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Clinical Presentation, Management, and Outcomes of Idiopathic Pain in Percutaneous Bone-anchored Hearing Implants

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Objective: To identify clinical features and investigate treatment outcomes of patients with idiopathic pain related to a percutaneous bone-anchored hearing implant (BAHI) and to propose management recommendations.

Study Design: Retrospective chart analysis.

Setting: Tertiary referral center.

Patients: The clinical data of 14 patients who were treated for idiopathic pain around their percutaneous BAHI between May 2007 and February 2018 at our tertiary referral center were reviewed.

Main Outcome Measures: Pain after treatment and implant loss.

Results: All 14 patients received treatment with oral antibiotics. Nine patients received oral antibiotic combination therapy for 4 weeks, whereafter pain resolved in 4. Out of the five other patients, receiving either antibiotic monotherapy or shortened antibiotic combination therapy, pain resolved in two. In case of persistent pain (57.1%) after initial treatment, other pain management therapies were

attempted, however all with only limited effect. Six patients (42.8%) underwent elective removal of the implant. In two patients spontaneous implant loss occurred. In two of the four patients who underwent reimplantation, pain relapsed. In one of these, pain resolved after the removal of the new implant. In the other patient, pain persisted, despite abutment removal. With exception of this latter patient, all other 13 patients were pain free at the latest follow-up. Cone beam computed tomography did not offer additional information regarding diagnosis or treatment.

Conclusion: Idiopathic pain in BAHI is a rare but bothersome symptom which can result in implant removal. After oral antibiotic combination treatment, symptoms resolved in approximately 40% of patients. Therefore, we think conservative treatment with these antibiotics before implant removal surgery, is worth considering. **Key Words:** BAHA—BAHI—BCD—Hearing loss—Implants—Pain.

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Over the last few decades, the percutaneous bone-anchored hearing implant (BAHI) system has evolved into a well-established hearing rehabilitation that can be applied in a broad spectrum of hearing-impaired patients. Due to several improvements in implant designs (1–3) and surgical techniques (4,5), complications such as adverse skin reactions and implant loss have decreased, especially over the last two decades. These days, the wide-diameter implant (Ø 4.5 mm) is the most regularly used implant with

a long-term survival rate of 96.2 to 97.4% (1,2). Implant loss can be caused by trauma, failure of osseointegration, severe soft-tissue reactions, and, in some cases, elective implant removal. According to the literature, elective removal is performed in 4.5 to 7.0% of all implants (6–8) and is conducted because of chronic soft-tissue reactions, recurrent infection, or if other auditory implants are needed due to increased sensorineural hearing loss (7–9). Another indication for implant removal is persistent pain around the implant which is suggested to be related to skin reactions (9) or occipital neuropathy (10). However, in most cases no proper explanation for this type of pain is provided (7,10). Although varying in duration, several cases of idiopathic pain eventually leading to implant loss have been reported (6,9,11). Based on these literature reports, pain was thought to be a relevant clinical sign in the follow-up of BAHIs and was therefore implemented as a parameter in the newly developed IPS scale, a soft-tissue assessment scale for percutaneous and transcutaneous implants in which Inflammation (I), Pain (P), and Skin height/numbness (S) are determined (12).

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The etiology of idiopathic pain remains unclear and no diagnostic or treatment strategies have been defined (7). Defining an adequate therapy is of great importance because idiopathic pain seems to result in a high amount of implant loss. In this study, the clinical data of 14 patients treated for idiopathic pain related to a BAHl between 2007 and 2018 were retrospectively reviewed. Based on these results, recommendations for therapeutic management are proposed.

METHODS

All patients who underwent treatment for idiopathic pain related to their percutaneous BAHl at our tertiary referral center between May 2007 and February 2018 were included. This time-interval was chosen, because cases of idiopathic pain were systematically recorded since 2007. Idiopathic pain was defined as pain at the implant site typically increasing during manipulation (ticking on or tightening) of the abutment. Increasing pain suggested that pain was indeed related to the BAHl. Patients were included independent of pain duration. Patients were excluded when a probable cause for the pain, such as an adverse skin reaction (Holgers ≥ 2), was found during clinical examination. The medical records of all included patients were reviewed to obtain the following clinical data: demographic information, medical history, details regarding BAHl implantation and postoperative complications, symptoms as well as clinical examination at diagnosis and during follow-up, diagnostic and treatment details, removal surgery and total follow-up period.

