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Cost-Utility of Partially Implantable Active Middle Ear Implants for Sensorineural Hearing Loss: A Decision Analysis

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ABSTRACT

Background: Partially implantable active middle ear implants (aMEIs) offer a solution for individuals who have mild to severe sensorineural hearing loss and an outer ear medical condition that precludes the use of hearing aids. When otherwise left untreated, individuals report a lower quality of life, which may further decrease with increasing disability. In the lack of cost-effectiveness studies and long-term data, there is a need for decision modeling. **Objective:** To explore individual-level variance in resource utilization patterns following aMEI implantation. **Methods:** A Markov model was developed and analyzed as microsimulation to estimate the incremental cost utility ratio (ICUR) of partially implantable aMEIs compared with no (surgical) intervention in individuals with sensorineural hearing loss and an outer ear medical condition in Australia. Cost data were derived mostly from the Medicare Benefit Schedule and effectiveness data from published literature. A third-party payer perspective was adopted, and a 5% discount rate was applied over a 10-year time horizon. **Results:** Compared with baseline strategy, aMEIs yielded an incremental cost of Australian dollars (AUD) 13,339.18, incremental quality-adjusted life-year (QALY) of 1.35, and an ICUR of AUD 9,913.72/QALY. Of the respective number of simulated patients who visited each health state, 75.73% never had a minor adverse event, 99.82% did not experience device failure, and 97.75% did not cease to use their aMEIs. Probabilistic sensitivity analyses showed the ICUR to differ by only 0.95%. **Conclusions:** In the Australian setting, partially implantable aMEIs offer a safe and cost-effective solution compared with no intervention and are also well accepted by users.

Keywords: cost-utility, decision modeling, economic evaluation, middle ear implant.

Introduction

Partially implantable active middle ear implants (aMEIs) offer a solution for mild to severe sensorineural hearing loss when individuals are unable to wear or benefit from hearing aids (HAs). An accumulation of earwax or inflammation in the outer ear or the narrowing of the external auditory canal are common medical reasons precluding the use of HAs. These individuals are also unable to benefit from cochlear implants, as their hearing loss is not severe enough. Compared with normal-hearing peers, adults with an untreated hearing loss have a lower quality of life [1–4]. They are more likely to feel depressed, anxious, or insecure and less likely to participate in society [5–10]. Such emotional and psychosocial effects maybe more pronounced with increasing levels of hearing loss [1,2,4,11–14]. With aMEIs, individuals can achieve significantly better hearing and quality of life. For an additional review of devices approved by the U.S. Food and Drug Administration (FDA), see the report by Kahue et al. [15].

Most of the evidence on quality of life with aMEIs is limited to disease-specific health-related quality of life (HR-QOL) measures. Even though these are informative for demonstrating the benefit of health care interventions, generic measures of HR-QOL allow a comparison of outcomes across a wider range of diseases and are of more interest for policy makers [16]. A generic measure has been reported to have been used only twice in the literature on aMEI. Snik [17] used the Short Form Health Survey (SF-36), and Edfeldt et al. [18] used the Health Utility Index-Mark 3 (HUI-3) for calculating the short-term (<1 year) cost-effectiveness of different aMEIs from the health care perspective. There are ongoing studies collecting data on cost-effectiveness outcomes over a longer period. With the lack of sufficient long-term data covering a limited range of available treatment options, decision-analytic modeling can play an important role and at times may be the only way to formally inform decisions. Models can be used to test a wide range of scenarios and strategies to identify the most efficient allocation of resources and allow extrapolation to other countries, regions, and populations [19]. Furthermore, a comparison of all existing strategies in a single trial is ethically not feasible, especially when "gold standard" treatments are available and "no intervention" may preferably be considered a baseline strategy [19,20].

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An application was recently submitted to the Medical Services Advisory Committee (MSAC), in Australia to obtain national coverage for partially implantable aMEIs to treat individuals with sensorineural hearing loss and an outer ear medical condition [21]. FDA-approved aMEI systems considered in this study included the VIBRANT SOUNDBRIDGE (VSB) (MED-EL, Innsbruck, Austria) and the MAXUM (Ototronix LLC, Houston, TX), formerly known as the SOUNDTEC. A Markov cohort model was developed for the purpose.

