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Original Research

Paracervical block in laparoscopic hysterectomy for postoperative pain control: a randomized, multi-center, double-blind, placebo-controlled trial

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Abstract

Background: To determine the effect of a paracervical block in laparoscopic hysterectomy on postoperative pain relief. **Method**: A total of 86 patients scheduled for total laparoscopic hysterectomy for benign gynecologic diseases were randomly assigned to the experimental group (n = 43) and the control group (n = 43). Patients were received a paracervical injection that was either 10 mL of 0.5% bupivacaine with 1 : 200,000 epinephrine or 10 mL of normal saline. The primary outcome was the postoperative pain score which was assessed using a visual analog scale at 2, 4, 6, 8, and 12 hours after surgery. The secondary outcome was the postoperative rescue analgesic requirement within 12 hours after surgery. **Results**: Baseline characteristics were similar in both groups. Postoperative pain scores did not significantly differ between groups. Rescue analgesia requirements were also statistically similar in both groups. **Conclusion**: Adding a paracervical block with preemptive local analgesia in patients undergoing laparoscopic hysterectomy did not reduce postoperative pain and postoperative rescue analgesia requirements.

Keywords: Hysterectomy; Paracervical block; Pain

1. Introduction

Postoperative pain management is an important component of postoperative satisfaction and patient care [1,2]. However, according to a recent systematic review and analysis of post-discharge symptoms after surgery in the United States, 74% of postsurgical patients still experience moderate to extreme pain after discharge, and post-discharge pain was one of the most common causes for readmission after surgery [3].

Therefore, numerus strategies have been proposed to reduce postoperative pain after laparoscopic hysterectomy; the majority are focused on decreasing abdominal wall pain, and including a transverse abdominis plane (TAP) block [4–6], the approaches use a continuous wound infusion device of local anesthetic at a trocar insertion site [7,8], and a single injection of local anesthetic at skin incision site [9]. However, the visceral pain caused by pelvic tissue manipulation during the surgery (such as the uterine, parametrial, bladder, and vaginal dissection or cutting) are neglected for postoperative pain control despite the presence of nociceptors in the target anatomy [10].

A paracervical block is a single-injection of a long-acting local anesthetic around the uterine cervix at the time of surgery [11,12]. A paracervical block can minimize risks associated with opioid analgesics or intravenous or epidural patient-controlled analgesia (PCA), with fewer side effects and a faster recovery [11,13]. However, it is controversial whether paracervical blocks is required as a method for pain reduction in laparoscopic hysterectomies, because of inconsistent results of the current literature [14,15]. Therefore, the aim of this study was to evaluate the efficacy of a paracervical block on postoperative pain relief when applied with preemptive local analgesia using 0.5% bupivacaine in laparoscopic hysterectomy for benign gynecologic conditions.

2. Materials and methods

2.1 Study design and patients

This study was named the Paracervical block in laparoscopic hysterectomy for postoperative pain control (PALAPA) study and was a randomized, double-blind, placebo-controlled, parallel-group trial. The trial was prospectively conducted between February 2019 and October 2019 at two hospitals (Kangbuk Samsung Hospital, Seoul; Wonju Severance Christian Hospital, Wonju, Korea). The protocol was approved by the Institutional Re-

view Boards of each participating hospital and registered with ClinicalTrials.gov (Identifier: NCT03792009).

Inclusion criteria were as follows: indications for laparoscopic hysterectomy with or without salpingo-oophorectomy for benign or premalignant gynecologic conditions, American Society of Anesthesiologists physical status (ASAPS) classification I–II, and age between 18 and 65 years. Exclusion criteria were as follows: pregnant status at the time of surgery, history of cervical surgery such as cerclage or conization, difficulty performing paracervical block due to anatomical characteristics, (i.e., very small or atrophic cervix), allergy to bupivacaine or lidocaine, or planned concomitant other surgical procedures.

2.2 Randomization

Patients were randomized to receive a paracervical injection of either 10 mL of 0.5% bupivacaine with 1:200,000 epinephrine (the experimental group) or 10 mL of normal saline (the control group). Randomization was performed with a random block in a 1:1 ratio. A study coordinator prepared the opaque, sequentially numbered envelopes that were enclosed and thick enough so that their contents are not legible from the outside before starting the study. The circulating nurse who prepared the injection syringe for the paracervical block in operating room called the study coordinator just before general anesthesia on day of surgery to randomize the participants. The injection solutions for the paracervical block were visually indistinguishable after preparation. All other care providers (including surgeons, anesthesiologist, and outcomes assessors) and patients were blinded to allocation. The study was performed in accordance with the protocol.

