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Efficacy of Ethyl Chloride Spray versus Subcutaneous 1% Lidocaine Injection for Relieving the Pain of One-rod Contraceptive Implant Removal: A single-blinded randomized controlled trial

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ABSTRACT

Objectives: To evaluate the pain scores between using ethyl chloride spray and subcutaneous 1% lidocaine injection for relieving the pain from one-rod contraceptive implant removal.

Materials and Methods: A total of 120 women who intended to remove the one-rod contraceptive implant were randomly assigned to receive ethyl chloride spray or 1% lidocaine injection before the procedure. Clinical characteristics including depth of implant, were collected. Pain during anesthetic administration, implant removal, and overall pain were evaluated using a visual analog scale (VAS). Participant and procedure assistant satisfaction were assessed. The outcome evaluator was blinded from the anesthetic method.

Results: All patient characteristics were similar between two groups. Pain during anesthetic administration and overall pain in the ethyl chloride spray group was significantly lower than the lidocaine group (median VAS 0 and 3; $p < 0.001$ and median VAS 1 and 2.9; $p < 0.001$, respectively). However, pain during the procedure in the ethyl chloride spray group was found to be significantly higher compared to the lidocaine group (median VAS 1 and 0; $p = 0.001$). Implant removal duration in the ethyl chloride spray group was significantly shorter than the lidocaine group. Participant and procedure assistant satisfaction in the ethyl chloride spray group was significantly higher than the lidocaine group.

Conclusion: Using ethyl chloride spray was effective for relieving the pain during anesthetic administration and overall pain of one-rod contraceptive implant removal. But it was associated with higher pain score during the procedure.

Keywords: ethyl chloride spray, lidocaine, contraceptive implant, implant removal, pain.

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ประสิทธิภาพของยาชาชนิดพ่นเอทธิลคลอไรด์กับยาชาชนิดฉีดใต้ผิวหนังลิโดเคน 1% ในการลดความเจ็บปวดจากการถอดยาฝังคุมกำเนิดชนิดหนึ่งหลอด: การทดลองปกปิดทางเดียวแบบสุ่ม

นารถลดา มาไพศาลกิจ, พิชญ์ จันทร์ดียิ่ง, ศศิกาญจน์ ตั้งทัศนา

บทคัดย่อ

วัตถุประสงค์: *เพื่อประเมินคะแนนความเจ็บปวดระหว่างการใช้ยาชาชนิดพ่นเอทธิลคลอไรด์กับยาชาชนิดฉีดใต้ผิวหนังลิโดเคน 1% ในการลดความเจ็บปวดจากการถอดยาฝังคุมกำเนิดชนิดหนึ่งหลอด*

วัสดุและวิธีการ: *สตรีผู้มารับบริการถอดยาฝังคุมกำเนิดชนิดหนึ่งหลอดจำนวน 120 คน ถูกสุ่มให้ได้รับการระงับความรู้สึกเป็นกลุ่มที่ได้ยาชาชนิดพ่นเอทธิลคลอไรด์หรือยาชาชนิดฉีดใต้ผิวหนังลิโดเคน 1% ก่อนการทำหัตถการ มีการเก็บรวบรวมข้อมูลทางคลินิก รวมถึงระดับความลึกของยาฝังคุมกำเนิด ประเมินระดับความเจ็บปวดขณะการบริหารยาชา, ระหว่างการทำหัตถการ, และความเจ็บปวดโดยรวม โดยใช้ visual analog scale (VAS) ประเมินระดับความพึงพอใจของผู้เข้าร่วมวิจัย และผู้ช่วยทำหัตถการ โดยผู้ประเมินผลการวิจัยจะถูกปกปิดวิธีการระงับความรู้สึกที่ผู้เข้าร่วมวิจัยได้รับ*

