

## ORIGINAL ARTICLE

# EVALUATION OF THERAPEUTIC EFFICIENCY OF TOPICAL CLOTRIMAZOLE AND TOPICAL MICONAZOLE IN THE TREATMENT OF OTOMYCOSIS- A PROSPECTIVE STUDY

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## ABSTRACT

**Background:** Otomycosis a Superficial Fungal Infection of the External auditory canal causes lot of misery to the Patient with tendency of recurrence. Many Antifungals are used for treatment with different percentage of success; still a standard regime is not firmly established. So this study is undertaken to evaluate Therapeutic efficiency of Topical Clotrimazole and Miconazole in treating Otomycosis.

**Materials and Methods:** Present study was conducted on 156 clinically diagnosed cases of Otomycosis. Ear discharge was collected. Identification of fungi was done by standard protocol. Out of 156 cases 135 cases produced positive fungal isolates which were taken for further studies. Cases underwent thorough cleaning in Infected Ear. 1% Clotrimazole Ear drop was used in 70 cases and 1% Miconazole in 65 cases for 1 week and followed up for 1 week to 2 months for clearance or recurrence.

**Results:** Clotrimazole showed good response Symptomatically and Mycological clearance within one week in 66 cases. Persistence of disease to 2-4 weeks in 4 cases and no recurrence within 2 months of follow up with minimal side effects, Where as Miconazole showed good response within one week in 54 cases, 9 cases had persistence of disease to 2-4 weeks and 2 cases had recurrence, burning sensation in 9 patients and 1 case developed allergy and discontinued treatment.

**Conclusion:** Topical Clotrimazole is more Effective, Safe and well tolerated with better Symptomatic relief, Mycological clearance and low relapse rate compared to Topical Miconazole.

**Key words:** Clotrimazole, External Auditory Canal, Miconazole, Otagia, Otomycosis

## INTRODUCTION

Ear is a paired structure and a Specialised sense organ for hearing and balance which is constantly exposed to Biotic elements and various Microorganisms among which Fungal infections of External Ear are common. Otomycosis is a superficial fungal infection of the External Auditory Canal.<sup>1,2</sup> The prevalence of Otomycosis has been reported to be as low as 9% and as high as 30.4% of Otitis Externa.<sup>3</sup> The disease is worldwide in distribution, but the hot, humid and dusty environment of the tropics and subtropics make Otomycosis more prevalent in these regions.<sup>4</sup>

A variety of fungi are the agents responsible among which the most common etiological agents

are Aspergillus Species and Candida.<sup>5</sup> Among the Aspergillus A. Niger is the commonest isolate followed by A.Flavus and A.Fumigatus. Chronic infective disorders of the Ear remain a common source of misery for the patients, although not life threatening Otomycosis can be a frustrating condition due to the requirement for a long-term treatment, regular follow up and its tendency for recurrence.

Many Antifungals are used for treating Otomycosis with different percentage of success. But a standard regime for the treatment of Otomycosis is not firmly established. So the present study is undertaken to evaluate the therapeutic efficiency of Topical Clotrimazole and Miconazole in the treatment of Otomycosis.

## METHODOLOGY

The present study was undertaken on 156 clinically diagnosed cases of Otomycosis attending the ENT OPD at Basaveshwar Teaching and General Hospital Kalaburagi. The study was conducted over a period of one year. Ethical clearance was obtained from the Institutional Ethical Committee. An informed consent was obtained from all the patients before the start of study.

### Criteria for selecting Patients with Otomycosis:

**Inclusion criteria:** Patients diagnosed with Otomycosis based on

- Symptoms- Pruritis, Otagia, Otorrhea, Ear fullness and impaired hearing.
- Signs-Evidence of Otomycosis on Otoscopy- Wet Mycelial mats, Dry Mycelial mats, Wet blotting paper appearance or Creamy white debris.
- Positive fungal culture from the aural debris.

**Exclusion criteria:** Patients on Topical Antifungal drops and Negative Fungal isolates by Direct Microscopy or Culture were excluded from the study.

**Collection of Sample:** Mycological examination was done by taking with sterile cotton swabs from fungal mats seen in the Infected Ear Canal and sent immediately to Microbiology Laboratory and subjected for the following examinations.

