Executive Summary

The objective of this study is to provide a basic data for promoting use of hearing aids (HA) and associated satisfaction among the patients who need hearing aids clinically. The contents are as follows: 1) the current status of hearing aids use in Korea was investigated by using secondary data such as Korean National Health and Nutrition Examination Survey (KNHANES) IV, National Health Insurance Corporation (NHIC) data, and so on. Also hearing aids cost in Korea and abroad has been compared; 2) a survey on patients with sensorineural hearing loss (≥ 30 dB) and age ≥ 50 years old was performed to solicit patients' satisfaction and to identify barriers on hearing aids use; 3) a systematic review on domestic and international literature were used to compare the effect of hearing aids by each type and whether it is possible to recommend a type of hearing aids for a specific patient group.

1. The current status of patients with hearing loss and use of hearing aids in Korea

From the 2008 KNHANES IV results, those who reported a subjective hearing problem were projected to 11.97% of the total Korean population. Of those who reported a problem, the rate of using hearing aids was very low, about 5.46% of the population. Also the reporting was five times higher in the elderly (aged 65 or older) than those younger than 65. In a subgroup analysis on the group reporting a hearing problem, the usage of hearing aids was significantly higher among those suffering activity limitation from the hearing problem.

In Korea, the health insurance benefit for hearing aids is 80% of purchasing price up to 272,000 KRW (80% of purchasing price equal to

340,000 KRW). From an analysis of NHIC data, the total amount of benefits paid to patients for hearing aid devices in 2009 was 6.3 billion KRW while the total amount of reported purchased price was 29.7 billion KRW. These numbers indicate that the patients were actually receiving about 20% of purchased price as a NHIC benefit. According to a follow up analysis of medical claims on these patients who received HA benefits, only 12.2% used a medical service related to hearing loss or Ear Nose Throat (ENT) specialty service in a week after the purchase date and this percentage only increases to 30.4% if the period expanded to 100 days from the purchase date. These results suggest the management of hearing aid after purchase seems insufficient.

The hearing aid market size has been estimated by the statistical report of the Korea Medical Devices Industry Association statistics on HA production, HA import, and HA export related quantities and amounts. The results show a consistently increasing trend in HA stocking quantity from 69,000 in 2005 to 81,000 in 2006 and 99,000 in 2008. Although these quantities would include inventories, this trend suggests HA market is growing. In terms of HA sales, it reached as much as 31.5billion KRW in 2008, however, a caution is needed to interpret this figure since this estimated sales is based on the unit production/import cost not a consumer price observed in the market, i.e. highly likely under-estimated.

2. Barriers on use of hearing aids

Among the study groups (HA users, HA non-users, new to HA) who needs HA, a questionnaire survey was performed on 116 new to HA patients, 80 HA non-users, and 121 HA users. For the status of HA purchase history, < 1 year was highest among the HA users and HA non-users. For the purchasing path, it had the highest frequency in purchasing at the hospital with a doctor's prescription. The mean purchasing price of HA was 2.51 million KRW, and it was different

between HA users (2.65million KRW) and HA non-users (2.31 million KRW), about 340K KRW difference. The percentage of applying health insurance subsidy for disabled people also showed a difference between HA users (35.9%) and HA non-users (20.0%).

In terms of HA usage, most of HA users answered HA is ‘helpful’ in usual activities, while it was low for non-users. The satisfaction on HA use, repair service, and the attitude at purchasing place was different between HA users and HA non-users. It seems HA use is related to the aforementioned outcomes. For the difficulties related to use of HA, most of users answered ‘no-difficulty’, while the majority of non-users reported a difficulty. More specifically, 'noise/noisy situation' was the highest barrier factor of 36.7% among the users while ‘low effectiveness of wearing HA’ was the highest barrier factor (51.3%) among the non-users. However, willingness to repurchase was 67.1% among the non-users, hence, this may suggest existence of unmet needs. The reasons for not purchasing HA even though it is necessary (new to HA group) were found to be uneasiness of wearing HA, burden for high HA price, and negative image of wearing HA.

The following tools for HA related research were investigated: College Students Attitudes Toward Loss of Hearing Questionnaire (C-ALHQ), Hearing Handicap Inventory for the Elderly-Screening (HHIE-s), Abbreviated Profile of Hearing Aid Benefit (APHAB), Expectation for hearing aids (Meiser), and Satisfaction with Amplification in Daily Life (SADL). Except the Meiser tool and SADL, the mean difference among 3 study groups was statistically significantly different. In case of SADL, only users and non-users were surveyed and they showed statistically significantly different.

In the analysis results of C-ALHQ, HA users showed the most positive attitude towards HA, followed by new to HA group and HA non-users except on social stigma area. The analysis results of HHIE-s revealed hearing disability level was the most severe among HA non-users, followed by HA users and new to HA group. In the analysis results of

APHAB, new to HA group showed least difficulty in communication before using HA, followed by HA users and HA non-users. From the analysis results of expectation for HA (Meiser), HA users had the highest expectation level, followed by new to HA group and HA non-users. The analysis results of satisfaction on HA use (SADL) showed the satisfaction level is higher in HA users compared to HA non-users.

