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Earwax, clinical practice

Il tappo di cerume: pratica clinica

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SUMMARY

The “American Academy of Otolaryngology - Head and Neck Surgery Foundation” has issued the first comprehensive clinical guidelines for assessment, management, and treatment of impacted cerumen. Despite the high frequency and its important repercussions on health care management in Italy, Italian epidemiological data on earwax impaction have never been published before. Another factor differentiating the management of earwax impaction, between Italy and other countries, is a generalized tendency to reserve the diagnosis and treatment of this pathological condition almost exclusively to otolaryngologists and otologists. General practitioners and nurses usually neglect this pathological condition, as well as its treatment, resulting in few complications, on the one hand, and in an increase in the public health costs, on the other. The Authors, after a comprehensive review on the definition, epidemiology, relationship with infections, genetics and treatment options of earwax impaction, report on an evaluation of the ENT consultations from 1st January to 31st December 2008, at their hospital ENT Department. The consultations for earwax management account for an average rate of 12.80% of the total ENT consultations in the same timeframe. The question whether cerumen protects the ear against micro-organisms or, instead, supports their growth, has long been, and still remains, a subject of controversy. Interesting relationships between cerumen and other systemic diseases (psoriasis, cystic fibrosis, alkaptonuria, Parkinson disease, breast cancer, arteriosclerosis, etc.) have been described. Finally, the implications of earwax on industrial audiometry are discussed, mainly concerning the difficulty in treating earwax impaction in the industrial setting and the effect of cerumen on aural acuity. The Authors report results of a study on hearing threshold improvement following relief of earwax impaction in industrial noise-exposed workers.

KEY WORDS: External auditory canal • Earwax • Cerumen impaction • Clinical practice • Industrial audiometry

RIASSUNTO

La “American Academy of Otolaryngology - Head and Neck Surgery Foundation” ha emesso le prime linee guida generali in merito a valutazione, gestione e trattamento del tappo di cerume. A dispetto della sua particolarmente elevata frequenza e delle rilevanti ripercussioni sulla sanità in Italia, mancano al presente in letteratura dati italiani sull’epidemiologia del tappo di cerume. Un altro fattore di differenziazione riguardo al tappo di cerume tra l’Italia ed altri paesi è la tendenza, pressoché generalizzata, di riservarne quasi esclusivamente all’otorinolaringoiatra ed all’audiologo la diagnosi e la terapia. I medici di medicina generale e il personale infermieristico trascurano questa patologia ed il suo trattamento, il che, se da un lato comporta una ridotta incidenza di complicazioni, dall’altro si riflette in un incremento notevole dei costi pubblici di questa condizione patologica. Gli Autori, dopo una metodica revisione riguardante la definizione, l’epidemiologia, la relazione con le infezioni, la genetica e le opzioni terapeutiche del tappo di cerume, riportano uno studio delle visite specialistiche otorinolaringoiatriche effettuate dal 1 gennaio al 31 dicembre del 2008 presso la loro divisione ospedaliera. Le richieste di visita relative al tappo di cerume hanno inciso per un tasso medio del 12,80% su tutte le visite specialistiche complessive dell’anno in esame. Rimane controverso il rapporto tra cerume ed azione favorente od inibente la crescita microbica del condotto uditivo esterno, mentre interessanti correlazioni sono descritte con patologie sistemiche quali psoriasi, fibrosi cistica, alcaptonuria, morbo di Parkinson, carcinoma mammario ed arteriosclerosi. Infine si analizzano le relazioni tra cerume ed audiometria industriale, concernenti soprattutto la difficoltà di trattamento in ambiente industriale e l’effetto dello stesso cerume impattato sulla ricerca di soglia audiometrica. Gli Autori riportano uno studio sul miglioramento di soglia uditiva dopo rimozione di cerume occasionalmente riscontrato in lavoratori dell’industria sottoposti a rumore occupazionale.

PAROLE CHIAVE: Condotto uditivo esterno • Cerume • Tappo di cerume • Pratica clinica • Audiometria industriale

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Definition and composition of earwax and earwax impaction

Adopting the definition of the Clinical Practice guidelines¹ on cerumen impaction by the “American Academy of Otolaryngology – Head and Neck Surgery Foundation”:

- cerumen is a mixture of secretions (sebum together with secretions from modified apocrine sweat glands) and sloughed epithelial cells, and is a normal substance present in the external auditory canal. As cerumen migrates laterally, it may mix with hair and other particulate matter;

- cerumen impaction is defined as an accumulation of cerumen that causes symptoms, prevents a needed assessment of the ear canal/tympanic membrane or audiovestibular system, or both;
- although “impaction” usually implies that cerumen is lodged, wedged, or firmly packed in the ear canal, the definition of cerumen impaction does not require a complete obstruction.

Despite excessive and impacted cerumen being common ², the literature review suggests that its physiology, clinical significance and management remain poorly characterized. There are no well-designed, large, placebo-controlled, double-blind studies comparing treatments. Earwax removal is the otolaryngological procedure most commonly performed by general practitioners and by practice nurses and is their most common source of iatrogenic otolaryngological problems ³. The indications and best methods for aural wax removal are still not known.

In most subjects the ear canal is self-cleansing and the meatal skin has the natural tendency to extrude the wax as part of the self-cleansing mechanism. Epithelial migration carries the keratin debris laterally outward from the tympanic membrane for removal ⁴. A dot of ink, if placed near the centre of the drum, is found to lie near the margin of the drum in 3 weeks and, between 6-12 weeks, the dot migrates outwards on the meatal skin to emerge in wax at the orifice of the meatus. Therefore, cleaning of the ear canal is unnecessary. It has been shown ^{5 6} that the epithelial migration always occurs from the tympanic membrane to the canal wall and not vice versa and that the tympanic membrane represents the centre of this migration, the umbo being the epicentre. It may thus be hypothesized that tympanic membrane disorders may prevent the phenomenon of lateral migration thus contributing to cerumen impaction, especially in elderly age groups; moreover, age-related atrophy of modified apocrine glands leads to a decrease in the production of watery components, making cerumen dryer, harder, coarser and more easily impacted. Earwax is usually asymptomatic, but when it becomes impacted it can cause complications and can interfere with examinations of the tympanic membrane.

Cerumen impaction is diagnosed by direct visualization with an otoscope or microscope. Foreign bodies and the presence of a narrow canal can impair tympanic membrane visualization, white tympanic membrane should be evaluated before attempting cerumen removal.

Patients regularly using cotton buds to clean their ears, often push cerumen medially on to the tympanic membrane, making its removal very difficult by means of direct vision. Cotton buds can lacerate the ear canal skin, breaking the normal immune barrier and thus supporting canal haematoma and *otitis externa*.

In one study ⁷, cotton-tipped swabs were associated with 75% of cerumen occlusion on the left side, but not on the right side in paediatric patients. However, the study did

not show a causal relationship between the use of impacted cerumen and cotton-tipped swabs, which do not necessarily clear cerumen from the external canal. Many years ago, it was suggested that a warning notice be printed on each packet restricting the use to the orifice of the external canal ⁸, but the misconception of needing to clean the ear canal by introducing an object, and especially cotton swab, into the ear is rampant, at present, despite manufacturers’ advice against use of cotton swabs in the external auditory canal.

Cotton buds were developed in 1923 by Leo Gerstenzang, observing his wife cleaning his baby’s ears, and were initially called Q-tips Baby Gays (Q for quality) and the term Q-tips survives to this day ⁹. From 1972, complications started related to cotton buds (membrane perforation, *otitis externa* and earwax impaction) and, despite manufacturers’ advice, cotton bud-induced disorders are a common reason for otorhinolaryngological examinations ¹⁰.

Wax is hygroscopic and absorption of water during swimming or showering may completely occlude the outer ear ¹¹. This sudden deterioration will be perceived as a greater hearing loss than that which occurred gradually. Significant cerumen occlusion frequently occurs in whip-lash patients where the ear is affected by acute onset earache, fullness in the ears, or reduced hearing ¹². Wax may cause discomfort, tinnitus or otalgia and removal may be required only to allow adequate otoscopic examination, but many patients with a sensorineural hearing loss sometimes request repeated ear syringing in the mistaken belief that these will restore auditory acuity.

Potential complications of earwax impaction include pruritus, perforation, *otitis externa*, hearing loss, vertigo, syncope, chronic cough ¹³; moreover, cardiac arrest has been reported ¹⁴. Coughing or even cardiac depression may be found in the presence of stimulation of the canal due to cerumen impaction or removal attempts, since the external auditory canal is innervated by the auricular branch of the vagus nerve.

