

Bone anchored hearing aid and contralateral routing of signals in
patients with unilateral hearing loss
[Benförankrad hörapparat]

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Statement from HTA-centrum 2011-10-26

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HTA-centrum

Summary of the Health Technology Assessment

Method and patient group

Profound unilateral hearing loss is a permanent sensorineural hearing deficit in one ear. It is caused by dysfunction of the cochlea or auditory nerve, and can be of congenital or acquired origin. The patients experience impaired ability in speech recognition and sound localisation, thus affecting communication and quality of life. Current rehabilitation is the hearing aid solution, contralateral routing of signals from the deaf side to the normal hearing ear (CROS). In recent years, the bone anchored hearing aid (BAHA) has been advocated as an advantageous alternative.

Question at issue

Is bone anchored hearing aid system better than contralateral routing of signals or no hearing device in patients with profound unilateral hearing loss with regard to speech recognition, hearing threshold, sound localization, and quality of life?

PICO

P = Adults and children with unilateral deafness (or hearing loss) and normal hearing on the other side

I1 = BAHA

C1 = CROS (Contralateral routing of signals)

I2 = BAHA

C2 = No hearing device

I3 = CROS

C3 = No hearing device

O = Speech recognition, Hearing threshold, Sound localization, Quality of Life

Studied risks and benefits for patients of the new health technology

The systematic literature search identified one randomized controlled trial (RCT) and two cohort studies evaluating speech recognition and sound localisation ability with BAHA and CROS. The studies did not show any outcome differences between BAHA, CROS or no treatment in terms of speech recognition or sound localisation. The level of evidence according to the GRADE system for BAHA being superior to CROS or no hearing device for unilateral profound hearing loss regarding the outcomes speech recognition and sound localisation is very low (GRADE ⊕).

Four studies evaluated the subjective benefit of BAHA and CROS, one RCT and three cohort-studies. The studies did not show any outcome differences between BAHA, CROS or no treatment. The level of evidence according to the GRADE system for BAHA being superior to CROS or no hearing device for unilateral profound hearing loss regarding the outcome subjective benefit is very low (GRADE ⊕).

No serious complications following surgical implantation of BAHA have been reported. The most common adverse effects and complications of BAHA surgery are postoperative skin reaction which varies between 3 –30 %, and implant loss which varies between 1- 14 %.

Ethical questions

Should an expensive technique be offered when the level of evidence of an advantageous effect of BAHA on important outcomes is so low?

Economical aspects

The annual cost is estimated to be 1 500 000 SEK if all patients with profound unilateral hearing loss, 15-20 per year in region Västra Götaland, were offered BAHA or CROS.

Which health technology or method will be assessed?

Bone anchored hearing aid in patients with unilateral hearing loss

1a Who will lead the project?

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1e Are there any conflicts of interest for the proposer or any of the participants in the work group?

No.

Disease/disorder of Interest and Present Treatment

2a Disease/disorder of interest and its degree of severity

Single Sided Deafness (SSD) or profound unilateral hearing loss mean no functional hearing ability in one ear. It is a permanent functional deficit that affects communication, orientation and audition.

The unilateral hearing loss is due to a dysfunction in the cochlea or auditory nerve, i.e. a sensorineural hearing loss. It can be of congenital or acquired origin, due to malformation, disease or injury. Unilateral hearing loss can develop suddenly or in a progressive manner.

Patients with profound unilateral hearing loss often experience difficulties in sound

localisation, speech perception and recognition in noisy environments (Christensen 2010). Quality of life studies have reported significant disabling effects of this disorder (Gatehouse 2004, Borton 2009). Studies have also shown that children with unilateral hearing loss have lower academic and cognitive achievements, more behavioural problems, and a delayed language acquisition (Lieu 2010, Lieu 2004, Martinez-Cruz 2009).

- Risk of premature death
- Risk of permanent illness or damage, or reduced quality of life
- Risk of disability and health-related quality of life

2b Prevalence and incidence of the disease/disorder

Studies of prevalence and incidence of unilateral hearing loss are sparse and report conflicting results. Registration by ICD-10 is not possible to use for identification of these patient groups. Therefore, estimation has been made based on epidemiological studies, and a clinical database in Göteborg for rehabilitation of children with hearing impairment.

At Sahlgrenska University Hospital, a clinical database has been used to register children (0-18 years of age) with hearing rehabilitation needs since 15 years. According to the register, a total of 50 children with profound unilateral hearing loss and normal hearing in the contralateral ear are currently receiving rehabilitation services in the Göteborg area. Epidemiological calculations for the population aged 0-18 years in the Region Västra Götaland (n =340 000) yields a lowest incidence of 1.6 per 100 000 children. This incidence is in accordance with other reports (Vartiainen 1998, Mehl 2002).

In adults, profound unilateral hearing loss is typically caused by infections, trauma, acoustic neuromas, Ménière's disease or cerebrovascular disease. It is more common with increasing age. However, there are no reliable epidemiological data regarding the incidence and prevalence of profound unilateral hearing loss in these patient groups.

After surgical removal of an acoustic neuroma, most patients will be deafened on the side of intervention. The number of patients undergoing acoustic neuroma surgery is 12-18 per year in the Region Västra Götaland.

There are no data with regard to development of unilateral deafness due to trauma or Ménière's disease.

Based on the above-mentioned figures an estimation of the incidence of profound unilateral hearing loss in the Region Västra Götaland region yields a lowest estimated incidence of profound unilateral hearing loss of 5.8/100 000 per year (children: 10, adults: 30 sudden deafness, 15 acoustic neuromas, 5 trauma and 2 Ménière's disease).

The prevalence is dependent on the cumulative incidence and increases with age. However, in the estimation of the prevalence of unilateral hearing loss the expected bilateral hearing decline with age (presbycusis) also needs to be accounted for.

2c Present treatment of the disease/disorder in the outpatient setting/ inpatient setting.

Hearing aids for children and adults in the Region Västra Götaland are provided by the Habilitation & Health (H&H) Services. Provision of care includes prescription of CROS (contralateral routing of signal) or BAHA (bone anchored hearing aid) devices. It is important to point out that intervention by technical means is only one part of the hearing rehabilitation, and counselling and communication optimisation by educational support can also be of benefit for the patient with unilateral deafness.

The use of technical aids is dependent on the patient's needs and type of hearing loss. After audiological assessment the interventional team chooses together with the patients the type of hearing aid.

Patients with profound unilateral hearing loss who require hearing aids are first offered a trial period with the CROS system. If this test period comes out positive, the CROS system may be prescribed. In some patients BAHA is tested. If the test result is better than with the CROS, surgery for the BAHA is offered. The surgical procedure is performed in an inpatient or outpatient (i.e. day surgery) setting. Surgery can be done in local anaesthesia in adults, whereas most children will be operated on in general anaesthesia in a two-stage procedure.

Patients with CROS or BAHA devices need follow-up visits to audiologists in secondary health care services for adjustments, service, reparation and re-prescription. For patients with BAHA, follow-up visits to surgeons at outpatient Otorhinolaryngology clinics are also necessary.

2d Number of patients per year who undergo current treatment regimen?

From databases and registries at the Habilitation and Health Services and the four Departments of Otorhinolaryngology in Region Västra Götaland, the CROS and BAHA-users can be identified.

During the 5-year period of 2006-2010, a total of 27 CROS devices were prescribed for children, all from the Göteborg area. The number of prescriptions for CROS to adults was 160 in Västra Götaland. However, these numbers include both first-time prescriptions as well as re-prescriptions of CROS.

A total of 326 BAHA fittings were performed during 2006-2010 for children and adults. The majority of BAHA operations was performed at Sahlgrenska University Hospital, see table below.

Care provider in Västra Götaland	Paediatric	Adult
NU Hospital group	0	16
Skaraborg Hospital	0	1
Sahlgrenska University Hospital	45	129
Southern Älvsborg Hospital	0	0

2e The normal pathway of a patient through the health care system

See figure 1 in the appendix for a graphical presentation of current pathways.

Most children with profound unilateral hearing loss are identified by hearing screening procedures at birth, in pre-school or in elementary school. Also, some children are referred due to their parents' awareness or by established clinical guidelines for specific diseases.

Children younger than 5 years need special audiological procedures that are only available at four hospitals in the Region Västra Götaland. After the diagnosis has been established, habilitation services are initiated for these children with unilateral hearing impairment. The team services are multi-professional and include medical follow-up, educational intervention by specialists, and, whenever possible, the use of hearing aids or other technical aids. For the children under the age of one year, the Region Västra Götaland has special clinical guidelines for intervention services. (Andersson e et al). These can also be adhered to children and adolescents.

Adult patients most often contact the primary health care system due to sudden or progressive unilateral hearing loss. The patients will then be referred to a Department of Otorhinolaryngology for diagnostic work-up and/or treatment. Audiological assessments are performed by the Hearing & Deafness organisation.

There are no specific regional or national guidelines for rehabilitation of adults with profound unilateral hearing loss.

2f Actual wait time in days for medical assessment /treatment

All health care providers within Otorhinolaryngology offer a visit for medical assessment of suspected unilateral deafness within 90 days after referral.

The Habilitation and Health organisation reports audiological assessments and hearing aid fittings of all patients within 90 days after referral.

BAHA surgery is performed within 90 days after patient agreement.