ผลการศึกษา: *ข้อมูลทางคลินิกของผู้ป่วยทั้งหมดไม่แตกต่างกันระหว่างทั้งสองกลุ่ม ระดับความเจ็บปวดขณะการบริหารยาชาและระดับความเจ็บปวดโดยรวมในกลุ่มที่ได้ยาชาชนิดพ่นเอทธิลคลอไรด์ต่ำกว่ากลุ่มที่ได้ยาชาชนิดฉีดใต้ผิวหนังลิโดเคนอย่างมีนัยสำคัญ (ค่ามัธยฐานความเจ็บปวดประเมินโดย VAS 0 และ 3; $p < 0.001$ และค่ามัธยฐานความเจ็บปวดประเมินโดย VAS 1 และ 2.9; $p < 0.001$ ตามลำดับ) แต่อย่างไรก็ตามระดับความเจ็บปวดระหว่างการทำหัตถการในกลุ่มที่ได้ยาชาชนิดพ่นเอทธิลคลอไรด์สูงกว่ากลุ่มที่ได้ยาชาชนิดฉีดใต้ผิวหนังลิโดเคนอย่างมีนัยสำคัญ (ค่ามัธยฐานความเจ็บปวดประเมินโดย VAS 1 และ 0; $p = 0.001$)ระยะเวลาที่ใช้ในการถอดยาฝังคุมกำเนิดในกลุ่มที่ได้ยาชาชนิดพ่นเอทธิลคลอไรด์สั้นกว่ากลุ่มที่ได้ยาชาชนิดฉีดใต้ผิวหนังลิโดเคนอย่างมีนัยสำคัญ คะแนนความพึงพอใจของผู้เข้าร่วมวิจัยและผู้ช่วยทำหัตถการในกลุ่มที่ได้ยาชาชนิดพ่นเอทธิลคลอไรด์สูงกว่ากลุ่มที่ได้ยาชาชนิดฉีดใต้ผิวหนังลิโดเคนอย่างมีนัยสำคัญ*

สรุป: *การใช้ยาชาชนิดพ่นเอทธิลคลอไรด์มีประสิทธิภาพในการลดความการลดความเจ็บปวดขณะการบริหารยาชาและระดับความเจ็บปวดโดยรวมจากการถอดยาฝังคุมกำเนิดชนิดหนึ่งหลอด แต่สัมพันธ์กับคะแนนความเจ็บปวดที่เพิ่มขึ้นระหว่างการทำหัตถการ*

คำสำคัญ: *ยาพ่นเอทธิลคลอไรด์, ลิโดเคน, ยาฝังคุมกำเนิด, การถอดยาฝัง, ความเจ็บปวด*

Introduction

Subdermal contraceptive implant is one of the most effective reversible contraceptive methods[1, 2], having a one-year failure rate of only 0.05%[3]. Implanon NXT® is a three-year one-rod subdermal contraceptive implant that contains 68 mg of etonogestrel and a disposable applicator[4, 5]. This was developed to facilitate correct subdermal insertions and allow for easier palpation and removal.

In Thailand, beginning in 2014, the National Health Security Office (NHSO) created a policy to minimize teenage and unintended pregnancy by supporting subdermal contraceptive implants free of charge for women under 20 years of age[6]. Nowadays, the number of women who need removal of the contraceptive implant has increased due to completion of the maximum duration of contraceptive action, a desire to get pregnant or intolerable side effects such as abnormal uterine bleeding, weight gain, mood change, and/or acne[7, 8].

Contraceptive implant insertion and removal are both outpatient procedures. However, the implant removal is more complicated and requires more experience and skill. The time needed for implant insertion is around 0.5-1.1 minutes[4, 7, 9], and for implant removal, 2-3.5 minutes is required[4, 7, 9]. Difficult removals may create a need for more time and cause more pain and patient anxiety. There are many factors that cause difficult removals, such as deep insertions, fractured or bent rods, implant migration, vascular or nerve injuries[10], duration of implant placement and the experience of the operator[11]. Eventually, most of the contraceptive implant users will become afraid of implant removal, more than insertion, and will not desire to have a reinsertion.

Subcutaneous lidocaine injection is a widely used local anesthesia for relieving the pain of contraceptive removal. Due to onset of action, it can be used a few minutes prior to skin incision. This anesthetic reduces pain by blocking voltage-gated sodium channels in the peripheral nervous system, so pain transmission to the central nervous system is inhibited[12]. However, lidocaine injection also causes injection site pain and tissue swelling, which can result in a more difficult removal procedure.

