# A Cost-Utility Analysis of the Transcutaneous OSIA® System Compared to Percutaneous Devices for Hearing Loss in Sweden

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## INTRODUCTION

- Hearing loss has far-reaching consequences, negatively affecting speech and language development, relationships, social interactions, education, employment, quality of life, mental health and independence at various stages of life[1-4]
- Globally, more than 1.5 billion people experience a deterioration of hearing during their lifetime[4]
- Due to the aging population in Sweden and other developed countries, hearing loss is likely to become an increasingly prevalent disability[1]
- Surgical bone-conducting hearing implants (BCHIs) provide a benefit to eligible patients with conductive hearing loss (CHL), mixed hearing loss (MHL), and single-sided deafness (SSD),[5] when conventional hearing aids can no longer provide a benefit or are contraindicated[6,7]
- BCHIs are categorised as percutaneous or transcutaneous based on their method of attachment to the patient. Because percutaneous devices have direct contact with the skull, there is greater potential for adverse skin reactions compared to transcutaneous devices[5]
- The Osia® System (Osia) is an active (the transducer is implanted under the skin) transcutaneous solution and is the first osseointegrated steady-state implant approved for people with CHL, MHL, and SSD and bone conduction hearing loss up to 55 dB[8]
- Selecting the optimal BCHI requires consideration of general indications, guidelines, safety, patient preferences and costs

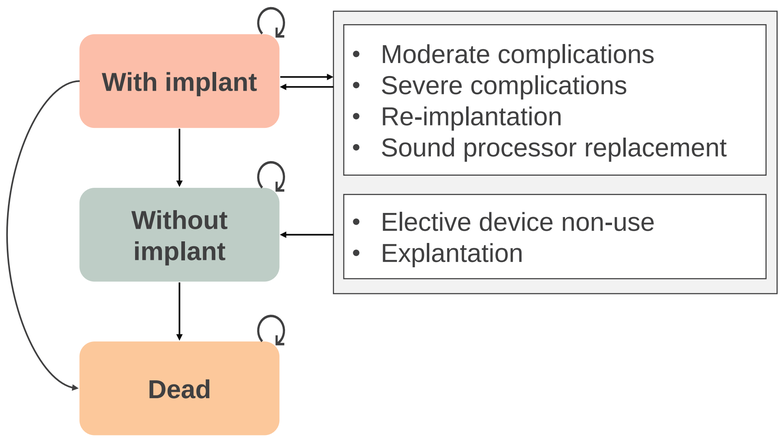
## OBJECTIVES

- The objective of this cost-utility analysis (CUA) was to assess the cost-effectiveness of treating CHL, MHL, and SSD patients with Osia compared to percutaneous implants over a lifetime horizon, from the perspective of the Swedish healthcare system

## METHODS

- The analysis used a Markov model (Figure 1) with three health states, six-month cycles and a lifetime horizon (to 100 years of age). A half-cycle correction was used to prevent over or underestimation of the costs and benefits of treatment, which were both discounted at an annual rate of 3.0%[9]
- In the initial “with implant” state, patients were implanted with either Osia or a percutaneous device. In this state, patients could experience moderate or severe complications, or explantation (removal of the device potentially followed by re-implantation), which results in additional costs and patient burden
- Patients could transition to a “without implant” state based on a probability of non-use (e.g. patients who discontinue their device due to low effectiveness), and a probability of explantation without re-implantation due to a severe complication. No direct costs or risks of complications associated with implants were assigned to patients in the “without implant” state
- To estimate mortality, 2019 life expectancy data for Sweden was used from the World Health Organisation, assuming hearing loss did not impact mortality[10]

**Figure 1 – Model structure**




- The model considered adult patients with hearing loss ≤55 dB and aged 59 years and older
- Utilities derived from the Health Utilities Index Mark III (HUI3) questionnaire were sourced from the literature and were used to calculate quality-adjusted life years (QALY) (Table 1)
- Individuals receiving an implant had an improvement in health-related quality of life that was assumed to not deteriorate over time, provided they continued to use their device

**Table 1 – Health utilities**

| Health state | Utility | Reference |
|---|---|---|
| Baseline (without implant) | 0.670 | Brunner et al. 2024[11] |
| Osia (mean change) | 0.090 | Brunner et al. 2024[11] |
| Percutaneous devices (mean change) | 0.048 | Van Hoof et al. 2020[12] |

- Complications were divided into moderate complications, which were assumed to require a physician visit and conservative management, and severe complications, which required hospitalisation or revisional surgery (Table 2)
- The cost of each surgical procedure and the cost of management required to treat various complications were derived from the Swedish National Board of Health and Welfare[13] (Table 3)

