The safety and effectiveness of different methods of earwax removal: a systematic review and economic evaluation


CRD summary
This well-conducted review found that, although softeners appeared beneficial, the specific softeners that were most effective remained uncertain due to limited good-quality evidence. There was equal evidence on the effectiveness of methods of irrigation or mechanical removal. The authors’ conclusions reflect the evidence and their recommendation for further research seems appropriate.

Authors' objectives
To assess the clinical and cost effectiveness of interventions currently available for the removal and/or softening of earwax.

Searching
MEDLINE, EMBASE, the Cochrane Library, Science Citation Index, Conference Proceedings Citation Index, BIOSIS Previews, DARE, HTA, NHS EED, CINAHL, National Research Register (historical), UK Clinical Research Network, Current Controlled Trials and ClinicalTrials.gov were searched from inception to December 2008. No language or publication status restrictions were applied. Search terms were reported. Grey literature and primary care conference proceedings (from 2004) were scanned. Experts in the field were contacted for further studies. Reference lists of relevant papers were also examined.

Study selection
Randomised controlled trials (RCTs) and controlled clinical trials (CCTs) of adults or children with a build-up of earwax requiring removal that investigated all methods of removal or softening (including drops, irrigation, mechanical removal other than syringing, other methods, or a combination of methods) were eligible for inclusion. Trials had to report at least one of the following outcomes: measures of hearing, adequacy of clearance of wax, quality of life, time to recurrence or further treatment, adverse events or cost-effectiveness. Cohort studies were eligible for inclusion for adverse event assessment.

Included trials were of adults and children. Trials were undertaken in primary care (including emergency care), secondary care, other settings, or were studies of self-care. A wide range of interventions were used; in some trials, the intention was to use a softening agent alone; in other trials, a softening agent was always used and irrigation was the intervention. Sixteen different softeners (with or without irrigation) were used in various different comparisons. The outcomes reported in the controlled trials measured the degree of occlusion, ease of wax removal, participant satisfaction, recurrence of earwax, and consistency of earwax.

Two reviewers independently assessed studies for inclusion and disagreements were resolved by consensus or arbitration.

Assessment of study quality
Methodological quality was assessed by one reviewer and checked by another using criteria recommended by the CRD (similarity at baseline, inclusion criteria, blinding, statistical reporting, intention-to-treat analysis, withdrawals and drop-outs were assessed for RCTs and CCTs; additionally, randomisation and allocation concealment were assessed for RCTs only). Discrepancies were resolved through discussion or referral to a third reviewer.

Data extraction
Data were extracted by one reviewer and checked by another.

Methods of synthesis
The trials were synthesised narratively and presented by setting (primary care, secondary care, self care, and other care settings), and by immediate or delayed follow-up. Data were also presented for softeners or softeners with irrigation,
and by patient population (ie. adults, children, or mixed populations).

**Results of the review**

Twenty-six trials (with 64 treatment arms) were included in the review (n=2,291 participants; trial sizes ranged from 36 to 237). Overall, twenty-two were RCTs and four were CCTs. Follow-up was immediate in most trials, but could range up to 14 days, with one trial following up at 12 months.

Of the fourteen trials conducted in a primary care setting, 12 were RCTs and two were CCTs; all were deemed poor quality.

Of the eight trials conducted in secondary care, seven were RCTs and one was a CCT; all were deemed poor quality.

There were two RCTs of self care; one was reasonable quality and one was poor quality.

One RCT and one CCT were conducted in other care settings; both were deemed poor quality;

**Results for clearance of wax**: Cerumol, sodium bicarbonate, olive oil and water were more effective than no treatment for the removal of ear wax. Triethanolamine polypeptide was better than olive oil in the volume of water used in syringing. Wet irrigation was more effective than dry irrigation for ease of wax removal; sodium bicarbonate drops followed by irrigation by nurse was more effective than sodium bicarbonate drops followed by self-irrigation; softening with triethanolamine polypeptide and self-irrigation was more effective than self-irrigation only; and endoscopic de-waxing was superior to microscopic de-waxing.

**Results assessing ease of subsequent irrigation**: Cerumol was superior to dioctyl, triethanolamine polypeptide and sodium bicarbonate plus Audax were better than Earex. Exterol and otocerol were more effective than cerumol in reducing the number of patients requiring irrigation after treatment with softeners.

Adverse events appeared to be minor and limited in extent. The main adverse events reported were minor pain, discomfort and irritation/itching of the ear. These were mainly related to irrigation. No serious adverse events were reported.

Patient satisfaction was also reported in the review and a separate review of adverse events was presented in the review.

**Cost information**

The exploratory economic model found that softeners followed by self-irrigation (£24,433 per quality-adjusted life-year (QALY)) were more likely to be cost-effective than softeners followed by irrigation at primary care (£32,130 per QALY) compared with no treatment. When the two active treatments were compared, the additional gain (associated with softeners followed by irrigation at primary care over softeners followed by self-irrigation) was at a cost of £340,000 per QALY. When compared over a lifetime horizon with no treatment, the incremental cost-effectiveness ratios for softeners followed by self-irrigation was £24,450 per QALY and for softeners followed by irrigation at primary care was £32,136 per QALY.

**Authors’ conclusions**

Although softeners appeared to be beneficial, the specific softeners that were most effective remained uncertain due to limited good-quality evidence. Evidence on the effectiveness of methods of irrigation or mechanical removal was equivocal.

**CRD commentary**

The review question was well defined and supported by inclusion criteria for participants, interventions, study design and outcomes. Published and unpublished studies were sought from a wide range of sources in any language, which reduced the possibility of publication and language bias. Two reviewers were involved in all stages of the review process, which minimised the possibility of reviewer error and bias.

Trial quality (which was generally poor) was assessed using appropriate criteria and taken into consideration in the analysis. Due to heterogeneity of participants, outcomes, intervention and quality of trials, a narrative synthesis appeared appropriate. However, the synthesis of data was limited and findings were often based on one trial. The
authors acknowledged the lack of, or limited reporting of data and methods, which affected the generalisability of the findings. They also noted the wide variation in publication dates (i.e. 1950 to 2007).

The authors’ conclusions reflect the limited evidence and the recommendation for further research seems appropriate.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that further research is required to identify the most effective method for the removal of earwax for different groups of people, focusing on elements where uncertainty remains and that have the potential to impact on patients, the provision of the service and value for money.

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**Other publications of related interest**


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