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# Comparison of pain-reducing effect between topical ethyl chloride spray versus subcutaneous 1% lidocaine injection during two rods system contraceptive implant insertion: A randomized controlled trial

Decha Saechoen[a], Srisuda Songthamwat[a], Taniya Manosomrit[b], Nitaya Chinsri[b], Ueamporn Summart[c], Metha Songthamwat[a,*,1]

[a] Department of Obstetrics and Gynecology, UdonThani Hospital, UdonThani, Thailand
[b] Department of Nursing, UdonThani Hospital, UdonThani, Thailand
[c] Faculty of Nursing, Western University, Buriram, Thailand

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ABSTRACT

*Objective:* To compare the effectiveness of topical ethyl chloride spray (ECS) and subcutaneous 1% lidocaine injection (LI) to reduce pain during the two rods system insertion.
*Materials and methods:* One hundred and ten women, who underwent two rods contraceptive implant insertion during January 2021 to July 2021, were enrolled and randomly allocated to ECS and 1% LI groups. After the skin was sterilized, the assigned anesthetic method was administered before insertion of two rods contraceptive implant using the standard procedure. Pain levels during; (1) the administering of the anesthetic, (2) the insertion of the implant, (3) at 20 min after insertion and (4) overall pain levels, were evaluated, using a 10 levels visual analogue scale (VAS).
*Results:* All basic clinical characteristics between the two groups showed no significant difference. Mean VAS during anesthetic in the ECS group were significantly lower than in the LI group (3.92 and 2.89, mean difference −1.03, 95%CI −1.76 to −0.31, $p < 0.01$). However, the mean VAS during; (1) implant insertion, (2) 20 min after implant insertion and (3) overall pain, in the ECS group were significantly higher than in the LI group (4.83, 1.61, 3.11 versus 0.98, 0.09, 1.66) (mean difference 3.85, 1.52, 1.44 (95%CI 3.12 – 4.58, 1.13 – 1.92, 0.97 – 1.92, $p < 0.01$)).
*Conclusion:* ECS should not be used solely as an anesthetic option for the two rods system of implant insertion. It provides for less pain during the administering of the anesthetic but significantly less analgesic effect than LI.



## Introduction

A contraceptive implant is one of the most effective, long-acting and reversible methods of contraception compared to other reversible contraceptive methods. It also has several advantages, including immediate postpartum usage, no effect on breastfeeding, and long-acting effect [1]. It was first introduced as a 6-rods system containing levonorgestrel (Norplant®). However, the problems related to insertion and removal of Norplant lead to the development of the 1–2 rods device for easier insertion [2].

Two Rods System contraceptive implantation was introduced in Thailand in 1990[2], however, its utilization rate is still low. According to a reproductive health survey conducted by Thailand's Ministry of Public Health in 2019, implant contraception accounts for only 2.7% of all contraceptive techniques used in undesired adolescent pregnancy. Lack of contraceptive knowledge, fear of side effects, and high costs are the factors that may influence the usage of this method. The fear of pain during implantation is another important barrier to its use [3,4].

According to The Faculty of Sexual & Reproductive Healthcare (FSRH) recommendations, subcutaneous injection of 1% lidocaine (LI) is the accepted standard local anesthetic for implant insertion. It produces anesthesia by inhibiting excitation of nerve endings or by

* Correspondence to: Department of Obstetrics and Gynecology, UdonThani Hospital, 33 Po Niyom Road, Mueang Udon Thani District, Udonthani 41000, Thailand.
*E-mail address:* udonhome@yahoo.com (M. Songthamwat).
[1] UdonThani, Thailand; Department of Obstetrics and Gynecology, UdonThani Hospital.

