Paracervical Block for Intrauterine Device Placement among Class II Obese Women: A Single-Blinded Randomized

Original Article

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ABSTRACT

Background: The intrauterine contraceptive device (IUCD) is the most widely used reversible contraceptive, with around 120 million users worldwide. Its popularity stems from its high efficacy, reversibility, and proven safety. However, pain during insertion can limit its use, particularly among obese women. To address this, both non-pharmacologic and pharmacologic pain management strategies are employed, with paracervical block being a common technique that is regarded as both safe and easy to perform during IUCD insertion.

Aim: To assess the effectiveness of paracervical block for management of pain during IUCD insertion in class II obese women..

Materials and Methods: A prospective randomized controlled trial was conducted at the family planning clinic, Obstetrics and Gynecology department of Ain Shams hospitals during the period from 1/1/2024 to 31/12/2024. A total of 140 women undergoing IUCD insertion were divided into two groups: Group A (non-intervention group): Includes 70 women who didn't receive and local anethesia. Group B (intervention group): Includes 70 women who received paracervical block before IUCD insertion.

Results: The demographic characteristics of participants in both groups were comparable, Women who received the paracervical block reported less pain with IUCD insertion compared to women who received no block (median VAS: 3 vs. 5, $p<0.0001$), they also experienced less pain during vulsellum application (median VAS: 1 vs. 2, $p<0.0001$), uterine sounding (median VAS: 2.5 vs. 3, $p<0.0001$) and five minutes post-insertion (median VAS: 1 vs. 3, $p<0.0001$) which is statistically significant, However, there was no statistically significant perceived pain difference during specu-lum insertion (median VAS: 4 vs. 3, $p=0.3248$).

Conclusion: 20 ml lidocaine 1% paracervical block significantly decreased perceived pain during IUCD insertion compared to no intervention.

Key Words: Intrauterine contraceptive device, lidocaine, pain, paracervical block, ..

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INTRODUCTION

Contraceptive use globally is shaped by socioeconomic status, cultural norms, and healthcare access. An estimated 65% of reproductive-aged women use contraception, with intrauterine contraceptive devices (IUCDs), oral pills, and sterilization being most common (United Nations, 2022). Utilization remains lower in low-income regions due to limited access to family planning and education. Expanding availability and awareness is associated with fewer unintended pregnancies and improved maternal outcomes[1].

The IUCD is the most widely used reversible contraceptive, with about 120 million users—10–15% of women of reproductive age—due to its high efficacy, reversibility, and safety[2]. Standard insertion involves bimanual examination and uterine sounding, followed by device placement and thread trimming. It can be performed at any time during the menstrual cycle if pregnancy is excluded[3].

Pain during insertion remains a barrier, particularly for young or nulliparous women. Discomfort may occur at various stages—vaginal examination, speculum and tenaculum use, uterine traction, hysterometry, and insertion[4]. Pain transmission occurs via pelvic splanchnic nerves through the uterosacral ligaments.

Management strategies include non-pharmacologic methods like counseling and distraction, though their efficacy is uncertain[5]. Pharmacologic options include

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oral analgesics, cervical ripening agents, local anesthesia, NSAIDs, and opioids[6].

Paracervical block (PCB) is commonly used, involving 10 mL of anesthetic at the 4 and 8 o'clock positions near the hypogastric nerves. It reduces pain significantly, with onset in 3–5 minutes and rare complications such as hematoma, bleeding, or infection[7,8].

Obesity, classified by BMI as Class I (30–34.9), II (35–39.9), and III (≥40 kg/m²), increases contraceptive risks, particularly VTE, MI, and stroke with estrogen use[9,10]. The IUCD is a safe, first-line option for obese women, with a failure rate below 1 per 100 woman-years. However, insertion may be more challenging due to difficulty in visualizing the cervix and assessing uterine orientation, often necessitating additional manipulation and longer instruments. In such cases, PCB may be especially beneficial[11].

AIM OF THE WORK

The study aims to investigate the efficacy of paracervical block in pain management for intrauterine device placement among class II obese women.

