Original Article

J Babol Univ Med Sci
Vol 17, Issu 4; Apr 2015; P:29-35

A Study on the Effectiveness of Boericke Alcohol and Miconazole Ointment for the Prevention of Outer Ear Infections after Suction Clearance

K. Kiakojori (MD)[1], A.K. Gooran (MSc)[2], R. Rajabnia (PhD)[3], S. Mahdavi Omran (PhD)*[3]

1.Department of Otolaryngology, Babol University of Medical Sciences, Babol, I.R.Iran

2.Babol University of Medical Sciences, Babol, I.R.Iran

3.Infectious and Tropical Diseases Research Center, Babol University of Medical Sciences, Babol, I.R.Iran

Received: July 21th 2014, Revised: Sep 24th 2014, Accepted: Feb 4th 2015.

ABSTRACT

BACKGROUND AND OBJECTIVE: Cerumen (or earwax) impaction is usually asymptomatic, although in some cases, it leads to symptoms such as hearing loss and discomfort in the ear. Various approaches with different side-effects have been applied for the removal of earwax buildup. In this study, we aimed to evaluate the prevalence of external otitis after suction clearance. We also investigated the prevention of possible infections.

METHODS: This clinical trial (IRCT:201104176208N1) was conducted on 184 patients, diagnosed with cerumen impaction, referring to the Ear, Nose and Throat Clinic of Ayatollah Ruhani Hospital in Babol city, Iran. Patients were examined at the time of admission and earwax was removed, using microscope-guided suction clearance. The patients were randomly divided in two groups. The first group (87 patients) received no special treatments and the second group (97 patients) underwent a prophylactic treatment, which consisted of acidifying the ear with 2% Boericke alcohol and application of miconazole ointment by a swab. Two weeks after the treatment, the patients were re-examined in terms of infections. Also, part of the earwax was cultured in an appropriate medium, and the type or species of microorganisms was determined via conventional techniques.

FINDINGS: External otitis was reported in none of the patients in the two groups. The most common bacteria in the cerumen samples were Bacillus (19.58%) and coagulase-negative Staphylococcus (15.22%), respectively. Also, the most common cultivated fungi in cerumen samples were Aspergillus niger (21.2%) and Penicillium (13.04%), respectively.

CONCLUSION: The results showed that the use of Boericke alcohol and miconazole ointment does not lead to any side-effects for the patients. Therefore, this preventive method is recommended to general practitioners with less experience in differentiating pure cerumen from cerumen with fungal infections.

KEY WORDS: Cerumen, External otitis, Suction, Miconazole.

Please cite this article as follows:

Kiakojori K, Gooran AK, Rajabnia R, Mahdavi Omran S. A Study on the Effectiveness of Boericke Alcohol and Miconazole Ointment for the Prevention of Outer Ear Infections after Suction Clearance. J Babol Univ Med Sci. 2015; 17(4):29-35.

***Corresponding Author: S. Mahdavi Omran (PhD)**

Address: Research Center of Infectious and Tropical Diseases, Department of Parasitology and Mycology, Babol University of Medical Sciences, Babol, I.R.Iran

Tel: +98 11 32199936

E-mail: mahdavios@yahoo.co.uk

Introduction

Earwax or cerumen is a hydrophobic compound which covers the ear canal and protects the skin of the outer ear canal against water damage, infection, trauma, and foreign objects. Cerumen leads to the trapping of particles in the ear and facilitates the destruction of bacteria (1). Cerumen impaction is usually asymptomatic, while in some cases, it leads to symptoms such as hearing loss and discomfort in the ear (2, 3). Cerumen is a mixture of viscous secretions from sebaceous glands and cerumen in the outer one-third of the external auditory canal. Earwax contains a combination of cerumen, desquamated skin, normal skin flora, and probably removed hairs (4-6). Cerumen impaction is defined as the accumulation of compressed cerumen in the external ear canal; this condition leads to certain symptoms in patients and prevents the monitoring of ear canal (2).

Cerumen impaction is the most common problem in physician referrals. It occurs in about 6% of common people and a larger number of individuals, suffering from common, known health conditions (5, 6). For earwax removal, cerumenolytic agents, ear washing, and manual extraction (using curette method, suctioning, etc.) have been applied (7). Earwax removal by these methods can lead to conditions such as external otitis, allergic reactions, ruptured eardrum, trauma to the ear canal, itching, dizziness, and transient hearing loss (8, 9). Infectious agents, allergies, and skin diseases can cause acute external otitis. The most common cause of external otitis is bacterial infection (10). This condition can occur at any age (11). Approximately 10% of people will suffer from external otitis in their lifetime. According to an annual survey in the United States, cerumen impaction had the highest incidence rate during childhood, following a downward trend by advancing age (12).

