Healthy Hearing Ears
Improving outcomes in COM-related hearing loss

The high impact of chronic otitis media with current standard of care: why bone conduction implantation should be considered earlier

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Abstract

Aim: To assess the impact of chronic otitis media (COM) on patients' hearing, quality of life and hearing disability following standard of care (SoC) interventions, consisting of middle ear surgery and conventional hearing aids. The secondary objective was to assess the effectiveness of bone conduction hearing devices (BCHD) to remedy COM-related hearing loss in the same patients.

Methods: Seventeen adult subjects with COM-related hearing loss were recruited from participating clinics across Spain. They completed an adapted version of the Client Service Receipt Inventory (CSRI) to gain insights into the health care consumption with SoC. The Chronic Otitis Media Outcome Test (COMOT-15) and the Speech, Spatial and Qualities of Hearing Scale (SSQ12) questionnaires were employed pre-operatively and 6 months post implantation. In addition, sound-field thresholds and speech recognition were evaluated in the BCHD aided versus unaided condition.

Results: CSRI data show that SoC results in high health care consumption. COMOT-15 data highlights that COM-related hearing loss is the largest contributor to reductions in quality of life, followed by the chronic infection itself. BC implantation provides significantly higher quality of life and better subjective hearing abilities compared to SoC. Moreover, there was a statistically significant improvement in sound-field thresholds and speech recognition with the BCHD compared to the unaided situation. Overall, patients were satisfied with the BCHD and reported that they would have been implanted sooner if they had been informed about this treatment option earlier by their clinician.

Conclusion: In certain patients, treatment of COM-related hearing loss with SoC (i.e., middle ear surgery and conventional hearing aids) is associated with a high health care consumption and a significant impact on patients' quality of life compared to the outcomes that can be expected with BCHD. These insights should urge clinicians to treat COM-related hearing loss more proactively with BCHD in patients that don't get satisfactory outcomes with SoC. as that will provide improved quality of life and subjective hearing abilities.

Introduction

Chronic Otitis Media (COM) is a chronic inflammation of the middle ear and/or mastoid cavity, often characterized by recurrent ear discharge.[1] COM is one of the most common inflammatory diseases worldwide: around 328 million people suffer from COM and approximately half will develop a related hearing loss.[2] Most COM patients have a purely conductive hearing loss, followed by mixed and sensorineural types, with the hearing loss ranging from 20 up to 60 dB HL.[3,4] It has been estimated that COM may contribute more than half the global burden of hearing impairment.[1] Additionally, COM appears to have a high impact on patients well-being as it has been linked to low levels of quality of life, low self-reported hearing abilities, anxiety, and even depression.[5-8]

The current standard of care (SoC) for patients with COM primarily focuses on managing the infection through middle ear surgery. Secondly, the COM-related hearing loss is addressed through surgical interventions like tympanoplasty and/or ossiculoplasty. A systematic literature review has demonstrated that, based on air-bone gap (ABG) closure to within 20 dB, reconstructive middle ear surgery successfully restores hearing in 70% of COM patients.[9] Hence, it is not uncommon for patients to undergo revision surgery, which have lower success rates than primary surgery (i.e., about 60%).[10,11] In fact, COM represents a major cost for the health care system, with in-patient care and revision surgeries being the key drivers of the health care costs.[6,12] Additionally, even after closure of the air-bone gap to < 20 dB some patients still require amplification due to sensorineural hearing loss being three times more common in COM patients than in the general population.[13,14] Although conventional hearing aids may exacerbate the infection as they obstruct the ear canal and may contribute to further cycles of discharge and infection, they are considered SoC in these patients.[15] Indeed, clinical experience shows that COM patients regularly return to the clinician with their hearing aids because of feedback issues or insufficient amplification, since high power output is often needed to address the hearing loss.[16]

Bone conduction hearing devices (BCHD) offer an alternative treatment option for patients with COM-related hearing loss. BCHD consists of an external sound processor that captures and processes sound which is then converted into mechanical vibrations transmitted through the skull bone to the cochlea. For patients with COM, a key advantage of BCHD is that they do not occlude the ear canal, minimizing moisture accumulation and skin irritation. Also, as the conductive part of the hearing loss is bypassed with BCHD, there is less need for amplification resulting in less feedback problems and distortion. In current practice, BCHD are merely introduced when conventional hearing aids cannot be worn or cannot provide enough amplification.[16]

Despite the high prevalence of COM, clinical research on the resulting hearing loss and its treatment is limited, preventing clinicians from making evidenced-based treatment decisions. The current study was established to help guide best practice in treating patients with COM-related hearing loss. The primary objective was to assess the impact of COM on healthcare consumption, health-related quality of life and hearing disability and to compare the outcomes with SoC to the outcome with a BCHD. The secondary objective was to assess the effectiveness of BCHD to remedy COM-related hearing loss.

