

Literature Review

BUZZY® IV ACCESS; PHLEBOTOMY

Canbulat N, Ayhan F, Inal S. Effectiveness of External Cold and Vibration for Procedural Pain Relief During Peripheral Intravenous Cannulation in Pediatric Patients. Pain Management Nursing, 2015 Feb;16(1):33-9.

The authors describe 176 patients aged 7 to 12 years who were randomized to either a control group that received no cannulation intervention and the experimental group that received external cold and vibration via Buzzy. The same nurse conducted the peripheral IV cannulation in all children. Cold and vibration were applied 1 minute before the peripheral IV and continued until the end of the procedure. Pre-procedural anxiety did not differ. Comparison of the two groups showed significantly lower pain and anxiety levels in the experimental group than in the control group during the peripheral IV cannulation. "Buzzy can be considered to provide an effective combination of cold and vibration that can be used during pediatric peripheral IV cannulation by pediatric nurses."

Bahorski J, Hauber RP et al. Mitigating procedural pain during venipuncture in a pediatric population. Int J Nurs Stud. 2015 Oct; 52(10):1553-64.

Children 18 months to 17 years requiring venipuncture were randomized to Buzzy vibration only, LMX4, or both. A 3x4 factorial design was used, evaluating age, ethnicity, sex, and intervention. For the 173 children participating, CHEOPS and WBFPs ratings of pain relief did not significantly differ between Buzzy and LMX. For Caucasian children, the combination of Buzzy AND LMX provided improved pain relief compared to either group ($p=.006$) No difference by age or gender was noted. Per the authors, "mechanical vibration [Buzzy] appears to be as effective as a topical anesthetic in children regardless of age, ethnic group, or sex. It has the advantage of being a fast-acting, cost effective, non-pharmacological preparatory intervention for venipuncture in children."

Inal S, Kelleci M. Relief of pain during blood specimen collection in pediatric patients. MCN Am J Matern Child Nursing. 2012 Sep;37(5)339-45.

In this randomized controlled trial, 120 children

aged 6 to 12 years underwent phlebotomy, either with no intervention for pain management or using the Buzzy device with cold and vibration throughout the procedure. The Buzzy group showed significantly lower pain ($p<.001$) and anxiety levels ($p<.001$) throughout the blood specimen collection. Authors concluded that Buzzy decreased perceived pain and reduced anxiety throughout blood collection, without decreasing the effectiveness of the procedure.

Baxter AL, Cohen LL et al. An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department. Pediatric Emerg Care 2011 Dec;27(12):1151-6.

In this first study of pediatric patients undergoing phlebotomy or IV cannulation in a pediatric emergency department, patients were block randomized by use of LMX or no intervention in triage. When the 4 to 18 year olds were cannulated, they were randomized to Buzzy or cold spray. In the 81 children, median age 10 years, Buzzy was associated with both lower pain scores than cold spray by self report on the Faces Pain Scale Revised (-2 on 10 point scale), by observer report, and by parent report. Venipuncture success was more likely with Buzzy, OR 3.05; 95%CI 1.03-9.02). Cold and vibration significantly decreased pain while improving procedural success.

Whelan HM, Kunselman AR et al. The Impact of a Locally Applied Vibrating Device on Outpatient Venipuncture in Children. Clin Pediatr 2014 Oct;53(12):1189-95.

As part of a quality improvement project, patients and phlebotomists were surveyed prior to initiation of implementation of the vibrating device Buzzy. Prior to the device, 17 of 29 children (59%) indicated they wished something had been used to decrease venipuncture pain. 80% of those using the vibrating device ($n=35$) indicated that they would like it used for future procedures. Children with previous venipuncture experiences appeared to benefit most. 81% of phlebotomists reported the vibration made the procedure easier; none reported it complicated the procedure. The study concluded that locally applied vibration appears to be a well-accepted technique to minimize discomfort that may facilitate the procedure.

Literature Review

Baxter AL, Leong T, Mathew B. External Thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. Clin J Pain 2009 Oct;25(8):705-10.

This was a crossover pilot study of 16 adult patients using Buzzy or nothing and 14 patients using vapocoolant spray or nothing. The Buzzy device prototype significantly reduced pain ($p=.035$) while vapocoolant spray did not. **Those with greater needle anxiety were more likely to experience pain relief with Buzzy:** each 20 mm of prior anxiety increased the likelihood of intervention pain relief (odds ratio 2, $P=0.043$).

BUZZY® - INJECTIONS AND ADHERENCE

Sahiner N, Inal S. The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. J Perianesth Nurs. 2015 Jun;30(3):228-35.

