A Systematic Review on the Safety and Effectiveness of the Active Middle Ear Implant in the Treatment of Conductive and Mixed Hearing Loss

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OBJECTIVES

An active middle ear implant (aMEI) was evaluated by the New Health Technology Assessment Committee (nHTA) in Korea in 2012 as a safe and effective technique for sensorineural hearing loss. However, for conductive hearing loss (CHL) and mixed hearing loss (MHL) it was determined a technique requiring further research due to insufficiency evidence. This systematic review aimed to evaluate safety and effectiveness of aMEI in CHL and MHL patients who do not expected achieve sufficient hearing gain with conventional treatment options.

METHODS

Ovid-MEDLINE, Ovid-EMBASE, Cochrane library and five Korean databases were searched on 27 January 2022. The risk of bias was assessed using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist 2014. The entire process was conducted in collaboration with otolaryngology experts.

PICO

- Patient: CHL and MHL patients who do not expected achieve sufficient hearing gain with conventional treatment options
- Intervention: Active middle ear implant (aMEI)
- Comparators
  - Bone conduction hearing implants (BCHI)
  - conventional hearing aid (cHA) in the same patient
- Outcomes
  - procedure-related adverse events, loss of residual hearing
  - Pure-tone thresholds, functional gain, speech discrimination
  - Patient satisfaction and quality of life

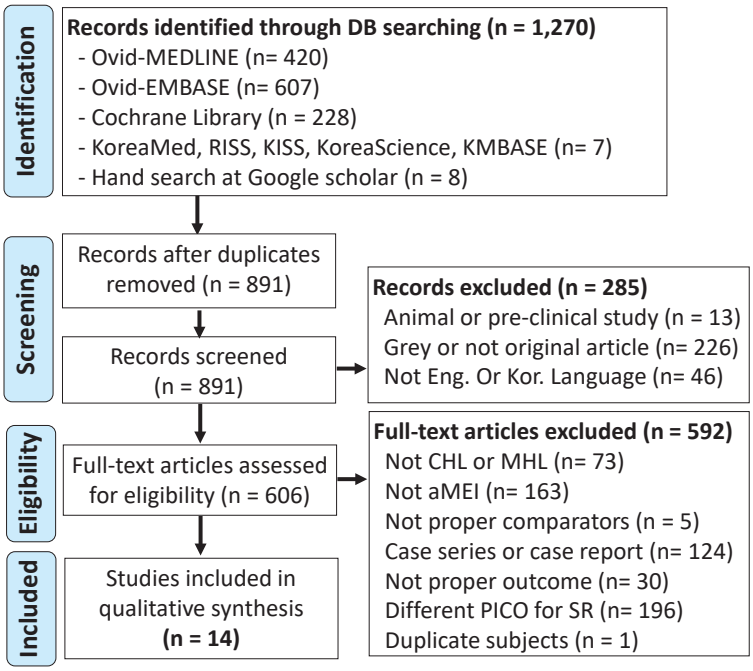

Fig 1. PRISMA Flow Diagram

RESULTS

Of the total 1,270 retrieved articles, 14 articles were selected. Three cohort studies compared aMEI to bone conduction hearing implants (BCHI) and twelve case-crossover studies compared aMEI with conventional hearing aid (cHA) in the same patient.

The hearing thresholds in the range of 500 to 8,000 Hz were significantly lower aMEI than cHA. The meta-analysis result based on five studies showed a significantly greater functional gain in aMEI compared to BCHI or cHA (MD = 9.57 dB, 95% CI = 8.35, 10.78, I^2 = 0%; Fig. 1).

In four studies, speech discrimination was significantly better with aMEI compared to cHA. Patient satisfaction was higher with aMEI compared to cHA, but no differences with BCHI.

Adverse events such as device dislocation, mild dizziness, wound infection, and facial palsy, were reported. However, these cases were rare and fully recovered with treatment. Additionally, there was no post-operative loss of residual hearing.

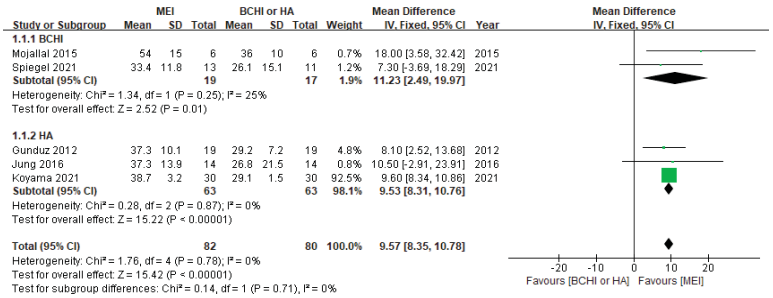

Fig 2. Forest plot – functional gain

CONCLUSIONS

aMEI has been proven to be a safe and effective option for hearing rehabilitation in CHL and MHL patients who do not achieve sufficient hearing gain with conventional treatments or unable to use cHA due to anatomical limitations.

The nHTA committee determined aMEI to a safe and effective technique, and announced through the Korean Ministry of Health and Welfare (MOHW) bulletin No. 2022-150 (23 June 2022).

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