


## ORIGINAL ARTICLE

# Cold and vibration for children undergoing needle-related procedures: A non-inferiority randomized clinical trial

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## Abstract

The use of a rapid, easy-to-use intervention could improve needle-related procedural pain management practices in the context of the Emergency Department (ED). As such, the Buzzy device seems to be a promising alternative to topical anesthetics. The aim of this study was to determine if a cold vibrating device was non-inferior to a topical anesthetic cream for pain management in children undergoing needle-related procedures in the ED. In this randomized controlled non-inferiority trial, we enrolled children between 4 and 17 years presenting to the ED and requiring a needle-related procedure. Participants were randomly assigned to either the cold vibrating device or topical anesthetic (4% liposomal lidocaine; standard of care). The primary outcome was the mean difference (MD) in adjusted procedural pain intensity on the 0–10 Color Analogue Scale (CAS), using a non-inferiority margin of 0.70. A total of 352 participants were randomized (cold vibration device  $n=176$ , topical anesthetic cream  $n=176$ ). Adjusted procedural pain scores' MD between groups was 0.56 (95% CI: -0.08–1.20) on the CAS, showing that the cold vibrating device was not considered non-inferior to topical anesthetic. The cold vibrating device was not considered non-inferior to the topical anesthetic cream for pain management in children during a needle-related procedure in the ED. As topical anesthetic creams require an application time of 30 min, cost approximately CAD \$40.00 per tube, are underused in the ED setting, the cold vibrating device remains a promising alternative as it is a rapid, easy-to-use, and reusable device.

## KEYWORDS

children, cold and vibration, emergency, medical device, needle-related procedures, pain management, pediatric

## 1 | INTRODUCTION

Needle-related procedures are considered by children to be painful and distressing.<sup>1–3</sup> Inadequate pain management during

procedures can be harmful to children and can result in needle phobia.<sup>4,5</sup> Long-term consequences include increased pain perceptions,<sup>6</sup> avoidance of medical care,<sup>7</sup> and noncompliance with vaccinations,<sup>8</sup> among others.

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In previous decades, there has been a plethora of evidence evaluating the effectiveness of pharmacological and non-pharmacological interventions for pain management in children undergoing needle-related procedures. Despite efficacy of some interventions, procedural pain management remains often suboptimal, and their use remains limited,<sup>9-13</sup> particularly in the emergency department (ED) where it is a significant challenge due to time constraints, limited resources, and interruption in the continuity of care.<sup>14,15</sup> Additionally, some strategies may be expensive and require additional training.<sup>15,16</sup>

The current recommended pharmacological intervention for needle-related procedure, at the study's site, is the application of a topical anesthetic cream at the insertion site prior to the procedure.<sup>17</sup> Despite ample data showing benefit,<sup>18-20</sup> the required application time, ranging from 30 to 60 min, limits its implementation and routine use in the ED setting.<sup>9,21</sup> Papa & Zempsky<sup>22</sup> aimed to evaluate nurses' perception on pain management during needle-related procedures through online surveys ( $N=2187$ ). Only 28% of the ED nurses acknowledged using a topical anesthetic cream for pain management during needle-related procedures in children. Most of the nurses reported avoiding the use of topical anesthetic cream because of the associated delays related to the application time, as well as perceived vasoconstriction of blood vessels with some cream, despite the use of topical anesthetic proven to reduce procedural time and increasing success on first attempt.<sup>22</sup> A more recent study, by Alobayli & Blackman<sup>23</sup> also underlined the time constraint relating to topical anesthetic creams showing that procedural factors such as time concerns had a significant and direct influence on the use of topical anesthetics with a path coefficient of 0.26.

The optimal intervention for needle-related pain management in the ED setting should be rapid, easy-to-use with few adverse effects. To satisfy these criteria, a device combining cold and vibration (Buzzy®, MMJ Labs, Atlanta, Georgia, USA) has been developed specifically for needle-related pain management in children. This bee-shaped device, combining a battery-operated vibrating motor with removable ice wings, is based on two pain control mechanisms: the Gate Control Theory<sup>24</sup> and the diffuse noxious inhibitory controls,<sup>25</sup> both playing a role in the modulation of the transmission of pain.<sup>26</sup> The mechanical and thermal effect generated by the cold-vibrating device stimulates the A- $\alpha$  and A- $\beta$  fibers which communicate the information they receive faster than the other fibers (A- $\gamma$  and B) which are responsible for the transmission of pain, with the belief effect of closing the gates to painful impulses generated by the needle-related procedure.<sup>24</sup>

A systematic review<sup>24</sup> showed that despite the majority of trials supporting the efficacy of the cold vibrating device for needle-related pain and distress management in children, the quality of evidence was very low; the sample size of study limited the possibility to draw statistically significant results for 3/5 of the secondary outcomes measured (*Success of the procedure at the first attempt* (RR=0.71; 95% CI: 0.35-1.43;  $I^2=0\%$ ;  $p=0.34$ ),

*Satisfaction* (SMD: 0.40; 95% CI:-0.17 to 0.96; $p=0.17$ ) and *Side effects Adverse events* (SMD: 0.40; 95% CI:-0.17 to 0.96; $p=0.17$ )). Therefore, high quality randomized controlled trials with improved methodology are essential to demonstrate the non-inferiority of such a device. The primary objective of this trial was to determine if a device combining cold and vibration is non-inferior (no worse) to liposomal lidocaine anesthetic cream for pain management in children undergoing needle-related procedures in the ED. This agent is the standard treatment for needle-related procedures at the study's site.