**Table 2 – Complication probabilities**

| Intervention | Complication | Six-month probability | References |
|---|---|---|---|
| Osia | Moderate complication | 1.35% | Key et al. 2023[14] |
| | Severe complication | 1.80% | Key et al. 2023[14] |
| | Explantation | 6.10%* | Key et al. 2023[14] |
| | Reimplantation | 78.04%† | Crowder et al. 2021[15] |
| | Non-use | 2.60% | Cowan et al. 2023[15] |
| Percutaneous devices | Moderate complication | 2.72% | Teunissen et al. 2024[16] |
| | Severe complication | 1.93% | Teunissen et al. 2024[16] |
| | Explantation | 10.12%* | Teunissen et al. 2024[16] |
| | Reimplantation | 83.24%† | Teunissen et al. 2024[16] |
| | Non-use | 0.58% | Teunissen et al. 2024[16] |

*Conditional to severe complications; †Conditional to explantation

## METHODS (continued)

**Table 3 – Costs**

| | Osia | Percutaneous devices |
|---|---|---|
| Procedure | 121,334 SEK | 28,587 SEK |
| Moderate complication | 4,467 SEK | |
| Severe complication | 20,060 SEK | |
| Explantation | 12,408 SEK* | 5,029 SEK† |
| Reimplantation | 121,334 SEK | 28,587 SEK |

*Assuming 20 minutes procedure; †Assuming 5 minutes procedure

- In Sweden, no public willingness to pay (WTP) thresholds are available. Therefore, various thresholds were used to determine cost-effectiveness following the methodology identified by the Swedish Agency for Health Technology Assessment and Assessment of Social Services[17]

## RESULTS

- Osia was associated with an increased cost of 79,293 SEK and increased QALYs of 0.73 compared to percutaneous devices, resulting in an incremental cost-effectiveness ratio of 108,318 SEK /QALY gained (Table 4)

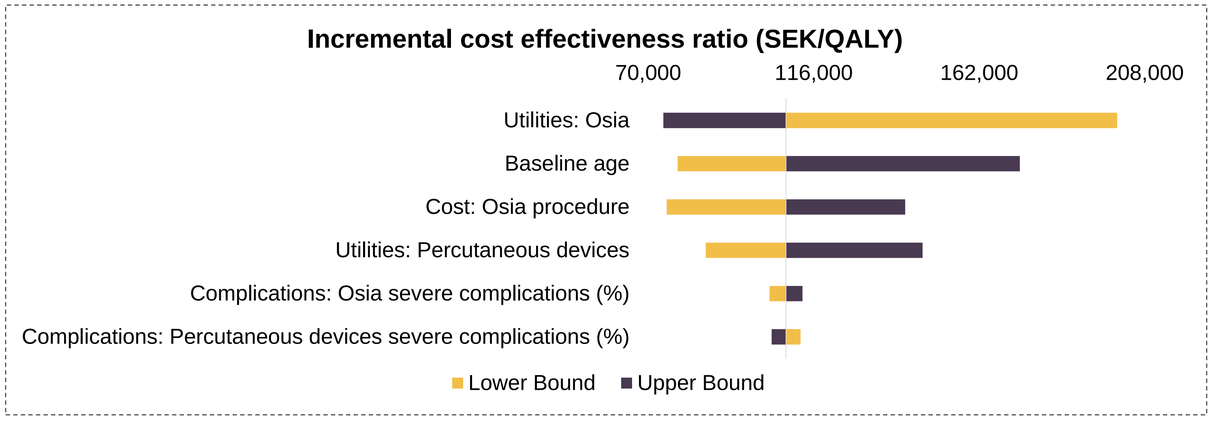
**Table 4 – Results**

| | Osia | Percutaneous devices |
|---|---|---|
| Total costs per patient | 336,642 SEK | 257,349 SEK |
| Total QALYs per patient | 15.28 | 14.55 |
| Incremental cost per patient | 79,293 SEK | |
| Incremental QALYs per patient | 0.73 | |
| **ICER** | **108,318 SEK/QALY** | |