2.3 Study treatment

A single surgeon from each participating hospital performed all surgeries at that hospital. All participating surgeons had comparable surgical skills, a preference for minimal invasive surgery, and more than 1000 cases of total laparoscopic hysterectomy experiences before the study started. General anesthesia was performed with the same protocol in both groups. First, 0.2 mg of glycopyrrolate was administered intramuscularly as a premedication, followed by 1% propofol, remifentanil, and rocuronium intravenously. To achieve a bispectral index of 40–60, general anesthesia was maintained using sevoflurane and remifentanil infusion. Then, the patients were placed in the Trendelenburg position, and the intervention for the paracervical block was performed. The paracervical injection was administrated into the cervical stroma at the 3 and 9 o'clock positions with a depth of 1 to 2 cm after insertion but before fixation of the uterine manipulator (RUMI II; Cooper Surgical, Trumbull, CT, USA) and Koh cervical cup (Cooper surgical, Trumbull, CT, USA) onto the cervix [11]. A total laparoscopic hysterectomy was performed with various commercial ports (or trocars), laparoscope and laparoscopic instruments, based on each surgeon's preference and the patient's condition. The surgical technique has been previously reported in detail [2,16,17]. All patients were injected with 10 mL of 0.5% bupivacaine with 1:200,000 epinephrine into the skin of the trocar insertion site to reduce postoperative wound pain at the end of laparoscopic surgery. However, all patients were routinely given preemptive analgesics using intravenous pethidine and antiemetics using intravenous ramosetron at the time of wound closure.

2.4 Outcome measures

The postoperative pain score was the primary outcome measure. The postoperative pain was measured using a visual analog scale (VAS) at 2, 4, 6, 8, and 12 hours after surgery by several assessors who were blinded to the interventions. The secondary outcome measure was the number of rescue analgesics requested. Narcotic and non-narcotic use were measured by number of rescue injections received within 12-hour after surgery. Postoperative complications (defined as complications that required intervention of various degrees) were recorded up to three months after surgery according to the Clavien-Dindo classification [18]. Paracervical block-related complications such as severe bleeding on injection site, anaphylaxis, decreased or abnormal sensation in genitalia or legs, or decreased bladder function were also obtained [11].

2.5 Statistical analysis

The sample size was determined on the basis of the difference in the postoperative pain at four hours after surgery. Twenty consecutive patients who underwent total laparoscopic surgery without a paracervical block before this study at one participating institution (Kangbuk Samsung Hospital), were retrospectively reviewed resulting in a mean postoperative pain score of 4.4 ± 1.6 (authors' unpublished data). Therefore, we estimated that 43 participants would be needed per group to provide a type I error of 0.05, a power of 80%, and a predicted dropout rate of 5% to detect a 1-point difference, which was considered clinically relevant between both groups.

All statistical analyses were performed using SPSS software version 20.0 (SPSS, Inc., Chicago, IL, USA). The demographic characteristics and study outcomes were compared between both groups with the Fisher's exact test or the χ^2 test for categorical variables, and the Mann-Whitney U test or the Student's t test for continuous variables, as appropriate. A p value of <0.05 was considered to indicate statistically significant.

2.6 Systematic literature review

We conducted a systematic literature review to assess the current evidence on the potential benefit of a paracervical block in laparoscopic hysterectomy. The literature search included the following electronic databases from

