Canadian Audiologist

The Official Publication of the Canadian Academy of Audiology

OTC and Observations on the Humes et al Study

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Published May 4, 2017

Reprinted from HEARINGREVIEW.COM 1 FEBRUARY 2016

Part 1: Commentary by Marshall Chasin:

Perhaps the most well-read article of 2017 is “The effects of service-delivery model and purchase price on hearing-aid outcomes in older adults: a randomized double-blinded placebo-controlled clinical trial” by Larry Humes and his colleagues at Indiana State University, published in the March 2017 edition of the *American Journal of Audiology*.[1]

Once you get past the mouthful of a title and get into the meat of the article, one realizes that it was a Herculean effort. Without the subjects or the audiologists involved, being aware of who was who and what was what, subjects were divided randomly into three groups: 1) Those who were fitted and counseled regarding amplification, verification, and the use of hearing aids (Audiology Best practices model, or AB); 2) Those who were “provided” with hearing aids in a consumer-decided over-the-counter (OTC) model where consumers choose their own pre-programmed hearing aids (CD), and 3) Those who were assigned to a Placebo (P) group.

In the first two groups (AB and CD), the hearing aids were set to the appropriate NAL prescriptive hearing aid fitting formula for Program #1, with Programs #2-4 being set up as a volume control. The Placebo (P) group had hearing aids set to 0 dB insertion gain- no amplification. Data logging assessed at the end of the experiment showed that about 3/4 of the time subjects used program #1.

Here are a few of the interesting findings:

- Overall, the CD model of OTC service delivery yielded only slightly poorer outcomes than the AB model.
- Purchase price had no effect on the outcome measure (PHAB), independent of PHAB result, but more rejected the hearing aids who paid more for them,

- The overall satisfaction of the Audiology Best practices (AB) group was 81%.
- The overall satisfaction of the Consumer Decides (CD) group was 55%.
- The overall satisfaction of the Placebo (P) group was 36%.
- Subjects in the CD and P groups underwent an additional four week intervention by audiologists according to audiology best practices and these subjects significantly improved.

These results provide us with some insights. For some subjects with a mild sloping to moderate hearing loss (where open hearing aid fittings are appropriate), some level of satisfaction was achieved when consumers were allowed to make a selection of pre-programmed hearing aids. This level of satisfaction was significantly improved by a 4-week audiology-based follow-up. More than a third of subjects in the Placebo group (with no amplification) were satisfied with the hearing aids, implying that for many subjects a trial of any hearing device was better than nothing, even one that provided no improvement in audibility.

It should be pointed out that the "Consumer Decides (CD)" group used in this study is *not* the same as the OTC model that has been discussed in the PCAST recommendations[2] or even necessarily the subsequent discussions in the National Academy of Sciences (NAS) recommendations.[3] These models do not include any programming and audiometric testing that was included in the Humes study,1 so caution should be exercised to extend the findings reported here to a model that does not include professional hearing care services.

While it can be argued that studies such as this have some limita-tions, this study can provide some insight into the dollar value of audiology input and that the value is only, in part, related to the prescription and the verification of an optimal hearing aid fitting.

For hard-of-hearing consumers who do require some mid-frequency amplification and therefore a (semi) occluding eartip or earmold, the dangers of the consumer decision (CD) group become more apparent where overly high sound levels can be achieved that may lead to rejection of the hearing aids and even possibly a hearing aid-induced hearing loss caused by overly high and unverified outputs.

Part 2: Commentary by Steve Aiken:

As a profession, we have a responsibility to look for ways to minimize the impact of hearing loss for everyone. Access to hearing and communication is just too important to be limited on the basis of financial means. Audiologists have been engaged in efforts to improve accessibility since the very inception of the field, but cost is a barrier that is still faced by many people. Therefore, it makes sense to consider the merits of service delivery models that may reduce cost, such as over-the-counter (OTC) sales.

One thing worth keeping in mind is that the OTC model in the Humes et al paper was different from what many people may be envisioning (eg, hearing aids sold without any involvement of the hearing care professional). In this excellent study, all participants underwent an audiological assessment in advance of the OTC trial to ensure that they were suitable candidates. Although the study did not investigate the value of including this assessment for hearing aid outcomes, there would be obvious concerns with foregoing the assessment entirely. Many people with hearing loss require other

audiological or medical care, and many are not suitable candidates for hearing aids.

For example, individuals with cholesteatomas, eighth nerve tumours, otosclerosis, or sudden hearing losses would be poorly served by a system that led them to treat the hearing loss without detection of the underlying medical condition. Children with hearing loss or adults with greater degrees of loss would be at a disadvantage without an audiologist fitting the aid, counseling, and working to ensure that they have access to other important support services and technologies (eg, FM systems in the classroom).

In sum, while OTC hearing aid sales may be useful for improving access, a proper diagnostic test and consultation at the outset is an important component of hearing healthcare, and should be part of any approach that includes low-cost OTC-type delivery as an option for suitable candidates. We should not encourage the adoption of a model that achieves lower costs by foregoing hearing healthcare services altogether, thereby putting the health of people at risk and disadvantaging those who require professional service. And while the best-practice model might cost a bit more, there is clear value in that model—even for the people with small amounts of hearing loss in this study. For those with greater degrees of loss, the value of the best-practice model is likely much higher. No one is talking about OTC hearing aids for severe hearing loss or do-it-yourself cochlear implant kits! Our overall goal should be better access and better health and hearing outcomes *for everyone*, not improved access at the expense of poorer outcomes.

Reference

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