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Effectiveness of paracervical block in endometrial sampling procedures for pain control: a randomized controlled clinical trial

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ABSTRACT

Objectives: We aimed to evaluate the effect of paracervical block (PCB) on endometrial sampling procedures, to assess the effect on pain of waiting between PCB and intervention, and to compare the effectiveness of PCB with oral non-steroidal anti-inflammatory drugs (NSAID) for decreasing the pain levels associated with endometrial biopsy.

Material and methods: A total of 123 participants were divided into four groups as Group 1: Waiting 1 minute after PCB, Group 2: Waiting 3 minute after PCB, Group 3: Control group, and Group 4: Waiting 60 minute after taking oral NSAIDs. The success of analgesic measures used for endometrial biopsy during and 30 minutes after the procedure was compared with the Numeric Pain Rating Scale (NPRS) system.

Results: The Numeric Pain Rating Scale (NPRS) 0 score was 2.60 (± 2.42) in Group 1; 1.60 (± 1.73) in Group 2; 5.30 (± 2.10) in Groups 3; 5.63 (± 1.99) in Groups 4. NPRS 30 score was 0.80 (± 0.88) in Group 1; 0.43 (± 0.81) in Group 2; 1.90 (± 1.32) in Groups 3; 2.70 (± 1.41) in Groups 4. The pain was significantly less in the paracervical block groups compared to control and oral NSAIDs groups. However, there was no significant difference in NPRS 0 ($p = 0.196$) and NPRS 30 ($p = 0.191$) scores between Group 1 and Group 2. There was no significant difference in NPRS 0 and NPRS 30 scores between control group and oral NSAID group.

Conclusions: Paracervical block (PCB) is an effective method and superior to oral NSAIDs. Waiting 1 minute or 3 minutes after PCB were equally effective.

Key words: endometrial sampling; numeric pain rating scale; oral NSAIDs; pain control; paracervical block

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INTRODUCTION

Currently, office-based endometrial procedures are preferred over diagnostic dilation and curettage. Short operation time, low uterine perforation risk, no need for an operating room, and low cost are the benefits of sampling procedures.

Office sampling procedures do not cause severe pain, but several approaches are used by clinicians to reduce the discomfort due to the operation. Oral nonsteroidal anti-inflammatory drugs (NSAID) taken 30 minutes before the procedure, intrauterine instillation of local anaesthetics, topical 10% lidocaine spray, and paracervical block are the accepted methods [1–3].

Frankenhauser (or uterovaginal) plexus contains fibers derived from the inferior hypogastric plexus (T10-L1) and sacral nerve roots (S1–S4). Paracervical block targets this plexus before it enters the uterus at the level of the internal cervical os. The paracervical block is a single-shot nerve block that involves a one-time injection of local anaesthetic adjacent to the uterovaginal nerve plexus. The block provides analgesia during the cervical pass of the sampling device or manipulation of the cervix. A study showed that paracervical block decreased the pain during intrauterine device placement in 64 nulliparous women [4].

Objectives

The paracervical block seems to work within a few minutes after injection, but the optimal waiting time between injection and the procedure is not known. This prospec-

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tive, randomized controlled, non-blinded study aimed to determine the effect of a waiting time of 1 minute and 3 minutes after paracervical block in endometrial sampling procedures using the Pipelle cannula on pain during and after endometrial sampling and compare with NSAIDs taken before the procedure.

MATERIAL AND METHODS

We enrolled 123 participants who underwent endometrial biopsy due to abnormal uterine bleeding in the current study in the Ege University Hospital from September 29, 2020, through November 3, 2020. Inclusion criteria were absence of major psychiatric symptoms, Turkish language comprehension, and age 35 years or older. Pregnancy, pelvic infections, current heavy menstrual bleeding, and NSAID allergy were the exclusion criteria (Fig. 1). Two participants with findings of pelvic infection and a pregnant participant were excluded from the study. Participants were divided into 4 groups using a computer-generated randomization list. These groups were Group 1: Waiting 1 minute after paracervical block, Group 2: Waiting 3 minute after paracervical block, Group 3: Control group, and Group 4: Waiting 60 minute after taking oral NSAIDs. The Numeric Pain Rating Scale (NPRS) system was used to assess pain for each case during and 30 minutes after the procedure. According to this system, "0" indicated no pain, and "10" points represented the most severe pain.