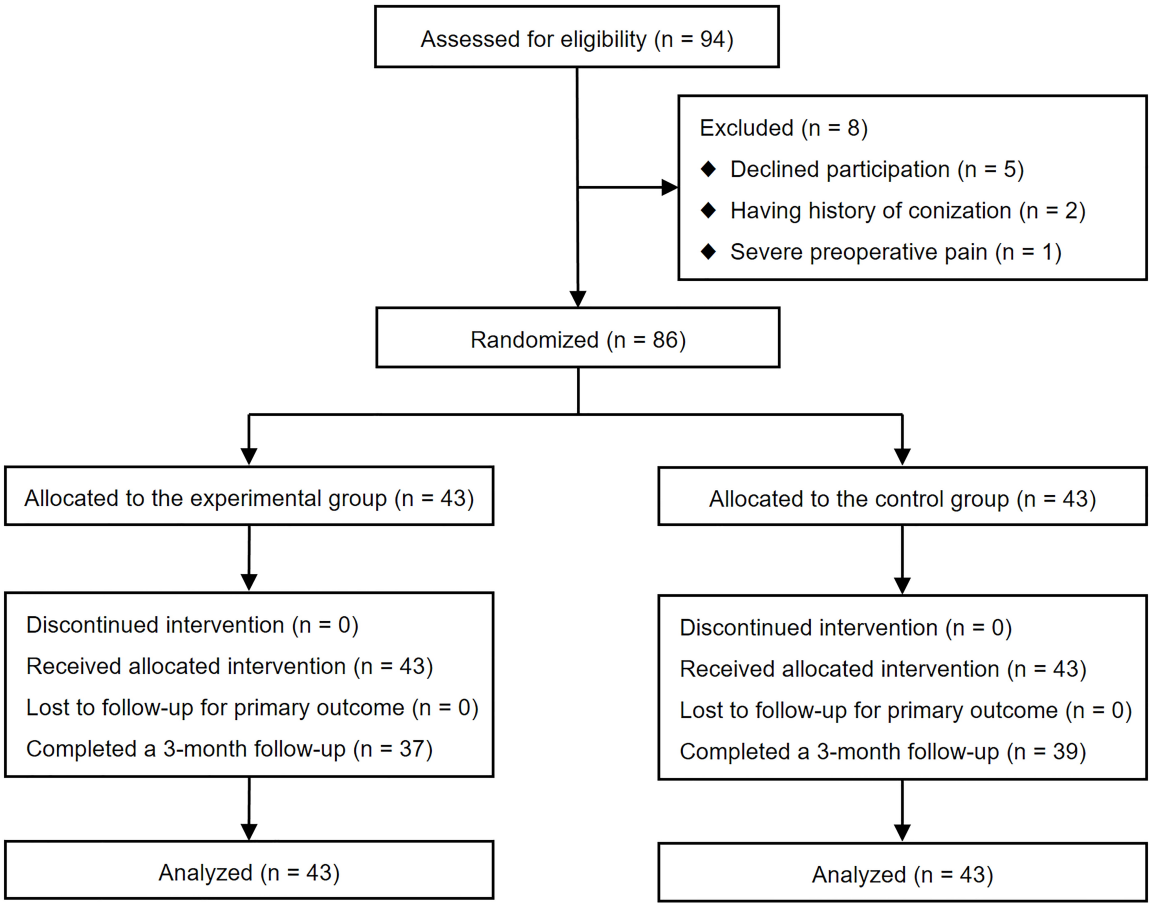

Fig. 1. Enrollment, randomization, and follow up of the study patients.

their inception through December 2020 without restriction on languages, publication type, or region: Medline, Google Scholar, and the Cochrane Library. The literature search was performed using keywords such as 'hysterectomy' for problem; 'paracervical block' for intervention; and 'pain' for outcome. Final inclusion and exclusion were based on the laparoscopic hysterectomy randomized controlled trial.

3. Results

Enrollment was from February 2019 through October 2019, and the three-month follow-up was concluded in January 2020. Of 94 patients who were invited to participate in the study, five declined participations and three were ineligible because of the exclusion criteria; thus, 86 patients were randomized, 43 each to the experimental and control groups (Fig. 1).

The baseline characteristics of both groups are described in Table 1. The mean age and body mass index of the study patients were 47.5 $\pm$ 6.1 years and 24.3 $\pm$ 4.3 kg/m^2, respectively, with no significant differences between groups. There were no significant differences between both groups in terms of other baseline characteristics, including parity, marital status, menopausal status, history of abdominal surgery, main indication of hysterectomy, extracted uterine weight after surgery, and surgical procedure ($p > 0.005$, all).

