

SUCTION CLEARANCE AND 2% TOPICAL MICONAZOLE VERSUS THE SAME COMBINATION WITH ACIDIC DROPS IN THE TREATMENT OF OTOMYCOSIS

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Abstract. From April 2003 to September 2004, 59 ears from 55 patients received suction clearance and topical miconazole 2% (regimen 1) and in September 2004 to December 2005, 64 ears from 58 patients received the same combinations plus acidic drops [acetic acid 3% (v/v) in 97% ethanol]. The mean age of patients treated with regimen 1 was 35.76±16 years and in regimen 2 was 37.98±15 years. *Aspergillus* sp and *Candida* sp were seen in 35 (59.3%) and 24 (40.7%) cases treated with regimen 1 and in 43 (67.2%) and 21 (32.8%) cases treated in regimen 2, respectively. Relapse occurred in 2 (3.4%) ears treated with regimen 1, but none in cases treated with regimen 2 (p=0.228). The findings reveal that there were no statistically significant differences between the two regimens and both may be used for the treatment of otomycosis.

INTRODUCTION

Otomycosis comprises up to 6% of all patients with symptoms of ear disease seen in outpatient clinics and includes about 25% of all cases of otitis caused by infectious agents. More than 21% of all cases of otitis externa are of fungi origin (Grigoriu *et al*, 1979; Kombila *et al*, 1989; Paulose *et al*, 1989). The most common fungal pathogens found are *Aspergillus* spp and *Candida* sp (Pavlenko *et al*, 1990; Garcia-Martos *et al*, 1993; Nong *et al*, 1999; Burgos Sanchez *et al*, 2000; Ologe and Nwabuisi, 2002; Mishra *et al*, 2004; Hueso Gutierrez *et al*, 2005). The main symptoms are pruritus, otorrhea, pain, hypoacusia and hearing loss. Physical examination shows masses of white, gray, black or creamy caseous debris, invading the external auditory

meatus (EAM), which is sometimes inflammatory (Kombila *et al*, 1989; Jung and Jin, 2003; Mishra *et al*, 2004).

Many agents have been recommended for treating otomycosis but no preparation has been widely accepted (Paulose *et al*, 1989; del Palacio *et al*, 2002; Van Hasselt *et al*, 2004). Treatment with antifungal agents is not enough to ensure complete cure. Treatment should aim at restoring the physiology of the external auditory canal (Hueso Gutierrez *et al*, 2005). Using 4% boric acid solution in alcohol and frequent suctioning of the ear canal has been used to treat otomycosis, but 23% of patients had relapses (Ozcan *et al*, 2003). Antifungal solutions, such as clotrimazole or nystatin, may prove effective against candida infections but do not cover aspergillus. Aspergillus infections may prove difficult to treat; it is recommended to treat this infection with oral itraconazole (Ruckenstein, 2005). Several studies have reported that aspergillus is the most common etiologic agent for fungal otitis externa

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(Pavlenko *et al*, 1990; Garcia-Martos *et al*, 1993; Nong *et al*, 1999; Burgos Sanchez *et al*, 2000; Ologe and Nwabuisi, 2002). The purpose of this study was to compare the efficacy of suction clearance and 2% topical miconazol with the same regimen plus Barrow solution in the treatment of otomycosis.

MATERIALS AND METHODS

This study was conducted in two steps at outpatient clinic of the Department of Otolaryngology, Babol Medical University, Iran. During the first step, April 2003 to September 2004, all patients with otomycosis received suction clearance and 2% topical miconazole (regimen 1). During the second step, September 2004 to December 2005, all patients received the same combinations plus acidic drops [acetic acid 3% (v/v) in 97% ethanol] (regimen 2). Patients with diabetes mellitus or with immunodeficiency were excluded from the study. The diagnosis of otomycosis was performed by isolation of fungus from material obtained from the ear(s) of the patients. Suction clearance was performed in both groups on the first day of treatment. After suctioning, 2% miconazol cream was applied to the auditory canal of each patient receiving regimen 1. In regimen 2, after suction clear-

ance, acidic drops and 2% miconazol cream were applied. Each patient was treated once. Each patient has follow-up of days 7, 14, and 21, where the efficacy of the treatment was recorded. All subjects were then followed at two-month intervals for 6 months. The ethics committee of Babol Medical University approved the study and all cases gave informed consent. Categorical variables were tested by two-tailed chi-square test and Fisher exact test. The efficacies for each regimen were compared. Statistical significance was set at $p < 0.05$.

RESULTS

During the first step, 70 ears of 59 patients were treated with regimen 1, 59 ears of 55 patients were included in the study. The remaining cases were excluded from the study. During the second step, 73 ears of 65 patients were treated with regimen 2, of which 64 ears of 58 patients were included in the study. The mean age of patient treated with regimen 1 was 35.76 ± 16 years and was 37.98 ± 15 years for regimen 2.

