

# Comparison of effectiveness of 7.5% Povidone-iodine with 1% Clotrimazole ear drops and lignocaine in Otomycosis

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## Author's Contribution

<sup>1</sup> Conception of study

<sup>1,4</sup> Experimentation/Study conduction

<sup>1,2,3,6</sup> Analysis/Interpretation/Discussion

<sup>1,2,4</sup> Manuscript Writing

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## Abstract

**Objectives:** Our study is comparing the effectiveness of 7.5% Povidone-iodine with 1% Clotrimazole ear drops and lignocaine in the management of Otomycosis to highlight the importance of replacing conventional antifungals in routine practice.

**Setting:** Department of ENT and Head and Neck Surgery, Holy Family Hospital, Rawalpindi, Pakistan.

**Study design:** A prospective randomized control trial

**Methodology:** This study was conducted for 12 months in our institute from July 2014 to June 2015. A total number of 148 patients with clinically diagnosed Otomycosis between the ages group 15 to 55 years were studied. All patients with a clinical diagnosis of Otomycosis presenting with all four features of earache, itching, ear-blockage, and ear discharge in ENT OPD were included. Ear swabs were taken and sent for fungal culture. Patients were divided into A and B groups each comprising of 74 patients. Group A received 1% Clotrimazole ear drops and lignocaine and group B received 7.5% Povidone-iodine for 14 days after the results of cultures were received. At the end of 14 days, patients of both groups were compared based on the resolution of symptoms and signs.

**Results:** At the end of 14 days, 32 out of 74 patients (43%) in group A receiving 1% Clotrimazole ear drops and lignocaine reported resolution of all symptoms, and 52 out of 74 patients (70%) showed complete resolution of all signs, while in group B, 68 out of 74 patients (91%) showed complete resolution of symptoms and 69 out of 74 patients (93%) showed complete resolution of signs. Our study showed significant improvement in signs and symptoms of Otomycosis achieved by treatment with 7.5% Povidone-iodine compared to that achieved by 1% Clotrimazole ear drops and lignocaine.

**Conclusion:** 7.5% Povidone-iodine is a more effective antifungal agent in the treatment of Otomycosis as compared to 1% Clotrimazole ear drops and lignocaine.

**Keywords:** Otomycosis, Povidone-iodine, Clotrimazole.

## Introduction

Otomycosis is a superficial fungal infection of the external auditory canal and is worldwide in distribution characterized by inflammation, pruritus, scaling, and severe discomforts like suppuration and pain.<sup>1</sup> This disease can also spread to the middle ear if the tympanic membrane is perforated.<sup>2</sup> It is usually unilateral and more common in the younger age group.<sup>2</sup> It is estimated that almost 5% to 25% of total cases of Otitis Externa (inflammation of the external auditory canal) are due to Otomycosis.<sup>3</sup> It is common in a hot and humid climate like the south Asian region, mostly in people belonging to lower socioeconomic backgrounds.<sup>3</sup> The most common causative agent isolated from Otomycosis patients is from the genus *Aspergillus* followed by *Candida* Species. Among the genus *Aspergillus*, *Aspergillus niger* is most common followed by *A.flavus* and *A.fumigatus*.<sup>4</sup>

In patients of Otomycosis, debris in the external auditory canal does not always consist of purely fungal elements but is mixed with bacterial invaders like *Pseudomonas aeruginosa*, *Staphylococcus*, and *Streptococcus*.<sup>5</sup> Otoloscopic examination reveals a grayish-white mass in the external auditory canal along with hyperemia and sometimes edema as well. Patients commonly present with pain and itching in the ear.<sup>6</sup> The diagnosis of Otomycosis is based on history, otoscopic examination, and fungal culture. Direct preparation of the specimen specifically with optic brightener, mycological culture, and histological examination is strongly recommended for correct diagnosis. The microscopic examination of fungal cultures after the preparation of slides with Potassium hydroxide shows discrete clumps of hyphae with conidiophores.<sup>7</sup>

Many pharmacological preparations like drugs from Azole class, Nystatin, 7.5% Povidone-iodine, Tolnaftate, Acetic acid, and Gention violet are currently used widely for the treatment of Otomycosis without knowing the exact efficacy of drug class.<sup>8</sup> Further studies are required to find out the antifungal activity of each class of drugs and the comparison of their resistance patterns in detail to aid in evidence-based decision-making to prevent the potential risk of antifungal resistance which not only increases disease burden but is also cost-intensive.

