Evaluation of Bone-Anchored Hearing Instruments in Chronic Otitis Media: A Multicenter Prospective Study

Original Investigation

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Abstract

Objective: This study aims to assess the effectiveness of bone-anchored hearing instruments (BAHIs) in patients with chronic otitis media (COM), using objective and subjective measures. It is a multicenter, prospective trial involving patients with COM who have undergone surgical treatment and have been rehabilitated using BAHIs.

Methods: COM Questionnaire-12 (COMQ-12), Speech, Spatial, and Qualities of Hearing Scale (SSQ), World Health Organization (WHO) Quality of Life-BREF questionnaire, and audiometric tests were used for assessment.

Results: Twenty-eight patients were included. The average duration of COM was 20.1±13.32 years. Among the patients, 60.7% (17) were using hearing aids, with a mean usage duration of 10.8±10.7 years (ranging from 1 to 36 years). Seven patients received the PONTO device, two received the BAH aid (BAHA) connect system, and 19 were implanted with the BAHA attract system. COMQ-12, SSQ, WHO questionaries, and audiometric tests showed significant improvement, and the results were found stable during follow-up.

Conclusion: This study reinforces the effectiveness of BAHIs in improving hearing thresholds and quality of life for patients with COM.

Keywords: Chronic otitis media, hearing loss, bone-anchored hearing aids, hearing rehabilitation, quality of life

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Cite this article as: *Ardıç FN, Gülmez Mİ, Okuyucu Ş, Şahin Mİ, Başkadem Yılmazer A, Özmen ÖA et al. Evaluation of bone-anchored hearing instruments in chronic otitis media: a multicenter prospective study. Turk Arch Otorhinolaryngol. 2025; 63(1): 10-15*

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Received Date: 24.12.2024
Accepted Date: 25.02.2025
Epub: 16.06.2025
Publication Date: 19.06.2025

DOI: 10.4274/tao.2025.2024-12-6

Introduction

Chronic otitis media (COM) is one of the most common ear conditions characterized by symptoms such as ear fullness, tinnitus, pruritus, otalgia, recurrent ear discharge, and, most significantly, hearing loss (1). In addition to the social burden of hearing impairment, patients also face the risk of chronic infections in the cranial bone. The global incidence of COM is 4.76% (2). It is estimated that 31 million new cases are diagnosed every year (3). Most of these are in less developed countries and one-fifth are children aged under five years (3). Typically, surgery is recommended to most patients to eradicate infection and restore hearing function. Approximately 70% of surgical cases were successful, with patients achieving an air-bone gap of less than 20 dB. However, 29% of patients had an air-bone gap greater than 20 dB (4). Bone conduction thresholds are also crucial, as these patients are at risk of developing sensorineural hearing loss (5). These two factors together indicate that a significant proportion of patients require hearing rehabilitation.

The first-line option for hearing rehabilitation is the use of hearing aids. Although patient compliance with hearing aid usage has improved, many individuals with hearing loss still do not use their hearing aids (6). Thirty-eight percent of patients were reported as a non-user in a recent meta-analysis (7). The reasons were lack of awareness of their condition, low perceived benefits, finding the device uncomfortable, social stigma, insufficient income, lack of social support and older age. Additionally, patients with COM, even those who have been adequately treated, may experience challenges such as acoustic feedback, improper fitting molds, background noise, sound distortion, discomfort in the ear canal, irritation, infection, and persistent discharge. Bone-anchored hearing instruments (BAHIs) offer a valuable alternative for these individuals. It is reported that there was no significant difference between hearing aids and BAHIs on audiometric test parameters (8).

This study aims to assess the effectiveness of BAHIs in patients with COM using objective and subjective measures.

Methods

This study is a multicenter, prospective trial involving patients with COM who have undergone surgical treatment and have been rehabilitated using BAHIs. Written informed consent was obtained from all participants or, in the case of pediatric patients, from their parents or legal guardians, and ethical approval was granted by the Pamukkale University Non-Interventional Clinical Research Ethics Committee (number: 14, date: 28.07.2020). The study is registered at clinicaltrials.gov, NCT06047639.

The observed effect size in a reference study was strong (dz=2.447). A power calculation showed that including a minimum (min.) of 24 participants would yield a study power of 80% at a 95% confidence level (9).

