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Cost-effectiveness of Stapedectomy vs Hearing Aids in the Treatment of Otosclerosis

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← Invited Commentary page 48

IMPORTANCE Otosclerosis can be managed through surgical treatment, such as stapedectomy, or through hearing amplification with hearing aids. To our knowledge, there has been no cost-effectiveness analysis of these 2 treatment methods.

OBJECTIVE To determine the cost-effectiveness of stapedectomy vs hearing aid use for the treatment of otosclerosis.

DESIGN AND SETTING In this cost-effectiveness analysis, a decision tree was built to model the treatment choices for otosclerosis. The tree was run as a Markov model of a case patient aged 30 years. The model spanned the patient's lifetime to determine total costs of management of otosclerosis with stapedectomy or hearing aids. Cost-effectiveness was measured using an incremental cost-effectiveness ratio, with a willingness to pay of \$50 000 per quality-adjusted life-year (QALY) considered cost-effective. One-way sensitivity analyses were performed for all variables. A 2-way sensitivity analysis was performed for the cost of stapedectomy vs the cost of hearing aids. Probabilistic sensitivity analysis was performed to determine the likelihood that stapedectomy would be cost-effective across a range of model inputs.

INTERVENTIONS Stapedectomy vs hearing aid use.

MAIN OUTCOMES AND MEASURES The primary objective of this study was to determine the cost-effectiveness of stapedectomy vs hearing aids in the treatment of otosclerosis. The secondary objectives were to determine which factors are associated with the cost-effectiveness of the interventions.

RESULTS Stapedectomy had an estimated lifetime cost of \$19 417.95, while hearing aids had an average lifetime cost of \$16 439.94. Stapedectomy also had a benefit of 16.58 QALYs, and hearing aids had a benefit of 15.82 QALYs. Stapedectomy increases lifetime costs by \$2978.01, with a benefit of 0.76 QALYs compared with hearing aids. The incremental cost-effectiveness ratio for stapedectomy is \$3918.43 per QALY. The model was sensitive to the cost of stapedectomy and the cost of stapedectomy revision surgery. Probabilistic sensitivity analysis showed that stapedectomy was cost-effective compared with hearing aids 99.98% of the time.

CONCLUSIONS AND RELEVANCE Stapedectomy appears to be a cost-effective option for treating otosclerosis compared with hearing aid use, from the patient perspective.

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Otosclerosis is caused by abnormal bone remodeling of the otic capsule and fixation of the stapes footplate that leads to a progressive mixed (conductive and sensorineural) hearing loss. The current management of otosclerosis and its complications associated with conductive hearing loss consists of either hearing amplification via hearing aids or cochlear implantation or stapes surgery, which consists of either stapedectomy or stapedotomy.¹ Stapedectomy is a surgical intervention and thus has more associated risks than hearing aid use. However, stapedectomy has a success rate of more than 90%,² and most serious complications occur at a rate below 1%.³ Another drawback of surgery is that patients may require revision surgery,⁴ and otosclerosis may progress to include sensorineural hearing loss that could eventually require hearing amplification as well.¹ Similarly, there are several well-known problems with hearing aid use that result in health care dollar expenditures besides their normal replacement costs. These problems include the need for periodic cerumen management because this problem is exacerbated by wearing hearing aids,⁵ skin allergies to the material of the hearing aid molds, foreign-body dislodgement associated with open-fit hearing aids, loss or breakage of hearing aids necessitating early replacement, otitis externa associated with obstruction of the ear canal, and erosive changes of the ear canal necessitating surgery.⁶

To our knowledge, there has been no cost-effectiveness analysis comparing hearing aids with stapedectomy for the management of otosclerosis. Although surgery is expensive and contains additional risks compared with the use of hearing aids, it is possible that the net benefit of not requiring the yearly maintenance costs of hearing aids and the quality-of-life improvement of functional hearing may offset the initial costs and risks of surgery. Hearing aids have a large variation in price. In addition, they can be very expensive and are often not covered by medical insurance.⁷ Finally, otosclerosis can present at a fairly young age⁸; thus, individuals will live with the consequences of the disease for many years. This means that the decreased quality of life and the yearly costs, for example, of wearing a hearing aid over a lifetime may offset the initial costs of the intervention.