3a Name/description of the health technology at issue

Contralateral routing of signals - CROS

The traditional hearing aid solution for patients with profound unilateral hearing loss and normal hearing in the other ear has been contralateral routing of signals, CROS (Harford & Barry 1965). With a CROS device, the sound is transmitted from the deaf side to the normal hearing ear. This is done by the use of a hearing aid microphone on the deaf ear and a cord or a wireless FM transmission that present the auditory signals to the amplifier on the normal ear. In the normal ear an open ear mould is inserted in the ear canal. Hereby, the system transmits sound energy from the deaf side by air conduction through the external ear canal, eardrum and the middle ear ossicles of the normal ear to the normally functioning cochlea and auditory system of the hearing side.

Bone anchored hearing aid - BAHA

A bone anchored hearing aid transfers sound by bone conduction. The sound processor is anchored to the temporal bone by a titanium implant that needs to be surgically installed. The specially designed transducer creates vibrations that are transmitted via the bone of the skull to the cochleae and sound is perceived.

Before surgery, the effect of a BAHA can be simulated and tested by transcutaneous stimulation when the system's hearing aid is pressed by a softband against the skull.

At surgery the BAHA implant (3 or 4 mm long) is placed in the temporal bone and penetrates the skin after the removal of soft tissues. Normally the surgical procedure takes less than 60 minutes. After healing, the transducer is attached to the implant. The BAHA is worn on the deaf side and transmits sound via bone conduction to the contralateral normal functioning cochlea.

Both the CROS and BAHA devices compensate the head shadow effect and, thus, may improve speech intelligibility in noise, and ease of listening. Complete restoration of directional hearing cannot be achieved since input from two cochleae is required for normal sound localisation. Both techniques are well established for transmission of amplified sound, and are used clinically.

3b The work group's understanding of the potential value of the health technology

Patients with unilateral profound hearing loss often have severe problems to communicate in challenging listening conditions. With an appropriate hearing aid it may be possible to compensate for sounds from the deaf side, and, thereby, improve speech reception and recognition in certain situations. Positive benefit of hearing aids has been reported by disease-specific quality of life questionnaires with regard to communication, hearing in background noise, and in reverberation, in patients with unilateral hearing loss.

Today, many of these patients are offered a CROS device. However, this aid is seldom

preferred by the patient due to inconvenience. In many countries, a BAHA is offered as an alternative hearing aid.

Most probably, the majority of patients with unilateral profound hearing loss in Region Västra Götaland have no hearing aids. Patients with such hearing disabilities and challenging communication needs, should be offered test periods with both the CROS and the BAHA devices. It is likely that many patients will find one of these devices beneficial for their hearing demands. Thus, most probably many patients in the Region Västra Götaland could be better rehabilitated and achieve a higher quality of life. With the standards in practice today in Västra Götaland, patients are rehabilitated neither optimally nor equally.

3c The central question for the current HTA project in one sentence

Is bone anchored hearing aid system better than contralateral routing of signals or no hearing device in patients with profound unilateral hearing loss with regard to speech recognition, hearing threshold, sound localization, and quality of life?

3d PICO (P= Patients, I= Intervention, C= Comparison, O=Outcome)

PICO

P = Adults and children with unilateral deafness (or hearing loss) and normal hearing on the other side

I1 = BAHA

C1 = CROS (Contralateral routing of signals)

I2 = BAHA

C2 = No hearing device

I3 = CROS

C3 = No hearing device

O = Speech recognition, Hearing threshold, Sound localization, Quality of Life

3e Key words

Unilateral hearing loss, hearing aids, bone conduction

4 Search strategy, study selection and references – appendix 3

During February, 2011, the library performed searches in PubMed, the Cochrane Library, EMBASE, CINAHL, PsycInfo and a number of HTA-databases. Reference lists of relevant articles were also scanned for additional references. A total of 193 articles were identified after removal of duplicates, of which 109 abstracts were excluded by the library. Another 46 articles were excluded by the library after having been read in full text. 35 articles, 1 systematic review and 2 HTA reports were sent to the work group for assessment. 15 of these articles are included in the report, 4 are controlled studies and have been critically appraised.

The appraisal of articles is based on checklists from SBU regarding randomized controlled trials and other checklists developed by Olle Nyrén, professor, Karolinska Institutet, Stockholm,

Search strategies, eligibility criteria and a graphic presentation of the selection process are accounted for in appendix 3. The literature search and exclusion of abstracts were made by two librarians (TF, ELD) in consultation with the HTA-centre and the work group.

5a Describe briefly the present knowledge of the health technology

Speech recognition

The systematic literature search identified one randomised, controlled trial (RCT) and two non-randomised, controlled cohort studies reporting the effect on speech recognition with BAHA and CROS. All studies had serious limitations in study quality and uncertain external validity. The total number of patients in these studies was 77.

No differences were observed when BAHA, CROS or no hearing aid were compared with each another.

The level of evidence according to the GRADE system for BAHA being superior to CROS or no hearing device for unilateral profound hearing loss regarding the outcome speech recognition is very low (⊕).

Sound localisation

The three studies mentioned above also reported the effect on the ability to localise sound.

No differences were observed when BAHA, CROS or no hearing aid were compared with each another.

The level of evidence according to the GRADE system for BAHA being superior to CROS or no hearing device for unilateral profound hearing loss regarding the outcome sound localization is very low (⊕).

Quality of Life (Subjective experience)

The systematic literature search identified four studies that reported the subjective experience of BAHA or CROS devices. One was a randomised, controlled trial and three were non-randomised, controlled cohort-studies. All studies had serious limitations in study quality and uncertain external validity. The total number of patients was 392.

No differences in the subjective appreciation of a beneficial effect were observed when BAHA, CROS or no hearing aid were compared with each another.

The level of evidence for a subjective benefit of BAHA compared to CROS or no hearing device in patients with profound unilateral hearing loss is very low (GRADE ⊕).

Complications

In the analysis of complications to BAHA-surgery, only studies with more than 30 patient series were included. The majority of the patients in these studies were operated on for other indications than profound unilateral hearing loss. The rate and type of complications can be applied also on the present indication of profound unilateral hearing loss.

Early complications, such as necrosis of the skin around the implant, occurred in less than 1 % of the patients. Skin reactions around the implant, loss of osseointegration or implant failure, were the most commonly reported late complications. Adverse skin reactions were documented in 3 % - 30 % of the patients. Most skin reactions could be handled with local care, but the need of revision surgery was reported in up to 22 % of all cases. Lost osseointegration, and, as a consequence, a loosened? lost?implant, was reported in 1 - 14 %. A lost implant could be re-installed, but it requires additional surgical procedure.

The probable reasons for the different complication rates in various case series are the use of different surgical techniques, and variations of skin care around the implant performed by the patient and/or caregivers.

It can be concluded that BAHA is an established and relatively safe surgical procedure, and the complications associated with the implantation are not severe.

5b Outcome tables – appendix 1

5c Excluded articles – appendix 2

5d Ongoing research

No randomised, controlled or non-randomised controlled study with relevance to the question at issue of this HTA-report was identified in www.clinicaltrials.gov.

All BAHA patients at the large BAHA-center in Nijmegen, The Netherlands, are prospectively followed and results will be published.

A Polish national quality register of patients who have received BAHA was started in 2009. It has been reported that 18 % of the patients treated with BAHA had unilateral profound hearing loss as the indication for the procedure. More data are expected to be reported from this database.

6 Which medical societies or health authorities recommend the new health technology?

Bone anchored hearing aids for patients with unilateral profound hearing loss are reimbursed in many European countries such as the UK, Poland, The Netherlands, Belgium, Denmark and Switzerland.

In 2002 the Food and Drug Administration (FDA) approved the BAHA produced by the Cochlear company (previously Entific AB) for use in patients older than five years with unilateral hearing loss. In 2009 the BAHA of the Oticon Medical company was also approved. It has since then been reimbursed on the indication unilateral profound hearing loss within the American health insurance system. More than 50 % of the BAHAs in the USA are fitted for the unilateral profound hearing loss indication.

In Sweden, there are presently no national guidelines with regard to BAHA.

Ethical aspects

7a Ethical consequences

Given the very low level of evidence of the any beneficial effect of BAHA or CROS for profound unilateral hearing, an introduction of both techniques can be questioned. However, in the modern society with increasing demands on communication, some patients will most probably experience a better quality of life with BAHA or CROS.

7b Will other patient groups or other treatments be adversely affected (pushed aside) due to an introduction of the new health technology?

A systematic rehabilitation of patients with unilateral profound hearing loss would increase the prescription of BAHA and CROS. Without increase in resources, this could be disadvantageous for patient groups with other hearing impairments. A more efficient clinical pathway could to a certain degree compensate these consequences.

Organisation

8a When can this new health technology be put into practice?

The BAHA and CROS are already used in some patients with profound unilateral hearing loss, and also for other indications.
A structured rehabilitation program with both devices can be put into practice without delay.

8b Is this technology used in other hospitals in Region Västra Götaland?

Surgical implantation of BAHA is performed at three hospitals in the Västra Götaland region. More than 90 % of all the BAHA implants are currently performed at Sahlgrenska University Hospital. Both CROS and BAHA hearing devices are presently prescribed within the Hearing & Deafness centres in the region.

