

# **Bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf: a systematic review and economic evaluation**

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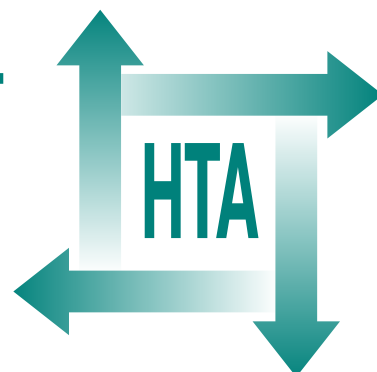


## ***Executive summary***

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# Executive summary

## Background

A bone-anchored hearing aid (BAHA) consists of a permanent titanium fixture, which is surgically implanted into the skull bone behind the ear, and a small detachable sound processor that clips onto the fixture. Sound is transmitted to the cochlea via bone conduction. BAHAs are suitable for people with conductive or mixed hearing loss who cannot benefit fully from conventional hearing aids. They can be used unilaterally or bilaterally for people with bilateral hearing loss.

## Objectives

- To assess the clinical effectiveness and cost-effectiveness of BAHAs for people who are bilaterally deaf. The evaluation will consider BAHAs compared with conventional hearing aids, ear surgery and the unaided condition, and the use of unilateral or bilateral BAHAs.
- To adapt an existing economic model or develop a new economic model relevant to the UK setting.
- To identify areas where further research is required.

## Methods

### *Data sources*

Nineteen electronic databases, including MEDLINE, EMBASE and The Cochrane Library, were searched from inception to November 2009. Bibliographies of relevant papers were checked and experts were contacted to identify additional studies.

### *Study selection*

Titles and abstracts were screened for eligibility and inclusion criteria defined a priori were applied to the full text of selected papers by two reviewers independently. The inclusion criteria were as follows:

- Participants: adults or children with bilateral hearing loss.
- Interventions: BAHAs attached to a surgically implanted titanium fixture.
- Comparisons: unilateral versus bilateral BAHAs, conventional hearing aids [air conduction hearing aid (ACHA) or bone conduction hearing aid (BCHA)], unaided hearing, ear surgery (tympanoplasty, myringoplasty, ossiculoplasty, stapedectomy and stapedotomy).
- Outcomes: hearing measures, aided hearing thresholds, speech recognition scores, validated measures of quality of life (QoL) and patient satisfaction, adverse events, measures of cost-effectiveness [cost per quality-adjusted life-year (QALY); cost per life-year saved] and consequences for health-service resources.
- Types of studies:
  - Systematic review of clinical effectiveness – randomised controlled trials, controlled clinical trials, prospective cohort analytic studies (with control group), prospective cohort pre and post studies (one group, before and after BAHA surgery), cross-sectional 'audiological comparison studies' (one time point) and prospective case series. Only

studies with the most rigorous designs were included for each comparator. Where higher level evidence was limited to BAHA models no longer in current use, lower level evidence for models in current use was included. Abstracts were considered if sufficient information was presented.

- Systematic review of cost-effectiveness – full economic evaluations reporting both costs and outcomes were eligible. Conference abstracts were not eligible for inclusion in the cost-effectiveness section.

### **Data extraction and quality assessment**

Data extraction and quality assessment were undertaken by one reviewer and checked by a second reviewer, with differences resolved through discussion.

### **Data synthesis**

Clinical effectiveness data were synthesised through a narrative review with full tabulation of results. Audiological outcome measures were discussed throughout the review of clinical effectiveness as reported by the included studies, including the use of descriptions such as ‘improvement’ or ‘deterioration’. To aid interpretation of the data, lower hearing thresholds were considered to be ‘better’ than higher thresholds, but it is acknowledged that this is a simplistic approach and, although true in many cases, it is not necessarily so.

## **Results**

### **Quantity and quality of studies**

Searching identified 665 references; 41 of these met the inclusion criteria. After selecting the highest level of evidence available for each comparator and identifying additional studies with BAHA models in current use, 12 studies (reported in 15 publications) were included in the review of clinical effectiveness (seven cohort pre–post studies and five cross-sectional audiological comparison studies). No studies with a control group were identified. Seven studies compared BAHAs with conventional hearing aids, three of these and one additional study compared BAHAs with unaided hearing, and four studies compared unilateral and bilateral BAHAs. No prospective studies comparing BAHAs with ear surgery were identified. The overall quality was rated as weak for all included studies and meta-analysis was not possible due to differences in outcome measures and patient populations.