Before the procedure, the cervix and vaginal vault were prepared with povidone-iodine. A vaginal speculum was used for optimal exposure and manipulation of the cervix. All procedures were performed without grasping the cervix with a tenaculum. Two-point (at 4 and 8 o'clock position only) technique was used for the paracervical block for Group 1: Waiting 1 minute after paracervical block and Group 2: Waiting 3 minute after paracervical block. For these groups, a total of 10 ml of 2% prilocaine (VEM İlac, Tekirdag, Turkey) was injected at 4 o'clock and 8 o'clock positions approximately 10 mm into the cervical stroma at the cervicovaginal junction with a 22-gauge hypodermic needle. The capped needle model was used for Group 3: Control group. After cervical and vaginal preparation with povidone-iodine, a capped needle touched the cervicovaginal junction at the 4 and 8 o'clock position. Participants in Group 4 took 550 mg of naproxen sodium (Abdi Ibrahim, Turkey) 60 minutes before the procedure.

For all procedures, a low-pressure sampling device (Pipelle Cannula, Medbar Medical Equipment Inc.) was inserted into the cavity, and endometrial samples were obtained using a corkscrew rotation combined with a repeating cephalic-caudal motion. The procedure was repeated

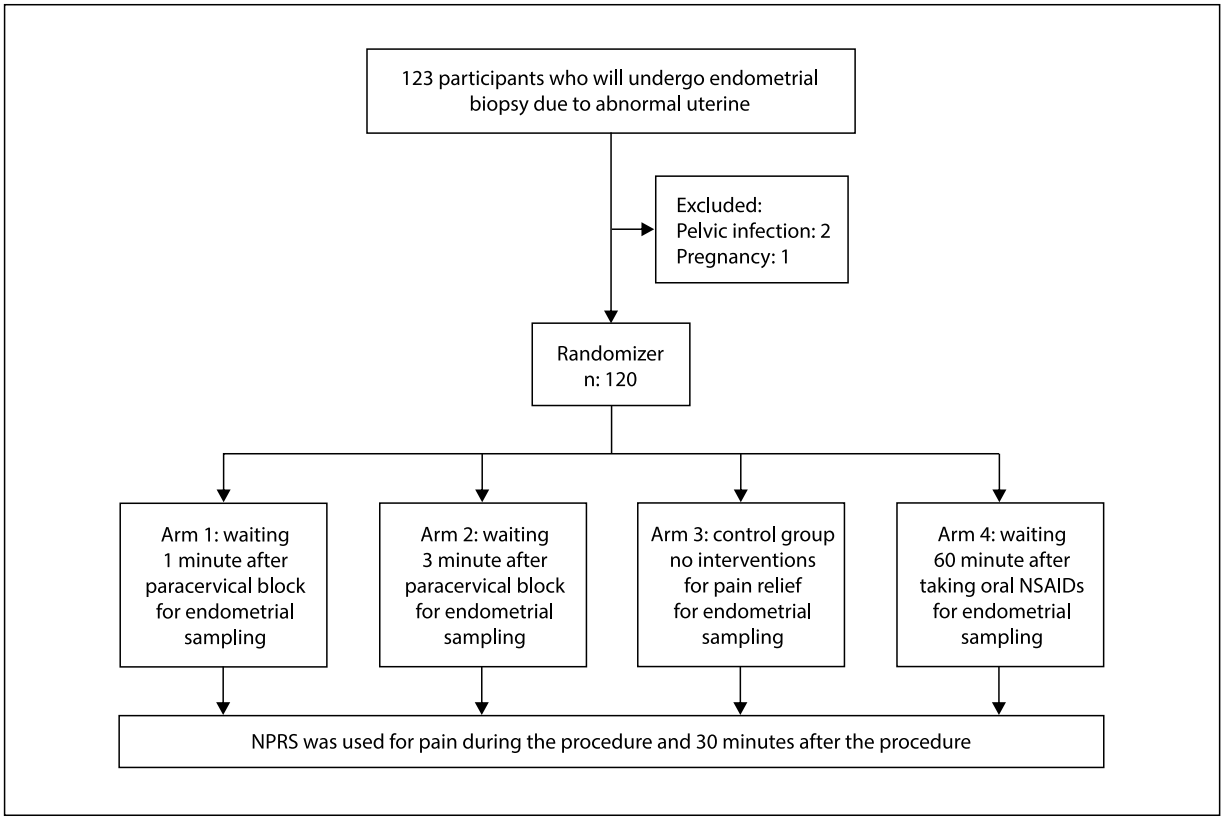

Figure 1. Participant's Flow Chart; NSAID — non-steroidal anti-inflammatory drugs; NPRS — Numeric Pain Rating Scale

twice in each case to ensure standardization. All endometrial biopsies were performed by the same operator.

The NPRS system was explained to all groups after the procedure, and the participants were requested to grade the pain during the procedure. Thirty minutes after the procedure, the participants were asked to rate current pain according to the NPRS system.

According to previous trials, we calculated those 123 participants would be required for 80% power with a type I error (α) rate of 5% to detect this difference with 3% drop-out rate [4, 5]. Categorical variables were analysed with frequency tables, and descriptive statistics were calculated for continuous variables. The Shapiro-Wilk normality test was used to analyse whether continuous data were normally distributed. As the data were not normally distributed, the Kruskal-Wallis test was used for comparing more than two independent groups. When the difference between the groups was statistically significant, Bonferonni correction was made in post hoc comparisons after the Kruskal-Wallis test. Spearman's correlation coefficient was used to analyze the relation to between continuous variables. The significance level was taken as 0.05 in all hypothesis tests. All statistical analyses were performed using the IBM SPSS Version 25.0 statistical package program.