8c According to the work group, will there be any consequences of the new health technology for personnel?

New routines for patient information need to be implemented as well as tools for patient selections. Information of a structured rehabilitation program for children and adults with profound unilateral hearing loss needs to be communicated to professionals working within audiology.

8d Will there be any consequences for other clinics or supporting functions at the hospital or in the whole Western Region of Sweden?

An increased volume for BAHA surgery would require additional resources for anaesthesia of children and some adults. Most probably a large proportion of surgeries could be performed in day-care, thus, resources can be used more efficiently.

Economy

9a Present costs of currently used technologies and the new technology

An estimation of the costs for BAHA and CROS has been performed and is presented below. Data on the number of surgeries, hearing device prescriptions and direct medical costs have been retrieved from regional computerised administrative systems. Data on surgeries and thus direct medical costs are judged as accurate. Data on hearing prescriptions are not valid, since data have not been registered consistently in the region.

In Region Västra Götaland approximately 180-190 patients were fitted with a CROS-device and 7 patients with a BAHA due to profound unilateral hearing loss and normal hearing in the contralateral ear during 2006 - 2010.

The table presents the number of fittings for BAHA and CROS-devices and the estimated costs.

	TOTAL	FyrBoDal/NU	Göteborg HDV/SU	Skaraborg	S Älvsborg
CROS-device No. of fittings for unilateral deafness	186 (estimation)	no data	111	25	25
Estimated cost per device	SEK 4 500 excl VAT				
Estimated cost for personnel per fitting	SEK 3 500				
Total cost	SEK 8 000				
No. of BAHA surgeries for unilateral deafness	7 adults	0 children 1 adult	0 children 6 adults	0 0	0 0
Estimated cost per surgical intervention	Day surgery: SEK 18 000 In-hospital surgery: SEK 26 000	Day Surgery: SEK 14 500	Day Surgery: SEK 18 100 In-hospital surgery: SEK 26 000	No data	-
Estimated cost per device	SEK 31 400				
Estimated cost personnel per fitting	SEK 4 400				
Total cost- Day surgery In-hospital surgery	SEK 53 800 SEK 61 800				

9b Total change of costs

Given that 60 new patients develop profound unilateral hearing loss yearly, it can be anticipated that about one third of these patients would choose technical rehabilitation with CROS or BAHA (Hol 2010). Final prescription would be for only one of these devices. Thus, the maximal estimated cost corresponds to the cost for BAHA, but since some patients would choose the CROS the cost will be lower.

The estimated cost for 20 new CROS-patients is 160 000 SEK.
If BAHA were offered to 20 new patients, the total cost would be between 1 200 000 SEK.

For patients with a long history of profound unilateral hearing loss, a time-dependent higher demand for rehabilitation services can be anticipated. This number of patients is difficult to estimate, but may be between 15-30 per year over a four-year period, corresponding to an additional annual cost of 120 000 – 240 000 SEK (CROS) or 900 000 – 1 800 000 SEK (BAHA) respectively during this period.

Costs for re-prescriptions of hearing devices and handling of surgical complications have not been calculated in this HTA-report.

The annual cost of a structured rehabilitation program for profound unilateral hearing loss during the first four years is estimated to be up to 400 000 SEK (160 000 + 240 000; see above) if all patients receive CROS. If all patients are treated with BAHA the corresponding cost is estimated to be up to 3 000 000 SEK (1 200 000 + 1 800 000; see above).

9c Can the new technology be adopted and used within the present budget (clinic budget/hospital budget)?

No.

9d Are there any available analyses of health economy? Cost advantages or disadvantages?

No health economic studies have been published of BAHA in patients with unilateral hearing loss. A cost-effectiveness analysis on the use of BAHA used for all indications has recently been published. The study has been performed in Birmingham, UK. For all indications, of which unilateral deafness is one, the average cost per QALY (Quality Adjusted Life Year) was estimated to be £17 610 (this corresponds to 180 000 SEK). The threshold at which treatment is considered cost-effective by the National Institute for Health and Clinical Effectiveness is £ 20 000-30 000 (Monksfield 2011).

Unanswered Questions

10a Important gaps in scientific knowledge?

Well designed RCTs of the efficacy of BAHA and CROS are still lacking.

One hypothesis is that patients in need of audibility in noisy environments, especially when sound is presented to the deaf side, will benefit (such as taxi/bus drivers, teachers, and other professionals with special communication needs) by BAHA or CROS. However, studies in these subcategories of subjects with unilateral hearing loss are also lacking.

10b Is there any interest in your own clinic/research group/organisation to start studies/trials within the research field at issue?

Yes.

1. An epidemiological study with the purpose to clarify the true incidence of unilateral severe and profound sensorineural hearing loss in children and adults.
2. A prospective, observational cohort study with the aim to identify the patients with greatest demands of hearing rehabilitation and to assess their functional outcome.
3. A randomised, controlled trial comparing the outcome of different hearing aids for the studied indication.

Utlåtande och sammanfattande bedömning från Kvalitetssäkringsgruppen

Benföranckrad hörapparat hos patienter med ensidig dövhet

Frågeställning:

Är ett benföranckrat hörselhjälpssystem bättre än ett hjälpmedel med kontralateral ljudöverföring eller inget hörselhjälpmedel alls avseende taluppfattning, hörseltröskel, lokalisering av ljud och livskvalitet hos patienter med uttalad unilateral hörselnedsättning?

PICO

P = Vuxna och barn med ensidig dövhet och normal hörsel på andra sidan

I1 = Benföranckrat hörselhjälpssystem (BAHA= boneanchored hearing aid)

C1 = Kontralateral ljudöverföring (CROS = Contralateral routing of signals)

I2 = BAHA

C2 = Inget hörselhjälpmedel

I3 = CROS

C3 = Inget hörselhjälpmedel

O = Taluppfattning, hörseltröskel, lokalisering av ljud, livskvalitet

Resultat av HTA-processen:

Metod och målgrupp:

Patienter med en permanent sensorineural hörselskada på ena örat har en uttalat nedsatt hörsel på den aktuella sidan. Detta leder till en nedsatt förmåga att korrekt uppfatta det talade språket och att lokalisera ljud. Idag rehabiliteras dessa patienter med hörselhjälpmedel som leder ljudsignaler från den skadade sidan över till det friska örat (s.k. CROS). Under senare år har en benföranckrad hörapparat (s.k. BAHA) utvecklats och framförts som ett alternativ i behandlingen av denna patientgrupp.

Evidensläge:

Taluppfattning

Den systematiska litteratursökningen identifierade en randomiserad, kontrollerad studie (RCT) och två icke-randomiserade, kontrollerade observationsstudier som har rapporterat effekterna av BAHA och CROS avseende förmågan att uppfatta talat språk. Alla studierna hade allvarliga begränsningar i studiekvalitet och extern validitet. Inga skillnader förelåg när BAHA, CROS eller inget hörselhjälpmedel alls jämfördes med varandra.

Avseende taluppfattning är det vetenskapliga underlaget otillräckligt för att bedöma om BAHA är bättre än CROS eller inget hörselhjälpmedel alls (GRADE ⊕).

Lokalisera ljud

Samma studier som rapporterat effekterna på taluppfattning har även redovisat sina resultat avseende förmågan att korrekt lokalisera ljud. Inga skillnader förelåg när BAHA, CROS eller inget hörselhjälpmedel alls jämfördes med varandra.

Avseende förmåga att lokalisera ljud är det vetenskapliga underlaget otillräckligt för att bedöma om BAHA är bättre än CROS eller inget hörselhjälpmedel alls (GRADE ⊕).

Livskvalitet (Subjektiva upplevelser)

Den systematiska litteratursökningen identifierade fyra studier som har rapporterat effekterna av BAHA och CROS med avseende på patienternas subjektiva upplevelser. En studie var en randomiserad, kontrollerad studie (RCT) och tre var icke-randomiserade, kontrollerade observationsstudier. Alla studierna hade allvarliga begränsningar i studiekvalitet och extern validitet. Inga skillnader förelåg när BAHA, CROS eller inget hörselhjälpmedel alls jämfördes med varandra.

Avseende livskvalitet är det vetenskapliga underlaget otillräckligt för att bedöma om BAHA är bättre än CROS eller inget hörselhjälpmedel alls (GRADE ⊕).

Komplikationer och biverkningar:

Tidiga komplikationer som hudnekros runt implantatet av den benförankrade hörapparten inträffade hos mindre än 1% av alla patienter som fått en BAHA inopererad (oavsett indikation). Sena hudkomplikationer runt implantatet har rapporterats hos 3 – 30 % av alla patienter som erhållit BAHA. Frekvensen av fall där implantatet lossnar från sin benförankring eller helt upphör att fungera av annat skäl varierar mellan 1 – 14 %, och behovet av kirurgisk revision har rapporterats inträffa hos upp till 22 % av all patienter.

Etiska aspekter:

Ska en dyrt medicinskt hjälpmedel som benförankrad hörapparat erbjudas i rehabiliteringen när behandlingseffekterna är oklara och evidensläget är otillräckligt?

Ekonomiska aspekter

Kostnaden för ett strukturerat rehabiliteringsprogram i vilket alla patienter med ensidig dövhet behandlas med CROS beräknas till 400 000 kronor årligen under en fyra årsperiod. Om alla patienter i stället skulle behandlas med BAHA uppskattas den motsvarande årliga kostnaden till 3 000 000 kronor.