All patients were recruited from the otolaryngology departments. After careful ear examination, computed tomography, pure tone audiometry, and speech discrimination tests were performed. The subjects who volunteered to join the study completed the Clinical Service Recipient Inventory (18 questions) (10).

Inclusion Criteria:

- Adults
- No difficulty in attending follow-up visits
- Sufficient communication skills to interact with researchers
- Indication for BAHIs due to COM

Exclusion Criteria:

- Severe systemic illnesses (e.g., cancer, human immunodeficiency virus)
- Patients with compliance issues regarding hearing tests
- Use of medications or medical devices that could interfere with the study outcomes
- Inability to adhere to regular follow-ups or non-compliance with device usage

Parameters

The following tools were used for the subjective evaluation of BAHIs: the COM Questionnaire-12 (COMQ-12), the Speech, Spatial, and Qualities of Hearing Scale (SSQ) (48 questions), and the World Health Organization (WHO) Quality of Life-BREF questionnaire (27 questions) (11,12).

Surgical notes and middle ear risk index were also recorded (13). Hearing performance was measured using pure tone audiometry, speech discrimination scores (%), and free-field audiometry. The mean of 500, 1000, 2000, and 4000 Hz was used to compare pure tones.

All assessments were conducted preoperatively and postoperatively in the third and twelfth months. All different brands of bone-anchored devices were accepted. The specific surgical manuals for every device were used for surgical implantation. Transcutaneous [PONTO (Oticon Medical) and BAHA connect (Cochlear Inc.)] or percutaneous [BAHA attract (Cochlear Inc.)] were included.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows version 25.0. Continuous variables were reported as mean ± standard deviation, median (25^{th} and 75^{th} percentiles), and min.-max. values, while categorical variables were presented as frequency and percentage. The Shapiro-Wilk test was used to study the normality of the data distribution.

If parametric test assumptions were met, the independent sample t-test was applied for comparisons between independent groups. Otherwise, the Mann-Whitney U test was used. For comparisons within dependent groups, the paired sample t-test and repeated measures analysis of variance (with post hoc Bonferroni correction) were employed when parametric assumptions were met; otherwise, the Wilcoxon signed-rank test and the Friedman test were used. A p-value of <0.05 was considered statistically significant.

Results

A total of 28 patients, 16 male and 12 female, participated in the study. Their average age was 43.46±13.9 years, ranging from 11 to 64 years. The average duration of (COM was 20.1±13.32 years. Of the patients, 60.7% (17) were using hearing aids, with a mean usage duration of 10.8±10.7 years (ranging from 1 to 36 years).

Recurrent infections were reported in 72% of the patients, and 84% had middle ear problems. Additionally, 45% had other chronic conditions such as hypertension or diabetes, and 76% had undergone multiple ear surgeries. On average, patients visited their physician 3.42±3 times in the past six months and missed 2.29±6.73 workdays over the same period.

Regarding the implants, seven patients received the PONTO device (Oticon Medical), two patients received the BAHA Connect system (Cochlear Inc.), and 19 patients the BAHA Attract system (Cochlear Inc.). Fifteen patients had the implant on the left side and 13 on the right side.

All patients completed the COMQ-12 questionnaire during follow-up. Clinical improvements COM were observed in the 3rd month (p<0.05), with further improvements noted by the 12th month (p<0.01). There was no statistically significant difference between the 3rd- and 12th-month evaluations (p>0.05) (Figure 1).

According to the results of the WHO questionnaire, there was significant improvement in the general health of the patients (p<0.01), though other parameters showed no significant changes (Table 1).

The SSQ showed marked improvements across all measured parameters, with significant increases observed and sustained over the 12 months (p<0.001) (Table 1, Figure 2).

Audiometric evaluations revealed that all patients had benefitted from the implant. A statistically significant improvement was found when the mean air conduction threshold of the implanted side was compared with the mean postoperative free-field audiometric thresholds (p<0.001). This improvement persisted at the 12-month follow-up (p<0.001), with no significant difference between the 3rd and 12th-month evaluations (p>0.05) (Figure 3).

