Randomized Trial of Amplification Strategies

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Background: Little is known about quality of life after the use of specific types of hearing aids, so it is difficult to determine whether technologies such as programmable circuits and directional microphones are worth the added expense.

Objective: To compare the effectiveness of an assistive listening device, a nonprogrammable nondirectional microphone hearing aid, with that of a programmable directional microphone hearing aid against the absence of amplification.

Design: Randomized controlled trial.

Setting: Audiology clinic at the VA Puget Sound Health Care System, Seattle, Wash.

Patients: Sixty veterans with bilateral moderate to severe sensorineural hearing loss completed the trial. Half the veterans (n=30) had hearing loss that the Veterans Affairs clinic determined was rated as “service connected,” which meant that they were eligible for Veterans Affairs–issued hearing aids.

Intervention: Veterans with non–service-connected hearing loss, who were ineligible for Veterans Affairs–issued hearing aids, were randomly assigned to no amplification (control arm) or to receive an assistive listening device. Veterans with service-connected loss were randomly assigned to receive either the nonprogrammable hearing aid that is routinely issued (“conventional”) or a programmable aid with a directional microphone (“programmable”).

Main Outcome Measures: Hearing-related quality of life, self-rated communication ability, adherence to use, and willingness to pay for the amplification devices (measured 3 months after fitting).

Results: Clear distinctions were observed between all 4 arms. The mean improvement in hearing-related quality of life (Hearing Handicap Inventory for the Elderly) scores was small for control patients (2.2 points) and patients who received an assistive listening device (4.4 points), excellent for patients who received a conventional device (17.4 points), and substantial for patients who received a programmable device (31.1 points) (P<.001 by the analysis of variance test). Qualitative analyses of free-text diary entries, self-reported communication ability (Abbreviated Profile of Hearing Aid Benefit) scores, adherence to hearing aid use, and willingness to pay for replacement devices showed similar trends.

Conclusions: A programmable hearing aid with a directional microphone had the highest level of effectiveness in the veteran population. A nonprogrammable hearing aid with an omnidirectional microphone was also effective compared with an assistive listening device or no amplification.


Hearing loss is one of the most common chronic illnesses in the United States, especially in elderly persons. It affects more than 25% of Americans older than 65 years. Rates are even higher in men; more than 40% of the men in the Framingham cohort aged 65 to 70 reported hearing impairment, and this proportion increases to more than 80% of men between the ages of 85 and 90. The diminished ability to communicate or appreciate music is frustrating in and of itself, but the strong association of hearing loss with depression and functional decline adds further to the burden on the hearing impaired.

There is strong evidence that hearing aids significantly improve quality of life for patients with sensorineural hearing loss. In a seminal randomized clinical trial of 194 elderly veterans with bilateral hearing loss at the San Antonio Veterans Affairs (VA) Hospital, San Antonio, Tex, patients were randomly assigned...
PATIENTS AND METHODS

PATIENT POPULATION

Patients aged 50 years or older were recruited from those seeking diagnostic visits or hearing aid evaluations at the audiology clinic of VA Puget Sound Health Care System. Patients were included if they had symmetric, bilateral, sensorineural hearing loss. To maximize the homogeneity of hearing loss, however, strict exclusion criteria were applied:

1. Asymmetric hearing loss. For frequencies between 500 Hz and 3 kHz (0.5, 1.0, 1.5, 2.0, and 3.0 kHz), this was defined as any of the following differences between ears: a 20-dB difference or greater at 1 or more frequencies, a 15-dB difference or greater at 2 or more frequencies, or a 10-dB difference or greater at 3 or more frequencies.
2. Conductive hearing loss. This type of loss was defined as a 10-dB air-bone gap or greater at any frequency from 500 to 3000 Hz.
3. Loss other than mild to moderately severe. Patients with pure-tone thresholds outside the following range in either ear were excluded: 500 Hz, 10- to 40-dB hearing loss; 1000 Hz, 15- to 50-dB hearing loss; 2000 Hz, 30- to 60-dB hearing loss; and 3000 Hz, 40- to 75-dB hearing loss.
4. Upsloping hearing loss of 5 dB per octave or greater between 500 and 3000 Hz.
5. Poor word recognition (discrimination) scores, defined as Maryland consonant-noun-consonant (CNC) scores (tested 10 dB above the 3000-Hz threshold) of 80% or worse in either ear.
6. Atypical causes of sensorineural hearing loss, such as ototoxicity, sudden sensorineural loss, or Meniere disease.