The study was approved by Ege University Institutional Ethics Committee with 20-6.1T/67 reference number on 25 June 2020. Written informed consent was obtained from all participants. All procedures performed in the current study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Trial registry name is "Effectiveness of Paracervical Block in Endometrial Sampling Procedures for Pain Control" and Clinical Trial Registration Number is NCT04572828. Initial participant was enrolled on September 29, 2020 [6].

RESULTS

Mean age was 48.23 (± 11.74) years in Group 1; 46.23 (± 5.33) years in Group 2; 51.78 (± 8.21) years in Groups 3; 46.53 (± 7.10) years in Groups 4. There was no significant difference in demographic data between groups (Tab. 1, Tab. 2). Mean endometrial thickness was 8.66 (± 2.86) mm in Group 1; 8.71 (± 2.93) mm in Group 2; 8.74 (± 2.61) mm in Groups 3; 9.66 (± 3.02) mm in Groups 4. Sixty-six of the participants were in the premenopausal period, and the remaining 54 were in the postmenopausal period.

NPRS 0 score was 2.60 (± 2.42) in Group 1; 1.60 (± 1.73) in Group 2; 5.30 (± 2.10) in Groups 3; 5.63 (± 1.99) in Groups 4. NPRS 30 score was 0.80 (± 0.88) in Group 1; 0.43 (± 0.81) in Group 2; 1.90 (± 1.32) in Groups 3; 2.70 (± 1.41) in Groups 4 (Tab. 3).

NPRS 0 score was significantly less in Group 1 compared to control ($p < 0.001$) and oral NSAIDs groups ($p < 0.001$). NPRS 30 score was significantly less in Group 1 compared to the control group ($p < 0.001$) and the oral NSAIDs group ($p < 0.001$). As expected, NPRS 0 score was significantly less in the waiting 3 minute after paracervical block group compared to Group 3 ($p < 0.001$) and Group 4 ($p < 0.001$). Further, NPRS 30 score was significantly less in the waiting 3 minute after paracervical block group compared to Group 3 ($p < 0.001$) and Group 4 ($p < 0.001$). However, there was no significant difference in NPRS 0 ($p = 0.196$) and NPRS 30 ($p = 0.191$) scores between Group 1: Waiting 1 minute after paracervical block and Group 2: Waiting 3 minute after paracervical block (Fig. 2). Furthermore, there was no significant difference in NPRS 0 ($p = 0.643$) and NPRS 30 ($p = 0.064$) scores between Groups 3: Control group and Groups 4: Waiting 60 minute after taking oral NSAIDs (Fig. 3).

