Original Research Article

Efficacy of 1% clotrimazole drops vs. 1% clotrimazole cream vs 10% povidone-iodine in the treatment of otomycosis - A randomized controlled study

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Abstract

Introduction: Otomycosis is a term used to describe the epithelial infection caused by yeast and filamentous fungi, in the External Auditory Canal (EAC). It is one of the common infections seen in ENT OPD because of its prevalence in hot and humid climate. Due its high recurrence rate and different treatment modalities, it's important to come out with ideal treatment modality.

Aim: To compare efficacy of 1% clotrimazole drops vs. 1% clotrimazole cream vs 10% povidone-iodine in the treatment of otomycosis.

Materials and methods: Randomized control study was performed for 2 months on clinically diagnosed otomycosis patients. Total 60 patients were included in the study, which were randomly divided in 3 groups and treated by 1% clotrimazole drops, 1% clotrimazole cream and 10% povidone-iodine respectively. Patients were reviewed after 7 days on the basis of clinical response and symptoms of pain, ear blockage, pruritus and burning sensation.

Results: After 7 days of treatment groups treated with 1 % clotimazole drops and cream had good response of 90% and 95% as compared to 10% povidone-iodine group which was 70%. Clotrimazole cream group had more ear blockage complain which was 75% and clotrimazole drops group had more burning sensation complain which was 55%.

Conclusion: 1% clotrimazole drops and cream are equally effective in management of otomycosis but 10% povidone-iodine can be considered if patient has complain of ear blockage and burning sensation.

Key words

Otomycosis, 1% Clotirmazole, Cream, Drops, 10% povidone-iodine.

Introduction

Otomycosis is a term used to describe the epithelial infection of the External Auditory Canal (EAC) caused by yeast and filamentous fungi [1, 2]. It is very commonly prevalent in hot, humid climate. Nowadays, prevalence of otomycosis is increasing because of excessive use of antibiotics drops. Frequent swimming, immunocompromised patients, open mastoidectomy, tympanic membrane perforation, hearing aid usage and self cleaning with cotton swabs are other predisposing factors [3, 4]. The common organism that cause otomycosis are Aspergillus fumigatus, Aspergillus niger, Candida albicans of which Aspergillus niger is found to be predominant [5, 6].

Careful debridement of the EAC is crucial to facilitate the elimination of the infectious organism and to allow topical medications to reach the target tissue. Topical treatment cures most cases, although recurrence rates are high [7]. Clotrimazole (1%) cream/ drops is most commonly used topical antifungal [8]. Due to the high recurrence rate, its difficult to treat otomycosis by ENT surgeon. In this study comparison is done between clotrimozole 1% drops, Clotrimozole 1% cream and 10% Povidone-iodine.

Materials and methods

This study was done on 60 patients for the period of 2 months in ENT OPD Dhiraj Hospital, Vodadara, Gujarat.

Inclusion criteria:

All patients who gave consent and diagnosed with otomycosis on otoscopy having pain, ear blockage and pruritus were included.

Exclusion criteria:

All patients who had no otomycosis on Otoscopy, history of ear surgery and external ear anomaly.

All 60 patients were divided randomly in 3 Groups ‘A’, ’B’ and ‘C’. A proper suction clearance of the external canal was done endoscopically for all the 3 Groups. All patients received paracetamol 500 mg twice daily for 7 days.

Group A patients were treated with 4 drops of clotrimozole 1% drops 4 times a day.

Group B patients were treated by installing clotrimozole 1% cream by 2cc syringe and 18 number ear suction cannula.

Group C patients were treated by cleaning and painting the ear canal with 10% Povidone-iodine.

All groups of patients were examined after 7 days. They were assessed on the basis of symptoms and clinical response.

Results

In this study, total 60 patients were analyzed and divided in three Groups 'A', 'B' and ‘C’ with 20 patients each. All patients were analyzed for treatment respond on 8^{th} day.

This Study was done on 60 patients with 20in each Group. All the 3 Groups had almost equal gender wise distribution. All the patients were evaluated after seven days and the same symptoms were noted. External auditory canal of all the patients was checked with microscope and findings were recorded. The result after 7 days is as per **Table – 1, Graph - 1**. All the patients in Group A and B responded to treatment but 1 patient (5%) form Group C did not respond to 10% Povidone-iodine . 2 patients (10%) and 1

patient (5%) from Group A and B respectively had partial response to the treatment, whereas only 5 patient (25%) from Group C had partial response. Complete response was seen in 18 patients (90%) and 19 patients (95%) of Group A, B respectively where as in Group C14 patients (70%) had complete response.

Table - 1: Clinical response after 7 days.

Groups	No Response	Partial Response	Good Response
A	0	2(10%)	18(90%)
B	0	1(5%)	19(95%)
C	1(5%)	5(25%)	14(70%)

Graph - 1: Clinical Response after 7 days.

