
OBSTETRICS

Comparison between Lidocaine Spray and Cryotherapy for Pain Reduction from Amniocentesis in Second Trimester Pregnancy; A randomized controlled trial

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ABSTRACT

Objectives: To compare the pain level from amniocentesis between lidocaine spray, cryotherapy prior to the procedure and control groups in second trimester pregnant women.

Materials and Methods: This was a prospective randomized-control trial study. It was conducted at Maternal and Fetal Medicine clinic at Thammasat University Hospital, Pathum Thani, Thailand between July 2021 and December 2021. Participants were pregnant women undergoing amniocentesis at gestational ages between 15 and 20 weeks. They were divided into three groups namely lidocaine, cryotherapy, and control. Subjects in lidocaine or cryotherapy groups received an administration of 8 spritzes of 10% lidocaine (80 mg) spray or cold gel packs (-18 to -24 degrees Celsius) onto the marked puncture site for five minutes before amniocentesis, respectively. The control group underwent amniocentesis in the same manner without any analgesia. Anticipated pain (Te), pain during the procedure (T0), 15 and 30 minutes after the procedure (T15 and T30) were evaluated based on 10-cm visual analog scale (VAS).

Results: A total of 330 pregnant women were recruited and allocated (110 cases per group). Mean maternal age was 36.1 years old. The demographic characters of the three groups were comparable. Pregnant women who received lidocaine had significantly less pain than control at T0, T15 and T30 (3.00 ± 2.18 vs 3.97 ± 2.27 , $p = 0.001$, 0.95 ± 1.41 vs 1.95 ± 1.75 , $p < 0.001$, 0.48 ± 1.11 vs 0.95 ± 1.28 , $p = 0.004$, respectively). Those who received cryotherapy had significantly less pain than control at T0 and T15 (3.39 ± 1.84 vs 3.97 ± 2.27 , $p = 0.038$ and 1.48 ± 1.49 vs 1.95 ± 1.75 , $p = 0.032$, respectively). Lidocaine had less pain level than cryotherapy group at T15 and T30 (0.95 ± 1.41 vs 1.48 ± 1.49 , $p = 0.008$ and 0.48 ± 1.11 vs 0.93 ± 1.20 , $p = 0.005$, respectively).

Conclusion: Participants in both the lidocaine spray and cryotherapy groups had comparable

pain levels during the procedure. In contrast, at 15 and 30 minutes after the procedure, the lidocaine spray group had less pain than the cryotherapy group.

Keywords: lidocaine spray, cryotherapy, amniocentesis, pain.

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การทดลองแบบสุ่มเปรียบเทียบประสิทธิภาพระหว่างสเปรย์ลิโดเคนและการประคบเย็นก่อนการเจาะตรวจน้ำคร่ำเพื่อลดความเจ็บปวดขณะเจาะตรวจน้ำคร่ำในสตรีตั้งครรภ์ไตรมาสที่สอง

จณิสตา ขุนพระบาท, เด่นศักดิ์ พงศ์โรจน์เฒ่า, อธิตา จันทเสนานนท์, สวรรยา เบ็ญจหงษ์, จรรยา ภัทรอาชาชัย, คมสันต์ สุวรรณฤกษ์

บทคัดย่อ

วัตถุประสงค์: เพื่อเปรียบเทียบอาการปวดจากการเจาะน้ำคร่ำระหว่างการฉีดสเปรย์ลิโดเคน การประคบเย็น และกลุ่มควบคุมในสตรีตั้งครรภ์ไตรมาสสอง