External otitis occurs mostly during summer, which could be due to humidity and high contact with water. Earwax prepares an acidic environment in the ear to prevent the growth of bacteria and fungi. In addition, the consistency of cerumen leads to its extraction in form of debris. Also, due to its hydrophobic features, cerumen prevents humidity in the ear canal and thereby dampens the growth of fungi and bacteria. The breakdown of the cerumen-skin barrier is the first step in the pathogenesis of external otitis. Skin inflammation leads to the obstruction of glandular structures and itching. Moreover, scratching leads to abrasion and further problems. The succession of these events leads to changes in the quality and quantity of earwax, epithelial migration, and pH changes in the ear canal. In fact, a dark, warm, alkaline, and moist environment in the ear canal is ideal for the growth of different microorganisms. Many factors contribute to the development of external otitis. Excessive earwax removal from the ear and inappropriate scratching not only remove cerumen, but also create abrasions on the thin skin layer of the ear, allowing organisms to penetrate deeper into ear tissues. In addition, pieces of cloth or paper with which ears are scratched may remain in the ear, causing severe skin reactions and ear infections.Swimming is a proven risk factor for external otitis. In fact, excessive wetness of the ear damages the skin and cerumen; this is why external otitis is more frequent in swimmers and people in contact with water. Moreover, hearing aid tools such as headphones and earphones could predispose people to external otitis (13, 14). Extraction of cerumen must be performed via proper methods and materials. Selection of a method for earwax removal should be based on expert experience, available time, and tools. Since a percentage of earwax contains various fungal and bacterial contaminants, ear washing can promote the growth of fungi and bacteria and lead to severe external otitis, which is accompanied by severe pain and swelling. Therefore, this procedure by intensifying the need for various medications (either systemic or topical treatment) imposes medical costs on patients and can be time-consuming.

The use of Boericke alcohol and miconazole ointment has no costs or side-effects for patients. Therefore, in this study, by informing the subjects about the effectiveness of this prophylactic treatment for preventing further complications, a group of patients underwent the treatment after suction clearance. This study was conducted to investigate the prevalence of fungal and bacterial infections after suction clearance. We also aimed to determine if these infections can be prevented via this prophylactic treatment method in order to reduce the medical costs and physician referrals.

Methods

This clinical trial (IRCT: 201104176208N1) was conducted on 184 patients with a diagnosis of cerumen impaction, referring to the Ear, Nose and Throat Clinic of Ayatollah Ruhani Hospital in Babol in April 2012. A permission was obtained from the Ethics Committee of Babol University of Medical Sciences. Patients with

earwax buildup were entered to the study and were diagnosed using a microscope guide. During examination, the subjects had no symptoms or signs of infection. The exclusion criteria were as follows: 1) previous history of ruptured eardrum, 2) recent history of bacterial ear infections; 3) prior history of surgery on the middle or external ear; 4) subject's unwillingness to cooperate; and 5) lack of referral for re-examination. Patients were examined at the time of admission and data such as age, sex, history of ear infections, symptoms, clinical signs, and type and color of earwax were recorded. Then, all the patients underwent microscope-guided suction clearance for earwax removal.

The subjects were randomly divided in two groups. The first group (control group) received no special treatments after suction clearance (similar to common procedures). After two weeks, the subjects were re-examined in order to detect the possibility of new ear infections. The second group (case group) underwent a new method of prophylactic treatment, which included acidifying the ear with Boericke alcohol 2% and application of miconazole ointment by a swab. These patients were also re-examined two weeks after the procedure. In order to prevent any possible interference in the outcomes, no lubricant was used for cerumen extraction. The patients underwent clinical examination two weeks after the procedure in order to determine the possibility of any sort of infections. The use of Boericke alcohol and miconazole ointment has no costs or side-effects for patients. Therefore, by informing patients about the effectiveness of this prophylactic treatment (for preventing further complications), a group of patients underwent this treatment after suction clearance.

Also, the extracted cerumen via suction clearance was immediately cultured in proper media such as blood agar (Merck, Germany) and chocolate agar (Merck, Germany) for bacterial growth. sabouraud dextrose agar (Biolife, Italy), supplemented with Chloramphenicol (Merck, KGaA Germany), was used for fungal growth. The culture media were stored at 37 °C and 25 °C up to 48 hours and two weeks, respectively.

