Letters

RESEARCH LETTER

Personal Sound Amplification Products vs a Conventional Hearing Aid for Speech Understanding in Noise

Presently, hearing aids can only be purchased in the United States through a licensed professional, with a mean cost of $4700 for 2 hearing aids (uncovered by Medicare).[1-3] According to nationally representative estimates based on 2605 adults from 1999 through 2006, less than 20% of adults with hearing loss report hearing aid use.[4] Personal sound amplification products (PSAPs) are less-expensive, over-the-counter devices not specifically labeled for hearing loss treatment, but some are technologically comparable with hearing aids and may be appropriate for mild to moderate hearing loss.[1] We compared a sample of these devices with a conventional hearing aid among individuals with mild to moderate hearing loss.

Methods | This study protocol was approved by the institutional review board at Towson University and Johns Hopkins, and written informed consent was obtained from each participant. From April 2016 through January 2017, we screened adults aged 60 to 85 years at a university audiology clinic to recruit a convenience sample for a randomized study. Inclusion criteria included mild to moderate hearing loss (20-55 dB HL; pure-tone average, 500-4000 Hz), no prior amplification use, and no cognitive impairment (Mini Mental State Examination score, >24).

Participants completed the AZBio sentence-in-noise task,[5] a routinely used measure of speech understanding to assess functional hearing. Participants repeated sentences in the presence of background noise under 7 conditions: unaided, with a hearing aid, and with 5 PSAPs. To control for order effects, sentence lists and devices were randomly ordered using a Latin square design balancing first-order carryover effects. Accuracy (percentage of words repeated correctly; range, 0%-100%) was recorded for each condition (20 sentences per condition).

All testing was completed in a calibrated sound booth by an audiologist. To simulate a moderately difficult listening environment, sentences were presented via a speaker at a 0° azimuth (ie, directly in front of the participant) at 35 dB HL while speech babble noise was concurrently presented at a 180° azimuth (ie, directly behind) at 30 dB HL. A sample of 9 of the most-sold PSAPs via a large e-commerce retailer was assembled and tested for electroacoustic properties. Of the 9, the 4 PSAPs with the most favorable electroacoustic properties and 1 PSAP available in retail pharmacies were chosen and compared with 1 hearing aid commonly dispensed in a university audiology clinic. The same units were tested in each participant, unilaterally fit and adjusted to each participant's hearing in their better-hearing ear using best-practice verification methods by an audiologist.

Linear mixed-effects regression models were used to model the within-participant change in performance with each device. Analyses were performed using R (R Foundation), version 3.3.2.

Results | Of 63 adults screened, 42 met inclusion criteria (mean age, 71.6 years; women, 67%). The change in accuracy in speech understanding from unaided to aided varied by device (**Table**). The hearing aid and 4 of the PSAPs improved speech understanding from the unaided condition. The mean unaided accuracy was 76.5%. The hearing aid improved speech understanding accuracy to 88.4% for an absolute improvement difference of 11.9 percentage points (95% CI, 9.8 to 14.0). Three

Table. Accuracy in Speech Understanding in Noise From Unaided to Aided With PSAPs and a Hearing Aid Among 42 Older Adults With Mild to Moderate Hearing Loss[a]

	Cost, US $[b]	Mean Accuracy, % (95% CI)	Change From Unaided Hearing, Percentage Points (95% CI)	Difference Between PSAP and Hearing Aid Change, Percentage Points (95% CI)
Unaided hearing		76.5 (72.7 to 80.3)		NA
Oticon Nera 2 hearing aid[c]	1910.00	88.4 (84.5 to 92.4)	11.9 (9.8 to 14.0)	
PSAP				
Sound World Solutions CS50+	349.99	87.4 (83.5 to 91.4)	11.0 (8.8 to 13.1)	−1.0 (−2.7 to 0.8)
Soundhawk	349.99	86.7 (82.7 to 90.6)	10.2 (8.0 to 12.3)	−1.8 (−3.5 to 0)
Etymotic BEAN	299.99	84.1 (80.2 to 88.1)	7.7 (5.5 to 9.8)	−4.3 (−6.1 to −2.5)
Tweak Focus	269.99	81.4 (77.4 to 85.3)	4.9 (2.8 to 7.0)	−7.0 (−8.8 to −5.3)
MSA 30X Sound Amplifier	29.99	65.3 (60.1 to 70.4)	−11.2 (−15.2 to −7.3)	−23.1 (−26.9 to −19.4)

Abbreviations: NA, not applicable; PSAP, personal sound amplification products.