Cost-effectiveness models can be used to determine the lifetime costs and benefits of particular interventions and can compare interventions with one another. They incorporate both initial and yearly costs, as well as health-related quality of life to determine the overall value of an intervention. This modeling helps create a more accurate picture of the quality of an intervention than simple cost analyses or outcomes studies. The primary objective of this study was to determine the cost-effectiveness of stapedectomy vs hearing aids in the treatment of otosclerosis. The secondary objectives were to determine which factors are associated with the cost-effectiveness of the interventions. The goal is to help broaden knowledge about interventions for otosclerosis to aid physicians and audiologists in counseling patients about their management options.

Key Points

Question Is stapedectomy a cost-effective method of treating otosclerosis compared with hearing aids?

Findings This cost-effectiveness analysis found that, although stapedectomy was associated with increased lifetime costs by \$2978.01 compared with hearing aids, stapedectomy had an incremental cost-effectiveness ratio of \$3918.43 per quality-adjusted life-year.

Meaning This model suggests that stapedectomy is a cost-effective option for treating otosclerosis from a patient perspective.

Methods

Decision Tree Model of Otosclerosis

For this cost-effectiveness analysis, we developed a Markov model to compare the cost-effectiveness of the management of otosclerosis. **Figure 1** shows a state-transition diagram that outlines our model. In this model, the individual decides whether to manage otosclerosis with stapedectomy or hearing aids. The individual then incurs the cost of the procedure or the initial cost of the placement of a hearing aid. Hearing aids also lead to a penalty of decreased quality of life owing to hearing loss, which is not experienced by patients who have a successful stapedectomy. The individual who chooses hearing aids then has to pay yearly maintenance costs of the hearing aids until death. The individual who chooses stapedectomy has some probability of needing a revision surgery, which adds additional cost. The individual who chooses stapedectomy also has some probability of progressing to hearing loss; if that individual does experience hearing loss, then he or she will then need to pay the initial cost of hearing aids and the yearly cost of hearing aid maintenance and will have the decreased quality of life with hearing loss.

To determine cost-effectiveness, we constructed a Markov model to incorporate costs, outcomes, and quality of life associated with stapedectomy or hearing aid use. In general, Markov models have advantages over classic decision trees in that they more seamlessly simulate multiyear outcomes.^{9,10} Each potential outcome in the tree is represented by a probability (the probability of developing hearing loss, the probability of needing revision surgery, or the probability of death), and each health state (hearing loss or normal health) is assigned a cost and a health utility that represents the “worth” of the specific outcome in terms of quality of life, ranging from 0 (death) to 1 (perfect health).¹¹ Only direct costs were used in the model. In this model, the costs for stapedectomy were determined based on the payer perspective, which was taken from Medicare reimbursement rates for stapedectomy. The cost of hearing aids was determined from the patient perspective and was based on the mean estimated cost of hearing aid use, including fitting the device and the device itself. Personal costs such as loss of productivity were not included. The Markov model assumes that the individual resides within a specific health state, as defined by the decision tree, and transitions

Figure 1. State-Transition Diagram for Stapedectomy vs Hearing Aids in the Treatment of Otosclerosis