The type or species of grown microorganisms was specified, using conventional methods of bacterial (e.g., including culturing in differential media, and evaluation of the presence of enzymes) and fungal identification (e.g., preparation of split samples, slide culture, germ tube tests, and chlamydospore formation). Based on the obtained results, the level of cerumen contamination with bacteria or fungi was determined. For data analysis, Chi-square and independent sample t-test were performed, using SPSS version 22. P-value less than 0.05 was considered statistically significant.

Results

In this study, 184 patients were enrolled. In total, 87 subjects (47.28%) received no treatments after suction clearance, while 97 cases (52.72%) underwent prophylactic treatment. The mean age of all patients was 37.83±22.06 years. Also, the mean age of patients in the case and control groups was 37.92 and 37.72 years, respectively. There was no significant difference between the two groups in terms of age. The majority of patients were within the age range of 41-60 years (29.35%) and the minority were above 60 years of age (15.76%). Also, there was no significant difference in the frequency of physician referral between case and control subjects within different age ranges.

Overall, 90 (48.91%) and 94 (51.09%) patients were male and female, respectively. In the case group, 46 patients (47.42%) were men and 51 patients (52.58%) were female. Also, in the control group, 44 subjects (50.57%) were male and 43 cases (49.43%) were female. In addition, there was no statistically significant difference between the two groups in terms of gender. Overall, 41 cases (22.28%) had been previously treated by suction clearance or ear washing by general practitioners. Among these cases, 24 patients (13.04%) were in the case group and 17 cases (9.24%) were in the control group; no significant difference was observed between the two groups. Hearing loss (57.06% of cases), followed by the feeling of fullness in the ear (34.78%) was the most common complaint of patients. Also, 143 patients (77.72%) had received no treatments for cerumen removal before physician referral. Overall, 108 patients (58.77 %) presented with cerumen impaction in the examination. Cerumen impaction, along with skin debris, was reported in 4.35 % of patients. Also, cerumen impaction, as well as inflammation signs, was seen in 36.96% of patients. In term of difference in cerumen color, 22.28%, 39.13%, and 38.59% of patients had dark brown, brown, and light brown cerumen, respectively. None of the patients in the case group showed any signs of infection after suction clearance two weeks after the procedure.

The most common fungi in cerumen samples were *Aspergillus niger* (21.2%), *Penicillium* (13.04%), *Cladosporium* (10.33%), and *Candida* species (10.33%), respectively (table 1). The most common fungi in cerumen samples of men and women were

Aspergillus niger and *Penicillium* spp., respectively. In some cases, different types of fungal growth were reported. Also, the most common bacteria in the samples were *Bacillus* spp. (19.58%), coagulase-negative *Staphylococcus* (15.22%), *Streptococcus* spp. (7.61%), and *diphtheroids* spp.(7.61%), respectively (table 2).

Table 1. Distribution of cultivated fungi in cerumen samples of patients with cerumen impaction

Fungal species	Gender	Case group N	Control group N	Total N(%)	P-value
Penicillium	Male	0	9	9(4.89)	0.173
	Female	10	5	15(8.15)	
Cladosporium	Male	7	3	10(5.43)	0.409
	Female	4	1	5(2.72)	
Aspergillus flavus	Male	3	5	8(4.35)	0.312
	Female	4	4	8(4.35)	
Aspergillus fumigatus	Male	11	2	13(7.07)	0.304
	Female	2	2	4(2.17)	
Aspergillus species	Male	2	7	9(4.89)	0.280
	Female	2	2	4(2.17)	
Aspergillus niger	Male	9	5	14(7.61)	0.228
	Female	9	16	25(13.59)	
Candida albicans	Male	2	3	5(2.72)	0.310
	Female	3	4	7(3.8)	
Fusarium species	Male	0	1	1(0.54)	0.647
	Female	2	1	3(1.64)	
Rhizopus species	Male	4	1	5(2.72)	0.422
	Female	1	2	3(1.63)	
Candida species	Male	4	4	8(4.35)	0.591
	Female	6	5	11(5.98)	
Other fungal species	Male	4	1	5(2.72)	0.513
	Female	4	2	6(3.26)	
No fungal growth	Male	0	1	1(0.54)	0.333
	Female	4	1	5(2.72)	
Total	Male	46	44	90(48.91)	0.669
	Female	51	43	94(51.09)	

