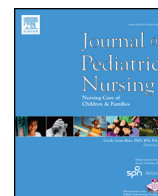




Contents lists available at ScienceDirect

Journal of Pediatric Nursing



Research paper

Efficacy of Non-pharmacological Methods of Pain Management in Children Undergoing Venipuncture in a Pediatric Outpatient Clinic: A Randomized Controlled Trial of Audiovisual Distraction and External Cold and Vibration☆☆☆

Piera Bergomi, MSN, RN^{*}, Luigia Scudeller, MD, Serena Pintaldi, RN, Alberto Dal Molin, PhD, MSN, RN

IRCCS Policlinico San Matteo Foundation, viale Camillo Golgi, 19, 27100 Pavia, Italy

ARTICLE INFO

Article history:

Received 2 October 2017

Revised 21 April 2018

Accepted 21 April 2018

Available online xxxxx

ABSTRACT

Purpose: Venipuncture generates anxiety and pain in children. The primary aim of the study was to evaluate two non-pharmacological techniques, vibration combined with cryotherapeutic topical analgesia by means of the Buzzy® device and animated cartoons, in terms of pain and anxiety relief during venipuncture in children.

Designs and Methods: 150 children undergoing venipuncture were randomized into four groups: the 'no method' group, the Buzzy® device group, the animated cartoon group and the combination of Buzzy® and an animated cartoon group. Children's pain and anxiety levels along with parents' and nurses' anxiety levels were evaluated by means of validated grading scales.

Results: Overall children's pain increased less in the non-pharmacological intervention groups as compared to the group without intervention. Notably, the difference was statistically significant in the animated cartoon group for children's perception of pain. Children's anxiety and parents' anxiety decreased more in non-pharmacological interventions groups as compared to the group without intervention.

Conclusions: The study showed the effectiveness of non-pharmacological methods of pain management during venipuncture. Notably, distraction with animated cartoons was superior in terms of children's perception of pain when compared to Buzzy®, and to the combination of cartoons and Buzzy®. Buzzy® was significantly effective at the secondary analysis for children younger than 9. Children's and parents' anxiety is decreased by non-pharmacological methods. Furthermore, nurses' involvement in pediatric care can be enhanced.

Practice Implications: Non-pharmacological methods of pain management during venipuncture represent an easy way to achieve an increased level of compliance among children and parents.

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Background

Invasive procedures, particularly those involving the use of needles, can generate anxiety and pain in pediatric patients (Ellis, Sharp, Newhook, & Cohen, 2004). Patients who are fearful of needles because of pain could be reluctant to undergo further procedures (Inal & Kelleci, 2012a). In fact, the use of needles is one of the most traumatic experiences during hospitalization; it is distressing even for parents (Cummings, Reid, Finley, McGrath, & Ritchie, 1996; McMurtry, 2013; Pölkki, Pietilä, & Rissanen, 1999).

There is evidence that supports the use of non-pharmacological methods for pain control in children. Non-pharmacological means, such as distraction and cryotherapeutic topical analgesia, are advantageous

because they are cost saving and can be employed independently by nurses (Wente, 2013). Distraction is a simple and cost-effective strategy for pain management and it could simplify repeat procedures (Dahlquist, 2002).

Nevertheless, evidence about distraction techniques is conflicting. Bellieni et al. (2006) reported that distraction by showing TV programs is more effective compared to other active techniques for distraction. However, Cassidy et al. (2002) observed that watching TV cartoons does not distract children during injections and does not decrease pain. Some evidence supports the fact that the efficacy of distraction techniques depends on children's age, temperament and interests (Cohen et al., 2006; Kleiber & Harper, 1999). According to a review by Murphy (2009), passive means of distraction (books, guided imagination, virtual reality, cartoons) are more effective compared to active techniques (e.g., an interactive toy). Moreover, the efficacy of a technique also depends on the attentive capacity of the child. In addition, a study by MacLaren (2005) seems to confirm the superiority of passive distraction for venipuncture. More recently, a research study conducted at Gaslini Hospital in Genoa showed that audiovisual distractions

☆ Conflict of interest: none.

☆☆ Funding source: this research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

* Corresponding author.

E-mail address: p.bergomi@sanmatteo.pv.it (P. Bergomi).

improve pain management as well as children's cooperation and trust during venipuncture (Bagnasco, Pezzi, Rosa, Fornoni, & Sasso, 2012).

Non-pharmacological methods can help children to cope with stressful events and are mostly devoid of side effects (Lim, 2006). Some minor side effects do however exist, for example when using the vapocoolant spray, since its application may be painful, thus reducing the beneficial analgesic effect. Moreover, the vapocoolant spray cannot be recommended for routine use in children or adults (Hogan, ShahM, & Taddio, 2014).

Distraction techniques are shown to be effective also when compared to the use of drugs. Shah, Taddio, and Rieder (2009) conducted a systematic review and meta-analysis of 32 research articles studying the efficacy and tolerability of various drugs and combined interventions that were aimed at decreasing procedural pain in children during immunizations. The authors concluded that some combined interventions, such as breastfeeding, topical local anesthetic agents, sweet solutions, are recommended to obtain a reduction in the pain experienced by children in clinical practice. According to Schechter et al. (2007), the use of distraction techniques during injection can be based on A-level evidence, according to the US Preventive Services Task Force levels of evidence, which states that "level-A recommendations are based on good consistent scientific evidence" (Agency for Healthcare Research and Quality, 2006); this is the highest and most recommendable type of evidence in research, since meta-analysis studies are conducted in order to endorse a specific intervention (Peterson et al., 2014). The benefits of using non-pharmacological methods include decreased pain, distress, and anxiety reported by the parent, child, and/or observer (Wente, 2013).