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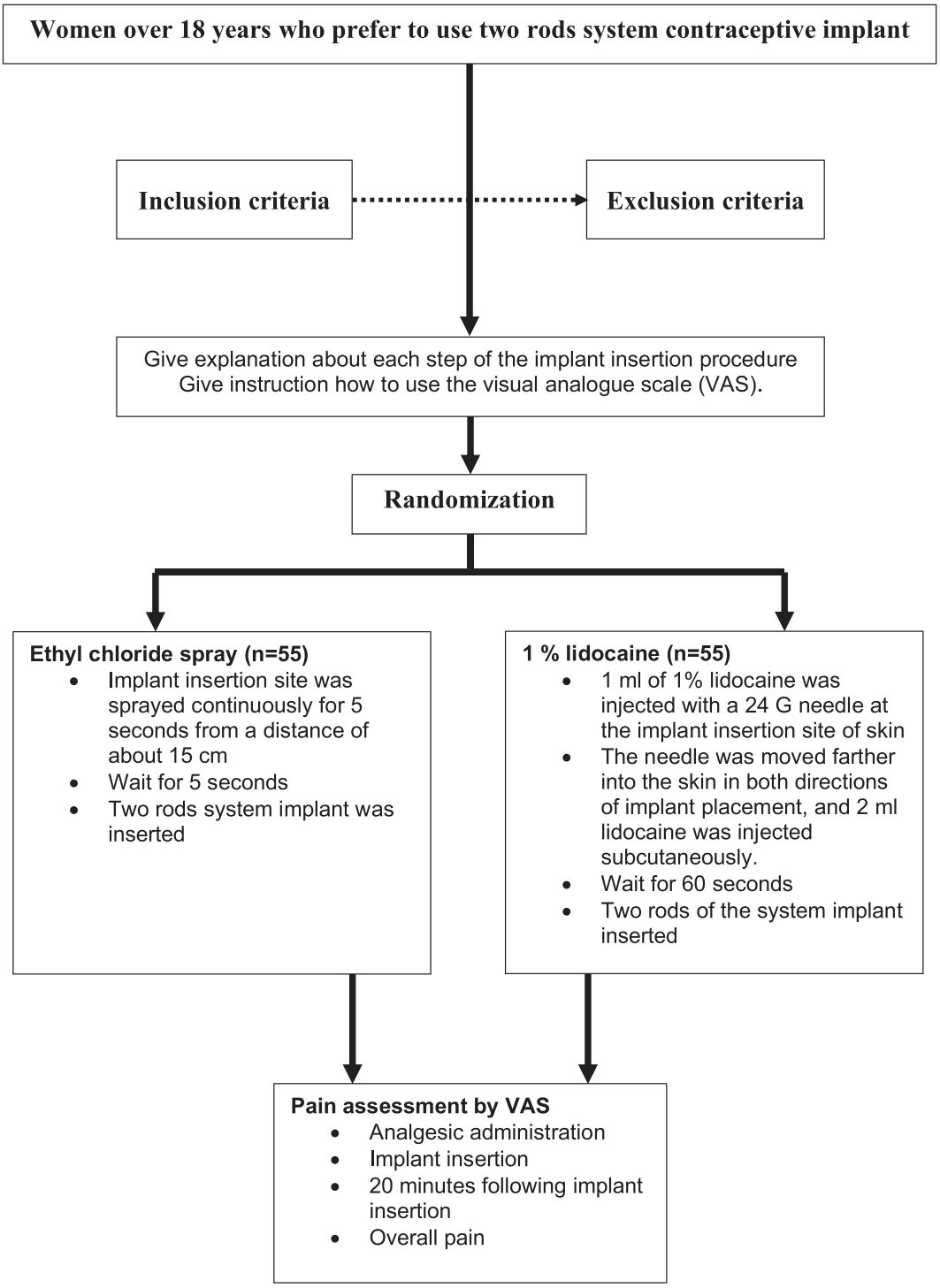


**Fig. 1.** Diagram flow chart.

blocking voltage-dependent sodium channels [5]. However, the LI is painful due to the skin penetration by needle, with a potential chance of needle stick injury to the operator. Another local anesthetic approach is ethyl chloride spray (ECS) which needs no injection. The volatile liquid spray evaporates quickly from the skin surface, lowering the temperature from 33 °C to below 10 °C about 10 s after application. This cooling action causes a transient cessation of pain sensation, either due to the desensitization of pain receptors or the activation of pain-transmitting ion channels, resulting in rapid cutaneous anesthetic [6,7]. The FSRH and GDG (Guideline Development Group) consider that ethyl chloride spray is a good alternative to lidocaine for implant insertion procedures where the skin is not affected by conditions such as eczema or broken prior to the procedure. Ethyl chloride spray may be of particular benefit for individuals who wish to avoid needles [4].