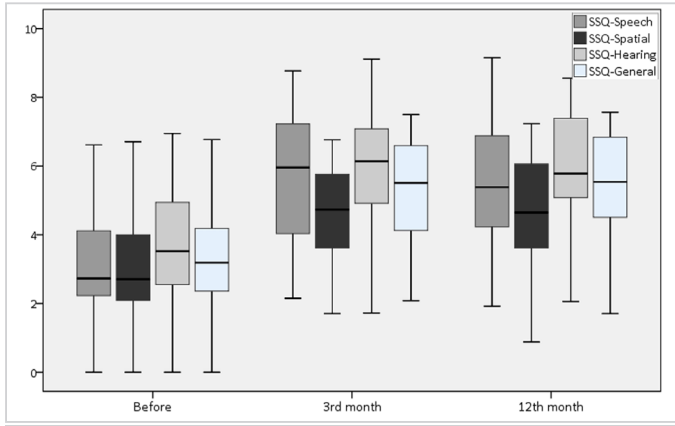

Figure 2. Changes in the Speech, Spatial, and Quality of Hearing Scale parameters were observed during the follow-up. There was a statistically significant change (p<0.001) in all parameters in the 3rd month, and it was stable during the 12 months

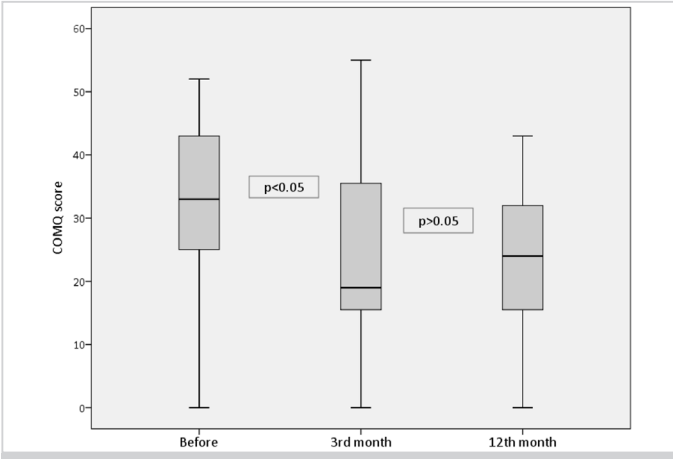

Figure 1. Chronic Otitis Media Questionnaire-12 continued to improve during the follow-up. There was a statistically significant decrease in the 3rd month (p<0.05) and the 12th month (p<0.01). But there was no difference between the 3rd and 12th months (p>0.05)

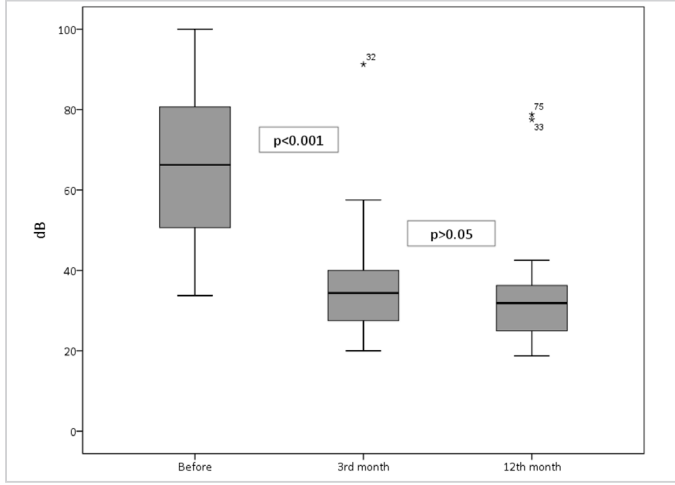

Figure 3. The mean air conduction threshold measured before the operation was compared with the mean free field thresholds after the implantation

Table 1. WHO Quality of Life-BREF Questionnaire was filled at the study's beginning and end. Speech, Spatial, and Qualities of Hearing Scale and audiometric tests were done before implantation and 3rd and 12th months after the operation