Sammanfattning och slutsats

Evidensläget avseende effekterna av benförankrad hörapparat hos patienter med ensidig dövhet avseende taluppfattning, lokalisering av ljud och livskvalitet är otillräckligt (GRADE ⊕).

För HTA-kvalitetssäkringsgruppen
Göteborg, Sverige, 2011-10-26

Christina Bergh, Professor

Denna HTA har genomförts på begäran av Hasse Ejnell, verksamhetschef, Verksamhet Öron- näs- och halssjukvård, Sahlgrenska Universitetssjukhuset.

En arbetsgrupp ledd av Joacim Stalfors, överläkare, Öron- näs- och halssjukvård, Sahlgrenska Universitetssjukhuset, Radoslava Jönsson, överläkare, Öron- näs- och halssjukvård, Sahlgrenska Universitetssjukhuset, och Mehrnaz Seitooi, audiolog, Hörsel- och dövverksamheten, Habilitering och hälsa, Borås, har tagit fram rapporten.

Från HTA-centrum har professor Christina Bergh och docent Ola Samuelsson varit ansvariga, dessutom har Thomas Franzén, chef för Kliniska centralbiblioteket, Sahlgrenska Universitetssjukhuset, och bibliotekarie Eva-Lotte Daxberg deltagit i projektet.

HTA-rapporten och åberopad och förtecknad litteratur har sedan granskats av Karin Manhem, universitetslektor, Medicin, Sahlgrenska Universitetssjukhuset, samt Anders Larsson, överläkare, Neurologi, Södra Älvsborgs Sjukhus.

Slutsatser har diskuterats vid möten mellan HTA-centrum och HTA-projektgruppen. Ett utlåtande har tagits fram, diskuterats och fastställts vid HTA-kvalitetssäkrings-gruppens möte 2011-10-26

Projektet har pågått under perioden 2011-02-09—2011-10-26. Sista uppdatering av artikelsökning 2011-02-10

Statement from HTA-Centre, Region Västra Götaland

Bone anchored hearing aid in patients with unilateral hearing loss

Question at issue:

Is bone anchored hearing aid system better than contralateral routing of signals or no hearing device in patients with profound unilateral hearing loss with regard to speech recognition, hearing threshold, sound localization, and quality of life?

PICO

P = Adults and children with unilateral deafness (or hearing loss) and normal hearing on the other side

I1 = BAHA

C1 = CROS (Contralateral routing of signals)

I2 = BAHA

C2 = No hearing device

I3 = CROS

C3 = No hearing device

O = Speech recognition, Hearing threshold, Sound localization, Quality of Life

Summary of the health technology assessment:

Method and patient category:

Profound unilateral hearing loss is a permanent sensorineural hearing deficit in one ear. The patients experience impaired ability in speech recognition and sound localisation. Current rehabilitation is the hearing aid solution with contralateral routing of signals from the deaf side to the normal hearing ear (CROS). In recent years, the bone anchored hearing aid (BAHA) has been advocated as an advantageous alternative.

Level of evidence:

Speech recognition

The systematic literature search identified one randomised, controlled trial (RCT) and two non-randomised, controlled cohort studies reporting the effect on speech recognition with BAHA and CROS. All studies had serious limitations in study quality and external validity. No differences were observed when BAHA, CROS or no hearing aid were compared with each another.

The level of evidence according to the GRADE system for BAHA being superior to CROS or no hearing device for unilateral profound hearing loss regarding the outcome subjective benefit is very low (GRADE ⊕).

Sound localisation

The same three studies as above also reported the effect on the ability to localise sound. No differences were observed when BAHA, CROS or no hearing aid were compared with each another.

The level of evidence according to the GRADE system for BAHA being superior to CROS or no hearing device for unilateral profound hearing loss regarding the outcomes sound localisation is very low (GRADE ⊕).

Quality of Life (Subjective experience)

The systematic literature search identified four studies that reported the subjective experience of BAHA or CROS devices. One was a randomised, controlled trial and three were non-randomised, controlled cohort-studies. All studies had serious limitations in the study quality and uncertain external validity. No differences in the subjective appreciation were observed when BAHA, CROS or no hearing aid were compared with each another. The level of evidence according to the GRADE system for BAHA being superior to CROS or no hearing device for unilateral profound hearing loss regarding the outcome subjective benefit is very low (GRADE ⊕).

Side effects and complications:

Early complications, such as necrosis of the skin around the implant, occurred in less than 1% of the patients after implantation of a BAHA (regardless of the indication).

Late complications with skin reactions around the implant have been reported in 3 – 30 % of BAHA patients. The frequencies of loss of osseointegration or implant failure have varied between 1 – 14 %, and the need of revision surgery has been reported to occur in up to 22 % of all patients.

Ethical aspects:

Should an expensive technique be offered when the level of evidence of an advantageous effect of BAHA on important outcomes is so low?

Economical aspects

The annual cost of a structured rehabilitation program for profound unilateral hearing loss during the first four years is estimated to be up to 400 000 SEK if all patients receive CROS. If all patients are treated with BAHA the corresponding cost is estimated to be up to 3 000 000 SEK.

Concluding remarks

The level of evidence for a beneficial effect of bone anchored hearing aid to improve speech recognition, sound localization, and quality of life in patients with unilateral hearing loss is very low (GRADE ⊕).

On behalf of the Regional HTA Centre, Region Västra Götaland in Sweden
Göteborg, Sweden, 2011-10-26

Christina Bergh, Professor, MD.
Head of Regional HTA Centre,

The Regional Health Technology Assessment Centre (HTA-centrum) of the Western Region in Sweden (Region Västra Götaland, VGR) has the task to make statements on HTA reports carried out in VGR. The statement should summarise the question at issue, level of evidence, efficacy, risks, and economical and ethical aspects of the particular health technology that has been assessed in the report.

The Head of the Department of Otorhinolaryngology, Sahlgrenska University Hospital, Göteborg, Sweden, Hasse Ejnell requested the present HTA.

The HTA was accomplished during the period of 2011-02-07 – 2011-10-26. A working group under the chairmanship of Joacim Stafors, MD, at the Department of Otorhinolaryngology, Sahlgrenska University Hospital, Göteborg, Sweden, produced the HTA report. The other members of the working group were Radoslava Jönsson, MD, Department of Otorhinolaryngology, and Mehrnaz Seitooni, Audiologist, Hearing & Deafness organisation, Habilitation & Health, Southern Älvsborgs Hospital, Borås, Sweden.

The participants from the HTA centre were Christina Bergh, MD, professor, Ola Samuelsson MD, PhD, Eva-Lotte Daxberg, librarian, and Thomas Franzén, Head of the Clinical Library, Sahlgrenska University Hospital, Göteborg, Sweden.

Anders Larsson MD, PhD, and Karin Manhem, MD, PhD, have critically appraised the report.

Table 1. Outcome variable: Speech perception/recognition.

CROS=Contralateral Routing Of Sound. BAHA = Bone-Anchored Hearing Aid. CIC = CROS device Completely In Canal.

SRT = Speech reception threshold expressed as dB Signal/Noise ratio. A lower SRT value corresponds to better performance.

Author, year	Country	Study design	Number of patients n=	With-drawals - dropouts	Result				Comments	Quality (may vary according to outcome)
					Control and interventions					
Bosman et al. 2003	The Netherlands	Non-randomised, cross-over study	9	0	<u>Unaided:</u> SRT ⁱ Hearing side = -2.8 Deaf side = 1.8	<u>CROS:</u> SRT ⁱ Hearing side = -2.0 Deaf side = 0.5	<u>BAHA:</u> SRT ⁱ Hearing side = -3.5 Deaf side = 0.4		No statistical analysis performed. Authors concluded that CROS and BAHA "were equally successful".	Low
Hol et al. 2010b (Eur Arch Otorhinolaryngol)	The Netherlands	Randomised, cross-over study	10	2 CROS 1 BAHA 3 CIC	<u>Unaided:</u> SRT ⁱ Hearing side = -4.3 Deaf side = 0.5	<u>CROS:</u> SRT ⁱ Hearing side = -2.7 Deaf side = -1.7	<u>BAHA:</u> SRT ⁱ Hearing side = -2.0 Deaf side = 0.4	<u>CIC:</u> SRT ⁱ Hearing side = -4.6 Deaf side = 0.7	No statistical analysis performed. An observation was a trend of deteriorating SRT for CROS and BAHA when speech was presented to the ear with normal hearing.	Low
Martin et al. 2010	UK	Randomised, cross-over study	19		<u>Difference in SRT between BAHA and Unaided:</u> Speech and Noise in front: = - 0.4; p = 0.90 Speech front, Noise BAHA side: = - 5.3; p = 0.06 Speech front, Nose non-BAHA side: = 8.1; p = 0.06				The test with or without activated BAHA was performed on the same day.	Low

Footnote: i. Estimated from Figure 1 in the publication.

Table 2. Outcome variable: Subjective benefit.

CROS=Contralateral Routing Of Sound. BAHA= Bone-Anchored Hearing Aid. CIC = CROS device Completely In Canal.