Although ethyl chloride anesthetic spray is not labeled as sterile, its use does not affect the sterility of injection sites [8,9]. Because of its rapid onset, ECS has been used in minor procedures with short operative times, such as intravenous cannulation and incision and drainage. Several prior studies have reported its efficacy [10–19] with a study that evaluated its efficacy in one-rod implant insertion [10], however, no study about its efficacy in two-rods contraceptive

**Table 1**
Demographic Characteristics.

| Demographic data | Ethyl chloride spray (n = 55) | Lidocaine injection (n = 55) | p-value |
|---|---|---|---|
| Age (year), mean ± SD | 21.61 ± 4.22 | 20.58 ± 4.46 | 0.21[a] |
| BMI (kg/m2), mean ± SD | 23.54 ± 5.04 | 23.19 ± 4.23 | 0.69[a] |
| Parity, mean ± SD | 1.41 ± 1.18 | 1.12 ± 0.79 | 0.13[a] |
| Previous vaginal delivery, n (%) | 29 (52.73) | 28 (50.91) | 0.84[b] |
| Previous cesarean section, n (%) | 13 (23.64) | 15 (27.27) | 0.66[b] |
| Previous abortion, n (%) | 10 (18.18) | 10 (18.18) | 1.00[b] |

[a] Independent Student T test,
[b] Chi square test

implantation has been reported. Compared to the LI, ECS may help minimize pain and the risk of needle stick injury during anesthetic administration. Therefore, the objective of this study was to compare the effectiveness of topical ECS and subcutaneous 1% LI in pain reducing during two rods system contraceptive implant insertion.

## Materials and methods

### *Ethical approval*

This was a randomized controlled trial study, conducted in women attending the family planning clinic, Department of Obstetrics and Gynecology, UdonThani Hospital, UdonThani, Thailand, during the period January to July 2021. The study protocol was approved by the UdonThani Hospital Ethical Committee on human research and was registered in the Thai Clinical Trials Registry (TCTR20201218001).

### *Participants*

The inclusion criteria were Thai women over 18 years who preferred to use the two rods system contraceptive implant and had no contra-indication for the use of the two rods system implant. The exclusion criteria included; known allergic reaction to either analgesic method, known underlying dermatological condition that relates to cold temperature, removal and reinsertion of contraceptive implant at the same time, those who had received analgesic drugs within 4 h prior to the procedure. All eligible participants were informed about the research study and their written informed consent was obtained before their participation in this study.

The participants were randomly assigned, using computer-generated numbers, to one of two anesthetic groups: 1% LI or topical ECS. The randomized treatment assignments were sealed in opaque envelopes and opened individually for each participant who volunteered to participate. Before the procedure, the participants were informed about the study drugs, the implant insertion procedure and how to use the visual analogue scale (VAS) for pain assessment. The demographic data (age, body mass index (BMI), history of vaginal delivery, cesarean section and abortion, prior birth control methods, number of previous contraceptive implants) were collected.

### *Anesthetic administration*

All patients had identical skin preparation performed. Skin was sterilized with a povidone iodine solution. In the ECS group, the implant insertion site was sprayed by ECS continuously for 5 s, with a distance of about 15 cm from the skin [10–19]. Then, the two rods system implant was inserted within 10 s after spray administration. In 1% LI group, 1 ml of 1% lidocaine without adrenaline was slowly injected with a 24 G needle at the implant insertion site of skin with a depth of 2–3 mm. The needle was moved farther into the skin in both directions of implant placement, and 2 ml lidocaine was injected subcutaneously. After 60 s, two rods of the system implant were placed.

### *Visual analogue scale (VAS)*

The client's pain at the time of analgesic administration, implant insertion, 20 min following implant insertion, and overall pain were assessed using a 10 levels visual analogue scale (VAS), with 0 being no pain and 10 being the most extremely painful. The clients were asked to rate their pain on a 10 levels visual analogue scale by marking it on their own. The diagram flow chart is shown in Fig. 1.

### *Sample size calculation*

The sample size was calculated by the formula for comparing two independent means using the STATA statistical program version 13. The mean VAS of the control group at 2.75 (SD 2.01) and 1.6 (SD 2.05) of the treatment group were used [10], with a type I error of 5% and a power of 90%. The calculated number was then added to, by 10% of the calculated number of subjects. There were 55 subjects needed to be enrolled in each group.