	Before			3rd month			12th month			
	Mean±SD	Median (IQR)	Min.-max.	Mean±SD	Median (IQR)	Min.-max.	Mean±SD	Median (IQR)	Min.-max.	p-value
WHO-general	40.62±24.44	43.75 (25)	0-100				59.72±22.28	62.5 (25)	12.5-100	0.001
WHO-physical	58.16±11.81	58.92 (10.7)	25-82.1				58.2±14.24	57.15 (25)	35.7-85.7	0.77
WHO-psychologic	58.33±15.12	58.3 (15.6)	20.8-83.3				60.03±15.64	58.3 (16.6)	25-100	0.44
WHO-social	55.95±22.32	58.3 (31.3)	16.7-100				62.96±23.71	66.66 (33.33)	8.3-100	0.15
WHO-environmental	60.6±16.6	62.5 (21.1)	25-96.9				66.66±12.73	65.62 (25)	46.9-90.6	0.14
COMQ-12	32.54±13.52	33 (19)	0-52	23.57±15.75	19 (55)	0-55	23.22±11.52	24 (43)	0-43	0.01
SSQ-speech	3.02±1.45	2.73 (1.9)	0-6.6	5.7±1.85	5.96 (3.32)	2.15-8.8	5.43±1.94	5.38 (3)	1.9-9.2	0.001
SSQ-spatial	3.01±1.53	2.7 (1.9)	0-6.7	4.67±1.4	4.73 (2.25)	1.7-6.8	4.73±1.64	4.64 (2.7)	0.9-7.2	0.001
SSQ-hearing	3.66±1.82	3.52 (2.4)	0-6.9	5.9±1.86	6.14 (2.27)	1.72-9.1	5.93±1.64	5.77 (2.44)	2.1-8.6	0.001
SSQ-total	3.26±1.51	3.19 (1.9)	0-6.8	5.41±1.57	5.51 (2.56)	2.08-7.5	5.37±1.58	5.54 (2.48)	1.7-7.6	0.001
Mean AC (dB)	66.38±17.44	66.25 (30.6)	33.8-100	65.58±18.18	66.25 (25)	30-100	65.69±17.09	653.75 (23.75)	32.5-100	0.97
Mean BC (dB)	30.52±16.09	27.5 (21.9)	3.8-67.5	31.65±15.61	29.37 (21.56)	6.3-61.3	32.45±16.21	32.5 (23.75)	7.5-63.8	0.90
FF w/implant (dB)				31.35±6.97	32.5 (12.5)	21.3-41.3	28.75±7.45	29.37 (15.63)	18.8-37.5	
WD w/o implant (%)				90±9.7	90 (19)	76-100	87.6±14.5	90 (19)	56-100	
WD w/implant (%)				96.8±3.1	96 (5)	92-100	96±4.2	96 (8)	88-100	

WHO: World Health Organization, SSQ: Speech, Spatial, and Qualities of Hearing Scale, AC: Air Conduction threshold of implanted side and BC: Bone conduction threshold of implanted side, FF: Free field audiometry, WD: Word discrimination, COMQ-12: Chronic Otitis Media Questionnaire-12, w/: with, w/o: without, Min.: Minimum, Max.: Maximum, SD: Standard deviation, IQR: Interquartile range.

There were no statistical differences between transcutaneous and percutaneous instruments regarding free-field implant gain and SSQ parameters (p>0.05).

Discussion

This study's findings show the positive impact of BAHIs in patients with COM. With an average duration of 20 years living with COM, the patient cohort reflects the challenges faced by those who suffer from recurrent infections, middle ear problems, and other chronic conditions. Notably, 60.7% of the patients had been using hearing aids, yet many still experienced limitations in hearing function, suggesting a need for more effective interventions like BAH systems.

These results align with previous studies that reported similar improvements in patients with conductive or mixed hearing loss using bone-anchored devices. The stability of these improvements between the 3rd and 12th months (p>0.05) further highlights the long-term effectiveness of BAHIs in improving quality of life. Lewis et al. (14) also reported improved both hearing and health-related quality of life.

The WHO questionnaire results indicated significant improvement in the general health of the patients (p<0.01), although other parameters did not show statistical changes. This can be attributed to the fact that the scope of BAHIs is primarily auditory. Nevertheless, improved hearing often leads to better communication, social interaction, and emotional well-being, which may explain the overall improvement in the general health perception of the patients. Twenty-seven patients were asked about their preference after using BAHIs for seven years, and 89% of them stated to prefer BAHIs over hearing aids (15). This preference for BAHIs over air-conduction hearing aids was reported as 58% in 1996 (16). In a follow-up study, 34 patients were asked about their BAHI and previous air-conduction hearing experiences. Majority of them stated to prefer BAHIs over air-conduction hearing aids; albeit the preference was primarily influenced by the decrease in ear infections rather than improved speech recognition (17). This finding was supported by significantly less hospital visits during a five-year follow-up period in COM patients using BAHIs (18).

