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CONTENTS

REVIEWS

SCIENTIFIC ARTICLES

ASSESSING THE EFFECTIVENESS OF A THERMOMECHANICAL DEVICE (BUZZY®) IN REDUCING VENOUS CANNULATION PAIN IN ADULT PATIENTS

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Running head: Buzzy® for relief of cannulation pain in adults.

Keywords: Buzzy, cannulation pain, intravenous cannulation, pain scores.

Abstract

Background: Intravenous cannulation is a painful procedure in which analgesia is rarely provided for. The Buzzy® device is a non-invasive, easy to use device, originally used in children, that combines vibration and cold modalities to block pain sensation. The objective of this study was to assess its usefulness in reducing cannulation pain in adult patients.

Methods: One hundred and eighty four patients, 18-65 years old, requiring venous access for elective surgery were randomized into four groups. All patients had the Buzzy® device applied prior to cannulation. The four groups had the following intervention: Group B: complete Buzzy® device, Group V: vibration switched ON with ice pack at room temperature, Group C: vibration switched OFF with cold ice pack; Group P: Buzzy® device without activation and with ice pack at room temperature. All patients were cannulated with a 20G venous cannula after application of this device. We compared pain scores during cannulation using the Visual Analogue Scale (VAS) and patient preferences for the device.

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Results: Buzzy® usage during cannulation significantly resulted in the lowest pain score 33.92 ± 15.59 (p = 0.016) amongst all groups. When compared with the Placebo group, patients in both the Buzzy® and Vibration groups recorded significantly lower pain scores (p = 0.031 and p = 0.037 respectively). In terms of preference, 81.0% of patients in the complete Buzzy® group were satisfied with the device.

Conclusion: The Buzzy® device and its vibration component significantly reduced venous cannulation pain in adult patients.

Introduction

Venous cannulation is often a painful procedure that is distressing to patients. Needle aversion often leads to avoidance of medical treatment, refusal for vaccination and a reduction in the number of potential blood donors[1-3]. Current practices in anesthesia to reduce cannulation pain involve a myriad of techniques ranging from topical local anesthetics (LA) application to the use of flash lights via a distraction technique[4-7]. Among these, topical anesthesia with LA is the most frequently used technique but the long onset time often precludes its usage in the acute setting[8]. Whilst application of topical anesthesia is often used for children, most adult patients undergo venous cannulation without analgesia. Sado et al[9] found that less than 50% of junior doctors used any LA for cannulation of large bore IV cannulas and none of them used LA for 20 G to smaller sized cannulas.

A technique to reduce cannulation pain utilizes a thermomechanical device called Buzzy® (MMJ Labs, Atlanta, GA). The Buzzy® is a battery operated, handheld plastic 'bee' with a vibrating motor and a mechanism to attach an ice pack underneath (Figure1). It can be pressed in place or secured to a limb via a Velcro strap or tourniquet. The site of application corresponds to the dermatomes that supply cutaneous innervation to the area of planned cannulation. It is postulated to work based on the Gate Control Theory, which suggests that pain is transmitted from the peripheral nervous system to the central nervous system via modulation through a gating system in the dorsal horn of the spinal cord[10]. The vibration component of this device will stimulate the A-beta fibers (fast non noxious motion nerves), which subsequently block the A-delta C–fibers (afferent pain receptive nerves)[11]. The cold component on the other hand will stimulate the C fibers and if applied prior to the pain stimulus will block the A-delta pain signal as well. An alternative postulated mechanism in which the cold stimulus provides pain relief is by triggering the descending noxious inhibitory controls, activating a supraspinal modulation and raising the body's overall pain threshold[12].

Fig. 1
The application of Buzzy ® at C7 dermatome prior to cannulation at dorsum of hand.
(With permission from buzzyforshots.com)

The Buzzy® has been shown to reduce venepuncture pain in children. Baxter et al[13] showed that the Buzzy® decreased venepuncture pain significantly when compared to standard care using a vapocoolant spray in the pediatric population. In the adult population, a pilot study conducted by the same investigator, found a significant reduction of pain on the visual analogue score (VAS) when cannulation was done using the Buzzy® compared to no intervention[14]. However, being a pilot study with a small sample size of 30 subjects and a small reduction in pain score of 0.99 cm, these findings were regarded as clinically insignificant by some investigators[15-16].

The aim of this study was to determine the effectiveness of Buzzy® versus placebo in reducing cannulation pain among adult patients. Also it was intended to determine whether the individual components of the Buzzy® were as effective as its complete unit.