The primary and secondary study outcomes are presented in Table 2. The postoperative pain score did not significantly differ between the experimental and control groups at 2-hour (4.49 $\pm$ 1.50 vs. 4.53 $\pm$ 1.47, $p = 0.689$), 4-hour (4.36 $\pm$ 1.88 vs. 4.32 $\pm$ 1.61, $p = 0.789$), 6-hour (4.23 $\pm$ 1.72 vs. 4.20 $\pm$ 1.58, $p = 0.857$), 8-hour (3.59 $\pm$ 1.68 vs. 3.62 $\pm$ 1.77, $p = 0.759$), and 12-hour (3.33 $\pm$ 1.55 vs. 3.22 $\pm$ 1.63, $p = 0.811$) after surgery. The number of rescue analgesics requested were also statistically similar in both groups (1 [0–3] in the experimental group vs. 1 [0–4] in the control group, $p = 0.839$). Surgical outcomes of both groups are summarized in Table 2. Operative time, operative blood loss, transfusion, change in serum hemoglobin, failure of intended surgery, and length of postoperative hospital stay did not differ between groups. No intraoperative complications (defined as a major vessel injury, bowel injury, urinary tract injury, or any other severe unplanned adverse events) were observed in either group. One reported postoperative complication developed in each group (2.3% vs. 2.3%): one case was an ileus that developed seven days after the surgery which required readmission and was managed with supportive care until the eleventh postoperative

Table 1. Baseline characteristics.

	Experimental group (n = 43)	Control group (n = 43)	*p*-value
Age (years)	47.7 ± 6.3	47.4 ± 5.8	0.789
Body mass index (kg/m^2)	24.2 ± 4.2	24.4 ± 4.4	0.579
Parity (%)			0.771
Nulliparous	8 (18.6%)	6 (14.0%)	
Parous	35 (81.4%)	37 (86.0%)	
Marital status (%)			0.444
Single, separated, widowed, or divorced	12 (27.9%)	8 (18.6%)	
Married, or cohabitating	31 (72.1%)	35 (81.4%)	
Menopausal status (%)			0.792
Premenopausal	33 (76.7%)	35 (81.4%)	
Postmenopausal	10 (23.3%)	8 (18.6%)	
History of abdominal surgery	12 (27.9%)	10 (23.3%)	0.805
Preoperative hemoglobin (mg/dL)	12.3 ± 1.5	12.6 ± 1.8	0.465
Main indication for hysterectomy			0.468
Fibroids and/or adenomyosis	36 (83.7%)	34 (79.1%)	
Cervical pathology	2 (4.7)	5 (11.6%)	
Endometrial pathology	3 (7.0%)	1 (2.3%)	
AUB, or pelvic pain	2 (4.7%)	3 (7.0%)	
Uterine axis (cm)			
Long diameter	11.4 ± 4.1	10.7 ± 3.6	0.862
Short diameter	7.7 ± 2.8	8.1 ± 2.3	0.790
Extracted uterine weight (gram)	315.8 ± 140.5	320.2 ± 135.5	0.753
Surgical procedure			0.435
Hysterectomy alone[a]	34 (79.1%)	30 (68.2%)	
With ovarian surgeries	4 (9.3%)	8 (18.2%)	
With other surgeries[b]	5 (11.6%)	6 (13.6%)	
Initial port placement			0.724
Single port	39 (90.7%)	38 (88.4%)	
Multiple port	4 (9.3%)	5 (11.6%)	

Abbreviations: AUB, abnormal uterine bleeding.

[a]In almost all study patients, opportunistic salpingectomies for ovarian cancer risk reduction were performed after the preoperative consultation. Opportunistic salpingectomies were included in the 'Hysterectomy alone' category. [b]Other pelvic surgeries include incidental appendectomy, massive adhesiolysis, and peritonectomy for deep infiltrating endometriosis.

day in the experimental group, and one was a case of vaginal cuff infection that developed nine days after surgery and was treated with intravenous antibiotics in the control group.

Based on our literature search, a total of six potentially relevant randomized trials were identified. However, three studies were excluded because the trials were conducted in patients who underwent vaginal hysterectomy [19–21]. Finally, three studies were included in this review [14,15,22]. The characteristics of a total of four studies including the present study are summarized in Table 3 (Ref. [13,14,21]). Of the four studies, three of the studies were based in the USA [14,15,22] and one was in South Korea. Of the four studies, three studies were conducted in conventional laparoscopy [14,15] and one was in robotic-assisted laparoscopy [22]. Of the four studies, three studies were performed in total hysterectomy [14,22] and one was in supracervical hysterectomy [15]. Of the four studies, the primary outcome of three studies was postoperative pain [14,22] and one was overnight admission [15]. The postoperative pain score was not significantly different between groups in three studies [15,22] but it was significantly decreased in the experimental group in one study [14]. Postoperative opioid requirement was only evaluated in three studies [15,22], and the requirements did not differ between groups.

Table 2. Primary, secondary, and surgical outcomes.