วัสดุและวิธีการ: การศึกษาทดลองแบบสุ่มไปข้างหน้าในสตรีตั้งครรภ์ที่มารับการเจาะตรวจน้ำคร่ำทางพันธุกรรม ณ หน่วยเวชศาสตร์มารดาและทารกในครรภ์ โรงพยาบาลธรรมศาสตร์ ระหว่างเดือน กรกฎาคม พ.ศ. 2564 ถึงเดือนธันวาคม พ.ศ. 2564 อาสาสมัครหญิงตั้งครรภ์ อายุครรภ์ 15-20 สัปดาห์ที่เข้ารับการเจาะตรวจน้ำคร่ำได้รับการแบ่งแบบสุ่มเป็นสามกลุ่มคือ กลุ่มลิโดเคน กลุ่มประคบเย็น และกลุ่มควบคุม กลุ่มลิโดเคนได้รับการพ่นร้อยละ 10 ของสเปรย์ลิโดเคน 8 พัดต่อเนื่องกัน (80 มิลลิกรัม) บริเวณหน้าท้องที่จะเจาะน้ำคร่ำ กลุ่มประคบเย็นได้รับการประคบเจลความเย็น (อุณหภูมิ -18 ถึง -24 องศาเซลเซียส) บริเวณหน้าท้องที่จะเจาะน้ำคร่ำเป็นเวลา 5 นาที ก่อนทำการเจาะน้ำคร่ำทั้งสองกลุ่ม และกลุ่มควบคุมได้รับการดูแลตามมาตรฐานปกติ บันทึกข้อมูลระดับความเจ็บปวดที่คาดหวัง ขณะเจาะน้ำคร่ำ (T0) หลังเจาะ 15 (T15) และ 30 นาที (T30) โดยคะแนนความเจ็บปวด (VAS) 0-10 คะแนน

ผลการศึกษา: สตรีตั้งครรภ์จำนวน 330 ราย (กลุ่มละ 110 ราย) อายุเฉลี่ย 36.1 ปี กลุ่มที่ได้รับสเปรย์ลิโดเคนสามารถลดความเจ็บปวดขณะการเจาะน้ำคร่ำ หลังการเจาะ 15 และ 30 นาที ได้ดีกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ($p = 0.001$, < 0.001 และ 0.004 ตามลำดับ) กลุ่มที่ได้รับการประคบเย็นสามารถลดความเจ็บปวดขณะการเจาะน้ำคร่ำ หลังการเจาะ 15 นาที ได้ดีกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ($p = 0.038$ และ 0.032 ตามลำดับ) และผลของสเปรย์ลิโดเคนดีกว่าการประคบเย็นในการลดความเจ็บปวด ที่เวลา 15 และ 30 นาทีหลังการเจาะอย่างมีนัยสำคัญทาง

สถิติ ($p = 0.008$ และ 0.005 ตามลำดับ)

สรุป: สเปรย์ลิโดเคนและการประคบเย็นสามารถลดความเจ็บปวดขณะการเจาะตรวจน้ำคร่ำทางพันธุกรรมและหลังการเจาะที่เวลา 15 นาทีได้อย่างมีนัยสำคัญเมื่อเทียบกับกลุ่มควบคุม และหลังการเจาะที่เวลา 15 และ 30 นาที สเปรย์ลิโดเคนสามารถลดความเจ็บปวดได้ดีกว่าการประคบเย็นอย่างมีนัยสำคัญ

คำสำคัญ: สเปรย์ลิโดเคน, การประคบเย็น, การเจาะน้ำคร่ำ, ความเจ็บปวด

Introduction

Prenatal diagnosis is an investigation to detect genetic or structural abnormalities of a fetus in utero. Early detection, proper management, fetal surveillance and scheduled appropriate date of pregnancy termination depended on the prenatal diagnosis result. Prenatal diagnosis may be performed by means of invasive or non-invasive procedures⁽¹⁾. Amniocentesis is an invasive diagnostic procedure where a needle is inserted through the abdominal wall into the uterus and used to extract a small sample of amniotic fluid for further analysis. Amniocentesis is accepted as a standard for detecting chromosomal anomalies in the second trimester of pregnancy and is easily conducted with low risk of maternal and fetal complications. The level of patients' pain perception is a hindrance to patient cooperation. Unfortunately, the standard protocol for amniocentesis does not utilize local anesthetics or pain relievers. Factors that affected pain perception were number and the age of gestation, body mass index, and a history of previous abdominal surgery with an incision near the amniocentesis site⁽²⁾.