Benefit derived from hearing implants is variable, depending primarily on the onset, severity, and impact of hearing loss [22–28]. The variety and subsequent uncertainty in patient-level outcomes can be represented and evaluated by using microsimulation, but not with cohort simulation. Events occurring along individual pathways can also be counted in such models with the implementation of tracker variables [29]. The aim of this study was to adapt the previously developed Markov cohort simulation to a Markov model analyzed as microsimulation to represent individual-level variability in resource utilization patterns following aMEI implantation. The MAXUM or SOUNDTEC systems were not included in the microsimulation because no published data were available to inform a cost-utility analysis [30–32].

Methods

Sensorineural hearing loss is considered a chronic condition with a life-long impact on health and is characterized by ongoing recurrence of events and risk. Thus, a Markov modeling technique is appropriate to represent the decision problem [33,34]. A state-transition model was built to compare the effects of partially implantable aMEIs and the natural history of untreated disease. The model was programmed and analyzed in TreeAge 2016 (TreeAge Software, Inc., Williamstown, MA).

Target Population

The population of interest consisted of male and female adults aged 18 to 75 years who had postlingual mild to severe sensorineural hearing loss and could not use or benefit from HAs because of medical reasons.

Setting and Location

The model simulated the pathways by which a person with sensorineural hearing loss might or might not receive an aMEI and experience clinical events after being assessed for implant candidacy in the Australian setting.

Model Perspective

A third-party payer perspective was adopted; hence, only the direct costs associated with each intervention were used.

Comparators

For the target population, aMEIs represent the only course of treatment available, since these individuals are unable to wear HAs because of medical reasons and their hearing loss is not severe enough to warrant the application of cochlear implants. The relevant baseline strategy accepted by the MSAC is “no (surgical) intervention,” which reflects the natural history of untreated hearing loss. Individuals with outer ear pathologies are at risk of recurring pathologies, and the treatment pathway associated with medical interventions was included in the model, particularly because this is then the only way to alleviate symptoms.

Choice of Outcomes

The outcome was incremental cost-utility ratios (ICURs) in AUD per quality-adjusted life-year (QALY) gained.

Currency, Price, and Date

The currency used in the study was Australian dollars. The costing index year for the analyses was 2015.

Model Structure

This baseline strategy of “no intervention” is followed for patients who do not fulfill aMEI candidacy criteria or decide against receiving an implant. Patients who remain unaided are assumed to be at constant risk of experiencing recurring pathologies in the same ear. Hence, the three most common outer ear pathologies—otitis externa, external auditory canal exostoses, and excessive cerumen—and the costs of medical treatment were considered. These recurring pathologies are not expected to alter quality of life but may incur higher costs if medical treatment is unsuccessful and further treatment is required.

Figure 1 shows all health states and transitions included in the “aMEI implantation” strategy. A patient can remain in one health state or move to another. After transitioning to the “cease MEI” state, a patient can either remain in this health state or die. This does not imply that individuals stop using their implant immediately after device activation or that aMEI implantation leads to death. Dying from natural causes is similar to that in the general population and can occur in either health state. Those who were “successful” were assumed to be continuous users. Furthermore, a surgical revision was assumed to fully resolve the respective adverse event and reimplantation was expected to occur in the same ear from which a failed device was extracted from.

The model cycle length was 6 months to reflect the occurrence of events in clinical practice. Trackers were incorporated into the model to accumulate individual case histories.

Time Horizon

The time horizon of the model was 10 years. This is long enough for differences between interventions to become apparent and to avoid extrapolating too far beyond available data. A 10-year time horizon has also been used in a decision model for bone anchored hearing aids [35].

Discount Rate

Although normally a discount rate of 3% is applied in health economic studies [36], all costs and effectiveness outcomes were discounted at 5%, as recommended by the MSAC [37].

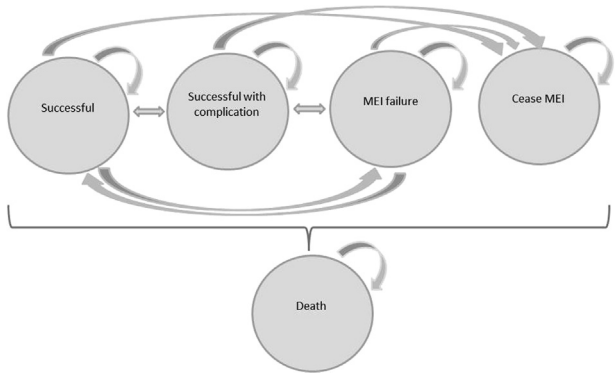

Fig. 1 – Structure of the Markov model. MEI, Middle ear implant.