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Effects of Thermomechanical Stimulation during Vaccination on Anxiety, Pain, and Satisfaction in Pediatric Patients: A Randomized Controlled Trial[1,2]

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ABSTRACT

Purpose: Vaccination can be a significant source of pain for pediatric patients, which could result in fear of medical procedures and future reluctance to seek medical care. It is important for nurses to provide pain prevention during these procedures. This study sought to measure the impact of an intervention combining cold and vibration on pain scores during routine pediatric immunization.
Design and Methods: A prospective, open-label, randomized controlled trial to examine the effectiveness of the Buzzy device (thermomechanical stimulation) compared to no intervention (control group) in reducing child-reported pain during routine immunization. The Wong Baker Faces scale was used to collect child, parent, and observer reported anxiety and pain. Parents reported satisfaction with the procedure and overall office visit.
Results: Fifty children between the ages of 3 and 18 were included in the present analysis. Mean child-reported pain scores were significantly lower in the group receiving thermomechanical stimulation compared to control (3.56 vs 5.92, $p = 0.015$). Buzzy did not impact child-reported anxiety or how much pain the child expected. Parent-reported satisfaction did not vary significantly between groups, but was strongly associated with parent-reported pain scores.
Conclusions: Thermomechanical stimulation with the Buzzy device significantly reduced pain during pediatric immunization over a wide range of ages compared to control, but did not impact pre-procedure anxiety.
Practice Implications: The Buzzy device is an easy to implement intervention to reduce pediatric pain during vaccination. It may have the greatest impact in younger children but could be offered during all immunizations.
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Introduction

Procedures that require a needle stick are among the most common procedures for pediatric patients in the health care setting and are a source of pain (Cummings, Reid, Finley, McGrath, & Ritchie, 1996; Inal & Kelleci, 2012a). Routine vaccination has been suggested to be the most common cause of iatrogenic pain during childhood (Taddio et al., 2009). The pain that accompanies these procedures may induce anxiety in both pediatric and adult patients, with significant consequences. Needle phobia is estimated to affect approximately 10%–20% of the population (Hamilton, 1995; Taddio et al., 2012). While it is believed that a majority of needle phobia is due to genetic factors and the experience of vasovagal reflexes, the remaining 30% are considered classic phobias arising due to traumatic experiences, particularly during pediatric venipunctures in which the patient perceives that medical personnel completed procedures without any effort to relieve pain or anxiety (Lynn, 2010). Fear or anxiety associated with needle procedures does not always resolve with time or age, and may result in delays in care or avoidance of treatment in both pediatric and adult patients (Taddio et al., 2010). Specifically, the success of immunization programs has been suggested to be impacted in part due to fear-induced non-compliance. Managing the emotional and physical effects of needle procedures has become an important part of nursing practice, and interventions to prevent pain during vaccination have been advocated (Rogers & Ostrow, 2004; Taddio et al., 2012).

Many types of interventions have been studied with the goal of reducing pediatric pain during venipuncture including pharmacologic (EMLA cream), behavioral distractions (music, video games, kaleidoscopes), tactile interventions (stroking, ShotBlocker), sweet solutions for infants (glucose or sucrose), and cold analgesia (vapocoolant

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sprays), with varying results. Fewer studies have focused on the impact of intervention on immunization pain in pediatric populations. The effects of EMLA and vapocoolant spray were studied in infants using duration of cry as a measure of pain with no impact compared to breastfeeding during vaccination (Gupta et al., 2017). Similarly, a systematic review of interventions suggested that vapocoolant sprays are not effective in preventing vaccination pain in children, however EMLA creams were successful when compared with control (Shah et al., 2015).

In 1984, Bini et al. reported an interesting phenomenon: the research group induced pain in healthy research subjects using electrical stimulation in order to test whether common maneuvers such as vibration, massage, warming, or cooling would affect subjects' pain experience (Bini, Cruccu, Hagbarth, Schady, & Torebjork, 1984). Vibration provided the most effective response on its own, however, a combination of vibration and cooling provided the most potent analgesic effect of those investigated, at times completely inhibiting moderate pain. Though impressive pain reduction was observed when cold and vibration were combined (thermomechanical stimulation), the two have not been used in conjunction in a clinical setting until recently.

The Buzzy device, a vibrating motor with ice pack, combines multiple approaches by supplying cold analgesia, tactile stimulation, and distraction. Buzzy is thought to provide pain relief via gate control theory, by stimulating nerves with cold to "close" the fast pain gate. It is hypothesized that by simultaneously stimulating A_{β} mechanoreceptors with vibration, one can also close the fast pain gate via presynaptic inhibition at the dorsal horn; the combination of the two would provide optimal pain relief (Melzack & Wall, 1965). Pilot data in adults demonstrated greater pain relief using Buzzy compared to vapocoolant sprays (Baxter, Leong, & Mathew, 2009). Similarly, studies investigating the use of this device in pediatric populations have also demonstrated superior pain relief in children while confirming the feasibility of its use in a fast-paced care setting (Baxter, Cohen, McElvery, Lawson, & von Baeyer, 2011).