Table 2. Distribution of cultivated bacteria in cerumen samples of patients

Bacteria	Gender	Case group N	Control Group N	Total N(%)	P-value
Bacillus species	Male	9	4	13(7.07)	0.045
	Female	15	8	23(12.51)	
Coagulase-negative Staphylococcus		7	9	16(8.7)	0.302
	Female	6	6	12(6.52)	
Diphtheroids	Male	3	4	7(3.8)	0.218
	Female	2	4	6(3.26)	
Streptococcus species	Male	4	1	5(2.72)	0.118
	Female	6	3	9(4.89)	
Pseudomonas	Male	4	3	7(3.8)	0.213
	Female	3	0	3(1.63)	
Staphylococcus aureus	Male	2	2	4(2.17)	0.551
	Female	1	0	1(0.54)	
Klebsiella species	Male	1	0	1(0.54)	0.527
	Female	0	0	0(0)	
No bacterial growth	Male	16	21	37(20.11)	0.877
	Female	18	22	40(21.74)	
Total	Male	46	44	90(48.91)	0.669
	Female	51	43	94(51.09)	

Discussion

The results of this study showed that neither the case group (the group receiving miconazole ointment and Boericke alcohol after the suction clearance) nor the control group (the group receiving no treatment) showed any symptoms of external otitis two weeks after suction clearance. Similarly, in a study by Guidi et al., in which 1457 cerumen samples were manually harvested at an ear, throat and nose clinic, no signs of external otitis were reported in patients two weeks after the procedure (15). This indicates the safety of this method for preventing possible ear infections after cerumen extraction. Also, the absence of infection signs in these two studies can be attributed to the skillfullness of experts during the procedure.

In a study by Aung and colleagues on the medical records of 312 patients, who had undergone ear washing for cerumen removal, the most common complication was incomplete earwax removal (25%), followed by external otitis (17%) (16). In the present study, there were no signs of external otitis in patients two weeks after suction clearance. This finding was contrary to the results obtained by Aung and colleagues. This might be due to the absence of water or saline during suction clearance, which prevents humidity and facilitates the growth of pathogens.

Zikk and colleagues investigated the prevalence of malignant external otitis, following ear washing. In their three-year study, 24 patients had malignant external otitis, among whom 9 patients (35.7%) had malignant external otitis due to ear washing; eight of these patients had diabetes and one had a prior history of radiotherapy. Therefore, ear washing was not recommended for patients with diabetes or weakened immune system; instead, suction clearance under direct vision could be applied (17). In the present study, no findings indicated malignant external otitis caused by suction clearance, which is due to suctioning under direct vision; this type of suctioning leads to a more controlled clearance and lower possibility of trauma to the ear canal, compared to other techniques. Also, unlike suction clearance, ear washing prepares the environment for the growth of pathogens.

The results of the current study are consistent with the findings obtained by Stroman et al., who examined cerumen microbiology in healthy subjects in terms of the percentage of Gram-positive and Gram-negative bacteria. In our study, 10% and 90% of bacteria were Gram-negative and Gram-positive, respectively. The most common bacteria in the extracted cerumen samples were *Bacillus* spp. coagulase-negative *Staphylococcus*, and *Streptococcus* spp., respectively. The most common grown species in the study by Dibb were *S. epidermidis* and *diphtheroids* (19). The results are roughly consistent with our findings. A major discrepancy was the high rate of *Bacillus* spp. in our study, which could be due to the high regional outbreak of this bacterium. It should be mentioned that this bacterium, similar to the majority of other common bacteria, is considered a normal flora and played no significant role in our study. The most common bacteria in a study by Stroman et al. included *Staphylococcus epidermidis*, *diphtheroids*, and *Streptococcus* spp. (18), which are considered normal flora, similar to the common cultured bacteria in our study. In studies by Stroman et al. and Campos et al., these bacteria were also observed in healthy individuals (5, 18).

In our study, pathogenic bacteria such as *Pseudomonas* spp. *Staphylococcus aureus*, and *Klebsiella* spp. were reported. The low amount of cerumen in these patients could be associated with the absence of diseases. Preparing a proper environment for the growth of pathogens (followed by ear washing) and increasing their population can lead to diseases in patients. In the study by Stroman et al., the most common fungi were *Penicillium* and *Candida species*; no other fungi were reported in our study (18).