Lidocaine is one of the most widely used anesthetic agents either for local or neuraxial application. It can be administered in major or minor surgery for pain reduction. Lidocaine can be applied topically in the form of gel or spray. It works by stabilizing the neuronal membrane through inhibition of the ionic fluxes required for the initiation and the conduction of neural impulses, thereby affecting local anesthetic action⁽³⁾.

Cryotherapy has been used for pain reduction for many

years in localized tissue trauma. A reduction in soft tissue temperature by 10 to 15 degrees Celsius can show pain reduction efficacy by slowing local metabolic activity and decreasing oxygen requirement. Reduction in tissue swelling, bleeding, bruising, and local pain were benefits of soft tissue temperature reduction via vasoconstriction⁽⁴⁾.

Homkrun and coworkers reported a significant pain reduction by the application of lidocaine spray before amniocentesis⁽⁵⁾. Benchahong and colleagues showed that cold therapy before and after amniocentesis was the most effective in pain reduction during amniocentesis compared to only exclusively cold therapy before or after amniocentesis⁽⁶⁾. Similar to Hanprasertpong's study which demonstrated that cryoanalgesia prior to amniocentesis could significantly alleviate pain from the procedure⁽⁷⁾.

Contrarily, Gordon reported in 2007 that there was no significant pain difference between 1% lidocaine local infiltration and non-analgesia during amniocentesis⁽⁸⁾. Similarly, Wax and coworkers showed no significant difference in procedural pain between amniocentesis using a needle chilled at -14 degrees Celsius as compared to a needle at the room temperature⁽⁹⁾. Supportively to Gordon's and Wax's literatures, Pongrojpraw in year 2007 reported that the application of 1 gm of lidocaine-prilocaine cream and placebo cream had similar pain results during amniocentesis⁽¹⁰⁾.

From previous literature, local lidocaine spray and cryotherapy were both effective for pain management and convenience for use during

amniocentesis. Hence, the aim of this study was to compare the pain levels between local lidocaine spray, cryotherapy and control groups during second trimester amniocentesis.

Materials and Methods

This was a prospective randomized-control trial study. It was conducted at the Maternal and Fetal Medicine clinic, Thammasat University Hospital, Pathum Thani, Thailand between July 2021 and December 2021. The study was approved by the Human Research Ethics Committee of Thammasat University and was registered in Thai Clinical Trials Registry (TCTR20210331005).

The participants in this study were pregnant women undergoing amniocentesis at a gestational age between 15 and 20 weeks during the study period. The exclusion criteria were multifetal pregnancies, known fetal abnormalities detected by ultrasonography, threatened abortion, alteration in amniocentesis site after administration of intervention subsequently from fetal repositioning, more than one attempt of amniocentesis, allergy to lidocaine, infection of the abdominal wall, underlying maternal psychiatric conditions, and refusal to participate in the study.

According to Homkun's⁽⁵⁾ and Hanprasertpong's studies⁽⁷⁾, pain reduction differences were calculated to compare lidocaine spray and cryotherapy, post-amniocentesis pain measured at 2.3 ± 2.9 vs 3.2 ± 1.6 (mean \pm SD), respectively, $\alpha = 0.01$, $\beta = 0.10$. This study was an open-label trial and aimed at an intention-to-treat analysis. The minimal sample sizes that made the statistic significant were 94 cases per group. Ten percent addition for to account for potential lost cases were applied. The sample in the current study was 110 cases per group. The treatment assignment ratio of the study was 1:1:1 in each group.

After the details of the procedure were disclosed to the participants and the consent forms were signed, all eligible participants were consecutively allocated into three groups: lidocaine, cryotherapy, and control. The randomization process was carried out by a random manual draw system without stratification. Demographic

data of all participants were recorded, namely maternal age, the number of gestations, gestational age, body mass index (BMI), history of abdominal surgery, and the results of standardized ultrasonographic examination of fetal biometry and anomaly screening.

