graft uptake and hearing gain when compared with gelfoam packing group in endoscopic myringoplasty. Hence, myringoplasty can be performed safely without using any gelfoam in the middle ear cavity.

KEY WORDS

Absorbable gelatine sponge, Air-bone gap, Air-bone gap closure, Chronic otitis media, Myringoplasty

INTRODUCTION

Chronic otitis media (COM) is a common middle ear disease in otorhinolaryngology. COM is defined as a chronic inflammatory disease of the middle ear cleft, which can lead to symptoms such as purulence, tympanic membrane perforation, hearing loss, tinnitus, vertigo, and long-term or permanent changes in the tympanic membrane, including atelectasis, perforation, tympanosclerosis, retraction pocket development, or cholesteatoma.[1,2]

Inadequate antibiotic treatment, frequent upper respiratory tract infections, nasal diseases, and poor living conditions with poor access to medical care are related to the development of COM. Risk factors associated with a higher prevalence rate of COM include poor housing, poor hygiene, and poor nutrition.[3-5]

Absorbable gelatine sponge (AGS, gelfoam) has become the most commonly used middle ear packing materials in clinical practice. This material has been widely used in otology, with applications such as middle ear packing, eustachian tube occlusion, vestibular window occlusion and skull base repair. At present, whether myringoplasty is performed with a microscope or an endoscope,it is generally followed by use of gelfoam (absorbable gelatin sponge) or another absorbent material packing in external auditory canal and tympanic cavity to provide support to the tympanic membrane grafts and ossicular chain, maintain aeration of the middle ear, and promote hemostasis.[6-9] Gelfoam has its advantages of being non-antigenic, non-ototoxic, non-allergenic, biocompatible, easy to handle, well tolerated and easily absorbable.[10,11] However, this material also has disadvantages of causing severe connective tissue hyperplasia, resulting in adhesion and fibrosis surrounding the tympanic membrane and ossicular grafts, with subsequent chain distortion and tympanic membrane retraction, especially when the middle ear mucosa is damaged.[7,12-14] Also, long term retention of gelfoam under some conditions can cause infection leading to poor post-operative hearing improvement.

Therefore, this study will help to compare the differences between packing with gelfoam and packing without gelfoam in external auditory canal and tympanic cavity during endoscopic myringoplasty in an over-under technique and find a procedure that provide better outcome in terms of graft uptake rate and hearing results.

METHODS

This was a prospective and longitudinal comparative study conducted from 1st November, 2021 to 1st May, 2023. Informed consent was taken from the patients before conducting the study. The ethical approval was taken from institutional review committee of Kathmandu University school of medical sciences (IRC-KUSMS Approval No. 225/2021). The inclusion criteria were: COM mucosal inactive type, small to subtotal perforation size, age ≥ 18 years, mild to moderate conductive hearing loss (ABG ≥ 20 dB). The exclusion criteria were: patient undergoing revision surgery, pregnant, smoker, those with sensorineural hearing loss and mixed hearing loss, systemic illness (Hypertension, Diabetes mellitus, Chronic obstructive pulmonary disease, heart disease) which may affect the outcome of surgery, patient with marginal or attic perforations, those with COM squamosal type, otitis externa, otomycosis, ossicular fixation, ossicular discontinuity, upper respiratory tract infection at the time of surgery.

Preoperatively general ENT evaluation was done along with otoscopic examination of both ears, tuning fork tests were performed. Pre-operative pure tone audiometry was done 1 month prior to the surgery. The air conduction threshold and the bone conduction threshold included the frequency of 0.5kHz,1kHz, 2kHz,4kHz. The air-bone gap (ABG) was calculated by taking differences between air conduction and bone conduction thresholds. The air-bone gap closure was calculated by taking the difference between pre-operative air-bone gap and post-operative air-bone gap. Audiometric assessment was done 3 months post-operatively.

Thus, the data collection was done in pre-operative and then in the six weeks and 3 months post-operatively.