**Direct Microscopy:** In 10% Potassium Hydroxide (KOH) Preparation and Grams Stain Examination.

**Culture Methods:** Sabaourauds Dextrose Agar (SDA) used for fungal isolation and identification by Cultural characteristics by standard procedure. For isolation of Fungi, growth on media was confirmed by Lacto Phenol Cotton Blue (LCB) preparation and Grams Stain. Species identification of Candida was done by Sugar Fermentation Test, Sugar Assimilation Test, Germ Tube Test, and Pigment Production on Chrome agar and Detection of Chlamyospore Formation on Corn meal agar.<sup>6</sup>

All the cases underwent thorough cleaning of Fungal mats and Debris in Infected Ear Canal, either by Dry mopping, Syringing or Suction Clearance under Microscope and then treated by Topical Antifungal Agents 1% Clotrimazole Eardrop was used in 70 cases and 1% Miconazole in 65 cases for one week and were followed up for a minimum of one week to two months for noting the clearance or recurrence of the disease.

During treatment Patients were advised to avoid water entering the Ear; to keep Ear dry; to install advised Antifungal Ear drops three times a day till further advice; Regular follow up at ENT OPD; and to consult immediately in case of side effects like-Burning, Local irritation, Allergy or Drowsiness.

The Culture was repeated at the end of three weeks. In those Patients, where a Positive Culture was obtained, treatment was continued for another one week and Culture was repeated again. Thus all Patients were followed up till complete Mycological clearance.

The cases with associated conditions having Local Bacterial Infection of Ear were treated with Antibacterial Ear Drops, Scalp Dandruff was treated with Ketaconazole solution and Systemic Diseases like Diabetes Mellitus, Hypertension and Pulmonary Tuberculosis were treated in accordance to their Standard line of Treatment.

## RESULTS

Out of 156 clinically diagnosed cases of Otomycosis only 135 cases produced Positive Fungal Isolates, these constituted 85.94% which were taken up for further studies. In our study it is observed that incidence of Otomycosis is slightly higher in Males than in Females. The most common predisposing factor was use of unsterile materials/swabs for cleaning the Ear. Itching in the Ear was the most common symptom in 127 cases (94.07%).

In our study it was found that Hyperaemia of Ear skin and Tympanic membrane was the most commonest Inflammatory sign observed in 118 cases (87.40%) followed by Oedema of canal in 70 cases (51.85%) and Granulation tissue in 37 cases (27.40%) and Physical Signs encountered were lack of Cerumin or unhealthy Wax was the most commonest characteristic feature noted in 125 cases (92.59%), Mastoid tenderness was seen in 8 cases (5.92%) and Tragal Sign Positive in 5 cases (3.70%). In Tuning Fork Test Renne's Test was Positive and Webber's Lateralisation in 47 cases (34.81%) and decreased Absolute Bone Conduction was noted in 9 cases (6.66%) as evident in Table 1. Most common Fungi isolated were Aspergilli followed by Candida species, Mucar and Penicillium.

Table 2 elucidates the Methods used in cleaning the Infected Ear Canal. Dry mopping was used in 132 cases (98%), Suction Clearance under Microscope in 6 cases (4.4%) and Syringing in one case (0.74%).

**Table 1: Clinical Signs of Otomycosis**

Signs	No. (%)
Hyperemia of Canal skin and Tympanic membrane	118 (87.40)
Edema of Canal	70 (51.85)
Granulation Tissue	37 (27.40)
Lack of Cerumin or Unhealthy Wax	125 (92.59)
Mastoid Tenderness	08 (5.92)
Tragal sign positive	05 (3.70)
Tuning Fork Tests	
a)Rhinne’s Test Positive	47 (34.81)
b)Webber’s Lateralization	47 (34.81)
c)Decreased Absolute Bone Conduction	09 (6.66)

Clotrimazole was used in 70 cases, showed good response Symptomatically as well as Mycological clearance within 1 week in 66 cases (94.28%) and

persistence of disease up to 2 to 4 weeks in four cases (5.71%) and no recurrence of cases within 2 months of follow up. Miconazole was used in 65 cases showed good response symptomatically as well as Mycological clearance within one week in 54 cases (83.07%), 9 cases (13.84%) had persistence of disease up to 2 to 4 weeks and 2 cases (3.07%) had recurrence on follow up as depicted in Table 3.

**Table 2: Methods of Cleaning the Infected Ear Canal**

Methods	No. (%)
Dry Mopping	132 (98.00)
Suction Clearance	06 (4.40)
Syringing	01 (0.74)

**Table 3: Comparative Results of Topical Clotrimazole and Topical Miconazole in treating Otomycosis**

Topical Antifungal Agents	Clotrimazole	Miconazole
Cases	70	65
Response (Symptomatic &Mycological Clearance within 1 week) (%)	66 (94.28)	54 (83.07)
Persistence of Disease up to 2-4 weeks (%)	04 (5.71)	09 (13.84)
Failure/Recurrence of Disease within 2 months (%)	Nil (0.00)	02 (3.07)

The side effects of Topical Antifungal Agents used to treat Otomycosis in our study were Clotrimazole had fewer side effects which include Burning Sensation after instilling the Ear Drops in 7 patients (5.18%). Miconazole also showed Burning Sensation in 9 cases (7.64%) and one case developed Allergy and discontinued the Treatment.