Ethyl chloride spray is another topical anesthetic method. It is sprayed on intact skin just before minor surgical procedures. Vapocoolant spray reduces pain by rapidly decreasing skin temperature and decreasing nerve conduction velocity, thus interrupting the nociceptive inputs to the spinal cord[13]. This produces an immediate anesthetic effect that is temporary (1-4 minutes)[14]. Although there is no label that describes the sterility of ethyl chloride spray, the spray was found not to alter injection site sterility[15].

There are several studies that have investigated the efficacy of ethyl chloride spray for reducing pain prior to procedures[16-20]. These previous studies reported the efficacy of ethyl chloride spray in reducing the pain from one-rod contraceptive implant insertion[21, 22]. However, to our knowledge, there is no published work regarding the effectiveness of ethyl chloride spray for contraceptive implant removal. The primary objective of this study was to evaluate the pain scores between using ethyl chloride spray and subcutaneous 1% lidocaine injection for relieving the pain from one-rod contraceptive implant removal. The secondary objectives were to determine patient and procedure assistant satisfaction, as well as the duration of the contraceptive implant removal procedure. In addition, the depth of the contraceptive implant, which may be associated with the level of pain, is classified and also evaluated.

Materials and Methods

This is a single-blinded randomized controlled trial conducted at the Gynecology outpatient clinic, Charoenkrung Pracharak Hospital between December of 2018 and June of 2019. The study was approved by the Bangkok metropolitan administration ethics committee for human research (BMAEC) and registered with the Thai clinical trial registry at http://www.thaiclinicaltrials.gov (TCTR20190205001).

All women undergoing one-rod contraceptive implant removal were included in this study. Exclusion criteria were as follows: patients with a non-palpable

contraceptive rod; those who were willing to immediately reinsert a new contraceptive implant; patients who received analgesics within 6 hours before the procedure; those with an inability to evaluate pain using the visual analog scale (VAS); those with a history of hypersensitivity to ethyl chloride spray or lidocaine; those with a known dermatologic condition that is aggravated by cold temperatures; patients with a skin infection at the implant area; and patients who currently use anticoagulant or antiplatelet medications.

All eligible participants were clearly informed about the research study and signed written informed consents prior to study enrollment. The participants were randomly assigned to receive either ethyl chloride spray or 1% lidocaine injection by computer-generator, using a block size of 4 with a 1:1 fashion. The randomized numbers were placed in sealed opaque envelopes, which were individually opened by a physician immediately prior to the procedure. The demographic data (age, body mass index (BMI), medical diseases and parity) and clinical characteristics (depth of implant, reason of implant removal and duration of current contraceptive implant use) were recorded.

In this study, we classified the depth of the contraceptive implant into three groups: group 1 indicates the rod is easily identified using vision and palpation, group 2 indicates the rod cannot be identified by vision but can be identified through light palpation, and group 3 indicates the rod cannot be identified through vision but can be identified by deep palpation. After randomization, all participants were placed in the supine position with their planned procedure arm flexed and externally rotated with their hand next to their head. The contraceptive implant was located and marked at the tip. The skin was routinely prepped with 70% ethyl alcohol solution. In the ethyl chloride spray group, the implant removal site was continuously sprayed for 5 seconds from about 15 cm above. Subsequently, the standard contraceptive implant removal was performed. In the lidocaine injection group, 1 ml of 1% lidocaine (without adrenaline injection) was administered subcutaneously (2-3 mm in depth) using a 24 G needle at the site of the planned incision. The standard contraceptive implant removal was performed 120 seconds after injection. In both groups, an additional 1 ml of 1% lidocaine could be injected if the participants could not tolerate the pain.

All contraceptive implant removal procedures were performed by the same physician who had 2 years of implant removal experience. This was to maintain consistency as per the following steps: a 2 mm skin incision was made near the tip of implant, a mosquito clamp was used to grasp the distal end of the rod, the fibrotic tissue was separated, the implant was gently removed through the incision and the skin was closed using a sterile strip and water-proof transparent dressing.

Pain scores were assessed using a 10 cm visual analog scale (VAS) at 3 different time points: during anesthetic administration, implant removal, and overall pain. The participants made a mark on a 10 cm line, which had 2 ends. The left end was 'no pain' and the right end was the 'worst pain'. Participant and procedure assistant satisfaction were evaluated using the five-point Likert scale. In this scale, 5 indicates 'extremely satisfied' and 1 indicates 'least satisfied'. Duration of implant removal (time from skin incision to the successfully removed implant), removal failure rate, adverse reaction, and additional analgesia were also recorded. The outcome evaluator was blinded from the anesthetic method. However, the participants and the physician were not blinded.