	Experimental group (n = 43)	Control group (n = 43)	*p*-value
Postoperative pain score			
At 2-hour after surgery	4.49 ± 1.50	4.53 ± 1.47	0.689
At 4-hour after surgery	4.36 ± 1.88	4.32 ± 1.61	0.789
At 6-hour after surgery	4.23 ± 1.72	4.20 ± 1.58	0.857
At 8-hour after surgery	3.59 ± 1.68	3.62 ± 1.77	0.759
At 12-hour after surgery	3.33 ± 1.55	3.22 ± 1.63	0.811
Number of rescue analgesics requested[a]	1 (0–3)	1 (0–4)	0.839
Non-opioids	1 (0–2)	1 (0–3)	0.768
Opioids	0 (0–1)	0 (0–1)	0.924
Operative time (min)	85.7 ± 20.6	83.5 ± 18.6	0.355
Operative blood loss (mL)	98.5 ± 25.3	93.1 ± 24.9	0.291
Change in serum hemoglobin (mg/dL)	1.4 ± 0. 6	1.5 ± 0.5	0.488
Transfusion	1 (2.3%)	0	>0.999
Failure of intended surgery	1 (2.3%)	1 (2.3%)	>0.999
Insertion of additional trocar	1 (2.3%)	0	
Conversion to LAVH	0	1 (2.3%)	
Conversion to open surgery	0	0	
Length of hospital stay (days)	2 (2–3)	2 (2–3)	0.701
Operative complications			
Intraoperative complications	0	0	
Postoperative complications	1 (2.3%)	1 (2.3%)	>0.999
Vaginal cuff problem[b]	0	1 (2.3%)	
Paracervical block-related	0	0	
Other (ileus)	1 (2.3%)	0	

Abbreviation: LAVH, laparoscopically assisted vaginal hysterectomy.

[a] It calculates the number of rescue analgesics used within 12-hour after surgery. [b] Vaginal cuff problem includes vaginal cuff bleeding, infection, dehiscence, and vesicovaginal fistula.

4. Discussion

We conducted this randomized controlled trial to evaluate postoperative pain control with paracervical blocks using bupivacaine with epinephrine in laparoscopic hysterectomies for benign indications. The main finding of this study was that a paracervical block in laparoscopic hysterectomy did not reduce postoperative pain at 2, 4, 6, 8, and 12 hours after surgery. We also found that a paracervical block did not decrease the use of rescue analgesics in patients who underwent laparoscopic hysterectomy.

A paracervical block is an injection of a local anesthetic around the cervix to temporarily paralyze the surrounding nerves. Cervical dilatation and variable uterine interventions (such as intrauterine device insertion, hysteroscopy, endometrial biopsies, dilatation and curettage, and suction terminations) can be performed without any analgesia or anesthesia. Many gynecologists have used paracervical blocks for uterine interventions [11], but the efficacy and safety of this method are unclear. Tangsiriwatthana *et al*. [12] searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, and referenced lists of articles. They included a total of 26 studies involved 2790 patients that underwent uterine interventions in their Cochrane review [12]. Patients were randomly allocated to the paracervical block or placebo injection (saline or water) groups. The authors found that patients had statically less pain during cervical dilatation with a paracervical block than with a placebo but this difference may be no significance. A paracervical block had no effect in five uncontrolled studies. Therefore, based on the conflicting reports, the authors concluded that there is currently no evidence that a paracervical block could reduce pain, compared to alternative regional anesthetic methods or systemic analgesics and sedatives [12].

As shown in Table 3, our analysis did not provide clear evidence on the clinical benefit of a paracervical block in laparoscopic hysterectomy because of the current contradictions in the literature. When designing the present study, we planned to perform a meta-analysis to determine if there was useful data in the existing literature. However, the timing of measurement of postoperative pain (the primary outcome of this study) varied too much between currently reported studies. We assessed the postoperative pain at 2, 4, 6, 8, and 12 hours after surgery, because of the

Table 3. Summary of published randomized trials investigating the effect of paracervical block in laparoscopic hysterectomy.