Hearing test

A pure tone audiometer (MAICO MA 41 diagnostic audiometer (Germany) was used to evaluate the hearing level of patients within 1 month prior to the surgery and 3 months after the surgery in sound treated double room setup. The hearing assessment was done by comparing pre-operative and post-operative air bone gap (ABG) and ABG closure in speech frequencies (0.5kHz,1kHz, 2kHz,4kHz).

Surgical procedure

1. Injection of local anesthetic

Surgery was performed under local anesthesia. The patient was sedated with 50mg pethidine and 25mg promethazine intramuscularly as per body weight. In the operating ear the four quadrants of the EAC around the bony cartilaginous junction was injected with 1 ml of Inj Lignocaine with epinephrine (1:100000). The local anesthetic was also infiltrated around the area of the tragus. A 3CCD (charge-coupled device) Karl Storz camera unit and 0-degree Hopkins rod nasal endoscope with 4mm diameter and 18 cm in length was used for the transcanal myringoplasty to assess the perforation size and site, ossicular chain mobility and the middle ear mucosa.

2. Refreshening the margins of the perforations

The margins of the perforation was then refreshened by using a straight needle and under surface of remnant tympanic membrane made raw with a round knife.

3. Elevation of tympanomeatal flap

The tympanomeatal flap was elevated using the round knife and the Plester flag knife. A lateral circumferential incision was performed 4-6 mm lateral form the tympanic annulus. The incision was integrated with radial rosen incisions at the 6 o'clock and 12 o'clock positions and then the tympanomeatal flap was elevated along with annulus from the sulcus then middle ear entered, malleus skeletonized from the lateral process to tip. Ossicular continuity was confirmed by demonstrating a round window reflex. During this step the hemostasis was maintained using the adrenaline-soaked cotton ball.

4. Harvesting of graft material

Graft material used for the procedure was autologous tragal perichondrium. The tragal perichondrium was obtained during the surgical procedure from the tragus. About 2 cm vertical incision was given by a number 15 blade from the incisura terminalis upto intratragal notch which was around 5mm medial to the tip of the tragus. A single stroke skin incision was given upto tragal cartilage. The assistant held the tissue with tip of the tragus by non-tooth forceps and maintained a bloodless field.

The operating surgeon then dissects perichondrium from the tragal cartilage with the help of fine tissue cutting scissors. The cartilage along with the perichondrium was then excised and kept upon a silastic graft board for readjusting the shape of the graft. The perichondrium was removed from the cartilage. The perichondrium was used for the graft and the cartilage was repositioned to the tragus to its original position. The skin closure was done using prolene 3/0 by simple interrupted technique.

In patients who were in the control group (GFPG), gelfoam was placed in the middle ear to prepare the bed for the graft and the graft was placed lateral to handle of malleus and medial to remnant TM and annulus and the tympanomeatal flap was repositioned. Gelfoam was placed along the approximating margins of canal incision.

In patients who were in the case group (NGFPG), graft was placed lateral to the handle of malleus and medial to remnant TM and annulus, which acts as a support and prevent graft medialization. After that the tympanomeatal flap was repositioned. Packing of the EAC was then done with ribbon gauze soaked in ciprofloxacin ointment and adhesive tape was applied.

Post-operative care and follow up

All the patients were discharged on the 2nd day of operation. The ribbon gauge pack and the stitch were removed on the 7th postoperative day. After that, the patient was prescribed chloramphenicol and dexamethasone ear drop for 6 weeks. The patient was again followed up after 6 weeks for observing the status of the graft and again on 12 weeks for the hearing result and graft uptake. Pure tone audiometry was done postoperatively at 12 weeks following surgery and post-operative ABG, ACT was calculated and compared with preoperative ABG, ACT to establish hearing results. Postoperative ABG closure was calculated. A successful myringoplasty was defined as successful acceptance of the graft and intact healing of the TM without perforation, medialization or lateralization within a follow up period of three months from the operation.