Methods

Patients

Seventeen adult subjects with a documented diagnosis of COM and related bilateral hearing loss, were recruited from participating clinics across Spain. They were, on average, 68 years of age (range: 51-88 years) and 71% of them were women. All but one patient showed a mixed type of hearing loss. The remaining patient had a

sensorineural hearing loss. The average air and bone conduction thresholds were 83 ± 20 dB HL (mean ± SD) and 48 ± 14 dB HL, respectively. The patients had been receiving SoC, consisting of middle ear surgery and conventional hearing aids. Following evaluation of their medical and hearing condition, all were considered BC candidates and, consequently, they were implanted with the Cochlear™ Baha® Connect System (Cochlear Bone Anchored Solutions AB, Sweden). According to the severity of their hearing loss, they were fitted with the Baha 5 SuperPower sound processor (41%), the Baha 5 Power sound processor (35%) or the Baha 5 sound processor (24%).

Prior to implantation the patients were asked to complete three questionnaires: an adapted version of the Client Service Receipt Inventory (CSRI), the Chronic Otitis Media Outcome Test (COMOT-15) and the Speech, Spatial and Qualities of Hearing Scale (SSQ12). After the implantation patients completed the COMOT-15 and SSQ12.

The CSRI is an adaptable and widely used research instrument that facilitates retrospective collection of service utilization data and sociodemographic factors.[18] In the current study, the adapted version of the CSRI collected data on medical history, hearing rehabilitation, and health care utilization related to ear infection and/or hearing difficulties, referring to the six months before inclusion in the present study. The data collected through the CSRI could increase our knowledge about the health care consumption of COM patients with SoC.

The COMOT-15 is a 15-item questionnaire that is a reliable and sensitive instrument for measurement of health-related quality of life of subjects with COM[19,20]. The instrument consists of three subscales: ear symptoms, hearing function and mental health which form the total score. In addition, there is one question on the general evaluation of the impact of COM on quality of life and one question to indicate the frequency of doctor visits in the last six months because of COM.

The SSQ12 is a condensed version of the 49-item SSQ questionnaire.[21,22] It makes inquiries about the self-assessed level of disability in everyday life for speech perception, spatial perception and quality of sounds. In addition to an average score per subscale, a total score is calculated by averaging across all questions.

In addition, an audiological evaluation was completed pre- and at least 6 months post-implantation. This covered sound-field thresholds (250 Hz-4 kHz), word recognition in quiet and word recognition in noise, all measured in the unaided condition and when aided with the BCHD.

Sound-field thresholds at 250 Hz up to 4 kHz were measured with the loudspeaker located at 1 meter in front of the patient. The pure-tone average 0.5, 1, 2, 4 kHz (PTA4), expressed in dB HL, was calculated as the outcome measure. For word recognition, the test of Cárdenas and Marrero was used, which is a common clinical test in Castilian Spanish consisting of phonetically balanced disyllabic words.[23] To determine the word recognition score in quiet (% correct), the words were presented at 50-, 65- and 80-dB SPL in free-field from a loudspeaker located at 1 meter in front of the subject at 0° azimuth. To determine the word recognition score in noise (% correct), white noise was presented at 60 dB SPL from a loudspeaker located at 1 meter in front of the subject at 0° azimuth, while the words were presented at 60 dB SPL from a loudspeaker located at 1 meter at the side of the implanted ear, at 90° azimuth. Finally, the patients answered a few questions to evaluate their BCHD experience after six months of use.

The scores on the COMOT-15 and SSQ12, the sound-field thresholds and word recognition scores were compared pre-implantation (SoC) versus post-implantation (BCHD) through statistical analyses that were performed in IBM®

SPSS® Statistics Software Package (IBM Corporation, Armonk, NY, USA). For the COMOT-15, paired samples t-tests were performed for the subscale scores and total score. An unpaired t-test was executed for the general score due to one missing data point. Wilcoxon signed-rank tests were completed for the frequency of doctor visits (COMOT-15), the SSQ12 subscale scores and total score, the sound-field thresholds and word recognition scores. Adjustment for covariates was not required based on study design as each subject acted as their own comparator. Two-tailed *p*-values are reported, with an alpha level of 0.05. Although medians and interquartile ranges are more appropriate, means and standard deviations are reported to allow for comparisons to be drawn with other studies.