Patients were also excluded if they had any of the following: prior hearing aid experience, poor cognitive function (a score of ≤23 on the Mini-Mental State Examination), or poor manual dexterity (judgment by audiologists about the ability to change hearing aid batteries).

Informed consent was obtained from patients meeting the study criteria. No remuneration was provided. Enrollment began on October 1, 1998, and was completed on September 30, 1999.

RANDOMIZATION

The Veterans Health Administration provides hearing aids only to patients whose hearing loss is judged to be “service connected.” Therefore, veterans with non-service-connected hearing loss, who are ineligible for VA-issued hearing aids, were randomly assigned to no amplification (control arm) or to receive an ALD. Veterans with service-connected hearing loss were randomly assigned to receive either the nonprogrammable hearing aid that is routinely issued (conventional aid) or a programmable aid with a directional microphone (programmable aid) (Figure 1). The strict audiometric inclusion criteria previously detailed were used to maximize homogeneity of the hearing loss between service-connected and non-service-connected patients.

Randomization was performed in blocks of 4, with separate randomization for patients aged 50 to 65 years and patients older than 65 years to ensure relatively similar age distributions between treatment arms. Sealed envelopes were opened after enrollment and completion of baseline questionnaires and interviews. No blinding was feasible, given the obvious differences between hearing amplification devices. The construction of study and placebo devices would have required additional funding. Patients receiving hearing aids were told explicitly that there was no evidence that either aid was superior. Audiologists and study personnel were instructed to avoid describing differences between the 2 types of hearing aids to the patients.

HEARING AIDS

All patients were fit bilaterally with half-shell in-the-ear analog hearing aids. Hearing aid selection and fitting were conducted by VA audiologists. Because we were interested in hearing aid effectiveness, we allowed the audiologists to make decisions about the fitting requirements within the bounds of the experimental design. For example, the audiologist was free to order amplification options (eg, potentiometers, telecoil, canal length, and venting) as appropriate for each patient, with the following constraints.

The conventional hearing aid was a nonprogrammable nondirectional aid. Target gain was calculated using the National Acoustic Laboratories’–Revised prescriptive procedure.23 Probe microphone measures were used to ensure that the frequency-gain response provided an acceptable match to target. Each aid had a manual volume control. Output limiting was accomplished using compression limiting, with the compression threshold individually adjusted based on each patient’s loudness discomfort levels.

The programmable hearing aid had a switchable directional microphone and remote control. Volume control and 3 memories were available to the patient via the remote control. The first memory was set for quiet listening using a nondirectional microphone, with target gain calculated using the National Acoustic Laboratories’–Revised prescriptive formula. Probe microphone measures were used to ensure that the frequency-gain response provided an acceptable match to target. The second and third memories were set by the audiologist as appropriate for the patient’s communication needs. Typically, the second memory was adjusted to maximize speech understanding in background noise with the directional microphone, and the third memory was set for comfort in noise with the directional microphone.

In each case, patients received routine instructions on the use, care, and function of the hearing aid. All patients were seen for routine clinical follow-up, including counseling and adjustments as needed, 1 month after the hearing aid fitting.

Researchers found that the improvements were sustained 1 year after hearing aid fitting. A separate randomized trial12 confirmed the quality-of-life benefits of hearing amplification. In this study, 180 elderly hearing-impaired persons were offered a hearing aid only, an as-
DATA COLLECTION

Data were collected via individual interviews and through self-administered questionnaires at baseline before randomization, and then again at 1 and 3 months after receiving the hearing amplification device (Table 1). (Assistive listening devices were given to the patients the day of randomization. Hearing aids were fitted 4-6 weeks after randomization.) The questionnaires were mailed to patients 1 week before the follow-up interviews. In addition to the interviews and self-administered questionnaires, patients were asked to maintain a hearing diary for the duration of the study. Patients recorded the number of hours they used their hearing amplification device each day (amplification arms) or the number of hours each day that they encountered hearing-related difficulties (control arm). Patients who did not receive hearing aids were given their diaries on the day of randomization. Patients who received hearing aids received their diaries on the day they were fitted with their aids. The following assessments were made.

Audiometric Data

Unaided air conduction thresholds were recorded at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz, and bone conduction thresholds were recorded at 250 through 4000 Hz. Unaided speech recognition scores were measured using the Maryland CNC protocol at 10 dB above the 3000-Hz air conduction threshold.