APHAB = Abbreviated Profile of Hearing Aid Benefit questionnaire with four categories: EC = ease of communication. BN = background noise.

RV = reverberation. AV = aversion. A lower score corresponds to a more favourable outcome.

SSQ = Speech, Spatial and Qualities hearing scale with three domains: SHRS = speech hearing rating. SRS = spatial rating. SQRS = sound qualities rating.

A higher score corresponds to a more favourable effect.

Author, year	Country	Study design	Number of patients n=	Withdrawals - dropouts	Result				Comments	Quality (may vary according to outcome)
					Control and interventions					
Bosman et al. 2003	The Netherlands	Non-randomised, cross-over study	9	0	<u>Unaided:</u> <u>APHAB</u> EC = 16.7 BN = 67.6 RV = 37.7 AV = 32.3	<u>BAHA:</u> <u>APHAB</u> EC = 10.9 BN = 40.0 RV = 20.1 AV = 20.9	<u>CROS:</u> <u>APHAB</u> EC = 12.0 BN = 48.0 RV = 30.5 AV = 33.6		No statistical analysis performed.	Low
Hol et al. 2010b (Eur Arch Otorhinolaryngol)	The Netherlands	Randomised, cross-over study	10	2 CROS 1 BAHA 3 CIC	<u>Unaided:</u> <u>APHAB</u> EC = 28 BN = 60 RV = 45 AV = 35	<u>BAHA:</u> <u>APHAB</u> EC = 18 BN = 54 RV = 46 AV = 42	<u>CROS:</u> <u>APHAB</u> EC = 22 BN = 61 RV = 38 AV = 40	<u>CIC:</u> <u>APHAB</u> EC = 26 BN = 73 RV = 53 AV = 40	No statistical analysis performed.	Low
Martin et al. 2010	UK	Non-randomised, controlled observational study	54 BAHA 67 Controls	8 BAHA 18 Controls	<u>Controls:</u> <u>SSQ</u> ⁱ SHRS = 45 SRS = 33 SQRS = 67	<u>BAHA:</u> <u>SSQ</u> ⁱ SHRS = 50 SRS = 32 SQRS = 65			No significant differences between cases and controls.	Low
House et al. 2010	USA	Non-randomised, controlled observational study	126 BAHA 126 Controls	58 BAHA 65 Controls	<u>Controls:</u> <u>SSQ</u> ⁱⁱ SHRS = 5.3 SRS = 3.6 SQRS = 7.0	<u>BAHA:</u> <u>SSQ</u> ⁱⁱ SHRS = 5.7 SRS = 3.8 SQRS = 6.6			No significant differences between control and BAHA group on overall SSQ scores and subscales.	Low

i. The values represent the total sum of the entire subscale.

ii. The values represent the mean score of the entire subscale, estimated from Figure 1 in the publication.

Table 3. Outcome variable: Sound localisation.

CROS=Contralateral Routing Of Sound. BAHA = Bone-Anchored Hearing Aid CIC = CROS device Completely In Canal.

Sound lateralisation score presented as left/right in %. A score of 50% means that the lateralisation performance is equal to mere chance.

Author, year	Country	Study design	Number of patients n=	With- drawals - dropouts	Result				Comments	Quality (may vary according to outcome)
					Control and interventions					
Bosman et al. 2003	The Netherlands	Non-randomised, cross-over study	9	0	<u>Unaided:</u> “At the level of chance”	<u>CROS:</u> “At the level of chance”	<u>BAHA:</u> “At the level of chance”		No data presented. No statistical analysis performed.	Low
Hol et al. 2010b (Eur Arch Otorhino- laryngol)	The Netherlands	Randomised, cross-over study	10	2 CROS 1 BAHA 3 CIC	<u>Unaided:</u> <u>500 Hz</u> 54 % <u>3 000 Hz</u> 61 %	<u>CROS:</u> <u>500 Hz</u> 53 % <u>3 000 Hz</u> 49 %	<u>BAHA:</u> <u>500 Hz</u> 56 % <u>3 000 Hz</u> 59 %	<u>CIC:</u> <u>500 Hz</u> 53 % <u>3 000 Hz</u> 70 %	No statistical analysis performed.	Low

Table 4. Complications in bone anchored hearing aid surgery.
SSD = Single-sided deafness

Author, year,	Country	Study group	Postoperative complication	Skin reactions	Revision surgery / longer abutment	Implant loss	New implant	Comment
de Wolf et al 2008	The Netherlands	n = 142 <u>Follow-up</u> 1-10.5 years (mean 5.6)		n = 40 (28.2 %)	Revision surgery n = 20 (14.1 %) Longer abutment n = 6 (4.2 %)	n = 14 (9.9 %)		3 SSD patients
House et al 2007	USA	n = 149 Consecutive patients 2001-2005 <u>Follow-up</u> No data	Wound infection n = 2 (1.3 %) Flap necrosis n = 1 (0.7 %)	Skin overgrowth n = 11 (7.4 %)	n = 11 (7.4 %)	n = 5 (3.4 %)	n = 3 (2.0 %)	127 SSD patients.
Hol et al 2010a (Annals of Otolaryg...)	The Netherlands	n = 56 <u>Follow-up</u> No data	No data	No data	No data	n = 1 (1.7 %)		Patients with both congenital and aquired unilateral deafness.
Mace et al 2009	UK	n = 60 Surgery 1996-2006	No data	n = 17 (25.8 %)	Revision surgery n = 7 (10.6%)	n = 2 (3.0 %)	n = 2 (3.0%)	5 SSD patients
McDermott et al 2009	UK	n = 182 (230 implants) <u>Follow-up</u> 4-13 years <u>Age</u> <16 years 107 with significant medical history**	No data	n = 34 (18.7 %)	Revision surgery n = 14 (7.7 %) Longer abutment n = 15 (8.2 %)	n = 32 (17.6%) 25/32 lost implants were 3mm. Failure rate and age: <3 years: 40% 3-5: 38% 5-10: 8% >10 years: 1%	No data	No SSD patients
Reyes et al 2000	Sweden	n = 149 <u>Follow-up</u> 8 years	No data	Holger index for 149 patients: Grade >2 : n = 5 (3 %)	No data	n = 9 (6.0 %)	No data	No SSD patients
Shirazi et al 2006	USA	n = 58 <u>Follow-up</u> No data	Loss of skin graft n = 6 (10.3 %)	Skin overgrowth n = 3 (5.2 %)	Revision surgery n = 1 (1.7 %) Longer abutment n = 1 (1.7 %)	n = 2 (3.4 %)	n = 2 (3.4 %)	25 SSD patients

Table 4. Complications in bone anchored hearing aid surgery.
SSD = Single-sided deafness

Author, year,	Country	Study group	Postoperative complication	Skin reactions	Revision surgery / longer abutment	Implant loss	New implant	Comment
Van de Berg et al 2010	The Netherlands	n = 143 <u>Follow-up</u> 3-147 months	No data	Holger index for 143 patients: Grade >2 n = 16 (11,2 %)	n = 19 (13.3 %)	n = 3 (2.1 %)	n = 3 (2.1 %)	19 SSD patients.
Van Rompaey et al 2011	Belgium	n = 138 <u>Follow-up</u> 7-120 months (mean 61)	No data	Holger index for 82 patients: Grade >2 n = 24 (30 %) Skin overgrowth n = 19 (13.8 %)	n = 30 (22 %)	n = 9/82 (9 %)	No data	Number of SSD-patients not stated. Loose abutment reported in 20 patients (14.5 %).
Wazen et al 2008	USA	n = 218 (223 implants) <u>Follow-up</u> 4 -114 months (mean 44) <u>Age</u> 6-92 years, (mean 56)	n = 4 (1.8 %) Hematoma Abscess Bleeding Flap necrosis	Hypertrophic scar n = 10 (4.6 %) Dermatis n = 3 (1.4 %) Skin overgrowth n = 4 (1.8 %) Keloid formation n = 4 (1.8 %)	Revision surgery n = 10 (4.6 %) Longer abutment n = 1 (0.5 %)	n = 3 (1.4 %)	n = 3 (1.4 %)	114 SSD patients.
Welling et al. 1991	USA	n = 43 <u>Follow-up</u> up to 24 months <u>Age</u> 26-29 years, (mean 46)		Minor skin reaction: n = 19 (44 %) Need of flap revision: n = 1 (2.3 %)				

**Goldenhar syndrome, Treacher Collins syndrome, unusual chromosome deletions, Down syndrome, Pierre Robin syndrome, Turner syndrome, CHARGE syndrome.
SSD: single sided deafness, or unilateral profound hearing loss.