All amniocentesis procedures were performed by maternal-fetal medicine (MFM) staff under Thammasat University Hospital protocols, by which an ultrasound was used to locate the injection site before and during the procedure. The skin was disinfected with 10% povidone-iodine. A 22-gauge needle was used for amniocentesis with the collection of approximately 15-20 ml amniotic fluid per sample. Participants in the control group underwent the standard amniocentesis procedure without analgesia. Participants in the lidocaine group received 8 sprays of 10% lidocaine (80 mg) onto the marked puncture site five minutes prior to an amniocentesis. As for the cryotherapy group, the cold gel packs were stored at -24 to -18 degree Celsius for at least one hour. The cold gel pack was wrapped with 2mm thick cotton cloth sleeves. Then, the cold gel pack was placed at the marked puncture site for five minutes and amniocentesis was promptly performed in the same manner as lidocaine and control group. Once placed onto the participant's abdomen, the gel temperature was measured regularly in one-minute intervals, maintaining the gel temperature between 10 to 15 degrees Celsius. Participants underwent bed rest for thirty minutes to observe for complications. Routine ultrasonographic examinations for fetal heart rate and umbilical artery blood flow evaluation were performed before participants' discharge.

The goal of this study was to assess the effectiveness of local lidocaine spray and cryotherapy in decreasing the pain perception during and after amniocentesis. Participants estimated their anticipated pain level (expected pain: T_e) before amniocentesis, and recorded level of pain during the amniocentesis process (T_0), at 15 minutes (T_{15}) and 30 minutes (T_{30}) after the procedure in printed 10 - cm visual analog scale forms. The lowest and highest pain scores were 0 and 10 cm, respectively.

Demographic and clinical data were compiled

and electronically organized into a record form. The data was then processed into frequencies and percentages using Statistical Package for the Social Science (SPSS Inc., Chicago, IL USA) for Windows version 23. Continuous and category data were analyzed for statistical differences using analysis of variance (ANOVA) with repeated measurement and chi square or Fisher exact test when clinically applicable, respectively. A p value of less than 0.05 indicates a statistically significant difference.

Results

A total of 330 pregnant women who underwent

amniocentesis during the study period were recruited. They were allocated into three groups equally, namely control, cryotherapy and lidocaine groups (Fig. 1). Mean maternal age was 36.1 years old. The average gestational age of participants was 16.8 weeks. Average BMI was 25.1 kg/m². Half of participants had education level at the bachelor level or higher. Two-thirds of the participants were employees. Less than 10 percent of participants had prior experience of amniocentesis. There were no statistically significant differences between the groups in terms of maternal age, BMI, parity, education, occupation, history of abdominal surgery at randomization (Table 1).

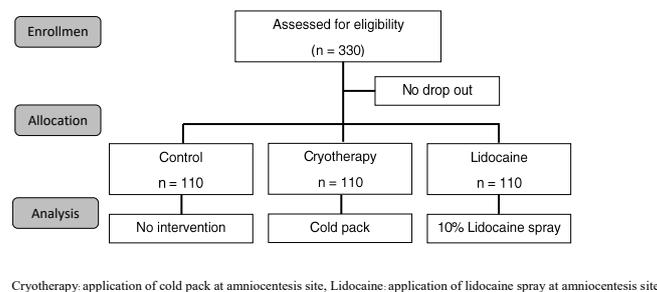


Fig. 1. Flow chart of this study.

Table 1. Demographic characteristics of amniocentesis cases for each group (n = 110 cases per group).