The SSQ results were highly encouraging, demonstrating substantial improvement across all parameters at both the 3rd and the 12th months ($p<0.001$). The result was comparable with previous studies (14). This highlights that patients experienced better sound localization, speech understanding in various environments, and overall sound quality. This improvement was also reported by the partners of the patients (19).

Audiometrically, all patients showed measurable improvements in hearing thresholds post-implantation. The significant decrease in air conduction thresholds, evident in free-field audiometry at both the 3rd and the 12th months ($p<0.001$), provides strong support for the functional benefits of BAHIs. Notably, the absence of significant differences between the 3rd and the 12th months suggests that the auditory benefits offered by the implants are immediate and stable over time.

There was no statistical difference between transcutaneous or percutaneous instruments on free field implant gain and SSQ parameters ($p>0.05$) in our study. Pure tone thresholds at 3 kHz and 4 kHz were reported to be better in percutaneous systems than in transcutaneous systems. This advantage did not affect sentence recognition in silence but was effective in noise (20). On the other hand, patients with percutaneous systems made more visits to outpatient clinics (21).

Cost-effectiveness arguments come to the fore when deciding the indication and selecting the implant type in patients with COM. Since COM patients using implants were observed not to benefit from conventional hearing aids, it is meaningless to discuss the economic issues between hearing aids and BAHIs. Comparison of different implants has nevertheless been a popular topic in the literature. Transcutaneous implants were reported as more cost-effective than the percutaneous implants (22). But the cost effectiveness of the latter became comparable in the long-term follow-up (23). Recent advancements in technology are likely to take this discussion further. Novel active implants will be a breakthrough in the hearing rehabilitation of COM patients (24). Especially better outcomes at higher frequencies compared to passive implants may increase patient compliance to BAHIs (25).

Ostevik et al. (26) showed that open-fit hearing aids could be an alternative solution in patients with mild to moderate conductive hearing loss who were unwilling to undergo a BAHI surgery.

Our study's strength lies in its longitudinal follow-up and use of multiple assessment tools, including the COMQ-12, WHO questionnaire, and SSQ, to comprehensively assess the impact of BAHIs on clinical symptoms and quality of life. However, some limitations should be acknowledged. The relatively small sample size and the predominance of BAHA Attract users (19 out of 28) may limit the findings' generalizability to other BAHI systems.

Conclusion

This study supports the effectiveness of BAHIs in improving hearing thresholds and quality of life in patients with COM. The significant clinical improvements, enhanced auditory perception, and stable long-term results suggest that BAHIs are valuable intervention strategy in patients who may not fully benefit from conventional hearing aids. Further research with larger cohorts and diverse BAHI systems are warranted to confirm these findings and explore the broader implications of BAHIs in improving overall patient well-being. Large-scale studies assessing the efficacy of BAHI s across various demographic groups are needed. Long-term assessments of device-related complications based on device type should be conducted.

Ethics

Ethics Committee Approval: This study was approved by the Pamukkale University Non-Interventional Clinical Research Ethics Committee (number: 14, date: 28.07.2020).

Informed Consent: Written informed consent was obtained from all participants.

Acknowledgment

We remember with respect our colleague and expected co-writer of this article, Assoc. Prof. Elif Tuğba Saraç, Ph.D., died in an earthquake on 6th February 2023.

Footnotes

Authorship Contributions

Surgical and Medical Practices: F. N.A., M. İ. G., Ş.O., M.İ.Ş., A.B.Y., Ö.A.Ö., M.T.K., Concept: F.N.A., M.İ.G., Ş.O., M.İ.Ş., A.B.Y., Ö.A.Ö., M.E., E.A., S.U., A.T., M.T.K., Desing: F.N.A., M.İ.G., Ş.O., M.İ.Ş., A.B.Y., Ö.A.Ö., M.E., E.A., M.T.K., Data Collection and/or Processing: F.N.A., M.İ.G., Ş.O., M. İ.Ş., A.B.Y., Ö.A.Ö., M.E., E.A., S.U., A.T., M.T.K., Analysis and/or Interpretation: F. N.A., Literature Search: F. N.A., Writing: F. N.A.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The author(s) declare that no financial interests or relationships that could be perceived as influencing the research presented in this article.

Main Points

- Hearing rehabilitation is essential in chronic otitis media.
- Bone-anchored hearing aids are good alternatives.
- They improved hearing performance and quality of life significantly.
- This effect was stable for 12 months.

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