Results

Client Service Receipt Inventory

The data collected through the CSRI are summarized in Table 1. In the six months prior to study inclusion, 82% of the patients needed one or more clinical consult or diagnostic tests (e.g. CT scan) because of ear infections or hearing difficulties, and 59% of the patients had to take medication because of an ear infection.

Over the course of their COM disease, they reported to take antibiotics three times a year and to be unable to work 24 days a year on average because of their condition. Many patients (71%) suffered from recurrent ear infections and even more suffered from problems in the middle ear (88%). 71% underwent middle ear surgery and 75% of them had one or more revision surgeries. On average they had suffered from COM for 36 years.

65% of the patients were using a conventional hearing aid of whom 45% were fitted bilaterally. In this patient group, 46% had been using their hearing device for more than 10 years, 18% for more than 5 years and 36% had started using a hearing aid less than 5 years ago. The daily hearing aid use ranged between 0 and 17 hours with an average of 11 hours. Two patients (18%) reported to not actively use their hearing aid.

Table 1. Summary of the data collected through the CSRI

	% of patients	Average	N, Range
In the past six months			
Otolaryngologist consult	82		1-5
Audiologist consult	41		1-2
General practitioner consult	24		0-6
CT scan	24		1-1
MRI	12		1-1
X-ray	6		1-1
Blood test	18		1-1
Medication for ear infection	59		
Over the course of their disease			
Years with COM		36	7-72
Days unable to work per year		24	0-365
Antibiotic treatments per year		3	0-20
Recurrent ear infections	71		
Middle ear problems	88		
Middle ear surgery	71		
≥ 1 revision surgery	75		
Conventional hearing aids	65		
Bilateral fitting	45		
Fitted < 5 years ago	36		
Fitted > 5 years ago	18		
Fitted > 10 years ago	46		
Daily hours of hearing aid use		11	0-17

COMOT-15

The outcomes of the COMOT-15 questionnaire are illustrated in Figure 1 and summarized in Table 2. The total score on the COMOT-15 questionnaire and all three subscale scores were significantly improved (lower) with the BCHD than with SoC (all $p < .001$). Likewise, the general score was significantly improved post- versus pre-implantation ($p < .001$). Furthermore, the average number of doctor visits in a six months' time interval was reduced by more than half following BC implantation when compared to SoC, i.e., 1.3 instead of 2.8 visits, respectively, which was a significant reduction ($p = .003$).

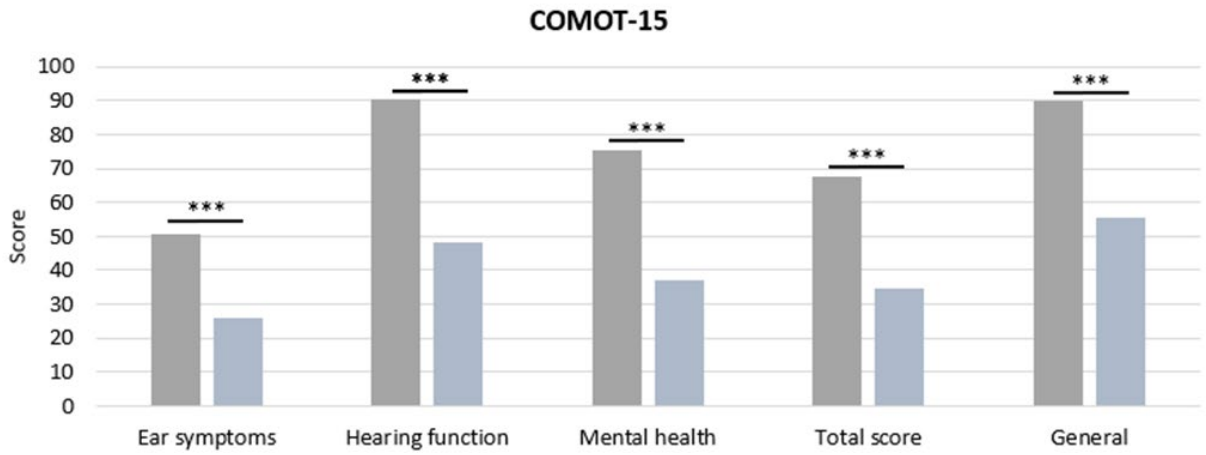

*Figure 1: COMOT 15 - Average scores on the three subscales, the total score, and the general score pre-implant (SoC; grey) and post-implant (BCHD; blue). ***p<0.001*