Methods

The study was a prospective, double blind, randomized clinical trial submitted for the approval by the Dissertation Committee of Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Center (UKMMC). Ethical approval was obtained from the Medical Research & Ethics Committee from UKMMC (project number: FF-2017-024) and Medical Research & Ethics Committee under the National Medical Research Register, Ministry of Health Malaysia [NMRR-15-2438-27337(IIR)].

The study was conducted by multiple operators consisting of anesthetic medical officers from the Department of Anaesthesia and Intensive Care, Hospital Kuala Lumpur who cannulated the patients. The investigator was responsible for application of the device. Different anesthetic medical officers who were 'blinded' to the intervention group recorded the patients' pain and satisfaction scores.

Adults presenting for surgery aged 18 to 65 years old, American Society of Anesthesiologists (ASA) 1 or 2 patients who were able to communicate and required venous access were enrolled. Patients with anticipated difficult intravenous access, known sensitivity to cold (eg: Raynaud's disease), patients who had any break of skin over the area where the device would be placed or who had pre-existing pain (e.g., peripheral neuropathy, chronic pain, fractures over the placement site) were excluded.

During preoperative assessment of the patients, inspection of the dorsum of the hand was done to identify suitable veins for cannulation. Informed consent was taken from patients presenting for elective surgery who were eligible for the study. Patients were briefed about the device, VAS and kept fasted overnight prior to surgery. No premedication was given. They were randomly divided via computer generated randomization into 4 groups: Group B, Group P, Group V and Group C. All groups had the Buzzy® applied around their wrist. Group B ('Buzzy') patients had the device vibrating motor switched ON with an ice pack applied prior and during venous cannulation on the dorsum of the hand. Group V (vibration only) patients had the Buzzy® applied and vibrating motor switched ON but the ice pack was kept at room temperature. Group C (cold only) patients had the ice pack attached underneath but the device was not switched ON. Group P (placebo) patients had a 'dummy device' in which the Buzzy® was not switched on and the ice pack was kept at room temperature prior to application and during cannulation.

The envelope containing the randomized intervention group was opened in the operating theater for the respective patients. Once a suitable vein had been identified on the dorsum of the patient's hand, the area overlying the vein to be cannulated was cleaned with an alcohol swab as standard practice and allowed to dry. A tourniquet was applied on the wrist and the device was placed proximal and as close as possible to the tourniquet, corresponding to the C7 dermatome. Depending on the intervention group, the device with the ice pack (cold or at room temperature) was either switched ON or switched OFF for one minute prior to cannulation, and continued until successful cannulation was completed. Cannulation using a 20G venous cannula was subsequently attempted. Only patients successfully cannulated on the first attempt were included for assessment of VAS score. Successful cannulation was defined as having 'flashback' and backflow of blood to the hub upon venipuncture with the ability to fully insert the cannula.

Patients in whom cannulation failed on the first attempt, were dropped out of the study. Reasons for failed cannulation were documented. Subsequent cannulation attempts were done at alternative sites and the patients were offered subcutaneous infiltration of lignocaine 2% at the new site of cannulation for reduction of pain.

The VAS score was assessed by another medical officer who was not involved in the cannulation process and was 'blinded' to the intervention group. This assessor was called to assess patients' VAS score after the cannula was secured. Patients were asked to indicate their pain score on the paper scale shown to them. The VAS is a 100 mm horizontal scale with two opposite ends describing pain intensities ranging from 0 which depicts no pain to 100 which represents the worst pain imaginable[17]. Patients' preference was also assessed by questioning their likelihood to use the device in the future. Side effects such as skin reaction,

Table 1
Demographic data presented as mean ± standard deviation or numbers(n)

	Group B (n=42)	Group V (n=43)	Group C (n=42)	Group P (n=42)	P-value
Age (years)	32.5 ± 13.1	32.7 ± 12.1	33.7 ± 12.1	33.6 ± 11.6	0.959
Gender (Male/Female)	18/24	22/21	18/24	19/23	0.851
Weight (kg)	61.5 ± 10.1	63.1 ± 9.9	60.4 ± 7.6	62.9 ± 10.0	0.550
Height (m)	1.59 ± 0.07	1.62 ± 0.06	1.59 ± 0.07	1.61 ± 0.06	0.321
BMI (ht/m^2)	23.6 ± 4.04	23.7 ± 3.18	22.9 ± 3.04	23.9 ± 3.08	0.519
ASA (I/II)	34/8	32/11	29/13	31/11	0.662

pain or discomfort over the device application site were recorded as well.

