

# The Role of Gentamycin Ointment in Postoperative Results after Myringoplasty

## Original Article

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## ABSTRACT

**Objectives:** The aim of this study was to compare the outcome of tympanic graft and the rate of postoperative infection following myringoplasty for the treatment of chronic tympanic membrane perforations.

**Background:** Tympanic membrane perforation is one of the most common conditions that otologists have to deal with in daily clinical practice. The majority (up to 80%) of these perforations have tendency to heal spontaneously. The remaining cases may be addressed to surgery, especially when patients experience major discomfort due to recurrent otorrhea, conductive hearing loss, or interdiction to water activities.

**Methods:** This prospective randomized study was conducted on 155 patients with chronic suppurative otitis media with perforation. These patients were divided into two groups as patients with or without local antibiotic usage after myringoplasty (Group A and B). All these patients were prepared for myringoplasty. Clinical assessment, audiogram and tympanogram was done before and after surgery (3 months) to all groups.

**Results:** There were female predominance in patients with chronic otitis media with perforation. There was also higher recurrence in group B than group A after operation during 6 months follow-up. There were no significant improvement between both groups in all items of audiogram and tympanogram after 3 months postoperatively.

**Conclusion:** Our study revealed that there are no difference about hearing in usage of local ointment after myringoplasty but with less recurrence rate of infection and residual perforation in patients who had used local antibiotic ointment.

**Key Words:** Audiogram, myringoplasty, otitis media, residual perforation.

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## INTRODUCTION

In the past, acute middle or inner ear infection was one of the life-threatening diseases. Usage of antibiotics and steroids in the management of these ear infections helps extremely to minimize the complications. The revolution of antibiotics/steroids ear drops or ointments are one of the main tools in the management of ear infections especially postoperatively. Middle ear infections may lead to tympanic membrane perforation that affect hearing. All this may be complicated to be presented by cholesteatoma over years<sup>[1]</sup>.

Tympanic membrane repair or myringoplasty has been successfully used to close this defect using grafts of different nature. This technique may need to elevate flap from the external auditory canal (EAC) to fix this graft below this flap, and to reach to the middle ear cavity away from the perforation. So that, there is need to do packing of the EAC, it is believed that this pack help to fix the graft

and play main role in protection of the EAC from any infection at site of the operation<sup>[2]</sup>.

There are many techniques used to repair of tympanic membrane perforation. These techniques may be trans-canal, prei-auricular or post-auricular. Graft materials also usually were attempted to close the perforation, these grafts varied from fascia as either temporal fascia or fascia lata, cartilage from either tragal cartilage or concha of the auricle. The perichondrium from the tragal cartilage showed high graft success rates, this could be explained by low metabolic rate, less blood supply needed. Plus, this graft is less liable to be infected<sup>[3]</sup>.

There are individual preferences about the favorable technique or graft used in myringoplasty, but majority of surgeons preferred to use antibiotic ointments in the postoperative EAC packing. Although, some recent

researches studied that ear packing has no role in graft uptake, this could reduce patient cost of outpatient visits<sup>[4]</sup>.

The role of this study is to discuss the success rate of graft uptake with only ointment injection over the graft position, this could help to reduce the infection rate postoperatively, and this ointment would be absorbed without any need for pack removal. Nevertheless, the antibiotic ointment may also adhere to the graft, ear canal or, in particular, the tympanomeatal flap, traumatizing these and disturbing the graft on removal<sup>[5]</sup>.

Aim of this study is to compare graft uptake and infection rates in patients with or without local antibiotic ointment injection to the EAC after underlay myringoplasty using perichondrium from tragal cartilage.

## **PATIENTS AND METHODS**

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This prospective randomized study was conducted on 155 patients with chronic suppurative otitis media (CSOM) with perforation in the period from January 2023 till June 2024. These patients were divided into two groups as patients with postoperative local gentamycin antibiotic ointment (Group A of 66 cases) and another group without postoperative local antibiotic (Group B of 89 cases). All these patients were prepared for myringoplasty under general anesthesia.

Both sexes were included in the study from age 18-45 years old with clinical assessment of chronic suppurative otitis media with non-marginal perforation otitis media. All chronic ear perforations should be dry for 3 months preoperatively. They were also small or medium sized with good Eustachian tube function tests. Other concomitant ear pathologies such as acute suppurative otitis media, or cholesteatoma were also excluded in the study. Also, previous history of ear surgery were not included in the analysis. Patients with diabetes, bleeding disorders, renal failure or recent upper respiratory infection were also excluded.

All patient data were included in this study were reviewed for the following (personal data & associated symptomatology). Onset and duration of tympanic perforation were also recorded. All patients with CSOM were diagnosed with clinical examination and audiogram. Patients were selected from general population aging from 18 up to 45 years old including patients reporting to Otorhinolaryngology outpatient clinics of our institutes. Computed topography was done on temporal bone to all patients to exclude any chronic ear infection, tumors or cholesteatoma.