Table 2: COMOT-15 & SSQ12 - Average scores (± SD) on the subscales as indicated by the patients before and after BC implantation and the calculated total score. The respective p-values, demonstrating the statistical significance of the improvement in scores with BCHD compared to SoC, are outlined in the final column.

	Pre-implant (SoC)	Post-implant (BCHD)	*P*-value
COMOT-15			
Ear symptoms	50.8 ± 20.2	25.9 ± 22.6	< .001
Hearing function	90.2 ± 24.5	48.2 ± 27.1	< .001
Mental health	75.6 ± 27.3	37.1 ± 29.6	< .001
Total score	67.5 ± 18.5	34.5 ± 22.5	< .001
General	90.0 ± 16.3	55.3 ± 32.8	< .001
SSQ12			
Speech	1.9 ± 1.6	6.0 ± 2.2	< .001
Spatial	1.7 ± 1.6	4.9 ± 2.4	< .001
Quality	2.0 ± 1.7	5.9 ± 2.5	< .001
Total score	1.9 ± 1.2	5.7 ± 2.2	< .001

SSQ12

SSQ12 questionnaire scores are illustrated in Figure 2 and summarized in Table 2. Statistically significant improvements in total score and all subscale scores were reported when comparing between BCHD and SoC (all p < .001).

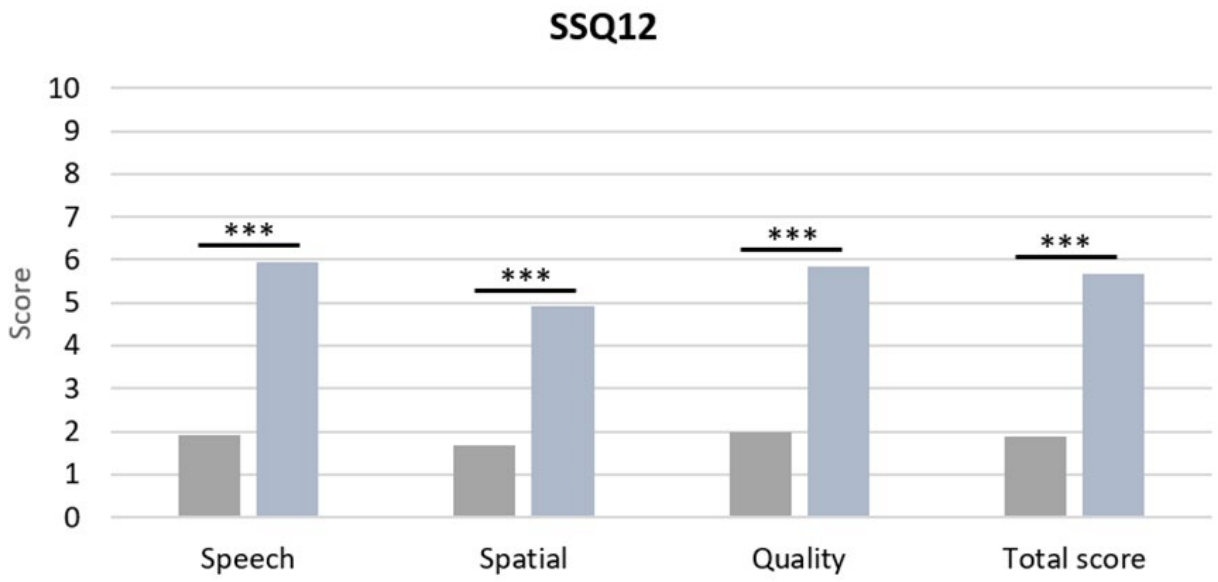

*Figure 2: SSQ12 - Average scores on the three subscales and the total score pre-implant (SoC; grey) and post-implant (BCHD; blue). ***p<0.001*

Sound-field thresholds

In the unaided condition, the average PTA4 was 64 ± 24 dB HL, which improved to39 ± 16 dB HL when aided with the BCHD. This improvement was statistically significant ($p < .001$).