Sample size was calculated using the difference in the mean pain score from pilot study pain score. From 10 subjects in each anesthetic group, the mean overall pain (VAS) in the ethyl chloride spray group was 1.4 cm (standard deviation (SD) = 1.0) and in the lidocaine injection group, the VAS was 2.6 cm (SD = 1.5). With a power of 80% and a 2-sided type I error of 0.05, at least 18 participants in each group were required. With a 10% addition for possible data loss and 3 groups with differing contraceptive implant depths (for subgroup analysis), the total number of participants for each anesthetic group was 60.

An intention-to-treat analysis was performed using STATA version 15.1 (Stata Corporation). Descriptive statistics were reported using the median

and interquartile range for continuous data and the number with percentages reported for categorical data. For outcome comparisons, the continuous variables were tested for normal distributions using the Kolmogorov-Smirnov test. Independent student t-tests were used for parametric data analysis and the Wilcoxon rank sum test was used for nonparametric data. Pearson chi-square or Fisher's exact test were used for categorical variables. Additionally, the effect of the depth of implants group on pain scale was also assessed using a Wilcoxon rank-sum test. The a p value < 0.05 was considered to be statistically significant.

Results

A total of 120 women who met the eligibility criteria (60 in the ethyl chloride spray group and 60 in the lidocaine group) were enrolled from 185 participants. Eleven patients denied to participate, 52 patients needed to immediately reinsert a new contraceptive implant and 2 patients that could not evaluate the pain using VAS were excluded from the study. The consort flow diagram is shown in Fig. 1.

