Use of an External Vibratory Device as a Pain Management Adjunct for Injections of the Foot and Ankle

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Introduction and Purpose

Injection therapy is a common modality utilized by the podiatric physician for a wide variety of purposes such as local anesthesia, pain management or as a diagnostic aid. These injections often elicit significant pain due to the sensitivity of the foot and the depth of these injections. The pain caused by injections has been associated with impaired patient compliance[1] or deferring further injections due to needle phobia[2].

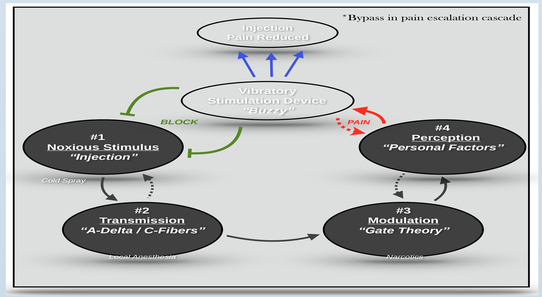
There are a range of modalities to reduce the pain of injection such as topical anesthetics or cold spray applied to the injection site. Recently there has been interest in utilizing vibratory stimulation to stimulate Aβ which reduce pain utilizing the pain gating phenomena. Previous studies have shown promising results in both pediatric[3] and adult[4] subject groups.

Specifically, the Buzzy® (MMJ Labs, Atlanta, GA), or external vibratory device, has been used to aid in injections in the pediatric population.

As of writing this study there have been no studies performed investigating the usefulness of this device in foot or ankle applications.

The purpose of this study is to determine the efficacy of combining vibratory and cold stimulation in reducing the pain associated with injections of the foot or ankle.

Figure 1 (below)



Methodology

The design of this study was a prospective randomized trial using 42 patients at the Temple University Foot and Ankle Institute (FAI) and 66 patients from a private practice clinic. Consent to participate in the study was obtained.

Subject Population: Patients for whom an injection of the foot or ankle was deemed necessary by the attending physician. Exclusion criteria were as follows: skin compromise over the Buzzy® application site, history of peripheral neuropathy, fibromyalgia or CRPS, cognitive or verbal impairment, patients not fluent in the English language. Use of analgesics within 4 hours before office visit.

Randomization: After informed consent, patients were randomized into the control or intervention group immediately prior to injection. The control group would receive vapocoolant spray (cold spray) only, and the intervention group received vapocoolant spray in addition to a Buzzy® vibratory device placed near, but proximal to the injection site. At the FAI, randomization was performed by using sealed opaque envelopes which would designate control or intervention. This envelope would be opened shortly before the injection was performed. At the private practice clinic randomization was done via random number assignment.

Procedure: After consent and randomization were performed the skin over the injection site would be prepped with betadine or alcohol per injection site protocol. If the patient was designated as an intervention, a Buzzy® unit was placed on the skin over the anatomic course of the appropriate nerve 2-3 inches proximal to the injection site and turned on for 1 minute prior to injection. Both groups received vapocoolant spray at the injection site immediately before the injection. At the FAI injections were performed by 3rd and 4th year medical students under the direct supervision of the attending physician (above authors). All injections at the private practice clinic were performed by CK (above author). Patients were asked to look away from the injection and to focus on sensation in the foot or ankle.

Instruments: Patients were given a 10 point numerical pain rating scale (NPRS) for which they would rank their pain. The attending physician would provide a scripted explanation of the NPRS. Additionally the attending physician would record the patients pain level using the Wong Baker Faces Pain Scale (WBPFS). Vibratory stimulation was delivered via the use of the a Buzzy® XL Healthcare unit which is applied to the extremity using a Velcro strap (see figure 1).

Results

Table 1 (below): A comparison of pain ranked by NPRS and by the Wong Baker Faces Pain Scale (WBPFS).