An anatomic deformity and an increased number of hairs in the external auditory canal, as well as physical barriers to natural wax extrusion (e.g., cotton swabs, hearing aids, earplug-type hearing protectors) have also been reported to be associated with an increased incidence of cerumen impaction ^{15 16}. The auditory canal is the only cul-de-sac of *stratum corneum* in the body. Therefore, physical erosion cannot routinely remove *stratum corneum* in the auditory canal during turnover. Cerumen offers a means to expel *stratum corneum*.

Cerumen is secreted both by the ceruminous and sebaceous glands and the accumulated cerumen is made up of a mixture of keratin debris and the secretory products of the ceruminous and sebaceous glands in the external auditory canal ¹⁷. The human ceruminous glands ¹⁸, which have been estimated to be between 1,000 and 2,000 (modified apocrine glands) ¹⁹ are located in the cartilaginous two-

thirds of the external auditory canal. The simple coiled tubules of the ceruminous gland course with their ducts through the dermis to empty into a hair follicle on the epidermal surface¹⁸. The gland is lined with a single layer of secretory cells resting on myoepithelial cells²⁰.

Hairs in the external third of the canal also produce glandular secretions that contribute to the composition of the cerumen. It was recently demonstrated²¹ that the eccrine secretion occurs as a typical exocytosis by fusion of the limiting membrane of the secretory granule with the apical plasmalemma. The apocrine secretion is more complex and takes place in sequential steps: bulging of the cellular apex into the lumen, constriction of the projection, and detachment of it from the cell. This mechanism generally causes sudden removal of the entire projection by decapitation at its base.

The two distinct forms of human cerumen, dry and wet, are associated with race and controlled by two autosomal alleles²².

Earwax has been found to contain amino acids, fatty acids, neurostearic acid, cerotic acid, cholesterol (6-9%), triglyceride, hexone bases, lysozyme, immunoglobulin, glycopeptide, copper, and other components, although differences in composition between the cerumen types have been described^{23 24}.

Cerumen triglyceride levels appear to decline between November and July, although cholesterol levels remain constant²⁵. The proportions of the lipid constituents of cerumen were found to vary with age, sex and menstrual stage. In cerumen, the main lipid constituent stimulated at puberty appears to be squalene²⁶.

Cerumen lipid and amino acid composition seems to differ considerably from that expressed in the *stratum corneum*. For example, uncontaminated *stratum corneum* does not appear to express the squalene and wax esters (two of the sebaceous lipids in cerumen). Squalene accounts for between 12% and 20% of the wax²⁷.

Wet cerumen is characterized by a relatively high concentration of lipid and pigment granules; dry cerumen tends to express lower levels of these components: dry wax contains around 20% lipid, compared to approximately 50% in wet cerumen²⁸. Other than these, the two forms show few other biochemical differences²⁹.

Earwax-related anatomy and pathology of the human external auditory canal

The external auditory canal extends from the external auditory meatus to the tympanic membrane and measures 2.5 cm in length. The lateral 1.5 cm portion is a continuation of the fibrocartilage of the auricle and is surrounded by subcutaneous fat and skin. The medial segment is a bony canal formed above by the squamous portions of the temporal bone and behind by the mastoid. The remaining anterior-inferior ring of the canal is formed by the triangu-

lar tympanic bone that forms an arch from the squamous to the mastoid bone. This bone also forms the posterior wall of the mandibular fossa and the lateral wall of the middle ear and eustachian canal. The bony portion of the external auditory canal is covered by only a thin layer of periosteum and skin, without soft tissues surrounding the bone, so diseases of the external auditory canal are frequently quite painful. The cerumen may mask existing diseases of the skin in the entrance of the external ear canal. In the event of a ceruminous obstruction, an adequate assessment of the external auditory meatus should be performed only after cleaning, which may demask existing dermatosis.

On computerized tomography (CT) scans, fat planes delineate the outer margin of the undulating funnel-shaped cartilaginous portion of the external auditory canal. The lateral external auditory meatus may not be visible on the same axial section as the bony medial canal since the canal frequently slopes inferiorly, producing the false impression of a soft-tissue atresia. Multiple axial or coronal sections can confirm the patency of the meatus. The soft tissues covering the bony portion of the medial external auditory canal may not be visible because they are so thin. The tympanic membrane is best seen on coronal CT sections as a thin filamentous structure parallel to the plane of the long axis of the malleus. Cerumen may fill the external auditory canal, producing a pseudotumour and simulating a polypoid soft-tissue tumour. This can usually be recognized since a thin rim of air will surround the plug. Most are seen in elderly patients presenting symptoms of ear pain, tinnitus, and dizziness.

“*Keratosis obturans*” is an accumulation of keratin debris that forms a pearly white plug in the ear canal. These abnormalities are probably secondary to faulty development and migration of squamous epithelial cells. The precise aetiology is unknown but it is thought that an increased rate of desquamation and poor epithelial migration are the cause. The accumulation of desquamated epithelium may form a large impacted mass in the meatus causing, moreover, erosion of the bony canal. In similar conditions, the radiological appearance may simulate malignancies of the external auditory canal, which frequently involve the lateral margin of the middle ear cavity and the mastoid bone. With time, the keratin plug exerts pressure on the deep bony ear canal, leading to slow bone resorption. This condition is more common in younger people, which requires the ENT surgeon for management. The ear canal may be very sensitive and the underlying skin inflamed or granulomatous. Otological antibiotics may be required, followed by a period of close surveillance.

Occurrence of cholesteatoma of the external ear canal is rare: from an estimated rate of 1.2 primary cases per 1,000 new otological patients³⁰ to a total incidence rate of 5 cases per 1,000 patients³¹. Despite this rare occurrence rate, it is interesting to note that between 24% and 31% of primary cases are asymptomatic³² and a considerable number of

the cases are found for other reasons, for instance, post-operative check-up or routine wax cleaning³³. Microscopic examination of the ear following meticulous removal of wax, especially in elderly patients, is useful in detecting cholesteatoma of the external ear canal. Regardless of the hypothesized aetiological factors of cholesteatoma of the external ear canal, age-related changes in epithelial migration and cerumen glands, resulting in a drier wax composition, have been considered factors leading to entrapment and accumulation of epithelial cells. Possibly recurrent trauma, combined with a vascular ischaemia, predisposes patients to periostitis and bone sequestration, which are associated with cholesteatoma of the external ear canal. In spontaneous cases, local periostitis is thought to trigger the process of invasion. An epithelial abnormality with increased keratotic activity has been proposed. This may explain the prominence of the hard wax and debris that has been described at the site of the lesions³³.

Some extensive types of mastoidectomy alter the anatomy of the ear, producing an enlarged meatus. In such cases, the skin of the mastoid cavity does not migrate satisfactorily and wax accumulates, requiring frequent removal.

Impacted cerumen might occur, according to a recent theory, from a failure in the separation of keratinocytes that normally occurs in the external auditory canal as part of skin turnover. Hard cerumen plugs consist of more keratin sheets than softer wax and corneocytes, in softer wax, seem to undergo expansion³⁴. Possibly, subjects prone to recurrent episodes of impacted cerumen present insufficient quantities of an unidentified “keratinocyte attachment destroying substance (KADS)”³⁵. According to this theory, patients whose corneocytes fail to separate probably lack KADS that destroys the attachments that bind individual corneocytes to each other, thereby maintaining the integrity of the superficial keratin layer. KADS releases those attachments and allows the cells to break down into individual flakes and desquamate. In patients who do not have KADS, the keratin sheet does not break down as it reaches the superficial canal; instead, it maintains its integrity. As a result, it tends to roll back on itself, accumulate, and become coated with cerumen. Eventually, it forms a plug. Furthermore, according to this theory, cerumen accumulation is a medical disorder rather than a natural phenomenon. It is probably a disorder of the migratory epithelium in the superficial external auditory canal, and it is possibly genetic. The Author suggests that there might be more than one KADS and that one of these substances might be steroid sulfatase, which is an aryl-sulfatase-C enzyme. Steroid sulfatase is normally present in epithelial cells, fibroblasts, and leukocytes. It is the only enzyme known to be involved in the process of epidermal cell desquamation. The cohesion of the cells of the *stratum corneum* is maintained by cholesterol sulfate, which acts as an intercellular cement. Steroid sulfatase is

believed to block the action of cholesterol sulfate and allow the bonds to become free from each other. In normal subjects, steroid sulfatase activity is greater in the epithelium of the deep external auditory canal than in the superficial external canal. Therefore, steroid sulfatase appears to be responsible for the separation of the keratinocytes as they migrate outwards. Steroid sulfatase is responsible for an X-linked recessive ichthyosis in which scales of keratin adhere to the skin and, over time, accumulate and turn dark brown: a similar mechanism is thought to be responsible for cerumen accumulation.