[a] The pure-tone average was 500-4000 Hz; the mean dB HL was 34.7 in the right ear and 36.1 in the left ear.

[b] The cost of the hearing aid was the wholesale price paid by the Johns Hopkins University Audiology Clinic. PSAPs were purchased online (Sound World Solutions CS50+, Soundhawk, Etymotic BEAN, Tweak Focus) and storefront retail (MSA 30X Sound Amplifier). All devices were purchased between January 2016 and April 2016.

[c] Oticon Nera 2 is a US Food and Drug Administration–regulated hearing aid, whereas all other devices are PSAPs.

of the PSAPs demonstrated an improvement that was within 5 percentage points of the hearing aid (Sound World Solutions CS50+: accuracy, 87.4%, difference, 11.0 percentage points [95% CI, 8.8 to 13.1]; Soundhawk: accuracy, 86.7%, difference, 10.2 percentage points [95% CI, 8.0 to 12.3]; Etymotic BEAN: accuracy, 84.1%, difference, 7.7 percentage points [95% CI, 5.5 to 9.8]). For 1 PSAP, mean aided speech understanding was worse than the unaided condition (MSA 30X: accuracy, 65.3%, difference, −11.2 percentage points [95% CI, −15.2 to −7.3]).

Discussion | Select PSAPs were associated with improvements in speech understanding for individuals with hearing loss that were similar to results obtained with a hearing aid, whereas 1 demonstrated little improvement and 1 degraded speech understanding. To our knowledge, this is the first study of PSAPs that controlled for between-participant variability and order effects. The study was limited by a modest number of participants, sampled by convenience, who were tested in a controlled audiological setting under unilaterally aided conditions and with only a limited sample of currently available hearing technologies. Whether similar results would have been obtained with other devices or if the user self-programmed the device is unknown. Results lend support to current national initiatives from the National Academies,[1] White House,[2] and bipartisan legislation[3] requesting that the US Food and Drug Administration create a new regulatory classification for hearing devices meeting appropriate specifications to be available over the counter.

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COMMENT & RESPONSE

Osteoporotic Fractures Associated With Dabigatran vs Warfarin

To the Editor In a retrospective population-based cohort study including adult patients newly diagnosed with nonvalvular atrial fibrillation and subsequently prescribed dabigatran, a non-vitamin K antagonist oral anticoagulant (NOAC), or the vitamin K antagonist warfarin, Mr Lau and colleagues reported lower osteoporotic hip plus vertebral fracture risk among dabigatran vs warfarin users (incidence rate ratio [IRR], 0.38; 95% CI, 0.22 to 0.66).[1] This is an important finding that requires careful interpretation.

The lower hip plus vertebral fracture risk in dabigatran vs warfarin users could result from a decrease in the risk with dabigatran rather than an increase in the risk with warfarin because posthoc analysis in patients newly diagnosed with nonvalvular atrial fibrillation showed that dabigatran use was associated with lower fracture risk compared with nontreated patients (IRR, 0.52; 95% CI, 0.33 to 0.81). The possibility is also supported by accumulating clinical data indicating that warfarin use is unlikely to cause fragility fractures, especially the most severe hip fracture, generally due to falling among older patients.[2-4]

The lower hip plus vertebral fracture risk in dabigatran vs warfarin users[1] was marked in patients with a history of falls or fractures (IRR, 0.12; 95% CI, 0.04 to 0.33) but was not found in those without such history (IRR, 0.95; 95% CI, 0.45 to 1.96) and was present after less than 1 year of use (IRR, 0.41; 95% CI, 0.21 to 0.79). These results theoretically imply a rapid and strong antifracture efficacy associated with dabigatran use; the mechanisms involved are unknown, but dabigatran use might result in the prevention of falls rather than the improvement of bone fragility because the latter takes time considering the antifracture efficacies of current osteoporosis drugs.

Further studies are expected, as suggested by the authors,[1] to clarify the risk not only of age-related fractures