# Ear Disorder

# **Cerumen Impaction**

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Cerumen, or earwax, is the product of the sebaceous and ceruminous glands combined with débrided epithelial cells and hair from the external auditory canal. Cerumen is usually extruded by a combination of jaw movements from chewing and speech, and natural epithelial migration. However, cerumen may become impacted, especially among older adults and individuals with mental retardation. Cerumen impaction may cause hearing loss, otitis externa, vertigo, tinnitus, or cough. There are multiple methods for removing earwax, with limited evidence to support any of the current practices. Irrigation or manual disimpaction using a curette have long been the accepted earwax removal methods, yet neither has been subjected to comparative trials with other methods. Irrigation alone is effective in up to 70% of cases of impacted cerumen. Ceruminolytics or eardrops are effective in up to 40% of cases without irrigation, and when combined with irrigation can be effective up to 97%. Cotton ear buds and ear candling should be avoided.

Key words: cerumen, earwax, irrigation, ceruminolytic, impaction

#### Introduction

Cerumen (also known as earwax) is composed of sebaceous and apocrine gland secretions, sloughed epithelial cells, hair from the external auditory canal, and debris. It protects and lubricates the ear canal and is normally extruded as a result of jaw movements from chewing and talking. Occlusion of one or both ear canals can occur, resulting in discomfort, hearing loss, tinnitus, and dizziness, and potentially contributing to otitis externa.<sup>1,2</sup> Cough or even cardiac depression may occur with cerumen impaction or attempted removal because the external auditory canal is innervated by the auricular branch of the vagus nerve.<sup>1,3,4</sup>

The prevalence of cerumen impaction is noted to be particularly high in older adults and also in individuals with mental retardation, most likely because cerumen impaction has been associated with anatomical deformities of the ear canal, an increased number of hairs in the ear canal, and physical barriers to normal extrusion process (e.g., hearing aids, earplug-type hearing protectors, and cotton swabs).<sup>1,5,6</sup> Cerumen impaction is present in up to 57% of older adults in long-term care facilities and 36% of persons with mental retardation, compared with approximately 5% among normal healthy adults and 10% among children.<sup>1</sup> Cerumen removal is the most common ear, nose, and throat procedure performed in primary care; approximately 4% of primary care patients consult their physician for treatment of cerumen impaction.<sup>7</sup>

#### Diagnosis

Cerumen impaction is diagnosed by visualization during otoscopic examination. For patients presenting with hearing problems, particularly older patients or those with mental retardation, it is reasonable to evaluate for cerumen impaction as a potential etiology. Similarly, it is appropriate to assess for cerumen impaction among older adults upon admission to a hospital or an institution, as well as periodically thereafter, since it is a recurring condition. 35% of hospitalized patients over the age of 65 years had cerumen impaction and 75% of those had improved hearing following documented cerumen removal.<sup>5</sup>

Routine examination for cerumen impaction is not indicated except in the previously named populations. Examination for the condition is also called for when the presenting complaint may be related to cerumen impaction (typically, decreased hearing), or when the physician needs to evaluate the tympanic membrane as part of an examination. Reexamination of the external auditory canal and tympanic membrane should be performed following cerumen removal to confirm adequate removal and assess for possible complications, such as lacerations to the canal or tympanic membrane perforation.4,8-10

#### Treatment

Several methods of cerumen removal are available to physicians and include irrigation of the external auditory canal, with or without the use of ceruminolytics; the use of ceruminolytics alone; and manual removal using a curette, forceps, or suction. While the evidence on cerumen removal is limited, systematic reviews and one meta-analysis have evaluated these treatment methods.<sup>11–15</sup>

Manual removal with a curette is considered standard management by many practitioners, but no published trials have compared it (or other manual removal methods) with other removal methods.<sup>11</sup> There are also no controlled trials comparing the different irrigation tools or comparing irrigation alone versus no treatment.