Appendix 2

Study (author, publication year)	Reason for exclusion
Andersen 2006	Case series with less than 30 patients
Arndt 2010	Not the correct intervention
Bergeron 2006	Systemic review including only case series
Bovo 2011	Case series with less than 30 patients
Christensen 2010	Case series with less than 30 patients
CADTH 2010	Systematic review based on a limited literature search
Danhauer 2010	Systematic review of another patient category
Gluth 2010	Case series with less than 30 patients
Hol 2004	Case series with less than 30 patients
Hol 2005b (Audiol Neurotol)	Case series with less than 30 patients
Hol 2005a (Otology & Neurotol)	Case series with less than 30 patients
Kunst 2008	Case series with less than 30 patients
Lin 2006	Case series with less than 30 patients
Linstrom 2009	Not the correct comparison
McLarnon 2004	Case series with no data on complications reported

Appendix 2

Study (author, publication year)	Reason for exclusion
Niparko 2003	Case series with less than 30 patients
Ontario Health Technology Assesment series 2002	Systemic review including only case series
Pfiffner 2009	Case series with less than 30 patients
Priwin 2007	Not the correct patient category
Vaneecloo 2001	Case series with less than 30 patients
Wazen 2003	Case series with less than 30 patients
Wazen 2010	Case series with less than 30 patients
Yuen 2009	Case series with less than 30 patients

Appendix 3: Search strategy, study selection and references

Question(s) at issue:

Is bone anchored hearing aid system better than contralateral routing of signals or no hearing device in patients with profound unilateral hearing loss with regard to speech recognition, hearing threshold, sound localization, and quality of life?

PICO (P= Patients, I= Intervention, C= Comparison, O=Outcome)

The central question at issue includes three different comparisons, i.e. PICO 1 - 3

P = Adults and children with unilateral deafness (or hearing loss) and normal hearing on the other side

I1 = BAHA

C1 = CROS (Contralateral routing of signals)

I2 = BAHA

C2 = No hearing device

I3 = CROS

C3 = No hearing device

O = Speech recognition, Hearing threshold, Sound localization, Quality of Life

Quality of Life

Health care costs

Search strategy:

PubMed (2011-02-10)

bone-anchored hearing aid OR bone-anchored hearing aids OR baha OR Osseointegrated hearing aid OR Osseointegrated hearing aids OR CROS OR Contralateral Routing of Signals
AND

Hearing loss, unilateral OR ((unilateral OR one-sided OR single-sided) AND (deafness OR deaf OR hearing impairment))

90 results

The Cochrane Library (2011-02-10)

bone-anchored hearing aid):ti,ab,kw or (bone-anchored hearing aids):ti,ab,kw or (BAHA):ti,ab,kw or (osseointegrated hearing aid):ti,ab,kw or (Osseointegrated hearing aids):ti,ab,kw OR (CROS):ti,ab,kw or (Contralateral Routing of Signals):ti,ab,kw
AND

((unilateral):ti,ab,kw or (one-sided):ti,ab,kw or (single-sided):ti,ab,kw) AND deafness):ti,ab,kw or (deaf):ti,ab,kw or (hearing impairment):ti,ab,kw)) OR (hearing loss, unilateral):ti,ab,kw)

10 results

Cochrane reviews **0**

Other reviews **1**

Clinical trials **5**
Technology Assessments **4**
Economic evaluations **0**

EMBASE (OVID SP) (2011-02-10)

bone-anchored hearing aid.mp OR exp bone anchored hearing aid OR bone-anchored hearing aids.mp. OR BAHA.mp OR Osseointegrated hearing aid.mp. OR Osseointegrated hearing aids.mp. OR CROS.mp. OR Contralateral Routing of Signals.mp.

AND

unilateral hearing loss OR ((one-sided.mp. OR single-sided.mp. OR unilateral mp.) AND (deafness.mp. OR deaf,mp) OR exp hearing impairment))

101 results

CINAHL (EBSCO) (2011-02-10)

TX bone-anchored hearing aid OR TI bone-anchored hearing aids OR TX BAHA OR TX osseointegrated hearing aid OR TX osseointegrated hearing aids OR CROS

AND

((TX Unilateral OR TX one-sided OR TX single-sided) AND (TX deaf OR deafness OR TX hearing impairment)) OR TX hearing loss, unilateral

30 results

PsycInfo (2011-02-10)

bone-anchored hearing aid.mp. OR bone-anchored hearing aids.mp. OR BAHA.mp. OR osseointegrated hearing aids.mp. OR osseointegrated aids.mp. OR CROS.mp. OR Contralateral Routing of Signals.mp.

AND

((unilateral.mp. OR one-sided.mp. OR single-sided.mp.) AND (exp deaf OR deafness.mp. OR hearing impairment)) OR hearing loss, unilateral.mp.

4 results

CRD (2011-02-10)

BAHA OR (bone-anchored AND hearing AND aid) OR (bone-anchored AND hearing AND Aids) OR CROS

13 results

CADTH (Canadian Agency for Drugs and Technologies in Health) (2011-02-10)

1 results

SBU, Kunnskapssenteret, Sundhedsstyrelsen

Nothing new was identified.

Reference lists:

A comprehensive review of reference lists brought no new references.

Exklusions- och inklusionskriterier**Studietyp:**

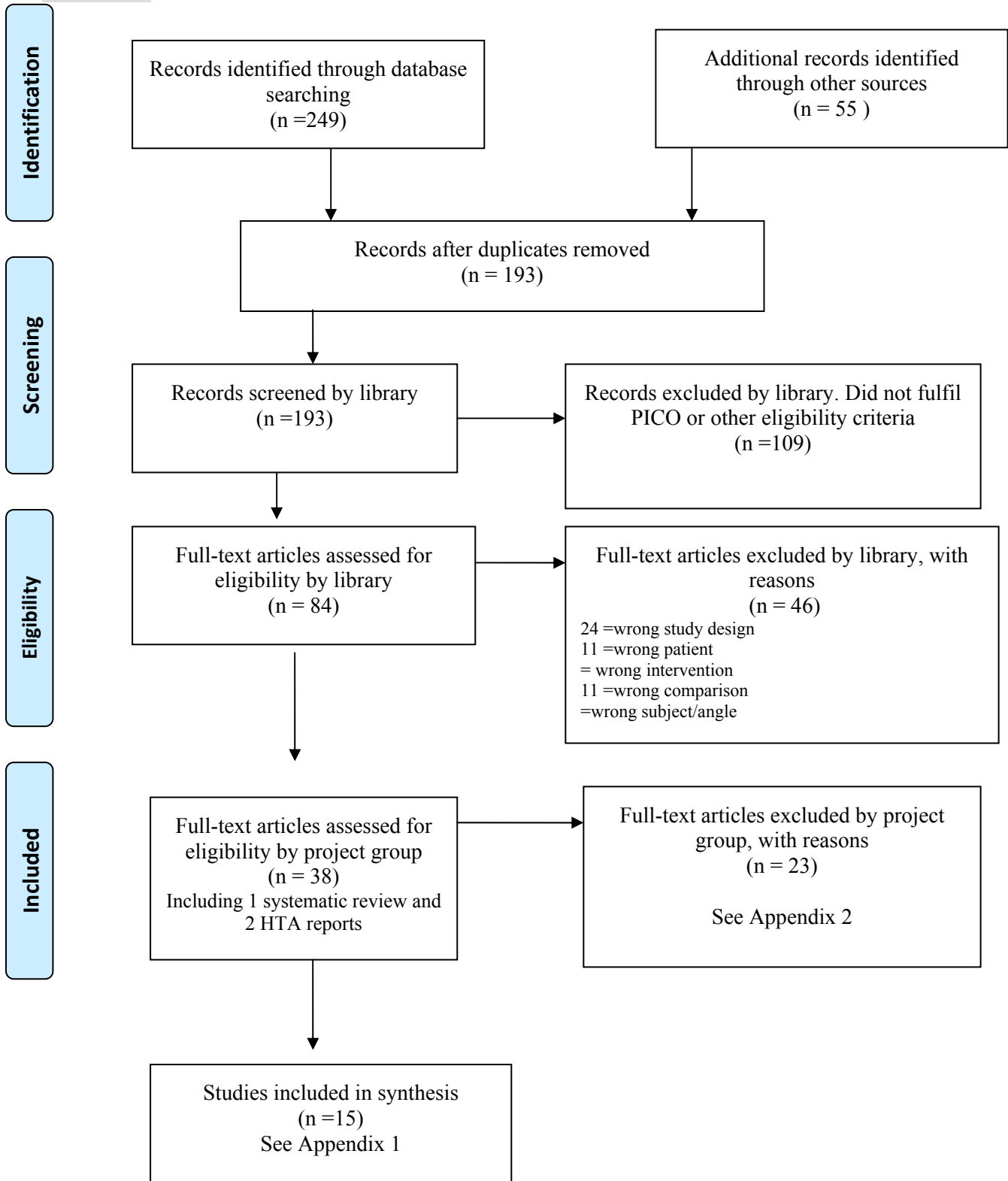
- Studies with some kind of control group (RCT/Observation studies)
- Case series ≥ 30 patients – only complications
- Systematic reviews
- No case reports or review articles

Limits

Language: English, Danish, Norwegian, Swedish and non English with English abstracts

Publication date from 1977-

Selection process – flow diagram



References

Included articles:

Bosman AJ, Hol MK, Snik AF, Mylanus EA, Cremers CW. Bone-anchored hearing aids in unilateral inner ear deafness. *Acta Otolaryngol.* 2003 Jan; 123(2):258-60.

de Wolf MJ, Hol MK, Huygen PL, Mylanus EA, Cremers CW. Clinical outcome of the simplified surgical technique for BAHA implantation. *Otol Neurotol.* 2008 Dec; 29 (8):1100-8.

Hol MKS, Kunst SJW, Snik AFM, Cremers CWRJ. Pilot study on the effectiveness of the conventional CROS, the transcranial CROS and the BAHA transcranial CROS in adults with unilateral inner ear deafness. *European Archives of Oto-Rhino-Laryngology.* 2010b June; 267 (6):889-96.