In another study, it was suggested that carotenoids might contribute to the pathogenesis of impacted cerumen: experimental administration of retinoids increases epidermal hyperplasia and ceruminous gland activity. Such changes could promote cerumen production and increase the likelihood that the wax will become impacted. Certainly, cerumen contains carotenoids, although their role in the pathogenesis of impacted cerumen requires further confirmation²⁹.

Rare ceruminous gland adenomas have been described as the most common external auditory canal tumours. A dual cell population has been demonstrated of basal myoepithelial-type cells and luminal ceruminous cells. Cerumen pigment, CK7, and p63 can help to distinguish this tumour from other neoplasms that occur in the region. Complete surgical excision results in an excellent long-term clinical outcome³⁶.

Epidemiological data on earwax impaction

A study on 1,507 patients screened for adult hearing loss revealed suspected occluding wax in 2.1%². Approximately 150,000 earwax removal procedures are performed each week in the United States^{37 38}. Cerumen impaction is present in approximately 10% of children, 5% of normal healthy adults, up to 57% of older patients in nursing homes³⁹, and up to 30% of patients with mental retardation^{15 40 41}. Approximately 4% of primary care patients will consult their physician for cerumen impaction³⁴. In one study, 35% of hospitalised patients aged > 65 years complained of earwax impaction and, of those patients, 75% referred to hearing improvement following earwax impaction removal¹⁵.

Certain individuals are at increased risk of either producing cerumen in excess or having problems clearing it: young children, the elderly, mentally disabled, and institutionalized patients. Furthermore, they are also less likely to report decreased hearing or other symptoms associated with cerumen impaction, which may delay recognition and appropriate treatment.

Impaction is more common in paediatric age groups and, as age advances, the tendency of wax is generally not to cause impaction although, in the elderly population, the tendency to impaction again predominates, thus show-

ing a bimodal representation of impaction in the extreme age groups. This tendency has been related to sebaceous gland secretion, because *sebum* secretion begins to increase at about the age of 7 years and continues to do so well into the teens⁴² and, thereafter, shows a gradual decline⁴³.

The reasons for the increased prevalence of impacted cerumen among patients with mental retardation, or children, are not clear. However, anatomical differences in the structure of the canal (for example, associated with trisomy 21) or excessive cerumen production may play, at least, associated roles³⁸.

In a recent report on individuals with mild intellectual disabilities participating in athletic endeavours in countries throughout the world, 855 athletes were screened. Of these, 58% passed the Distorsion Product Otoacoustic Emissions (DPOAE) screen. Of the remaining 42%, 186 did not pass pure-tone screening. Among these 186 athletes, 104 failed tympanometry. The rate of ear canals blocked (partially or totally) with cerumen was 65% in the 104 athletes failing both pure-tone screening and tympanometry and of 38% in the 82 athletes failing pure-tone screening but passing tympanometry.

Management of impacted cerumen in certain patients, such as diabetics and immuno-compromised subjects, can represent problems for secondary care physicians⁴⁵.

In the study of Smeeth et al.⁴⁶, 8% of the 32,656 patients aged at least 75 years reported "a lot" of difficulty hearing; 42% reported "a lot" or "a little" difficulty; 26% (3,795) of the 14,877 who underwent a whispered hearing test failed. However, wax removal reversed hearing loss in 343 of the 3,795 patients (9%) who failed the whisper test.

Of interest was the finding⁴⁷ that the evaluation of hearing and mental status, following removal of cerumen resulted in a statistically significant improvement in hearing and "cognition" when compared with controls. The mean change in the standardized Folstein Mini-Mental Status Exam score was 1.05 ± 1.6 for participants who had cerumen removed compared with -0.30 ± 0.95 for the controls.

The uncommon frequency of earwax was investigated in spinal cord injury patients with high levels of paralysis⁴⁸. It is suggested that the sebaceous and the modified sudoriferous glands of the ear canals that together produce cerumen and are responsive to noradrenaline⁴⁹ may play a role in the dysreflexic sweating that occurs⁵⁰ frequently - daily or several times a day - in some individuals with spinal cord injury. In this study, patients with C2 tetraplegia accumulated more earwax and requested its removal more often than patients with lower levels of paralysis. However facial blood flow, and, conceivably, wax production, may be increased with the patient lying supine on account of the impaired defense of the circulation against gravity⁵¹.

Earwax impaction in different geographical areas

In agreement with Matsunaga et al.⁵², in 1962, the frequencies of wet cerumen in different parts of Japan varied within the range 12.6-22.4%.

The incidence of complaints due to earwax in general practice, in The Netherlands, is 39.3 per 1,000 patients⁵³. In Scotland, general practitioners managed a population of approximately 650,000 individuals, and it was estimated that some 44,000 ears are syringed each year in this population⁵⁴.

In Dublin, earwax impaction is the second most common otorhinolaryngological complaint⁵⁵. The picture in developing countries also showed similar trends.

In a study⁵⁶ on otoacoustic emission procedures, used to assess hearing disorders in school-age children, of 454 children from the 1st grade of the public elementary school system of São Luiz, Brazil, between 6 and 11 years of age, the otoscopic exam was carried out in 908 ears, of which 169 (18.6%) had impacted wax. Of 802 primary school children, in rural and urban Dar es Salaam, Tanzania, examined to determine the prevalence of otitis media, hearing impairment and cerumen impaction by otoscopy and pure tone audiometry, 126 (15.7%) had cerumen impaction. Cerumen impaction was found in 20.45% of the rural school children and in 14.8% of the urban school children, but this difference in prevalence between the two groups was not statistically significant⁵⁷. In Nigeria, impacted earwax was a predictor of hearing impairment in the children of Lagos⁵⁸. Children from whom impacted cerumen had been removed were more likely to have hearing loss, and of a more permanent nature. They were also likely to have more *otitis media* with effusion. Impacted wax was observed in 38.4% in black, and in 49.9% in Indian, pre-school children of various ethnic groups in the Durban Central Region⁵⁹. A study, in Malaysia, also suggested a significant association of impacted wax with hearing loss in children⁶⁰. In Oman, the national prevalence of impacted earwax was 11.7%. Nearly 181,000 subjects in Oman⁶¹ were estimated to have impacted wax in the ear canal of at least one ear, impacted wax was more common in females than in males and in subjects > 60 years of age, in whom the rate increases to 23.9%. As in the report on Nigerian children, in this study, the presence of impacted wax, in the ear canal, seems to be significantly associated with middle ear diseases (dry eardrum perforation, *otitis media* with effusion, chronic suppurative *otitis media*). The Authors also calculated that the mean time taken for removal of impacted wax was 15 minutes (even using wax softeners and with the assistance of a qualified nurse during the entire procedure), and that the cost of managing impacted earwax would be approximately US \$20 (thus the total cost of managing all subjects with impacted earwax, in Oman, would be, approximately US \$3.6 million).

Earwax and infection: a controversial relationship

The function of cerumen in protecting the ear against invasion of micro-organisms has long since been, and continues to be, at present, a subject of controversy. In recent studies, it was suggested that cerumen is unable to prevent infection and that the rich nutrients of earwax support growth of bacteria and fungi. The evidence that cerumen plays a biologically or clinically significant role in host defense seems relatively weak and the empirical observations support suggestions that the only role of cerumen is to provide a mechanism for excreting keratin³⁴.

Impacted cerumen, exposed to water, possibly from shampoo or a chlorinated swimming pool, is associated with an increased risk of infection²⁹.

On the other hand, in less recent studies, it was suggested that cerumen might have anti-microbial activity, although little evidence has been presented to support this theory.

A recent ultrastructural and histochemical analysis of human ceruminous glands revealed that the ceruminous gland is a modified apocrine gland contributing to the defense of bacteria by secreting anti-microbial agents. In addition, the ceruminous gland, together with the sebaceous gland, contributes to the complex lipids of the cerumen⁶². Moreover, cerumen was recently demonstrated to have potential anti-microbial effects on strains of *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans*⁶³.

The theory that the cerumen acts as a trap for dust and other particles entering the ear canal is widely accepted⁶⁴.

Chai TJ & Chai TC⁶⁵ demonstrated anti-bacterial activity of cerumen on each of 10 strains of bacteria tested, in contrast to reports by other investigators⁶⁶. Differences in the cerumen used could possibly account for this discrepancy. Chai used dry-form cerumen, whereas others may have used the wet form.

A study in children aged around the peak incidence time of *otitis media* revealed an inverse relationship between wax and infection⁶⁷. Schwartz et al.⁶⁴ found the melting point of wax to be over 45°C. Fairey et al.⁶⁷ hypothesized that a transudate from an inflamed eardrum contains cerumenolytic properties, and this, perhaps combined with a raised temperature, may be responsible for the reduction in the amount of earwax in children with *otitis media*. A recent study confirmed the lower incidence of impacted wax in deaf children compared with others⁶⁸.