The available data, which were gathered mainly from office and emergency department settings, primarily compare various ceruminolytic agents used alone or prior to irrigation.<sup>11–15</sup> One small study comparing ceruminolytics with watchful waiting (natural expulsion) found that 5.3% of patients who did not receive treatment had complete clearing of impacted cerumen and 26.3% had moderate clearing after 5 days.<sup>16</sup>

# **Cerumen Impaction**

Medication	Indications	Dosing	Comment
Water-Based Cerumenex® (10% Triethanolamine polypeptide oleate-condensate)	Soften cerumen prior to irrigation	Fill affected ear canal for 15–30 minutes, then flush	Can be irritating to the ear canal and should not be used for a prolonged period
Colace (Docusate sodium 10 mg/cc) liquid	Soften cerumen prior to irrigation	1 cc in affected ear 15–30 minutes prior to syringing	In one study 1 in 5 tympanic membranes visualized without syringing <sup>31</sup>
Hydrogen peroxide (3% solution)	To soften cerumen prior to irrigation	Fill affected ear canal 15–30 minutes, then flush	If not completely removed, bubbling may interfere with ability to visualize the tympanic membrane
Acetic acid 2.5%	Home treatment of impacted cerumen	2–3 cc in affected ear twice a day for up to 14 days <sup>23</sup>	More effective in children than adults <sup>31</sup>
Sodium bicarbonate (10% solution)	Soften cerumen prior to irrigation or as an alternative to syringing	2–3 cc into affected area 15–30 minutes prior to irrigation, or alternatively for 3–14 days at home with or without irrigation <sup>24,18</sup>	More effective in children than adults <sup>31</sup>
Water	Soften cerumen prior to irrigation	If irrigation is attempted without prior softening and ineffective with first syringe, wait 15 minutes prior to repeating irrigation <sup>21</sup>	
Oil-Based			
Cerumol® (arachis oil 57.3%, chlorbutol 5%, para-dicholorbenzene 2%, oil of turpentine 10%)	Remove cerumen without irrigation or soften cerumen prior to irrigation	5 cc in affected ear(s) twice a day for 2–3 days	Not available in U.S.
Otocerol® or Earex® (arachis oil, almond oil, rectified camphor oil)	Remove cerumen without irrigation or in preparation for irrigation	4 drops in each ear twice a day for up to 4 days	Not available in Canada or U.S.
Olive oil or almond oil	Soften wax prior to irrigation	3 drops in affected ear at bedtime for 3–4 days	
Nonwater/ Nonoil-based			
Carbamide peroxide (Debrox)	To soften cerumen prior to irrigation or as an alternative to irrigation	Put 5–10 drops into the affected ear twice daily for up to 7 days	
50% Choline salicylate and glycerol (e.g., Earex Plus, Audax); ethylene oxide polyoxypropylene glycol (Addax); propylene glycol	To soften cerumen prior to irrigation or as an alternative to irrigation	Put 3 drops into the affected ear twice daily for 4 days	Not available in Canada or the U.S.
Source: Adapted from McCarter D et al., 2007. <sup>33</sup>			

# Manual Removal

Manual removal of cerumen involves the use of a metal or plastic loop or spoon. Although there are no trials comparing this method with others in regard to efficacy or safety, it is generally considered effective.<sup>11</sup> Manual removal may lessen the risk of infection since it does not expose the ear canal to moisture. There is a risk of trauma to the external ear canal or tympanic membrane; therefore, more clinical skill is required with this method, and a cooperative patient is beneficial.<sup>17,18</sup>

Advantages of manual removal are that it is typically quicker than other procedures and allows direct visualization of the procedure via a monocular otoscope or floor- or wall-mounted binocular microscope. Binocular microscopes improve depth perception and may enhance safety and patient comfort, but these are generally only available in otolaryngology offices. Another alternative is a lighted curette. This is a disposable loop or spoon made of plastic that connects to a light source and transmits the light through the instrument.<sup>19</sup>

# Irrigation

There are several different irrigation methods available in the office setting. These methods may be attempted alone or in combination with ceruminolytic pretreatment. Ear syringes are readily available and inexpensive but may be poorly balanced, slow, or cause minor ear trauma due to poor pressure control.<sup>10,18,20</sup> Oral jet irrigators are fast, portable, and inexpensive; however, they too have disadvantages. These devices have been associated with trauma to the stapes and cochlea as well as perforation of the tympanic membrane.<sup>9,10,18,20</sup> The use of an ear irrigator tip, which keeps water from hitting the eardrum and eliminates pressure buildup, can decrease the risk of tympanic membrane perforation. Since these devices are not recommend or designed for cerumen removal by the manufacturer, the clinician is susceptible to litigation should a complication occur.<sup>10,20</sup> It is also possible to construct an irrigation system using a 20 to 30 cc syringe with either an 18-gauge plastic

intravenous catheter or a plastic catheter from a butterfly needle once the wings and needle have been carefully removed.<sup>20</sup> Regardless of the irrigation system chosen, the irrigant should be at body temperature to prevent caloric stimulation.

