Main Article

# Otomycosis with Tympanic Membrane Perforation : Treatment using Clotrimazole - Soaked Gelfoam

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## ABSTRACT

### Introduction

*Otomycosis with perforated tympanic membrane is commonly encountered in clinical practice and can pose a challenge to treat since commonly used clotrimazole solution can irritate the middle ear cavity. Here, the objective of the study was to use self-absorbing material like gelfoam soaked in antifungal cream as a patch over the tympanic membrane perforation to reduce seepage of clotrimazole solution into the middle ear and patient's compliance was studied.*

### Materials and Methods

*26 patients presenting to the out-patient department with otomycosis and a perforated ear drum underwent thorough aural toileting followed by placing multiple pieces of gelfoam soaked in clotrimazole cream to patch the perforation and were asked to instill clotrimazole ear drops for 2 weeks and followed up. Compliance to treatment in the form of pain tolerance and response to treatment were noted down.*

### Results

*44% of patients complained of pain of which 28% experiencing mild and 11% experiencing moderate pain at the beginning of therapy. 13 out of 26 experienced mild pain on continuing therapy and all but one were compliant with the entire treatment. 73% of patients had complete resolution at the end of 2 weeks and the remaining 6 out of 26 needed additional week of ear drops for complete resolution. 3 of them with a pinpoint perforation had a healed membrane at the end of the therapy.*

### Conclusion

*Using Clotrimazole-soaked gelfoam pieces may be a safer and more effective alternative for enhancing treatment compliance, achieving better disease clearance, and reducing the number of follow-up visits.*



### Keywords

*Otomycosis; Tympanic Membrane Perforation; Medicated Gelfoam*


Otomycosis is one of the common conditions encountered in a general otolaryngology clinic setting. It poses a challenge for both patient and the doctor since patient requires a long term treatment in order to prevent recurrence. Treatment generally involves thorough aural toileting and use of topical clotrimazole preparations in the form of ear drops which need to be given for 2-3 weeks. The treatment can be more challenging in the event of a tympanic membrane perforation associated with otomycosis. The perforation can be a pre-existing condition secondary to a otitis media or can be a new perforation secondary to the existing otomycosis. In event of such perforation use of clotrimazole ear drops can pose a challenge since exposure of middle ear mucosa to the preparation can cause intense pain and burning sensation for patient and also long term use is known to cause ototoxicity. Alternative treatment therapy using instillation of drops with a cotton bud applicator or use of other preparation like

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clotrimazole creams has been tried with varying success. Various alternatives like paper patch has been tried to prevent the seepage of drops to middle ear during instillation. But most act as a foreign body in long run and need frequent changing and removal thereby increasing out patient visit and burden to the patient. Using a self absorbing material as a patch to block the tympanic to prevent seepage and exposure of middle ear mucosa to the drops would be beneficial by reducing the outpatient visit of the patient since the material need not be removed or changed over a long periods. Hence the study was undertaken.

## Materials and Methods

The aim of the study was to note the compliance of the patients to Clotrimazole ear drops given for otomycosis with a perforated Tympanic membrane and to study the outcome of the treatment in such cases. 26 patients visiting Out Patient Dept of ENT at a peripheral center of our institute with Otomycosis with a perforated Tympanic membrane were included in the study from July 2023 to June 2024 after obtaining informed consent and after ethical clearance obtained from the institutional ethics board. All the patients >18yrs suffering from Otomycosis with a perforated Tympanic membrane were included in the study. Patients with an active middle ear disease and patients with Diffuse Otitis externa or narrow canal with difficult access for insertion of gelfoam were excluded from the study. Most cases included in the study were diagnosed with otomycosis clinically, microscopic examination of the debris was done using Gram's and/or Lactophenol Cotton Blue staining in a few doubtful cases (Figure 1 & 2). Included patients were assessed for the extensiveness of the hyphae in the EAC (Figure 3), TM and middle ear[11] as 0 - None ( No mycotic hyphae), 1 - Mild (Mycotic hyphae of one side of EAC), 2 - Moderate (Mycotic hyphae of two or more sides of EAC), 3 - Severe (Diffuse mycotic hyphae involving EAC and the middle ear), then underwent thorough aural toileting and the Tympanic Membrane findings were noted down (Figure 4) followed by insertion of multiple pieces of Clotrimazole cream soaked gelfoam, of appropriate sizes, to cover the perforation (Figure 5) and Clotrimazole ear drops were instilled in the OPD itself. Pain was noted according to the Pain assessment scale and any other discomfort were noted down. Patients were asked to continue the drops three times a day for 2 weeks and were asked to review. History of any pain or discomfort were assessed on follow up and presence of any residual disease and Tympanic Membrane findings were noted down (Figure 6).