Study	Year, country	Experimental local analgesia	Surgical approach	Patients, n (ratio)	Primary outcome	Postoperative pain score	Postoperative opioid requirement	Postoperative complication
Barr Grzesh *et al*. [14]	2018, USA	20 mL of 0.25% bupivacaine with epinephrine	Laparoscopic supracervical hysterectomy	132 (1:1)	Overnight admission[a]	Not different between groups[b]	Not different between groups	Not different between groups
Balwin *et al*. [21][c]	2018, USA	10 mL of 0.5% bupivacaine with epinephrine	Robotic total laparoscopic hysterectomy	82 (1:1)	Pain score at 1, 2, 4, 8, and 24 h after surgery	Not different between groups	Not different between groups	Not reported
Radtke *et al*. [13]	2019, USA	10 mL of 0.5% bupivacaine with epinephrine	Total laparoscopic hysterectomy	41 (1:1)	Pain score at 30 min and 60 min after surgery	Decreased in the experimental group	Not evaluated	Not reported
Present study	South Korea	10 mL of 0.5% bupivacaine with epinephrine	Total laparoscopic hysterectomy	86 (1:1)	Pain score at 2, 4, 6, 8 and 12 h after surgery	Not different between groups	Not different between groups	Not different between groups

[a]The researchers reported that the unplanned overnight admission rate was 34% for the treatment group and 27% for the placebo group ($p = 0.25$). They concluded that a paracervical block with bupivacaine and epinephrine in laparoscopic supracervical hysterectomy did not decrease the overnight admission rate. [b]The researchers evaluated the postoperative pain five times (at hours 1, 2, and 4 and at days 1 and 2 after surgery). They reported that pain scores at hours 1, 2, and 4 and on days 1 and 2 after surgery were not significantly different between the groups. [c]The full-text of this study has not yet been published. This study is an abstract (No. 142) presented at the AAGL Global Congress on Minimally Invasive Gynecology which was held in Las Vegas, NV, USA from 11–15 November 2018.

pharmacokinetic profile of 0.5% bupivacaine with 1:200,000 epinephrine which has an onset of action within 15 to 30 minutes and with duration of anesthesia within 5 to 15 hours [11,23]. After analyzing the results of this study, we determined that a paracervical block using bupivacaine with epinephrine should not be applied in our routine clinical practice for total laparoscopic hysterectomies.

The results of the present study were inconsistent with the results reported for paracervical blocks in vaginal hysterectomies. Three randomized controlled trials evaluated paracervical blocks during vaginal hysterectomy with either 0.5% bupivacaine with epinephrine or 0.5% ropivacaine [19–21]. None of the studies showed a difference in pain scores at 24 hours after surgery; however, there were significantly lower pain scores in the experimental group vs. the control group within 8 hours after surgery. All three studies demonstrated a significant reduction in opioid requirements in the first 24 hours after surgery.

There were some limitations to this study. First, the study was conducted in conventional total laparoscopic hysterectomy cases. Therefore, results might not apply in other surgical settings. Second, the length of hospital stay in this study was longer than those reported in other studies [14,15]. The length of hospital stay in our country (Republic of Korea) is greatly affected by the insurance and financial systems. Because the medical expenses in our country are less expensive, relative to other countries, patients tend to stay longer in hospital. Moreover, because medical expenses are fixed at a certain amount according to the diagnosis (using the diagnosis-related group (DRG) system), so is the length of postoperative hospital stay is also fixed at two days. Therefore, the length of hospitalization is not an index that accurately reflects the postoperative recovery in our trial. However, this study's strengths include the randomized, multi-center, double-blind, placebo-controlled design and a large sample size with a diverse patient population.

5. Conclusions

In conclusion, adding a paracervical block with 0.5% bupivacaine in patients undergoing conventional total laparoscopic hysterectomy did not reduce postoperative pian or postoperative rescue analgesia requirements. However, a paracervical block in laparoscopic hysterectomy was well-tolerated and had no adverse side effects. Additional studies conducted in various surgical settings (total hysterectomy vs. supracervical hysterectomy, laparoscopic hysterectomy vs. vaginal hysterectomy, conventional laparoscopy vs. robotic-assisted laparoscopy, bupivacaine vs. extended-release liposomal bupivacaine) are needed to obtain more conclusive data.

Author contributions

SHL, TJK, and TS designed the research study. SHL and TS performed the research. NHL, SYJ, and JL analyzed the data. SHL and TS wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

All patients gave the informed consent for inclusion before they participated in the study. The study protocol was approved by the Institutional Review Boards of Kangbuk Samsung Hospital (Approval number: KBSMC-2019-01-001) and Wonju Severance Christian Hospital (Approval number: WCH-2019-01-0250). The study was registered with ClinicalTrials.gov (Identifier: NCT03792009).

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Conflict of interest

The authors declare no conflict of interest.

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