	Control*	Cryotherapy*	Lidocaine*	p value
Age (years)**	36.42 ± 3.99	36.03 ± 4.27	35.79 ± 4.67	0.55 [†]
BMI (kg/m ²) **	24.51 ± 3.96	24.92 ± 3.85	25.32 ± 5.05	0.08 [‡]
Nulliparity	37 (33.6)	37 (33.6)	60 (54.5)	0.74 [†]
Education level				0.06 ^{††}
≤ Primary	3 (2.7)	8 (7.3)	6 (5.4)	
Secondary	62 (56.4)	49 (44.5)	42 (38.2)	
≥ Bachelor	45 (40.9)	53 (48.2)	62 (56.4)	
Occupation				0.729 [†]
Government officer	14 (12.7)	12 (10.9)	14 (12.7)	
Business owner	12 (10.9)	21 (19.1)	15 (13.7)	
Employee	75 (68.2)	69 (62.7)	70 (63.6)	
Others	9 (8.2)	8 (7.3)	11 (10)	
No history of surgery	70 (63.6)	71 (64.6)	74 (67.3)	0.918 [†]
History of amniocentesis	8 (7.3)	10 (9.1)	7 (6.4)	0.74 [†]

Control: no intervention before amniocentesis, Cryotherapy: application of cold gel pack at amniocentesis site, Lidocaine: application of lidocaine spray at amniocentesis site
 BMI: body mass index, No history of surgery: no history of abdominal surgery, C/S: cesarean delivery

*n (%), **mean ± standard deviation (SD), † analysis of variance, ‡ Chi-square test, †† Fisher exact test

Table 2 represents the indications of amniocentesis in this study. The majority of cases were of advanced maternal age (85%) followed by family history of abnormal chromosomes with an

average of 4.86% among the groups while patient's desires were the least common indications. Abnormal prenatal screening accounted for an average of 4.8%.

Table 2. Indications for amniocentesis in each group (n = 110 cases per group).

	Control*	Cryotherapy*	Lidocaine*
Advanced maternal age	94 (85.6)	92 (83.6)	95 (86.4)
Family history of chromosome abnormality	7 (6.4)	6 (5.5)	3 (2.7)
Abnormal prenatal screening	5 (4.5)	5 (4.5)	6 (5.4)
Patient's desires	1 (0.9)	0 (0)	1 (0.91)
Previous child with chromosome abnormality	3 (2.7)	7 (6.4)	5 (4.5)

Control: no intervention before amniocentesis, Cryotherapy: application of cold pack at amniocentesis site, lidocaine: application of lidocaine spray at amniocentesis site, Advanced maternal age: maternal age \geq 35 years old, n (%)

Comparison of pain score visual analog scale (VAS). during amniocentesis at timely manner: expected pain before amniocentesis (Te), during amniocentesis (T0), 15 minutes (T15) and 30 minutes after amniocentesis (T30) were presented in Table 3 and Fig. 2. The expected pain of amniocentesis before the procedure among three groups of participants were comparable. Patients with cryotherapy administration experienced a significantly lower pain level compared to the control group during amniocentesis and 15 minutes after procedure (3.39 ± 1.84 vs. 3.97 ± 2.27 , $p = 0.038$ and 1.48 ± 1.49 vs. 1.95 ± 1.75 , $p = 0.032$, respectively). Nevertheless, the pain level at 30 minutes post amniocentesis was not different between the two aforementioned groups (0.93 ± 1.20 vs 0.95 ± 1.28 , $p = 0.871$). In a similar manner, local lidocaine spray significantly reduced

the pain score at T0 and T15 after amniocentesis compared to the control group (3.00 ± 2.18 vs 3.97 ± 2.27 , $p = 0.001$ and 0.95 ± 1.41 vs 1.95 ± 1.75 , $p < 0.001$, respectively). Surprisingly, at 30 minutes post procedure, local lidocaine spray still had a significant impact on the pain reduction compared to the control group (0.48 ± 1.11 vs 0.95 ± 1.28 , $p = 0.004$). The comparison of pain reduction efficacy from local lidocaine spray and cryotherapy was also taken into consideration. At T0, the patients with local lidocaine spray and cryotherapy administration had comparable pain scores (3.00 ± 2.18 vs 3.39 ± 1.84 , $p = 0.154$). However, lidocaine spray had a higher efficacy on pain reduction than cryotherapy at 15 and 30 minutes post amniocentesis (0.95 ± 1.41 vs 1.48 ± 1.49 , $p = 0.008$ and 0.48 ± 1.11 vs 0.93 ± 1.20 $p = 0.005$, respectively).