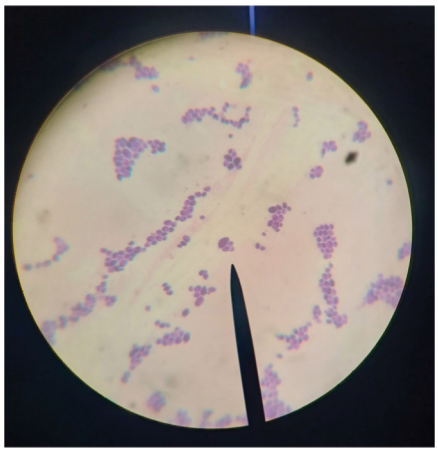

**Fig. 1. Shows Gram positive budding yeast cells under Gram's stain in 100x**

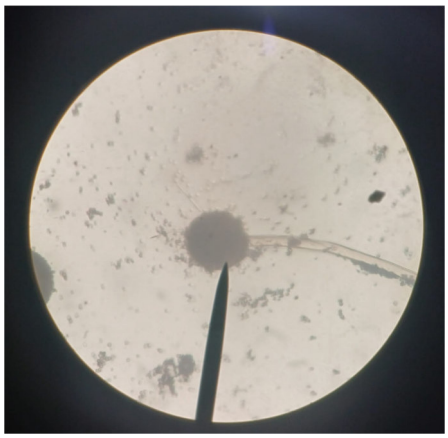

**Fig. 2. Shows Aspergillus niger under LPCB mount in 40x**

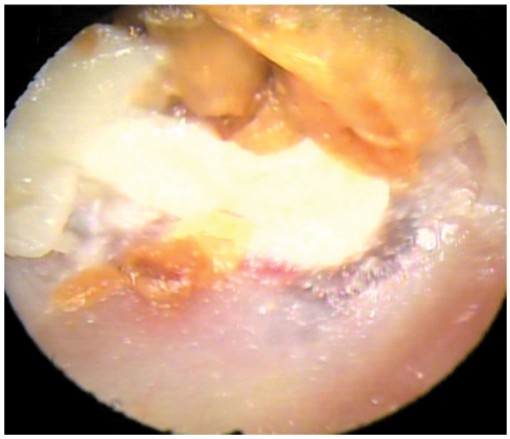

Fig. 3. Otomycotic debris seen adhered to the Tympanic Membrane.

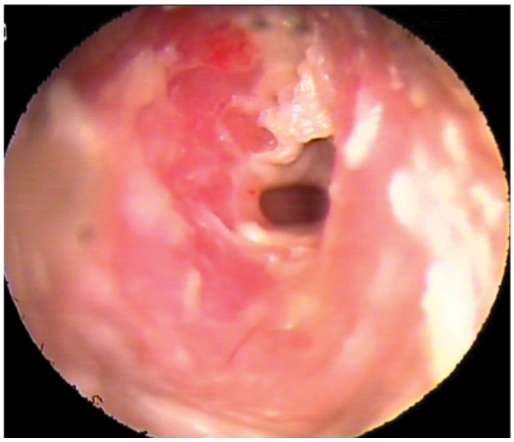

Fig. 4. Small Central Perforation seen involving Anterior quadrant after aural toileting.

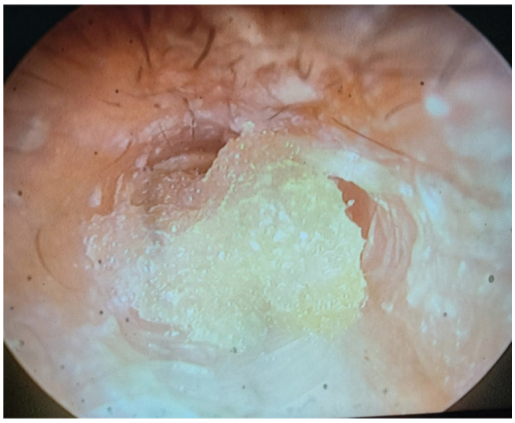

Fig. 5. Medicated Gelfoam inserted into the canal.