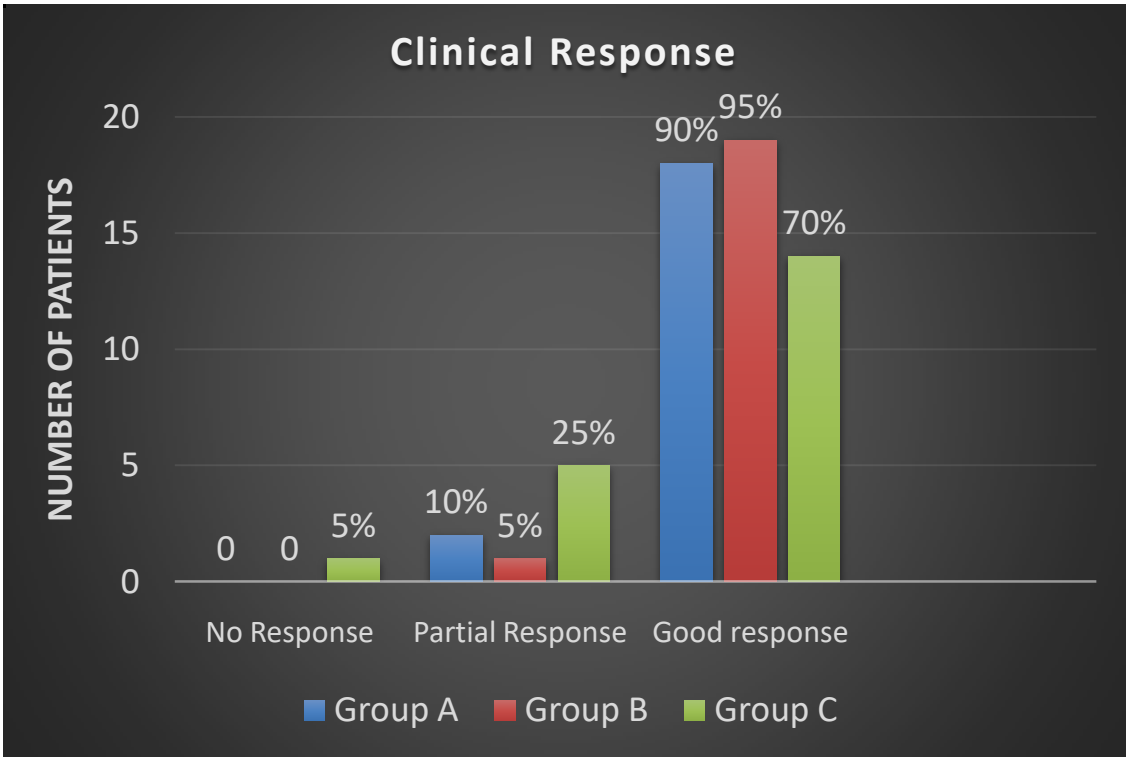
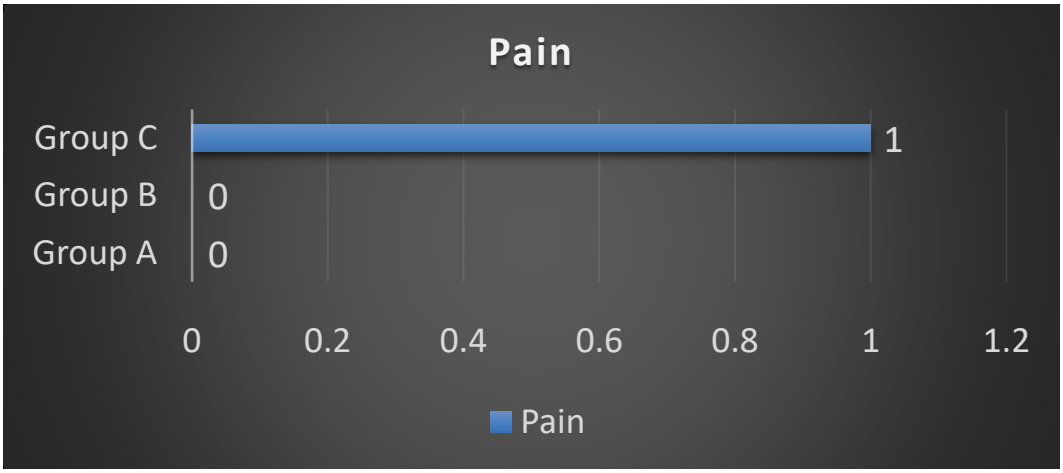


Table - 2: Symptoms after 7 days.