### **Summary of clinical effectiveness**

#### **BAHAs versus BCHA**

Two studies found an improvement in sound field pure-tone average and warble-tone thresholds with BAHAs, but statistical analysis was reported by only one study ( $p < 0.01$ ). One study found hearing was better with the BCHA at 0.25 and 0.50 kilohertz (kHz) [ $p$ -value not reported (NR)]. Studies reported improvements in 100% speech audiometry discrimination [62 decibels hearing level (dB HL) vs 48 dB HL], location of a sound (0% vs 80% of cases) and maximum phoneme score [mean standard deviation (SD) 36.1% (28.9%) vs 48.7% (31.7%)], but statistical significance was not reported. An improvement in speech reception threshold in quiet {mean difference 2.7 decibels (dB) (SD 4.4 dB),  $p < 0.05$ } and speech-to-noise ratio [2.5 dB (SD 2.2 dB),  $p < 0.05$ ] was found in one study, but another study found no difference in speech recognition threshold {mean decibels A-weighted [dB(A)] (SD): 40 (7.1) vs 38.8 (11.1),  $p = \text{NR}$ }. No statistically significant difference in mean sound field speech discrimination score at 63 dB was found by one study. Statistically significant improvements in QoL were found with a disease-specific instrument but not with generic QoL measures in one study.

### BAHAs versus ACHA

Results for sound field pure-tone or warble-tone thresholds were inconsistent between the studies; for example, one study found the ACHA produced better results between 1 and 4 kHz ( $p = \text{NR}$ ), another found an improvement in mean thresholds (0.5–4.0 kHz,  $p < 0.0.1$ ) with the BAHA. The direction of the effect was also unclear for speech audiometry. Three studies reported better outcomes with the ACHA for speech discrimination scores [mean (SD) 91.6% (14.7%) vs 84% (22.3%),  $p = \text{NR}$ ], maximum phoneme score [mean (SD) 81.6% (8.7%) vs 67.6% (22.2%),  $p = \text{NR}$ ] or speech recognition threshold [mean (SD) 39 dB(A) (10.8) vs 45 dB(A) (5),  $p = \text{NR}$ ; mean deterioration with BAHA  $-6.4$  dB (SD 3.7),  $p < 0.05$ ]. One study found no difference in maximum phoneme score [difference 1.0% (SD 5.4%),  $p = \text{not significant}$ ]. However, three studies found an improvement in speech-to-noise ratio with BAHA (difference range 1.1–2.5 dB). Speech discrimination score was statistically significantly better with the BAHA in the congenital group but not in the chronic suppurative otitis media group in one study. Statistically significant improvements in QoL were found with a disease-specific instrument but not with generic QoL measures in one study.

### BAHAs versus unaided hearing

Of the four included studies, all found improvements in sound field thresholds with BAHA, which were statistically significant in the two studies reporting analysis. Three studies reported speech audiometry and found improvements with BAHAs compared with unaided hearing.

### Unilateral versus bilateral BAHAs

An improvement in sound field average tone thresholds with bilateral BAHAs compared with unilateral BAHAs was found in adults (2–15 dB) and a small group ( $n = 3$ ) of children [30 (SD 5) dB HL vs 25 (SD 5) dB HL].

Speech recognition thresholds in quiet were statistically significantly lower with bilateral BAHAs in two studies [41.5 dB(A) vs 37.5 dB(A); 38.7 dB HL vs 33.3 dB HL], although one study found similar results between unilateral and bilateral BAHAs. Three studies demonstrated that bilateral BAHAs produced better results than unilateral BAHAs when noise was presented from the baffle/best side (the side with the BAHA in the unilateral condition), but not when noise was presented from the shadow side (the side opposite to the BAHA in the unilateral condition); this is due to the increased noise transmitted to the ears with an extra BAHA on the shadow (noise) side. Three studies found that localisation of sound was improved with bilateral BAHAs. Two studies suggested that BAHAs enable binaural hearing. Similar results were found for unilateral and bilateral BAHAs on the Meaningful Auditory Integration Scale and Meaningful Use of Speech Scale and the International Outcomes Inventory for Hearing Aids for most items.

### Adverse events

The included studies reported very limited data on adverse events. Five prospective case series reported rates of loss of implants ranging between 6.1% of implants (9–25 months' follow-up) and 19.4% of implants (median 6 years' follow-up). The vast majority of participants experienced no, or minor, skin reactions.

### Summary of cost-effectiveness studies

Systematic searches identified no relevant, published full economic evaluations of BAHAs. One unpublished economic evaluation, with a minority of participants having bilateral hearing loss, was identified. Two cost studies were identified, one of which was used to help inform the cost analysis for the economic model. One QoL study was also identified, but on further inspection data were of limited value.

### Summary of economic model

A decision-analytic model was developed to estimate the cost-effectiveness of unilateral BAHAs compared with BCHAs for a cohort of adults and children with hearing loss and who were ineligible for conventional ACHAs. The model was informed by a systematic search of the literature to identify parameters on the natural history and epidemiology for people with profound hearing loss, health-related QoL and costs. The intervention effects in terms of improvement in hearing and adverse events were derived from the systematic review of clinical effectiveness. The perspective of the analysis was that of the NHS and Personal Social Services. The model estimated the costs and benefits of unilateral BAHAs over a 10-year time horizon, applying discount rates of 3.5%. The outcome of the economic evaluation is reported as cost per case and cost per successful implantation.