PATIENTS AND METHODS

A prospective, single-blinded, randomized controlled trial was conducted at the Family Planning Clinic of the Obstetrics and Gynecology Department, Ain Shams University Hospitals, from January 1 to December 31, 2024. Participants were selected using simple random sampling, and randomization was performed by labeling 140 envelopes with sequential numbers and randomly assigning each to either the paracervical block group or the no-intervention group; envelopes were opened in order, and patients were assigned accordingly. The study included women aged 18–45 years, with a BMI of 35–39.9 kg/m², planning for intrauterine contraceptive device (IUCD) insertion, and presenting during the postmenstrual period. Exclusion criteria included confirmed or suspected pregnancy, being 48 hours to less than 4 weeks postpartum, uterine anomalies or fibroids distorting the cavity, sexually transmitted or ongoing pelvic infections, septic abortion or postpartum endometritis within the past 3 months, abnormal vaginal bleeding, uterine or cervical neoplasia, gestational trophoblastic disease, and severe thrombocytopenia (<50,000/μL), thalassemia, sickle cell disease, or iron-deficiency anemia, known allergies to lidocaine, sensitivity to copper or Wilson's disease, recent analgesic or anxiolytic use within 6 hours before procedure and refusal to participate.

Basic assessment

All patients were subjected to:

Personal history: Name – age – parity – occupation – special habits of medical importance). Family history Any gynaecological complaint including: Amenorrhea. Unexplained vaginal bleeding. Postcoital or contact bleeding. Vaginal discharge. Vulval itching or pruritis. Pelvic heaviness or pain. Pain during intercourse. Painful urination.

Obstetric history:

Nulliparity. Known current or suspected pregnancy. Delivery or miscarriage in the last 4 weeks. Current infection after delivery or miscarriage (puerperal sepsis, septic abortion). Past ectopic pregnancy.

Menstrual history:

Last menstrual date. Irregular menses, Excessive or prolonged menses, intermenstrual bleeding. Severe Dysmenorrhea.

Gynecological history:

Known current cervical, endometrial, ovarian cancer or gestational trophoblastic disease. Known uterine anatomical abnormalities or other abnormalities (including cervical stenosis or cervical lacerations). Previous or current pelvic inflammatory disease. Previous or current sexually transmitted infection. Cervicitis or vaginitis. Current contraception method used and duration of usage.

Medical history:

Known anemia (Thalassemia, Sickle disease and Iron deficiency anemia). Systemic lupus erythematosus with severe thrombocytopenia. Immunosuppressive therapy. Known drug allergies. Known pelvic tuberculosis.

Surgical history:

General Examination: Vital signs (Blood pressure, pulse, temperature, respiratory rate; body mass index (BMI). and blood pressure). Assessment of anthropometric measurements as: weight, height, BMI (kg/m2),: Body height and weight were measured on the digital scale with no shoes. The following formula was used to evaluate BMI: BMI—body mass index [kg/m^2] = body mass (kg) / height (m)^2

Study intervention:

Patients were randomly assigned into 2 groups: Group A (non-intervention group): (70) patients who did not receive any local anethesia. Group B (intervention group):

(70) patients who had paracervical block. In Group A, a placebo procedure involved gentle application of a capped needle at the vulsellum site and vaginal fornices before IUCD insertion without analgesia to maintain blinding[12]. In Group B, a 20 cc paracervical block, 18 cc 1% lidocaine (Debocaine 50ml DBK Pharma) with 2 cc sodium bicarbonate (Otsuka 8.4% 25ml) was administered—2 cc superficially at the vulsellum site and 18 cc equally at the 4 and 8 o'clock vaginal fornices, with precautions to avoid intravenous injection[13]. Procedures were performed under consultant supervision with participants in dorsolithotomy position and instructed to have a full bladder. Standard pelvic exam and vaginal cleaning with 10% povidone iodine preceded IUCD placement 5 minutes after block or placebo. Pain was measured by a 10-point Visual Analog Scale (VAS) at six stages: speculum placement, vulsellum placement, paracervical block, uterine sounding, IUCD insertion, and 5 minutes post-insertion. Pain was categorized as none (0), mild (1–3), moderate (4–6), or severe (7–10). Participants were offered oral NSAIDs post-procedure; prophylactic antibiotics were not given due to lack of significant benefit.

Study outcome

To assess the effectiveness of paracervical block for management of pain during IUCD insertion in class II obese women by using a 10-point visual analogue scale (VAS) at 6 different points: Cusco speculum placement, vulsellum placement, paracervical block, uterine sounding, IUCD insertion and 5 mins after IUCD placement.