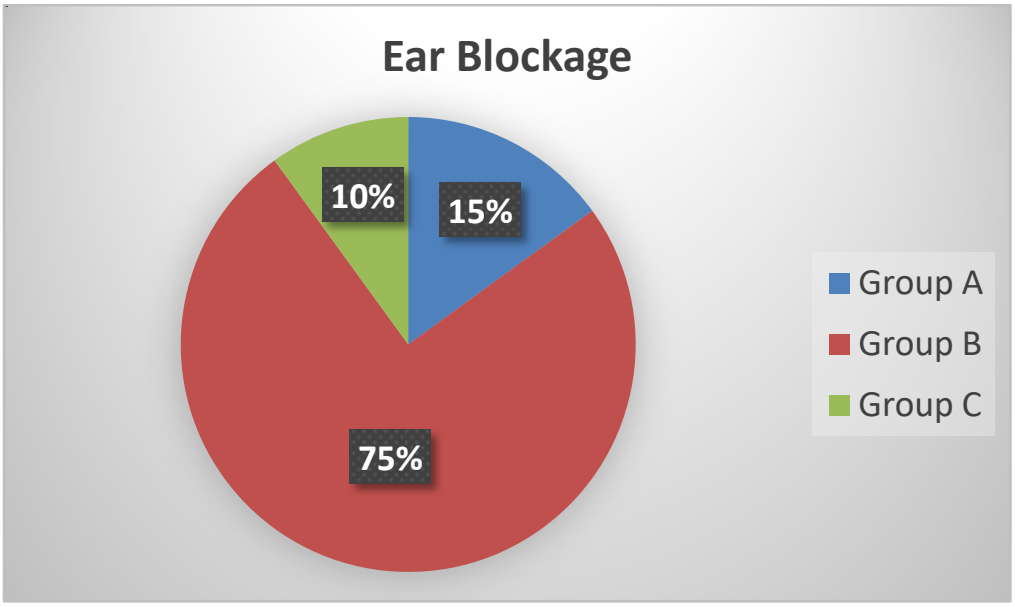
Groups	Pain	Ear blockage	Pruritus	Burning sensation
A	0	3(15%)	2(10%)	11(55%)
B	0	15(75%)	5(25%)	0
C	1(5%)	2(10%)	4(20%)	1(5%)

In **Table – 2**, symptoms were noted after 7 days of treatment which showed pain was cured in Group A and B but 1 patient (5%) had pain in Group C. Group B had maximum complaint of ear blockage due to the cream installation which was 15 patients (75%) followed by 3 patients (15%) from Group A and 2 patients (10%) from Group C. Pruritus was maximum in Group B having 5 patients (25%) followed by Group C having 4 patients (20%) and Group A having 2 patients (10%). Almost half the patients 11 (55%) in Group A had Burning sensation due to the drops as compared to Group B with no patients and 1 patient (5%) in Group C (**Graph – 2.1, 2.2, 2.3, 2.4**).

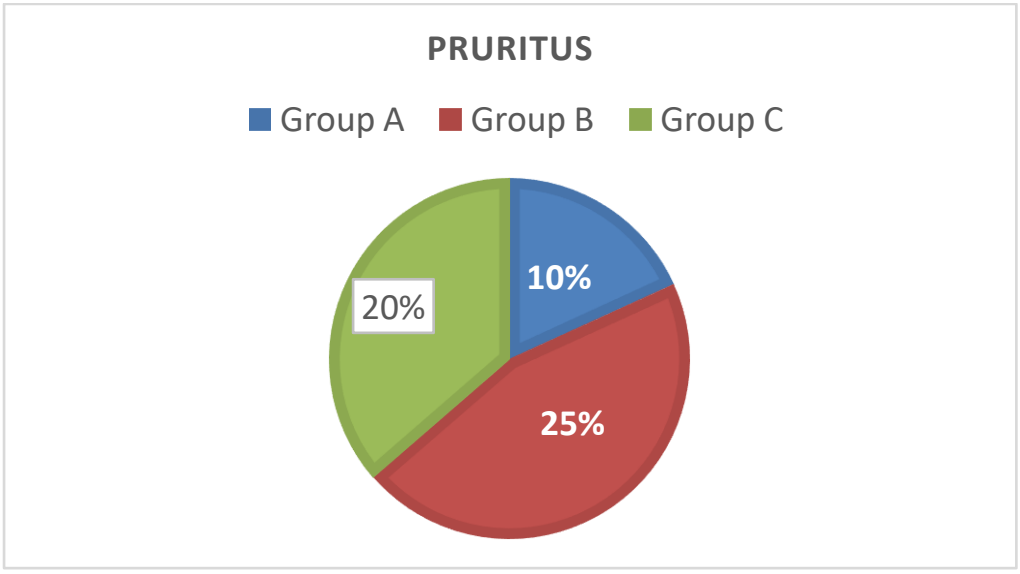
Graph - 2.1: Pain Symptom after 7 days.