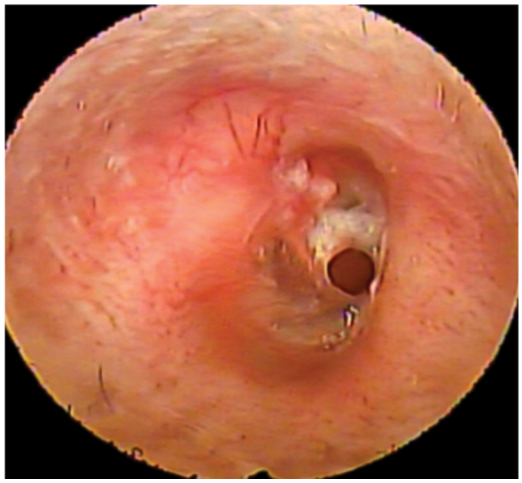

Fig. 6. Two weeks follow up showing disease clearance and a residual perforation

## Results

Table I: Age Distribution

| AGE DISTR-IBUTION | <20 YRS | 21-30 YRS | 31-40 YRS | 41-50 YRS | 51-60 YRS | 61-70 YRS |
|---|---|---|---|---|---|---|
| Subjects | 0 | 5 | 8 | 5 | 2 | 6 |

Table II: Grading of Extensiveness of Otomycosis

| EXTENSIVENESS OF OTOMYCOSIS | AT PRESENTATION | AFTER 2 WEEKS OF THERAPY |
|---|---|---|
| Grade 0 | 0 | 19 |
| Grade 1 | 7 | 6 |
| Grade 2 | 9 | 0 |
| Grade 3 | 10 | 0 |

In our study we included 26 patients with otomycosis and a perforated eardrum over one year, including 8 males and 18 females (Table I). The average patient age was 44 years (Table I). Initial use of Clotrimazole drops caused pain in 44% of patients, with 28% experiencing mild pain and 11% moderate pain (table III). One patient reported very severe pain upon instilling the drops at the clinic. Following gel foam insertion, 7 out of 26 patients felt a blocked sensation

**Table III: Pain Scale on Instillation of Drops**

| PAIN DURING INSTALLATION OF DROPS | AT THE HOSPITAL (WONG - BAKER SCALE) | AT HOME (VISUAL DESCRIPTOR SCALE) |
|---|---|---|
| No pain | 18 | 12 |
| Mild pain | 5 | 13 |
| Moderate pain | 2 | 0 |
| Severe pain | 0 | 1 |
| Very severe pain | 1 | 0 |
| Worst pain | 0 | 0 |

**Table IV: Status of Tympanic Membrane Perforation**

| TYMPANIC MEMBRANE STATUS | AT PRESENTATION | AT 2 WEEKS FOLLOW UP |
|---|---|---|
| Small CP | 13 | 10 |
| Medium CP | 9 | 9 |
| Large CP | 4 | 4 |
| Subtotal CP | 0 | 0 |
| Healed membrane | 0 | 3 |

in their ear canals. After one week of treatment, 13 patients experienced mild pain when applying drops at home, and all but one patient adhered to the treatment plan (Table III). The non-compliant patient reported severe pain and blocked sensation on the third day, returned for suction clearance of the gel foam, and chose an alternative treatment. The majority of patients (15 out of 26) had no prior ear issues. At the start, 10 patients had grade 3 otomycosis (Table II), and a small central perforation was the most common finding after aural toileting. After two weeks of treatment, 73% of patients showed complete disease clearance, and in 3 patients with pinpoint perforations, the membrane healed completely (Table IV). No gel foam was seen in the ear canal, at 2 weeks follow up, in all but six patients who had grade 1 residual disease (with remnant gel foam) and required an additional week of Clotrimazole drops.