When attempting irrigation, gentle traction should be applied upward and backward on the pinna to straighten the external auditory canal.<sup>20</sup> A small basin or other receptacle should be held below the ear to collect the irrigant. The irrigant should be instilled gently, and the canal should be examined intermittently to monitor treatment progress. Irrigation should be stopped and the external auditory canal and tympanic membrane examined if the patient experiences any sudden pain, hearing loss, tinnitus, or vertigo.<sup>20</sup>

Irrigation should not be performed if a tympanic membrane perforation or myringotomy tube is present. Additional contraindications to irrigation include a history of middle ear disease, a history of ear surgery, radiation therapy to the ear or surrounding area, severe otitis externa, sharp foreign bodies in the external auditory canal, or a known inner ear disturbance, such as vertigo.<sup>20</sup> Irrigation is generally considered to be safe and effective; however, there are no studies comparing it with other removal methods.<sup>11</sup> One study did find that irrigation alone was effective approximately 70% of the time.<sup>21</sup>

# Ceruminolytics

There are three types of cerumen-softening preparations: water-based, oil-based, and nonwater-based/nonoil-based (Table 1).<sup>16,21–24</sup> Oil-based preparations lubricate the wax, whereas water-based and nonwater-based/nonoil-based products increase cerumen miscibility.<sup>13,22,23</sup> Water-based preparations include 10% triethanolamine polypeptide oleate condensate, docusate sodium, 3% hydrogen peroxide, 2.5% acetic acid, 10% sodium bicarbonate, and water or saline.

Nonwater-based / nonoil-based preparations include carbamide peroxide (Debrox<sup>®</sup>), choline salicylate and glycerol

(e.g., Earex Plus<sup>®</sup> and Audax<sup>®</sup> [brands not available in Canada or the U.S.]), or ethylene oxide polyoxypropylene glycol (Addax<sup>®</sup> [brand not available in Canada or the U.S.]).

Oil-based preparations include products based on Arachis oil (i.e., peanut oil)(e.g., Cerumol<sup>®</sup>, Earex<sup>®</sup>, and Otoercol<sup>®</sup> [Cerumol is available in Canada; the other brands are not available in Canada or the U.S.]), almond oil, olive oil, maize oil, or mineral oil.<sup>13</sup> As with irrigation, ceruminolytics are contraindicated for patients with a suspected breach of the tympanic membrane from previous surgery, insertion of myringotomy tubes, or tympanic membrane perforation.

#### **Ceruminolytics Alone**

In one systematic review of ceruminolytics, investigators concluded that triethanolamine was more effective than saline. It was also found that a longer treatment duration with softening agents was more effective than a shorter duration (14%, 19%, and 35% clear at 1, 3, and 4 days, respectively; p<.0001). These two findings were the only ones that were statistically significant. The review did not find a statistically significant difference between the effect of docusate sodium and that of triethanolamine or saline.<sup>13</sup> A randomized controlled trial with an untreated control group was included in the review. No statistically significant difference was found between the ceruminolytic therapy and no treatment.<sup>16</sup> Although longer treatment duration appeared to increase the effectiveness of ceruminolytics when used alone, overall effectiveness is still uncertain due to the limited evidence available.<sup>13</sup>