Hol MKS, Kunst SJW, Snik AFM, Bosman AJ, Mylanus EAM, Cremers CWR. Bone-anchored hearing aids in patients with acquired and congenital unilateral inner ear deafness (Baha CROS): clinical evaluation of 56 cases. *Annals of Otology, Rhinology & Laryngology.* 2010a: 119(7):447-54.

House JW, Kutz Jr JW, Chung J, Fisher LM. Bone-anchored hearing aid subjective benefit for unilateral deafness. *Laryngoscope.* 2010 March; 120 (3):601-7.

House JW, Kutz JW, Jr. Bone-anchored hearing aids: incidence and management of postoperative complications. *Otol Neurotol.* 2007 Feb; 28(2):213-7.

Mace ATM, Isa A, Cooke LD. Patient quality of life with bone-anchored hearing aid: 10-year experience in Glasgow, Scotland. *Journal of Laryngology and Otology.* 2009 Sept; 123 (9):964-8.

McDermott AL, Williams J, Kuo M, Reid A, Proops D. The birmingham pediatric bone-anchored hearing aid program: a 15-year experience. *Otol Neurotol.* 2009 Feb; 30 (2): 178-83.

Martin TP, Lowther R, Cooper H, Holder RL, Irving RM, Reid AP, et al. The bone-anchored hearing aid in the rehabilitation of single-sided deafness: experience with 58 patients. *Clin Otolaryngol.* 2010 Aug; 35(4):284-90.

Reyes RA, Tjellström A, Granström G. Evaluation of implant losses and skin reactions around extraoral bone-anchored implants: A 0- to 8-year follow-up. *Otolaryngol Head Neck Surg.* 2000 Feb; 122 (2): 272-6.

Shirazi MA, Marzo SJ, Leonetti JP. Perioperative complications with the bone-anchored hearing aid. *Otolaryngol Head Neck Surg.* 2006 Feb; 134(2):236-9.

Van de Berg R, Stokroos RJ, Hof JR, Chenault MN. Bone-anchored hearing aid: a comparison of surgical techniques. *Otol Neurotol.* 2010 Jan; 31 (1): 129-35.

Van Rompaey V, Claes G, Verstraeten N, van Dinther J, Zarowski A, Offeciers E, et al. Skin reactions following BAHA surgery using the skin flap dermatome technique. *Eur Arch Otorhinolaryngol.* 2011 Oct; 268:373-76.

Wazen JJ, Young DL, Farrugia MC, Chandrasekhar SS, Ghossaini SN, Borik J, et al. Successes and complications of the Baha system. *Otol Neurotol.* 2008 Dec; 29(8):1115-9.

Welling DB, Glasscock ME, 3rd, Woods CI, Sheffey RC. Unilateral sensorineural hearing loss rehabilitation. *Otolaryngol Head Neck Surg.* 1991 Dec; 105(6):771-6.

Excluded articles:

Andersen HT, Schroder SA, Bonding P. Unilateral deafness after acoustic neuroma surgery: subjective hearing handicap and the effect of the bone-anchored hearing aid. *Otol Neurotol*. 2006 Sep; 27(6):809-14.

Arndt S, Aschendorff A, Laszig R, Beck R, Schild C, Kroeger S, et al. Comparison of pseudobinaural hearing to real binaural hearing rehabilitation after cochlear implantation in patients with unilateral deafness and tinnitus. *Otol Neurotol*. 2010 Jan; 32(1):39-47.

Bergeron FF. Bone-anchored hearing aids: summary: report prepared for AETMIS. Québec May 2006

Bone anchored hearing aid: an evidence-based analysis. Ontario Health Technology Assessment series 2002; Vol. 2, No 3. 47 s.

Bovo R, Prosser S, Ortoro RP, Martini A. Speech recognition with BAHA simulator in subjects with acquired unilateral sensorineural hearing loss. *Acta Oto-Laryngologica*, 2011: Early Online, 1-7.

Christensen L, Richter GT, Dornhoffer JL. Update on bone-anchored hearing aids in pediatric patients with profound unilateral sensorineural hearing loss. *Arch Otolaryngol Head Neck Surg*. 2010 Feb; 136(2):175-7.

CADTH. Completely-in-the Canal and Bone Anchored Hearing Aids: A review of the Clinical Effectiveness and Cost-effectiveness, 2010.

Danhauer JL, Johnson CE, Mixon M. Does the evidence support use of the Baha implant system (Baha) in patients with congenital unilateral aural atresia? *J Am Acad Audiol*. Apr; 21(4):274-86.

Gluth MB, Eager KM, Eikelboom RH, Atlas MD. Long-term benefit perception, complications, and device malfunction rate of bone-anchored hearing aid implantation for profound unilateral sensorineural hearing loss. *Otol Neurotol*. 2010 Dec; 31(9):1427-34.

Hol MKS, Bosman A, Snik AFM, Mylanus, Cremers CWR. Bone-anchored hearing aid in unilateral ear deafness: a study of 20 patients. *Audiol Neurootol*; 2004 Sept-Oct; 9(5): 274-81

Hol MKS, Bosman A, Snik AFM, Mylanus, Cremers CWR. Bone-anchored hearing aids in unilateral inner ear deafness: an evaluation of audimetric and patient outcome measurements. *Otology & Neurotology* 2005a Sept; 26(5): 999-106.

Hol MKS, Bosman A, Snik AFM, Mylanus, Cremers CWR. Does the bone-anchored hearing aid have a complementary effect on audiological and subjective outcomes in patients with unilateral conductive hearing loss? *Audiol Neurootol* 2005b May-Jun; 10(3): 159-68.

Kunst SJW, Leijendeckers JM, Mylanus EAM, Hol MKS, Snik AFM, Cremers CWRJ. Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: Audiometric results. *Otology and Neurotology*. 2008 Jan ; 29 (1):2-7.

Lin LM, Bowditch S, Anderson MJ, May B, Cox KM, Niparko JK. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. *Otol Neurotol*. 2006 Feb; 27(2):172-82.

Linstrom CJ, Silverman CA, Yu GP. Efficacy of the bone-anchored hearing aid for single-sided deafness. *Laryngoscope*. 2009 Apr; 119(4):713-20.

McLarnon CM, Davison T, Johnson IJM. Bone-Anchored Hearing Aid: Comparison of Benefit by Patient Subgroups. *Laryngoscope*. 2004 May; 114 (5):942-4.

Niparko JK, Cox KM, Lustig LR. Comparison of the bone anchored hearing aid implantable hearing device with contralateral routing of offside signal amplification in the rehabilitation of unilateral deafness. *Otol Neurotol*. 2003 Jan;24(1):73-8.

Pfiffner F, Kompis M, Stieger C. Bone-anchored Hearing Aids: correlation between pure-tone thresholds and outcome in three user groups. *Otol Neurotol*. 2009 Oct; 30(7):884-90.

Priwin C, Jonsson R, Hultcrantz M, Granstrom G. BAHA in children and adolescents with unilateral or bilateral conductive hearing loss: a study of outcome. *Int J Pediatr Otorhinolaryngol*. 2007 Jan; 71(1):135-45.

Vaneeecloo FM, Ruzza I, Hanson JN, Gerard T, Dehaussy J, Cory M, et al. [The monaural pseudo-stereophonic hearing aid (BAHA) in unilateral total deafness: a study of 29 patients]. *Rev Laryngol Otol Rhinol (Bord)*. 2001; 122(5):343-50.

Wazen JJ, Spitzer JB, Ghossaini SN, Fayad JN, Niparko JK, Cox K, et al. Transcranial contralateral cochlear stimulation in unilateral deafness. *Otolaryngol Head Neck Surg*. 2003 Sep; 129(3):248-54.

Wazen JJ, Van Ess MJ, Alameda J, Ortega C, Modisett M, Pinsky k. The Baha system in patients with single-sided deafness and contralateral hearing loss. *Otolaryngol Head Neck Surg* 2010 Apr; 142(4): 554-559.

Yuen HW, Bodmer D, Smilsky K, Nedzelski JM, Chen JM. Management of single-sided deafness with the bone-anchored hearing aid. *Otolaryngol Head Neck Surg*. 2009 Jul; 141(1):16-23.

Other:

Andersson E, Andersson M, Börjesson E, Heneskog R, Jönsson R, Lundqvist AL et al. Spädbarn med hörselnedsättning: diagnostik och habilitering. Vällingby: Hjälpmedelsinstitutet; Göteborg:- Västra Götalandsregionen, 2002 [updated 2010 Feb 1; cited 2011 Sept 21]. Available from: <http://www.hi.se/Global/pdf/2002/02364.pdf>

Borton SA, Mauze E, Lieu JE. Quality of life in children with unilateral hearing loss: a pilot study. *Am J Audiol*. 2010 Jun;19(1):61-72.

[Checklists from SBU regarding randomized controlled trials. [Internet]. [cited 2011 Oct 13] Available from: http://www.sahlgrenska.se/upload/SU/HTA-centrum/Hj%c3%a4lpmedel%20under%20projektet/SBU_granskningsmall_RCT.pdf

Gatehouse S, Noble W. The Speech, Spatial and Qualities of Hearing Scale (SSQ). *Int J Audiol*. 2004 Feb;43(2):85-99.

