Article

A Novel Device for the Evacuation of Cerumen

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Abstract

Objectives: The aim of this study was to assess a new device designed to safely remove cerumen from the external auditory canal in an office setting with minimal training.

Methods: The research was conducted in the Department of Otolaryngology at Kaplan Medical Center in Israel. Patients with cerumen were treated with the device. Efficacy, safety, and pain were evaluated using scales developed for this experiment. The cerumen obstruction scale (0-5) was assessed before and after the procedure. Improvement by 2 or more grades was considered to indicate at successful procedure.

Results: Fifty-nine ears in 46 patients were treated. Seventeen patients (37%) had recurrent cerumen impaction, and 14 (30.4%) used cotton swabs frequently. Fifty-two ears (88%) had hard cerumen. The procedure was successful in 51 ears (86.4%). In 48 ears (81%) there was no pain or mild pain, and in 11 ears (19%), the patient reported the procedure to be uncomfortable. Seven patients (15.2%) asked to abort the procedure because of discomfort or pain. In 39 ears (66%), the cerumen was evacuated easily. Inspection after the procedure revealed no injury in 56 ears (95%). Three ears (5%) had mild irritation of the ear canal, and none had injury to the tympanic membrane. Median length of the procedure was 30 $\pm$ 42.1 seconds (range, 2-240 seconds). The median number of insertions of the device in 1 procedure was 2 (range 1-7; SD, 1.3).

Conclusions: The tested device is an effective and safe device for the evacuation of cerumen. It can be used by general practitioners, pediatricians, and audiologists.

Keywords

external auditory canal, cerumen

Introduction

Ear cerumen is composed of dead skin cells, secretions of ceruminous glands, which are sweat glands, and sebum secreted by hair follicle sebaceous glands of the external ear canal. Cerumen has fungicidal, bactericidal, and waterproof properties.[1] The incidence of cerumen impaction in the general population is between 7% and 35%,[1] and the balance of secretions from the sebaceous and ceruminous glands varies among ethnic groups. This can partly explain the differences in the amount of cerumen among different ethnic groups.[2] Usually, the ear canal has migratory movement toward the external ear meatus, which prevents cerumen impaction, but cerumen can accumulate in the external ear canal and become impacted. This can cause discomfort, a sensation of fullness in the ear, pain, itching, tinnitus, foul odor, discharge, and conductive hearing loss.[3] Cerumen impaction increases the risk for external ear infection.[2] Patients using hearing aids are prone to cerumen accumulation, which can cause difficulty inserting the ear mold. Cerumen can also occlude the vent and cause device malfunction. Accumulation of cerumen, especially when wet, can cause rapid blockage and symptoms due to swelling of the dead skin cells. Cerumen may cause a diagnostic obstacle by blocking the view to the medial part of the ear canal and the tympanic membrane, making diagnosis of middle-ear pathologies impossible. Cerumen can influence hearing tests such as audiometry, tympanometry, auditory brainstem evoked responses, and otoacoustic emission tests and causes difficulties in the mold preparation process for hearing aids.

Impacted cerumen is among the most common reasons for referral to an otolaryngologist. There are a number of reasons for cerumen impaction. Patients with narrow ear

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canals are prone to recurrent cerumen impaction. External ear pathologies such as exostosis and osteomas can also cause cerumen impaction. The mechanism of impaction of cerumen involves failure in the separation of keratinocytes that normally occurs in the external ear canal as part of skin turnover.[2] The use of cotton swabs to clean the meatus and external ear canal is a known cause of cerumen impaction.[4] Hearing aids are another common cause believed to prevent the natural evacuation of the cerumen, although one retrospective study found no association between hearing aid use and cerumen impaction.[5] There are several options to treat cerumen impaction, such as irrigation, wax softeners, and manual removal under a microscope or a headlight using steel microinstruments.[6] In most countries, safe manual cerumen removal under vision can be performed only by an otolaryngologist. The equipment needed is expensive, and its use requires training. General practitioners (GPs) and pediatricians do not have an efficient and safe modality for cerumen evacuation, and patients are often referred to an otolaryngologist.

Removing cerumen varies not only by techniques used and advantages but also by possible adverse effects. Irrigation can cause pain, damage to the tympanic membrane, and vertigo, especially when performed without directly seeing the external auditory canal and tympanic membrane, and therefore is not strongly recommended.[3,6] The noise of suctioning associated with the irrigation may intimidate patients, especially children. Manual removal with steel tools may cause pain and/or damage to the external ear canal and tympanic membrane, especially if done by an inexperienced clinician.[6]

The clinical practice guidelines of the American Academy of Otolaryngology–Head and Neck Surgery, published in 2017,[3] state that when a patient is diagnosed with impacted cerumen, it is strongly recommended to evacuate the cerumen or to refer to a clinician who can perform the procedure. Asymptomatic patients, or those in whom the cerumen does not prevent proper examination, do not require cerumen removal. However, hearing aid users, young children, and individuals with cognitive impairment should be inspected for cerumen even if asymptomatic. Therefore, a cerumen removal device, which has no need for an otologic microscope, is clearly advantageous because it can improve the quality of ear examination, reduce symptoms of impacted cerumen, and reduce the referral rate to specialists.