Current Treatment

At our institution, clinicians were advised to initially treat idiopathic pain around a BAHl with oral antibiotics, preferably a combination of Ciprofloxacin 500 mg twice daily for 2 weeks and Clindamycin 300 mg three times a day for 4 weeks (adult dosage). The rationale behind this treatment was that the pain might have been caused by an inflammation of the deeper soft-tissue layers and/or bone around the implant, which was not visible on the outside. Because of the good oral availability and excellent bone penetration of both agents, the above-mentioned antibiotic regimen was determined in consultation with the microbiologist. This treatment was advocated independent of duration of pain, to prevent further spread of possible inflammation. In case of persisting pain after antibiotic treatment, the following treatment options were available: extending/repeating antibiotics, removal of the abutment and/or implant or, in case of suspected occipital neuralgia, consultation of our institution’s specialized pain management team. This pain management team either prescribed oral analgesics or conducted a diagnostic anesthetic block in the region of most intense pain (10,13). When pain relief was obtained, pulsed radiofrequency treatment of the occipital and/or C2 nerve was performed. The choice for a certain treatment was individually determined by the ENT-specialist based on the effect of oral antibiotics, the severity and duration of complaints, the clinical benefit of the BAHl, and the patient’s preference. In most patients, a cone beam computed tomography (CBCT) scan was performed to detect signs of bone resorption around the implant (14,15). To evaluate the usability and utility of CBCT in BAHl patients with idiopathic pain, scans were assessed by an ENT-surgeon, radiologist, and technician specialized in implantology and 3D technologies.

Statistical Analysis

Clinical features were reported as frequencies (%), means (SD) in case of normally distributed data, and as medians with interquartile range (IQR) in case of not-normally distributed data. With the Chi-square test, associations between clinical variables and the effect of antibiotics were assessed. Data analysis was carried out using SPSS software version 25.0. The level of significance was defined as a *p* value of ≤0.05 using a confidence interval (CI) of 95%.

Ethical Consideration

Ethical approval for conducting this study was obtained from the local ethical committee.

RESULTS

Clinical Parameters

Between May 2007 and May 2018, 14 patients were identified (Table 1). The study population consisted of 2 men and 12 women with a median age at implantation of 45 years (Fig. 1A). Four patients (28.6%) were implanted bilaterally yet experienced pain only unilaterally. None of the patients had a history of diabetes mellitus, skin disease, or radiation of the skull. Implantation was performed between 1995 and 2014. Since the wide-diameter implant only became available in 2010, most patients had a previous generation implant. Eleven

TABLE 1. Clinical parameters of 14 BAHl patients with idiopathic pain

Clinical Parameter	Frequency (%)
Sex	
Male	2 (14.3)
Female	12 (85.7)
Age at diagnosis in years, median (range)	45 (5–75)
Implant side	
Right	6 (42.9)
Left	4 (28.6)
Bilateral	4 (28.6)
Implant type	
Previous generation implant	11 (78.6)
Wide-diameter implant	3 (21.4)
Surgical technique ^a	
Dermatoma technique	1 (7.1)
Linear incision with tissue reduction	11 (78.6)
Linear incision with tissue preservation	1 (7.2)
Implant loss	
No	6 (42.9)
Elective removal without reimplantation	3 (21.4)
Elective removal with reimplantation	3 (21.4)
Spontaneous implant loss and reimplantation	2 (14.3)
Patients with persistent pain at latest follow-up	
No	13 (92.9)
Yes	1 (7.1)
Pain-free patients at latest follow-up ^b	
With bone implant in situ	8 (61.5)
Without bone implant in situ	5 (38.5)

^aIn one patient surgical technique was missing.

^bOne patient was not pain free at latest follow-up. BAHl indicates bone-anchored hearing implant.