# Ceruminolytics prior to Irrigation

The evidence currently available suggests that the use of ceruminolytics prior to irrigation may improve the success of irrigation by as much as 97%.<sup>13</sup> Studies evaluating the use of ceruminolytics prior to irrigation have found that triethanolamine (a water-based preparation) was more effective than carbamide peroxide (a nonwater-based / nonoil-based preparation)<sup>13,25</sup> and that water

instilled for 15 minutes before irrigation was more effective than immediate irrigation.<sup>26</sup> No other statistically significant differences were noted between any of the preparations, although there was weak evidence to suggest that Arachis oil (Cerumol<sup>®</sup>) is slightly more effective than olive oil and maize oil.<sup>13</sup> There was no significant difference associated with treatment duration; use of a ceruminolytic preparation for 15–30 minutes before irrigation was determined to be as effective as several days of treatment.<sup>13</sup>

Overall, no ceruminolytics appeared to be superior to water, which makes water an effective and inexpensive firstline agent.<sup>13</sup> Based on current evidence, if treatment with a ceruminolytic agent followed by irrigation is chosen in lieu of manual removal, an initial attempt at irrigation with water should be performed. If this is unsuccessful, the water should be instilled in the external auditory canal for 15-30 minutes, after which another attempt at irrigation should be made. If the second attempt is also unsuccessful, it would be reasonable to use an alternative ceruminolytic agent for 2-3 days, followed by another attempt at irrigation.<sup>21</sup>

#### Home or Alternative Treatments

Home treatments for cerumen impaction are not unusual, and many of the treatments mentioned above are available individually over the counter or in earwax-removal kits. Cotton ear buds are not definitively associated with cerumen impaction, but they have been implicated in impaction and otitis externa, and should be avoided.<sup>27–29</sup>

Ear candling appears to be a common home treatment that also should be avoided. Ear candling involves inserting a hollow candle into the external auditory canal while the patient is lying on the opposite ear and lighting the candle. In theory, the lit candle creates a vacuum and the suction removes cerumen from the external auditory canal. However, one study clearly demonstrated that ear candles neither create suction nor remove cerumen, and actually lead to the occlusion of the ear canal with candle wax in persons with previously clean ear

### **Key Points**

The use of ceruminolytics alone becomes more effective with a longer treatment duration; however, it may only clear impaction 40% of the time.

The effectiveness of irrigation may be improved by the use of ceruminolytics prior to treatment.

Applying water or an alternative ceruminolytic 15–30 minutes prior to irrigation is as effective as treatment with ceruminolytics for several days before irrigation.

No ceruminolytic is superior to any other, nor is any ceruminolytic superior to water.

Ear candling should be avoided.

canals. Primary care physicians should make their patients aware of potential complications from ear candling, including occlusion of the ear canal with candle wax, local burns, and tympanic membrane perforation.<sup>8,30,31</sup>

# Criteria for Appropriate Referral

If the patient is unable to tolerate attempted cerumen removal due to severe pain, lubricating the ear canal with olive oil for a few days with additional removal attempts can be tried. If pain persists, further attempts at cerumen removal should cease and a referral should be made to an otolaryngologist. If vertigo occurs during irrigation, despite the use of water at body temperature, perilymphatic fistula or perforation of the oval window should be considered and referral to an otolaryngologist should be made. Referral should also be considered for patients with a very swollen ear canal, unusual anatomy, or a history of tympanic membrane perforation, radiation, or surgery.<sup>10,18</sup> If the patient has hearing deficits or continued hearing loss after cerumen removal, a formal hearing evaluation should be considered.

# Prevention of Cerumen Impaction

To date, only one study has evaluated prevention of cerumen impaction. A very small randomized controlled trial evaluated the treatment of ear canal skin with a lotion that contains paraffinum liquidum, cyclomethicone, and Buxus chinensis (Ceridal lipolotion) and the recurrence of cerumen impaction. When the treatment group was compared with the control group, an overall decrease in recurrence of cerumen impaction was seen (19% and 52%, respectively; p < .05).<sup>32</sup> Further studies are needed to clarify the role of preventive treatment for cerumen impaction.

#### Conclusion

Cerumen impaction is a common condition in the older adult population that can be easily identified and treated. Manual removal is generally considered the standard treatment, but it has never been compared with alternative methods. Irrigation and ceruminolytics are alternative treatment options and appear to be most effective when used in combination. Treatment with ceruminolytics for 15-30 minutes prior to irrigation is just as effective as several days of treatment, and no ceruminolytic agent has been shown to be superior to water. Ear candling should be avoided as it has not been shown to be effective and may, in fact, harm the patient.

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