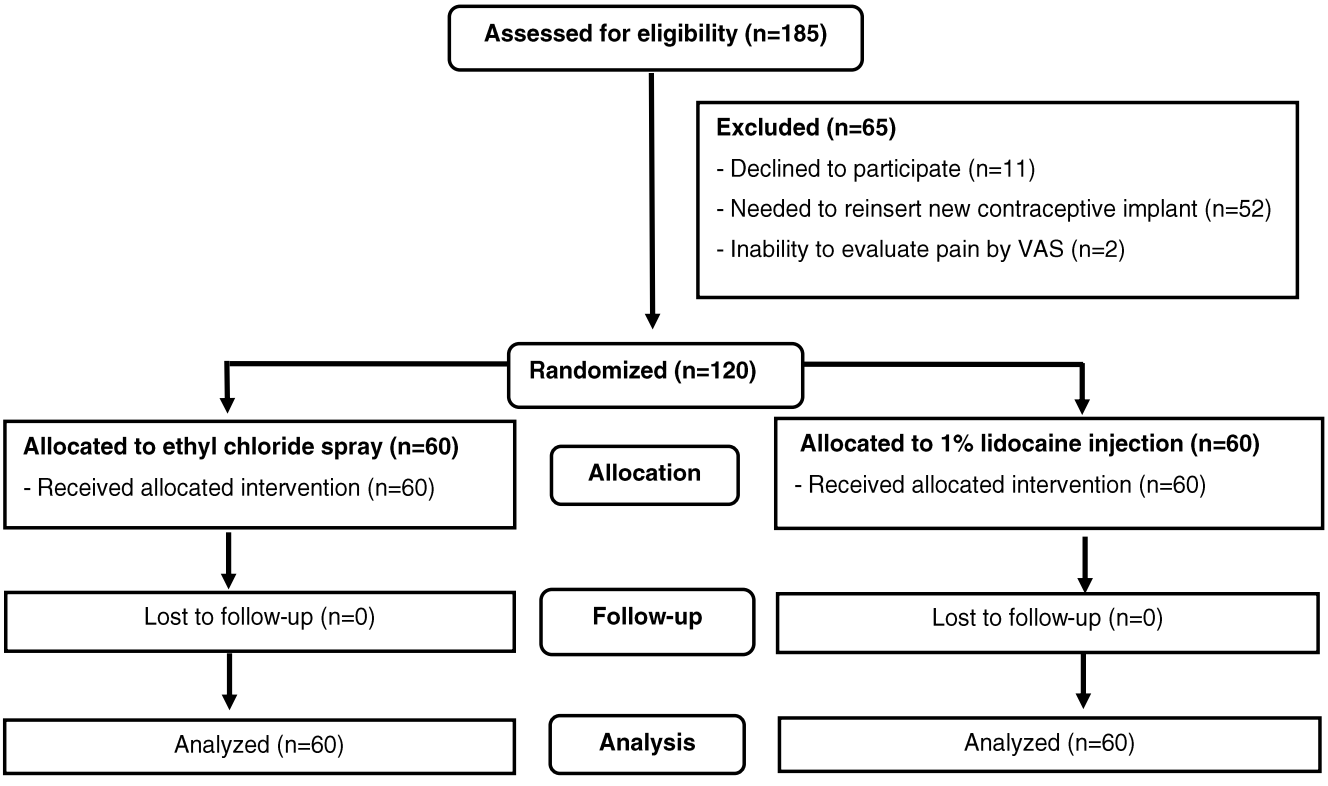

Fig. 1. Consort flow chart of randomization.

Table 1 demonstrated clinical characteristics of the participants between the two groups. Both groups were comparable in terms of age, BMI, medical diseases, parity, duration of current contraceptive implant use, reasons for implant removal, and groups of implant depth. The reasons for implant removal included a completion of the 3-years duration of contraceptive action (90.8% of the participants) and intolerable side effects (9.2% of the participants). Most of the participants were included in the depth of contraceptive implant group 2 (78%). Even though all removal procedures were successfully completed without any adverse reactions or complications, there were 5 participants in each

group that received an additional 1 ml of subcutaneous 1% lidocaine injection for pain control. All of these patients were in the depth of contraceptive implant group 3.

Table 1. Clinical characteristics and demographic data between the two groups (N=120).

	Ethyl chloride spray (n = 60)	Lidocaine injection (n = 60)	p value*
Age (years), median (IQR)	25.79 (22.63, 32.25)	27.83 (23.50, 31.38)	0.491
BMI (kg/m^2), median (IQR)	24.24 (19.93, 27.53)	22.21 (19.13, 27.31)	0.201
BMI category, n (%)			0.443
Underweight	6 (10)	12 (20)	
Normal	28 (46.7)	27 (45)	
Overweight	16 (26.7)	14 (23.3)	
Obesity	10 (16.7)	7 (11.7)	
Medical diseases, n (%)	5 (8.3)	4 (6.6)	0.729
Parity, n (%)			0.130
0	6 (10)	1 (1.7)	
1	36 (60)	33 (55)	
2	12 (20)	22 (36.7)	
≥ 3	6 (10)	4 (6.7)	
Duration of current contraceptive implant use (years), median (IQR)	3 (3, 3)	3 (2.99, 3)	0.902
Reasons for implant removal, n (%)			0.343
Complete 3 years	56 (93.3)	53 (88.3)	
Intolerable side effects	4 (6.7)	7 (11.7)	
Depth of contraceptive implant, n (%)			0.625
Group 1	6 (10)	7 (11.7)	
Group 2	49 (81.7)	45 (75)	
Group 3	5 (8.3)	8 (13.3)	

BMI: body mass index; IQR: interquartile range.
* Wilcoxon rank sum test used for continuous variables and Chi square or Fisher's exact test, as appropriate, for categorical variables

Pain score during anesthetic administration, implant removal, and overall pain were compared between the two groups as shown in Table 2. Median VAS during anesthetic administration and overall pain reported by patients in the ethyl chloride spray group was significantly lower than the lidocaine group (0 vs 3 cm; $p < 0.001$ and 1 vs 2.9 cm; $p < 0.001$, respectively). However, the median VAS during the procedure in the ethyl chloride spray group was found to be significantly higher than the lidocaine group (1 and 0 cm; $p = 0.001$).