Multiple regression analyses revealed that hearing disability level significantly affects on the decision to use HA, the hearing ability of better ear was significant among HA non-users while the ability of worse ear was significant among HA users. In addition, more positive attitude was associated with higher chance of using HA. Elderly (>65 years old) had more positive attitude towards HA across all groups. Employed people showed more positive attitude towards HA among HA users whereas blue collar occupation had higher satisfaction level compared to unemployed among both HA users and HA non-users.

3. Hearing aid cost investigation in foreign countries and Korea

Due to the limitations of available data and differences in warranty (periods and conditions), it was impossible to compare across the countries. However, the price range of HA in Korea seems rather higher than countries such as US, UK and Australia while it was similar to Japan.

4. Reimbursement policy comparison on hearing aids: foreign countries and Korea

The reimbursement level in Korea was found to be relatively low compared to many foreign countries, especially in terms of considerations such as severity of hearing loss and hearing aids support for hearing difficulty in both ears. In case of UK, a patient with hearing loss is examined by Ear, Nose, Throat (ENT) specialist first and then HA can be

rented from a National Health Service (NHS) hospital. This free HA has limitations such as long waiting hours and no selection for HA available. Instead, the patient can purchase her/his favorite HA from a private vendor with 100% out of pocket payment. In France, also an ENT specialist prescribes HA after a hearing examination. The extent of reimbursement coverage depends on age but on average about 65% of total cost is reimbursed. Germany and Belgium have a similar system like France except for hearing difficulty in both ears which can be reimbursed only if both ears satisfy a pre-set standard. In Swiss, the reimbursement amount varies depending on hearing loss decided by ENT specialists. In USA, HA reimbursement largely depends on type of health insurance plan. Medicare does not cover HA but it can cover 80% of hearing test cost if medically necessary. Medicare Advantage covers HA but the reimbursement level varies according to geographic region, for example, Minnesota plan covers up to 50% of one HA per two years. Medicaid also has variety of reimbursement levels for HA: 30 states cover partially or fully while 20 states do not cover HA at all. Canada also has significant geographical variety in HA reimbursement. In Australia, voucher system covers full cost of HA for juveniles under 21 years old, pensioners, veterans, and the soldiers in service while other adults aged 21 to 65 years old have to pay 100% out of pocket payment for HA. Compared to Korean reimbursements for HA, the aforementioned foreign countries have a more fine tuned system. For example, in Korea, there is no reimbursement standards by hearing loss levels nor special clause for hearing loss in both ears.

5. Comparison on effectiveness of hearing aids by types using systematic literature review

In the present study, the effectiveness of hearing aids for the patients suffering from hearing difficulty was examined by systematic literature review. For that purpose, the effectiveness of each HA type was

compared and a review of possibility whether patient characteristics can be matched to HA types was performed. Based on a predefined literature review strategy, a review was conducted for both international and domestic databases and total 17,983 articles were found. The final selection matched by this study goals included 38 international studies and 5 domestic studies. Of total 43 studies selected, only 2 studies were randomized clinical trials. Only 13 studies compared different types of HA and the rest of studies were before-and-after studies.

There was high level of heterogeneity in terms of types of HA, comparison group, and outcomes, therefore, a meta analysis was not feasible and only descriptive analysis was performed on these studies. The results were summarized on effectiveness of HA and quality of life including satisfaction by before-and-after studies or comparative studies. Most of studies reported HA is effective on hearing difficulty. To match patient characteristics and effective HA type, different patient group were investigated such as patients with sensorineural hearing loss, patients using bone anchored hearing aids (BAHA) or patients having a problem in bone conduction, patients with any type of hearing loss. Each patient group cannot be matched to HA types since there was lack of evidence and lack of statistical significance results. From a qualitative review of final selection of 43 literature showed an overall quality of "very low quality."

6. Conclusions

The significance of the present study is that this is the first study utilized multiple source of data to examine the current status of HA in Korea: Korea National Health and Nutrition Examination Survey (KNHANES), National Health Insurance Corporation (NHIC) reimbursement data on HA, and Korea Medical Device Industry Association (KMDIA) statistical reports were used. Another significance is a survey on patients with hearing difficulty was performed to investigate HA use, attitudes on

HA, and satisfaction on HA by groups such as HA users, HA non-users, and new to HA group. Finally, a systematic literature review showed there is a very low quality evidence that HA is effective.

In conclusion, it was confirmed that social attitude towards HA and satisfaction level on HA is still long way to go even though patients suffering from hearing difficulty and patients who need HA to overcome social restrictions are increasing. Therefore, it is necessary to establish a system to provide a HA prescription fits to the characteristics of each patient with hearing difficulty by a systematic classification of various types of HA along with post-management of HA. In addition, it is necessary to develop an appropriate management program to increase satisfaction level of HA accompanied with education, dissemination, and an expansion of financial support for HA purchase.