GRADE Working Group. Grading quality of evidence and strength of recommendations. *BMJ*. 2004 Jun 19; 328(7454):1490-4.

GRADE Working Group. List of GRADE working group publications and grants [Internet]. [Place unknown]: GRADE Working Group, c2005-2009 [cited 2011 Oct 13]. Available from: <http://www.gradeworkinggroup.org/publications/index.html>

Harford E, Barry J. A rehabilitative approach to the problem of unilateral hearing impairment: the contralateral routing of signals CROS. *J Speech Hear Disord*. 1965 May; 30:121-38.

Holmgren S, Bertilsson Uleberg G, editors. RED10 research evaluation : reports from the evaluation of all research at the University of Gothenburg 2010. Göteborg: University of Gothenburg, 2011

Lieu JE, Tye-Murray N, Karzon RK, Piccirillo JF. Unilateral hearing loss is associated with worse speech-language scores in children. *Pediatrics*. 2010 Jun;125(6):e1348-55.

Lieu JE. Speech-language and educational consequences of unilateral hearing loss in children. *Arch Otolaryngol Head Neck Surg*. 2004 May;130(5):524-30.

Martinez-Cruz CF, Poblano A, Conde-Reyes MP. Cognitive performance of school children with unilateral sensorineural hearing loss. *Arch Med Res*. 2009 Jul;40(5):374-9.

Mehl AL, Thomson V. The Colorado newborn hearing screening project, 1992-1999: on the threshold of effective population-based universal newborn hearing screening. *Pediatrics*. 2002 Jan; 109 (1): E7.

Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med*. 2009 Jul 21; 6(7):e1000097.

Monksfield P, Jowett S, Reid A, Proops D. Cost-effectiveness Analysis of the Bone-Anchored Hearing Device. *Otol Neurotol*. 2011 Oct; 32 (8): 1192-7.

[Nyren, Olle. Karolinska institutet. Checklists original articles not RCT]. [Internet]. [cited 2011 Oct 13] Available from: <http://www.sahlgrenska.se/upload/SU/HTA-centrum/Hj%c3%a4lpmedel%20under%20projektet/SBU%20granskningsmall%20utan%20RCT%20o%20SR%202011.pdf>

Schrøder SA, Ravn T, Bonding P. BAHA in single-sided deafness: patient compliance and subjective benefit. *Otol Neurotol*. 2010 Apr; 31(3):404-8.

Vartiainen E, Karjalainen S. Prevalence and etiology of unilateral sensorineural hearing impairment in a Finnish childhood population. *Int J Pediatr Otorhinolaryngol*. 1998 May 15; 43 (3): 253-9.

Summary of Findings Table

Bone anchored hearing aid (BAHA) in comparison to contralateral routing of signals (CROS) or no intervention

Outcome variable	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Level of evidence GRADE
Number of studies								

Speech recognition								
3	1 RCT 2 observational studies	Very serious limitations (-2)	No important inconsistency	Uncertainty (-1)	Imprecision (-1)	Unlikely	Not relevant	⊕ Very low
Sound localisation								
3	1 RCT 2 observational studies	Very serious limitations (-2)	No important inconsistency	Uncertainty (-1)	Imprecision (-1)	Unlikely	Not relevant	⊕ Very low
Subjective experience								
4	1 RCT 3 observational studies	Very serious limitations (-2)	Some inconsistency (?)	Uncertainty (-1)	Imprecision (-1)	Unlikely	Not relevant	⊕ Very low

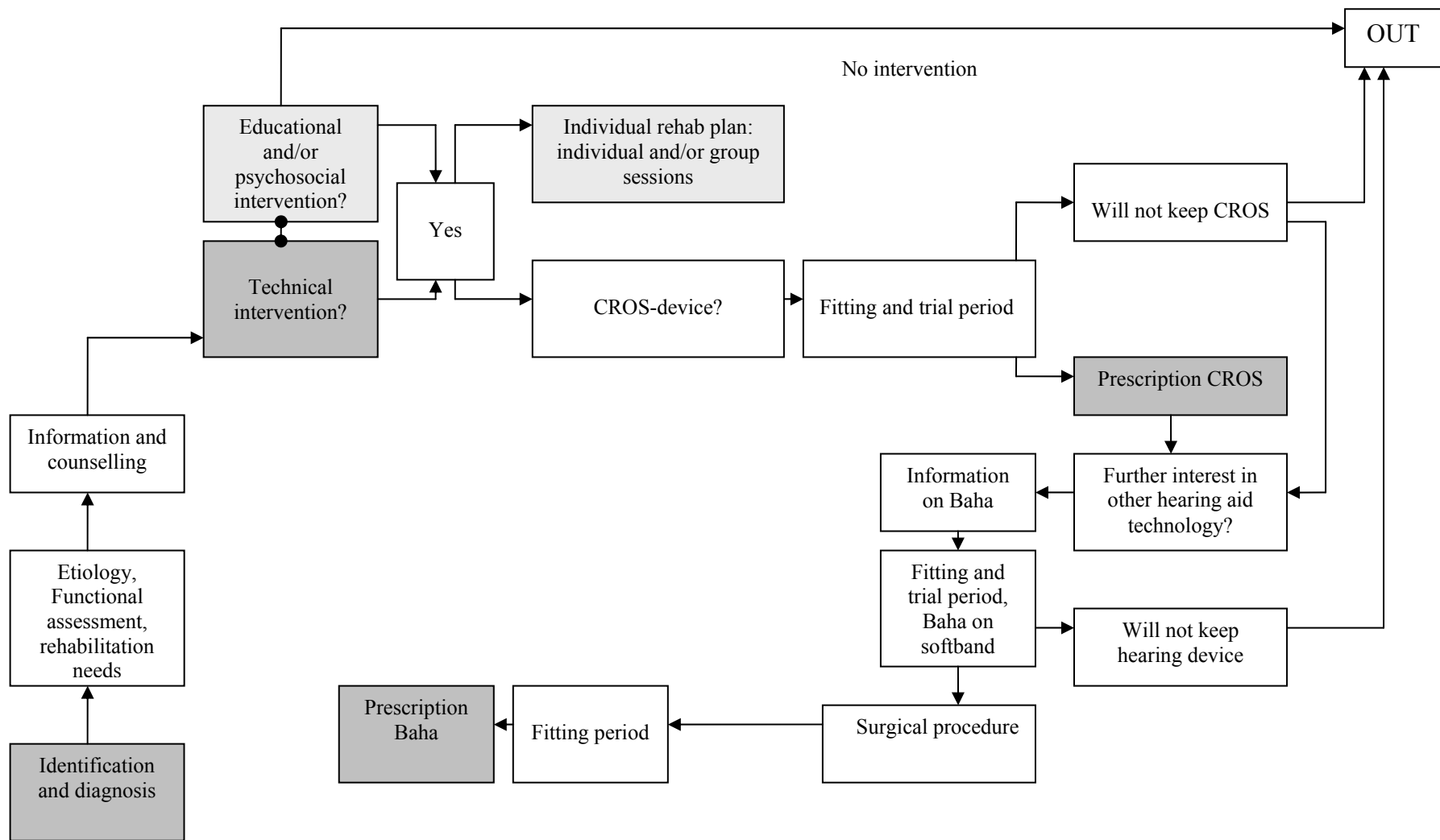
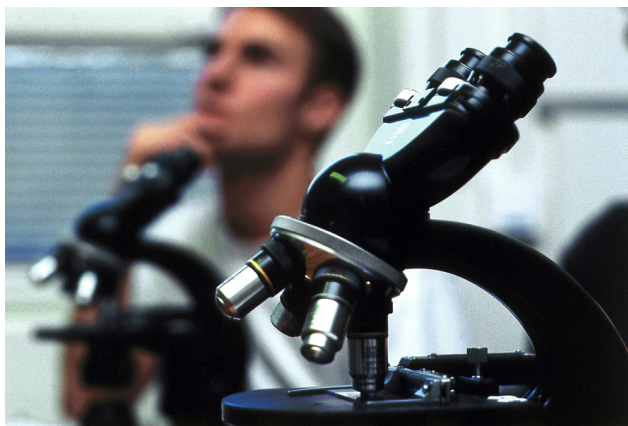


Figure 1. The normal pathway of a patient with unilateral severe hearing loss through the health care system. After prescription of hearing device, the patient will return for service, reparation of the hearing aid, and re-fitting after 5-7 years.



HTA

Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the quality of evidence the Centre of Health Technology Assessment in Region Västra Götaland is

currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High quality of evidence	= ⊕⊕⊕⊕
Moderate quality of evidence	= ⊕⊕⊕
Low quality of evidence	= ⊕⊕
Very low quality of evidence	= ⊕

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

For diagnostic studies, the GRADE system should be applied for clinical outcomes and we have thus chosen not to use it for diagnostic accuracy studies.. In the present report, we have evaluated the level of evidence for diagnostic accuracy according to the system previously used by SBU, (Swedish Council on Health Technology Assessment), briefly described below.

High level of evidence

At least two studies of high quality or a systematic review of good quality

Moderate level of evidence

One study of high quality and at least two studies of moderate quality

Low level of evidence

At least two studies of moderate quality

Very low level of evidence

Only studies of low quality

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