### *Statistical analysis*

Statistical analyses were performed using STATA statistical program version 13. Continuous data were reported as the mean and standard deviation. Categorical data were shown as the number and percentage. The statistical analysis was carried out using independent student's t test for comparison of continuous data and ordinal data, and Pearson Chi- square test for categorical data. The comparison between groups utilized the intention-to-treat method. All reported probability values are two-tailed; $p < 0.05$ was considered to be statistically significant.

## Results

These were one hundred ten women recruited for the analysis, 55 in the ECS group and 55 in the LI group. The demographic characteristics of the subjects are presented in Table 1. There was no statistical difference in age, BMI and previous delivery modes.

VAS at analgesic administration, implant insertion, 20 min after implant insertion and overall pain of both anesthetic groups are shown in Table 2. There was a statistically significant difference in VAS between the 2 anesthetic groups ($p < 0.01$). Clients in the LI group reported less pain during implant insertion, 20 min after implant insertion and overall pain than in the ECS Group ($p < 0.01$). However, clients in the LI group reported more pain during anesthetic administration than in the ECS group ($p < 0.01$). None of the participants experienced adverse effects with either anesthetic agents. Fig. 2.

**Table 2**
VAS pain score.

| VAS Pain Score | Ethyl Chloride Spray (n = 55) | Lidocaine injection (n = 55) | Mean Diff (p-value) | 95% CI |
|---|---|---|---|---|
| Analgesic administrationmean ± SD | 2.89 ± 1.91 | 3.92 ± 1.92 | - 1.03(< 0.01[a]) | -1.76 – −0.31 |
| Implant insertionmean ± SD | 4.83 ± 2.09 | 0.98 ± 1.76 | 3.85(< 0.01[a]) | 3.12 – 4.58 |
| 20 min after implant mean ± SD | 1.61 ± 1.43 | 0.09 ± 0.34 | 1.52(< 0.01[a]) | 1.13 – 1.92 |
| Overall painmean ± SD | 3.11 ± 1.52 | 1.66 ± 0.90 | 1.44(< 0.01[a]) | 0.97 – 1.92 |

