The Use of Medical Grade Honey in the Prevention of Bone Anchored Hearing Aid Associated Skin Breakdown

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Background

Medical grade honey has recently became much more widely used and research continues to prove its strong antimicrobial effects. Medical grade honey is currently used across medicine for burns, wound infections, skin ulcers and more. In otolaryngology, it has been used for post-tonsillectomy pain, radiation induced mucositis, necrotizing fasciitis, and allergic fungal sinusitis (1). One study previously looked at the use of Medihoney to treat BAHA associated skin infections and saw a decrease in healing time from 5.25 weeks with just antibiotics, to less than 2 weeks with the addition of Medihoney (2).

Bone anchored hearing aids (BAHAs) implantation is a common otologic operation done today. BAHAs are generally reserved for those who fail conventional air conduction hearing aids, typically secondary to external or middle ear pathology such as aural atresia or a chronically draining ear (3). BAHAs can be done in a single step or two-part operation. A titanium screw is placed into the mastoid bone for osteointegration. An abutment is then attached to the screw which protrudes through the skin. A sound processor then attaches to this abutment to allow bone conduction to the cochlea. Complications due to this procedure are relatively few; due to the abutment that comes through the skin, soft tissue infections are the most common, followed by failure of integration (4).

The Holger scale is typically used when classifying skin complications post operatively. It involves a scale from 0-4, 0 being no involvement, 4 being involvement that necessitates BAHA removal. Depending on the severity of the disease, treatment can include anything from topical antibiotics, topical steroids and wound care for mild cases, to oral antibiotics and steroid injections for moderate cases, to simple skin excision or skin flaps for the more severe involvement (5).

A typical post-operative course after BAHA surgery at our institution includes bacitracin ointment with a bandage that stays on for seven days. After the seventh postoperative day, the bandage is removed and bacitracin is applied two times per day for the next two weeks.

Since medical honey has been shown useful for treatment of skin complications after BAHA, we propose using medical honey in the postoperative period, which we believe will decrease the number of skin infections and lower the average Holger score.

Objective/Research Question

Does postoperative use of medicinal grade prevent bone anchored hearing aid (BAHA) associated skin breakdown better than standard care alone in adult patients?

Hypothesis

Postoperative use of medicinal honey will decrease the rate of BAHA associated complications caused by skin breakdown and reactions in adult patients.

Methodology

This will be a prospective study. Multiple surgeons will perform the BAHA implantation surgery and their combined patients will be used in this study. Patients presenting in clinic for BAHA implantation surgery will be explained the details of the study, asked to participate and if agreeable asked to sign an informed consent document. The surgeon who will be performing the surgery or the resident working with that surgeon will recruit participants. Patient demographic information, including age, sex, and reason for implantation will be collected and recorded in a table.

The patients will be randomized to either postoperative medicinal honey and standard care or postoperative standard care alone using a random number generator. There will be a total of two patient groups. The type of BAHA device used, laterality and the surgical technique will be recorded in a table. The different types of implanted hearing devices will include BAHA Connect, BAHA Attract and Sophono brand hearing devices.

a. Treatment groups
    i. Group 1 - patients undergoing BAHA implantation who will be postoperatively treated with medicinal honey.
    ii. Group 2 - patients undergoing BAHA implantation who will be postoperatively treated with standard care.

b. Postoperative care
    i. Standard care: BAHA abutment incision is coated in bacitracin. A healing cap is placed over the abutment and left on for a week. The healing cap is removed on postoperative day 7. Patient is instructed to apply bacitracin ointment to the area for 2 weeks.

ii. MediHoney: BAHA abutment incision is coated with MediHoney. The healing cap will be placed over the BAHA site. The healing cap is removed on postoperative day 7. Patient is instructed to apply MediHoney daily to the area for 2 weeks.

Patients will be seen in clinic 1-week post-op, 1-month post-op, 3 months post-op and 6 months post-op. During each visit the BAHA site will examined. Pictures will be taken of the site and blindly reviewed by appropriate clinicians. Any skin breakdown will be graded based on the Holgers Classification: Grade 0 = no reaction; Grade 1 = reddish discoloration of the skin around the implant; Grade 2 = red and moist surface of the skin around the implant; Grade 3 = formation of granulation tissue around the implant; and Grade 4 = extensive soft-tissue reaction that requires implant removal or leads to implant loss.

The study will be included on clinicaltrials.gov.

Inclusion Criteria
Adults >18 years old undergoing bone-anchored hearing aid implantation surgery.

Exclusion Criteria
Patients who are undergoing revision BAHA surgery, history of radiation to the implantation site.

Data Analysis
The main study hypothesis will be evaluated using one-way ANOVA to compare the rates of skin breakdown in the group treated with medicinal honey versus the group treated only with standard care for both the adult patients.

Additionally, between-group differences in demographics and relevant clinical characteristics will be probed using ANOVA and chi-square analyses. If significant group differences in these factors are detected, follow-up ANOVA analyses will be conducted to control for covariates that may influence group differences in weight gain.

Power analysis
To achieve statistical significance of power and alpha of 0.05 for a 2 group ANOVA, we will calculate the minimum total sample required to detect difference.

Typical postoperative BAHA skin reactions occur at a rate between 5-20%. One study looking at medihoney in secondary intention wound healing saw a 12.2% increase in wound healing in the medihoney group at 12 weeks.

Using 16% for a incidence rate in the control group and 3.8% as a possible incidence in the experimental group; at a 5% significance level and a power of .8 a sample size of 186 would be required.

Data Safety Monitoring Plan

Patients' medical record numbers will be recorded on the data collection sheet for purpose of accurate retrieval of records. For the analysis of the data the Excel file will have a log number assigned to each patient. This log number will be used to identify subjects in the database to be created. Chart reviews will be conducted only by the principal authors and those directly involved with the research project. No patient-identifiable protected health system information will be removed from the hospital. Conscious effort will always be made to keep all patient-related information logs and sheets in a secure place free from public display and access. All electronic data will be stored on a password-protected computer drive. If data are emailed, email encryption will be used.

References

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Data Collection Tables

I. Patient Demographics: age, gender, race, comorbidities, type of hearing loss (HL), hearing loss etiologies
II. Type of Hearing Aid, Laterality and Surgical Technique
III. Post-Operative Complications

Table I. Patient Demographics

	Age	Gender	Race	Type of HL	HL Etiology	Level of HL
Patient ID						

Table II. Type of Hearing Aid, Laterality and Surgical Technique

	Hearing Aid	Laterality	Surgical Technique
Patient ID			

Table III. Post-Operative Complications

	1 week	1 month	3 months	6 months
Patient ID				