## 2 | METHODS

The full study protocol<sup>25</sup> was published and the trial was registered ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02616419): NCT02616419). An authorization from the Medical Device Bureau of Health Canada was granted (#272708). The funding organization, Quebec Network on Research on Nursing Interventions-Réseau de Recherche en Interventions en Sciences Infirmières du Québec (RRISIQ), had an independent role within this trial.

### 2.1 | Trial design and study setting

This study was an open-labeled randomized controlled non-inferiority trial with two parallel groups and a 1:1 allocation ratio. The study setting was the ED of a Canadian university teaching pediatric tertiary care hospital in Montreal, Quebec, Canada. Ethics approval was obtained from the research ethics board (REB) of the institution.

### 2.2 | Participants

Children were eligible for inclusion if they were: (1) 4-17 years old (The Buzzy device selected for this study could not be used on children younger than 4 years); (2) presenting to the ED and requiring a needle-related procedure (venipuncture or intravenous (IV) catheter insertion); (3) able to communicate in either French or English and (4) accompanied by at least one parent/legal guardian who could understand, read and speak French or English. Children were excluded if they had: (1) a diagnosed neurocognitive disability (children with neurocognitive disability may have difficulty to self-report their pain level<sup>27</sup>); (2) inability to self-report pain; (3) critical or unstable health status (Canadian Triage and Acuity Scale of 1 or 2); (4) Raynaud's syndrome or sickle cell disease with extreme sensitivity to cold; (5) a break or abrasion on the skin where the device would have been applied; (6) or nerve damage with limited sensation in the extremity where the needle-related procedure would be performed. Parents and/or legal guardians provided written informed consent and assent was obtained from children over 7 years old.

## 2.3 | Interventions

Children were randomly assigned, in a 1:1 allocation ratio, either to the experimental or control group. Participants assigned to the experimental group received the device intervention (Buzzy®, MMJ Labs, Atlanta, Georgia, USA. Model # 56921 00300), a bee-shaped device combining cold (removable and reusable ice wings) and vibration (body of the bee). The cold vibrating device was used in accordance with the manufacturer's recommendations: (1) Immediately before the needle-related procedure, a set of ice wings were retrieved from the freezer; (2) Ice wings were installed on the back of the device through the elastic band; (3) The device was placed as close as possible to the insertion site (3–5 cm) with a reusable tourniquet and the vibrating mode was activated; (4) The device was maintained in place throughout the needle-related procedure. All clinicians were trained to use the Buzzy and the lidocaine cream by the nurse clinician educator in the emergency room. Children assigned to the control group had 4% liposomal lidocaine topical anesthetic cream (Maxilene, RHR Pharma, LaSalle, Ontario, Canada) applied over the insertion site at least 30 min before the needle-related procedure. Both interventions were tried only at first attempt. In case of multiple attempts, participants were excluded from the study.

## 2.4 | Randomization and allocation

The randomization sequence was generated by an independent biostatistician using a computer-generated random listing of the two interventions with a permuted block design and stratification by age-group (4–7 years; 8–12 years; 13–17 years). Allocation concealment was ensured using sequentially numbered, sealed, opaque envelopes containing the intervention assignment which were opened once eligibility criteria were met, and consent was obtained. Blinding of participants and personnel was not possible due to the nature of both interventions.

## 2.5 | Outcomes

The primary outcome was the mean difference (MD) in pain scores during the needle-related procedure between groups. It was assessed immediately after the procedure using the self-reported 0–10 Color Analogue Scale (CAS).<sup>26</sup>

Pre-specified secondary outcomes included: (1) MD between groups for procedural distress as assessed by proxy with Procedure Behavior Check List (PBCL)<sup>28</sup> and self-reported with the Children's Fear Scale (CFS),<sup>29</sup> (2) Proportion of nurses experiencing success of the procedure on the first attempt, (3) Caregiver's and nurses satisfaction regarding both interventions using tailored questionnaires developed for the needs of the study, (4) MD in pain scores between groups was assessed by a research assistant, trained by the pain clinic, through a phone call 24 h after the needle-related procedure (recall of pain) using the Faces Pain Scale Revised (FPS-R) and 5) adverse events.