## Discussion

Otomycosis is one of the common conditions encountered in a general otolaryngology clinic setting and its prevalence has been quoted to range from 9%[1] to 27.2%[2] among patients who present with signs and symptoms of otitis externa and up to 30%[3] in patients with discharging ears. It is worldwide in distribution with a higher prevalence in the hot, humid, and dusty areas of the tropics and subtropics[4]. Symptoms of otomycosis include pruritis, pain, otorrhoea, and hearing loss. Otomycosis can also lead to tympanic membrane perforations[4] and spread to the middle ear. In a clinical study by Ram Kumar, the incidence of tympanic membrane perforation in otomycosis was found to be 11%, and perforation was more common with otomycosis caused by Candida albicans.[5]

The most widely used treatment regimen for otomycosis includes mechanical debridement of the ear canal along with local antifungal agents. However, the presence of TM perforation is associated with 2 problems: antimycotic solutions are irritant to middle ear and may be ototoxic to the cochlea. Namely, direct instillation of antifungal agents with a dropper is associated with stinging and burning sensation.[6] Clotrimazole, which is the most commonly used antimycotic medication, is practically insoluble in water. Solvents used in dermatologic solution are propylene glycol, isopropyl alcohol, and polyethylene glycol. Although they have a good drying effect, they are irritant to middle ear mucosa and cause burning or stinging sensation.[6] Some of the antifungal agents also known to be potentially ototoxic.[7] These medications may reach the inner ear by perfusion via the round window membrane.[8] Arguably, some of the antimycotic agents have been implicated as a cause of sensorineural hearing loss by inflicting damage to the inner hair cells of the organ of corti.[9] Various treatment methods have been

proposed to avoid exposure of middle ear cavity to the antimycotic solutions.

In a study done by Hurst et al, twenty two patients with perforated Tympanic membrane secondary to otitis externa where studied. They treated them by inserting a gauze wick saturated with hydrocortisone, clotrimazole, framycetin, and gramicidin.[10] Inserting ear wick saturated with antifungal solution or cream can increase the contact period with canal skin and prevent seepage of medication into the middle ear but the wick can act as a foreign material in the canal and may need frequent follow ups for changing.

Abou-halawa et al proposed self medication with clotrimazole solution using Q-tips. They compared them with a group who had a gauze wick impregnated with clotrimazole cream inserted in the ear with wick being changed every third day for a week. After three weeks all patients in Q-tip group and ear wick group had relief of their ear itching and complete disappearance of fungal growth but patients in ear wick group had sense of ear blocking and wetness during period of treatment and transient burning sensation was reported by 2 patients in Q-tip group.[6] Also self medication needs proper training in technique to avoid any additional injury.

A study done by Görür K et al included Fifty-six otomycosis patients with central tympanic membrane perforations were randomized into two groups as patched (PG), were the perforated tympanic membrane was covered with carbon paper soaked in Castellani's solution, and non-patched (NPG) groups. In both groups, Castellani's solution was applied to the external auditory canal. They found that the time to complete recovery and disease recurrence was significantly shorter in patched group than non patched group.[11]

In our study we used Clotrimazole soaked gefoam as a barrier to avoid seepage of Clotrimazole ear drops into middle ear when instilled at home by patients. We noted that all but one patients had no to mild pain on instilling drops at home following gelfoam insertion and were compliant for the entire treatment course. 19 out of 26 had complete disease clearance and 3 of them with a pinpoint perforation had a healed membrane at follow up. Our study is comparable to a study done by Dorasala S et al who used a similar technique in six patients of recalcitrant Otomycosis and achieved complete cure with no further recurrence of otomycosis. The gelfoam acts as a very good desiccant by absorbing the excess water and reducing the moisture in the external auditory canal. It holds the antifungals instilled and swells up maintaining contact with the external auditory canal skin for prolonged time and also facilitating slow release.[12] It also prevents seepage of solution to middle ear to a large extent and being absorbable doesn't demand frequent follow ups or clearance.

## Conclusion

The study concluded that treating otomycosis with a perforated eardrum presents challenges due to the stinging sensation and potential effects of Clotrimazole drops on the middle and inner ear. Various treatments have been explored to improve treatment compliance and disease clearance.The use of Clotrimazole-soaked gelfoam pieces may be a safer and more effective alternative for enhancing treatment compliance, achieving better disease clearance, and reducing the number of follow-up visits.

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