In ancient studies, *Staphylococcus* was found to be the predominant organism (69% Senturia⁶⁹ and 56% Perry & Nichols⁶⁶) with coryneforms (diphtheroids) being the second most commonly isolated organism. Although the taxonomy has changed since the 40s and 50s, the results of these studies are consistent with the more recent literature^{70 71}. Recently, *Turicella otitidis* has been that most commonly associated with patients having *otitis media*^{72 73}, despite the

fact that it has also been isolated from healthy patients⁷⁴. In another recent study⁷⁵ it was hypothesized that probably it is normal flora, in the external canal and cerumen (54% of the isolated *Turicella otitidis* was from adults, and 46% was from children).

The same is probably true of *Alloicoccus otitis* since it represented more than 95% of the streptococci-like bacteria isolated in both the canal and the cerumen. Although *Alloicoccus* has been recovered from children with acute *otitis media*, its presence, as a normal saprophyte in the healthy ear, raises doubts about its pathogenicity⁷⁶⁻⁷⁸. If *Alloicoccus otitis* was isolated from children in 63% of the cases and in normal adults in the remainder, it was probably saprophytic rather than pathogenic. The second most frequently isolated coryneform, *Corynebacterium auris*, has previously been reported from paediatric patients with *otitis media*⁷⁹. It was isolated in 6 healthy adults and 2 children. Therefore, all bacteria isolated from earwax may be saprophytic rather than pathogenic.

It appears that cerumen offers a rich medium supporting microbiological growth, with a mean of 10⁶ micro-organisms per millimetre⁸⁰. Several studies have reported the efficacy of cerumen as a growth medium^{75 81 82}.

Moreover, immunohistochemical studies suggest that antibody-mediated immune reactions, rather than cerumen, protect the external auditory canal from infection.

Sirigu et al.⁸³ in an immunohistochemical study isolated IgA, IgM and IgG immunoreactive cells in the dermis surrounding human sebaceous and ceruminous glands. Human ceruminous glands contain acid phosphatase, non-specific esterase, glucose-6-phosphate dehydrogenase, 6-phosphogluconate dehydrogenase, and seem to secrete peroxidase⁸⁴. Ito et al.⁸⁵ described immunohistochemical differences between adenoid cystic carcinoma of the external auditory canal and non-neoplastic tissue. These Authors showed, in non-neoplastic tissue, a positive reaction of an unidentified cytokeratin and, occasionally, positive lysozyme staining. The secretory component of IgA, smooth muscle actin, vimentin, and S-100 protein were negative in normal ceruminous glandular cells. The presence of glycoconjugates in the ceruminous gland of the North American raccoon⁸⁶, the goat⁸⁷, and the horse⁸⁸ indicates a natural barrier that may coat receptors for several bacterial adhesions and toxins⁸⁹.

Another immunohistochemical study⁹⁰ of the external auditory canal skin reported the expression of anti-microbial peptides both in the epithelium and the glands of the cerumen, also confirmed by Western blotting, which might provide the first line of defense against microbes in the external auditory canal and are called human beta defensins 1 and 2 (hBD-1 and hBD-2).

Other studies, also in animals, suggest that the secretions from the ceruminous glands of normal appearance, in the external auditory meatus in cats, are mucous while those in dogs are serous in character. Depending on the nature

of the secretions from the ceruminous glands located in the external auditory meatus, cerumen was concluded to be capable of creating suitable media for external ear diseases⁹¹.

Kalcioglu et al.⁹² reported the risk of contracting acquired immune deficiency syndrome (AIDS) with cerumen and the other body fluids and secretions. No virus had been cultured from cerumen, although antibody had been found.

In a similar study⁹³ on Hepatitis B virus (HBV) infection, 27.5% of serum HBV DNA-positive patients were also positive for cerumen. According to this study, the presence of HBV in cerumen raises questions related to public health: all standard infection control precautions must be applied during otological examinations. Another study⁹⁴ stated that the cerumen and otorrhoea of chronic HBV patients have a low risk of infectivity (positive HBe Ag, which implies that it is associated with the increased risk of disease progression and infectivity, was not detected in any of the cerumen samples).

Genetics and pathological associations of earwax

The cerumen locus, rs17822931, in the ABCC11 gene on chromosome 16, was assigned to the wet and dry cerumen phenotypes²⁸. Identification of the earwax locus could contribute to further anthropogenetic studies and physiological and pathological understanding of the apocrine gland development.

Inheritance seems to follow simple Mendelian rules. Thus, the allele encoding the wet form (W) is dominant over the dry form (w), the genotype of wet cerumen being WW or Ww and the genotype of dry cerumen ww. The dry allele is predominant in Mongoloid populations of Asia and in American Indians, whereas the wet allele is found predominantly in Caucasian and African Americans^{20 94 95}. Dry cerumen also shows an "intermediate frequency" among populations from Eastern Europe, the Middle East, the Pacific Islands and South Africa^{28 96}.

The dimorphism in human normal cerumen was first studied almost exclusively in Japan, while European and American research workers have, hitherto, paid very little attention to this phenomenon: perhaps because the variation in cerumen is not so marked among Caucasians and Negroes as in the Mongolian race.

Unlike in humans, the cerumen of mammals, including monkeys, is generally of the wet type and their characteristic odours of apocrine sweat glands undoubtedly play a significant role in attracting a partner for mating. The monomorphism in mammalian cerumen, therefore, seems to have been fixed as a result of natural selection, since animals with their characteristic odour are at an obvious advantage in mating. A question may arise as to whether or not such a selective mechanism, as in mammals, could occur also in man⁹⁷.

According to Matsunaga⁹⁷, the usual type of cerumen among Japanese is grey, brittle and dry in nature and is commonly called "rice-bran ear-wax", in Japan, because it looks like a particle of rice-bran. The colour of cerumen of this type varies from light-grey to brownish-grey, and when accumulated in the external ear canal, for a long period, a thin slice of cerumen of fairly large size will often be formed. The other type of cerumen, which is less common in Japan, is brown, sticky and wet in nature; because it looks like honey, this type of cerumen is sometimes called "honey ear-wax", or "oily ear-wax". The colour may be darkened when exposed to air for a long time. These two types were then referred to simply as wet and dry types, respectively. The distinction between the two types is usually sharp, so that diagnosis can easily be made by inspection of the external ear canal if no pathologic complication is involved. The intermediate type which can be classified neither as wet nor dry, occurs at a rate of only about 0.5% among healthy Japanese^{28 96}.

The secretory function of the ceruminous glands is apparently dependent, to some extent, upon age, probably due to a hormonal effect, but the two types of cerumen are significantly manifested soon after birth, and they do not seem to be subject usually to any particular change in nature throughout life. Most individuals with wet cerumen develop axillary odour at puberty⁵².

It is generally held that the difference in the nature of wet and dry cerumen is to be attributed to the difference in the secretory products of the ceruminous glands. The morphological structure of the ceruminous glands is similar to that of the axillary glands⁹⁹.

Nagashima observed that there were abundant lipid droplets and pigment granules in the cytoplasm of the secretory cells in individuals with wet cerumen, while in those with dry cerumen, these cytoplasmic components were very few. The striated cuticular borders of the secretory cells were found in nearly every cell in subjects with wet cerumen, but in those with dry cerumen, they were found only in few secretory cells¹⁰⁰.

There are several differences between adult and paediatric cerumens: paediatric cerumen is much more moist than that in adults and it requires less hydration for cell lysis than in adults. Moreover, the bolus of cerumen may be smaller in children than in adults, therefore, it is easier to distinguish impacted wax in children than in adults. Finally, the cerumen bolus in adults might be denser, probably because cerumen has been present in the ear for longer and might be drier (sometimes adults might compact their wax with cotton buds). Thus, strategies to remove cerumen might differ in efficacy depending on age.

The cerumen single nucleotide polymorphism is the first example of DNA polymorphism determining a visible genetic trait¹⁰².

The development of multidrug resistance to cancer chemotherapy is a major obstacle in the effective treatment of

human malignancies, and, in this development, it has been established that membrane proteins, in particular multidrug resistance protein (MRP), 9 of which have been found in human genome, play important roles. MRP8 is a cyclic nucleotide efflux pump able to transport a variable range of lipophilic anions. A single nucleotide polymorphism in MRP8 (538G -> A) is responsible for the cerumen phenotype in man. The AA genotype is associated with the dry earwax phenotype in man, and GA and GG, with the wet type.

Moreover, cerumen genotype is related to apocrine colostrum secretions: the frequency of women without colostrum, among dry-type women, was found to be significantly higher than that among wet-type women, and the measurable colostrum volume, in dry-type women, was significantly smaller than in wet-type women ¹⁰³.

Earwax may reflect local and systemic disease.