The most common fungi in cerumen samples included *Aspergillus niger*, *Penicillium*, and *Candida* species. In terms of the number and type of isolated fungi, our study differed from the study by Stroman et al., which might be related to the higher prevalence of fungi in the region (due to the humid climate of the region) or the accuracy in the extraction and detection of microorganisms in our study. Moreover, in a study by Kiakojori et al., the most common fungi included sterile mycelium and *Cladosporium* spp. (20). These results were inconsistent with the current findings, which might be associated with the differences in the living area of patients or the season of physician referral. In total, the results of cerumen culture in our study were mostly consistent with previous studies. The insignificant differences could be associated with the geographic location, place of residence, ethnicity, living conditions, and differences in sampling methods and laboratory procedures. According to the results of this study, suction clearance is a safe method, with few associated complications. Based on the evaluation of extracted cerumen samples, the majority of subjects were susceptible to external otitis, which occurs if the

conditions required for pathogen growth (present in the cerumen) are prepared (via ear washing). Although in our study, prophylactic treatment was shown to be of no significance, the absence of infections after cerumen removal might be due to the expertise of physicians. Therefore, this prophylactic treatment is recommended to inexperienced practitioners for the prevention of external otitis.

Acknowledgements

Hereby, we would like to thank the Vice-Chancellor for Research and Technology at Babol University of Medical Sciences for the financial support. We also extend our gratitude to Meghdad Bagheri (at the Microbiology Laboratory), Seyed Javad Mosavi (at the Mycology Laboratory), and all the patients who helped us through this research.

References

1.Olajide TG, Ologe FE, Alabi BS. Management of impacted ear wax: An observational report. Aust Fam Physician. 2005;34(5):395-6.

2.Roland PS, Smith TL, Schwartz SR, Rosenfeld RM, Ballachanda B, Earll JM, et al. Clinical practice guideline: cerumen impaction. Otolaryngol Head Neck Surg. 2008;139(3 Suppl 2):S1-21.

3.Lum CL, Jeyanthi S, Prepageran N, Vadivelu J, Raman R. Antibacterial and antifungal properties of human cerumen. J Laryngol Otol. 2009;123(4):375-8.

4.Guest JF, Greener MJ, Robinson AC, Smith AF. Impacted cerumen: composition, production, epidemiology and management. QJM. 2004;97(8):477-88.

5.Campos A, Arias A, Betancor L, Rodriguez C, Hernandez AM, Lopez Aguado D, et al. Study of common aerobic flora of human cerumen. J Laryngol Otol. 1998;112(7):613-6.

6.Burkhart CN, Burkhart CG, Williams S, Andrews PC, Adappa V, Arbogast J. In pursuit of ceruminolytic agents: astudy of earwax composition. Am J Otol. 2000;21(2):157-60.

7.Jabor MA, Amedee RG. Cerumen impaction. J La State Med Soc. 1997;149(10):358-62.

8.Moore AM, Voytas J, Kowalski D, Maddens M. Cerumen, hearing, and cognition in the elderly. Journal of the American Medical Directors Association. 2002;3(3):136-9.

9.Mitka M. Cerumen removal guidelines wax practical. JAMA. 2008;300(13):1506.

10.Stone KE, Serwint J. Otitis externa(In brief). Pediatr Rev. 2007;28(2):77-8.

11.Beers SL, Abramo TJ. Otitis externa review. Pediatr Emerg Care. 2004;20(4):250-6.

12.Centers for Disease Control and Prevention (CDC). Estimated burden of acute otitis externa--United States, 2003-2007. MMWR Morb Mortal wkly Rep. 2011;60(19):605-9.

13.Agius AM, Pickles JM, Burch KL. A prospective study of otitis externa. Clin Otolaryngol Allied Sci. 1992;17(2):150-4.

14.Osguthorpe JD, Nielsen DR. Otitis externa: review and clinical update. Am Fam Physician. 2006;74(9):1510-6.

15.Guidi JL, Wetmore RF, Sobol SE. Risk of otitis externa following manual cerumen removal. Ann Otol Rhinol Laryngol. 2014;123(7)482-4.

16.Aung T, Mulley G. Removal of ear wax. BMJ. 2002;325(7354):27.

17.Zikk D, Rapoport Y, Himelfarb MZ. Invasive external otitis after removal of impacted cerumen by irrigation. N Engl J Med. 1991;325(13):969-70.

18.Stroman DW, Roland PS, Dohar J, Burt W. Microbiology of normal external auditory canal. Laryngoscope. 2001;111(11pt 1):2054-9.

19.Dibb W. The normal microbial flora of the outer ear canal in healthy Norwegian individuals. NIPH Ann. 1990;13(1):11-6.

20.Kiakojori K, Mahdavi Emran S, Majidian AR, Ferdosi Shahandashti E, Daroonkolaii A, Rajabnia R. Comparing cerumen bacterial flora in acute otitis externa patients and healthy controls. Iran J Otorhi. 2010;22(60):93-6.