104 7-year olds receiving the Tdap vaccine received either Buzzy or standard care during the vaccination. Pain was rated by parents, nurses, and by self-report, with all showing significant pain reduction of 71-75%. In addition, despite slightly greater initial anxiety in the Buzzy group (often associated with greater reported pain), researchers found **anxiety was also reduced by 70%** on average during the immunization in the group using Buzzy.

Russell K, Nicholson R, Naidu R. Reducing the Pain of Intramuscular Benzathine Penicillin Injections in the Rheumatic Fever (RF) Population of Counties Manukau District Health Board J Paediatric Child Health. 2014 Feb;50(2):112-7.

Benzathine penicillin injection into the gluteal area is painful, and can lead to decreased adherence with rheumatic fever prevention. In this study, 405 RF patients receiving 4 weekly injections were offered lidocaine and/or Buzzy for pain management. Pre and post surveys of pain and fear were included. Overall pain scores were significantly reduced over all four time points. 71% chose an analgesic intervention. **After 5 months, 43% continued to use Buzzy.** The authors concluded that the pain reduction strategies were popular in this population, decreasing pain and increasing adherence.

BUZZY® - ALLERGY TESTING ITCHING

Troger, A. Robinson H et al. Helping Children Cope with Discomfort Associated with Skin Prick Testing in a Pediatric Setting: A Quality Improvement Report. J Allergy Clin Immunol 133 (2) 2014:A.

In this prospective study, the authors evaluated 54 children's coping with the administration and waiting portion of itching skin tests. Interventions included Buzzy (without ice wings), an electronic tablet distraction, parental comforting, and no intervention by parents. On a 5 point likert scale of coping from 1 (poor) to 5 (very well), **Buzzy was the best waiting intervention**, with 90% of patients at a 4 or 5, compared to 65-75% for the other interventions. Of note, ice provides 60% of Buzzy's pain relief, so future testing including ice may improve results.

ITCHING - ALLERGY TESTING

Waibel KH, Katial RK. Effect of topical vapocoolant spray on skin test wheal, flare, and pain responses. Ann Allergy Asthma Immunology 2005 Aug;95(2):149-53.

Whether cold affects the outcomes of histamine and wheal/flare reactions is a concern with proven cold interventions. 18 adults participated in a randomized, crossover double-masked, placebo controlled study of ethyl chloride vapocoolant and placebo spray. Areas of wheal and flare were outlined, scanned, and digitally measured. There was no difference between histamine wheal ($p=.53$) or flare ($p=0.39$), or aeroallergen wheal or flare. Pain scores were not significantly different.

Yoon WY, Chung P, et al. Analgesic pretreatment for antibiotic skin test: vapocoolant spray vs. ice cube. Am J Emerg Med 2008 Jan;26(1):59-61.

50 adult volunteers compared ice cube and vapocoolant for the pain of an intradermal test. During both pretreatment and skin test burn, the ice cube was superior ($p<.0001$ for both). Ice is recommended.

Literature Review

BUZZY® PLASTIC SURGERY – FACIAL INJECTIONS

Nahai FR. CME Demonstration of Fillers; Lasers and New Technology. State-of-the-Art in Facial Aesthetics, 2014, Atlanta GA.

In these independent sessions, the presenter demonstrated techniques to decrease pain with injections of BTX-A and Fillers. Placement of Buzzy cold wings for 10 seconds, then vibration only in the VI distribution for brow injections and adjacent to mouth and nasolabial fold placement for fillers was demonstrated. **80-90% preference for Buzzy** was reported in the presenter's filler population. Laser use with Buzzy® was reported on one neck port-wine stain treatment of an adolescent with good results.

AESTHETIC SURGERY – FACIAL INJECTIONS

Mally P, Czyz CN, Chan NJ, Wulc AE. Vibration Anesthesia for the reduction of pain with facial dermal filler injections. Aesthetic Plast Surg. 2014 Apr;38(2):413-8.

According to the authors, "Vibration anesthesia is an effective pain-reduction technique for facial cosmetic injections," but insufficient studies have been conducted for fillers compared to botulinum toxin. 41 patients were injected in a split-face crossover design. 95% of patients reported a preference for vibration anesthesia during facial dermal filler injections, which was both clinically and statistically significant pain relief. No adverse events were reported.

Sharma P, Czyz CN, Wulc AE. Investigating the efficacy of vibration anesthesia to reduce pain from cosmetic botulinum toxin injections. Aesthet Surg J. 2011 Nov;31(8):966-71.