The purpose of this study is to evaluate the antifungal property of 7.5% Povidone-iodine to promote an alternate, effective and cheaper treatment of

Otomycosis. Povidone-iodine has effective antibacterial, antifungal, and antiprotozoal properties. Previous studies have shown promising results of the antifungal activity of Povidone-iodine in the treatment of Otomycosis. We want to evaluate whether the same is true in our population and the comparative pros and cons of using it instead of 1% Clotrimazole ear drops and lignocaine preparation.

## Materials and Methods

A randomized control trial was conducted in our institution for 12 months. The institutional research board clearance was taken before the commencement of the study and detailed informed consent was also taken from the subjects. All the patients with clinically diagnosed Otomycosis within the age range of 15 to 55 years were included in the study. Patients with Chronic Suppurative Otitis, Media, Malignant Otitis Externa, post-operative mastoidectomy cavities, and Diabetes Mellitus were excluded from this study. All the patients who presented to us through OPD with symptoms of earache, itching, ear blockage, and ear discharge were included. These patients were diagnosed based on history, examination with an otoscope, and fungal culture of ear swab taken. The cultures were grown on Sabouraud Dextrose agar at 25°C and incubated for 24 hours. We also did an aural toilet with a suction machine. Otoloscope and suction machines were the main instruments used to aid in the diagnosis of Otomycosis in our research. The symptoms and signs of these patients were documented after taking written informed consent from each of them. We divided the patients into two equal groups: A and B, comprising of 74 patients in each group. Group A received 1% Clotrimazole ear drops and lignocaine drops, 3 drops each to be instilled in the affected ear three times a day for 14 days. Group B received 7.5% Povidone-iodine ear drops also prescribed as 3 drops thrice a day for 14 days. The evaluation of patients in both the groups was done on the 14<sup>th</sup> day based on the resolution of symptoms and signs however on the 7<sup>th</sup> day all the patients were called for the suction toilet to clear the fungal debris. Data was analyzed and entered using SPSS version 18.

### Target sample size and rationale:

The sample size was calculated using the WHO sample size calculator, keeping the power of test 90% level of significance 5%, resolution of otalgia in

Clotrimazole group 100%, and resolution of otalgia in Povidone-iodine group 86.7%. The sample size was 148.

**Results**

In this study, out of a total of 148 patients, there were 46 (62.16%) males and 28 (37.8%) females in group A. In group B there were 51 (68.91%) males and 23 (31.01%) females. The male to female ratio in group A was 1.6:1 and in group B was 2.2:1. The graphical representation of gender distribution is shown in fig.1 below. According to the culture results from ear swabs, *Aspergillus Niger* was isolated in 63% of culture results whereas *Candida albicans* were detected in 33% of cultures from both the groups.

The number of patients with persisting symptoms of earache, itching, ear blockage, and ear discharge in group A after 14 days of treatment was 35 (47%), 42 (57%), 31 (42%), 38 (51%) respectively out of a total of 74 patients, while in group B the number of patients with these persisting symptoms was 4 (5.4%), 3 (4.1%), 5 (6.7%) and 6 (8%) patients respectively as shown in Figure 2 and Table 1.