The current study showed that menopausal status, day of menstruation, and endometrial thickness had no effect on pain during the endometrial sampling procedure. There were no patient-reported adverse effects and major complications during the trial.

DISCUSSION

Low-pressure endometrial sampling devices such as the Pipelle cannula are the most popular biopsy devices in modern gynaecological practice [7]. The diagnostic value of low-pressure sampling devices depends on the types of indications, BMI, age, and menopausal status [8]. Although endometrial sampling with a Pipelle is relatively painless, a mild-moderate pain is reported by women in the absence of measures to minimize discomfort during the operation [1]. These techniques are sedoanalgesia, oral NSAID intake before the procedure, and administration of a paracervical block and topical local anaesthetic spray application to the cervix [9]. Sedoanalgesia ensures sufficient conditions for cervical dilatation and uterine intervention. According to a prospective randomized double-blind study, intravenously administered lidocaine reduced the pain scores compared to the control group during colposcopic cervical biopsy and endocervical curettage [10]. However, PCB offers an alternative for cervical dilatation and uterine intervention in high-risk patients for sedoanalgesia or if no anaesthesiologist is available. Cervical dilatation or cervical pass with a sampling device is one of the significant causes of pain associated with the procedure [11]. Therefore, one should aim to minimize the pain experienced during this part of the procedure with a paracervical block.

Paracervical block (PCB) is an effective and easy-to-perform method for gynaecologists, especially before intrauterine interventions, although many nerve blocks are performed by anaesthesiologists. However, the efficiency of

Table 1. Demographic data — 1

Trial arms			Statistic	Standard error
Gravida	Waiting 1 minute after paracervical block	Mean	2.93	0.389
		Standard deviation	2.132	
		Minimum	0	
		Maximum	9	
	Waiting 3 minutes after paracervical block	Mean	2.47	0.190
		Standard deviation	1.042	
		Minimum	0	
		Maximum	4	
	Control group	Mean	3.13	0.481
		Standard deviation	2.636	
		Minimum	0	
		Maximum	15	
	Waiting 60 minutes after taking oral NSAIDs	Mean	2.53	0.229
		Standard deviation	1.252	
		Minimum	1	
		Maximum	7	
Parity	Waiting 1 minute after paracervical block	Mean	2.90	0.388
		Standard deviation	2.123	
		Minimum	0	
		Maximum	9	
	Waiting 3 minutes after paracervical block	Mean	2.33	0.188
		Standard deviation	1.028	
		Minimum	0	
		Maximum	4	
	Control group	Mean	2.53	0.355
		Standard deviation	1.943	
		Minimum	0	
		Maximum	11	
	Waiting 60 minutes after taking oral NSAIDs	Mean	2.33	0.205
		Standard deviation	1.124	
		Minimum	1	
		Maximum	7	

NSAID — non-steroidal anti-inflammatory drugs

PCB is controversial and the optimal waiting time after PCB is unknown. There are two opinions for how the PCB works: it may have an infiltrative part, relying on distention, or it may work as a peripheral nerve block, requiring time to diffuse into the neurons to block pain. The distention action would be immediate; the blockage of pain transmission would need 1 to 3 minutes for the onset of action when prilocaine is used. Hall et. al. [12] concluded that the addition of PCB to general anaesthesia for first trimester abortion did not influence pre- and postoperative pain scores significantly or analgesic consumption. In a prospective, randomised-controlled study, no beneficial effect was found when a PCB was added to either systemic or local analgesics for pain control during and 30 min after hysterosalpingography [13]. Conversely, in a randomised, double-blind, placebo-controlled trial, significant pain reduction was achieved for both intraoperative and postoperative period with PCB or lidocaine spray during first- trimester surgical abortion [5]. Kalkat & Cartmill [14] demonstrated that impedance controlled endometrial ablation procedure for menorrhagia is acceptable for use in an outpatient setting under PCB with high acceptance and success rates. In a randomized controlled trial, a wait of 3 min after PCB was more effective in reducing pain than no waiting before a first-trimester surgical abortion, although the difference did not reach a significant level [15]. Phair et. al. [16] found that delay between PCB and intervention