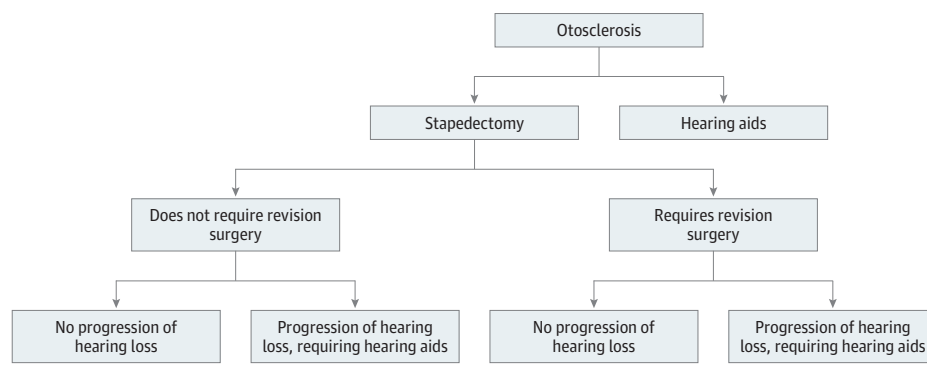


Table 1. Model Inputs for Cost-effectiveness Analysis

Variable	Distribution Type	Value	Range or SD	Reference
General variables				
Probability of death from natural causes	NA	Probability of death varies by age	None	Social Security Life Table ¹³
Patient age, y	Binomial	30	20-60	Ealy and Smith, ¹² 2010
Health utility of hearing loss	β	0.61	0.24	Grutters et al, ¹⁴ 2007
Stapedectomy variables				
Cost of stapedectomy, \$	γ	5394.02	150.00 ^a	Medicare National mean payment ¹⁵
Probability of revision surgery, %	β	15.0	10.0-20.0	Meyer and Lambert, ⁴ 2004
Cost of revision surgery, \$	γ	5671.48	150.00 ^a	Medicare National mean payment ¹⁵
Progression of hearing loss, y, %	β	3.5	2.5 ^a	Redfors and Möller, ¹⁶ 2011
Hearing aid variables, \$				
Initial cost of hearing aid	γ	2350.00	500.00 ^a	National Academy of Sciences, Engineering and Medicine ¹⁷
Yearly cost of hearing aid	γ	580.00	100.00 ^a	National Academy of Sciences, Engineering and Medicine ¹⁷

Abbreviation: NA, not applicable.
^a SD estimated.

between health states occur over a fixed time interval. Once the model has been run to completion, the individual's total costs and health utility are added and compared between the 2 management options.

Our modeled reference case patient was aged 30 years, based on the mean age of incidence of otosclerosis.¹² Each cycle length was 1 year, and we ran the model for 90 years to extend over the lifetime of the patient. This extension allowed us to account for lifetime costs and decreased quality of life. All statistical analyses, including cost-effectiveness and sensitivity analyses, were conducted using TreeAge Pro R, version 2.1 (TreeAge Software Inc).

Model Inputs

Data on costs for stapedectomy, hearing aids, revision rates, disease progression rates, and health utility for hearing loss were obtained from the published literature. Model inputs, including costs, health utilities, and transition probabilities, are described in Table 1.^{4,12-17} Health utility variables for quality of life were based on the Health Utility Index, where a score of 1.0 is assigned to perfect health and a score of 0 is assigned

to death.¹⁸ The baseline health utility of an individual without hearing loss was assumed to be 1.0.

The costs of stapedectomy and revision were taken from Medicare reimbursement rates and from the Physician Fee Schedule for 2019. The initial cost of hearing aids was based on the mean cost of purchasing hearing aids. The yearly cost of a hearing aid was determined by assuming that replacement of hearing aids was required every 4 years.⁷ All costs were adjusted for inflation for 2019.

Cost-effectiveness Analysis

Cost-effectiveness was measured with the incremental cost-effectiveness ratio, which is defined as the difference in total costs (lifetime cost of stapedectomy - lifetime cost of hearing aids) in US dollars divided by the difference in effectiveness (lifetime quality of life-years for stapedectomy - lifetime quality of life-years for hearing aids). Effectiveness is measured by quality-adjusted life-years (QALYs), which are defined as the health utility multiplied by time, where 1 QALY is equivalent to 1 year of perfect health. We used a willingness-to-pay threshold of \$50 000

per QALY, which is the most commonly used value in cost-effectiveness analyses,¹⁹ for all interventions to determine whether the incremental cost-effectiveness ratio for stapedectomy was cost-effective. An incremental cost-effectiveness ratio less than \$50 000 per QALY would be considered cost-effective. To adjust for inflation in costs over time,²⁰ a discounting rate of 3% per year was used on all costs and health utility scores that occurred after the first cycle of the model.

Sensitivity Analyses

One-way sensitivity analysis was performed for all model variables, including costs, health utilities, and transition probabilities. One-way sensitivity analysis alters the value of each variable to see how changes in that variable affect the cost-effectiveness of a procedure. To perform the analysis, the incremental cost-effectiveness ratio was assessed across a range of values for each variable. The variable value at which the incremental cost-effectiveness ratio crossed the willingness-to-pay threshold of \$50 000 per QALY was determined.