Data entry was done by using Microsoft excel 2010 and was analyzed using international business machines (IBM) Statistical Package for Social Service version 25 (SPSS 25). Biostatistician was consulted. Data analysis was done using independent student t-test and chi-square test. A p value of less than 0.05 was taken to be statistically significant. All the participants were informed about the study in detail and written consent was taken. The respondents voluntarily participated in the study and they may also withdraw from the study at any time. The identity of the respondents and their response was kept confidential and the data was used for research purpose only.

RESULTS

A total of 50 patients were enrolled in this study, out of which 25 patients had gelfoam in the middle ear cavity and external auditory canal (GFPG) and 25 patients had no gelfoam in middle ear cavity and external auditory canal (NGFPG). All of the patients completed the follow up.

Demographic Profile of the Study Population

The mean age of the study population was 31.68 ± 9.98 years in NGFPG and 32.32± 10.98 years in GFPG. There was no significant difference between the two groups (p = 0.830). The sex distribution in the study population consisted of 9 males and 16 females in NGFPG and 8 males and 17 females in GFPG.

Comparison of the graft uptake rate between NGFPG and GFPG

Among 25 patients who underwent the surgery without gelfoam in middle ear cavity and external auditory canal, 24 patients had successful graft uptake whereas 1 patient had graft failure. Similar results were obtained among the 25 patients who underwent the surgery with gelfoam in middle ear cavity and external auditory canal. There was no statistically significant difference in the graft uptake between the two groups. (P= 0.83). The graft uptake rate was 96% in both groups.

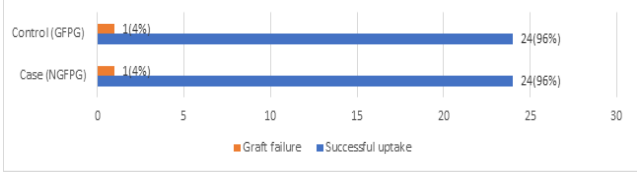

Figure 1. Comparison of the graft uptake rate between NGFPG and GFPG (n=50).

Comparison of ABG and hearing gain (ABG closure)

The average pre-operative ABG in NGFPG 31.75±10.15 dB was reduced to 20.60±7.75 dB post-operatively with a net gain of 11.15±2.4dB. This observed difference was found to be statistically highly significant with P value of 0.001.

The average pre-operative ABG in GFPG 30.35±7.86dB was reduced to 17.90±7.68 dB postoperatively with a net gain of 12.45±0.18 dB. This observed difference was found to be statistically highly significant with P value of 0.001

The mean ABG closure among the patients in NGFPG was 11.15±2.4 dB whereas the mean ABG closure among the patients in GFPG was 12.45±0. 18dB.The difference in mean ABG closure between the two groups were not statistically significant

The comparison of ABG and hearing gain (ABG closure) in NGFPG and GFPG were as shown in table 1:

Table 1. Comparison of ABG and hearing gain

Variables	Pre-operative ABG	Postoperative ABG	P value	Hearing gain (ABG closure)	P value
NGFPG	31.75±10.15	20.60±7.75	0.001	11.15±2.4	0.190
GFPG	30.35±7.86	17.90±7.68	0.001	12.45±0.18	

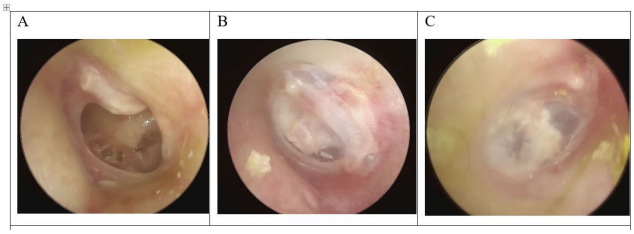

Figure 2. A. Endoscopic picture of tympanic membrane perforation B. Endoscopic picture of graft uptake without gelfoam after 3 months. C. Endoscopic picture of graft uptake with gelfoam after 3 months.