Table 2. Demographic data — 2

Trial arms			Statistic	Standard error
Caesarean history	Waiting 1 minute after paracervical block	Mean	0.47	0.133
		Standard deviation	0.730	
		Minimum	0	
		Maximum	2	
	Waiting 3 minutes after paracervical block	Mean	0.60	0.170
		Standard deviation	0.932	
		Minimum	0	
		Maximum	3	
	Control group	Mean	0.67	0.168
		Standard deviation	0.922	
		Minimum	0	
		Maximum	3	
	Waiting 60 minutes after taking oral NSAIDs	Mean	0.73	0.191
		Standard deviation	1.048	
		Minimum	0	
		Maximum	3	
Day of menstruation	Waiting 1 minute after paracervical block	Mean	8.97	1.753
		Standard deviation	9.601	
		Minimum	0	
		Maximum	30	
	Waiting 3 minutes after paracervical block	Mean	9.50	1.262
		Standard deviation	6.912	
		Minimum	0	
		Maximum	26	
	Control group	Mean	6.67	1.367
		Standard deviation	7.489	
		Minimum	0	
		Maximum	23	
	Waiting 60 minutes after taking oral NSAIDs	Mean	6.87	1.087
		Standard deviation	5.952	
		Minimum	0	
		Maximum	20	

NSAID — non-steroidal anti-inflammatory drugs

does not have an impact on pain during first trimester elective abortion.

The current study was conducted to compare the effectiveness of pain control after a wait of 1 and 3 min following a PCB and oral intake of NSAİD 60 min before the procedure. The evaluation was made using NPRS 0 and NPRS 30 scores. In our study, the lowest NPRS 0 and NPRS 30 scores were in Group 2: Waiting 3 minute after paracervical block. Group 2 was followed by Group 1: Waiting 1 minute after paracervical block. However, the difference did not reach a statistically significant level. The study results suggest that the distention mechanism predominates because a waiting period produced no additional anaesthetic effect. Regardless of waiting times, maximum pain control was achieved in the paracervical block groups compared to control and oral NSAID groups during the procedure and 30 minutes after the procedure. We did not find a significant difference in pain scores between the intervention and control groups according to the menopausal status, contrary to previous studies [15, 16].

A randomized controlled trial showed that the administration of 550 mg of naproxen sodium 60 min before the procedure was equally effective as intrauterine lidocaine injection [2]. However, we did not find any significant difference in NPRS 0 and NPRS 30 scores between control group and Oral NSAIDs group.

Table 3. The Numeric Pain Rating Scale (NPRS) scores for each arm

Trial arms			Statistic	Standard error
NPRS 0	Waiting 1 minute after paracervical block	Mean	2.60	0.451
		Standard deviation	2.472	
		Minimum	0	
		Maximum	10	
	Waiting 3 minutes after paracervical block	Mean	1.60	0.317
		Standard deviation	1.734	
		Minimum	0	
		Maximum	6	
	Control group	Mean	5.30	0.384
		Standard deviation	2.103	
		Minimum	2	
		Maximum	10	
	Waiting 60 minutes after taking oral NSAIDs	Mean	5.63	0.364
		Standard deviation	1.991	
		Minimum	2	
		Maximum	10	
NPRS 30	Waiting 1 minute after paracervical block	Mean	0.80	0.162
		Standard deviation	0.887	
		Minimum	0	
		Maximum	3	
	Waiting 3 minutes after paracervical block	Mean	0.43	0.149
		Standard deviation	0.817	
		Minimum	0	
		Maximum	3	
	Control group	Mean	1.90	0.241
		Standard deviation	1.322	
		Minimum	0	
		Maximum	6	
	Waiting 60 minutes after taking oral NSAIDs	Mean	2.70	0.259
		Standard deviation	1.418	
		Minimum	1	
		Maximum	7	