A probabilistic sensitivity analysis was performed to determine the effect of simultaneously varying all model parameters. Probability distributions for each variable input were created using the mean and SD presented in Table 1.^{4,12-17} For variables that did not have an SD or that had a range instead of an SD, the SD was estimated. Gamma distributions were noted for cost variables, beta distributions were noted for health utility scores and probabilities, and binomial distributions were noted for age. A Monte Carlo simulation was performed with 10 000 trials to plot the proportion of trials in which stapedectomy is cost-effective across different willingness-to-pay thresholds.

Results

Cost-effectiveness Analysis

For our reference case of a modeled 30-year-old patient, the estimated lifetime cost of managing otosclerosis with stapedectomy was \$19 417.95, and the mean lifetime cost of managing otosclerosis with hearing aids was \$16 439.94 (Table 2). The effectiveness of stapedectomy was 16.58 QALYs, and the effectiveness of hearing aids was 15.82 QALYs. Stapedectomy increased the overall cost by \$2978.01, with a corresponding increase in incremental effectiveness of 0.76 QALYs; thus, the cost-effectiveness of stapedectomy in this model was \$3918.43 per QALY.

Sensitivity Analyses

One-way sensitivity analysis showed that the model was sensitive to the cost of stapedectomy and the cost of revision. The model was not sensitive to the patient's age, the probability of requiring revision surgery, the probability of the progression of hearing loss after stapedectomy, the initial cost of hearing aids, or the yearly maintenance cost of hearing aids. Our base case estimated cost of a stapedectomy was \$5394.02, and if the cost of stapedectomy increased by more than \$40 571.29,

Table 2. Base Case Analysis

Variable	Outcome
Cost, \$	
Stapedectomy	19 417.95
Hearing aids	16 439.94
Incremental cost	2978.01
Effectiveness (QALYs)	
Stapedectomy	16.58
Hearing aids	15.82
Incremental effectiveness	0.76
Cost-effectiveness (ICER), \$	3918.43

Abbreviations: ICER, incremental cost-effectiveness ratio; QALYs, quality-adjusted life-years.

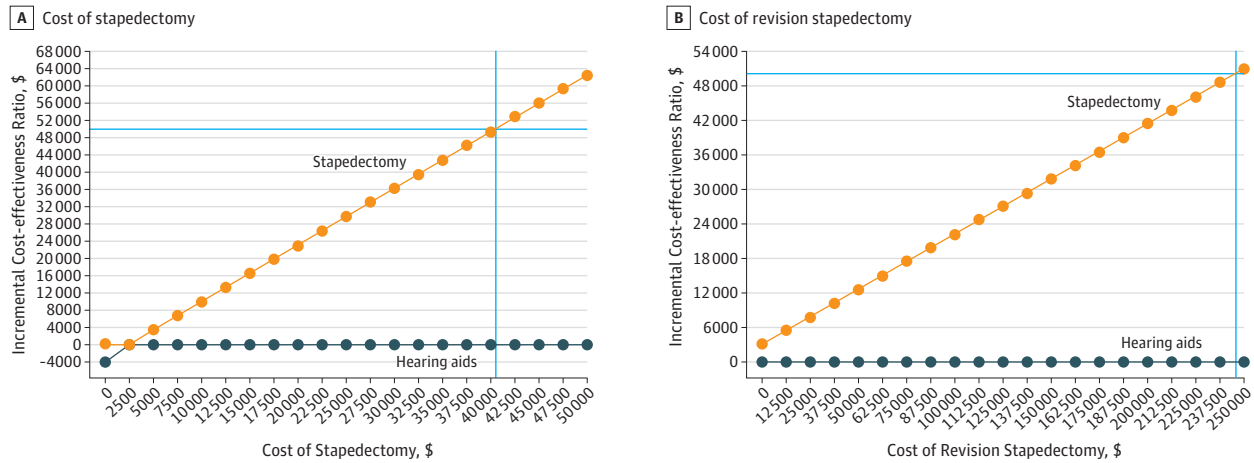
then stapedectomy would no longer be considered cost-effective at a willingness-to-pay threshold of \$50 000 per QALY (Figure 2A). Similarly, our base case estimated cost of a revision surgery was \$5671.48, and if the cost of revision surgery increased by more than \$254 786.16, then stapedectomy would no longer be considered cost-effective (Figure 2B). Results of the probabilistic sensitivity analysis are shown in Figure 3. At a willingness-to-pay threshold of \$50 000 per QALY, stapedectomy is cost-effective compared with hearing aids 99.98% of the time.