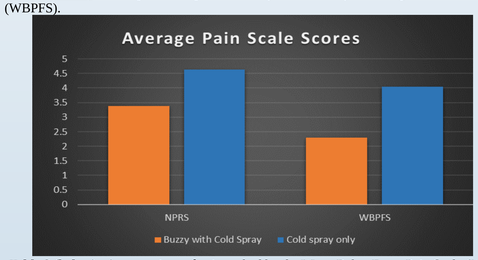


Table 2 (below): A comparison of pain ranked by the Wong Baker Faces Pain Scale (WBPFS) whereby the Cold Spray "standard of care" was compared against Cold Spray with addition of the Buzzy arranged highest to lowest value recorded.

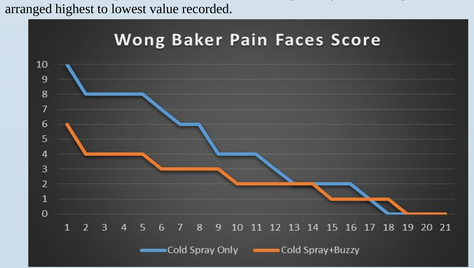
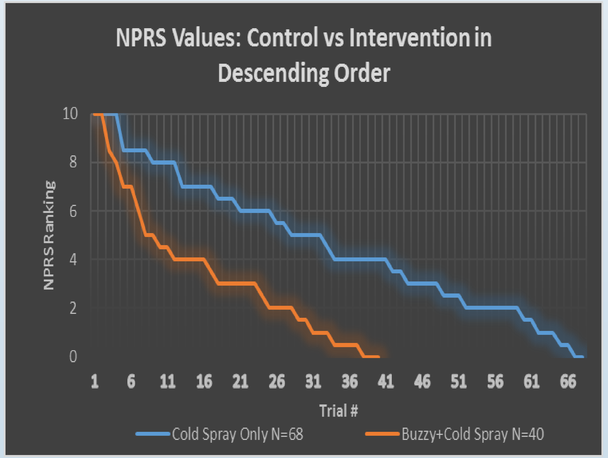


Table 3 (below): This table examines the same data set as in Table 2, but arranges the values highest to lowest with regards to NPRS value obtained. The NPRS score is our primary outcome measure.



Discussion and Conclusion

- The unpaired t test indicated a significant difference in both NPRS (p=0.022) and WBPFS (p=0.030) between the control and intervention groups with significance set at a p value of 0.05. The use of this device decreased pain 1.3 points on the NPRS and 1.76 on the WBPFS.
- The use of vibratory stimulation via the Buzzy® unit provided a worthwhile decrease associated with foot and ankle injections. The unit demonstrated to be a cost effective, user friendly, and well tolerated pain management adjunct.
- There were limitations to this study as follows: injections were on different anatomical sites, injection technique, and ability.
- There exists opportunities to further investigate this modality by controlling for age, anatomical site, the effect of injectable material, or optimizing the positioning of the vibratory stimulus. We believe there may be further benefits to be discovered by undertaking additional investigations of these attributes.
- **Conclusion**: The use of vibratory stimulation was demonstrated to produce a decrease in pain associated with injections to the foot and ankle. Further studies are needed to optimize the use of this modality for foot and ankle injections.

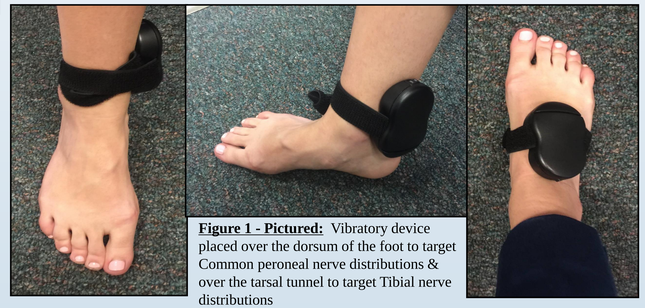


Figure 1 - Pictured: Vibratory device placed over the dorsum of the foot to target Common peroneal nerve distributions & over the tarsal tunnel to target Tibial nerve distributions

References

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