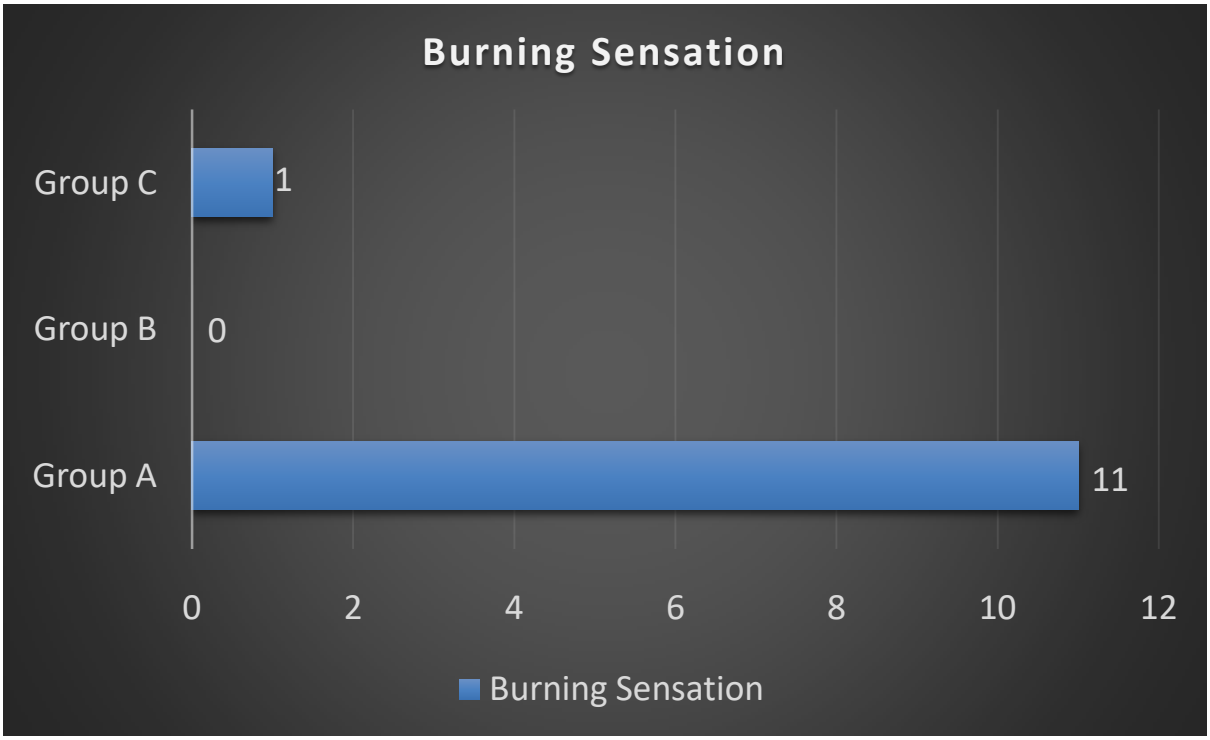
Group - 2.2: Ear blockage Symptom within 7 days.



Graph - 2.3: Pruritus symptom after 7 days.



Graph - 2.4: Burning sensation symptom within 7 days.



Discussion

A fungal infection of external auditory canal is called otomycosis. Due to high humidity and high temperature, otomycosis is seen frequently in ENT practice. Use of appropriate antifungal agent along with debridement remains the mainstay of treatment. Amongst anti-fungals topical azole Group remains widely used agent [9]. Romsaithong, et al. [10] study states that 1% clotrimozole solution is more effective for otomycosis where as Ologe FE, et al. [11] reported, 1% Clotrimazole cream to have better efficacy in the treatment of otomycosis. Mofatteh, et al. [12] reported the efficacy of betadine and clotrimazole to besame for the treatment of otomycosis.

In our study, both clotrimozole 1% drops and cream showed slight edge over 10% povidone-iodine used for otomycosis. Half the patients who were treated with 1% clotrimozole drops had burning sensation during the course of treatment which was not noted in clotrimazole cream and 10% Povidone-iodine.

Patients who were treated with clotimazole cream had main complaint of ear blockage which was not significant in other two Groups. Even the study conducted by Hurst WB [13] showed that clotrimazole cream had more ear blockage. Ear blockage can be annoying for some patients so 1% clotrimazole drops should be considered as both has equal efficacy. In our study few patients has burning sensation after using the drops , for these patients cream should be considered.

Patients who are not willing for clotrimazole cream and drop, for these patients 10% Povidone-iodine can be considered which has significant efficacy.

Conclusion

This randomized study concludes that both 1% clotrimazole cream and drops are effective in otomycosis. But 1% clotimazole cream has more blockage sensation and 1% clotrimazole drops has burning sensation, so 10% Povidone-iodine can be an alternative which showed significant efficacy.

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