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A COMPARITIVE STUDY ON THE ROLE OF TOPICAL ANTIFUNGAL AGENTS IN OTOMYCOSIS IN EXTERNAL AUDITORY CANAL

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ABSTRACT

A study titled “A COMPARITIVE STUDY ON THE ROLE OF TOPICAL ANTIFUNGAL AGENTS IN OTOMYCOSIS IN EXTERNAL AUDITORY CANAL” was conducted jointly in the Department of Otorhinolaryngology and Head and Neck Surgery and Department of Microbiology of Santosh Medical College and Hospital, Ghaziabad (U.P). The cases were selected from ENT outpatient department of the associated hospital. In all 202 patients attending the Out-patients Department of E.N.T of Santosh hospital, during the period July 2011 –April 2012, were included in this prospective study. It is a prospective study. In all 202 patients attending the Out-patients Department of E.N.T of Santosh hospital Ghaziabad , during the period July 2011 –April 2012, were included in this prospective study. Only hundred and fifty patients were taken up for the study according to inclusion and exclusion criteria. The patients divided at random into 3 equal groups irrespective of age, sex, clinical presentation and degree of involvement. The response to treatment evaluated on subjective improvement of signs and symptoms.

INTRODUCTION

Otomycosis is type of otitis externa. It denotes fungal infection of the external auditory canal. Other synonyms being otitis externa mycotica, tropical ear, hot weather ear, swimmers ear, Singapore ear and mildew ear. It is characterized by a symptom-complex of itching, discharge, blockade of the external ear canal and ear ache. Overuse of antibiotics, corticosteroids and immunosuppressive drugs have all been blamed in the past.

Abraham tucker may well have a point-After all perhaps we have no greater enjoyments among us than those of eating when we are hungry, drinking when we are thirsty, lying down when we are sleepy or as the second Solomon has pronounced, then “scratching where it itches” .Even the most cursory review of the topic will bring to fore, the many controversial and yet unexplained facets of the disease.

Bacteria play a significant role in the natural course of this disease so that few authors initially thought them to be the primary pathogens. However, they certainly add to the morbidity of otitis externa.

A myriad of conditions have been thought to predispose to this disease, by various authors in the past-scratching the external auditory canal, local hot and humid conditions worse confounded by instillation of all types of oil, anatomical obstructions due to excessive tragal hair or stenosis of the canal. Systemic causes like diabetes, immunosuppressive conditions and agents.

Many authors have studied the entity of otomycosis the past most of the pioneering work having been started in the last world war. Starting with the work of Clark who studied the disease for the first time in India¹. Much work has been done by Indian authors, Sinha, Sood and Mohapatra contributed significantly to the experimental aspects of the disease and studied the regional factors pertaining to India².

This prospective study was undertaken to study the spectrum of the disease in the patients presenting to outpatient clinics, types of fungi, predisposing factors, treatment taken from local doctors, and to standardize its optimal therapy.

MATERIAL AND METHODS

A study titled “A COMPARITIVE STUDY ON THE ROLE OF TOPICAL ANTIFUNGAL AGENTS IN OTOMYCOSIS IN EXTERNAL AUDITORY CANAL” was conducted jointly in the Department of Otorhinolaryngology and Head and Neck Surgery and Department of Microbiology of Santosh Medical College and Hospital, Ghaziabad (U.P). The cases were selected from ENT outpatient department of the associated hospital.

In all 202 patients attending the Out-patients Department of E.N.T of Santosh hospital, during the period July 2011 –April 2012, were included in this prospective study.

Study Design: Prospective study.

Sample Size (n): =150

INCLUSION CRITERIA:-

1. All patients attended OPD of ENT Department of Santosh Hospital Ghaziabad who are clinically diagnosed as a case of otomycosis.
2. Only most common fungi were considered for the present study- *Aspergillus niger*, *Candida*, *Aspergillus fumigatus*.

EXCLUSION CRITERIA:-

- Operated cases.
- Cases of chronic suppurative otitis media.
- Diabetic patients.
- Patients with pulmonary Koch's.
- Immunocompromised patients.
- Patients with mixed fungal infection.
- Patients with uncommon fungal growth.
- The patient who did not turn up for follow up.