DISCUSSION

The fifty patients included in our study were divided into two groups, the case group (NGFPG) and the control group (GFPG), with 25 patients in each group. The study population was limited to adults between the ages of 18 and 60. This age range was chosen because numerous factors have been proposed to explain the poorer myringoplasty outcomes in children compared to adults, such as a higher frequency of upper respiratory tract infection, otitis media, Eustachian tube dysfunction, and hypertrophic adenoid. This factor was taken into account in the study of Vrabec et al., who found that myringoplasty outcomes improve with advancing age.[15]

In our study, mean age was 31.68±9.98 years in the case group and 32.32±10.98 years in the control group. This is comparable to the study conducted by Ramalingam et al. where the mean age of the study population was 32 years (± 9.667).[16] The mean age in the study conducted by Wang et al. was 44.05 ± 10.87 years for the non-gelatin sponge group and 49.50 ± 9.76 years for the gelatin sponge group.[3] In the similar study conducted by Kim et al. the mean age was 49 years for both gelfoam and no gelfoam group.[17] Likewise the study conducted by Han JS et al., patients were aged between 10 and 81 years with a mean age of 51.5 years.[18]

In our study, the young adults are more prevalent because they are more socially active and health-conscious. Additionally, they are more easily convinced to undergo surgery than older patients who may have more comorbidities and be reluctant to undergo surgery.

The gender distribution of patients in this study showed a female predominance, with a male-to female ratio of 0.56 in the case group (NGFPG) and 0.47 in the control group (GFPG). This is similar to the findings of other studies, such as the one conducted by Han et al. which found a male-to-female ratio of 0.51, and the study by Kim et al. which found a male-to-female ratio of 0.50.[17,18] The probable reason for this female predominance in our study is that the majority of patients who visited our ENT department were from Kavrepalanchowk district, which has a higher female population, according to the National Census Bureau 2078 B.S.

The graft uptake rate was 96% in both our study groups, with no statistically significant difference between the two groups (p value > 0.01). The graft failures in our study were due to recurrent upper respiratory tract infections, which led to recurrent episodes of middle ear infections in both groups. The graft uptake rates in other studies have been similar. For example, Kim et al. reported a graft uptake rate of 99.1% in the Gelfoam group and 99.2% in the no-Gelfoam group.[17] Bhavana et al. reported a graft uptake rate of 89% in the no-Gelfoam group and 81% in the Gelfoam group.[6] Lou et al. reported a graft success rate of 87.8% in the Gelfoam group and 97.6% in the biodegradable Synthetic Polyurethane Foam (BSPF) group.[19] Ghiasi et al. reported a graft uptake rate of 91% in the Gelfoam group and 89% in the no-Gelfoam group.[20] Han et al. reported a graft uptake rate of 98.4% without the use of middle ear packing material, with satisfactory hearing results (postoperative ABG was closed to ≤ 20 dB in 86.9%).[18]

The high graft uptake rates in our study can be attributed to the use of various anchoring techniques to increase graft support. For example, Gristwood and Venables described an underlay myringoplasty technique that creates two anterior tunnels for graft stabilization.[21] Hung et al. invented an anterosuperior anchoring technique that positions the graft medial to the malleus handle and lateral to the external auditory canal, which has produced excellent results in both adults and children.[22]

In our study, the graft was placed lateral to the handle of the malleus and medial to the remnant tympanic membrane and annulus to avoid the risk of tympanic membrane

lateralization. This technique is similar to the one used by Li et al. who also utilized the support of the handle of the malleus along with an anterosuperior tunnels anchoring technique.[23] In this technique, the graft is placed lateral to the handle of the malleus to achieve proper tension in the tympanic membrane and to support the graft.