## 2.6 | Sample size

A sample size of 352 participants provided 90% power to show the non-inferiority of the cold vibrating device compared to a topical anesthetic cream, considering a one-sided alpha level of 0.025 with the use of a non-inferiority margin of 0.70 for the measure of pain intensity during the procedure.<sup>25</sup>

## 2.7 | Determination of the non-inferiority margin

To determine the non-inferiority margin, an electronic survey was sent to 34 pediatric emergency physicians, members of the Pediatric Emergency Research Canada, working in a pediatric ED setting in Quebec or Ontario. All of the physicians responded to the survey. The following scenario and question were presented: "You are seeing a four-year-old female requiring an intravenous catheter for drug delivery. You are considering two interventions for pain management during the needle-related procedure: a topical anesthetic application (liposomal lidocaine 4% cream) or the Buzzy device. You need to assume that both of these interventions have the potential for reducing needle-related pain." "What is the smallest difference in mean pain reduction, on a numerical rating scale from 0 to 10cm, between the topical anesthetic (liposomal lidocaine 4% cream) and the Buzzy device you are willing to accept to routinely adopt the use of the Buzzy device over the topical anesthetic (liposomal lidocaine 4% cream) for needle-related procedures?" Respondents had to choose a difference ranging from 0.1 to 1.5cm with 0.1 increments. The mean answer was 0.70; consequently, this value was chosen as the non-inferiority margin.<sup>25</sup> We did not account for dropouts. The sample size was calculated using the G\*Power software version 3.0.10.

## 2.8 | Statistical analyses

All statistical analyses were performed using R for Macintosh Version 2022.7.1 and data analysis was only on participants first attempt.

The primary outcome was analyzed by calculating the confidence interval (CI) of the adjusted MD in pain scores between study groups. The cold vibrating device would be considered non-inferior to the topical anesthetic cream if the upper limit of the two-sided 95% CI ( $1-2\alpha \times 100\%$  CI) for the adjusted MD in pain scores between groups is less than the predetermined non-inferiority margin of  $\Delta$  0.70.<sup>25</sup> We performed both a primary intention-to-treat (ITT) analysis and a secondary per-protocol (PP) analyses, as required for non-inferiority trials.<sup>30</sup> Both analyses were also performed with adjustment (covariance analyses) according to their respective baseline scores. A pre-specified explanatory subgroup analysis according to age-groups was also performed to determine if the intervention was more effective in a specific age-group.

All secondary outcomes were designed to test the superiority of the cold vibrating device over the topical anesthetic cream and were analyzed on an ITT basis. Analyses of covariance was

performed for procedural distress scores with adjustments for baseline scores. The Fisher's Exact Test was used to compare the proportion of participants whose procedure succeeded on the first attempt. The Mann-Whitney Test was performed to compare the MD on pain recall between groups as these results were not normally distributed. Descriptive statistics were used to report satisfaction scores.

## 3 | RESULTS

### 3.1 | Characteristics of participants

From April 2017 through September 2018, a total of 585 children were screened for eligibility. Of these, 352 were enrolled and randomly assigned to the intervention group ( $n=176$ ), or to the control group ( $n=176$ ). Among them, a total of 346 participants were included in the primary ITT analyses and 328 participants were included in the PP analyses (Figure 1).

The baseline sociodemographic and clinical characteristics of participants included in the ITT analysis were similar in both groups (Table 1, Table S1). Mean age of participants and standard deviation (SD) was 9.8 (3.9) years and a slight majority were female (51.2%,  $n=177/346$ ). The most common needle-related procedure was venipuncture (73.0%,  $n=251/346$ ) (Table 1). Baseline characteristics of the PP sample are shown in Table S1.

### 3.2 | Primary outcome

As per ITT analyses, the adjusted mean per-procedural pain scores for both the cold vibrating and 4% liposomal lidocaine cream groups were respectively 3.77 and 3.22, thus a Mean Difference (MD) of 0.56 (95% CI:  $-0.08$ – $1.20$ ) between groups on the CAS scale. Therefore, the cold vibrating device was not considered non-inferior to the topical anesthetic cream for decreasing per-procedural pain scores, as the upper limit of the CI was not lower than the predetermined non-inferiority margin ( $\Delta 0.70$ ).<sup>25</sup> Results of univariate analyses for per-procedural pain yielded similar results. In the PP analysis, adjusted MDs in per-procedural pain scores were slightly decreased between both groups. Adjusted subgroups analyses according to age-groups showed similar results among the 8–12-year-old and 13–17-year-old age-groups. The adjusted subgroups analyses of 4–7-year age-group showed higher per-procedural pain scores with a significantly higher MD for children of the intervention group ( $p=0.04$ ) (Table 2).

### 3.3 | Secondary outcomes

Main results on secondary outcomes are presented below and summarized in Table 3.

#### 3.3.1 | Procedural distress hetero-evaluation and reported fear

For the per-procedural distress, adjusted MD between groups were not statistically significant on the PBCL scale (MD=0.89 [95% CI:  $-0.18$ – $1.97$ ],  $p=0.104$ ) and for reported fear on CFS (MD=0.11 [95% CI:  $-0.15$ – $0.36$ ],  $p=0.421$ ) scale.

#### 3.3.2 | Procedural pain (FPR-S)

Procedural pain measured with the FPS-R showed no statistically significant adjusted MDs between groups (MD=0.43 [95% CI:  $-0.26$ – $1.13$ ],  $p=0.219$ ).

#### 3.3.3 | Success of procedure at first attempt

Success of the needle-related procedure at first attempt occurred in 136 of the 172 children (79.1%) in the cold and vibration group and in 137 of the 172 children (79.7%) in the topical anesthetic cream group. Difference between both groups was not statistically significant ( $p=1.000$ ).