Skin disorders are associated with changes in the cerumen. *Tinea versicolor* infection of the outer ear is more common in subjects with wet cerumen ¹⁰⁴. Psoriasis can occasionally cause an increase in waxy material in the ear ¹⁰⁵. In cystic fibrosis, there are lower concentrations of most electrolytes and less water, which considerably reduces the amount of cerumen and makes it very dry ¹⁰⁶. Many haemodialysis patients complain of dry skin and pruritus, possibly due to decreased function of the sebaceous glands. It is, therefore, surprising that the cerumen does not become drier in the majority of haemodialysis patients ¹⁰⁷. Patients with alkaptonuria have dark brown or black cerumen from an early age, along with other changes in pigment ¹⁰⁸. Parkinsonian patients, who often have greasy, seborrhoeic skin, may produce excess wax which blocks one or both ears ¹⁰⁹.

Matsunaga ⁹⁷ suggested that the two cerumen types differ in lipid metabolism and that, "an association between earwax types and some internal diseases, such as arteriosclerosis" should be sought. Subsequently, such an association between wet cerumen and arteriosclerosis, without hypertension, was briefly reported ^{110 111}. In those studies, the Authors did not comment on the barely significant decrease of hypertensive arteriosclerosis and heart disease with wet cerumen. In an unstated number of observations, they found no relationship between cerumen type and serum cholesterol. It is conventional, in studies of disease association, to treat the first claim with due suspicion. At this point, the relevance of cerumen types to lipid metabolism and arteriosclerosis can be neither asserted nor rejected ¹¹².

In a Lithuanian population, the interrelation was recently investigated of genetic dimorphism of earwax and the level of apolipoproteins: the ratio apoB/apoA-1 proved to be higher in the donors with wet earwax than in those with dry wax, but the lack of differences in the concentrations of the two alleles, between the patients with coronary artery atherosclerosis and the control population, indicated

that the genetic characters, under study, exerted no marked change in the incidence of atherogenesis ¹¹³.

The cerumen type correlates also with the risk of breast cancer. There may be many factors - genetic, cultural, or non-specific - that influence the risk of breast cancer. Petrakis, in 1977, postulated that both protection and risk are due to differences in the levels of metabolic and secretory activity of the breast ¹¹⁴. Chinese and Japanese women with dry-type cerumen had a lower percentage of successful aspirations than those with the wet type, thus suggesting that genetic factors may be associated with breast fluid secretion in non-lactating women ¹¹⁵. Women with the dry cerumen genotype (common among Asians and rare among whites) have lower levels of secretory activity in the epithelial cells that line the breast ducts than women with the wet cerumen genotype, and, moreover, a statistically significant greater proportion of pre-menopausal white women with the wet cerumen phenotype, compared to women with the dry cerumen type, were found to have epithelial dysplasia ^{116 117}.

An association between earwax impaction and nasal polyposis was recently reported ¹¹⁸.

Techniques used in removal of earwax impaction

a) Ear syringing

The removal of earwax has been practised since the ancient Egyptians syringed suppurating ears with olive oil, frankincense, and salt ¹¹⁹.

All non-otorhinolaryngologist health care professionals, before attempting to remove earwax impaction, should gain appropriate technical knowledge.

Irrigation or ear syringing may be attempted alone or following cerumenolytic pretreatment. Ear syringing is often an effective measure for removing simple wax. This should be performed only by experienced doctors. The water finds a passage past the wax, rebounds off the drum and pushes the wax outwards. Hard wax may require the use of drops before syringing. Ideally, the wax is initially loosened with the aid of cerumenolytic treatment. Ear syringes are inexpensive and readily available, however, some can be slow, poorly balanced, or cause minor ear trauma ^{120 121}. Oral jet irrigators are fast, portable, and inexpensive; nonetheless, they have been associated with some trauma, including tympanic membrane perforation. When a dental irrigating device is used for ear irrigation, however, a soft non-obstructive tip and the lowest irrigating pressure setting have always to be used.

A 20- to 30-cc syringe should be used for a child, with slow, gentle pressure. For an adult, a 50- to 60-cc syringe may be used. It is also possible to improvise an irrigation system using a 20- to 30-cc syringe with either a plastic catheter from a butterfly needle (being careful to remove the needle and wings) or an 18-gauge plastic intravenous catheter ^{119 120}.

Manual irrigation, performed using a 100- to 150- cc syringe, typically made of metal or glass, is the method most commonly employed in otorhinolaryngological practice. The wider extremity of a variably shaped truncate cone metal tip is then connected to this syringe, while the narrow extremity has to be carefully inserted into the external auditory meatus for ear irrigation.

Fluency of the syringe is very important because a metal plunger flows in a larger cylindrical tube: calcium accumulations may reduce the fluency with the risk of sudden pressure variations and creation of a sometimes potentially violent water jet interfering with hearing. The use of a frontal light considerably improves ear syringing, because it allows the operator to better estimate insertion of the syringe tip into the external auditory meatus and also its movements in order to achieve the best possible angulation needed for ear syringing.

Irrigation should be performed at body temperature to avoid a caloric-reflex response. Sterile irrigation fluid is not required. Peroxide added to the irrigation fluid may improve the chances of successful cerumen removal¹²². Gentle traction should be placed upward and backward, on the external ear, to help straighten the external auditory canal. The water should be instilled gently and the canal should be checked intermittently for clearance of the cerumen.

An experienced practitioner should always examine the ear for complications after cerumen removal. Erythema of the canal is common following cerumen removal. It is difficult to ascertain whether the cerumen or the instrumentation (or both) have caused erythema. It is important to assess the degree of inflammation and intervene accordingly. Erythema will generally resolve without any specific treatment. With any superficial excoriation, it is common practice to use drops of an antibiotic for 3 to 5

days to prevent infection from developing. In the event of tympanic membrane perforation occurring after irrigation, the patient should be referred to an otolaryngology specialist. With the possible exception of the severely immuno-compromised patient, use of oral antibiotics is virtually never needed following cerumen removal.

Ear canal irrigation is contraindicated in the event of a known or suspected tympanic membrane perforation (including a patent myringotomy tube), monomeric or dimeric tympanic membrane (a thin, weak area of the membrane where one or two layers have healed after perforation), the presence of vegetable matter, such as a bean or a pea, the presence of a watch or hearing aid battery, evidence of a purulent exudate filling the canal. In addition, patients with a history of middle-ear disease, ear surgery, radiation therapy performed in the area, severe *otitis externa*, or vertigo should not undergo irrigation¹²¹.

Syringing is contraindicated in the presence of gross wax impaction in the deep ear canal or when tympanic membrane perforation cannot be excluded. Large osteomas may narrow the meatus to a chink so that wax accumulates and it is difficult to syringe.

The principal contraindications to ear syringing are outlined in Table I.

Syringing is by far the most common method for removing earwax; according to an English survey⁵⁴, it is used by 95% of general practitioners, despite the fact that only 19% of the general practitioners surveyed, always performed earwax removal: the other general practitioners routinely referred patients to their practice nurse. However, nurses, typically, receive no instruction regarding syringing.

According to another study, manual earwax syringing is better accepted if performed by nursing staff¹²⁴. Wilson and Roeser¹²⁵ suggested that management of earwax im-

Table I. Clinical situations in which ear irrigation has to be avoided.

-
1. Patient has experienced complications following this procedure in the past
 2. Patient has a history of a middle ear infection in the last 6 weeks
 3. Patient has undergone ear surgery (apart from grommets that have extruded at least 18 months previously and the patient has been discharged from the ENT Department)
 4. Patient has a perforation or a history of a mucous discharge in the last year
 5. Patient presents monomeric or dimeric tympanic membrane (a thin, weak area of the membrane where one or two layers have healed after perforation)
 6. Patient has a cleft palate (repaired or not)
 7. In the presence of acute otitis externa; oedematous ear canal combined with pain and tenderness of the pinna; evidence of purulent exudate filling the canal
 8. Patient presents a vegetable matter such as a bean or a pea
 9. Patient presents a watch or hearing aid battery
 10. Patient had a history of radiation therapy to the area
 11. Patient complains of vertigo
 12. Patient has external ear dermatosis or keratosis obturans
-

paction should be within the scope of audiologists' practice. The danger of perforating a normal eardrum is what worries many of those who do not advocate delegating the syringing of ears to non-medical personnel. Training the health staff, in the proper procedures, could further reduce the risk of perforation⁶¹. Regardless of this risk, three points are very important: the syringe inclination, the pressure and the fluency of the irrigation flow, in order to avoid lack of homogeneity and a violent impact on the tympanic membrane.

Manual earwax syringing is a relatively safe procedure; it is easy to learn and may offer, if carefully performed, gratifying results¹²⁶. Motor-driven syringe pumps, which can generate high pressures, are potentially dangerous and should not be used¹²⁷.