The most common symptoms were pain, pruritus, and discharge found in 86.4, 81.4 and 58.2% of cases treated with regimen 1 and in 85.9, 79.7 and 60.3% of cases treated

Table 1
Characteristics of patients in 2 regimens used to treat otitis externa.

| Characteristics of the patient | Regimen 1 (N=55) | Regimen 2 (N=58) |
|--|------------------|------------------|
| Mean age \pm SD (yr) | 35.7 \pm 16.2 | 37.9 \pm 15.7 |
| Sex | | |
| Male | 23 (41.8%) | 26 (44.8%) |
| Female | 32 (58.2%) | 32 (55.2%) |
| No. of cases with both ear involvement | 4 (7.3%) | 6 (10.3%) |
| Swelling of auditory canal | 3 (5.5%) | 5 (8.6%) |
| Swelling with purulent discharge | 32 (58.2%) | 35 (60.3%) |
| Pruritus | 48 (81.46%) | 51 (79.7%) |
| Pain | 51 (86.4%) | 55 (85.9%) |

There were no significant differences in clinical manifestations between these two groups.

Table 2
Isolated fungi in two groups of patients treated for otitis externa.

| Isolated fungus | Regimen 1 59 ears (%) | Regimen 2 64 ears (%) | Total 123 (%) |
|-----------------------|--------------------------|--------------------------|------------------|
| <i>Aspergillus</i> sp | | | |
| <i>A. niger</i> | 22 (37.3) | 26 (40.6) | 48 (39) |
| <i>A. flavus</i> | 9 (15.3) | 12 (18.8) | 21 (17.1) |
| <i>A. fumigatus</i> | 4 (6.8) | 5 (7.8) | 9 (7.3) |
| <i>Candida</i> sp | 24 (40.6) | 21 (32.8) | 45 (36.6) |
| Total | 59 (100) | 64 (100) | 123 (100) |

There were no significant differences between the two groups in the fungi isolated.

with regimen 2, respectively (Table 1). There were no significant differences in clinical symptoms between the two groups of patients ($p > 0.05$). *Aspergillus niger* was more common in both groups [22 (37.3%) cases in group 1, and 26 (40.6%) cases in group 2]. *Candida* sp were seen in 24 (40.6%) cases in group 1, and in 21 (32.8%) cases in group 2. Other isolated fungi are shown in Table 2. Relapse was seen in 2 (3.4%) cases treated with regimen 1, but in none treated with regimen 2 ($p = 0.228$).

DISCUSSION

The key point in assessment of a treatment regimen for otomycosis is the rate of relapse. In this study, the relapse rate with regimen 1 was 3.4% and with regimen 2, no relapses were seen. There was no statistically significant difference between these two regimens. Cleaning of the external auditory canal remains the mainstay for treatment of otomycosis, but suitable topical therapy may also be important in dealing with this capricious infection. Other studies from different tropical countries showed similar results using dyes, such as mercocrurom, to treat their patients (Chander *et al*, 1996; Mgbor and Gugnani, 2001), this combination is unacceptable to many patients due to the need to paint the auditory canal, but the dye may extend to the

neck or even the clothes. The relapse rates with both our regimens were lower than relapse rates reported using a single instillation of 0.1 or 1% silver nitrate gel for the treatment of otomycosis (8% and 28%, respectively) (Van Hasselt *et al*, 2004). The best way of preventing otomycosis is education regarding ear health and wearing ear protection while bathing or swimming (Ozcan *et al*, 2003). Eleven percent ciclopiroxolamine cream, 1% ciclopiroxolamine solution plus boric acid along with mechanical suction of debris have been used in a limited number of cases with relapse rates of 20, 5 and 27.5%, respectively (del Palacio *et al*, 2002). Otomycosis may cause perforation of the tympanic membrane and appropriate treatment may help with spontaneous healing of most perforations (Hurst, 2001). Among 90 patients with otomycosis treated with nitrofungin, clotrimazol and 1% decamine ointment, 6 patients had relapses, which is a higher relapse rate than both regimen in our study (Pavlenko, 1990). Using 1% bifonazole lotion, in 21 patients, the relapse rate was 9.5% (Piantoni *et al*, 1989). Among topical antifungal agents, merthiolate, clotrimazole and nystatin have the widest spectrum of activity (Stern *et al*, 1988). One study showed that clotrimazole, econazole and miconazole had broad-spectrum antifungal activity and should be the treatment of choice for otomycosis and may be safely used as otic drops (Bassiouny

et al, 1986). Local treatment with a solution containing viform and salicylic acid in 72 patients gives a relapse rate of up to 18% (Macotella-Ruiz *et al*, 1976). In 35 cases of otomycosis treated with clotrimazole there was a relapse rate of 5.7% (Kley, 1976). Better efficacies with shorter duration of therapy with both regimens used in this study are the advantages of both regimens in this study compared to other regimens studied for the treatment of otomycosis.

This study showed that suction clearance and 2% topical miconazole and the same combination with barrow solution are effective and may be used for the treatment of otomycosis.

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