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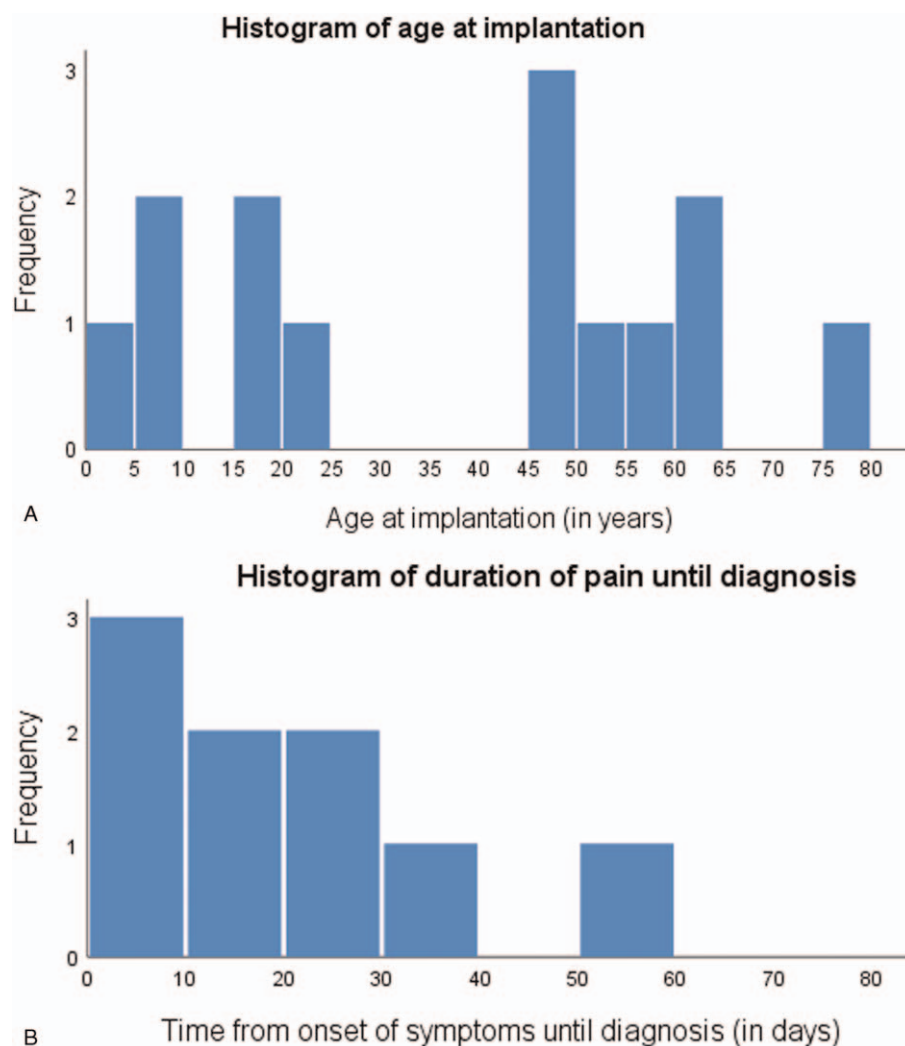


FIG. 1. A, This histogram shows the distribution of age at diagnosis (in years) for all patients. B, This histogram presents the range in time of the duration of pain until diagnosis (in days).

patients were implanted in our tertiary referral hospital and three were referred to us by secondary centers. The 11 patients implanted at our tertiary referral hospital accounted for 1.2% of all 933 patients implanted with a BAHl in our center within this time period. Intraoperative and postoperative complications were assessed for all 14 patients. Exposure of the sigmoid sinus was described in two patients and exposition of the dura mater in one patient. The following postoperative complications were observed: hematoma in one patient and persisting wound dehiscence in two patients. The wound dehiscence lasted for approximately 5 weeks in one patient, in the other patient time to healing was not documented.

Diagnosis

The time-interval from implantation until onset of pain varied from directly postoperative to 7 years after implantation, with a median duration of 3.2 years. The

patient who suffered from a wound dehiscence for an unknown duration developed pain 3 months after implantation. In the other two patients with a postoperative complication, onset of pain was reported years after implantation. After onset of pain, median time until diagnosis was 19 days (IQR 10 d to 3 mo, Fig. 1B). The type of pain was either characterized as pain around the implant (12 patients) or as a deep pain below the implant (2 patients), whereby pain in all patients increased during abutment manipulation. At diagnosis, no signs of inflammation were present: Holgers 0 (no skin reaction) was observed in 64.3% and Holgers 1 (redness with slight swelling) in 28.6%. However, when looking at medical history, five patients (36%) received treatment for a BAHl-related infection (i.e., Holgers ≥ 2) within 1 month before idiopathic pain was diagnosed. Although the infection was successfully treated (defined as Holgers ≤ 1), pain persisted and was therefore considered idiopathic. Three other patients had suffered from