Table 3. Comparison of pain score visual analog scale (VAS) from amniocentesis among participants in control, cryotherapy and lidocaine groups (n = 110 cases per group).

	Control*	Cryotherapy*	Lidocaine*	p value [†]		
				Con vs Cryo	Con vs Lido	Cryo vs Lido
Te	5.75 ± 2.09	5.95 ± 1.84	5.81 ± 2.12	0.453	0.823	0.612
T0	3.97 ± 2.27	3.39 ± 1.84	3.00 ± 2.18	0.038	0.001	0.154
T15	1.95 ± 1.75	1.48 ± 1.49	0.95 ± 1.41	0.032	< 0.001	0.008
T30	0.95 ± 1.28	0.93 ± 1.20	0.48 ± 1.11	0.871	0.004	0.005

VAS: visual analog scale(range 0-10), Control: no intervention before amniocentesis, Cryotherapy: application of cold pack at amniocentesis site, Lidocaine: application of lidocaine spray at amniocentesis site, Te: expected pain before amniocentesis, T0: pain during amniocentesis, T15: pain at 15 minutes after amniocentesis, T30: pain at 30 minutes after amniocentesis, Con vs Cryo: between control and cryotherapy, Con vs Lido: between control and lidocaine group, Cryo vs Lido: between cryotherapy and lidocaine group
* mean \pm standard deviation (SD), [†] post hoc test (LSD)

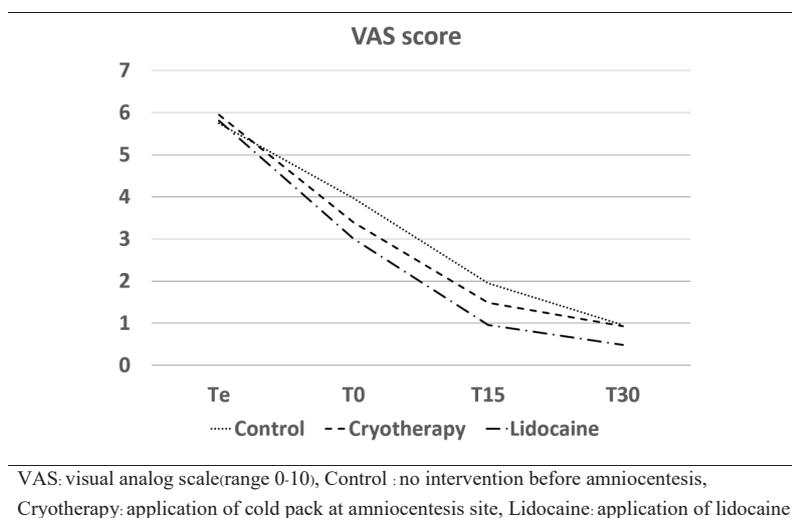


Fig. 2. Comparison of pain score (visual analog scale score) during amniocentesis at timely manner among participants in control, cryotherapy and lidocaine group.

Discussion

Amniocentesis is a type of prenatal diagnostic that is particularly invasive in nature, inciting some degree of concern such as the magnitude of procedural pain or possible complications towards the patient and the fetus which may follow. Lidocaine and cryotherapy were methods of interest for pain reduction in amniocentesis. Various methods of lidocaine application either with topical or injection were reported from previous literature.

