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Transformations in the Hearing Aid Industry Caused by Over-the-Counter Hearing Aids

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ABSTRACT

Over the last decade, South Korea has experienced a notable annual increase in its elderly population, leading to a significant upsurge in the prevalence of hearing loss (HL) among individuals aged 65 and above. However, the adoption of hearing aids (HAs) in South Korea has been hindered by various barriers. This paper aims to provide a comprehensive exploration of the concept of over-the-counter (OTC) HAs, the legislative development that surround them, and the potential implications of these changes. The primary focus is on how OTC HAs have the potential to improve accessibility and affordability for individuals dealing with mild to moderate HL. Furthermore, this paper delves into the global market for OTC HAs, shedding light on its current status and future projections. It also considers the role played by personal sound amplification products in the broader soundscape of hearing assistance devices. Additionally, the paper discusses the emerging sound amplification features integrated into smartphones and their impact on the HA landscape. As the study concludes, it emphasizes the critical need for empirical research to assess the adoption of OTC HAs among the elderly population. Furthermore, it highlights the importance of providing adequate user support to ensure the successful integration of these devices into the lives of elderly individuals, given the demographic characteristics of the primary user base. In essence, this paper provides a comprehensive overview of the evolving landscape of hearing assistive devices, with OTC HAs at its forefront, and the potential transformations and challenges associated with their adoption.

KEY WORDS: Hearing loss; Presbycusis; Hearing aids; Correction of hearing impairment; Behind-the-counter drugs.

Introduction

Over the past decade, South Korea has witnessed the most pronounced annual increase in its elderly demographic within the OECD countries. Consequently, the prevalence of hearing loss (HL) among individuals aged 65 and above in South Korea has surged to a notable 57%.[1)] Recent research has shed light on the growing association between HL and dementia,[2)] thereby intensifying interest in the field of HL treatment.

Hearing aids (HAs) are widely acknowledged as the pre-eminent modality for hearing rehabilitation. Nonetheless, in

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the context of South Korea, various impediments, including financial constraints, societal biases, stigma, and multifarious challenges, have culminated in only 17.4% of patients with HL being able to procure HAs. Moreover, an insubstantial 12.6% of this demographic effectively integrate these devices into their daily lives.[3)]

In an endeavor to mitigate these issues and augment the accessibility and affordability of HAs for a broader segment of the populace, the U.S. Food and Drug Administration (FDA) introduced legislative provisions pertaining to over-the-counter (OTC) HAs in August 2022. The current study is poised to investigate OTC HAs comprehensively and engage in a prospective discussion regarding the transformative potential of OTC HAs within the HA market.

Definition of Over-the-Counter Hearing Aids

The term 'OTC HA' means that[4)]:

a) It utilizes the same core scientific technology as traditional air conduction HAs or wireless air conduction HAs.
b) Its primary intended users are adults aged 18 and older who experience mild to moderate HL as perceived by the individual.
c) It provides users with tools, tests, or software that enable them to control and customize the device to suit their specific hearing needs.
d) It may incorporate wireless technology and may offer self-assessment tests for users to evaluate their own HL.
e) It is available for purchase OTC without requiring supervision, prescription, or any form of intervention from a licensed professional. Consumers can obtain it through in-person transactions, by mail, or online.

Legislation Pertaining to Over-the-Counter Hearing Aids

In 2015, the "Aging America & Hearing Loss: Imperative of Improved hearing Technologies" report, issued by the President's Council of Advisors on Science and Technology (PCAST), brought attention to the growing prevalence of hearing-related issues attributable to the rapidly aging population. To address this concern, the report not only recommended the dissemination and utilization of HAs but also advocated for the availability of OTC auditory devices, such as personal sound amplification products (PSAPs), for individuals experiencing mild to moderate HL. Consequently, PCAST proposed the withdrawal of the "Draft Guidance for Industry and Food and Drug Administration Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products," which had been issued by the FDA in 2013. Moreover, they recommended permitting the use of PSAPs for the purpose of auditory compensation among individuals dealing with mild to moderate HL.[5)] Similarly, the "Hearing Health Care for Adults: Priorities for Improving Access and Affordability" report, published by the National Academies of Sciences, Engineering, and Medicine (NASEM) in 2016, also advocated for the creation of a new FDA category specifically tailored to OTC auditory devices intended for adult patients with mild to moderate HL.[6)]

In August 2017, the United States Congress passed the "OTC HA Act of 2017," which mandated the FDA to establish a new category for HAs that could be sold as OTC HAs without the requirement for professional intervention. The FDA was further tasked with ensuring the safety and efficacy of these OTC HAs. In response to this legislative directive, hearing healthcare professional associations in the United States issued regulatory recommendations in August 2018 under the title "Regulatory Recommendations for Over-The-Counter Hearing Aids: Safety & Effectiveness."[7)] Due to delays incurred as a result of the COVID-19 pandemic, the final rule pertain to these OTC HAs was announced in October 2022.[8)]

These legislative developments represent a notable shift in the regulation and availability of hearing assistive devices, with a particular focus on enhancing accessibility and affordability for individuals experiencing mild to moderate HL. The regulatory landscape continues to evolve in response to the pressing public health needs associated with hearing health and improved accessibility.

Global Market for Over-the-Counter Hearing Aids

The global market value for OTC HAs was approximately $1.06 billion in 2022 and is expected to grow at a compound annual growth rate of 6.6% from 2023 to 2030.[9] OTC HAs are becoming increasingly popular due to their more affordable price point and easier accessibility compared to traditional HAs.