Methodology:

The patients were examined and a presumptive diagnosis of otomycosis was made as per established criteria and clinical presentation of the fungus, vide- infra:-

- Pain in the ear.
- Ear discharge.
- Heaviness/ “blocked” feeling in their ear.
- Hearing loss.
- Presence of fungus in the ear (otoscopic examination or under microscope, as required).

Score:-

The severity of the diseases was elicited for three subsequent visits and recorded according to the following grading:-

Sign and symptoms	0	1	2
Pain	Absent	Improved but present	Present
Discharge	Absent	Improved but present	Present
Itching	Absent	Improved but present	Present
Hearing impairment	Absent	Improved but present	Present
Oedema	Absent	Improved but present	Present
Hyperaemia or ulceration	Absent	Improved but present	Present
Blockage	Absent	-----	Present

All Patients which were diagnosed with Otomycosis were randomly assigned the following numbers 1, 2, 3 and were divided into the following groups as per drug used irrespective of age and sex.

Patient assigned number 1= Group A

Patients assigned number 2= Group B

Patients assigned number 3= Group C

Group A– received CLOTRIMAZOLE oticdrops(1% clotrimazole solution.)

Group B – received FLUCONAZOLE oticdrops(0.3% w/v fluconazole solution.)

Group C– received ACETIC ACID oticdrops(2% acetic acid solution.)

After the clinical diagnosis was made a sterile swab was taken from the external auditory canal for culture. The samples were sent to the Microbiology Department of Santosh Medical College Ghaziabad. (U.P) and species were identified and diagnosed.

Particular emphasis was laid to elicit the history of pre-disposing factors in a particular patient; duration of symptoms, treatment taken the response to the earlier treatment, as these variables were thought to influence the occurrence of otomycosis and its subsequent course.

All diagnosed patients, were subjected to laboratory investigations in the Microbiology Department of Santosh Medical College.

Microbiological Analysis:

A sterile cotton swab was used to collect the specimen from the external auditory canal. An inoculum of the specimen was made on Sabouraud's Dextrose Agar slope. The tubes were incubated at 25⁰c and 37⁰c in the incubator. These tubes with inoculum were examined daily for patterns of fungal growth. Generally, good fungal growth was observed in 3 to 4 days. The culture tubes were examined for at least four weeks before being discarded.

The external ear were meticulously cleaned under the operating microscope by dry mopping , by irrigation with sterile normal saline or by suction clearance after which patient was prescribed different antifungal drugs (CLOTRIMAZOLE, FLUCONAZOLE , ACETIC ACID) .The patients were instructed to keep the ear dry and instil 3 to 4 drops of drug thrice a day in the affected ear. Patients were followed up with weekly examination for three subsequent weeks at days 7,14 and 21 and response to the drug was noted. On each of this visit the canal was re-examined. The response to the treatment was noted with respect to the pain, blockade, discharge, itching, hearing impairment, oedema of the ear canal, hyperaemia or ulceration of the skin of the external auditory canal and subjective grading score of the symptoms were made, for each symptom ranging from 0 to 2.

Statistics:-

ANOVA (analysis of variance) test was used to compare three drugs.

It is used to know the significant variation.

Two way ANOVA was used in study, which is used as repeated follow up's and as comparison of drugs on the basis of improvement in signs and symptoms and duration was made.