NSAID — non-steroidal anti-inflammatory drugs

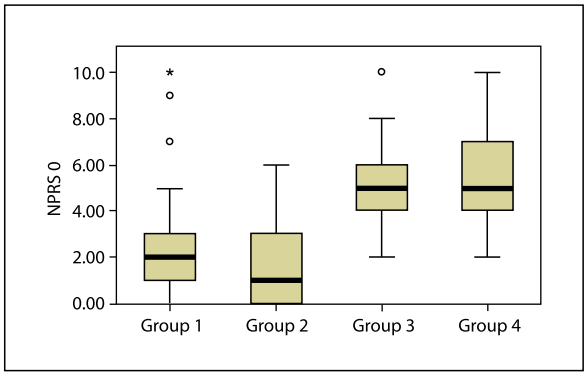

Figure 2. Numeric Pain Rating Scale (NPRS) 0 Scores in Groups

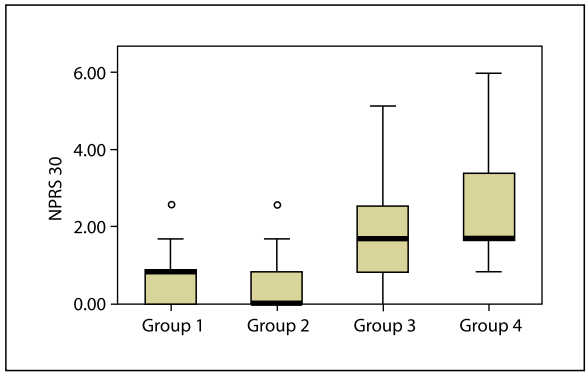

Figure 3. Numeric Pain Rating Scale (NPRS) 30 Scores in Groups

The strengths of this study are randomized controlled design and the use of the NPRS system for pain assessment. Further, the procedures were performed by the same physician to avoid differences between operators. The limitation of this trial was combining pre- and post-menopausal women, although it represented local demographics.

CONCLUSIONS

Paracervical block is an effective method for pain control for endometrial sampling procedures and superior to oral NSAIDs. Waiting 1 minute or 3 minutes after PCB were equally effective in terms of pain during endometrial biopsy with a low-pressure sampling device.

Conflict of interest

All authors declare no conflict of interest.