Signs of fungal debris, erythema of canal, and erythema of tympanic membrane persisting after 14 days were seen in 20 (27%), 22 (30%), and 7 (9%) patients respectively in group A while in group B they were seen in 2 (2.7%), 5 (6.7%) and 1 (1.3%) patients respectively out of a total of 72 patients in both groups as shown in Figure 3 and Table 2 along with their p values.

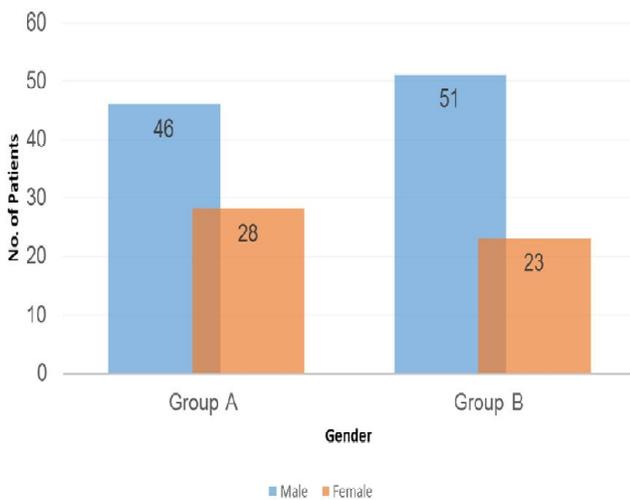


Figure 1: Male to Female ratio graph

Table 1: Post-treatment symptoms (After 14 Days)

Post treatment symptoms	Group A (1% Clotrimazole & lignocaine) (n=74)	Group B (7.5% Povidone-iodine) (n=74)	P value
Otalgia	35 (47%)	4 (5.4%)	0.042
Pruritus	42 (57%)	3 (4%)	0.031
Ear blockage	31 (42%)	5 (6.7%)	0.023
Ear discharge	38 (51%)	6 (8%)	0.041

(n=148)

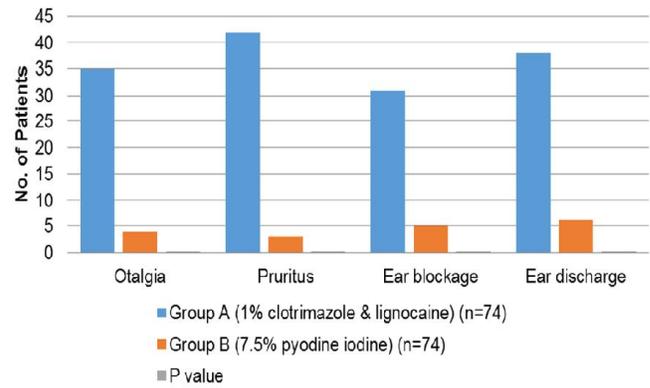
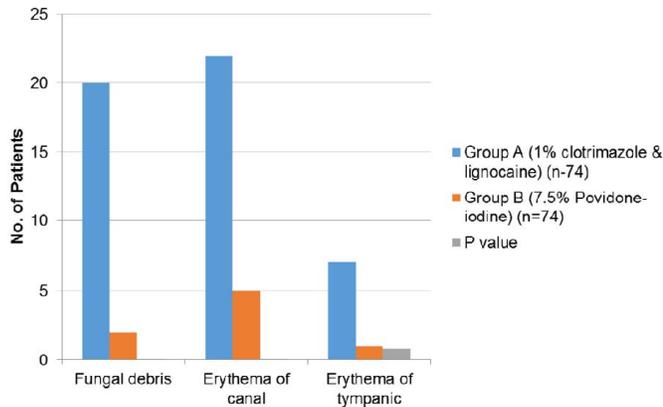


Figure 2: Comparison of post-treatment symptoms of both groups

Table 2: Post-treatment signs: (After 14 Days)

Post treatment signs	Group-A (1% clotrimazole & lignocaine) (n=74)	Group-B (7.5% Povidone-iodine) (n=74)	P value
Fungal debris	20 (27%)	2 (2.7%)	0.045
Erythema of canal	22 (30%)	5 (6.7%)	0.032
Erythema of tympanic membrane	7 (9%)	1 (1.3%)	0.812