The use of gelfoam can interfere with hearing outcome and graft uptake. An experimental study performed in animals by Hellstrom et al showed that the use of gelfoam increased the incidence of adhesions and post-operative inflammatory reactions.[7] Another study conducted in animals by Han et al. also demonstrated fibrosis or inflammatory reaction in the middle ear cavity and poor healing of the neotympanum.[18]

In our study, the average air-bone gap (ABG) closure was 11.15 ± 2.4 dB in the case group (NGFPG) and 12.45 ± 0.18 dB in the control group (GFPG). This showed similar hearing improvements in both groups with p=0.190. But the comparison of pre with post-operative hearing results, the p value in both NGFPG and GFPG was 0.001.

In the study conducted by Ramalingam et al. the ABG closure was 11 dB in both the control (gelfoam) and test (no gelfoam) groups. The improvement in hearing was statistically significant (p = 0.0001) in both groups and the study population as a whole.[16]

In the similar study conducted by Bhavana et al., an ABG < 20 dB was noted in 86% of patients in group A (with gelfoam) and 84% in group B (without gelfoam) with p value < 0.0001, which was statistically significant.[6]

The hearing outcome following myringoplasty is mainly affected by the following factors: the condition of the ossicular chain, residual perforation of the tympanic membrane, graft uptake, medialization or lateralization of the intact graft, and postoperative inflammation, fibrosis, and adhesions.[24] There are few reports that gelfoam can induce an inflammatory reaction and cause fibrosis and adhesions within the middle ear, which can lead to conductive hearing impairment due to the adherence of the grafted tympanic membrane to the promontory or fixation of the ossicular chains.[25] Postoperative inflammation, fibrosis, adhesions, and predominant polynuclear cell invasion in the middle ear cavity with subsequent ossicular chain distortion have been known as one of the reasons for unsuccessful hearing results after myringoplasty.

Despite the routine use of gelfoam as a complement in ear surgery, its use may not always be rewarding as it can provoke tissue inflammation. The thought of using the available structure such as the handle of malleus for scaffold and using saline-soaked graft instead of gelfoam came into action to get rid of such tissue inflammations. The surface tension of saline holds the graft in place tucked beneath the margins of the perforation. The air pocket that is created is useful in the no-gelfoam technique, as stated by Takahashi, where the middle ear cleft is similar to the alveoli with ventilation taking place by transmucosal gas exchange rather than by the eustachian tube, especially in the postoperative period.[16] Furthermore, it is essential to maintain gas exchange between the round window and the eustachian tube orifice to obtain satisfactory hearing improvement, which may be hampered by the use of gelfoam as it can obstruct the eustachian tube orifice and round window.[26]

A study showed that gas exchange in the middle ear can occur through four main pathways: (1) gas exchange with the nasopharynx through the Eustachian tube; (2) gas exchange with the blood through the mucous membrane; (3) gas exchange with the external auditory canal through the tympanic membrane; and (4) gas exchange with the inner ear through the round window membrane. This suggests that gas exchange can be performed in many ways. Therefore, it is still unknown whether the gelatin sponge in the tympanic cavity can achieve the desired supporting effect and whether the absence of gelatin sponge packing will cause tympanic membrane collapse and affect the healing of the tympanic membrane perforation. However, in our study, the patients who did not receive gelfoam packing did not experience tympanic membrane collapse during follow-up, and they had satisfactory hearing results. Thus, these gas exchange pathways in the middle ear cavity may play a role in replacing the support of the gelatin sponge, which maintains the pressure balance inside and outside the tympanic membrane to avoid collapse of the tympanic membrane.[27]

The small sample size which may not reflect the core value of the study significantly. The longer the period of study, the better the results and the single institutional study may not represent the whole population.

CONCLUSION

This study concluded that the outcome of endoscopic myringoplasty in the patients included in Non Gelfoam Packing Group has similar graft uptake and hearing gain when compared with Gelfoam Packing Group. Hence, myringoplasty can be performed safely without using any gelfoam in the middle ear cavity.

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