#### 3.3.4 | Pain recall (memory)

There was no significant difference between groups on the adjusted mean scores for pain recall (memory) 24h after the needle-related procedure (MD=0.53 [95% CI:  $-0.49$ – $1.56$ ],  $p=0.305$ ). Since 56% of values were missing ( $n=192$ ), it can be assumed that they were missing at random and that the estimate was unbiased, as they were balanced in both groups.

#### 3.3.5 | Parents' satisfaction

A majority of parents from both groups reported being highly satisfied with the allocated intervention, cold vibrating device mean (SD)=7.81 (2.67), topical anesthetic cream mean (SD)=8.14 (2.40) (Table 4). Parents of both groups, cold vibrating device (88.2%,  $n=149/169$ ) and topical anesthetic cream (91.2%,  $n=156/171$ ), mentioned that they would opt for the same intervention for a subsequent needle-related procedure.

#### 3.3.6 | Nurses' satisfaction

Overall, nurses reported high levels of satisfaction with both interventions during needle-related procedures (Table 5). Most nurses (71.4%,  $n=15/21$ ) mentioned that the cold vibrating device was adapted to the ED environment. Most nurses (76.2%,  $n=16/21$ )

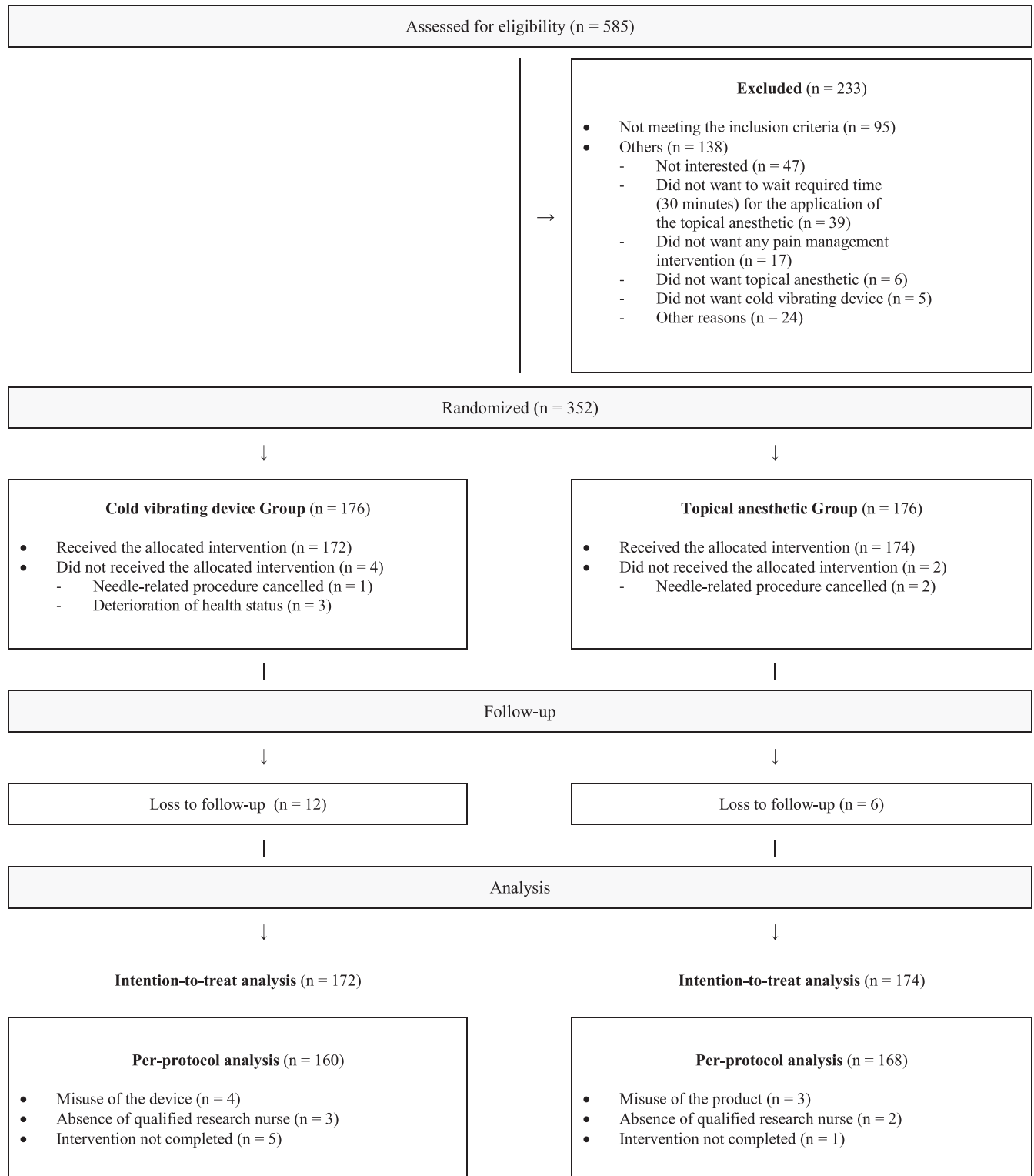


FIGURE 1 Study flow chart.

agreed to use the cold vibrating device again to perform needle-related procedures. Finally, more than half of the nurses (65.0%,  $n=13/20$ ) indicated that they preferred the cold vibrating device over the topical anesthetic cream for pain management in children during needle-related procedures.