On average, a pair of traditional HAs costs about $4,000 to $6,000, whereas OTC HAs are priced at around $200 to $1,000. In South Korea, where there is currently no reimbursement system for age-related HL, OTC HAs are predicted to rapidly gain a significant portion of the market share in the HAs sector due to their accessibility and affordability.

Implications of Over-the-Counter Hearing Aids

In the evolving landscape of audiological solutions, the introduction of OTC HAs promises transformative changes. As OTC HAs gain traction, there's an inherent expectation of a downward adjustment in the price metrics of these devices. This model undoubtedly elevates affordability. Yet, it is crucial to underscore that individuals on fixed incomes might still grapple with economic challenges, notwithstanding the ostensibly reduced costs.

Regulatory realignments promise to infuse the market with a broader array of device options. While this diversification – in terms of aesthetics, functionality, and cost – augments choices, it might also inundate users, eliciting potential decision paralysis. This highlights an emergent need for structured guidance in device procurement for specific user cohorts.

Predominantly, OTC HAs are geared towards self-fitting, integrating contemporary technological strides like Bluetooth and smartphone compatibilities. Such shift accentuates patient autonomy and curtails expenses linked to professional interventions. However, it's salient that segments of the elderly demographic might face impediments in embracing this autonomy. Hence, instituting a trial period, where users can return devices sans penalties upon facing self-fitting or usability issues, becomes paramount.

The OTC model inherently redefines the conventional roles assumed by hearing healthcare professionals. This model emancipates patients from erstwhile mandatory professional dependencies, both logistically and financially.

Furthermore, regulatory changes are poised to introduce new entrants into the HA market. Innovators may develop devices that are specifically tailored to the needs of older individuals, taking into account factors such as dexterity and vision issues.

To date, there are only a few studies on the clinical validity of OTC HAs. The majority of published studies have been related to the fitting of OTC HAs.

Other Types of Hearing Devices for Patients with Hearing Loss

PSAPs are wearable electronic devices available OTC, designed to enhance auditory experiences in specific contexts. They possess the capacity to amplify ambient sounds but remain outside the purview of FDA regulations, thus precluding their promotion as assistive tools for individuals with HL. The FDA has delineated permissible uses for PSAPs, encompassing activities like hunting, bird watching attending lectures at a distance, and facilitating the perception of faint sounds, even for those with unimpaired hearing.

Distinguished from OTC HAs, PSAPs exhibit two principal distinctions. Firstly, PSAPs are explicitly indicated for individuals without HL, with a primary focus on augmenting auditory perception in specific environmental settings. Nevertheless, due to their amplification capabilities and cost-effectiveness relative to traditional HAs, many individuals with HL opt to employ PSAPs as substitutes for conventional HAs.[10]

Secondly, PSAPs fall under the classification of electronic products rather than FDA-regulated medical devices. Consequently, a substantial portion of PSAPs lack validated safety and efficacy data. Prior to employing PSAPs as compensatory aids for HL, it is prudent to conduct comprehensive assessments, including electroacoustic analysis, real-ear

measurements, and clinical evaluations such as functional gain and speech audiometry, to ascertain their safety and clinical utility.[11,12]

The term "hearable" encompasses a broad spectrum of ear-level devices engineered to enhance or complement auditory experiences. These devices may encompass additional functionalities such as monitoring vital signs, tracking physical activity, enhancing auditory perception, streaming music, translating languages, or facilitating direct communication.

Recent developments indicate a burgeoning interest in sound amplification capabilities among major global smartphone manufacturers, including Apple and Samsung Electronics. For example, Apple offers a feature known as "Headphone Accommodations" on its iPhones. This feature empowers users to tailor sound settings according to their individual auditory preferences. Adjustment of sound parameters can be accomplished either by directly inputting audiogram data or by means of a series of hearing tests integrated into the iPhone interface. The customized sound output can then be experienced through Apple's AirPods. However, it is noteworthy that extant research on the efficacy of Apple's "Headphone Accommodations" as a hearing assistive device remains limited.

Samsung Electronics provides a parallel feature to Apple's, permitting users to modulate sound through the "Amplify Ambient Sound" functionality on Galaxy smartphones and Galaxy Buds. The key point of departure between the sound amplification features of Apple and Samsung Electronics lies in Apple's capacity to effectuate frequency-specific sound adjustments, whereas Samsung Electronics offers a more generalized sound amplification. Nevertheless, Samsung Electronics' sound amplification feature has demonstrated favorable outcomes under controlled laboratory conditions[13] and has garnered real-world clinical validation as well.[14]

Future Direction

The implementation of the OTC HA Act is poised to introduce a wide array of new hearing assistive devices to the market, characterized by significant diversity in terms of appearance, cost, and functionality. This legislation aims to make HAs more accessible through OTC channels, potentially lowering the financial barrier to acquiring such devices. However, the subsequent impact of this accessibility on adoption rates, particularly among the geriatric population, remains a question that requires empirical investigation.

It is important to recognize that the elderly demographic, which predominantly constitutes the consumer base for OTC HAs, often requires assistance with various aspects of these devices, including fitting, utilization, and maintenance. This poses a critical consideration in the successful implementation of the OTC HA Act. The need for user support, particularly for individuals who may not be technologically savvy or who may have physical limitations, must be addressed to ensure that the intended benefits of OTC HAs are fully realized.

In summary, while the OTC HA Act has the potential to democratize access HAs by diversifying their availability and potentially lowering costs, its impact on the adoption of these devices among the elderly population remains uncertain and merits further empirical investigation. Additionally, addressing the support and assistance needs of elderly users is crucial for the successful integration of OTC HAs into their lives, given the demographic characteristics of the primary user base.

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