**DISCUSSION**

External Ears are constantly exposed to Environment and are relatively attacked by many Pathogenic Microorganisms among which fungal infection are common. As the Fungal Infection are not highly infectious and run relatively mild course in an unrecognised manner than do the most of the Bacterial Infections, cause greater Morbidity than any other Disease of the External Ear.

Fungal flora and Spores present in the Air of Atmosphere act as the possible Agents of Otomycosis is a well known fact.<sup>7</sup> Fungi are also seen as normal commensal of External Auditory Canal, but for the proliferation of the Fungi a Favourable Environment has to be created. In Normal Ear Wax has an inhibitory effect on most of the Fungi containing various AminoAcids, Fatty Acids, Ly-

sosomes and Immunoglobulins that help in maintaining the pH of External Meatus on acidic side and also has some Bactericidal activity potent in killing dividing Bacteria.<sup>8</sup>

Despite of this protective Environment Otomycosis remains one of the commonest causes for Otitis Externa , because of certain predisposing factors and conditions which change the protective Environment to a favourable Environment for the Fungal growth.

Our study showed a slightly higher incidence in Males than Females which is in accordance with the findings of Shilpa KG et al<sup>2</sup>Khurana et al<sup>9</sup>, Mohanty and associates<sup>10</sup> and Talwar and others.<sup>11</sup> Use of unsterile sticks and swabs for cleaning the Ear and use of Oils and Mixture of Oils in Ear were the commonest predisposing factors as per our study which is in accordance with the study done by Mohanty<sup>10</sup> and Prasad SC.<sup>12</sup> Itching in the Ear, Otagia were most common symptoms followed by Fullness of Ear, Discharge from Ear, Tinnitus ,Deafness confirming the findings of earlier studies.<sup>3,13,14</sup>

Hyperaemia of Canal skin was seen in majority of cases(87.40%) followed by Oedema of canal and Granulation Tissue which is in accordance with

study done by Paulose KO et al.<sup>15</sup> The commonest Physical Sign of lack of Cerumin or Unhealthy Wax correlates well with the previous studies.<sup>15,16</sup> Most common fungal isolate found in our study was *Aspergillus* followed by *Candida*, *Mucor* and *Penicillium*. *Aspergilli* have an optimum pH range of 5.7 at a temperature of 37 and this is conducive for all species of *Aspergillus* as documented in our previous study<sup>17</sup> and also with other earlier studies.<sup>18,19</sup>

Clotrimazole was used in 70 cases and Miconazole in 65 cases and on follow up, for the results and Side effects of Drugs recorded, showed that Clotrimazole was effective in 66 cases (94.28%) and Miconazole in 65 cases (83.07%) at the end of one week of treatment showing Symptomatic and Mycological Clearance of the Disease. On further follow up it was seen that Disease persisted up to 2 to 4 weeks in 4 cases (5.71%) of Clotrimazole group and in 9 cases (13.84%) of Miconazole group. No recurrence was seen in Clotrimazole group and 2 cases (3.07%) had recurrence or failure within 2 months in Miconazole group, in which one patient left the treatment due to Allergy. During follow up, the side effects observed were very minimal. Only 8.07% complained of mild Burning sensation after instillation of Ear Drops which persisted for few minutes which is in accordance of study conducted by Paulose KO et al.<sup>15</sup> One Case had allergy to Miconazole drops and left the treatment.

The present study is comparable to the study done by Chander J et al,<sup>20</sup> where both Clotrimazole and Miconazole were effective Symptomatically as well as Mycologically but with different rate of Success of Treatment at the end of Two Weeks. The Anti-fungal Agents Clotrimazole and Miconazole are synthetic derivatives of Imidazole group act by inhibiting the Fungal Cytochrome P 450 enzyme Lanosterol 14-demethylase and thus impair Ergosterol synthesis leading to a cascade of membrane abnormalities in the Fungus.<sup>21</sup>

## CONCLUSION

In conclusion, It is observed from our study that Clotrimazole is more effective, safe and well tolerated Topical Anti Fungal Agent with better Symptomatic and Mycological clearance when compared to Miconazole. The study also concludes that thorough and meticulous cleaning of Fungal and Epithelial Debris from the Ear prior to the initiation of the Treatment is of paramount importance

along with elimination of Predisposing factors and Treatment of Associated Conditions.

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