Statistical Tests

Sample size calculation was based on a previous study comparing mean VAS score between the Buzzy® and no intervention at all by Baxter et al[10], in which the mean difference of VAS score was normally distributed with a standard deviation of 16. The α value was set at 0.05 and power of study at 80%. If the true mean VAS score between the placebo and device group is 9.9 mm, 42 subjects were needed for each arm. Assuming a 20% drop out rate, 51 patients per arm were required.

Table 2
Mean VAS score ± standard deviation (SD) among groups and post hoc group comparisons using Tukey's test. showed the mean difference was significant at 0.05 level*

	VAS	p-value[a]	Group	p-value[b]
Group B (n=42)	33.92 ± 15.59	0.016	B vs V	1.000
			B vs C	0.401
Group V (n=42)	34.18 ± 15.73		B vs P	0.031
			V vs C	0.442
Group C (n=42)	39.16 ± 15.99		V vs P	0.037
Group P (n= 42)	43.21 ± 13.91		C vs P	0.622

Note: [a] p value using ANOVA test
[b] p value of post hoc Tukey's test
* significant mean difference at 0.05 level

Table 3
Buzzy® preferability presented in number (n) and percentage (%) and group preference comparison using Pearson's Chi Square test

	Preferability		Group comparison	Pearson's chi square test p value
	Yes (%)	No (%)		
Group B (n=42)	81.0	19.0	B vs P	<0.0001
Group V (n=42)	69.7	30.2	V vs P	0.001
Group C (n=42)	54.8	45.2	C vs P	0.048
Group P (n=42)	33.3	66.7	B vs V	0.232
			B vs C	0.010

* statistically significant (p <0.05)

All analyses were performed using the IBM SPSS Statistics version 23. ANOVA was used to compare the pain scores across the four different groups. Where significant differences were detected, post hoc tests were done. The Chi square test was used to analyze the likeability score across the different groups. Statistical significance was set at $p<0.05$.

Results

A total of 184 patients were recruited for this study but only 169 patients were included in the final analysis. Fifteen patients were dropped out from the study due to failed cannulation on the first attempt. Nine of these failed cannulation attempts were due to failures to get "flashback' and backflow of blood to the hub after initial puncture and six were due to failures to advance the cannula. These patients were all successfully cannulated on subsequent attempts. The demographic data was comparable in all four groups (Table 1).

The mean VAS score was lowest in the Buzzy group followed by the Vibration group, Cold group and Placebo group in ascending order. The difference among these groups was statistically significant (Table 2). Further post hoc analysis revealed significant changes in mean VAS scores in the Buzzy® and Vibration groups when compared to Placebo. No other statistically significant differences were seen between other groups.

The Buzzy® group had the highest favorability percentage followed by Vibration, Cold and Placebo in descending order (Table 3). In terms of patients preference, all intervention groups showed significantly higher patients preference when compared to Placebo. Patients preference for Buzzy® and Vibration were comparable and the difference was not significant.

There were no adverse events recorded as a result of application of this device to all patients. However, two anesthetic trainees who were cannulating the patients complained of the device interfering with their cannulation site of choice. Even so, both of these trainees were still successful in cannulating their patients on the first attempt.

Discussion

The Buzzy® device, being both a non-invasive and fast acting in reducing pain during intravenous cannulation has been studied extensively in the pediatric population. In a recent study, Potts et al[18] showed the device to be equally effective when compared to standard care of lignocaine 4% cream in reducing pain and distress during intravenous cannulation in children. In adults, our study findings were comparable to the pilot study by Baxter et al[19]. The current study however, was different in several aspects from previous studies done before. We have compared the device with placebo instead of topical LA and we further compared the effectiveness of its individual components, namely the vibration component and the cold component.

Our findings confirmed that Buzzy® as a whole device effectively reduced pain compared to placebo. Interestingly, when the device was separated to its individual components and compared with placebo, it was the vibration modality that significantly reduced cannulation pain and not the cold ice pack component. In fact, in terms of patients preference, Vibration on its own was almost as preferred as the complete Buzzy® device. This finding is in accordance with a study by Hollins et al[20] which found that cutaneous vibratory stimulation was able to cause a decline in nociceptive sensitivity. Joseph et al[21] who used the Buzzy® vibration device also found significantly reduced sensory perception in the foot when the device was applied. The postulated mechanism was that the external vibratory sensation provided by Buzzy® produced transient diminished sensation.