Modern electronic irrigators (aural or oral jet), possibly equipped with controlled pressure systems could be used.

b) Cerumenolytic Agents

Softening earwax, with the specific intention of facilitating removal, dates back to the 18th Century¹²⁸. Since then, a large number of drugs, to loosen impacted cerumen, have been routinely used in general practice and as over-the-counter medications. Historical remedies include the injecton of goat's urine and gall and the instillation of steam¹²⁹. As with irrigation, cerumenolytics should be avoided in patients with a suspected breach of the tympanic membrane following previous surgery, insertion of myringotomy tubes, or tympanic membrane perforation. Agents, currently in use or under evaluation, include various formulations of oleic acid polypeptide complex, triethanolamine polypeptide, carbamide peroxide, olive oil, mineral oil, sodium bicarbonate, acetic acid, and docusate sodium. There are three types of cerumen-softening preparations: water-based, oil-based, and non-water-based/non-oil-based. Water-based and non-water-based/non-oil-based agents increase cerumen miscibility, whereas oil-based preparations lubricate the wax^{130 131}. Softeners (including oils and aqueous preparations) are often sufficient to treat mild cases of impacted cerumen, as well as reducing the need for surgical removal in more severe cases. These have two main actions: to soften wax prior to syringing or to disintegrate the wax thus avoiding syringing.

In numerous countries, including also the United Kingdom, most general practitioners prescribe (olive) oil as a ceruminolytic agent for persistent earwax⁵⁴. Interestingly, water has been shown *in vitro* to disperse wax better than a variety of commercial oils. In some of these studies, water – which was originally intended as a control substance – surprisingly, proved to be one of the fastest working and most effective agents^{132 133}.

One study showed that water quickly and efficiently dispersed earwax, not only *in vitro* but also in daily practice in affected patients. The alternative strategy using water

yielded similar results to the strategy of instilling oil, for three days, and returning to the practice afterwards¹³⁴.

A recent Cochrane Database Systematic Review¹³⁵ concluded that trials have been heterogeneous and generally of poor or moderate quality, thus making it difficult to offer any definitive recommendations on the effectiveness of cerumenolytics for the removal of symptomatic earwax. Using drops, of any kind, appears to be better than no treatment at all, but it is uncertain whether one type of drops is any better than another. Future trials should aim to be of high methodological quality, on large sample sizes, comparing both oil-based and water-based solvents with placebo, no treatment or both.

Recently, a new cerumenolytic agent was proposed, based on water extract of Lapacho (*Tabebuia Avellanedae*), that promises interesting results on clearing cerumen impaction. β -lapachone presents antitumour, anti-inflammatory, and anti-neoplastic effects, at different concentrations and conditions, with positive effects on wound healing¹³⁶.

The anti-tumoural efficacy of this compound completed Phase I studies and it is now in numerous Phase II studies for anti-tumoural activity against cancer of the pancreas and head-neck cancer and against leiomyosarcoma.

A prospective study was presented at the Annual Meeting of the "Società Italiana di Otorinolaringoiatria e Patologia Cervico-Facciale", held in Turin, in 2008¹³⁷. The Authors tested a new fast aqueous ceruminolytic agent, based on lapacho (*Tabebuia Avellanedae*), not presenting any chemical solvents.

A total of 300 outpatients with one or both ears totally impacted with wax were recruited and treated with ear irrigation after instillation of drops in the ears.

These participants had been randomly divided into 3 groups to receive: 1) 2 drops of the agent, 4 times a day, for 5 days, before irrigation of the ear; 2) 4 drops of the agent, 8 times a day, for 2 days before irrigation of the ear; or 3) 10 drops of the agent, followed by other 10 drops after 15 seconds, one hour before irrigation of the ear.

Ear irrigation was carried out using an ear irrigator with a controlled pressure system. After ear irrigation, complete clearance of the ear canals was achieved in 100% of the patients in each of the three groups, with minimum discomfort being referred by the patients in the third group.

Instilling this new agent did not result in discomfort, transient hearing loss, dizziness, or skin irritation, in any of the participants, in the three groups of patients.

Due to its anti-microbial activity this agent has 3 outcomes against earwax impaction: prevention, treatment and anti-infectious effect.

Further investigations are, however, needed for definitive validation of this medical device for earwax impaction treatment.

c) Suctioning and other mechanical removal

ENT surgeons will often remove wax and keratin with the aid of a microscope. Wax curettes and gentle suction ear toilet is generally well tolerated and safe. Patients with narrow stenotic ear canals or other ear diseases, such as tympanic membrane perforation, should be reviewed by a specialist for aural toilet and further management.

When contraindications, such as *otitis externa*, current or past history of a perforated-tympanic membrane, previous ear surgery are present, then suction or curettage, under direct vision, is probably the safest method to use. Both of these methods require special care, experience and expertise and are, therefore, probably best performed by the ENT specialist. Using a curette, or forceps, or a Jobson Horne probe, allows a clinician to view the procedure and the lack of water decreases the risk of infection.

Manual removal does not expose the ear canal to moisture and, therefore, may lessen the risk of infection. Other advantages of manual removal are that it is often quicker and allows direct visualization of the procedure via a hand-held monocular otoscope or floor- or wall-mounted binocular microscope. The use of a binocular microscope will improve depth perception and may enhance comfort and safety, but availability is generally limited to otolaryngology offices.

A randomized clinical trial¹³⁸ comparing endoscopic and microscopic wax removal, stated that endoscopic dewaxing is less uncomfortable for the patients as well as less painful, but that it is easier to perform and took less time than microscopic dewaxing.

One study revealed that microsuction is a noisy procedure which is uncomfortable for some patients. Microsuction generated a broadband sound with a peak at 2 kHz. Sound levels peaked at over 120 dB(A) in two patients.

The Author found no evidence of any shift in audiometric thresholds following microsuction aural toilet. The Author suggested that it is safe, but that the use of non-suction methods, may, at times, be preferable to improve patient comfort¹³⁹.

d) Ear candles

An estimated one third of the United States population chooses to undergo such treatments¹⁴⁰. Ear candles are a product promoted by alternative health practitioners primarily for cerumen removal. Their use requires introducing a hollow candle into the external auditory canal and lighting the opposite end. The lighted candle is considered to create a vacuum which draws the cerumen and other impurities from the external auditory canal. A dark brown waxy substance held to be cerumen, plus external auditory canal debris, is left in the stub of the candle.

One investigation demonstrated that ear candles do not generate any negative pressure and do not remove ceru-

men from the external auditory canal. Their use may also result in a number of complications. Physicians need to be aware of the dangers associated with ear candle use and counsel their patients accordingly^{141 142}.

Obstruction of the ear canal with paraffin and associated hearing loss and perforation of the tympanic membrane have been reported¹⁴³. Ear candling seems to be popular and is heavily advertised with claims that could appear to be scientific to lay people. However, the claimed mechanism of action has not been verified, no positive clinical effect has been reliably recorded, and it is associated with considerable risks. No evidence suggests that ear candling is an effective treatment for any condition¹⁴³. Based on its inefficiency and potential dangerousness, the FDA (Food and Drug Administration) does not recommend ear candles¹.

Clinical practice guidelines on cerumen impaction by the American Academy of Otolaryngology-Head and Neck Surgery Foundation

The American Academy of Otolaryngology - Head and Neck Surgery Foundation recently proposed clinical practice guidelines on cerumen impaction¹ aimed at identifying those subjects at increased risk of cerumen impaction and those who should be treated, appropriate interventions, and preventive measures. Recommendations fall into one of three categories: strong recommendation, recommendation, or option, using the grading system of A through D, depending upon the level of evidence found. The guidelines do not cover certain patient conditions that may be associated with a higher risk of complications when cerumen impaction interventions are employed (e.g. recurrent *otitis externa*, dermatologic conditions of the external canal, *keratosis obturans*, previous radiation of the affected ear, previous tympanoplasty or myringoplasty, or mastoidectomy).

The only strong recommendation is the need for intervention if cerumen impaction is symptomatic or interferes with adequate assessment of the ear. There are many recommendations: 1) assess the symptomatic wax impactions; 2) assess the conditions that may modify or change the approach to treatment (non-intact tympanic membrane, ear canal stenosis, exostoses, diabetes mellitus, immuno-compromised state, or anti-coagulant therapy); 3) regularly check the ears of patients with hearing aids for the presence of cerumen impaction; 4) treat cerumen impaction with cerumenolytic agents, irrigation, manual removal, or a combination of these procedures, avoiding ear candling; and, finally, 5) document the results of the treatment(s) used for cerumen impaction: if the impaction is only partially resolved, additional treatment to remedy

the situation should be employed and if a full or partial impaction remains and the symptoms for which cerumen impaction removal was attempted continue, consider another diagnosis.