Regarding groups of contraceptive implant depth, women in the ethyl chloride spray group reported overall

pain at significantly lower levels than the lidocaine injection group in both group 1 and 2 (0 vs 2.9 cm; p = 0.008 and 1 vs 2.9 cm; p < 0.001, respectively). Conversely, the overall pain score from patients in the ethyl chloride spray group was found to be higher than the lidocaine injection group, in group 3, although these differences were not statistically significant (4.9 vs 2.6 cm; p = 0.27) (Table 3). The details of the median pain scores at points of time according to groups of the contraceptive implant depth are shown in Fig. 2.

Table 2. VAS pain score outcomes.

	Ethyl chloride spray (n = 60)	Lidocaine injection (n = 60)	p value*
Anesthetic administration pain			< 0.001
Median (cm)	0	3	
IQR (25th, 75th)	(0, 1)	(2, 4.8)	
Implant removal pain			0.001
Median (cm)	1	0	
IQR (25th, 75th)	(0, 2)	(0, 0.9)	
Overall pain			< 0.001
Median (cm)	1	2.9	
IQR (25th, 75th)	(0, 2)	(1.9, 3.9)	

IQR: interquartile range. * Wilcoxon rank sum test

Table 3. VAS pain score outcomes.

	Ethyl chloride spray (n = 60)	Lidocaine injection (n = 60)	p value*
Group 1 (n = 13)	n = 6	n = 7	0.008
Median (cm)	0	2.9	
IQR (25th, 75th)	(0, 1)	(1, 5)	
Group 2 (n = 94)	n = 49	n = 45	< 0.001
Median (cm)	1	2.9	
IQR (25th, 75th)	(0, 1.1)	(2, 3.7)	
Group 3 (n = 13)	n = 5	n = 8	0.27
Median (cm)	4.9	2.6	
IQR (25th, 75th)	(4.8, 5)	(1.6, 5.1)	

IQR: interquartile range. * Wilcoxon rank sum test

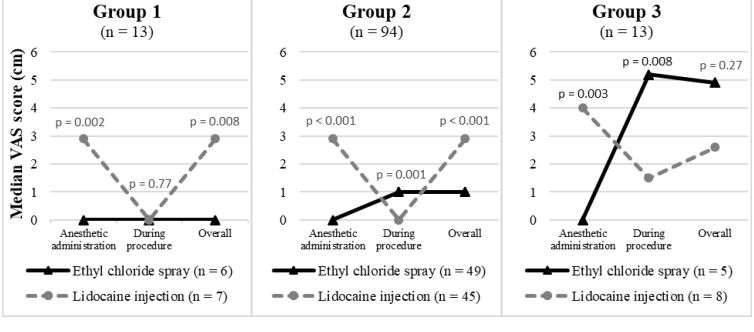

Fig. 2. Median pain scores according to the depth of contraceptive implant.

The comparisons of the satisfaction outcomes between the two groups are shown in Table 4. Participant and procedure assistant satisfaction in the ethyl chloride spray group were significantly higher than in the lidocaine group. In addition, significantly shorter durations were found in the contraceptive implant removal in the ethyl chloride spray group, compared to lidocaine group. The duration difference is approximately 13.5 seconds (median 31 vs 44.5 seconds; p = 0.007).

Table 4. Satisfaction outcomes.

Five-point Likert scale Median (IQR)	Ethyl chloride spray (n = 60)	Lidocaine injection (n = 60)	p value*
Participant	5 (4, 5)	4 (3, 5)	< 0.001
Procedure assistant	5 (5, 5)	4 (3, 4)	< 0.001

IQR: interquartile range. * Wilcoxon rank sum test

Discussion

The prevalence of contraceptive implant use is increasing and the incidence of teenage and unintended pregnancies are decreasing. However, some women hesitate to use this method due to its side effects, and because they are afraid of leaving an implant rod inside their body and fear the implant insertion and removal pain. While the insertion and removal procedures are only minor procedures, the procedures are associated with anxiety and pain.

In this study, we compared the widely used local anesthesia (subcutaneous lidocaine injection) with a topical vapocoolant anesthesia (ethyl chloride spray) for relieving the pain from one-rod contraceptive implant removal. During the procedure, ethyl chloride spray was found to result in significantly higher levels of pain compared to lidocaine injection. A possible explanation is that the contraceptive implant removal pain is mostly from the skin incision. Ethyl chloride spray is diffusely scattered over the application site and is not concentrated at the skin incision area, unlike using lidocaine injection[23]. Moreover, lidocaine injection has a volume effect and more anesthetic depth than ethyl chloride spray.