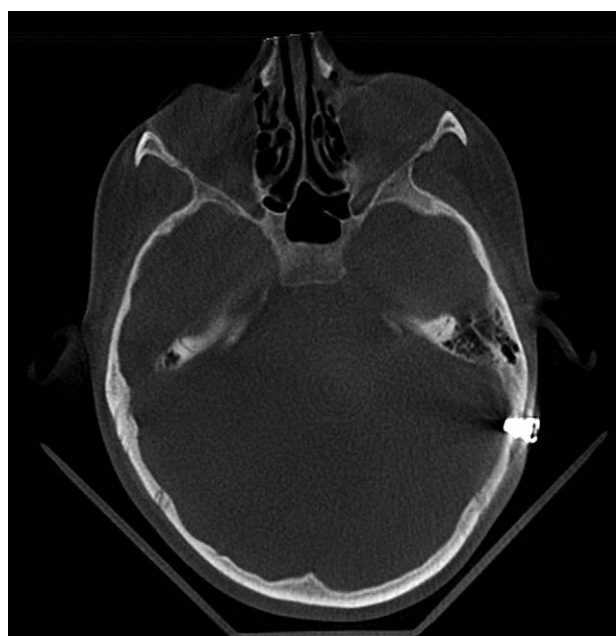


FIG. 2. Transversal coupe of CBCT scan in a patient with a BAHl and idiopathic pain. This CBCT slice shows artifacts which impair the image quality around the implant. Since image quality was structurally insufficient among all CBCT scans, (the amount of) bone resorption could not be systematically assessed. CBCT indicates cone beam computed tomography; BAHl, bone-anchored hearing implant.

recurrent adverse skin reactions in the past, with the last reported episode 8 to 12 months before onset of pain. In the remaining six patients (43%) no reports of skin problems were found. At the first visit to our clinic after onset of pain, increased skin height was observed in one patient and the presence of sebaceous glands in two patients. In two other patients, a loose abutment was detected and successfully tightened as part of standard care. A loose implant was reported in another patient. In this case, elective removal of the implant was scheduled.

In 11 patients (78.6%) a CBCT was performed. Unfortunately, assessment of these scans showed impaired quality of the implant region due to artifacts caused by implant and abutment (Fig. 2). Therefore, a systematic evaluation of these scans was not contributory to this study. Also, no therapeutic or diagnostic management changes were made based on these scans. In one patient, a non-contrast CT scan was already performed in the referring center. In retrospect, no bone resorption was detected on this scan; however, image quality was limited by artifacts. No other imaging techniques such as MRI or ultrasound examination were conducted in this cohort.

Treatment

All 14 patients were treated with oral antibiotics (Fig. 3). Before antibiotic treatment, local infiltration with an anti-inflammatory glucocorticoid was conducted