Ethical consideration

The study received approval from the Scientific Research Ethics Committee at Ain Shams University Faculty of Medicine. Informed consent was obtained from all participants after explaining the study's purpose, objectives, procedures, potential risks and benefits, and their rights. Participants could withdraw at any time without affecting their medical care. The study was self-funded by the investigator, and administrative permission was also secured.

Statistical analysis

Data were analyzed using Statistical package for Social Science (SPSS) version 27.0., Quantitative data were expressed as mean± standard deviation (SD) or Median (IQR) when indicated. Qualitative data were expressed as frequency and percentage.

The following tests were used: Independent-samples t-test of significance was used when comparing between two means. Chi-square (X2) test of significance was used in order to compare proportions between two qualitative parameters. Mann Whitney U test: for two-group comparisons in non-parametric data. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following: *P-value* <0.05 was considered significant. 140 patients were enrolled in the study. 70 patients in each group.

RESULTS

Demographics

Groups were comparable in demographic data (in terms of age, parity and BMI) and there was no statistically significant difference between groups (*p-value* > 0.05) (Table 1).

Table 1: Comparison between groups as regard demographic data

		Group with paracervical block (*n*=70)	Group without paracervical block (*n*=70)	*p-value*
Age (years)		33.91±7.38	31.93±7.4	0.114 *t*
BMI (Kg/m²)		36.49±1.11	36.59±1.09	0.598 *t*
Parity	Caesarean Section	30 42.9%	43 61.4%	0.06 ^{x2}
	Nulligravida	1 1.4%	1 1.4%	
	Vaginal Delivery	30 42.9%	24 34.3%	
	Vaginal Delivery and Caesarean Section	9 12.9%	2 2.9%	

Data expressed as mean ± SD, proportion and percent, t = student t test, X2 = chi square.

The two groups were demographically similar. The mean age was 33.91 ± 7.38 years in the paracervical block group and 31.93 ± 7.4 years in the control group (*p*=0.114), while the mean BMI was 36.49 ± 1.11 kg/m² and 36.59 ± 1.09 kg/m², respectively (*p*=0.598). Cesarean delivery history was more common in the control group (61.4% vs. 42.9%), whereas vaginal delivery was slightly more frequent in the block group (42.9% vs. 34.3%). A history of both delivery types was reported in 12.9% of the block group and 2.9% of the control group. Parity differences were not statistically significant (*p*=0.06), indicating well-matched groups.

Pain scores

Groups were compared in pain data by VAS score during the procedure steps and there was statistically significant difference between groups in all steps except for speculum application (*p-value* > 0.05) (Table 2).

Table 2: Comparison between groups as regard VAS data:

	Intervention Group (paracervical block) (*n*=70)			Non-intervention Group (no block) (*n*=70)			*p-value*[a]
	Range	Median	IQR	Range	Median	IQR	
Speculum	2-7	4	3-4	2-7	3	2-5	0.3248
Vulsellum	0-2	1	0-1	1-5	2	1-3	<0.0001
Uterine Sound	1-6	2.5	2-3	2-8	4	3-6	<0.0001
IUCD insertion	1-7	3	2-4	2-9	5	4-6	<0.0001
5 mins Post insertion	0-4	1	1-2	1-5	3	2.4	<0.0001

Data expressed as range, median and IQR. a = Mann-Whitney test

Table 3: VAS score during the block.

	Group paracervical block (*n*=70)		
	Range	Median	IQR
Paracervical block	1-4	2	1-3

As shown in Table 2, pain during speculum insertion was similar between groups (median VAS: 4 vs. 3, p=0.3248). However, the paracervical block group reported significantly lower pain during vulsellum application (1 vs. 2, p<0.0001), uterine sounding (2.5 vs. 3, p<0.0001), IUCD insertion (3 vs. 5, p<0.0001), and five minutes post-insertion (1 vs. 3, p<0.0001), demonstrating the block's effectiveness in reducing pain at multiple stages of the procedure.

Additionally, Table 3 reports the pain associated with the administration of the paracervical block itself, with a median VAS score of 2 (range: 1–4, IQR: 1–3). While the block effectively minimized procedural pain, its administration caused mild to moderate discomfort[13].

(Figure 1) shows that VAS pain scores were consistently lower in the paracervical block group across all IUCD insertion steps, except for speculum insertion, where pain was similar. The greatest pain reduction occurred during vulsellum application, uterine sounding, IUCD insertion, and five minutes post-insertion. Outliers in both groups indicate variability in pain perception, visually supporting the block's effectiveness in reducing procedural pain (Table 3).