Discussion

Our analysis found that stapedectomy was a cost-effective option from a patient perspective in that it had little cost but a maximum health benefit. However, based on this model, hearing aids were cost-effective from the perspective of the payer, Medicare, because they minimized cost to the payer and still gave benefit to the patient. The lifetime cost of stapedectomy was approximately \$4000 more than the lifetime costs of hearing aids. However, stapedectomy was associated with an improvement in quality of life of 0.76, which is equivalent to about 1 year of "perfect" health compared with individuals using hearing aids. This finding means that for each additional year without decreased quality of life owing to hearing loss, individuals who undergo stapedectomy spend an extra \$4000 more than those who manage their otosclerosis with hearing aids. This finding is significantly below the willingness-to-pay threshold of \$50 000 per QALY. Although the up-front cost of surgery can be high, the ability to delay or eliminate the need for hearing aids leads to a quality-of-life improvement that offsets the initial cost from a patient perspective.

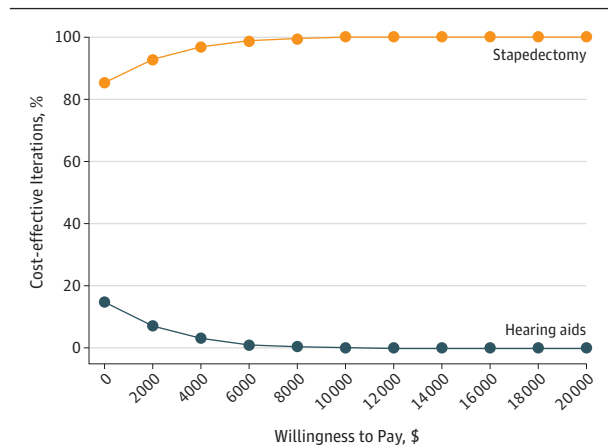
An important consideration for individuals in deciding between surgical intervention and hearing aid use is that surgical intervention is covered by insurance while hearing aids are often not covered by insurance, or are covered for only a fraction of the price. In this model, we used inputs for Medicare reimbursement rates for stapedectomy, which reflect a cost for the insurance payer. We compared these costs with the cost of hearing aid use, which reflect costs to the patient. Although

Figure 2. One-Way Sensitivity Analyses



A, The outcome on the cost-effectiveness of stapedectomy vs hearing aids in the treatment of otosclerosis of varying the cost of stapedectomy while all other inputs are kept constant. Stapedectomy remains cost-effective until the cost of stapedectomy surgery increases by more than \$40 571.29. B, The outcome on the cost-effectiveness of stapedectomy vs hearing aids in the treatment of otosclerosis of varying the cost of revision stapedectomy while all other inputs are kept constant. Revision stapedectomy remains cost-effective until the cost of revision stapedectomy increases by more than \$254 786.16.

Figure 3. Analysis of Cost-effectiveness Across Different Willingness-to-Pay Thresholds



At a willingness-to-pay threshold of \$50 000, stapedectomy is cost-effective 99.98% of the time.

these costs include some procedures, such as audiology and otolaryngology evaluation, that are covered by insurers, hearing aids themselves are often not covered by insurers and thus must be paid for directly by the consumer. This expense affects the overall cost-effectiveness of stapedectomy because most of the cost of stapedectomy is not covered by the consumer, which decreases the up-front costs of stapedectomy for the consumer and makes the incremental costs higher from a patient perspective. This scenario would make stapedectomy even more attractive from a cost-effectiveness standpoint for patients. However, for patients with high-deductible insurance plans, up-front surgery costs would be higher and would likely decrease the cost-effectiveness of stapedectomy from their perspective.