The device tested is designed for the evacuation of cerumen from the external auditory canal, but it is not yet approved by the US Food and Drug Administration for any purpose. It offers a novel approach for the evacuation of cerumen in the office. The coiled tip engulfs the cerumen, which is then pulled out of the ear. The device is made of flexible, soft, low-density polyethylene, which is intended to minimize pain and prevent injury to the external auditory canal. The device does not require the use of an otologic microscope or a headlamp, because direct vision of the ear canal is not needed. It is dispensable and therefore does not require maintenance or sterilization.

Methods

The research was conducted in the Department of Otolaryngology–Head and Neck Surgery at Kaplan Medical Center in Israel, affiliated with the Hebrew University in Jerusalem, and was approved by the institution's ethics committee (protocol no. 0125-16-KMC). The tested device is the EarWay PRO (Earways Medical Ltd., Rosh Ha'ayin, Israel). The inclusion criteria were arrival to the outpatient clinic or emergency department, or hospitalization, and cerumen impaction. Some patients presented with otologic symptoms, and in some, impaction was an incidental finding. The patients were treated by 2 otolaryngologists (U.K. and N.B.). The exclusion criteria were otitis externa, chronic otitis media, previous ear surgery, any kind of ear infection, and temporal bone tumors. Patient history was taken regarding the use of hearing aids, repeated cerumen impaction, history of hearing impairment, use of cotton swabs or other devices, and symptoms of ear fullness and pain in the ear. Patients were in a supine or a seated position when examined and treated. The ear canal was examined before and after the procedure using an office microscope. The physician estimated the grade of occlusion for each ear, using a scale developed for the purpose of this experiment (Supplement 1). The auricle was then pulled slightly in a superior-posterior direction, and the device was inserted to the external ear canal with clockwise rotation. This movement engulfs the cerumen and traps it in the center of the device until the second ring, which is 20 mm from the distal end of the device and is in line with the external auditory meatus (Figure 1). Assuming that the external ear canal depth averages 27 mm with a range of 20 to 34 mm,[7] a 20-mm safe bar was used to keep the safety margin on the lower depth range. Being flexible, the device compresses in narrow ear canals. In some patients who reported discomfort or pain, insertion was halted before reaching the second ring. The device was then gently pulled out of the external auditory canal without rotation. Cases in which the otolaryngologist could not assess the tympanic membrane or the patient did not report a relief of cerumen symptoms were not considered sufficient. If evacuation of cerumen was insufficient, the procedure was repeated. In cases in which the impacted cerumen could not be evacuated or when patients asked to stop the procedure, the cerumen was evacuated with standard otologic devices as suction or a blunt ear curette under direct vision. The contralateral ear was attended in the same manner if it had cerumen. The otolaryngologist then examined the external auditory canal again, and the grade of occlusion was determined. Improvement by 2 or more grades (Supplement 1) was considered to indicate a successful procedure. An improvement of 2 or more grades was defined as success because clinical assessment of the tympanic membrane

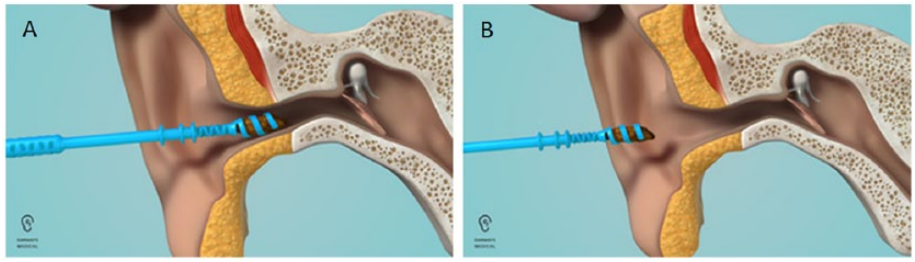

Figure 1. Illustration of the device's mechanism of action. (A) As the auricle is retracted, the device is inserted in a clockwise rotation, and the cerumen is trapped in the device. (B) The device is then gently pulled out of the external auditory canal without rotation.