Moreover, there are various options: a) if the cerumen impaction is asymptomatic and does not interfere with adequate assessment of the ear, no intervention is probably necessary; b) need for intervention in special populations (patients unable to adequately express cerumen impaction symptoms); c) cerumenolytic agents can be used in the management of cerumen impaction; d) irrigation in the management of cerumen impaction can be achieved with a large syringe or an electronic irrigator; e) with proper equipment, manual removal allows direct visualization of the canal and tympanic membrane during the process; f) an option, for prevention, is to counsel patients on control measures to prevent excessive cerumen build-up or impaction.

Earwax removal complications

During the manoeuvres employed for earwax impaction removal, regardless of the attention and caution adopted, a lot of complications could occur, which are briefly outlined in Table II.

Complications of ear syringing include failure to remove wax, perforation of the tympanic membrane, laceration of the ear canal skin and secondary *otitis externa*, bleeding (generally mild and self-limiting), coughing due to vagal reflex (eardrum innervated by the auricular branch of the vagus nerve, as mentioned above), syncope and dizziness with nystagmus (irrigator employed too cold or too hot). Residual water can also promote infection³⁹. It has been estimated that major complications occur in 1 in 1,000 ears syringed¹⁴⁴. Indeed, ear syringing can be associated with several potentially serious complications. In the general practitioner survey, by Sharp et al.⁵⁴, 38% of those that responded reported experiencing a total of 127 complications associated with cerumen removal (Table II). The Author reported a case of temporal lobe abscess as a complication of ear syringing.

It would appear that between 10-20% of traumatic tympanic membrane perforations arise from mechanical dam-

age and “very frequently by unprofessional attempts” to clean the meatus¹²⁹.

The risk of the tympanic membrane rupturing during ear irrigation depends on the anatomical and functional integrity of the eardrum. Normal tympanic membranes in cadavers rupture at an over-pressure of between 0.5 and 2.0 atmospheres. The difference highlights the wide variation, in membrane strength, between individuals. For example, atrophic tympanic membranes can rupture at a much lower overpressure, between 0.3 and 0.8 atmospheres. Moreover, the tensile strength of the membrane decreases with advancing age¹⁴⁵. In another study¹⁴⁶, the highest pressures were obtained in normal- or wide-dimension external auditory meatus when a metal syringe was used. With this device, the median maximum over-pressure was 240 mmHg (range 200-300 mmHg). Compared with the lowest over-pressures which can rupture tympanic membranes, the pressures measured in this study were not sufficient to rupture normal tympanic membranes but were sufficient to rupture atrophic tympanic membranes with the lowest tensile strength.

Tympanic membrane rupture can be associated with considerable inner ear damage. In three case reports, for instance, oral jet irrigation perforated the eardrum, led to ossicular disruption, round and oval window fistulae and subluxation of the stapedial footplate. Furthermore, in 25 fresh cadavers, oral jet irrigation ruptured the tympanic membrane in 6% of cases. A third of these occurred at full power. Two-thirds occurred when the jet irrigation was a third of full power¹⁴⁷. The cadaveric investigations could be less reliable, because of the lack of functional efficiency of the *tensor tympani* and stapes muscles.

The rupture pressures of the tympanic membrane, Reissner’s membrane, the round window membrane, and the annular ligament have all been measured in cadaver ears¹⁴⁸. The rupture pressure of the annular ligament equals the rupture force to the footplate divided by the area of the oval window.

The mean rupture pressures are 0.39 atm for the tympanic membrane, 0.047 atm for Reissner’s membrane, > 2 atm for the round window membrane, and 29.4 atm for the annular ligament. This last pressure corresponds to a 0.68 Kg force applied to the footplate. The ruptures of the tympanic membrane appeared, without exception, as small tears in the *pars flaccida*.

Some authors suggested⁴⁵ that patients with diabetes and immunocompromised subjects should not undergo irrigation for impacted cerumen, based on the consideration that in 9 out of 24 patients (37.5%) with invasive external otitis media, infection emerged following removal of impacted cerumen by irrigation under pressure. Less common complications include facial paralysis and loss of balance due to destruction of the vestibular labyrinth¹⁴⁹.

Table II. Rate of each type of complication associated with cerumen removal in Sharp general practitioner survey: 38% of 289 that responded reported experiencing a total of 127 complications.

Type of complications	Complication rate
Failure of cerumen removal	29%
Otitis externa	17%
Eardrum perforation	15%
Damage to the external canal	12%
Pain, vertigo, otitis media, discovered perforation	Each accounted for fewer than 10%

Table III. Evaluation of ENT consultations at ENT Department of San Giovanni Bosco Hospital, Turin, Italy from 1st January to 31st December 2008.

Types of ENT consultations	No. ENT consultations	No. earwax treatments	Rate of earwax treatment %
Emergency	4,601	375	8.15
Routine outpatients	6,098	937	15.36
Routine inpatients	1,485	19	1.27
Territorial district	475	294	39.46
Total	12,695	1,625	12.80

Finally, a case history¹⁵⁰ supports the anecdotal evidence that severe audiovestibular loss can follow ear syringing to remove cerumen.

Italian National Health Care System and ENT consultations for earwax impaction: data collection at ASL TO2, San Giovanni Bosco Hospital, Turin

Medical documentation was examined of ENT consultations at the ENT Department of the San Giovanni Bosco Hospital, Turin, Italy, from 1st January to 31st December, 2008. Over this time period, 4,601 ENT emergency room consultations have been carried out in the Hospital by the ENT specialists of the Department, as well as 6,098 ENT routine consultations on outpatients referred by General Practitioners and 1,485 ENT consultations on in-patients referred from other Departments of our Hospital. Moreover, during the same period, 745 ENT consultations were performed, by the above-mentioned specialists, on outpatients evaluated in the districts of the territory in the San Giovanni Bosco Hospital area.

Among these consultations cerumen impaction treatment, respectively, accounted for 8.15% (375/4,601 consultations), 15.36% (937/6,098 consultations), 1.27% (19/1,485 consultations) and 39.46% (294/745 consultations) (Table III).

The age of patients, treated for earwax impaction, ranged between 5 and 82 years and differences between sexes were not significant (832 male, 793 female).

The total number of consultations by our ENT specialists, related to removal of earwax impaction, was 1,625 (12.80% of the total number of ENT consultations in the same timeframe).

Earwax impaction and workers

Impacted cerumen has important implications in industrial audiometry, since, as universally recognized, a variable amount of hearing improvement is correlated with earwax impaction and, in the industrial setting, the audiometric test is less easily achieved than in the clinical setting, as recently reported by Dobie¹⁵¹.

According to this Author, the need for otologic evaluation in the differential diagnosis of noise-induced hearing loss is not universally appreciated; otolaryngologists should enlighten their medical and non-medical colleagues in this respect.

Earwax impaction assumes critical importance for medico-legal implications in the evaluation of noise-induced hearing loss in industrial audiometry.

According to Italian legislation¹⁵², occupational noise is potentially dangerous up to 80 dB(A), Lex 8 h, with progressively more stringent requirements from the lower band of action between 80-85 dB(A), Lex, 8 h, to follow, to the top of action between 85-87 dB(A), Lex, 8 h. The permitted level of exposure is 85 dB (A), which is above the mandatory use of hearing protectors; the limit value is expressed as 87 dB(A) Lex 8 h.

For workers using ear protectors, impacted cerumen represents a very troublesome problem.

Moreover, many otolaryngologists, audiologists and workers' physicians (industrial competent physician, doctors of the Public Services of control over work, etc.) for the evaluation of occupational hearing loss employ, in Italy, the Albera-Beatrice criterion^{153, 154}, in which a minimum value of hearing deficiency can affect the legal obligation to report to the authorities for occupational hearing loss.

The question of whether cerumen removal is able to improve hearing was evaluated by Williams¹⁵⁵ with a mini-review. Randomized controlled trials and non-randomized comparative studies have been assessed on the demonstration of an objective measure of hearing before and after ear irrigation.

Four studies were selected for critical appraisal. Only one study, a randomized controlled double-blind trial, measured outcome by number of individuals with hearing improved to a clinically significant level (33%). The results of this trial may be overestimated, and, therefore, more evidence is required to resolve the issue.

Two studies, performed before and after ear syringing, showed hearing loss of 5 dB (or up to 10 dB) due to earwax impaction^{54 156}.

Repeated insertion of a hearing aid mould may also cause wax impaction in the external auditory canal. Furthermore, wax may occlude the mould of the hearing aid. This leads to a reduction in effectiveness of the prosthesis and can exacerbate this feedback¹⁵⁷. Almost one third of hearing

Table IV. Effect of cerumen on aural acuity (hearing thresholds measured at 0.25, 0.5, 1 and 2 kHz before and after ear impaction removal) in 44 industrial workers (65 ears).