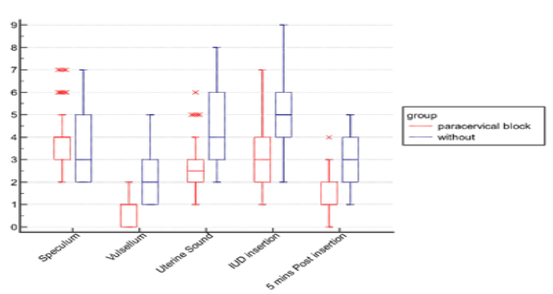

Fig. 1: Box and whisker graph between groups as regard VAS score

DISCUSSION

Intrauterine contraceptive devices (IUCDs) are highly effective reversible contraceptives, but fear of insertion pain—especially among adolescents and young women—remains a barrier[12]. Pain may occur at multiple stages: vaginal exam, speculum and tenaculum use, uterine traction, hysterometry, and IUCD insertion[14].

Negative IUCD perceptions, anxiety, and cesarean history are linked to greater pain, particularly among women with dysmenorrhea. Prior vaginal delivery with epidural, high parity, and prior IUCD use are associated with less pain. Anticipated pain correlates with actual pain[15].

Pain management options include NSAIDs, local anesthetics, and misoprostol[16]. Paracervical block (PCB) efficacy varies based on site, depth, volume, and anesthetic used. It may reduce pain during IUCD insertion[13].

This study aimed to evaluate PCB efficacy for IUCD insertion pain in class II obese women. 140 participants at Ain Shams University were randomized: Group A (no PCB) and Group B (received 20 mL buffered 1% lidocaine PCB). Pain was assessed via a 10 cm VAS[17-19], unlike other studies using 1–100 VAS[20-22].

Age, BMI, and parity showed no significant differences between groups, aligning with Mody *et al*.[13] and Khedr *et al*.[22] The median VAS score in the PCB group was 2 (1–3). A statistically significant reduction in pain during insertion was observed in the PCB group, consistent with Mody *et al*.[13] and Khedr *et al*.[22]. Mody *et al*.[21], however, found no reduction using unbuffered lidocaine.

Mody *et al*.[13] reported lower pain with 20 mL buffered 1% lidocaine in nulliparous women, although the injection itself was painful. Differences included their use of a sham block. Similarly, Khedr *et al*.[22] found PCB reduced pain,

though pain during administration increased. Unlike our study, they did not provide post-procedural NSAIDs.

Akers *et al*.[12] showed 10 mL lidocaine PCB reduced insertion pain in adolescents using the smaller LNG-IUCD and a 100-mm VAS. Cirik *et al*.[23] also found lower pain in PCB groups. Fahmy *et al*.[24], using 10 mL lidocaine, found no benefit compared to placebo or NSAIDs.

Renner *et al*.[25] found reduced pain during dilation and aspiration with PCB in early pregnancy, though block administration was painful. Goldthwaite *et al*.[26] found lidocaine injection more effective than gel for tenaculum placement. Karasu *et al*.[17] showed spray and injection reduced pain, with spray superior and injection ineffective for tenaculum-related pain.

Bayoumy *et al*.[27] concluded 10% lidocaine spray was effective and preferable to injection due to less discomfort. De Nadai *et al*.[28] found intracervical block reduced pain during LNG-IUCD insertion in nulligravidas. Clay *et al*.[29] observed reduced pain with cervical blocks, though results were not statistically significant. Fatah *et al*.[30] supported lidocaine spray for pain reduction.

Conversely, Karasu *et al*.[17], Conti *et al*.[31], and Cochrane review Lopez *et al*.[32] found lidocaine cream ineffective for tenaculum or IUCD insertion pain, aligning with Allen *et al*.[33] and Maguire *et al*.[34]. A meta-analysis by Perez-Lopez *et al*.[8] confirmed PCB reduced pain during tenaculum use and post-insertion, though more studies were recommended.

CONCLUSION

Paracervical block had a significant role in decreasing pain at time of IUCD insertion. Paracervical block is an easy, safe and effective way of pain control during intrauterine device insertion. Paracervical block may be reasonably considered in obese, nulliparous and/or overly anxious women during IUCD insertion.

CONFLICT OF INTERESTS

The author declares no conflict of interest related to this study.

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