Table 1. Patient Characteristics Related to Impacted Cerumen.[a]

Characteristic	Value
Age, mean, y	50.8
Recurrent events of impacted cerumen	37.0% (17)
Some degree of known hearing loss, not due to impaction	30.4% (14)
Regular use of cotton swabs	30.4% (14)
Wearing hearing aids on a regular basis	4.3% (2)
Cerumen-related symptoms	
Sensation of obstruction or fullness	23.9% (11)
Pain in ear	10.9% (5)

[a]Data are expressed as percentage (number) except as indicated.

usually does not mandate an ear canal completely free of cerumen, and so does a symptom-free patient. The external auditory canal and tympanic membrane were assessed to verify whether there was any kind of injury (Supplement 2). Patients were requested to answer questions regarding the discomfort they experienced during the procedure (Supplement 3). The otolaryngologist assessed the degree of difficulty in performing the procedure with the device (Supplement 4). The time the procedure took and the consistency of the cerumen were also documented.

Results

A total of 59 ears in 46 patients of a multiethnic group (24 male, 22 female) were included and treated using the device. The age range for the study group was 14 to 86 years, with 2 pediatric patients, aged 14 and 16 years. Patient characteristics are presented in Table 1.

Fifty-two ears (88%) had hard cerumen and 7 (12%) had soft to liquid cerumen. The procedure was successful as defined by the improvement on the cerumen obstruction scale in 51 ears (86%). In 39 of these cases, the otolaryngologist rated the procedure as easy or with some difficulty (grades 1 and 2; Supplement 4). In 6 ears (10%) that were considered successful, the procedure was aborted at the patient's request after reaching the goal of improvement. In 2 ears (3.4%), improvement was less than 2 grades. In 6 patients, the procedure failed because of difficulty evacuating the cerumen or direct request from the patient to abort the procedure. In 5 of these cases, the cerumen was evacuated using standard otologic tools. In 48 ears (81.4%), there was no pain or mild pain (grades 0-2; Supplement 3) as reported by the patient. The procedure was uncomfortable (grade 3 or more; Supplement 3) in 11 ears (18.6%), and in 7 cases the patient asked for the procedure to be aborted because of pain (grade 5).

In all patients, the ear canal and tympanic membrane were inspected using a microscope at the end of the procedure. Fifty-six ears (95%) were not in the least injured. Three ears (5%) had mild irritation and redness of the ear canal. There were no cases of hematoma of the ear canal or injury to the tympanic membrane. The median time of treatment was 30 $\pm$ 42.1 seconds (range 2-240 seconds). In 36 ears, the device was inserted only once or twice (median, 2; range 1-7; SD, 1.3). The device never broke or left any foreign debris in an ear canal.

Discussion

Cerumen impaction is a medical problem that affects patients of all ages. It has clinical implications and also poses an obstacle in performing a physical examination when there are symptoms that involve the ear. Syringing performed by a nurse or a GP was a common practice but has recently fallen out of favor because of potential damage to the external auditory canal, tympanic membrane, and middle ear. Therefore, GPs and pediatricians can only use ceruminolytic agents, which can be applied for 1 to 3 weeks, and then examine the patient again. This is time consuming and not always effective and ceruminolytic agents can sometimes cause exacerbation of otologic symptoms arising from further occlusion of the canal because of their fluid consistency. The GP is then left with the option of referring to an otolaryngologist, who is less available.

The present device offers a few advantages. It is a single-use device, and it does not use suction, which can cause vertigo and a loud noise. The material is softer than the steel tools that are usually used and is therefore less traumatic to

the ear canal. The device showed a high success rate and succeeded in evacuating most of the wax in most of the patients. The assessors of the device were 2 otolaryngologists, and therefore we speculate that the success rate might be lower when used by untrained GPs. Even when considering a conservative approach, assuming lower success rates by GPs, because of patient discomfort, the use of the device may substantially decrease the need for referral to an otolaryngologist. Failed cases (no statistical significance) included patients with extremely hard cerumen, those with a creamy type of wax that in their history was the use of ceruminolytic agents because they could not tolerate any manipulation of the external auditory canal. We therefore advise against using ceruminolytic agents before using the present device. The external auditory canal is among the most sensitive organs in the body, and therefore it is always a challenge to manipulate it with any tool. Most patients did not feel discomfort or felt tolerable discomfort. There were no significant injuries to the external auditory canal.

Our protocol included insertion of the device up to the second ring, which is 20 mm in depth, thus protecting the tympanic membrane and middle ear. There were no cases of damage to the tympanic membrane or middle ear; therefore, it is advisable to use the device up to the 20-mm bar only. In most patients, cerumen was evacuated on the second attempt, and repeated insertions were not needed.

Conclusions

The tested device is an effective, safe, and disposable tool for the evacuation of cerumen. It can be used by GPs and probably by audiologists and nurses as well. The use of the device may substantially decrease the need for referral to the otolaryngologist. Further research is needed to assess its affectivity in the pediatric population.

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Supplemental Material

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