Improving Patient Comfort of Vibratory Anesthetic Devices with a Cotton Dampener

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Objectives

The study aims to determine the effectiveness of cotton as a dampener for vibratory anesthetic devices (VADs) for dermatologic patients. It will compare patient preferences for VAD use with and without cotton across different anatomical sites and identify factors, such as chronic pain or neuropathy status, that may influence these preferences. Finally, the study seeks to generate preliminary data to inform potential modifications to VAD use, optimizing patient comfort in dermatologic procedures.

Background

Vibratory anesthetic devices (VADs) decrease pain associated with anesthetic, steroid, or botulinum toxin injection in dermatology patients through the application of vibratory stimulation on targeted anatomical site [1,2,3]. While VADs are effective at reducing injection pain, a number of factors influence their adoption by injectors. One factor is patient comfort [4]. Anecdotally, some patients have reported discomfort with VADs used before dermatologic procedures. As this may be influencing the utilization of VADs in dermatological procedures, further investigation into patient comfort with VAD is necessary. This study will determine whether utilizing cotton balls as a dampener is effective in improving patient comfort with VAD use.

Inclusion and Exclusion Criteria

The study will include potential participants based on their ability to provide informed consent and complete the study, while excluding those with skin conditions, sensitivities at testing sites, or allergies to nitrile gloves or cotton.

	Inclusion Criteria
1.	Age range: from 18+
2.	Dermatologic patients at Westlake Clinic
3.	Consent: Must provide informed consent to participate in the study.
4.	Availability: Able to complete the entire study session, which includes testing all sites in a single session

	Exclusion Criteria
1.	Broken skin or known peripheral neuropathy on anatomical site of vibration.
2.	Allergies: Known allergy or sensitivity to nitrile gloves or cotton
3.	
4.	

Study Design

The overall study design is a single-site, one-visit, participant-blinded, pilot study for up to 60 patients in the Westlake dermatology clinic.

Study Procedures

The study is a single-site, participant-blinded, pilot study for up to 60 patients in the Westlake dermatology clinic. Using the pen-like VAD, vibration will be applied with cotton on an anatomical site of one side (right or left) and without cotton on the same anatomical site on the other side. To fix cotton to the VAD, a cotton ball will be positioned at the tip of the VAD with placement into a nitrile glove (5). The VAD we are using for this procedure is the current standard of care and is not a novel device.

The anatomical sites were chosen in terms of sites with minimal subcutaneous fat and areas where patients have anecdotally reported discomfort with the VAD. The sites will be the lateral nasal wall, sub-malar region of the cheek, ear helix, lateral neck, and dorsal side of the forearm.

The order of the five anatomical sites and the order of conditions (VAD and VAD with cotton) will be randomized, and all possible orders will be placed into an envelope. One envelope will be randomly selected for each patient to determine the order of anatomical sites and order of condition for that particular patient. The patients will be blinded to what treatment is applied. For example, patients will be instructed to close their eyes or to look away from the application site.

There will be 10 total applications (VAD and VAD with cotton for five anatomical sites) each subject will undergo. Each application of the VAD will last for 20 seconds. Between each VAD application, there will be a delay of 10 seconds. After applying vibration to the same anatomical sites on the left and right side, patients will be asked which of the two treatments was preferred, which should take around one minute. To monitor participants for safety, participants will be encouraged to report any discomfort or adverse effects they experience during or after each vibration and after each VAD application, participants will be asked if they are ready to move on to the next one.

Before completion of the protocol, but after the informed consent, patients will be asked questions regarding their medical history. Additionally, before administering vibrations, patients will be trained to distinguish between small and large dowels, applying the minimum amount of pressure, while their eyes are closed to ensure accurate perception of the vibration.

Data will be patient reported and will be collected in a secure RedCap online database.

Study Timeline

Estimated time requirement of visit	**Visit 1**
Patient Screening and Informed Consent	10 minutes
Data Collection	15 minutes
Anatomical site vibration (10)	15 minutes

Data to be Collected for your study

The study will collect sociodemographic information, including age, gender, and race, to understand the generalizability of data. Medical history data will encompass past medical conditions, history of prior procedures, and any previous use of vibration before injection. Patient chart will be looked at for the purpose of validating patient survey questions. Chronic pain history will be recorded, including the participant's relationship with a chronic pain specialist, current use and duration of pain medication, the specific medication used, and the

type, location, and duration of chronic pain. The presence, history, and location of neuropathy will also be documented. Lastly, the primary outcome variable will assess participant preference for each anatomical site, comparing the use of cotton versus no cotton.

Data Analysis Plan

As this is a pilot study, we are not able to conduct a power analysis. However, similar studies at UH using this same VAD have a similar target of up to 60 patients. A binomial test will be used to determine whether the proportion of participants preferring cotton differs significantly from the expected 50/50 baseline for each anatomical site. Additionally, Chi-Square Tests of Independence will be conducted to assess whether preferences for cotton versus no cotton vary based on participant characteristics, including chronic pain status, neuropathy status, or anatomical site. Qualitative data on the reason behind preference will be asked and independently categorized by at least two raters.

Risks to Research Participants

Minor discomfort may be experienced by patients from vibration for a few seconds per site. Additionally, there might be an anxiety due to potential discomfort. There will also be a risk of breach of confidentiality. Participants will be informed that they can withdraw from the study at any time without penalty.

Provisions to Protect the Privacy Interests of Research Participants

Vibration tests will occur in private rooms. All collected data will be de-identified in RedCap, ensuring that no personally identifiable information is linked to study responses. Data will be securely stored in a password-protected, restricted-access database of REDCap, with access limited to authorized research personnel only. A coding system will be used, where a unique participant code is linked to each subject's data. Only authorized research personnel will have access to this code, and it will be securely stored separately from the study data in a linking log.

Potential Benefit to Research Participants

There is no direct benefit to research participants. Indirectly, if the use of cotton with vibration proves to be more comfortable for patients, it could provide a simple, cost-effective, and widely implementable solution for VAD use which optimizes patient comfort. This could be especially

beneficial for individuals with heightened pain sensitivity, such as those with chronic pain or neuropathy.

Withdrawal of Research Participants

Participants will be withdrawn from the study if they experience unexpected or intolerable discomfort that prevents them from completing the procedure. Additionally, participants may be withdrawn if they do not follow study instructions properly, which could compromise the integrity of the data collection process. If a participant withdraws before completing the procedure, their data will not be included in the study analysis. If a participant is withdrawn due to noncompliance or intolerable discomfort, their collected data will be discarded. Participants will be informed of their right to withdraw at any time without penalty.

Alternatives to Participation

The alternative to participation is not to participate.

Drugs or Devices

The pen-like vibratory anesthetic device which is the current standard of care in UH dermatology clinics and is not a novel device will be the main device used for this study on 5 anatomical sites each on the left and right side.

Additional Information

This VAD used is a current standard of care for dermatologic procedures, and this is not a novel device.

Community-Based Participatory Research

This is not community-based participatory research.

References

1. Govas P, Kazi R, Slaugenhaupt RM, Carroll BT. Effect of a Vibratory Anesthetic Device on Pain Anticipation and Subsequent Pain Perception Among Patients Undergoing Cutaneous Cancer Removal Surgery: A Randomized Clinical Trial. JAMA Facial Plast Surg. 2019 Dec 1;21(6):480-486. doi: 10.1001/jamafacial.2019.0733. PMID: 31513234; PMCID: PMC6743061.
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