The mechanism of pain control achieved by distraction techniques is still unclear. It is hypothesized that they could alter the nociceptive pathway in the nervous system, decreasing the perception of pain (Bagnasco et al., 2012). The combination of vibration and cryotherapeutic topical analgesia is widely supported in literature (Baxter, Cohen, McElvery, Lawson, & von Baeyer, 2011; Inal & Kelleci, 2012b) as being beneficial for patients of different ages. These techniques are cost and time saving and reusable. Buzzy® (MMJ Labs, Atlanta, GA, USA) is a vibrating bee-shaped device that is combined with an ice pack aiming to provide distraction and pain relief by means of cold and vibration. The Buzzy® device generates vibrations and cooling sensations that can affect the A β nociceptive fibers; these stimulate the production of enkephalin, an endogenous opioid which blocks the transmission of painful signals to the brain. The effectiveness of Buzzy® is based upon the Gate Control Theory, which asserts that if the nociception gates are closed, no pain is perceived (Melzack & Wall, 1965). Its efficacy has been demonstrated in both venipuncture in children (Baxter et al., 2011; Baxter, Leong, & Mathew, 2009; Inal & Kelleci, 2012b) and in painful procedures in adults, such as vaccination, removal of splinters, dental operations, etc. (Baxter et al., 2009). The Buzzy® device was also used for the prevention of pain and anxiety during routine vaccinations; the study by Redfern, Chen, and Sibrel (2018) showed that children and their parents enjoyed using the device.

The results of a randomized trial indicate that the combination of Buzzy® device and distraction with distraction cards reduces pain during blood sampling or intravenous (IV) cannulation, without adverse effects on the blood collection procedure (Inal & Kelleci, 2017). The efficacy of relieving pain during IV cannulation procedures in children by applying the Buzzy® device was also highlighted by the nurses of another study by Moadad, Kozman, Shahine, Ohanian, and Badr (2016). The results of a further study showed that children with cognitive impairment benefited from the analgesia provided by the Buzzy® device during vascular access procedures (Schreiber et al., 2016).

The primary aim of our study was the evaluation of two non-pharmacological interventions, i.e. vibration combined with cryotherapeutic topical analgesia delivered by the Buzzy® device and distraction by means of an animated cartoon, in terms of pain and anxiety control during venipuncture in children. At the Hospital

where this study was conducted, a standard venipuncture procedure would not normally include the application of either a pharmacological or a non-pharmacological method of pain control. However, the parents' involvement is routinely encouraged, in order to hold the child's hand or otherwise reassure them verbally or physically.

Design and Method

Protocol and Randomization

We conducted this randomized controlled study from October 2013 to January 2014, in the outpatient clinic of the Department of Pediatrics at a Hospital in the north of Italy. Formal authorization to conduct the study was obtained from the Hospital Ethics Committee on August 8th, 2013. We enrolled children aged 5 to 12 years, scheduled for a venipuncture procedure and able to understand Italian. We explained to the children and their parents that a non-pharmacological method of pain control might be used during venipuncture. Verbal informed assent was gained from children aged 5–8 years, and written informed assent was obtained from all children who were 9–12 years of age and older. The choice of the non-pharmacological method to be used (i.e., animated cartoons, Buzzy® device, animated cartoons and Buzzy® device, none) was randomized. The 1:1:1 randomization list was prepared by an independent statistician through the RALLOC method in Stata® 13, using blocks (with random size 4–8). Sequentially numbered opaque sealed envelopes (SNOSE) were prepared, including the allocation group. After the patients' enrolment, the nurse in charge of the venipuncture opened the corresponding envelope, allocated the patient to a group, and proceeded with the venipuncture. The study population was thus divided into four groups, according to the non-pharmacological method applied. The pain and anxiety assessment scales were explained and demonstrated to the children and their parents. Nurses were not blinded to the intervention during the venipuncture.

Intervention and Outcome Measures

Venipuncture was performed by means of the Vacutainer® system, using a 21G butterfly needle. All venipuncture procedures were performed by highly experienced pediatric nurses. The primary outcome was children's perception of pain, which was evaluated by using the Wong-Baker Faces Pain rating scale (WBFP) (Savino et al., 2013; Wong & Baker, 1988; Wong, Hockenberry-Eaton, Wilson, Winkelstein, & Schwartz, 2001). Secondary outcomes were nurses' and parents' perception of the child's pain and anxiety. Parents' anxiety was also evaluated. Nurses' and parents' perception of the child's pain and anxiety were evaluated by means of the WBFP scale and the Children's Emotional Manifestation Scale (CEMS) (Li & Lopez, 2006), respectively. Finally, parents' anxiety was assessed through the Numeric Rating Scale (NRS) by asking them to estimate their own level of anxiety with a number ranging from 0 to 10 (Barnason, Zimmerman, & Nieveen, 1995; Caraceni et al., 2004; Clarke et al., 2013; Movafegh, Alizadeh, Hajimohamadi, Esfehiani, & Nejatfar, 2008; Rodriguez, McMillan, & Yarandi, 2004; Thiadens, Vervat, Albertyn, Van Dijk, & Van As, 2011). All outcomes were evaluated before and after the procedure.

In the animated cartoon distraction group, we offered a list of 6 animated cartoons, selected according to the child's age and gender. The children chose their preferred cartoon. The venipuncture was performed two minutes after the start of the cartoon. In the Buzzy® group, the wings of the device were removed from the freezer and briefly warmed up in order to avoid causing the child discomfort from exposure to cold. The device was used according to the manufacturer's instructions; it was applied 5 cm proximally from the site of venipuncture. A venous tourniquet was applied proximally to the device, which was then switched on to activate the vibration. In order to achieve a successful non-pharmacological intervention, it was imperative that the needle was inserted within 15 s of the device being applied to the skin

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