Effects of Lidocaine Spray for Pain Relief during Manual Vacuum Aspiration: A study protocol of a randomized controlled trial

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Ethics: This study protocol was approved by the UdonThani Research Ethics Committee: Number 2566/081 I

Introduction

Manual vacuum aspiration (MVA) is a frequently used gynecological procedure in many conditions, such as abnormal uterine bleeding or termination of pregnancy (1,2). Pain during the MVA procedure is often caused; when the cervix is dilated, from uterine contractions and pain due to the anxiety during the procedure (4). The pain during the MVA using a visual analogue score is an average of 4-5 (8).

There are many ways to reduce pain during vacuum aspiration, both medical and non-medical. There are many types of analgesic used, such as the nonsteroidal anti-inflammatory drugs, local anesthesia or general anesthesia (3,5,6,7) and the use of each type is often determined by each center. A common pain relief method is intravenous analgesics, such as pethidine or diazepam. However, a study reported that 78.5 % of cases had severe pain (pain score $\geq$ 7) during the procedure despite the intravenous meperidine being used for pain relief (7).

Lidocaine is frequently used as the local analgesics to reduce pain during cervical and uterine procedures. The common lidocaine application is paracervical block. However, serious side effects have been reported. (7) The application of cervical Lidocaine spray has proved to be effective in; endometrial sampling and intrauterine device insertion procedures (7,8). This cervical lidocaine spray method is more convenient and safer when compared with the paracervical block technique.

This study aimed to evaluate the effectiveness of using local cervical lidocaine spray for pain relief during MVA procedure when compare with the placebo.

Methods and analysis

Study setting & design

This study is a randomized, double blinded, placebo-controlled trial conducted at UdonThani Hospital, UdonThani, Thailand.

Participants/Inclusion and Exclusion criteria

In this trial, the inclusion criteria is that the women are to be aged between 20 and 60 years and who have an indication for requiring a MVA procedure. The exclusion criteria are women who have; an allergy or hypersensitivity to lidocaine, the symptoms of reproductive tract infection or urinary tract infection, abnormal vital signs such as low blood pressure or fever, chronic liver or kidney disease.

Study methods

The study details will be explained to the participants and their written informed consent will be obtained before their participation. The randomization will be performed by computer generated numbers that were prepared in opaque, sealed envelopes. The eligible patients will be randomly assigned into two groups by the researchers. Group 1 received 4 puffs of 10% Lidocaine spray without adrenaline and intravenous opioid analgesic, group 2 received 4 puffs of the placebo (normal saline with the similar packaging (should this be) to the 10% Lidocaine spray) and intravenous opioid analgesic.

The MVA procedure will be performed at the gynecological ward. The patients will be informed about the procedure. The basic characteristics and the associated factors will be recorded in the case record form. The steps of the MVA procedure are as follows:

1. Participants lie in the dorsal lithotomy position.

2. The 50 mg intravenous Meperidine is used for analgesia 15-20 minutes before the operation.
3. The skin is cleaned using povidone iodine solution, then the sterile cloth is applied.
4. A speculum is inserted and the vagina is cleaned with a povidone iodine solution.
5. The lidocaine spray (10% Lidocaine spray without adrenaline) or the placebo (normal saline spray) is sprayed (4 puffs) onto the cervix. (9)
6. A tenaculum is clamped at the 2 and 10 o'clock positions of cervix. The pain score using visual analogue scale is assessed by the researcher.
7. The length of the uterine cavity is measured by a uterine sound.
8. The Karman cannula with the vacuum syringe is used to aspirate endometrium tissue in the uterine cavity. The size of cannula depends on the cervical os. The pain score is assessed by the researcher again.
9. After the procedure is completed, bleeding is checked and the device is removed. The overall pain score is assessed again.
10. The pain level is checked at 30 minutes after the procedure
11. The side effects of procedure are recorded such as nausea vomiting , hypotension ,abnormal bleeding, dizziness

To ensure confidentiality in the collection of the data, the subject identification code will only be used in the case record form. The information is recorded and entered in the Stata file and then is analyzed.

Blinding

Both patients and investigators are blinded in this study. The Lidocaine spray and placebo will be prepared by the pharmacists in similar packaging and place in opaque envelopes with the allocated number.

Outcomes

The primary outcome is to compare the pain scores during the operation between both groups. The secondary outcome is to evaluate the side effect of the local Lidocaine spray. The visual analog scale (scale 0-10) is used for pain evaluation. The data will be presented as continuous scores (with mean and standard deviation (SD), or median with interquartile range (IQR)) and/or as dichotomized scores (with number and percentage). All outcomes will be compared between groups using the mean difference and 95% confidence interval and the relative risk with 95% confidence. Analyses will be based on the intention-to-treat approach.

Sample size

Sample size is calculated by the Stata statistic program using the formula to test the two independent proportions. The proportion in the treatment group is 0.785, the proportion in the control group is 0.6(8). The calculated sample size is 97 per group and the 10% drop-out rate is added, the total sample size is 214.

Statistical analysis plan

The baseline characteristics of the participants will be compared between the Lidocaine spray and the placebo groups using unpaired T-test, Mann-Whitney U test, Chi-square test or Fisher's exact test when appropriate. A two-sided P-value <0.05 will be considered statistically significant. For the primary and secondary outcomes, we will report the mean difference of pain scores between groups with the 95% confidence interval for the continuous outcome and the relative risk with the 95% confidence interval for the dichotomous outcomes. For the main analysis, all outcomes will be analyzed using unpaired t test or logistic regression analysis. All analyses will be performed according to the intention-to-treat principle using Stata statistical program version 13.

Ethics

This study protocol was approved by the UdonThani Research Ethics Committee: Number 2566/081 I. The study results will be published in a peer-reviewed journal and shared with stakeholders and participants. This protocol is submitted before analysis of the results. After analysis and publication, data of this study will be available from the corresponding author upon reasonable request

Authors' contributions

PM, CC, MS, SS were involved in the conception and design of the study and protocol. PM, CC and MS collected the cases. MS and US designed the statistical analysis plan and analyzed the data. The manuscript was drafted by PM and MS. The manuscript will be reviewed and the final version of the manuscript will be approved by all authors.

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Competing interests statement

All authors report no conflict of interest.

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