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year

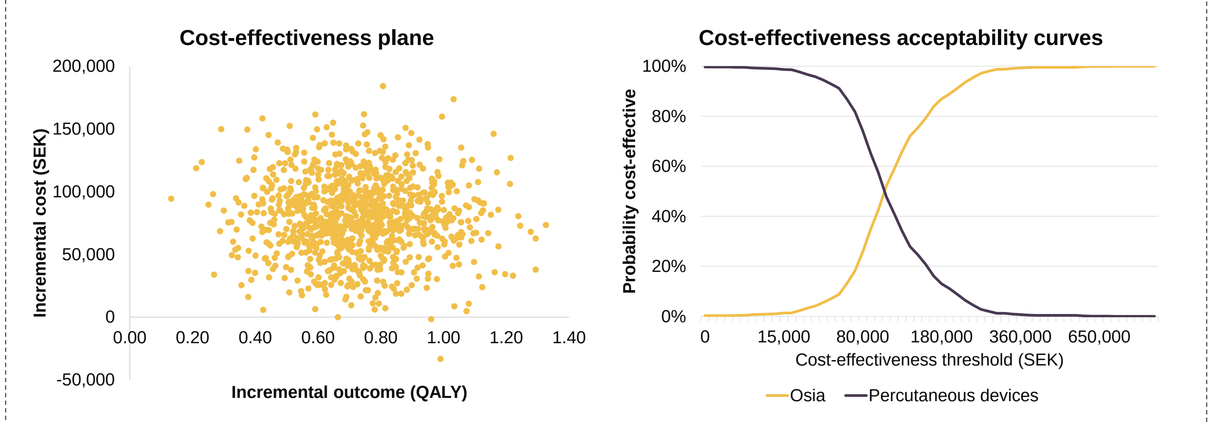
- A deterministic sensitivity analysis (DSA) showed that key drivers of the CUA were the baseline age, the cost of the Osia procedure, and the mean utility gain for Osia (Figure 2)
- In the DSA, all parameters were independently varied by +/-20% of the base-case parameter value

**Figure 2 – Tornado diagram**




- Results of the probabilistic sensitivity analysis (PSA) showed that the probability of Osia being cost-effective at a moderate cost per QALY WTP ranged from 43% (WTP equal to 100,000 SEK/QALY) to 100% (WTP equal to 500,000 SEK/QALY) (Figure 3)
- The cost per QALY was categorised as low (<100,000 SEK), moderate (100,000–499,999 SEK), high (500,000–1,000,000 SEK) or very high (>1,000,000 SEK) in the National Guidelines for cardiac care by the Swedish National Board for Health and Welfare[17,18]

**Figure 3 – Probabilistic sensitivity analysis results**




QALY, quality-adjusted life year

## DISCUSSION AND CONCLUSIONS

- This model was developed to compare the Osia active transcutaneous device with percutaneous implants for the treatment of CHL, MHL, and SSD in Sweden
- The results show that Osia is cost-effective compared to percutaneous devices over a lifetime horizon at relevant WTP thresholds in Sweden
- Both types of implants improve hearing outcomes; however, transcutaneous devices (such as Osia) have lower rates of skin reactions than percutaneous devices, which use protruding, skin-penetrating abutments
- The differences in utility scores may be linked to the different complication rates (reflected in the “pain” attribute) and patient preferences (“emotion” attribute); however, not all studies measuring HUI3 report scores for all attributes and comparisons were therefore not possible
- The main limitation of this model is the absence of a head-to-head study comparing Osia and percutaneous devices, and consequently, inputs were sourced from different clinical studies
- Lastly, no differentiation was considered for patients with CHL, MHL, or SSD due to the overall lack of disaggregated evidence for the individual conditions

## REFERENCES

1. Cunningham et al. *N Engl J Med*. 2017
2. Niemensivu et al. *Int J Audiol*. 2015
3. Nordvik et al. *BMC Ear Nose Throat Disord*. 2018
4. World Health Organization. *who.int*. 2021
5. Ellsperman et al. *Audiol Res*. 2021
6. Briggs et al. *Otol Neurotol*. 2022
7. Mylanus et al. *Otol Neurotol*. 2020
8. Cochlear Ltd. *cochlear.com*. 2024
9. Williams et al. *J Comp Eff Res*. 2023
10. World Health Organization. *who.int*. 2019
11. Brunner et al. *Mark Access Health Policy*. 2024
12. van Hoof et al. *Front Neurol*. 2020
13. Swedish National Board of Health and Welfare. *socialstyrelsen.se*. 2024
14. Key et al. *Laryngoscope*. 2024
15. Crowder et al. *Am J Otolaryngol*. 2021
16. Teunissen et al. *Otol Neurotol*. 2024
17. Swedish Agency for Health Technology Assessment and Assessment of Social Services. *esv.se*. 2023
18. Gumbie et al. *BMC Health Serv Res*. 2021



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