The incremental cost per user receiving a BAHA, compared with BCHA, was £16,409 for children and £13,449 for adults. The cost per case successfully treated with a BAHA was estimated at £18,681 for children and £15,785 for adults, over a 10-year time horizon. In an augmented, exploratory analysis (inferring QoL gains using the hearing dimension of the Health Utilities Index-3) the incremental cost per QALY gained was between £55,642 and £119,367 for children and between £46,628 and £100,029 for adults for BAHAs compared with BCHA, depending on the assumed QoL gain and proportion of each modelled cohort using their hearing aid for  $\geq 8$  hours per day.

Caution should be taken with the interpretation of the results from the economic evaluation owing to the paucity of evidence on the benefits of the BAHAs, particularly the absence of any robust mapping between audiological benefits (reported in studies included in the review of clinical effectiveness) and overall impact on QoL. As a consequence, the results of the economic evaluation should be regarded as exploratory.

### Sensitivity analyses

Deterministic sensitivity analyses suggested that the results of our cost analysis were generally robust to variation in the value of input parameters. The results were most sensitive to variation in the probability of re-operation (when implants lose bone integration), the cost of surgical implantation and, to a lesser extent, the probability of intolerable pain requiring removal of the BAHA fixture.

Deterministic sensitivity analysis of the exploratory cost-effectiveness model suggested that the results were generally robust to variation in input probabilities and cost. The greatest variation, in relation to these factors, was associated with initial failure of bone integration, failure of BAHA implantation due to intolerable pain, the probability of re-operation due to loss of bone integration, the cost of day surgery for implantation and the cost of components of the BAHA system. The results of the cost-effectiveness analysis were highly sensitive to the assumed proportion of people using their hearing aid for  $\geq 8$  hours per day, with very high incremental cost-effectiveness ratio values (in the range from £500,000 to £1,200,000 per QALY gained) associated with a high proportion of people using BCHA for  $\geq 8$  hours per day. More acceptable values (in the range from £15,000 to £37,000 per QALY gained) were associated with a low proportion of people using BCHA for  $\geq 8$  hours per day (compared with BAHA). In a threshold analysis, differences in the proportion of people using their hearing aid for  $\geq 8$  hours per day (for BAHA compared with BCHA) of between 30% and 40% for the lowest estimated utility gain from aided hearing, and between 15% and 18% for the greatest estimated utility gain from aided hearing, were required for BAHAs to be cost-effective at a willingness-to-pay threshold of £30,000 per QALY gained.

## Conclusions

The available evidence is methodologically weak and the results have a high risk of bias. As such, there is a high degree of uncertainty about the conclusions of this systematic review.

The findings suggest that hearing is improved with BAHAs compared with no hearing aid, and although there are audiological benefits of BAHAs when compared with conventional BCHAs, the audiological benefits of BAHAs when compared with ACHAs are less clear. Limited data suggest an improvement in QoL with BAHAs when compared with conventional aids, but there is an absence of evidence regarding other potential benefits, such as length of time the aid is able to be worn and improvement of discharging ears. The evidence suggests that there are some benefits of bilateral BAHAs compared with unilateral BAHAs. The results of our cost analysis demonstrate that BAHAs are significantly more costly than conventional BCHAs. The additional costs continue while individuals remain using their BAHA and are not restricted to the initial processes of surgical implantation and fitting of the BAHA sound processor. Our exploratory cost-effectiveness analysis of BAHAs versus BCHAs suggests that BAHAs are unlikely to be a cost-effective option where the benefits (in terms of hearing gain and probability of using of alternative aids) are similar for BAHAs and their comparators. The greater the benefit from aided hearing and, in particular, the greater the difference in the proportion of people using the hearing aid for  $\geq 8$  hours per day, the more likely BAHAs are to be a cost-effective option. The inclusion of other dimensions of QoL may also increase the likelihood of BAHAs being a cost-effective option.

## Recommendations for further research

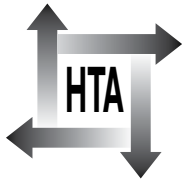
A national audit of BAHAs should be implemented to provide clarity on the many areas of uncertainty surrounding BAHAs. Further research into the non-audiological benefits of BAHAs, including QoL, is required. Good-quality trials are needed to establish the benefits of bilateral BAHAs compared with unilateral BAHAs in people who are bilaterally deaf.

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## Publication

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 08/25/02. The contractual start date was in May 2009. The draft report began editorial review in April 2010 and was accepted for publication in September 2010. 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.

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