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

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Executive summary

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Executive summary

Background

Earwax is a normal secretion, the purpose of which is generally thought to be to protect the ear from particles entering the deeper part of the ear. Normally, earwax moves these particles to the outer ear. Sometimes this process fails and significant build-up of earwax can occur. This can affect anyone, but appears to be more prevalent in the elderly, children and those with learning disabilities. Estimates suggest anything from 700,000 to 2 million adults in England and Wales may have a build-up of earwax. While not all of these people will consult with a health-care practitioner, it is believed to be a common reason for attendance in primary care. Current practice for the removal of earwax varies. In general, a softening agent is usually recommended, leading up to irrigation of the ear if required. However, there are a variety of different agents for softening the earwax, and with no national guidelines on the removal of earwax many procedures are based on local custom and practice rather than a strong clinical evidence base. The relative safety and benefits of the different methods of removal are not known for certain.

Objectives

The objectives of this evidence synthesis were to conduct a systematic review of the evidence, assessing the clinical effectiveness and cost-effectiveness of the interventions that are currently available for softening and/or removing earwax in children or adults. To systematically search for, appraise and summarise clinical trial and observational evidence for the harms or adverse events (AEs) associated with interventions for softening or removing earwax. To construct an economic model for the UK to estimate the relative cost-effectiveness of those interventions that are considered to be clinically effective. To identify future cost-effective research in the management of earwax through a value of information analysis, specifying key elements in the design of future studies.

Methods

A systematic review of the evidence on the clinical effectiveness and cost-effectiveness and an economic evaluation were undertaken using a priori methods.

Data sources

Eleven electronic resources (including MEDLINE, EMBASE, CINAHL, BIOSIS, etc.) were searched from inception to November 2008. Bibliographies of related papers were assessed and experts were contacted to identify additional published and unpublished references. These were used for the systematic review and to inform the development and population of the economic model.

Study selection

Studies were included if they fulfilled the following criteria:

- *Interventions* All methods of earwax removal or softening, including drops, irrigation, other mechanical removal, other methods and combinations of these methods.
- *Participants* Adults or children presenting with build-up of earwax requiring removal.
- *Outcomes* Measures of hearing, adequacy of clearance of wax, quality of life, time to recurrence or further treatment, AEs and measures of cost-effectiveness.
- *Design* Randomised controlled trials (RCTs) and controlled clinical trials (CCTs) for clinical effectiveness, cohort studies for AEs and cost-effectiveness, and costing studies for cost-effectiveness.

Studies identified were assessed for inclusion through two stages, with titles and abstracts and full papers of retrieved studies assessed by two reviewers, with differences in decisions resolved through discussion or through recourse to a third reviewer.

Data extraction and quality assessment

Data were extracted by two reviewers using data extraction forms developed a priori, with any disagreements resolved through discussion or through recourse to a third reviewer. The methodological quality of the studies included in the systematic review of clinical effectiveness and cost-effectiveness was assessed using recognised quality assessment tools. The quality criteria used were applied by two reviewers, with any disagreements resolved through discussion or through recourse to a third reviewer.

Data synthesis

Studies were synthesised through a narrative review with full tabulation of the results of all included studies.

Economic model

The economic evaluation developed a deterministic decision tree model to evaluate three alternative options, specifically the use of softeners followed by irrigation in primary care, softeners followed by self-irrigation and a 'no treatment' option. It assumed a UK National Health Service (NHS) perspective, focused on an adult population aged 35–44 years with no contraindications to treatment and assessed outcomes over different time horizons (7 weeks to 45 years). Outcomes were assessed in terms of benefits to patients (i.e. successful removal of earwax and quality of life) and costs incurred, with costs presented in terms of a cost–utility analysis [cost per quality-adjusted life-year (QALY) and incremental cost-effectiveness ratio (ICER)].

Results

Clinical effectiveness

A total of 26 clinical trials conducted in primary care (14 studies), secondary care (8 studies) or other care settings (4 studies), met the inclusion criteria for the review. Of these studies, there were 22 RCTs and 4 CCTs. A range of interventions was used in the studies – some 16 different softeners with or without irrigation in various different comparisons were used. In addition to the wide range of interventions used, studies were diverse in terms of the participants and outcomes used, and also varied on timing of the intervention, duration of follow-up and methodological quality (in part a reflection of the age of many of the included studies), including use or not of any statistical analysis of their data.

Considering the studies that report statistical significance testing and ignoring any variations in methodological quality, results assessing clearance of wax show that: Cerumol, sodium bicarbonate, olive oil and water are all more effective than no treatment; triethanolamine polypeptide (TP) is better than olive oil; wet irrigation is better than dry irrigation; sodium bicarbonate drops followed by irrigation by nurse is more effective than sodium bicarbonate drops followed by self-irrigation; softening with TP and self-irrigation is more effective than self-irrigation only; and endoscopic de-waxing is better than microscopic de-waxing. Results assessing ease of subsequent irrigation as the outcome show that: Cerumol is better than dioctyl, TP and sodium bicarbonate and Audax are better than Earex. AEs appear to be minor and limited in extent, and mainly related to irrigation. No studies reported serious adverse events (SAEs). Minor pain, discomfort and irritation/itching of the ear were the main AEs.

Cost-effectiveness

The systematic review of cost-effectiveness did not identify any economic evaluations. The de novo economic model developed for this assessment found that softeners followed by self-irrigation were more likely to be cost-effective (£24,433 per QALY) than softeners followed by irrigation at primary care (£32,130 per QALY) when compared with no treatment. Comparison of the two active treatments showed that 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 to the 'no treatment' option, the ICERs for softeners followed by self-irrigation and of softeners followed by irrigation at primary care were £24,450 per QALY and £32,136 per QALY, respectively. Sensitivity and scenario analyses showed the results are fairly robust to changes in the cost of irrigation in primary care, although changes in the utility associated with loss of hearing may have some effect. However, caution should be taken in interpreting the results of the economic evaluation due to the paucity of evidence on the safety, benefits and costs of the different strategies. As a consequence, the results of the economic

evaluation should be regarded as exploratory and should not be used as a basis for changing policy and practice.

Conclusions

The systematic review of clinical effectiveness and cost-effectiveness found limited good-quality evidence, making it difficult to differentiate between the various methods for removing earwax in terms of clearing wax, improving quality of life and satisfaction, AEs or cost-effectiveness. Although it showed that softeners have an effect in clearing earwax in their own right and as precursors to irrigation, which specific softeners have an effect remains uncertain. Evidence on the effectiveness of methods of irrigation or mechanical removal was equivocal. The limited evidence on benefits and costs of methods of earwax removal meant that the economic evaluation was speculative and for illustration only. Its findings should not be used for policy decisions. As such, further research is required to improve the evidence base. A well conducted RCT incorporating an economic evaluation would appear to provide the most appropriate method to assess the different ways of providing the service (i.e. practice nurse provision in primary care versus self-care) as well as the effectiveness of the different methods of removal (i.e. softeners and mechanical removal). As part of such research it would be important to assess the acceptability of the different approaches to patients and practitioners to ensure the most appropriate structure to the research. Other studies could be considered to improve specific data (e.g. a costing study of primary care costs); however, the poor quality of the evidence suggests additional research would be required.

Publication

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The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

The HTA programme is needs led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, from the public and consumer groups and from professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA programme then commissions the research by competitive tender.

Second, the HTA programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Third, through its Technology Assessment Report (TAR) call-off contract, the HTA programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA programme as project number 06/77/04. The contractual start date was in April 2008. The draft report began editorial review in April 2009 and was accepted for publication in October 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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