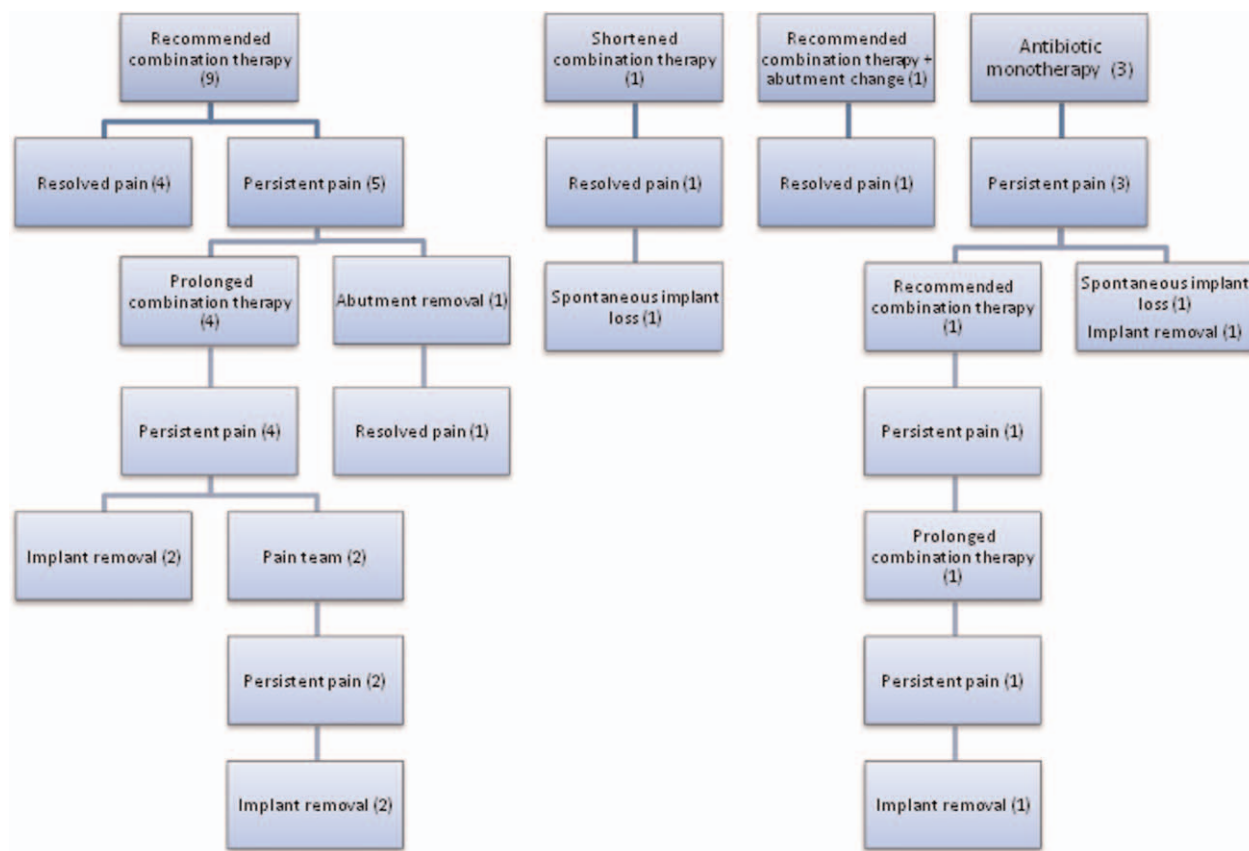


FIG. 3. Flowchart demonstrating the advocated treatment for all 14 patients.

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in two patients with temporary effect. The above-mentioned antibiotic combination therapy (ACT) was initiated in 10 patients. In one of these patients, abutment change was performed together with the initiation of antibiotics. Four patients received modified antibiotic therapy: in one patient, ACT was shortened because of an allergic reaction to Clindamycin. Another patient was treated with amoxicillin/clavulanic acid before ACT. Also, one patient was only treated with Clindamycin monotherapy for 6 weeks for an unknown reason and the patient with the loose implant screw was treated with Clarithromycin monotherapy for 1 week awaiting elective implant removal. Of the nine patients who received ACT only, pain resolved permanently in four (44%). Pain also resolved in the patient in whom ACT was shortened and in the patient in whom abutment change was performed simultaneously. Pain persisted in five patients who received ACT only and in the three patients who were treated with monotherapy. Among the patients in whom pain resolved after ACT only, median time between implantation and treatment was 3.2 years (range 1.4 mo to 7 yr) and median time between onset of pain and treatment was 18.5 days (range 0–30 d). One of these patients was recently treated for an infection around the BAHl. At follow-up, pain persisted in absence of signs of infection and therefore treatment with ACT was directly initiated. For patients in whom pain persisted after ACT only, median time between implantation and treatment was 4.6 years (range 2.1 mo to 8.7 yr) and median duration between symptoms and treatment was 29 days (range 4 d to 8.7 yr). In this group, three patients had recently been treated for an infection.

In case of persistent pain after initial antibiotics, ACT was extended/repeated (total treatment 8–12 wk) in four patients and initiated in the patient who received amoxicillin/clavulanic acid. In the latter patient, ACT was later prolonged because pain persisted. In all five patients who received extended/repeated ACT, pain persisted. Furthermore, abutment removal was performed in two of these patients with persistent pain where after pain resolved in one of them. The specialized pain team was consulted in two patients: one was unsuccessfully treated with oral analgesics and in the other one, a diagnostic block of the occipital and C2 nerve was performed, unfortunately without any effect on pain. Occipital neuralgia could not be identified objectively in these patients.