REFERENCES

1. Trolice M. Anesthetic efficacy of intrauterine lidocaine for endometrial biopsy: a randomized double-masked trial. Obstetrics & Gynecology. 2000; 95(3): 345–347, doi: 10.1016/s0029-7844(99)00557-8.
2. Dogan E, Celiloglu M, Sarihan E, et al. Anesthetic effect of intrauterine lidocaine plus naproxen sodium in endometrial biopsy. Obstet Gynecol. 2004; 103(2): 347–351, doi: 10.1097/01.AOG.0000109519.74229.30, indexed in Pubmed: 14754707.
3. Luangtangvarodom W, Pongrojpaw D, Chanthasenanont A, et al. The Efficacy of Lidocaine Spray in Pain Relief during Outpatient-Based Endometrial Sampling: A Randomized Placebo-Controlled Trial. Pain Research and Treatment. 2018; 2018: 1–5, doi: 10.1155/2018/1238627.
4. Mody SK, Farala JP, Jimenez B, et al. Paracervical Block for Intrauterine Device Placement Among Nulliparous Women: A Randomized Controlled Trial. Obstet Gynecol. 2018; 132(3): 575–582, doi: 10.1097/AOG.0000000000002790, indexed in Pubmed: 30095776.
5. Aksoy H, Aksoy U, Ozyurt S, et al. Comparison of lidocaine spray and paracervical block application for pain relief during first-trimester surgical abortion: A randomised, double-blind, placebo-controlled trial. J Obstet Gynaecol. 2016; 36(5): 649–653, doi: 10.3109/01443615.2016.1148681, indexed in Pubmed: 26926158.
6. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04572828?term=NCT04572828&draw=2&rank=1 (19.01.2022).
7. Leclair CM, Zia JK, Doom CM, et al. Pain experienced using two different methods of endometrial biopsy: a randomized controlled trial. Obstet Gynecol. 2011; 117(3): 636–641, doi: 10.1097/AOG.0b013e31820ad45b, indexed in Pubmed: 21343767.
8. Piątek S, Panek G, Wielgoś M. Assessment of the usefulness of pipelle biopsy in gynecological diagnostics. Ginekol Pol. 2016; 87(8): 559–564, doi: 10.5603/GP.2016.0044, indexed in Pubmed: 27629129.
9. Tangsiriwatthana T, Sangkomkamhang US, Lumbiganon P, et al. Paracervical local anaesthesia for cervical dilatation and uterine intervention. Cochrane Database Syst Rev. 2013(9): CD005056, doi: 10.1002/14651858.CD005056.pub3, indexed in Pubmed: 24085642.
10. Topdağı YE, Topdagi Yilmaz EP, Aydin ME, et al. Does intravenous lidocaine added to nonsteroidal anti-inflammatory drugs reduce pain during colposcopy? A prospective randomized double-blind study. Ginekol Pol. 2021; 92(12): 844–849, doi: 10.5603/GP.a2021.0058, indexed in Pubmed: 33914314.
11. Einarsson JI, Henao G, Young AE. Topical analgesia for endometrial biopsy: a randomized controlled trial. Obstet Gynecol. 2005; 106(1): 128–130, doi: 10.1097/01.AOG.0000165272.62416.61, indexed in Pubmed: 15994627.
12. Hall G, Ekblom A, Persson E, et al. Effects of prostaglandin treatment and paracervical blockade on postoperative pain in patients undergoing first trimester abortion in general anesthesia. Acta Obstet Gynecol Scand. 1997; 76(9): 868–872, doi: 10.3109/00016349709024367, indexed in Pubmed: 9351414.
13. Hacivelioglu S, Gencer M, Cakir Gungor A, et al. Can the addition of a paracervical block to systemic or local analgesics improve the pain perceived by the patient during hysterosalpingography? J Obstet Gynaecol. 2014; 34(1): 48–53, doi: 10.3109/01443615.2013.828025, indexed in Pubmed: 24359050.
14. Kalkat RK, Cartmill RSV. NovaSure endometrial ablation under local anaesthesia in an outpatient setting: An observational study. J Obstet Gynaecol. 2011; 31(2): 152–155, doi: 10.3109/01443615.2010.538772, indexed in Pubmed: 21281033.
15. Renner RM, Edelman AB, Nichols MD, et al. Refining paracervical block techniques for pain control in first trimester surgical abortion: a randomized controlled noninferiority trial. Contraception. 2016; 94(5): 461–466, doi: 10.1016/j.contraception.2016.05.005, indexed in Pubmed: 27235677.
16. Phair N, Jensen JT, Nichols MD. Paracervical block and elective abortion: the effect on pain of waiting between injection and procedure. Am J Obstet Gynecol. 2002; 186(6): 1304–1307, doi: 10.1067/mob.2002.123734, indexed in Pubmed: 12066113.
17. Güney M, Oral B, Mungan T. Intrauterine lidocaine plus buccal misoprostol in the endometrial biopsy. Int J Gynaecol Obstet. 2007; 97(2): 125–128, doi: 10.1016/j.ijgo.2006.11.017, indexed in Pubmed: 17316648.
18. Api O, Ergen B, Api M, et al. Comparison of oral nonsteroidal analgesic and intrauterine local anesthetic for pain relief in uterine fractional curettage: a randomized, double-blind, placebo-controlled trial. Am J Obstet Gynecol. 2010; 203(1): 28.e1–28.e7, doi: 10.1016/j.ajog.2010.02.029, indexed in Pubmed: 20435293.