Effectiveness of 10% Lidocaine spray on relieving local pain caused by intravenous (IV) intubation among women before Cesarean section: a double-blind randomized control trial

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Abstract

Background: Current evidence of the effectiveness of Lidocaine spay on relieving local pain caused by intravenous intubation among women before Cesarean section, while promising, is unknown. The objective of this study was to explore the effect of Lidocaine spray on relieving local pain caused by intravenous intubation among such participants.

Methods: Participants were assigned randomly into Group 1 (intervention group) or Group 2 (control group). Participants in group 1 received 3 sprays of 10% Lidocaine before the intravenous intubation while participants in group 2 received 3 spays of sterile water. A 100mm Visual Analogue Scale (VAS) was used to record the pain intensity directly after intravenous cannulation by the subjects. The adverse events and success rate of IV cannulation were also reported.

Results: The results indicated that the spray 10% Lidocaine had clinical significance in reducing the pain caused by intravenous intubation among women before Cesarean section. The VAS score in the intervention group was statistically lower than in the control group ($p<0.01$)

Conclusion: The results of the study suggest the effectiveness of 10% Lidocaine spray in managing intravenous intubation-related pain. It is recommended to perform further studies to compare the Lidocaine effect with other anesthetic options to determine the better technique for reducing pain associated with intravenous cannulation. A further trial to test the placebo effect of sterile water is also recommended.

Trial registration: Phenikaa University under register 42/QĐ-ĐHP-SĐH on January 13th, 2023

Keyword: pain, Lidocaine, VAS, women, C-session, intravenous.

Introduction

Intravenous (IV) cannulation is a technique in which a cannula is placed inside a vein through the patient's skin. It is the most commonly performed procedure in clinical settings. Nevertheless, it is also the second most painful procedure that significantly elevates a patient's anxiety levels (1, 2). IV cannulation is required for every patient before their operation. Managing this pre-operative pain has been listed as an indicator of the quality of anesthesia (3). As such, various interventions have been conducted to reduce the pain caused by intravenous intubation among patients. Non-pharmacological approaches to reduce this pain include using the flash of light to distract patients, cough tricks, Valsalva manoeuvers, and vapor coolant spray, essential oil (4-8). Pharmacological approaches for reducing local pain caused by IV include Lidocaine cream/patch/spray, EMLA (mixture of Lidocaine and Prilocain), diclofenac transdermal, and Piroxicam gel (9-12). However, none of these methods exhibited a clear superiority over the others. There is no clear consensus about which method is the best option to relieve pain induced by IV (10). Among pharmacological approaches, using Lidocaine provides some promising results in reducing pain related to IV insertion. Among the different dosage forms, Lidocaine spray is the most convenient with a fast effect. It is quickly absorption within 1 to 5 minutes (13). However, inconsistent results have been reported regarding this application (9, 10, 13-16). Notably, previous trials conducted in different populations, ages, settings, and needle sizes somewhat cause bias in the results. As such, more trials with rigorous design should be implemented to provide strong evidence to support the role of Lidocaine spray in reducing local paint caused by IV intubation. The objective of this study was to evaluate the effect of Lidocaine spray on relieving local pain caused by intravenous intubation. To ensure a homogeneous population, we chose the participants who were women before their Cesarean section delivery (C-section).

Methods

A randomized double-blind placebo-controlled trial design was performed at hospitals in Hanoi Obstetrics and Gynecology Hospital, Vietnam, from 12/2023 to 01/2024.

Inclusion criteria

Inclusion criteria comprised participants who were going to undergo a scheduled C-section delivery; were over 18 years old; able to read and write Vietnamese.

Exclusion criteria

Participants who were emergency cases for going to a C-section delivery

Sample size calculation

The sample size was determined using the equation for comparing two means with an alpha of 0.05, a power of 0.80, and an SD from the previous study to have a minimum sample of 50. As such we decided to recruit 150 participants (50 per group) to ensure the power of analysis.

Randomization, allocation, and blinding

This was a double-blinded study. The interventionist and the participants were blinded to whether the participants were receiving 10% Lidocaine spay or sterile water spray. Only the researcher who applied the spray was aware of the content. To ensure the success of blinding, the sterile water was contained in a bottle exactly like the 10% Lidocation spray. The nurses and participants were required to wear masks during the procedure. Block randomization was applied to keep an equal size for each trial arm. Eligible participants were randomized into two study groups in a 1:1 ratio, in blocks of four.

Trial arms:

There were one group receiving the intervention (group 1) and two control groups Participants in group 1 were given three sprays of 10% Lidocaine (Lidocaine 10% pump spray, Egis) 3 minutes before the interventionist performed the insertion of a catheter into their vein while the control group received 3 sprays of sterile water. Participants in usual care group receive standard IV placement procedures.

Study Procedures

The main researcher approached potential participants a day before their C-section and invited them to participate. After signing the consent form, participants were randomly

assigned to one of the two study groups. Before their C-section, the main researcher gave participants in group 1 three sprays of Lidocaion 10% (Lidocaine 10% pump spray, Egis) 3 minutes before the interventionist performed the insertion of a catheter into their vein while the control group received 3 sprays of sterile water. Each dose of the spray consisted of 0.1 ml liquid (4.8 mg Lidocaine/spray) and had the same colour and appearance as sterile water. The researcher sterilised the intended injection sites (2 sides) with alcohol swabs and applied Lidocaine spray/sterile water as the application aligns with the hospital's policy. After 3 minutes, the main researcher wiped the remained Lidocaine/sterile water and then marked the area. After that, the interventionist performed the IV cannulation using a 18 G IV cannula (Vasofix safety, BBraun). All IV cannulations were performed by two interventionists from Operation Room of the hospital. Before cannulation, the main researchers recorded any reaction on the skin. After successful cannulation, as confirmed by visible blood in the infusion needle, the needle was removed immediately. The participants recorded their pain perception directly after the procedure on a VAS, consisting of a nongraduated 100mm horizontal line ranging from '0 = did not hurt at all' to '100 = as painful as it could be'.

Measurements

The primary outcome was pain intensity directly after IV cannulation reported by the subjects using a 100mm Visual Analogue Scale (VAS). The secondary outcomes were adverse events, the success rate of IV cannulation.

Data analysis

Data were cleaned and analyzed by The Statistical Package for the Social Sciences v.20. The intention-to-treat (ITT) principle was adopted for analyzing the data. Between-group differences were examined using the T-Test or $\chi 2$ test with $p < 0.05$ indicating a statistically significant different.