[a] Independent Student T test

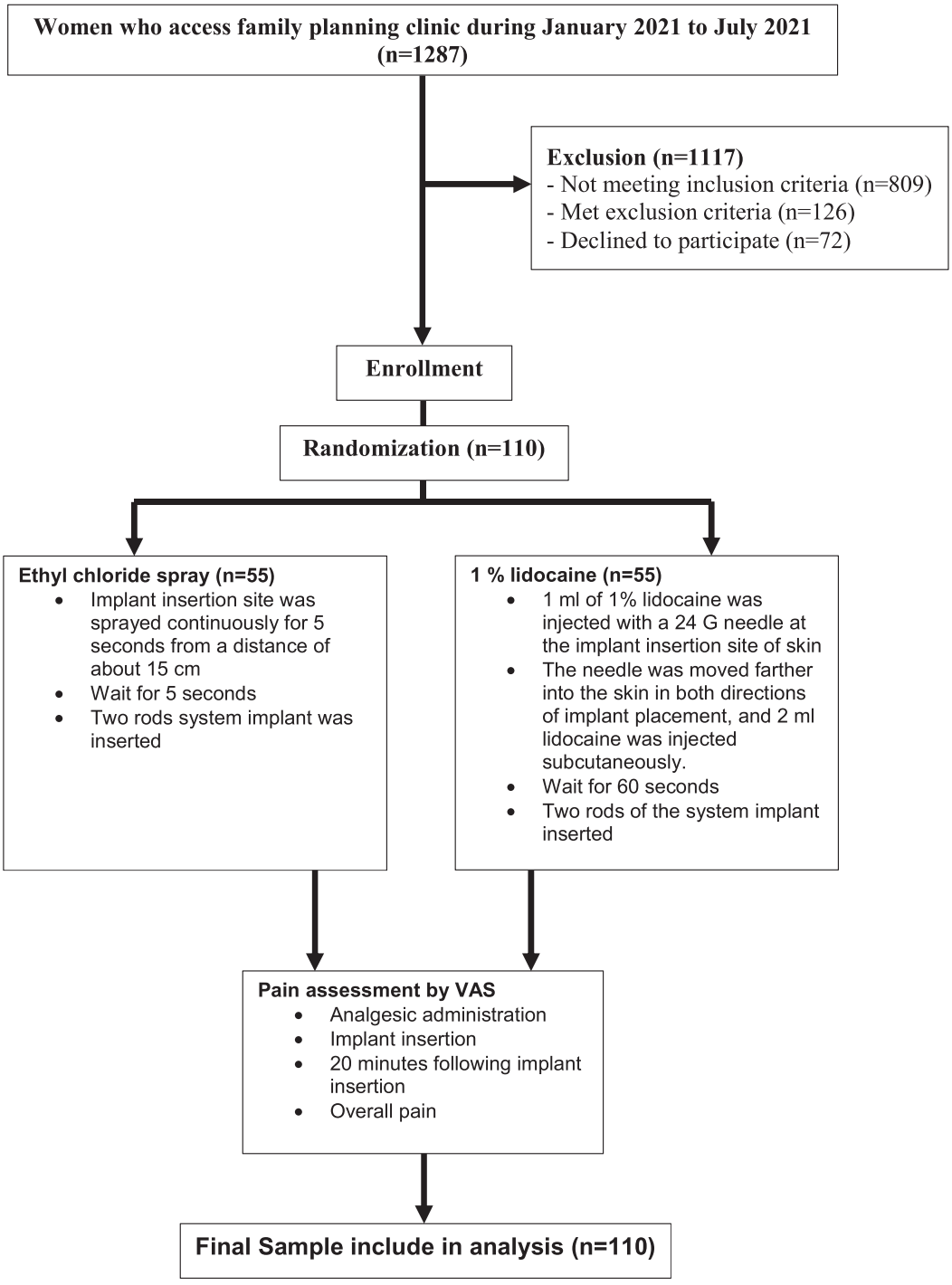


**Fig. 2.** Consort diagram.

## Discussion

From the literature review, several prior studies have reported ECS efficacy in minor procedures with short operative times, such as one-rod contraceptive implant insertion, intravenous cannulation, incision and drainage [10–19]. The advantage of ECS is no painful skin penetration during anesthetic compared with LI. The two rods system implant was a minor procedure with short operative times. Therefore, ECS can be used as the anesthetic of choice for this procedure to avoid the analgesic administered pain of LI.

In this study, the results showed significantly lower mean VAS during anesthetic in the ECS group compared to the LI group (3.92 and 2.89) ($p < 0.01$) which is compatible with a one-rod implant insertion study. However, mean VAS during implant insertion, 20 min after implant insertion and overall pain in the ECS group were significantly higher than in the LI group. This contrasting result compares with prior studies and might be due to the differences in the procedures. The Two rods system implantation required a longer duration. From the findings of this study, it indicated that ECS cannot be used as the sole anesthetic option for the two rods system implant insertion due to significantly less analgesic effect than LI.

### *Limitations and strengths*

The limitation of this study was its inability to blind to both investigators and participants due to the obvious different interventions which can make assessment bias of the subjective result (VAS). However, in order to avoid bias, investigators attempted to inform both groups of participants as extensively as possible about the study drugs, implant insertion technique, and how to use the visual analogue scale (VAS) for pain evaluation.

Furthermore, this study did not include operation time as a confounding factor. FSRH indicates that ethyl chloride spray produces a local anesthetic effect of rapid onset but short duration of action. The insertion procedure needs to be performed quickly after application as the anesthetic effect is of short duration (about 60 s) [4]. So, for participants whose procedures exceed that time, they may be more likely to experience more painful outcomes. Moreover, only the VAS was measured in this study. The participant's satisfaction was not evaluated.

The strength of this study was a randomized controlled trial. The participants were randomly assigned, using computer-generated numbers for allocation of two anesthetic methods. The implant insertion technique, both anesthetic administration methods, and pain assessment had been standardized. According to our knowledge, this study is the first RCT comparing differences between each analgesic method in two rods system contraceptive implant insertion.

## Conclusion

ECS cannot be used as an anesthetic option for the two rods system implant insertion. It provides less pain from anesthetic administration but significantly less analgesic effect than LI.

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## Data availability

The data that supports the findings of this study is available on request from the corresponding author within five years after publication.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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