### 3.3.7 | Adverse events

No adverse events occurred in the cold vibrating device group. A participant in the topical anesthetic cream group reported redness and swelling at the insertion site the day after the needle-related procedure.

**TABLE 1** Baseline sociodemographic and clinical characteristics of participants.

Participants' characteristics	Cold vibrating device (n = 172)	Topical anesthetic (n = 174)	Total (n = 346)
Age (year) Mean (SD)	9.7 (3.9)	10.0 (3.9)	9.8 (3.9)
Sex n (%)			
Girls	87 (50.6)	90 (49.4)	177 (51.2)
Boys	85 (49.4)	84 (48.3)	169 (48.8)
Types of needle-related procedure n (%)			
Venipuncture	119 (70.0)	132 (75.9)	251 (73.0)
IV catheter	51 (30.0)	42 (24.1)	93 (27.0)
Previous experience(s) with needle-related procedure(s) <sup>a</sup> n (%)			
Yes	112 (65.5)	111 (64.2)	223 (64.8)
No	59 (34.5)	62 (35.8)	121 (35.2)
Analgesia in the last 4 h n (%)			
Yes	66 (38.6)	63 (36.6)	129 (37.6)
No	105 (61.4)	107 (62.2)	212 (61.8)
Don't know	0 (0.0)	2 (1.2)	2 (0.6)
Site of the needle-related procedure n (%)			
Antecubital	126 (73.7)	132 (77.2)	258 (75.4)
Hand	32 (18.7)	36 (21.0)	68 (19.9)
Wrist	12 (7.0)	2 (1.2)	14 (4.1)
Other	1 (0.6)	1 (0.6)	2 (0.6)
Position during needle-related procedure n (%)			
Dorsal decubitus	101 (58.7)	73 (42.7)	174 (50.7)
Sitting alone	54 (31.4)	70 (40.9)	124 (36.2)
Sitting on parents	11 (6.4)	20 (11.7)	31 (9.0)
Dorsal decubitus with restraint	6 (3.5)	7 (4.1)	13 (3.8)
Other	0 (0.0)	1 (0.6)	1 (0.3)
Non-pharmacological co-intervention n (%)			
Yes	30 (17.4)	33 (19.0)	63 (18.2)
No	142 (82.6)	138 (79.3)	280 (80.9)
Pre-procedural pain (CAS) Mean (SD)	2.9 (2.6)	2.6 (2.7)	2.7 (2.6)
Pre-procedural pain (FPS-R) Mean (SD)	2.8 (2.6)	2.7 (2.9)	2.8 (2.8)
Pre-procedural distress (PBCL) Mean (SD)	9.6 (3.4)	9.0 (2.5)	9.3 (3.0)
Pre-procedural distress (CFS) Mean (SD)	1.7 (1.4)	1.5 (1.4)	1.6 (1.4)

Abbreviations: CAS, color analogue scale; CFS, children's fear scale; FPS-R, faces pain scale revised; PBCL, procedure behavioral check list.

<sup>a</sup>Previous experience(s) with needle-related procedure(s) excluding vaccination related to the Quebec immunization program.

However, this could be associated with the IV catheter insertion itself and not necessarily related to the topical anesthetic cream.

## 4 | DISCUSSION

In this randomized controlled non-inferiority trial comparing two interventions for pain management in children undergoing needle-related procedures in the ED setting, the cold vibrating device was not considered non-inferior to 4% liposomal lidocaine anesthetic cream.

Further, considering that children are known to report moderate-to-high pain intensity during needle-related procedures,<sup>2,5</sup> it is important to highlight that the cold vibrating device control procedural pain within a moderate intensity level (CAS<sub>adjusted</sub> = 3.77).<sup>31</sup> Also, recalled pain scores remained low but it remains in accordance to other studies with the same procedure.<sup>32</sup> In addition, the cold vibrating device has some advantages over the topical anesthetic cream for the ED environment. For instance, it does not require a pre-procedure application time, it is easy-to-use, reusable and with no reported adverse events within participants of this study. Considering that the topical anesthetic

TABLE 2 Adjusted pain scores according to study groups and age-groups analyses.

Outcomes	n	Cold vibrating device Mean (SE)		n	Topical anesthetic Mean (SE)		Mean difference MD [95% CI]
Procedural pain CAS							
Intention-to-treat analysis	158	3.77	(0.231)	161	3.22	(0.228)	0.56 [-0.08-1.20]
Per-protocol analysis	149	3.71	(0.234)	157	3.13	(0.227)	0.57 [-0.07-1.21]
Age group analysis							
4-7 years old <sup>a</sup> (n=116) Intention-to-treat analysis	46	5.04	(0.504)	47	3.54	(0.499)	1.50 [0.08-2.92]
8-12 years old (n=133)							
Intention-to-treat analysis	66	3.72	(0.335)	65	3.27	(0.335)	0.46 [-0.49-1.40]
13-17 years old (n=97)							
Intention-to-treat analysis	46	2.74	(0.344)	49	2.69	(0.333)	0.05 [-0.90-1.00]

Note: Adjusted analysis: All Procedural Pain. CAS scores have been adjusted with their respective Pre-procedural Pain CAS score collected at baseline.

Abbreviations: CAS, color analogue scale; CI: confidence interval; SE, standard error; MD, mean difference.

<sup>a</sup>The CAS scale is not validated for use with 4-year-olds. All results reported on the CAS by 4-year-old participants have therefore been replaced with missing values.

TABLE 3 Secondary outcomes.

Outcomes	n (172)	Cold vibrating device Mean (SD)	n (174)	Topical anesthetic Mean (SD)	Mean difference (95% CI)	p value ( $\alpha=0.05$ )
Procedural pain FPS-R						
Mean (SD)	167	3.95 (3.41)	170	3.46 (3.26)	0.49 [-0.22-1.21]	0.175
Adjusted mean		3.90		3.47	0.43 [-0.26-1.13]	0.219
Procedural distress PBCL						
Mean (SD)	171	12.77 (6.36)	170	11.35 (5.17)	1.41 [0.18-2.65]	0.025*
Adjusted mean		12.50		11.60	0.89 [-0.18-1.97]	0.104
Procedural distress CFS						
Mean (SD)	170	1.70 (1.46)	171	1.56 (1.39)	0.14 [-0.17-0.44]	0.370
Adjusted mean		1.69		1.58	0.11 [-0.15-0.36]	0.421
Success of the procedure at first attempt						
n (%)	172	136 (79.1)	172	137 (79.7)	-	1.000
Pain recall FPS-R						
Mean (SD)	75	3.55 (3.41)	79	3.01 (3.02)	0.53 [-0.49-1.56]	0.305

Note: Adjusted mean: All procedural scores have been adjusted with their respective pre-procedural scores collected at baseline.

Abbreviations: CI, Confidence interval; CFS, Children's Fear Scale; FPS-R: faces pain scale revised; PBCL, procedure behavioral check list; SD: Standard deviation.

TABLE 4 Parents' satisfaction.

Question	Cold vibrating device n (%)		Topical anesthetic n (%)			
Would you agree to reuse this intervention during a future needle-procedure with you child?						
Yes	149 (88.2)		156 (91.2)			
No	14 (8.3)		8 (4.7)			
No parent or guardian	6 (3.6)		7 (4.1)			
Outcomes	n (172)	Cold vibrating device mean (SD)	n (176)	Topical anesthetic Mean (SD)	Mean difference (95% CI)	p-value ( $\alpha=0.05$ )
Satisfaction						
0: 10	171	7.8 (2.7)	170	8.1 (2.4)	-0.34 [-0.89-0.22]	0.257

TABLE 5 Nurses' satisfaction regarding both interventions.

Statements	Cold vibrating device n (%)	Topical anesthetic n (%)
Number of utilizations of trial interventions during the study period		
0–5 times	11 (50.0)	4 (19.0)
5–10 times	5 (22.7)	8 (38.1)
10–15 times	1 (4.5)	2 (9.5)
>–15 times	4 (18.2)	6 (28.6)
The intervention helped children to control their pain during the procedure		
Strongly agree	1 (4.8)	4 (18.2)
Agree	16 (76.2)	12 (54.5)
Disagree	4 (19.0)	5 (27.3)
Strongly disagree	0 (0.0)	1 (4.5)
The intervention helped children to control their distress during the procedure		
Strongly agree	2 (9.5)	2 (9.1)
Agree	16 (76.2)	14 (63.6)
Disagree	3 (14.3)	5 (27.3)
Strongly disagree	0 (0.0)	1 (4.5)
The intervention helped children to cooperate during the procedure		
Strongly agree	2 (9.5)	1 (4.5)
Agree	17 (81.0)	18 (81.8)
Disagree	2 (9.5)	3 (13.6)
Strongly disagree	0 (0.0)	0 (0.0)
I would agree to reuse the intervention for subsequent department		
Strongly agree	7 (33.3)	8 (36.4)
Agree	9 (34.6)	8 (36.4)
Disagree	3 (14.3)	5 (22.7)
Strongly disagree	2 (9.5)	1 (4.5)
The intervention is tailored to the emergency department		
Strongly agree	8 (38.1)	3 (13.6)
Agree	7 (33.3)	7 (31.8)
Disagree	5 (23.8)	7 (31.8)
Strongly disagree	1 (4.8)	5 (22.7)
Nurses' preference	13 (65.0)	7 (35.0)

cream requires a minimum application time of 30 min, the device represents a feasible alternative to optimize procedural pain control, especially when time is limited.<sup>18,22</sup>

Other randomized controlled trials<sup>33–38</sup> have demonstrated the efficacy of the cold vibrating device for needle-related pain management in children. However, as shown in a systematic review,<sup>24</sup> these

studies presented a high risk of biases and represented a very low quality of evidence. Among these studies, some have compared the efficacy of the cold vibrating device to a topical anesthetic cream in the ED.<sup>37,38</sup> One of these trials,<sup>38</sup> involving children aged between 18 months and 6 years old, compared the efficacy of the device to an anesthetic lidocaine/prilocaine patch for pain management during IV catheter insertions. Mean pain scores and standard deviation (device mean [SD]=8.5/13 [2.6], patch mean [SD]=7.2/13 [2.4],  $p < 0.001$ ), showed that the cold vibrating device was not significantly different than the topical anesthetic cream. The second trial<sup>37</sup> demonstrated the non-inferiority of the cold vibrating device over 4% topical lidocaine cream for pain and distress management during needle-related procedures. However, this study presented some limitations concerning the trial design. Firstly, the choice of the non-inferiority margin was not justified adequately and was too large, which could have introduced a greater risk of mistakenly concluding a truly inferior intervention as non-inferior.<sup>39</sup> Further, they used a two-sided CI of 90% instead of the 95% recommended.<sup>30</sup>

Our results showed that the small sample of nurses in this study preferred the cold vibrating device over the topical anesthetic cream used. They also reported that it was more tailored and adapted to the ED environment, which represents a good indicator of its possible implementation and uptake in daily practice. As nurses are playing a critical role in the pain management process, it is important to provide them with tools that are adapted to their clinical environment.

## 5 | LIMITATIONS

Finally, our study has several limitations that must be acknowledged. First, blinding of participants and personnel was not possible considering the nature of both interventions. The lack of blinding could have influenced the behavior and responses of children to subjective outcomes. To minimize the performance bias, we used 4% liposomal lidocaine in order to generate similar expectation ratings from participants in both groups. Second, the choice of the non-inferiority margin of 0.70 may have been too small and it may explain the inconclusive results.<sup>30</sup>

## 6 | CONCLUSION

In this non-inferiority trial, we found that the device combining cold and vibration was not considered non-inferior to a topical anesthetic cream for pain management in children undergoing needle-related procedures. The trial demonstrated that the device had the potential to control pain and distress experienced by children during needle-related procedures and possibly to improve nurses' pain management practices in the ED setting. As the device was highly appreciated by parents and nurses, it has a potential to be implemented and uptake this setting. Finally, since most of the available topical creams for needle-related procedures require supplementary application time, the cold vibrating device may be a feasible option in pediatric ED settings.



## AUTHOR CONTRIBUTORS

Study supervision SLM; Study concept and design AB, CK; NP, EDT, BB; Analysis and interpretation of the data AB; Drafting of the manuscript AB; Critical revision of the manuscript AB, CL, OF, EG, EDT, BB, NP, SLM; Statistical expertise AB, OF, SLM; Acquisition of funding-SLM.

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## CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest relevant to this article to disclose. The trial had no commercial support, and the manufacturer of the device had no implication in the trial design, data collection, data analysis, or manuscript preparation and no access to the trial data. The authors have no financial relationship relevant to this article to disclose.

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## REFERENCES

1. Jeffs D, Wright C, Scott A, Kaye J, Green A, Huett A. Soft on sticks: an evidence-based practice approach to reduce children's needle-stick pain. *J Nurs Care Qual.* 2011;26(3):208-215.
2. Ortiz MI, López-Zarco M, Arreola-Bautista EJ. Procedural pain and anxiety in paediatric patients in a Mexican emergency department. *J Adv Nurs.* 2012;68(12):2700-2709.
3. Birnie KA, Chambers CT, Fernandez CV, et al. Hospitalized children continue to report undertreated and preventable pain. *Pain Res Manag.* 2014;19(4):198-204.
4. McMurtry CM, Pillai Riddell R, Taddio A, et al. Far From Just a Poke. *Clin J Pain.* 2015;31(10):S3-S11.
5. Taddio A, Ipp M, Thivakaran S, et al. Survey of the prevalence of immunization non-compliance due to needle fears in children and adults. *Vaccine.* 2012;30(32):4807-4812.
6. Armfield JM, Milgrom P. A clinician guide to patients afraid of dental injections and numbness. *SAAD Dig.* 2011;27:33-39.
7. Taddio A, McGrath P, Finley A. Effects of early pain experience: the human literature. *Progress in Pain Research and Management.* 1999;13:57-74.
8. Wright S, Yelland M, Heathcote K, Ng SK, Wright G. Fear of needles—nature and prevalence in general practice. *Aust Fam Physician.* 2009;38(3):172-176.
9. Chidambaran V, Sadhasivam S. Pediatric acute and surgical pain management: recent advances and future perspectives. *Int Anesthesiol Clin.* 2012;50(4):66-82.
10. Stinson J, Yamada J, Dickson A, Lamba J, Stevens B. Review of systematic reviews on acute procedural pain in children in the hospital setting. *Pain Res Manag.* 2008;13(1):51-57.
11. Birnie KA, Noel M, Chambers CT, Uman LS, Parker JA. Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database Syst Rev.* 2018;10:CD005179.
12. Stevens BJ, Harrison D, Rashotte J, et al. Pain assessment and intensity in hospitalized children in Canada. *J Pain.* 2012;13(9):857-865.
13. Uman LS, Birnie KA, Noel M, et al. Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database Syst Rev.* 2013;(10):CD005179. doi:10.1002/14651858.CD005179
14. Pretorius A, Searle J, Marshall B. Barriers and enablers to emergency department nurses' management of patients' pain. *Pain Manag Nurs.* 2015;16(3):372-379.
15. Fein JA, Zempsky WT, Cravero JP, et al. Relief of pain and anxiety in pediatric patients in emergency medical systems. *Pediatrics.* 2012;130(5):e1391-e1405.
16. Trottier ED, Ali S, Thull-Freedman J, et al. Treating and reducing anxiety and pain in the paediatric emergency department-TIME FOR ACTION—the TRAPPED quality improvement collaborative. *Paediatr Child Health.* 2018;23(5):e85-e94.
17. Procédures mineures: prise en charge de la douleur et de la détresse procédurales—Urgence CHU Sainte-Justine. 2023 <https://www.urgencehsj.ca/protocoles/analgesie-procedures-mineures/>.
18. Taddio A, Gurguis MG, Koren G. Lidocaine-prilocaine cream versus tetracaine gel for procedural pain in children. *Ann Pharmacother.* 2002;36(4):687-692.
19. Shah V, Taddio A, Rieder MJ. Effectiveness and tolerability of pharmacologic and combined interventions for reducing injection pain during routine childhood immunizations: systematic review and meta-analyses. *Clin Ther.* 2009;31:S104-S151.
20. Fetzer SJ. Reducing venipuncture and intravenous insertion pain with eutectic mixture of local anesthetic: a meta-analysis. *Nurs Res.* 2002;51(2):119-124.
21. Alobayli FY. Factors influencing nurses' use of local anesthetics for venous and arterial access. *J Infus Nurs.* 2019;42(2):91-107.
22. Papa A, Zempsky W. Nurse perceptions of the impact of pediatric peripheral venous access pain on nurse and patient satisfaction: results of a National Survey. *Adv Emerg Nurs J.* 2010;32(3):226-233.
23. Alobayli FY, Blackman I. Modelling nurses' use of local anaesthesia for intravenous cannulation and arterial blood gas sampling: a cross-sectional study. *Heliyon.* 2020;6(3):e03428.
24. Ballard A, Khadra C, Adler S, Trottier ED, Le May S. Efficacy of the buzzy device for pain management during needle-related procedures: a systematic review and meta-analysis. *Clin J Pain.* 2019;35(6):532-543.
25. Ballard A, Khadra C, Adler S, et al. External cold and vibration for pain management of children undergoing needle-related procedures in the emergency department: a randomised controlled non-inferiority trial protocol. *BMJ Open.* 2019;9(1):e023214.
26. McGrath PA, Seifert CE, Speechley KN, Booth JC, Stitt L, Gibson MC. A new analogue scale for assessing children's pain: an initial validation study. *Pain.* 1996;64(3):435-443.
27. Breau LM, Burkitt C. Assessing pain in children with intellectual disabilities. *Pain Res Manag.* 2009;14(2):116-120.

28. LeBaron S, Zeltzer L. Assessment of acute pain and anxiety in children and adolescents by self-reports, observer reports, and a behavior checklist. *J Consult Clin Psychol*. 1984;52(5):729-738.
29. McMurtry CM, Noel M, Chambers CT, McGrath PJ. Children's fear during procedural pain: preliminary investigation of the Children's fear scale. *Health Psychol*. 2011;30(6):780-788.
30. Mauri L, D'Agostino RB Sr. Challenges in the design and interpretation of noninferiority trials. *N Engl J Med*. 2017;377(14):1357-1367.
31. Tsze DS, Hirschfeld G, Dayan PS, Bulloch B, Von Baeyer CL. Defining No pain, mild, moderate, and severe pain based on the faces pain scale-revised and color analog scale in children with acute pain. *Pediatr Emerg Care*. 2018;34(8):537-544.
32. Nilsson S, Finnström B, Kokinsky E, Enskär K. The use of virtual reality for needle-related procedural pain and distress in children and adolescents in a paediatric oncology unit. *Eur J Oncol Nurs*. 2009;13(2):102-109.
33. Redfern RE, Chen JT, Sibrel S. Effects of thermomechanical stimulation during vaccination on anxiety, pain, and satisfaction in pediatric patients: a randomized controlled trial. *J Pediatr Nurs*. 2018;38:1-7.
34. Inal S, Kelleci M. The effect of external thermomechanical stimulation and distraction on reducing pain experienced by children during blood drawing. *Pediatr Emerg Care*. 2020;36(2):66-69. <https://journals.lww.com/00006565-900000000-98623>
35. Moadad N, Kozman K, Shahine R, Ohanian S, Badr LK. Distraction using the buzzy for children during an IV insertion. *J Pediatr Nurs*. 2016;31(1):64-72.
36. Schreiber S, Cozzi G, Rutigliano R, et al. Analgesia by cooling vibration during venipuncture in children with cognitive impairment. *Acta Paediatr*. 2016;105(1):e12-e16.
37. Potts DA, Davis KF, Elci OU, Fein JA. A vibrating cold device to reduce pain in the pediatric emergency department: a randomized clinical trial. *Pediatr Emerg Care*. 2019;35(6):419-425. <https://journals.lww.com/00006565-900000000-98807-98807>
38. Bourdier S, Khelif N, Velasquez M, et al. Cold vibration (Buzzy) versus anesthetic patch (EMLA) for pain prevention during cannulation in children: a randomized trial. *Pediatr Emerg Care*. 2021;37(2):86-91.
39. Piaggio G, Elbourne DR, Pocock SJ, Evans SJ, Altman DG, Group C. Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. *JAMA*. 2012;308(24):2594-2604.

## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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