(n=148)



**Figure 3: Comparison of post-treatment signs of both groups**

## Discussion

The treatment of Otomycosis has often been presented as a clinical challenge in many ENT practices. Munguia et al found that *Aspergillus* species and *Candida albicans* are the most common causative organisms.<sup>12</sup> Our study also found that *Aspergillus* species and *Candida albicans* are the most prevalent causative organism in our sample population. Many drugs have been investigated for the treatment of Otomycosis.<sup>8</sup> Antifungals from the Azole class seem to be the most effective, followed by Nystatin and Tolnaftate.<sup>12</sup> 1% Clotrimazole ear drops and lignocaine have been used for effective treatment of Otomycosis for a long time in the medical field.<sup>10</sup> Nneenia Mgbor et al used Clotrimazole in a comparative study in Nigeria and found it to be an effective drug.<sup>11</sup> Recently some researchers have also studied the efficacy of Povidone-iodine in Otomycosis treatment. In our clinical practice, we found that most patients do not show complete resolution of signs and symptoms of Otomycosis with the Azole group of antimycotics like Clotrimazole. This leads to treatment failure and frequent relapses due to the persistence of spores as well as the risk of developing serious complications like tympanic membrane perforation, hearing loss, and invasive temporal bone infection, although seen sporadically and only in immunocompromised patients.<sup>18</sup> It is because Clotrimazole eardrops are irritating, if used alone compliance is difficult to achieve by prescribing additional lignocaine drops; hence there is the need for studying newer agents. Frequent use of the Azole group of antifungals might be the main factor for its increased resistance worldwide. Van der Linden et al performed a prospective nationwide multicenter surveillance study

in Netherland and found that there was statistically significant resistance to the Azole group of antifungals in Otomycosis.<sup>13</sup> In another study acquired azole resistance in *Aspergillus fumigatus* was detected in 11 out of 17 European centers in 9 countries.<sup>15</sup> The overall prevalence of Azole group resistance was 3.2% which was also associated with worse patient outcomes.<sup>14,15</sup>

Povidone-iodine (PVP-I) also known as iodopovidone is an antiseptic used for skin disinfection before and after surgical procedures. Maral Gharaghani et al used Povidone-iodine in their study and reported it to be an effective antifungal agent.<sup>16</sup> Ajay Philip et al conducted a comparative study and also observed its effectiveness in the management of Otomycosis<sup>8</sup>. Pain, pruritis, and ear discharge are the most troublesome symptoms reported after Otomycosis which were relieved earlier in the group receiving Povidone-iodine compared to that receiving Clotrimazole.<sup>17</sup> Povidone-iodine is an inexpensive, nontoxic agent with good antimycotic properties and no drug resistance reported so far. In developing countries like Pakistan where cost-effectiveness is a serious issue, it is very important to study and advocate the use of cheaper and effective treatments like Povidone-iodine on a larger scale by ENT practitioners. Only a few studies have been conducted in this regard in Pakistan.

Our study also confirms a better resolution of signs and symptoms of Otomycosis with 7.5% Povidone-iodine compared to 1% Clotrimazole ear drops and lignocaine. Approximately one-third of patients (39.7%) in the 1% Clotrimazole eardrops and lignocaine receiving group were not cured. On the other hand, only 6.7% of patients in the 7.5% Povidone-iodine receiving group had treatment failure at the end of 14 days. This proves that 7.5% Povidone-iodine is significantly better than 1% Clotrimazole ear drops and lignocaine in the treatment of Otomycosis and future ENT consultants and specialists should prescribe it to the patients who are having fungal infections of the ears.

## Conclusion

7.5% Povidone-iodine is far effective in the treatment and management of Otomycosis as compared to 1% Clotrimazole eardrops and lignocaine.

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