Hearing-Related Quality of Life

“Quality of life” is increasingly common to consider in hearing aid studies, although there is no precise agreement over its definition and how to measure it. However, there is general agreement that health-related quality of life should include assessments of physical, social, and emotional function. We used 2 separate approaches to measure these functions.

First, we used an outcome measure (instrument) called the Hearing Handicap Inventory for the Elderly (HHIE), a 25-item hearing-related quality-of-life scale with 2 subscales that measure the emotional and social impact of hearing loss. The scale is scored from 0 to 100, with 100 representing the least handicap. A 9-point change in the HHIE score represents a clinically significant change. Second, we performed a qualitative (“clinimetric”) analysis of open-ended comments from the diaries. Open-ended text comments were organized into categories of quality-of-life issues, for which a taxonomy was developed. The frequency was tallied for taxonomy issues raised by individual patients.

Self-rated Communication Ability

This was assessed using 2 different validated outcome measures. The first was the Abbreviated Profile of Hearing Aid Benefit, a 24-item scale used to measure self-rated communication ability. There are 4 subscales in this measure, each of which is scored on a 100-point scale. We have chosen to represent worst scores as 0 and best scores as 100, so that a positive incremental score will represent an improvement in function. The first 3 subscales—ease of communication, background noise, and reverberation—reflect how well patients understand speech in various listening situations. An intervention that improves the scores of all 3 subscales by at least 5 points is considered to be clinically important. The fourth subscale measures version to amplified sounds.

The second measure was the revised Denver Scale of Communication Function, a 5-item instrument that reflects patients’ attitudes about their communication abilities. This scale was shortened from the original version, and is scored from 1 (worst) to 5 (best), but no numerical anchors for what would represent a clinically important difference have been established.

Adherence Data

Patients recorded in their diary the number of hours they used their amplification device each day.

Willingness-to-Pay Data

Willingness to pay is an economic construct popularized by health services researchers. It measures how much patients value a particular treatment (or health state). In its simplest form, patients are literally asked how much they would be willing to pay to have a treatment. We asked patients at their last visit, “If you lost your hearing device, how much would you be willing to pay to replace it?” Monthly incomes were recorded to adjust for variation in income.

DATA ANALYSIS

Outcome measures were scored using published algorithms. The qualitative (clinimetric) analysis was performed by tallying the frequency with which taxonomy issues were raised by patients in their diaries. Data were entered into a database (Microsoft Access; Microsoft, Seattle, Wash) with double-entry verification techniques to ensure accuracy. Age, pure-tone thresholds, and pure-tone average were analyzed for baseline differences using an analysis of variance (ANOVA). Dimensional (continuous) data were summarized using mean incremental differences between baseline and 3-month scores. The incremental scores were compared with t tests for pairwise comparisons and an ANOVA for multiple comparisons. Comparisons of dichotomous (frequency) data were analyzed with χ2 tests. Because multiple comparisons were used, we have highlighted only results that were statistically significant at α = .01. Statistical analyses were performed with SAS statistical software, version 6.12 (SAS Institute Inc, Cary, NC).

However, the relative impact of different types of hearing aids on quality of life is less clear. With advances in hearing aid technology resulting in an array of products with varying features and expense, more information about the relative effectiveness of different hear-
ing aids is needed to help clinicians provide informed treatment recommendations. Programmable and digital circuits, multiple memories and channels, and directional microphones are relatively new technologies, and little is known about how, or even whether, these features affect outcomes. Several trials on digital aids have been published, but methodological limitations and reliance on laboratory measures hamper efforts to determine whether this technology results in improved quality of life.

Recent attention has also focused on directional microphones, which allow selective amplification of sounds from one direction (eg, the amplification of noises directly in front and suppression of noises in back) of the hearing aid user. Subjects from a recent study compared their own nondirectional analog hearing aids with 2 digital aids, one with a directional microphone and the other without a directional microphone. The digital aid with the directional microphone was preferred, but no differences were noted between the nondirectional digital aid and the patients’ analog aids. The researchers concluded that the directional microphone was responsible for the preference. Gravel et al confirmed the listening advantages offered by directional microphones in a comparison of nondirectional and directional microphones in hearing-impaired children. Unfortunately, neither study gave patients the opportunity to wear the aids at home, so conclusions were based on laboratory measures alone.