We cannot disregard the role of cold sensation which is postulated to help reduce pain sensation not only via the Gate Control Theory, but through Descending Noxious Inhibitory Control (DNIC). The latter works by increasing the general pain threshold of the body when intense cold stimulus is applied[22]. In this study we found a reduction in mean VAS score in the Cold group, but the change was not statistically significant. It is possible that the ice pack was not cold enough to trigger the "intense cold stimulus" required to activate the DNIC mechanism. Unlike the study by Mawhoter et al[23] who used vapocoolant spray which

can achieve a skin temperature of 0^0C within seconds upon application, the ice pack that we used in this study had to be taken out of the freezer for usage. The lapse time, being taken from the freezer to skin application may have lessened its effectiveness as a cold pack.

We also felt that the Buzzy® as a device on its own provided an element of distraction when applied to patients. Most of our patients were quite amused with its colorful and animated design. That could explain the fact that a third of patients in the placebo group felt that the device helped to reduce their pain when in actual fact, it was not switched on. This finding was somewhat similar to the study by Karthryn et al[24] who found significant reduction in pain in children undergoing intravenous injection when cartoon distraction was used.

Limitations to this study include operator bias by having different anesthetic trainees cannulating our subjects. Different levels of competency and years of experience in inserting a cannula might influence the patients' pain perception and cannulation success hence affecting the outcome of the study. Perhaps in future studies, a single experienced operator should be assigned to cannulate all patients to reduce bias.

Conclusion

Our study demonstrated that both the Buzzy® device and its vibrating component when used without the ice pack component were effective in reducing venous cannulation pain when compared with ice pack application alone or placebo in adult patients.

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Prior to weaning from CPB, alveolar recruitment maneuvers were performed, but the left lung remained collapsed. The TEE probe was removed after chest closure, followed by another fiberoptic bronchoscopy showing the same findings as the previous exam.

The patient was transferred intubated to the intensive care unit on controlled mechanical ventilation with an oxygen blood saturation of 100%.

An immediate postoperative CXR revealed re-expansion of the left lung with some atelectatic changes in the left lung base. The patient was extubated five hours later and the postoperative course was uneventful.

In our patient, the left mainstem bronchus had slight narrowing (unknown preoperatively), as shown by bronchoscopy, probably due to extrinsic compression by the dilated pulmonary arteries and the enlarged left atrium. We speculate that it was further compressed by the TEE probe that was difficult to insert in the esophagus (though size is appropriate for patient's weight), thus leading to left lung collapse. Additionally, this was likely to be aggravated by the increased dynamic compression of the airway by the enlarged cardiovascular structures in response to positive pressure ventilation and muscle relaxation. At no time was lung ventilation done on an open chest without the TEE probe in place; however, left lung reexpansion after removal of the TEE probe, as shown in the postoperative CXR supports our hypothesis.

Case reports of compression at the level of left mainstem bronchus by the TEE probe have been limited to small pediatric patients[2,3], but none have been described in older adolescents. Of note, intraoperative bronchoscopy was not immediately performed when left lung collapse was noted and the TEE was in place. Such an intervention would have allowed us to directly visualize the left mainstem bronchus obstruction by the TEE probe and its reversal when the TEE probe was removed. As a result, a definitive diagnosis could have been established. However, this was not in our differential diagnosis during the intraoperative management.

In conclusion, this case demonstrates that we should be alert to the possibility of inadvertent compression of the left mainstem bronchus by the TEE probe in adolescent patients undergoing cardiac surgery, in particular with enlarged cardiovascular structures.

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1. Rajagopalan S, Mascha E, Na J, Sessler DI. The effects of mild perioperative hypothermia on blood loss and transfusion requirement. Anesthesiology. 2008; 108:71-7.
2. ROBINSON JS: *Modern Trends in Anaesthesia*, Evans and Gray Ch. 8, Butterworth Pub. Co., London 1967.

10. Tables

Tables capture information concisely and display it efficiently: They also provide information at any desired level of details and precision. Including data in tables rather than text frequently makes it possible to reduce the length of the text.

- Type or print each table with double spacing on a separate sheet of paper.
- Number tables consecutively in the order of their first citation in the text.
- Supply a brief title for each.
- Place explanatory matter in footnotes, not in the heading.
- Explain all nonstandard abbreviations in footnotes.
- Identify statistical measures of variations, such as standard deviation and standard error of the mean.

11. Figures

- Figures should be submitted in JPEG or TIFF format with a minimum of 150 DPI in resolution.
- Colored data if requested by author is chargeable.
- If a figure has been published previously, acknowledge the original source and submit written permission from the copyrights holder to produce the figure.

Abbreviations and symbols:

- Use only standard abbreviations.
- Avoid abbreviations in the title of the manuscript.
- The spelled-out abbreviations followed by the abbreviation in parenthesis should be used in first mention.

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