P value is calculated and significance has been noted. $P < 0.05$ (significant)

RESULTS

TABLE 1—MEAN & STANDARD DEVIATION OF DIFFERENT CLINICAL FEATURES FOR THE THREE DRUGS

S.NO.	CLINICAL FEATURES	MEAN±S.D.		
		CLOTRIMAZOLE	FLUCONAZOLE	ACETIC ACID
1	PAIN	88.89*±19.24	52.69±13.04	3.33±0
2	BLOCKED	87.5±14.43	91.25*±6.29	42.5±16.39
3	DISCHARGE	84.85*±26.24	69.49±19.45	0.953±1.65
4	ITCHING	100*±0	94.66±3.81	11.66±9.46
5	HEARING IMPAIRMENT	100*±0	93.3±0	0±0
6	OEDEMA	100*±0	70±10	0±0
7	HY/UL.	93.33*±11.54	60±10	0±0

*shows the highest reduction/improvement due to CLOTRIMAZOLE as compared with FLUCONAZOLE and ACETIC ACID and ANOVA shows a significant difference among three drugs for measuring the different clinical features.($p < 0.01$, significant)

In this study CLOTRIMAZOLE has found to be most effective drug in otomycosis as compared to fluconazole and acetic acid. Difference between the mean responses was statistically significant among the drugs ($p < 0.01$). **Thus the efficacy of CLOTRIMAZOLE in my study came to be 100%.** Clotrimazole as compared to other two drugs showed to be most effective drug statistically ($p < 0.01$)

DISCUSSION

This study was therefore undertaken to know the fungal species involved in otomycosis, in this part of the country, to gather an insight into the predisposing factors, to study their clinical presentation and to study the role of topical antifungal agents on most common fungi involved in otomycosis. Of all 202 patients 150 patients were selected for the study and remaining 52 patients were excluded as per the exclusion criteria. 150 patients, presenting to the ENT OPD of Santosh Hospital during the period of July 2011 to January 2013 were included in this study. The ages of the patients ranged from 0-76 and above. Maximum number of patients presented in the age group of years 15 - 30 (54%), that is adolescent to young adults. Patients in this age group would be the ones involve in maximum outdoor activity and hence exposure to dust, the chief source of fungal infection. One would also expect that the people of this age group are the ones who would be exposed to fungal infection from swimming, an activity unlikely to be taken up at extremes of age.^{3,6,9,4} The male to female distribution in this study was (58%) to (42%). One would expect this in India, since ladies have a limited exposure to outside environment as compared to their male counterparts, despite the changing social conditions. Again this trend is in accordance with what other workers have found from various parts of world.^{5,3,4}

A clear pattern was noted in the time of presentation of patients, majority of the cases, having presented in the months of august and September (55.4%).⁶

In this study one hundred and forty patients had unilateral diseases and only ten patients had bilateral diseases.^{4,9,6} The maximum numbers of cases in this study were students (48%) and housewives (23.3%). This can be explained by the fact that students move around in congested surroundings-buses, classrooms, etc. and are also involved in a lot of outdoor activity and so predisposing to fungal infection of the ear.¹¹ The habit of cleaning the ear with a matchstick or a hairpin has been noted in 52% cases. There was definite history of water having entered the external auditory canal, before the episode of illness in 32.66% cases. This finding is in accordance with what other workers have reported.^{6,11,2} Itching in the ear (82%) and blocked of the ear (80%) were the most common symptoms with which the patient presented in our patient clinic. Other symptoms were pain (60.66%), discharge (68.6%), hearing impairment (29.9%).^{6,11,9}

Examination of the ear for fungus revealed a black mycelial mass in (58.66%) cases, which on culture grew *Aspergillus niger*, white creamy paste like mass in (30%) cases, which on culture grew into *Candida*, greenish mass in (11.3%) cases, which on culture grew into *Aspergillus fumigatus*.³ *Aspergillus niger* was found to be the commonest isolate in our study other common fungi are *Candida* and *Aspergillus fumigatus*.^{2,10,11,7,8,12,13,14,15}.

Many anti-fungal drugs have been used by various workers. In this study the drugs CLOTRIMAZOLE 1%, FLUCONAZOLE 0.3% AND ACETIC ACID 2% was used as otic drops. Patients were given these drugs for instillation 3-4 times per day in the effected ear.

PAIN

In our study patients presented to ENT clinic diagnosed otomycosis having pain were 91 out of 150 that is 60.66% were treated with CLOTRIMAZOLE the mean value is 88.89 ± 19.24 as compared to FLUCONAZOLE (mean value is 52.69 ± 13.04) and acetic acid is (3.33 ± 0).