There have been recent changes under the US Food and Drug Administration (FDA) Reauthorization Act of 2017 that may dramatically decrease the price of hearing aids, which could alter their cost-effectiveness significantly. This legislation will make certain hearing aids available over the counter at a lower cost to those with mild to moderate hearing loss, while still maintaining FDA approval status. This change would increase patient access to hearing aids. Cost is often listed as a major factor limiting use of hearing aids in the US population,⁷ so a decrease in cost would improve the cost-effectiveness of hearing aids from a patient perspective. Hearing aids are an attractive option for payers such as Medicare because they are less expensive than surgical intervention and do lead to an overall improvement in quality of life for the patient with hearing loss.²¹

From a patient perspective, there are factors other than cost that decrease hearing aid use. For younger patients with otosclerosis, hearing aids carry a stigma and are considered an inconvenience.⁷ It is difficult to determine the changes in patient perspectives on hearing aids if they were covered by insurance, and patient preference was not included in this model.

This model analyzes cost-effectiveness for unilateral stapedectomy or hearing aids. However, otosclerosis can be bilateral; if this were the case, the total costs for both stapedectomy and hearing aids would double. Bilateral otosclerosis would likely not change the outcome, however, because both treatment groups would pay double the cost.

Sensitivity analyses show that the up-front costs of surgery and revision surgery would need to be extremely high to make stapedectomy not cost-effective from a patient perspective. In addition, our probabilistic sensitivity analysis shows that stapedectomy is almost always cost-effective across a range of costs, outcomes, and health utility values for hearing loss.

Limitations

Our model has several limitations. We did not include data on the cost or loss of quality of life owing to potential complications from surgery, including intraoperative trauma such as tympanic membrane perforation, transient dysgeusia (due to chorda tympani trauma), facial nerve trauma, and perilymphatic gusher, as well as postoperative complications such as surgical site infection, transient labyrinthitis, sensorineural hearing loss, vertigo, and facial palsy.³ However, these complications are extremely rare,² and we do not think that they occur at high enough rates to be included in the model. Although the costs of these complications are high and they may have a dramatic effect on quality of life, they occur so infrequently that they would likely not add much to the mean cost of stapedectomy and would not significantly alter the cost-effectiveness.

Another potential limitation is the use of Medicare claims data to determine the costs of stapedectomy and stapedectomy revision surgery, which may underestimate the true hospital-based costs. However, the sensitivity-based analyses of costs show that the true costs of stapedectomy and revision could be much higher and the model would still be cost-effective. We also did not include the potential need to progress to a cochlear implant in advanced stages of the disease; however, that would influence the costs of both stapedec-

tomy and hearing aids, which overall would not substantially affect the incremental costs between these 2 treatment strategies and thus would unlikely affect the cost-effectiveness results. Despite the limitations of using Markov models and cost-effectiveness analyses, they have been used to analyze the cost-effectiveness of several otology concerns, including cochlear implants in adults,²² partially implantable active middle ear implants in adults,²³ and endoscopic vs microscopic tympanoplasty for chronic otitis media.²⁴

Conclusions

This analysis of the cost-effectiveness of the treatments of otosclerosis showed that stapedectomy is a cost-effective strategy for treating otosclerosis from a patient perspective because it maximizes quality of life and minimizes patient cost. We also showed that hearing aids are cost-effective from a Medicare perspective because they minimize payer costs and give some benefit to the patient. The results of this model can help provide guidance for practitioners discussing treatment options with patients with otosclerosis. These findings can help provide guidance to both the patient and the physician when deciding between surgical intervention or hearing amplification.

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Concept and design: Both authors.

Acquisition, analysis, or interpretation of data: Both authors.

Drafting of the manuscript: Gillard.

Critical revision of the manuscript for important intellectual content: Harris.

Statistical analysis: Gillard.

Supervision: Harris.

Conflict of Interest Disclosures: Dr Harris reported receiving founder's stock from Otonomy Inc outside the submitted work. No other disclosures were reported.

Additional Contributions: James Murphy, MD, University of California, San Diego, provided guidance on presentation of methods and statistical analysis for cost-effectiveness research. He was not compensated for his contribution.

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Invited Commentary

What If a Stapedectomy Were Not Cost-effective?