The distinction between laboratory and “real-life” outcomes is important, because it is at the heart of the difference between efficacy and effectiveness studies. Efficacy studies measure the degree of benefit that a carefully defined group of patients in an experimental setting receives for treatment under ideal conditions. Effectiveness reflects the benefit received by typical community patients under ordinary conditions for the treatment under usual circumstances. For example, the hearing aid that significantly improves word recognition scores in a sound booth, but lies unused in the bottom of a drawer at home, is highly efficacious but ineffective. Efficacy and effectiveness are important, and investigators must decide which concept to emphasize. It is our belief that although efficacy is important to demonstrate, effectiveness is ultimately what matters most to patients.

Thus, we chose to measure effectiveness in this pilot study, which is part of a long-term project to examine the cost-effectiveness of hearing amplification. The initial step in a cost-effectiveness analysis is to establish differential effectiveness, after which the economic analyses may begin. We chose to compare the relative effectiveness of an ALD, a nonprogrammable hearing aid routinely issued at the VA Puget Sound Health Care System, Seattle, Wash (“conventional aid”), and a programmable aid with a directional microphone (“programmable aid”) against the absence of amplification. The primary comparison of interest was the relative effectiveness of the 2 hearing aids, and our hypothesis was that typical use of the programmable aid would result in better outcomes than use of the standard aid.

Demographic and baseline characteristics are shown in Table 2. The mean hearing thresholds for each group are shown in Figure 2. There were no significant differences in hearing sensitivity between groups for either ear. Of 64 patients enrolled in the trial, 60 completed the final 3-month follow-up visits. (One patient in the programmable aid arm died unexpectedly, and 3 others—one in the programmable arm and 2 in the standard arms—were unwilling to return for their 3-month follow-up visits.) All patients were men. No statistically significant differences for age or degree of hearing loss at baseline were noted between arms. To correct for minor variations in baseline scores for some outcome variables, mean incremental results are reported (scores at baseline subtracted from those at 3 months).

HEARING-RELATED QUALITY OF LIFE

Outcome Measures

The type of amplification strongly influenced HHIE scores. Table 3 lists incremental changes in HHIE scores from baseline to the 3-month follow-up. (Scores are reported so that positive values reflect improvement and negative values reflect worsening.) The overall HHIE score, which ranged from 0 to 100, did not change significantly in either the control or the ALD arm. However, it

Figure 1. Schematic of the hearing aid trial. VA indicates Veterans Affairs.
improved by 17 points in patients using the standard aid and by more than 31 points in patients using the programmable aid. One-way ANOVA testing was highly significant, and a 1-tailed t test demonstrated that the difference between the standard and programmable arms was statistically significant (P = .05). Patients in both hearing aid arms improved by more than the 9 points that are thought to represent clinically significant change, and the difference between the 2 hearing aid arms was also clinically significant.

**Qualitative Analysis**

Clear differences were apparent from the clinimetric analysis of open-ended diary comments as well. A taxonomy of quality-of-life issues was developed through an iterative process by consensus (B.Y. [an otolaryngologist] and P.E.S., M.B.S., and C.F.L. [audiologists]), who were content experts. The taxonomy is divided into 2 major categories. The first addresses intrinsic issues of hearing loss, such as functional, emotional, and social impairment. The second covers extrinsic factors associated with the hearing aid itself, including the acoustics of amplification, the physical comfort of the aid, the convenience of the aid, maintenance and reliability of the aid, cosmetic appearance and self-esteem with the aid, and satisfaction with technological features. Table 4 lists the number (percentage) of patients in each arm who raised selected issues. In general, positive (favorable) comments occurred more often as the technology became more advanced, and negative (unfavorable) comments occurred less often. This pattern was seen in most categories, although no differences were seen in the physical comfort and appearance domains between hearing aid arms (the physical sizes of the shells were similar).

**SELF-RATED COMMUNICATION ABILITY**

The type of amplification also strongly influenced incremental scores of the Abbreviated Profile of Hearing Aid Benefit and the revised Denver Scale of Communication Function (Table 5). Overall Abbreviated Profile of Hearing Aid Benefit scores improved minimally in the control arm, but increased by more than 16 points in the programmable aid arm (P = .01, ANOVA). The changes were clinically significant in the amplification arms, because the domain scores improved by more than 5 points in the ease of communication, background noise, and reverberation subscales. Interestingly, although patients using the standard aid had more aversion to amplified sounds, this difference was not present in patients with the programmable aid. The revised Denver Scale of Communication Function scores improved considerably in the hearing aid arms, with essentially no change in the nonhearing aid arms.