From previous studies, Gordon⁽⁸⁾ and Elimian⁽¹¹⁾ investigated the pain reduction among pregnant women who underwent amniocentesis. Gordon and Elimian used similar needle size for amniocentesis, 22-gauge vs 20- or 22-gauge spinal needle respectively. However, the needle sizes for lidocaine injection were different in these 2 studies. Gordon utilized a 27-gauge needle for an intradermal injection then switched to a 21-gauge needle for a deeper injection of lidocaine. On the other hand, Elimian performed lidocaine injection using a 21-gauge needle in one simultaneous step. Elimian reported that the local infiltration of lidocaine could reduce pain from amniocentesis while Gordon did not demonstrate any pain reduction.

Pongrojapaw reported that lidocaine cream application before amniocentesis could not reduce

pain⁽¹⁰⁾. Another study, Homkrun and colleagues reported that lidocaine spray application at the amniocentesis site had significant pain reduction from the procedure⁽⁵⁾. Their work reported that the efficacy of lidocaine spray for pain reduction was during and immediately after the procedure. From the current study, local lidocaine spray at the puncture site before amniocentesis was effective in reducing pain during amniocentesis in the second trimester. Moreover, the pain reduction effect persisted until 30 minutes after the procedure. The current study supports Homkrun's study that an administration of lidocaine spray before amniocentesis could reduce the pain level.

Wax and coworkers stated that subfreezing needle (-14 degrees Celsius) for amniocentesis could not reduce pain from the procedure⁽⁹⁾. The use of cryotherapy for reducing pain during amniocentesis was reported by Benchahong⁽⁶⁾ and Hanprasertpong⁽⁷⁾. Both studies demonstrated that cryoanalgesia application before amniocentesis could reduce pain. Benchahong's study showed that cryotherapy could reduce pain for up to 30 minutes. The present study supports Benchahong's and Hanprasertpong's works that cryotherapy could reduce pain from amniocentesis for up to 15 minutes after the procedure. Telapol reported that ethyl chloride spray before amniocentesis

could not reduce pain during the procedure⁽¹²⁾.

From the current study, application of cryotherapy and local lidocaine spray at the puncture site before amniocentesis were effective in reducing pain during amniocentesis in the second trimester. Both lidocaine spray and cryotherapy applications before amniocentesis had comparable pain reduction

during the procedure. While at 15 and 30 minutes, lidocaine spray was significantly more effective in pain reduction than cryotherapy. Hence, it seems that lidocaine spray had longer duration of pain reduction than cryotherapy. Comparison of the current study to previous literatures was summarized and presented in Table 4.

Table 4. Comparison of previous literature of pain reduction method in amniocentesis.

	Wax ⁽⁹⁾	Pongrojpraw ⁽¹⁰⁾	Gordon ⁽⁸⁾	Hanprasertpong ⁽⁷⁾	Elimian ⁽¹¹⁾	Telapol ⁽¹²⁾	Homkrum ⁽⁵⁾	Benchahong ⁽⁶⁾	Present
Years	2005	2007	2007	2012	2013	2018	2019	2021	2023
Country	USA	THA	USA	THA	USA	THA	THA	THA	THA
Cases (n)	62	120	204	372	76	148	570	480	330
Method	FN	LC	LI	Cryo	LI	ES	LS	Cryo	LS/Cryo
Time (min)		30		5			1	5	5
Pain	N	N	N	Y	Y	N	Y	Y	Y

THA: Thailand, Cryo: cryotherapy, LS: lidocaine spray, LI: lidocaine injection, LC: lidocaine-prilocaine cream, FN: freezing needle, ES: Ethyl chloride spray, Pain: pain reduction, Y: pain reduction efficacy, N: no pain reduction efficacy

Conclusion

Participants in both groups who received lidocaine spray and cryotherapy before the amniocentesis had comparable pain levels during the procedure. In contrast, at 15 and 30 minutes after the procedure, the lidocaine spray group had less pain than the cryotherapy group. Lidocaine spray was an easy, convenient, and non-invasive technique. Local lidocaine spray application before amniocentesis followed by cryotherapy after the procedure might be in the next investigation.

Potential conflicts of interest

The authors declare no conflicts of interest.

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