This study evaluated vibration pain relief for clinical facial procedures. 50 patients received BTX-A injections for cosmetic rhytid reduction. Random split-face crossover design was employed, with an immediate post treatment 5-point pain questionnaire and a follow up 3-4 weeks later. Patients reported less pain on the vibration-treated half of the face (1.3 vs 2.4, $p=.000$). There was no difference between first time BTX-A patients and repeat patients' preference for vibration. 86% of patients preferred to receive vibration with subsequent injections. Efficacy of BTX-A was not

affected. Locally applied vibration appears to be a well-accepted technique to minimize discomfort that may facilitate the procedure.

DERMATOLOGY – HYPERHYDROSIS INJECTIONS

Bechara FG, Sand M, Altmeyer P, Sand D, Hoffmann K. Skin cooling for botulinum toxin A injection in patients with focal axillary hyperhidrosis: a prospective, randomized controlled study. Ann Plast Surg. 2007 Mar 58(3):299-302.

Hyperhidrosis treatment is often painful. This elegant study first used a crossover design in 31 patients using no intervention or skin cooling with air. Pain scores averaged 2.5 for cooling vs 7.4 without. A second group of 10 patients both had low pain scores comparing air (2) and ice cubes (2.4) with no significant difference in relief. Authors concluded that skin cooling significantly relieves pain, ice and air cooling provide equal efficacy.

FACIAL INJECTIONS – ICE PAIN RELIEF

Saliew P, Preechawai P. Evaluating the effects of ice application on patient comfort before and after botulinum toxin type A injections. J Med Assoc Thai. 2010 Oct;93(10):1200-4.

In 60 patients, ice application significantly reduced pain ($p=.005$) and when applied prior to injection reduced bleeding (.0472). Cold includes gate control and descending noxious inhibitory control mechanisms to decrease pain. Cognitive distraction may also contribute to the efficacy of cold. 32 – 34 degrees F gives maximum effect.

Dixit S, Lowe P, Fischer G, Lim A. Ice anesthesia in procedural dermatology. Australas J Dermatol. 2013 Nov;54(4):273-6.

32 dermatologists (41% response rate) reported on use of ice for pain relief. Median ice time was 10 seconds, ice was most common method of anesthesia (75%) followed by topical anesthesia.

Literature Review



Sahiner N, Bal MD. The effects of three different distraction methods on pain and anxiety in children. J Child Health Care 2015;19(2)1-9.

In this prospective RCT, 120 children ages 6-12 underwent phlebotomy while using no intervention, DistrACTION cards, inflating a balloon or identifying music from cartoons. DistrACTION cards had the lowest reported pain ($p=.04$) and significantly lower anxiety than control group pain. This study is significant in that it demonstrates that given two active distraction activities, incorporating a visual task was superior to an aural/audio task. Likewise, breathing out is physiologically a useful anxiety reliever – this study supports that active visual distraction is superior to a deep breathing distraction as well.

Canbulat N, Inal S. Efficacy of distraction methods on procedural pain and anxiety by applying distraction cards and kaleidoscope in children. Asian Nurse Research 2014 Mar;8(1):23-8.

Kaleidoscopes have long been a visual distraction for patients undergoing painful procedures. They allow children to actively manipulate the device, while passively watching colors change. This study randomized 188 children ages 7-12 to control, DistrACTION cards, or kaleidoscope during phlebotomy. DistrACTION cards had the lowest reported pain (significantly lower than control) and significantly reduced anxiety ($p<.001$) compared to both other groups. Monkey Distraction Cards were used in this study, with questions including “How many monkeys are actually touching the bed” and “can you find the two monkeys which are identical?”

Inal S, Kelleci M. Distracting children during blood draw: Looking through distraction cards is effective in pain relief of children during blood draw *International Journal of Nursing Practice* 2012; 18: 210-219.

123 children were prospectively randomized to either DistrACTION cards or parental presence for phlebotomy. Patients in the DistrACTION group reported a pain of 3.90 +/- 1.94, 95% CI 3.91-4.39 compared to 6.51 +/- 1.65, 95% CI 6.10-6.92, $P<.001$. Procedural anxiety was also reduced. Of note, 97% in the DistrACTION card group reported the procedure was better compared to previous phlebotomy experiences, as opposed to none of those in the control group. For children who have anxiety from previous procedures, this finding implies that improving the experience may be able to change the anxiety or perception going forward.

Buzzy® and DistrACTION® cards are available at www.BuzzyHelps.com or contact orders@mmjllabs.com

Buzzy® is 510k cleared by the FDA.

Indications for use: Control pain associated with injections, venipuncture, IV starts, cosmetic injections and the temporary relief of minor injuries (muscle or tendon aches, splinters and bee stings). Also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension.