The Art and Science of Infusion Nursing

Effects of Thermomechanical Stimulation During Intravenous Catheter Insertion in Adults

A Prospective Randomized Study

Roberta E. Redfern, PhD ● Jennifer Micham, MSN, RN-BC ● Deana Sievert, MSN, RN ● John T. Chen, PhD

ABSTRACT

This was an open-label, randomized clinical trial comparing the effects of thermomechanical stimulation (Buzzy) versus no intervention in 105 adults undergoing intravenous (IV) catheter insertion before elective orthopedic surgical procedures. A visual analog scale was used to measure pain; satisfaction questionnaires were administered after IV catheter insertion. There was no significant difference in the mean pain score between the experimental (n = 49) and control (n = 56) groups (2.52 vs 2.43, $P = .86$). Subjects who reported higher preprocedure anxiety benefited most from the test intervention. It was determined that the application of cold and vibration is not universally effective for pain prevention during IV catheter insertion or for improvement in patient satisfaction in preoperative care.

Key words: Buzzy, catheter insertion, external cold and vibration, intravenous, procedural pain

Fear of painful procedures is often a concern among patients entering health care facilities, with needlesticks being the most common concern.[1] Intravenous (IV) catheter insertion is often required for hospitalized and preoperative patients. Most patients will require the procedure at some time because of its necessity for the treatment, diagnosis, prevention, and monitoring of health conditions. Pain related to IV catheter insertion can result in anxiety, fear, and avoidance of treatment.[2-4] Fear of needles, known as *needle phobia*, is a condition that affects as much as 20% of the population in the United States,[5] and is the sixth most common fear cited in a Gallup poll of American adults.[4,6] A vital nursing care goal is to alleviate as much procedural pain and anxiety as possible during catheter insertion using a variety of approaches, yet there is no established best practice.[7] Often, the standard approach in adults includes no pain-reducing interventions during IV catheter insertion.[7] Methods of alleviating the pain of needlesticks can vary from simple distraction techniques to pharmacologic interventions. The impact of lidocaine injections, vapocoolant sprays, analgesic creams, Valsalva maneuvers, and verbal assurances has been investigated, but reported benefits of each technique vary, and no consensus has been reached.[8-11]

Although the nature of pain is not clearly understood, Melzack and Wall[12] proposed the gate control theory of pain in 1965. It contends that certain nonpainful stimuli can close the gate to the brain, suppressing the sensation of pain.[12] In 1984, Bini and colleagues[13] studied the effects of vibration, warming, cooling, and massage on electrically stimulated pain in healthy test subjects. While vibration provided the most effective reduction of pain response, cooling the site also demonstrated significant analgesic effect on moderate pain. The use of cold and of vibration have been reported independently to reduce discomfort during medical procedures, but only recently have they been combined to alleviate pain in a clinical setting.[14]

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The Buzzy device (MMJ Labs; Atlanta, GA) is a reusable, battery-operated vibrating motor with a detachable ice pack. The apparatus was created for pediatric patients to lessen pain and create a diversion during venipuncture. The design considered the gate theory of pain, hypothesizing that simultaneous stimulation of mechanoreceptors with vibration and cold would close the fast pain gate, reducing the experience of pain. Initial studies in adults have suggested that the use of this device during venipuncture can significantly improve patient-reported pain compared with placebo or vapocoolant sprays.[14,15]

OBJECTIVE

The primary objective of the study was to determine whether the Buzzy thermomechanical system could reduce procedural pain, as measured by a 10-cm visual analog scale (VAS), during IV catheter insertion, without affecting insertion success rates in adults undergoing preoperative insertion. The secondary objectives were to evaluate whether Buzzy affects preprocedural anxiety in patients, to determine whether characteristics of individual subjects are related to postprocedural pain ratings, and to compare the satisfaction of patients who received no intervention versus those who used Buzzy.

METHODS

This was a prospective, randomized controlled trial to evaluate the use of thermomechanical stimulation in adult patients aged 18 years or older who were undergoing IV catheter insertion before a scheduled, elective orthopedic surgical procedure. Only patients who had a previous catheter insertion and were Buzzy naïve (ie, they had never used Buzzy during a previous venipuncture) were eligible to participate. Patients who were excluded from participation included those with Raynaud's syndrome or sickle cell disease with extreme sensitivity to cold, a break or an abrasion on the skin where the device would be placed, nerve damage affecting the extremity where the catheter would be placed, or neurodevelopmental delays or verbal difficulty. The study was open to enrollment at a single, dedicated orthopedic and spine hospital between August 2016 and October 2016. The institutional review board approved the study, and all participants provided written informed consent to participate.

Participants were randomly assigned (1:1) to receive no intervention (control group) or to receive Buzzy during IV catheter insertion (experimental group). The Buzzy is a reusable vibrating motor with a detachable ice pack, which is placed 5 cm above the access site during venipuncture procedures and is readily sanitized between uses. Before beginning enrollment, the research team created a randomization schedule to assign patients to the control group or the experimental group using Research Randomizer (Research Randomizer, version 4.0; www.randomizer.org). Patients were approached during appointments for advanced admissions testing, and group allocation was determined at the time of consent. Because of the nature of the study, it was impossible to blind research staff to the assigned intervention.

The sample size required to demonstrate statistical significance was calculated based on previous reports of adult pain during IV catheter insertion, using existing literature regarding the use of the study device in healthy volunteers.[14] While there is no gold standard pain-measurement tool, a VAS is the most familiar to measure pain intensity. Although there are few disadvantages, such as a participant's ability to indicate pain intensity abstractly, its benefits, including the simplicity of placing a mark and its high sensitivity, made it ideal for the study.[16]

Fifty patients per group were required to achieve 80% power at a .05 significance level, assuming a 0.9-cm difference in patient-reported pain.[17] Because the design anticipated consent occurring days to weeks before the procedure, enrollment was increased by 20% to allow for attrition; 120 patients were randomized with 60 per group.

At the time of consent, patients were asked to complete an intake form to provide demographic information, which included age, gender, race, education, number of previous IV catheter insertions, previous occurrence(s) of vasovagal response, presence of needle phobia, and whether the patient ever delayed medical care because of a fear of needles.

Immediately before the procedure, patients were asked to rate their level of anxiety about having an IV catheter inserted on a 10-cm VAS with labels that ranged from *no anxiety* to *extremely anxious*. They were also asked to rate how much they thought the IV catheter insertion was going to hurt on a 10-cm VAS. Immediately after the procedure, each patient rated how much the insertion hurt on a VAS; both pain scales were labeled from *no pain* to *pain as bad as it could possibly be*. Research staff recorded each patient's body mass index, the location of the catheter insertion, catheter gauge, number of attempts required, the nurse's rating of the difficulty of the insertion, and whether the Buzzy device had to be removed for successful catheter insertion. In cases in which the nurse rated the difficulty of insertion greater than 5, an explanation was collected.

Subjects were asked to rate their satisfaction with the catheter insertion and to indicate whether it was *the same*, *better*, or *worse* than their previous experience with an IV catheter insertion. Those who were randomized to the experimental group also were asked to rate—on a scale of 1 to 10 (*not at all* to *extremely uncomfortable*)—whether the device was uncomfortable because of coldness or vibration and whether they would prefer to use the device during a future IV catheter insertion.

Statistical Analysis

Descriptive statistics detailed patient characteristics when they entered the study. Chi-square and Student *t* tests were used to investigate categorical and continuous

variables, respectively. Generalized linear models were performed to examine the significance of potential factors affecting patient-reported postprocedural pain. Logistic regressions were used to analyze factors associated with patient-reported satisfaction scores. SAS version 9.2 (SAS Institute Inc; Cary, NC) was used for statistical analysis. A P value of $<.05$ was considered significant.

RESULTS

A total of 120 patients consented to participate. Eight were excluded because they met exclusion criteria, 4 patients canceled surgery and did not reschedule during the study, 1 was not included because of a staff oversight, and 2 patients withdrew consent (Figure 1). The final analysis included 49 patients in the experimental group and 56 in the control group. Neither the average age of the patients nor any other demographic variables considered—such as gender, race, or body mass index—varied significantly between groups (Table 1).

Patient-reported anxiety before the procedure did not differ by treatment group. Those receiving Buzzy during the insertion rated anxiety similarly to the control group (Table 2). Furthermore, subjects in the experimental group did not expect to experience significantly less pain than those in the control group (2.66 vs 3.20; $P = .31$). The location of the IV catheter insertion was similar between the 2 groups, as was the proportion of patients who received 18- and 20-gauge catheters (Table 2).

On average, subjects who received the study device during the insertion did not rate postprocedural pain lower than the control group (2.52 vs 2.43; $P = .86$). The use of the device in the experimental group did not appear to have a negative impact on the ability of the nurse to successfully perform the catheter insertion, as the percentage of patients requiring more than 1 attempt was nearly identical between the experimental and control groups ($P = .93$; Table 2). There was no significant impact on patient satisfaction with the use of the device. The distribution of responses to the question "Was this IV catheter insertion the same, better, or worse than IV catheter insertions you have had in the past?" was similar between the 2 groups. Patients who received the study device did not rate their satisfaction higher during insertion than those in the control group ($P = .36$; Table 2). Nineteen patients stated they would *definitely* or *probably* prefer to use Buzzy during IV catheter insertions in the future, while 22 indicated they would *definitely* or *probably not* want to use the device again. Only 2 patients indicated the device was uncomfortable because of cold, and 2 suggested discomfort associated with the vibration (rated ≥ 5 on a 10-point scale).

A generalized linear model was created to examine which patient characteristics and other procedural factors were associated with the patient-reported postprocedure pain rating. The overall initial model was significant but showed that preprocedural anxiety and how much the patient thought the procedure would hurt were essentially collinear (Table 3). As such, this variable was removed from the model; results of the new model suggested that age

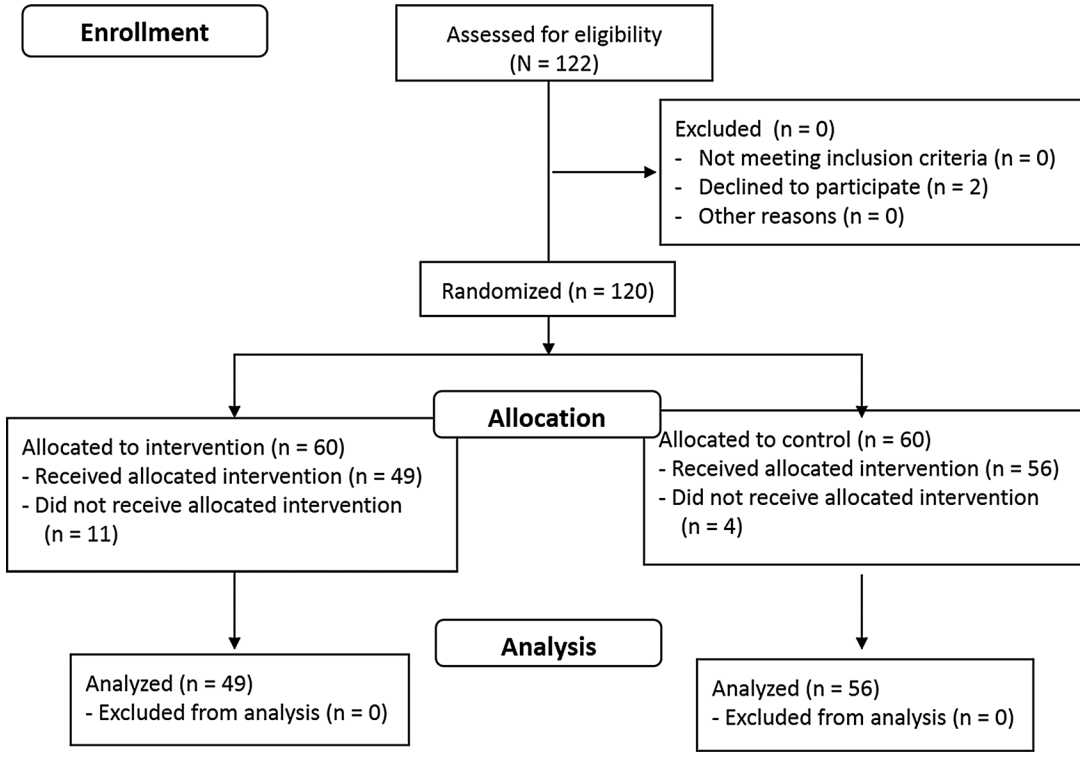

Figure 1 Patient flow diagram.

TABLE 1

Patient Characteristics When Entering the Study

Patient Demographics	Buzzy (n = 49)	Control (n = 56)	*P* Value
Age	63.86 ± 11.8	62.82 ± 11.0	.64
BMI	32.96 ± 6.5	31.69 ± 7.0	.42
Number of catheter insertions in past	2.45 ± 0.7	2.56 ± 0.6	.37
Gender			
Male	14 (28.6%)	19 (33.9%)	.55
Female	35 (71.4%)	37 (66.1%)	
Race/ethnicity[a]			
White	42 (85.7%)	49 (87.5%)	.94
African American	4 (8.2%)	3 (5.4%)	
Other	1 (2.0%)	1 (1.8%)	
Declined to answer	2 (4.1%)	3 (5.4%)	
Education			
High school	10 (20.4%)	14 (25.0%)	.74
Some college	17 (34.7%)	15 (26.8%)	
College	15 (30.6%)	16 (28.6%)	
Declined to answer	7 (14.3%)	11 (19.6%)	
Surgical procedure			
Hip	22 (44.9%)	20 (35.7%)	.78
Knee	14 (28.6%)	21 (37.5%)	
Spine	6 (12.2%)	7 (12.5%)	
Shoulder	4 (8.2%)	3 (5.4%)	
Other	3 (6.1%)	5 (8.9%)	
More fearful of needles than other adults?			
Yes	5 (10.2%)	5 (8.9%)	.79
No	42 (85.7%)	50 (89.3%)	

Abbreviation: BMI, body mass index.
[a]*Other* includes those who identified as Asian or Pacific Islander, Hispanic or Latino, and mixed race.

TABLE 2

Procedural Ratings Presented as Mean ± SEM or n (%), Where Appropriate

IV Insertion Ratings	Buzzy Mean ± SEM	Control Mean ± SEM	*P* Value
Preprocedure anxiety	1.97 ± 0.31	2.00 ± 0.36	.95
How much do you think it will hurt?	2.66 ± 0.33	3.20 ± 0.42	.31
Postprocedure pain	2.52 ± 0.37	2.43 ± 0.36	.86
Difficulty of venipuncture	2.84 ± 0.32	3.17 ± 0.34	.48
	n (%)	**n (%)**	***P* Value**
Patient satisfaction			
Strongly satisfied[a]	30 (61.2%)	39 (69.6%)	.36
Not strongly satisfied	19 (38.8%)	17 (30.4%)	
Location of catheter insertion			
Forearm	22 (44.9%)	26 (46.4%)	.23
Hand	21 (42.9%)	19 (33.9%)	
Wrist	4 (8.2%)	11 (19.6%)	
More than 1 attempt required			
Yes	11 (22.4%)	13 (23.2%)	.93
No	38 (77.6%)	43 (76.8%)	
Catheter gauge			
18 Fr	27 (55.1%)	30 (53.6%)	.41
20 Fr	22 (44.9%)	26 (46.4%)	
Patient rating of IV catheter insertion			
Worse	2 (4.1%)	2 (3.6%)	.58
Same	26 (53.1%)	22 (39.3%)	
Better	20 (40.8%)	26 (46.4%)	

Abbreviations: Fr, French; IV, intravenous; SEM, standard error of the mean.
[a]*Strong satisfaction* was defined as a rating of 9 or higher on a 1-10 Likert scale.

and the preprocedure anxiety were strongly associated with the postprocedure pain rating. To further examine this effect, post hoc analysis was completed to compare the pain ratings of patients as a function of preprocedure anxiety by treatment group. Subjects were ranked by reported anxiety into quantiles, separated by <50th quantile preprocedure anxiety (n = 54) and ≥50th quantile preprocedure anxiety (n = 51), and compared by Student *t* test. As shown in Figure 2, those who reported low preprocedure anxiety reported higher pain in the experimental group (2.13 ± 0.34) compared with the control group (1.31 ± 0.56). However, in subjects who reported higher preprocedure anxiety, the experimental group reported lower pain (0.84 ± 0.50) than the control group (3.92 ± 0.58); neither of these comparisons reached statistical significance.

DISCUSSION

This study evaluated the effectiveness of thermomechanical stimulation during preoperative IV catheter insertion in adult patients undergoing elective surgery. The results suggest that the use of the Buzzy device for this population is not effective in reducing procedural pain associated with IV catheter insertion. However, in subgroup analysis of the most anxious subjects, mean pain scores were lower in the experimental group who received the device compared with those in the control group. Overall, the use of Buzzy did not result in additional attempts required to insert catheters or improved patient-reported satisfaction.

Several previous studies have reported positive impacts of the Buzzy device in both pediatric and adult populations

TABLE 3

Generalized Linear Model to Examine Significant Factors Associated With Postprocedure Pain Rating[a]

Source of Variation	*df*	Sum of Squares	Mean Square	*F* Value	*P* Value
Group	1	3.49	3.49	1.07	.31
Age	1	11.55	11.55	3.54	.06
Gender	1	6.79	6.79	2.08	.15
BMI	1	4.07	4.07	1.25	.27
Education	2	0.41	0.21	0.06	.94
Needle phobia	1	7.18	7.18	2.20	.14
More than 1 attempt	1	3.75	3.75	1.15	.29
Preprocedure anxiety	1	0.20	0.20	0.06	.80
Expected pain	1	41.67	41.67	12.76	.0007
Rating of insertion	2	28.33	14.17	4.34	.02

Abbreviations: BMI, body mass index; *df*, degrees of freedom.
[a]The overall model is significant at $P < .001$.

undergoing venipuncture. In children, external cold and vibration were reported to reduce preprocedural anxiety and pain during venous access for blood draws and IV catheter insertion, without having a negative impact on success.[18-20] Unlike the current study, those reports suggested that the use of the Buzzy device affected the anxiety levels reported by subjects, which may account for some of the differences in pain scores which were not evident in this study.

The device also has been used in adult populations undergoing venous access as well, who also reported significant reductions in procedural pain. The initial study of the device by Baxter et al[14] compared the differences in pain reported by healthy volunteers who served as their own controls. IV catheter insertion was attempted in both hands in each patient, 1 receiving no intervention and the other receiving either vapocoolant spray or Buzzy. The authors reported that Buzzy resulted in significantly less pain than with no intervention and that it was also superior to the vapocoolant intervention.[14] However, the average age of the subjects was significantly younger than the current study, with the median age being 41 years compared with about 64 years in the authors' cohort. Moreover, because these were healthy volunteers who agreed to participate in a needle puncture procedure, it is unlikely that the subjects experienced needle phobia or increased anxiety compared with other adults.

Similar to the study by Baxter et al, Yilmaz et al[15] recently reported that compared with no intervention or placebo, the Buzzy device reduced pain scores and improved satisfaction. All participants of that study were healthy males presenting for blood donation, with a mean age of about 35 years, suggesting that anxiety and needle fear were unlikely issues for these subjects. Moreover, the authors report that the device was placed at the intended site of needle access for 60 seconds before insertion and left in place

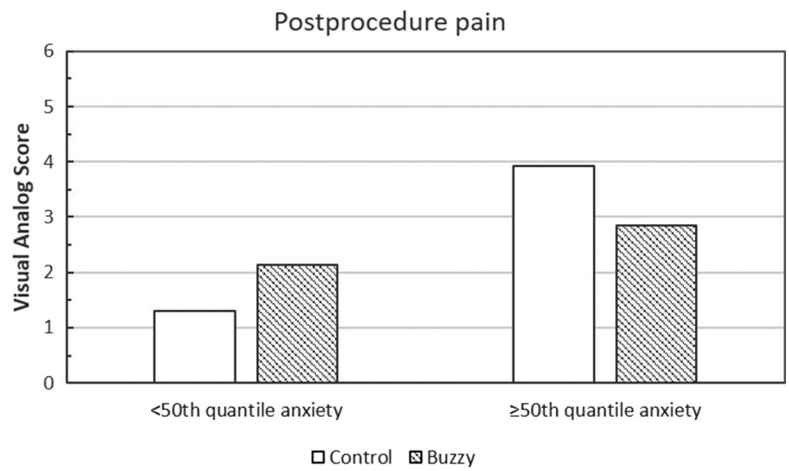

Figure 2 Patient-reported postprocedure pain ratings (visual analog scale results) comparison between patients reporting high anxiety and low anxiety by study group assignment.

during the procedure. In this study, the device was placed above the site and turned on immediately before access, according to the manufacturer's instructions, to prevent vasoconstriction.

In this study population, all participants were to receive an IV catheter insertion before undergoing orthopedic surgery. It's possible that anxiety levels were high in this group, which might modulate sensitivity to pain and have an impact on the effect of Buzzy compared with other adult studies, which included healthy volunteers. It might be presumed that healthy volunteers who are not required to undergo venipuncture are less anxious about the procedure and that the prevalence of needle phobia in that population would be low. In comparing the effects of Buzzy in the study's lowest- and highest-anxiety groups, it appears that those whose self-reported anxiety was highest received the most benefit from the device compared with the control group.

This suggests that the test device may impact perception of pain through 3 mechanisms, including the gate control theory, noxious inhibitory control, and distraction; distraction may be most effective for those with the greatest levels of anxiety, which may account for the differences in perceived effectiveness in this cohort.[14] Finally, the age of participants in the study was higher than in other adult studies evaluating external cold and vibration during venipuncture. A study by Inoue et al[21] indicated that thermal sensitivity declines as aging occurs. It is possible that the older patients may have a different response as the result of differences in skin integrity and sensitivity to stimulation.

Limitations

The results of this study may not be generalizable to the use of this device with patients outside a surgical setting. In addition, because the mean age of the population was high, it's possible that the results would not be replicable in younger adult patients, even those in a preoperative setting. Furthermore, the study was conducted in a single site of a dedicated orthopedic and spine hospital, which may limit the applicability of the findings. The instrument used for the measurement of anxiety and pain in the adults could also be a limitation, since previous reports suggest that older patients may have difficulty with VAS because of cognitive impairments or motor skill issues.[16,22] Finally, the study design did not include a placebo or sham device control. It's possible that bias, which could not be accounted for, was present as a result of the nonblinded nature of the study.

CONCLUSION

The results suggest that the application of cold and vibration is not universally effective for pain prevention in older adults undergoing IV catheter insertion in the context of preoperative care and did not improve patient satisfaction in this population. Patients who reported the highest level of preprocedural anxiety exhibited improved pain scores compared with controls. This study's data suggest that Buzzy may not be beneficial to incorporate into general practice for older adults undergoing venipuncture but may be valuable to offer to those who are particularly anxious before needlesticks. More research in different populations of adults undergoing compulsory procedures involving catheters are needed to determine their effectiveness in adults.

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