Elliott D. Kozin, MD

The management of otosclerosis is viewed by many as the *sine qua non* of an otologic practice. From the elegant otopathologic descriptions by Ádám Politzer¹ in the 19th century to surgical breakthroughs by Julius Lempert² and John Shea Jr³ in the mid-20th century, otosclerosis and its surgical management have inspired generations of students, researchers, and surgeons alike. The allure of stapedectomy may be, in part, the elegant tightrope walk to fix hearing loss along with the anticipation of a surgeon report card that arrives in the form of an audiogram. Although the surgical treatment of otosclerosis has not drastically changed since its description by Shea,³ otosclerosis and its management remain fertile ground for research, debate, and refinement. Indeed, novel 21st-century diagnoses—such as superior canal dehiscence syndrome; technological refinements, including otoendoscopy; and even inner-ear drug delivery⁴—appear to be viewed in connection to otosclerosis.

The Original Investigation by Gillard and Harris⁵ published in this issue of *JAMA Otolaryngology-Head & Neck Surgery* provides a fresh perspective on the management of otosclerosis. In their article, the authors pose a straightforward question: is stapedectomy cost-effective? In the climate of focused health care resource use, this question has important implications for the fluid patient-physician-payer-society relationship. Moreover, with the emergence of relatively inexpensive and technically advanced wearable hearing technology, the study is timely and progressive.

Gillard and Harris⁵ model the cost of a stapedectomy procedure as compared with that of a conventional hearing aid. The investigators construct their model with a host of variables, including the cost of surgery, probability of a revision procedure, progression of hearing loss, as well as the initial cost of hearing aids and costs of yearly hearing aid maintenance. Costs for stapedectomy were based on the payer perspective, and costs of hearing aids were determined from the patient perspective. The model simulation was run with a case patient who was 30 years old. The authors found that stapedectomy was cost-effective compared with hearing aids greater than 99% of the time at a willingness-to-pay threshold of \$50 000 per quality-adjusted life-year. The authors argue that though the upfront cost of surgery may be higher than hearing aids, the ability to mitigate the use of hearing aids during a patient's lifetime leads to improvement in quality of life that offsets initial costs.

There are always shortcomings to modeling methodologies, and Gillard and Harris appropriately acknowledged the limi-

tations of their study. They cite a range of variables that were challenging to incorporate, including differing costs by the patient, variability of claims data, complications from surgery, and disease progression. The age of the patient undergoing the initial stapedectomy was also fixed. Despite the limitations, the article is laudable because it is, to my knowledge, the first of its kind to model health care costs associated with stapedectomy, especially in comparison to hearing aids. It also refocuses the paradigm of otosclerosis management, including the need to consider issues not previously faced by Politzer, Lempert, or Shea.

Consideration of cost-effectiveness fosters outside-the-box thinking on emerging topics in otology that may soon be at the forefront of otosclerosis management, including (1) emergence of low-cost and sophisticated hearable technology, (2) priority of patient preferences, and (3) advanced audiometric testing. Over-the-counter hearing technology, including hearables, are undergoing a revolution with recent legislation increasing access to hearing amplification.⁶ The combination of rapidly declining costs of sophisticated hearing amplification and aggressive marketing by technology companies may result in greater societal acceptance of hearing-assistive devices. There is a direct, albeit limited, analogy to the popularization of eyewear over the past several decades that was stirred by major manufacturers.⁷ If an individual normally wears earbuds throughout the day for communication, music, and personal assistant devices (eg, Siri, Alexa, Google), high-quality and personalized sound amplification seems like an obvious extension of these services. It is not too far a stretch to envision a time when hearing aids in the guise of earbuds are turned on during periods of both privacy and socialization.⁸ That said, we need additional evidence to understand the benefits and effectiveness of low-cost hearing technologies. Once we are confident that they are an effective treatment, studies like the one by Gillard and Harris⁵ can help us determine whether they are cost-effective.

In addition to citing legislation that is rapidly bringing hearable technology to the masses, the article also highlights the emerging relevance of health utility and payer decision analysis. In addition to modeling retrospective data for economic analyses, prospective cost-benefit analyses, including contingent valuation analysis, are increasingly being used to reassess valuation of surgical procedures and medical devices.⁹ Novel methodologies of cost-benefit analyses alongside standardized patient-oriented outcome metrics will likely prove critical as otologic treatment modalities are benchmarked and contrasted. Moreover, the data are inherently linked to the



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