Thus clotrimazole came to be most effective in relieving pain.

BLOCKED

Patient diagnosed otomycosis having blocked were 120 out of 150 that is 80% were treated with CLOTRIMAZOLE the mean value is 87.5 ± 14.43 as compared to FLUCONAZOLE (91.25 ± 6.29) and ACETIC ACID (42.5 ± 16.39). In this case FLUCONAZOLE came to be most effective but in cases of blocked we do cleaning of the ear by suctioning or syringing with sterile water.

DISCHARGE

Patient diagnosed otomycosis having discharge were 103 out of 150 that is 68.6% were treated with CLOTRIMAZOLE the mean value is 84.85 ± 26.24 as compared to FLUCONAZOLE (69.49 ± 19.45) and ACETIC ACID (0.953 ± 1.65). Thus CLOTRIMAZOLE came to be most effective in relieving discharge.

ITCHING

Patient diagnosed otomycosis having itching were 123 out of 150 that is 82% were treated with CLOTRIMAZOLE the mean value is 100 ± 0 as compared to FLUCONAZOLE (94.16 ± 3.81) and ACETIC ACID (11.66 ± 9.46). Thus CLOTRIMAZOLE came to be most effective in relieving itching.

HEARING IMPAIRMENT

Patient diagnosed otomycosis having hearing impairment were 44 out of 150 that is 29.33% were treated with CLOTRIMAZOLE the mean value is 100 ± 0 as compared to FLUCONAZOLE

(93.3+/-0) and ACETIC ACID (0+/-0). Thus CLOTRIMAZOLE came to be most effective in improving hearing impairment.

OEDEMA

Patient diagnosed otomycosis having oedema were 31 out of 150 that is 20.66% were treated with CLOTRIMAZOLE the mean value is 100*+/-0 as compared to FLUCONAZOLE (70+/-0) and ACETIC ACID (0+/-0). Thus CLOTRIMAZOLE came to be most effective in reducing oedema.

HYPERAEMIA OR ULCERATION

Patient diagnosed otomycosis having hyperaemia or ulceration were 30 out of 150 that is 20% were treated with CLOTRIMAZOLE the mean value is 93.3*+/-11.54 as compared to FLUCONAZOLE (60+/-0) and ACETIC ACID (0+/-0). Thus CLOTRIMAZOLE came to be most effective in relieving hyperaemia or ulceration.

In this study CLOTRIMAZOLE has found to be most effective drug in otomycosis as compared to fluconazole and acetic acid. Difference between the mean responses was statistically significant among the drugs ($p < 0.01$). **Thus the efficacy of CLOTRIMAZOLE in my study came to be 100%.**^{16,17,18,19,12,14,20.}

CONCLUSIONS

The conclusions drawn in this prospective study were:-

1. Clotrimazole as compared to other drugs showed to be most effective, statistically ($p < 0.01$)
2. Otomycosis is no respecter of age or sex. The range of the patients, population affected varied from 8-75 years, with the maximum number of people being between 15-30 years.
3. Both males and females were affected. In this study males were affected more than females.
4. It was found to be more often seen in students and housewives.
5. It is predominantly a unilateral disease.
6. Scratching the ear canal was the most often seen predisposing factor. Other important predisposing factors affecting the diseases were – water entering the ear while bathing/swimming and regular covering of the head.
7. In our study of the various organism isolated, *Aspergillus niger* and candida were found the most common isolate from the culture.
8. Itching and blocked ear were the most common symptoms found. On direct clinical examination of the ear with otoscope, a good correlation could be made of *Aspergillus niger* with black fungal hyphae and spores seen, Candida white paper like appearance mass, *Aspergillus fumigatus* greenish appearance of discharge.

In short it was found that otomycosis, though an age old disease, still presented with challenging aspect of diagnosis and treatment. Isolation of the fungal organism involved is not just an academic exercise but important for clinical cure. Anti- fungal drug CLOTRIMAZOLE is most effective than FLUCONAZOLE and ACETIC ACID in treating otomycosis.

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