Six patients (42.9%) underwent elective implant removal because of persistent pain despite therapy. Two of these patients did not use their sound processor anymore and another two reported decreased usage due to pain. During removal surgery, bone resorption around the implant was observed in one patient. In another patient, exposed dura was found during removal surgery instead of the exposed sinus, which was reported during initial implant surgery. After implant removal, a new implant was inserted in three patients, at approximately 5 mm distance of the removed implant. Three patients did not want a new implant. Two of them could also opt for a conventional CROS device since they suffered from

single-sided deafness. The other patient had unilateral acquired conductive hearing loss and did not want a new implant out of fear of a relapse of pain after reimplantation. Spontaneous implant loss occurred in two patients. It occurred in the one patient who was already scheduled for surgical implant removal because of a loose implant screw. This patient was therefore rescheduled for the insertion of a new implant. The other implant loss occurred in the patient in whom pain had resolved after shortened ACT. At this moment, this patient is scheduled for reimplantation of a new implant. After implant loss/removal, the implant was examined by the manufacturing company, microbiologist, or pathologist in almost all cases. No abnormalities were found, except for one implant which was colonized with the staphylococcus epidermis bacteria.

Follow-up

Median follow-up after diagnosis and removal were 10.51 months (IQR 2.50–32.87) and 7.43 months (IQR 1.15–25.79), respectively. In two out of four patients who underwent reimplantation, pain relapsed. In one of these, pain resolved after the removal of the newly inserted implant. In the other patient, pain persisted, despite abutment removal. Implant removal was not scheduled in these patients, since pain was perceived as mild after abutment removal. Except for this latter patient, all other patients were pain-free at the last follow-up.

DISCUSSION

In the last 11 years, 933 patients were inserted with one or two percutaneous BAHl(s) at our center. In 1.2% of these patients, pain without any identifiable cause was reported. In addition, three patients who underwent implantation in other hospitals were referred to our center because of persistent idiopathic pain. Following our local treatment strategy, several treatments were advocated including ACT after which pain initially resolved in 44%. However, not all patients received the recommended therapy and, in the majority of patients, spontaneous implant loss occurred or elective implant removal was performed during follow-up.

Although scarce, some literature is available regarding idiopathic pain in percutaneous BAHl; however, these articles provide limited information regarding patient and treatment characteristics (6) or merely describe cases of persistent pain which resulted in implant removal. The current study provides a comprehensive overview of all patients treated for idiopathic pain at a tertiary referral center, including patients in whom pain resolved without implant removal. Badran et al. reported persistent pain in 4.2% of their patients; however, no clinical characteristics of these patients were provided. Implant removal due to persistent idiopathic pain was reported in 1.6% of all implants in the study of van der Pouw et al. and in 2.0% of all implants in the studies of Siau et al. and Mylanus et al. Also, the study of Mylanus et al. included

implants for auricular epitheses. In line with Siau et al., the majority of patients with idiopathic pain in our cohort were female. This is remarkable since approximately the same number of men and women is implanted with a percutaneous BAHl at our institution (16). A possible explanation might be the clinical finding that women are more sensitive to pain and are more at risk to develop chronic pain compared to men (17). Clinical parameters, such as implant type and surgical technique, varied among patients in our cohort. However, since numbers are small, it cannot be concluded that the development of idiopathic pain is independent of these parameters. Time of pain onset in our cohort varied between directly postoperative until years after implantation, which was also observed by Mylanus et al. However, van der Pouw et al. and Siau et al. did not report cases with onset of pain immediately after surgery.

Diagnosis and Treatment

Several causes for idiopathic pain have been hypothesized: Faber et al. suggested occipital neuropathy as a probable cause. At our institution, neuropathic pain was not identified objectively in any of the patients. In our cohort, pain relapse after reimplantation was observed in two of four patients. Because of the small number of patients, no firm conclusions can be drawn from this observation. However, relapse of pain after reimplantation was also noticed by Siau et al. in three of six patients. Therefore, patient-related factors might be of importance in the development of idiopathic pain. A possible patient-related factor might be hypersensitivity for titanium, which is described in patients with orthopedic and dental implants and might contribute to dental implant loss (18,19). However, in our cohort no signs of metal hypersensitivity, such as edema or severe redness, were observed.