Most reports of the device suggest it provides significant pain relief, however the majority of these studies completed in pediatric populations focused on children undergoing venous cannulation or venous access for blood draws (Baxter et al., 2011; Inal & Kelleci, 2012b, 2017; Moadad, Kozman, Shahine, Ohanian, & Badr, 2016; Whelan, Kunselman, Thomas, Moore, & Tamburro, 2014). A recent study reported that Buzzy significantly reduced pain during venipuncture in pediatric patients with cognitive impairment as well (Schreiber et al., 2016). While these studies have given some evidence of the device's efficacy, few have focused on thermomechanical stimulation during pediatric immunization. Benjamin et al. reported that vibration therapy alone (without cold analgesia) was not effective in reducing immunization pain (Benjamin, Hendrix, & Woody, 2016). However, a recent study of both cold and vibration during DTaP vaccine injection indicated that significant pain reduction was achieved per child self-report and observer scores (Canbulat Sahiner, Inal, & Sevim Akbay, 2015). This study aimed to determine whether Buzzy is effective over a range of vaccine injections and child ages.

Objective

The main objective of this study was to determine whether the Buzzy thermomechanical system reduced procedural pain as measured by the Wong Baker Faces Pain Scale (Wong, Hockenberry-Eaton, Wilson, Winkelstein, & Schwartz, 2001) during routine vaccination injections at well visits in a pediatric population. The secondary objectives included the evaluation of whether Buzzy affected pre-procedural anxiety in these patients and whether use of the device affects parent satisfaction compared to those receiving standard of care using 1–10 Likert scale questions as well as a categorical rating of better, same, or worse than expected rating for overall experience.

Methods

Design

This open label randomized clinical trial was conducted at ProMedica Toledo Hospital's Center for Health Services from April 2016 through September 2016 and assessed the efficacy of Buzzy during a vaccine injection. The necessary sample size to demonstrate a statistically significant difference in child-reported pain was calculated prior to enrollment. Assuming mean pain scores 3.0 ± 1.5 and 4.0 ± 2.0 the experimental and control groups in order to achieve 80% power at a significance level of 0.05, it was determined that 50 patients were needed per group, as previously described (Inal & Kelleci, 2012b; Julious, 2004). Preliminary analyses were planned in order to allow for early termination if significance was reached at the halfway point of recruitment for this project. A randomization schedule was created by research staff using www.randomizer.org in advance of recruitment to assign patients to either receive the Buzzy intervention or standard of care (no pain-reducing intervention) during injection. Folded paper tags with group allocation were placed into sequentially numbered, sealed envelopes and opened at the time of consent. Neither parents, children, nor research staff were blinded to the group assignment.

Participants

Children who were at least 3 through 18 years of age were eligible to participate if undergoing routine vaccination injection at their annual well visit and were Buzzy naïve. Participants were excluded if Reynaud's syndrome or sickle cell disease with extreme sensitivity to cold was present (per manufacturer's recommendation); there was a break or abrasion on the skin where the device would be placed; nerve damage was present which would affect the extremity being injected; neurodevelopmental delays or verbal difficulties were present; analgesia had been used within the past 6 h; or if they had been previously exposed to the Buzzy device. The number of injections required during the visit was not a factor in patient inclusion or exclusion so that children of all ages would be eligible to be included. The local Institutional Review Board reviewed and approved this study prior to commencement. Parents or legal guardians provided written informed consent for all participants. Verbal assent was gained from children who were 3–6 years of age and written assent was obtained from all children who were 7 years of age and older.

Setting

Subjects were enrolled within a single pediatric primary care office of this urban community care center, a medical office building on the campus of ProMedica Toledo Children's Hospital and ProMedica Toledo Hospital. The center includes multiple primary care and specialty physician offices, diagnostic testing, and behavioral health services. ProMedica Toledo Hospital is a 794-bed tertiary care center with over 30,000 annual admissions, accredited by The Joint Commission and located in Toledo, OH. The surrounding area is urban, with about 280,000 residents, of which approximately 65% are Caucasian, 27% African American, and 7% Hispanic or Latino.

Test Device

The experimental device evaluated in this study was applied to patients randomized to the experimental group. The Buzzy device (MMJ Labs, Atlanta, GA) is a reusable, battery-operated plastic vibrating motor resembling a bee or ladybug that combines cold and vibration using a thin (disposable or reusable) ice pack (wings). In this study, reusable ice packs were used and were solidly frozen prior to every application. The device can be secured to the patient with the use of an adjustable tourniquet or by pressing and holding the device in place

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