Randomization and allocation to study and control groups were conducted using the closed envelope technique. The numbers from 1 to 155 were written in

a small piece of paper and put in closed envelopes. The patients was randomly selected by numbers to be studied in each group.

Laboratory investigations were also made for all patients preoperatively as complete blood count, bleeding profile, liver and kidney functions. Audiogram was done before and after surgery by 3 months to all groups. All patients were prepared for myringoplasty under general anesthesia. Firstly, tympanic membrane was examined using otoendoscopy 0° (Karl Storz, Germany) to determine the exact size of the perforation using piece of sterile paper. Then, myringoplasty was done using perichondrial sheet from tragal cartilage that was harvested. Underlay technique was the ideal target to put the graft after elevation of the periauricular incision from 12 to 6 degree of the EAC. Finally, the antibiotic ointment (gentamycin 0.1%) was used directly without gel foam in Group A. On the other side, the gel foam was used without any medication directly on the graft in Group B. Consent was taken from patients before performing any investigations or surgical interventions, and they had the right to refuse at any time. The study was approved by the Research Ethics Committee of the Faculty of Medicine, Al-Azhar University. Ethics committee reference number is 3/2025ENT/21.

The patient was given oral daily analgesic (1g of paracetamol tablets) and antibiotic (levofloxacin 500mg tablet) postoperatively for 2 weeks. Follow up was admitted every week in first month. Local antibiotic ointment was showed every visit until complete obvious visualization of the drum within 2 weeks. Then audiogram was done to all patients after three months postoperatively to discuss the hearing outcome postoperatively.

Descriptive statistics included the mean value and standard deviation. The Chi-square test and t-test were used for the analysis of the correlation between data. The SPSS 22.0 program was used for statistical analysis. So, the *p*-value was considered significant as *P*-value less than 0.05 was considered significant.

## **RESULTS**

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The characteristics of the sample regarding age, sex, duration of CSOM in each group are summarized in Table (1). There were female predominance between patients with chronic ear perforation. There was no significant differences between both groups according to duration of illness.

There was high significant differences between both groups according to postoperative infection. Graft success was showed significant differences between both groups as in Table (2), Figure (1,2). Next, we conducted the audiographic data in Table 3 comparing preoperative and postoperative values between both groups who had tympanoplasty operation. There was no significant

differences between both groups before and after the operation by 3 months.

**Table 1:** Characteristic data:

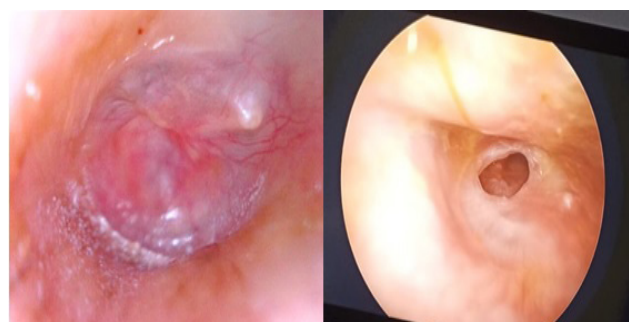
Variables	Group A (n= 66)	Group B (n= 89)	p-value		
Age (years)					
Min. – Max.	18.50–45.0	18.0–44.0	0.891		
Mean±SD.	27.30±14.51	36.50±9.70			
Sex					
	No.	%	No.	%	
Male	29	43.9	38	42.7	0.603
Female	37	56.1	51	57.3	
Duration of illness (months)					
Min. – Max.	14.5–31.5	18.0–39.5	0.352		
Mean±SD.	26.0±10.0	30.5±13.5			

SD: Standard deviation.

**Table 2:** Postoperative clinical results

Clinical results postoperatively	Group A (66 patients)	Group B (89 patients)	Chi-square test	P-value
- Infected graft in first 2 weeks	0	12		
- Infected graft after 2 weeks	3	4	12.590	0.013*
-Graft taken	64	77		
-Graft failed	2	12	11.165	0.025*

\*: significant P-value, SD: Standard deviation.



**Figure 1:** Preoperative and postoperative tympanic membrane perforation from Group A.



**Figure 2:** Preoperative and postoperative tympanic membrane perforation from Group B.

**Table 3:** Hearing improvement before and after operation by 3 months:

Hearing improvement	Group A (66 patients)	Group B (89 patients)	t-test	P-value
	Mean±SD			
Air conduction improvement	22.1±10.4	19.5±9.2	0.669	0.091
Air bone gap closure	15.4±3.6	14.6±4.3	0.397	0.078

SD: Standard deviation.

## DISCUSSION

Although temporary hearing affection after antibiotic ointment packing in the EAC postoperatively, it is used as tradition after myringoplasty. Postoperatively there was patient discomfort from the ear pack, there was significant success rate in group of patients with ointment packing in our study. However, we have been unable to establish the rationale, or evidence base, for this practice. On the contrary, some recent researches studied that there are no comparable results between usage of different types of ointments. Hirschmann *et al.*, emphasized that topical antibiotic ointments is ineffective to prevent postoperative wound infections either for dermatologic surgery. Ear packing of gauze with ointment had more anxiety in some researches than only local ointments that is usually have been absorbed in duration may reach up to 2 weeks<sup>[6,7]</sup>.

Lou Z. and colleagues presented a study using erythromycin injection in the EAC after lateral graft myringoplasty in group of patients (study group) and another group of patients without usage of any applicants (control group). However, the control group showed higher infection rate than that of the study group, but this difference wasn't significant between both groups in contrast to our study ( $P=0.312$ ). This result was similar to previous findings. However, this study of Lou *et al.*, was not statistically significant to recommend its use in routine practice (relative risk 0.430, 95% confidence interval (CI) 0.120–1.544). As well as, Dixon and colleagues compared the effect of applying antibiotic, or paraffin ointments to any surgical skin wound and without any ointment. The infection rate was 1.4% with no ointment, 1.6% for paraffin and 2.3% for mupirocin ( $P=0.490$ ). Total complication rates were 3.5, 4.7 and 4.8% for no ointment, paraffin and mupirocin respectively ( $P=0.590$ ). Some 10.9, 10.3 and 8.2% of patients respectively had a neutral or negative perception of their wounds at 6-9 months after surgery ( $P=0.650$ )<sup>[8,4]</sup>.

A randomized, double-blind, placebo-controlled study was admitted by Kalmeijer by 2002. This study was made over six hundred cases using either mupirocin or placebo nasal ointment application postoperatively after nasal surgery. Eradication rate of infection in situ was significantly effective in mupirocin group (83.5% versus

27.8%). Staphylococcal aureus infection rate was five times less in the mupirocin group with relative risk (0.3% versus 1.7%). From another point of view, the mmupirocin ointment did not reduce the duration of hospital stay<sup>[9]</sup>.

According to the otologic field, Meghji *et al.*, used chloramphenicol ointment versus paraffin paste in EAC packing after tympanoplasty. They found that both ointments showed comparable results. In addition, no use of antibiotic ointment may reduce postoperative symptoms, fullness, and pressure<sup>[10]</sup>.

In this study, gentamicin ointment was chosen to pack the EAC lateral to the graft. A lot of studies showed that Staphylococcus aureus and Pseudomonas aeruginosa were the most common bacterial organisms accompanying the chronic middle ear infection. Although these organisms showed high resistant rates to most of antibiotics, majority of authors studied the efficacy of gentamicin on Staphylococcus aureus<sup>[11,12]</sup>.

Yamamoto and colleagues made study about the histologic study of homograft cartilages implantation inside the middle ear. They showed that inflammatory reaction recorded inside the middle ear after partial absorption of graft<sup>[13]</sup>. The rate of graft necrosis and failure is confirmed to be increased without usage of local antibiotic after myringoplasty as showed in Lou's study, they found out 9 from 10 cases had partial or complete necrosis of the graft. On the other wise, some authors presented results proved that graft necrosis not affect the success rate of myringoplasty, although increased rate of postoperative otorrhoea and infection was significantly higher in patients without usage of local antibiotic. They also showed dry ear before the myringoplasty made higher success rate than wet ear<sup>[4,14]</sup>.

As well as, another research studied the histochemistry of cartilage autografts in myringoplasty. They showed lethal effect on cartilage graft lead to middle ear infection especially in wet tympanic membrane preoperatively. The main organisms detected in this study were either Pseudomonas Aeruginosa, or Staphylococcus Aureus<sup>[15]</sup>.

As well as in our study, the postoperative ABG showed significant improvement compared to preoperative in both groups, while no significant differences comparing hearing gain between both groups ( $P=0.745$ ). Our study showed that mean ABG gain was not significantly different ( $p=0.091$ ) and mean air conduction improvement with no significant difference ( $p=0.078$ )<sup>[4]</sup>.

Also, another study presented by Lou *et al.*, in 2022 showed that there is proved evidence of the usage of antibiotic ointment is more better than antibiotic ear drops in the EAC that affects graft lateralization, significant blunting, and graft infection following myringoplasty<sup>[16]</sup>.

However, the limitations of this study was small sample size, and short-term follow-up. In addition, bacterial culture and antimicrobial susceptibility testing were not performed for the patients with purulence discharge in both groups.

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## CONCLUSION:

However There is more susceptible infection rates if the otologic surgeon didn't use local antibiotic after ear surgery. The graft necrosis and its failure is more liable to be happened if the local antibiotic ointment wasn't used postoperatively.

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## CONFLICT OF INTEREST:

There are no conflicts of interest.

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## ETHICAL CONSIDERATIONS

All authors collected patients from outpatient clinic and were responsible for the design and analyzing data and share in writing the manuscript. MK and AI were major contributors in writing the manuscript. MA and MK analyzed and interpreted the patient data regarding the diagnosis and management of the cases. All authors read and approved the final manuscript.

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## CONFLICT OF INTERESTS

There are no conflicts of interest.

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