	Workers	Male	Female
Numbers of workers recruited	461	295	166
Total bilateral impaction	21	12	9
Total monolateral impaction	23	15	8
Total number of totally impacted ears	65	39	26
Hearing thresholds improvement ≤ 10 db	5	3	2
Hearing thresholds improvement between 5-10 db	4	3	1
Hearing thresholds improvement between 10-15 db	16	9	7
Hearing thresholds improvement between 15-20 db	27	17	10
Hearing thresholds improvement between 20-25 db	13	7	6

aids are malfunctioning solely because of wax occluding the mould¹⁵⁸. In the Sharp survey⁵⁴, the average increase in the hearing threshold, after removal of cerumen in 21 outpatients, was 5.45 dB at 250 and 500 Hz and 1, 2, and 4 kHz. Most of these patients had a medium to severe sensorineural hearing loss on high frequency.

In a recent study, impacted cerumen caused a significant conductive hearing loss, as demonstrated by an improvement of 11 to 20 dB in hearing in 50.5% of patients and an improvement of 21 to 30 dB in 29.4% of patients following removal of cerumen. Moreover, the average air-bone gap before and after cerumen removal, in all 109 ears, was 21.19 dB⁶⁰.

Similar results were obtained by us in a sample of 461 noise-exposed metal workers (295 male, 166 female), in whom we assessed the incidence of complete cerumen impaction and its influence on auditory capacity. Of the 461 workers, aged between 21 and 59 years, 21 (12 male, 9 female) had complete bilateral cerumen blockage and 23 (15 male, 8 female) had complete unilateral blockage, for a total of 44 subjects and 65 ears involved. Excluded were subjects with partial impaction of earwax.

The recruited subjects underwent pure-tone audiometry, at frequencies ranging from 250 Hz to 8 kHz, in a clinical setting. The cerumen was removed in a clinical setting using ear syringing without the use of ceruminolytic agents and ears were then re-examined following removal of the wax, and pure-tone audiometry was repeated. The effect of cerumen on hearing ability was tested at 250, 500, 1,000, and 2,000 Hz. Completely impacted cerumen led to a significant degree of conductive hearing loss, as demonstrated by an improvement in hearing of between 5 and 20 dB (Table IV). No aspect of cerumen occlusion was significantly associated with variables such as age, sex, or side of disorder.

Discussion

There are substantial differences between Italy, United States and other nations regarding the treatment of symp-

tomatic cerumen impaction. These differences can be summarized as follows:

- absence in Italy of epidemiological data on such a frequent and little studied disease;
- low tendency among family doctors, in Italy, to proceed with, or to delegate treatment to the nursing staff, if required. In fact, in Italy, the competence to deal with impacted cerumen belongs almost exclusively to the ENT specialist.

The reasons for the apparent lack of interest among Italian scientists would appear to be a view convinced of the banality of this condition, despite the fact that many findings described in the literature confirm that this is a completely unfounded allegation.

The exposed data reported herein show that the ENT specialist is the reference point between health professionals for the diagnosis and treatment of earwax impaction. As previously highlighted by the Department of Otolaryngology at the San Giovanni Bosco Hospital in Turin (ASL TO2), the total incidence of visits for removal of earwax impaction accounts for approximately 40% of the specialist activity in the districts of the territorial area of the hospital.

The main factor to be considered in the difference between hospital and territory, as far as concerns the treatment of earwax impaction, is the tendency, among family physicians, to send the more severe pathological conditions to the hospital, leaving the less severe to the districts of the territory. The management of cerumen impaction, however, accounted for 8% of first aid activity with code 0 (almost all of the accesses) and for 15% of hospital outpatient routine, with few differences between sexes.

Clearly, management of this problem cannot be organized according to homogeneous rules and very different costs are involved depending upon the form of health care practiced. Direct management by the family doctor or their staff, used in the United States, focuses, of course, on managing earwax impaction at a lower cost and with greater speed.

Based upon the data from the international literature on the impact of earwax plugs, we could estimate, in the current Italian population of 59.6 million, that approximately 2-4 million people will be suffering from wax impaction. Patients at increased risk of producing excess wax or who require thorough cleaning of the external auditory canal, for various reasons, are primarily young children, the mentally disabled, the elderly, especially institutionalized patients, the long-term workers using hearing protectors against noise and the hearing-loss patients who use hearing aids.

Wax can hide underlying diseases of the skin of the external auditory canal or the membrane of the eardrum. In the case of a wax plug, a meticulous assessment of the external auditory canal should be performed only after removal of wax, which may unmask pre-existing dermatosis or breakage or other infectious and non-infectious diseases of the tympanic membrane.

Concerning the technique used in removal of impacted cerumen, it has been found that the technique most used is the classic ear syringing; great care should be taken with regard to the material of the syringe, preferring the steel tool to the perishable glass material and prone to occasional breakages during use. The instrument should be treated with great care, especially with elimination of calcium deposits in the plunger: these do not allow a jet fluid and may cause occasional sudden increases in pressure of the jet or changes in the directionality of the movements; both situations can lead to injuries to the skin of the auditory canals or to the tympanic membrane. In general, the syringing operation should be performed at the lowest possible pressure jet. In this regard, the use of earwax solvents is desirable, especially in the light of all those clinical conditions in which the heavily impacted cerumen appears (which is perceptible with otoscopes) or in those cases in which a particular weakness of the tympanic membrane can be assumed (children and elderly).

In all cases, the removal must always be as least traumatic as possible. The procedures for manual removal, making use of various instruments (hooks, vacuum cleaners, tweezers, etc.), should preferably be carried out with the assistance of a microscope, which makes the same manoeuvres easier and safer. The choice of instrument depends on the characteristics of the impacted cerumen and its place in the external auditory canal. In the case of complications, recognition and clinical management, on the part of the health professional is extremely important. One issue, not yet fully resolved, in Italy, is which are the professionals who can ensure the removal of the impacted earwax. Certainly, the ENT specialist and the otologist have the ideal professional competence but the fact that, in the United States, this is provided by the family doctors and nurses would suggest that the Italian family doctors should at least provide the correct diagnosis and then address the patient for the most appropriate management of earwax impaction. It would appear from the high rate of

patients seeking the emergency room and the highly specialized infirmary, as has emerged from the analysis conducted on the area of the San Giovanni Bosco Hospital, Turin, demonstrates the poor management of the problem with an unjustified increase in costs for public health care administration.

Certainly earwax removal can give rise to complications (Table II) which suggest the need for care and caution. In particular, this issue could involve both family doctors and competent industrial physicians when diagnosing occasional earwax impactions in the periodic audiological monitoring procedures. In industrial medicine, the presence of earwax impaction can not lead to the use of PPE (Personal Protective Equipment) in the case of intra-aural inserts. The impacted wax may also create symptoms (for example, subjective vertigo) that may make some work very dangerous (e.g. movements on scaffolding or working near hazardous machinery, such as mechanical presses, etc.).

Finally, earwax conditions the detection of the audiometric threshold, especially on the low tones, undermining the morphological analysis of the audiogram for the purposes of assessment of suitability and for medico-legal purposes, for example in the procedures employed in reporting occupational disease or in understanding the time of onset and/or aggravation of a permanent hearing impairment in the presence of chronic professional acoustic trauma. In industrial audiology, interesting issues arise, related to the audiograms performed for the purpose of testing the health of the workers, which are very often made by non-medical professionals, whose legal responsibility does not allow them to manage earwax impaction. In addition, the competent industrial physicians, who are responsible for removing earwax impaction, often do not have the expertise or experience to do so.

Furthermore, the industrial setting often does not ensure the competent industrial physicians the equipment required and the ideal logistical conditions for the proper treatment of earwax impaction, making it necessary to send the patient to an ENT specialist for examinations and subsequent treatment.

Moreover, according to Italian law, if the earwax impaction is found by chance during periodical audiometry in the workplace, its removal can not be delegated to the National Health Care Service, but must be paid for by the employer¹⁵². It thus follows that audiometry must be postponed and the subject addressed to the most appropriate procedure for earwax removal, possibly preceded by repeated treatments with cerumenolytic agents. Only after cerumen removal can the worker undergo audiometry. As already mentioned, an audiogram performed in the presence of earwax impaction does not correspond to the appropriateness required by Italian legislation and, consequently, affects the assessment of work suitability. In conclusion, this review aims to offer a better under-

standing both of clinical and health care problems related to earwax impaction and the consequences on public health in the Italian scientific landscape.

Further investigations and research are, however, needed to solve the many unanswered questions regarding this very frequent pathological condition.

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