Another possible explanation for persistent pain could be an inflammation of the deeper soft-tissue layers and bone surrounding the implant, which is invisible on the outside. This hypothesis might be supported by histological studies examining implants removed because of chronic pain. In these studies inflammatory cells were found between the implant and the bony surface (9,11,20). However, inflammatory cytokine gene expression seems also elevated within the first few months after surgery, and in case of nicotine abuse (21). In our cohort, 57% of patients suffered from (recent) soft-tissue infections before onset of pain. In these patients, bacteria might have migrated along the implant itself into deeper soft-tissue layers and bone surrounding the implant. In dental implants a similar peri-implant disease is observed. This disease is called peri-implantitis and is characterized by a deep inflammation around the implant with progressive bone loss (22). Typical symptoms include bleeding on probing, swelling, and redness. In contrary to the patients in our cohort, pain is only reported sporadically in relation to dental peri-implantitis (23,24). In our cohort, spontaneous implant loss occurred in two patients, and after ACT pain resolved in 44%. On

top of that, non-antibiotic treatments such as oral analgesics, local infiltration with anti-inflammatory glucocorticoids, and anesthetic blocks of the occipital nerve did not resolve pain in our and other studies (7,9). Therefore, a certain manifestation of peri-implantitis might be a possible explanation for patients with persistent pain. However, this raises the question why pain did not resolve in all patients (with a recent infection) after ACT. There might either be another etiology, or the bacteria were insensitive or resistant to the applied antibiotics. Since dental peri-implantitis may result in implant failure and further progression of bone loss, dental literature states the importance of early detection of dental peri-implantitis by radiographic imaging, preferably by intraoral radiography (IR) (25,26). Since IR is not applicable in the field of BAHl and conventional radiography does not provide enough detail, CBCT was performed in 78.6% of our patients to evaluate bone resorption. CBCT is suggested to be accurate in detecting peri-implant bone defects in dental implants (14) and is considered to be a safe diagnostic tool with low patient burden because of the low costs, short scanning time, and low radiation exposure (27). Unfortunately, these scans were not accurately enough to assess bone resorption in our cohort of BAHl patients since artifacts limited the image quality. Although in one study, metal artifacts were only observed sporadically in CBCT (14), most studies reported impaired image quality due to artifacts and therefore limited value of CBCT (15,25). At this moment, CBCT is not considered a helpful tool in guiding management of BAHl patients with idiopathic pain. More research should be conducted on artifact-reducing techniques, before implementing CBCT as a standard diagnostic tool in assessing bone resorption around BAHl. Another option for the assessment of bone resorption might be a CT scan with single-energy metal artifact reduction, which is already shown to improve image quality in patients with aortic stents (28) and coiled intracranial aneurysms (29). With a contrast-enhanced CT scan the presence of soft-tissue inflammation or an abscess can also be detected.

At our institution, 65% of patients were initially treated with ACT whereafter pain resolved in 44% of these patients. The other patients received a modified antibiotic therapy with limited effect. Pain did not resolve in any of the patients who received prolonged ACT. Therefore, it could be suggested that repeating or extending antibiotic treatment might not be efficient. However, given the small number of patients and the retrospective nature of our study, this hypothesis is debatable. It is also possible that pain resolved because of a placebo effect or because the pain was caused by a self-limiting disease. Unfortunately, a randomized controlled trial is not achievable given the rare manifestation of idiopathic pain in BAHl patients. Since no other effective treatment options are available and oral antibiotics is a noninvasive treatment with low patient burden, we suggest prescribing ACT before implant removal. Especially since many patients (specifically those with a conventional

indication) have no other option for hearing revalidation. In patients with no improvement following 4 weeks of antibiotic therapy, additional antibiotics were not helpful, and are therefore not recommended. In case of persistent pain despite oral antibiotics, implant removal is the final option. However, beware that pain might relapse following reimplantation. During the preoperative work-up for initial BAH implantation, patients should be informed about the possible short-term and postoperative complications, including the (small) chance of developing idiopathic pain. Thereby, patients are able to make an informed decision. Not in the least, during follow-up visits after implantation, the presence of pain should be evaluated, for which the IPS scale seems an appropriate tool.

CONCLUSION

Idiopathic pain related to BAH is a rare but inconvenient symptom occurring any time after surgery. Upon today, no clear diagnostic nor treatment strategies have been defined. The lack of adequate treatment options often leads to elective implant removal or implant loss. After oral antibiotic combination treatment, symptoms resolved in approximately 40% of patients. Therefore, conservative treatment with oral antibiotic combination therapy should be considered before implant removal surgery, especially in patients for whom no alternative hearing rehabilitation options are available.

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