**ADHERENCE DATA**

Self-reported adherence to use of the hearing devices also varied significantly between arms (Figure 3). Patients used the programmable hearing aid an average of 8.8 h/d, and the standard hearing aid an average of 6.9 h/d.
Patients were clearly less adherent to the ALD, with 0.6 h/d of average use (P<.001, t test) between the control arm and each hearing aid arm. The graphical data show that the initial separation between the programmable and standard arms became less apparent as the study progressed. Several explanations are possible. First, it is possible that differential acclimatization to the standard aid may have closed the gap. Second, this may be a spurious result because of response bias. Response bias would occur if patients who are less adherent are also less likely to complete diary entries. In this study, there were fewer diary entries toward the end of the trial. If patients who were less adherent were less likely to continue completing diary entries, the calculated mean hours of daily use would be artificially elevated for the device to which patients were more adherent.

WILLINGNESS-TO-PAY DATA

Substantial differences between treatment arms were also noted for willingness-to-pay data. When patients were asked how much they would be willing to pay to have their amplification devices replaced if they lost them, patients using the ALD (n=15) offered a mean of $40 (range, $0-$500), or 1% of their monthly income, to replace the device. Patients using standard aids (n=14) said that they would be willing to pay a mean of $800 (range, $0-$1000).
In this randomized trial comparing the effectiveness of 3 amplification strategies against a control arm, clear treatment effects were apparent. Both hearing aids were superior to an ALD and the absence of amplification in all measures of outcome. These observations confirm the results of prior randomized trials comparing the use of a hearing aid against either no intervention or an ALD. Of greater interest is that we established differential treatment effectiveness between hearing aids, which, to our knowledge, has not been done previously. The programmable hearing aid with a directional microphone performed better than the standard nonprogrammable aid did. Results were particularly convincing for quality-of-life and willingness-to-pay data. The next logical step is to perform the cost-effectiveness analyses that will help determine if the improved effectiveness is worth the added expense.

We did not use blinding in this study. Blinding observers and subjects to different types of hearing aids, unlike medications and even selected surgical procedures, is difficult. In some cases, blinding is impossible (eg, consider the study that wants to address the effect of hearing aid size on satisfaction). Even when features can be disguised, substantial investments in expensive study and placebo hearing aids are required. A separate consideration is whether blinding is desired. Blinding is integral to the traditional randomized efficacy trial but is less important in effectiveness studies, because patients are supposed to be aware of the type of treatment they are receiving (just as they would be in real life). The obvious disadvantage is that effectiveness studies may be susceptible to bias. On the other hand, we explicitly chose to measure effectiveness (eg, quality of life and adherence to use), because this is ultimately what matters to patients and their physicians. The consistent findings among outcome measures suggest that our results are robust. However, we cannot state which features were responsible for the observed improvements in effectiveness. Although the sizes of the 2 hearing aid molds were similar, budget limitations forced us to simultaneously compare several technologies, such as directional microphones, programmability, and multiple memories. Future efforts will be directed toward isolating the effects of one hearing aid feature at a time.

This study has several other limitations. First, only patients with bilateral, symmetric, mild to moderately severe sensorineural loss were included. The results may not be applicable to patients with other types of hearing loss. Second, 2 populations (patients with service-connected and non–service-connected hearing loss) were used at baseline. The inclusion criteria were designed to maximize homogeneity between the 2 populations, but comparisons between non–hearing aid and hearing aid groups may be subject to unknown biases. However, we emphasize that the primary comparison of interest (nonprogrammable vs programmable aids) was made in the same population (patients with service-connected hearing loss only).

Hearing aids, and the programmable aid with the directional microphone in particular, were substantially more effective in this randomized trial. This conclusion was supported by 2 forms of hearing-related quality-of-life data (outcome measures and qualitative analyses), self-rated communication ability, adherence to hearing device use, and willingness-to-pay data.

Cost-effectiveness analyses are needed to understand the trade-offs between improved effectiveness and added expense of the programmable aid with the directional microphone.

We cannot state which features are responsible for the improvements in effectiveness. Future definitive randomized efficacy and effectiveness trials are needed to evaluate features such as digital processing and directional microphones to identify the technologies that are truly responsible for improved effectiveness.
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