Word recognition in quiet

For all presentation levels - 50, 65, 80 dB SPL - patients showed statistically significant improvements in word recognition scores in quiet when they used their BCHD compared to when unaided (all $p \leq 0.005$; see Table 3 and Figure 3).

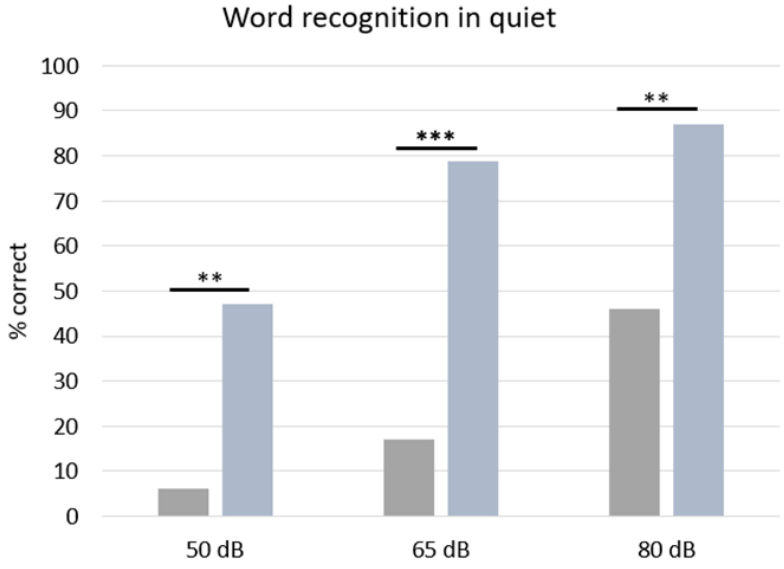

*Figure 3: Word recognition in quiet - Average word recognition scores, expressed as % correct, in the unaided condition (grey) and when aided with the BCHD (blue) for presentation levels 50 dB, 65 dB, and 80 dB. **p<.01 ***p<.001*

Table 3: Word recognition in quiet - Average word recognition scores (± SD) expressed as % correct in the unaided condition and when aided with the BCHD. The respective p-values, reflecting the statistical significance of the improvement in scores aided versus unaided, are outlined in the final column.

	Unaided	Aided	P-value
WRS in quiet			
50 dB	6.3 ± 25.0	47.2 ± 39.6	.005
65 dB	17.2 ± 27.9	78.7 ± 28.4	< .001
80 dB	46.0 ± 43.3	86.9 ± 22.6	.003

Word recognition in noise

In the unaided condition, the average WRS was 9.2 ± 28.7%. When aided with the BCHD, the WRS improved to 56.4 ± 33.6%.and the improvement was statistically significant when compared to the unaided condition (p = .007).

Experience with BCHD

When asked to rate the hearing treatment with their BCHD with a score between 1 and 10, the patients attributed a mean score of 7.8 ± 2.5.. The patients were specifically asked how they experienced hearing with their BCHD. The three responses outlined below can be considered representative for the implanted patients of the current study:

- *"I can hear very well. I don't take it off during the day. It has greatly improved my quality of life"*

- *"I can understand better than with my hearing aids. I'm happy in general"*

- *"I'm amazed with the sound sensation and I'm comfortable wearing the device"*

All but one of the patients reported that they would have preferred earlier implantation with a BCHD if they had been informed about the option by their clinician. Daily BCHD usage was estimated to on average 11 hours (range 0-18 hours) a day The patient who would not have opted for a BCHD if she had known sooner, was the only one not actively using the BCHD. Even so, this patient recognized that the BCHD improved her hearing, and her clinician reported that the BCHD provided excellent effective hearing gain. Regarding the treatment of the hearing loss in the contralateral ear, 13 were not using any amplification, three were fitted with a conventional hearing aid, and one was using a cochlear implant.

Discussion

The primary aim of this study was to assess the impact of COM-related hearing loss on patients' lives. More specifically, the outcome with SoC compared to BCHD. The secondary objective was to assess the effectiveness of BCHD in the treatment of COM-related hearing loss.