This result was consistent with the Rekawek, et al[23] study which found that during transabdominal chorionic villus sampling procedures, ethyl chloride spray was associated with a higher pain score, compared to lidocaine injection. However, conflicting results had also been reported. Techasomboon, et al[22] reported that there was no statistically significant difference in the pain score during implant insertion procedure between these two anesthetic groups. This might be because the contraceptive implant removal procedure needs more procedural steps (e.g. identify and grasp the implant rod, separate the fibrotic tissue) and more instruments (e.g. Mosquito clamp). The more complicated procedure may produce more pain.

Ethyl chloride spray was found to have higher efficacy than lidocaine injection for relieving the pain during anesthetic administration and overall pain caused by the one-rod contraceptive implant removal. This might be because of no injection site pain when using ethyl chloride spray and the participants perceived the anesthetic administered pain more than the procedural pain.

For the subgroup analysis, pain score during anesthetic administration in the ethyl chloride spray group was significantly lower than the lidocaine group in all groups of the contraceptive implant depth (groups 1, 2 and 3). During the procedure, ethyl chloride spray seemed to be effective only for the depth of the contraceptive implant group 1 because there was 'no pain' (median VAS was 0) during the procedure in the ethyl chloride spray group and it was not significantly different from the lidocaine group. On the other hand, pain scores during the procedure in the depth of the contraceptive implant group 2 and 3 were significantly

higher in the ethyl chloride spray group. A possible explanation is that deep insertion or difficult removal may produce more removal pain. Overall pain score in the ethyl chloride spray group was found to be significantly lower than lidocaine group for the depth of the contraceptive implant group 1 and 2. In the depth of the contraceptive implant group 3, overall pain in the ethyl chloride spray group was higher than the lidocaine group, but not statistically significant.

Due to the well-designed disposable applicator of one-rod contraceptive implant system, the contraceptive implant was mostly inserted in subdermal area correctly. Eventually, most of the participants were classified in the depth of the contraceptive implant group 2. In contrast with group 1 and group 3; an incorrect placement-too shallow or too deep, the number of participants were quite small. This may result in a limited statistical power to evaluate the efficacy of these types of associations.

From the participants and procedure assistant perspectives, ethyl chloride spray was the more satisfactory anesthetic method. Participant satisfaction in the ethyl chloride spray group was significantly higher than in the lidocaine group. This might be due to cooling sensation caused by the ethyl chloride spray and/or the less painful administration and the lack of needle anxiety (good for the needle-phobic patient). Also, the procedure assistant was satisfied with the ethyl chloride spray, possibly because of less needle injury risk and also less need for instrument preparation (e.g. syringe, injection needle), shorter procedure time and less blood loss due to the vasoconstriction effect caused by cooling.

Contraceptive implant removal duration was significantly shorter in ethyl chloride spray group. As mentioned before, ethyl chloride had no tissue swelling and distortion effect like lidocaine injection, so the rod can also easily be palpated after anesthetic administration.

There were several strengths in this study. First, to our knowledge, there has been no previously published randomized controlled study that evaluated the efficacy of ethyl chloride spray for reducing the pain from contraceptive implant removal. Secondly, all contraceptive implant removal procedures were performed by the same physician to maintain consistency in these procedures. Thirdly, the outcome evaluator was blinded from the anesthetic method to eliminate interviewer bias. Lastly, we classified the depth of the contraceptive implant by vision and palpation, which requires no special instruments or imaging. Even though this classification was subjective, it is simply and practically used daily.

Some limitations of this study should be noted. The participants and the physician who performed the procedure were not blinded from the anesthetic method because of the nature of the different intervention. There is no standard classification for the depth of a contraceptive implant. Moreover, the number of participants in the depth of contraceptive implant group 1 and 3 were too small. Future research with larger participant numbers and that aim to primarily investigate the effects of the depth of the contraceptive implant should be considered.

Conclusion

Using ethyl chloride spray was effective for relieving the pain during anesthetic administration and overall pain of one-rod contraceptive implant removal. But it was associated with higher pain scores during implant removal.

Potential conflicts of interest

The authors declare no conflict of interest.

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