The patients included in this study had been suffering from COM for 36 years on average. During this extensive period, they were unable to work for about five weeks every year because of the disease. This indicates that COM has a high impact on patients' professional life. The rate of recurrent ear infections was high, with 71% of the patients reporting them. Next to a high uptake of antibiotics, the rate of middle ear surgeries was high: 71% of the patients had undergone middle ear surgery and in 75% of the cases, one or multiple revision surgeries had to be undertaken. Clinical consults appear to be commonplace with most patients reporting to have visited an otolaryngologist, audiologist, or general practitioner several times over the six months before the BCHD implantation. These data demonstrate that COM is associated with a high health care consumption, which is in line with the findings of the registry study from Lewis

et al. (2022)[12] and a medical record review performed in the US by Thai et al. (2021)[24]. Through the COMOT-15, the patients in the current study reported to have had about three doctor visits on average in the six months prior to the study. Following BC implantation, this reduced to only one doctor visit, which suggests that BC implantation may yield reduced health care consumption when compared to SoC.

Referring to when receiving SoC, the patients reported a high impact on their quality of life. The scores differed considerably between the three subscales. The highest impact was attributed to 'hearing function', followed by 'mental health' and, finally, 'ear symptoms', with subscale scores of 90.2, 75.6, and 50.8, respectively. This means that hearing loss is the major cause of the reduced quality of life for patients with COM. The finding that COM-related hearing loss impacts patients' quality of life the most, even more than ear symptoms, i.e., the chronic infection, has been reported by Bauman et al. (2011)[25] as well. Likewise, Phillips et al. (2021)[6] demonstrated that COM patients with a greater degree of hearing loss showed to have poorer quality of life, which was not exacerbated by the presence of ear discharge. Next to reporting a high impact of COM on their quality of life through the COMOT-15, the patients gave low SSQ12 scores, which indicates that COM patients feel disabled in daily life activities that require their hearing with current SoC. Nevertheless, only 65% of the patients were using a conventional hearing aid. This relatively low uptake of amplification is likely to be explained by the general practice of providing conventional hearing aids to remedy COM-related hearing loss, even though a recent literature review[26] demonstrates that there is very limited evidence on the treatment outcomes with conventional hearing aids for patients with COM-related hearing loss. In fact, this review demonstrates that patients with COM-related hearing loss may show rather poor speech recognition with conventional hearing aids, particularly in noise. Even more, about 50% of COM patients appear to show temporary non-use of their conventional hearing aids due to drainage induced by the hearing aid use.[26]

Through the COMOT-15, the patients with COM included in the present study indicated that BC implantation had significantly improved their quality of life, as they experienced significantly less problems regarding ear symptoms, hearing function and mental health alike. Moreover, they experienced significantly improved hearing abilities in their day-to-day life with their BCHD compared to with SoC, as reflected in the significantly improved scores on all three subscales of the SSQ12, i.e., speech recognition, spatial hearing, and quality of sounds. The findings of the current study are very similar to the ones of Lewis and Gergely (2022).[7] Lewis and Gergely (2022)[7] investigated how BCHD impact patients with COM by analysing patient-reported outcomes from a longitudinal registry study. They found that BC implantation improved health-related quality of life and reduced subjective hearing disabilities.

In addition to showing that BC implantation significantly improved the patient's quality of life and subjective hearing abilities, a significant improvement in hearing performance was observed in the present study. When aided with BCHD, sound-field thresholds were significantly improved and significantly better for speech recognition, both in quiet and in noise, were observed over the unaided situation. The overall positive effect of BC implantation on the hearing performance of the COM patients resonated in the anecdotical feedback provided by their hearing care professionals:

- *"My patient adapted very well to the Baha System. When using a conventional hearing aid for many years, there was only little gain and limited satisfaction"*
- *"Despite being on the edge of the Baha System's fitting range, the patient shows good effective gain"*

In line with the positive feedback from the hearing care professionals, the patients expressed satisfaction about the BCHD treatment, giving it a score of 7.8/10. Moreover, all but one of the patients reported that they would have liked to be presented with the option of BCHD implantation earlier.

Conclusion

Altogether, the outcomes of this study should raise concern about current SoC as it relates to high health care consumption, poor quality of life, and poor subjective hearing abilities in certain patients. When compared to SoC, BCHD implantation may yield reduced health care consumption and generates significantly higher quality of life and subjective hearing abilities. The outcomes also demonstrate the importance of effective hearing rehabilitation in patients with COM. These insights should urge clinicians to consider BCHD earlier in the COM treatment pathway as it can effectively treat COM-related hearing loss and provide improved quality of life and subjective hearing abilities when compared to SoC.

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