Taiwanese Journal of Obstetrics & Gynecology 63 (2024) 186–191

Contents lists available at ScienceDirect

Taiwanese Journal of Obstetrics & Gynecology

journal homepage: www.tjog-online.com

Original Article

Paracervical block before laparoscopic total hysterectomy: A randomized controlled trial

Kemal Güngördük [a], Varol Gülseren [b,*], Leyla Taştan [a], İsa Aykut Özdemir [c]

[a] Muğla Sıtkı Koçman University, Faculty of Medicine, Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Turkey
[b] Erciyes University, Faculty of Medicine, Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Kayseri, Turkey
[c] Medipol University, Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Turkey

ARTICLE INFO

Article history:
Accepted 25 October 2023

Keywords:
Paracervical block
Laparoscopic hysterectomy
Randomized trial

ABSTRACT

Objective: To test the hypothesis that paracervical block with 0.5 % bupivacaine decreases postoperative pain after total laparoscopic hysterectomy (TLH).
Materials and method: This randomized double-blind placebo control trial included 152 women. We injected 10 mL 0.5 % bupivacaine (study group, n = 75) or 10 mL normal saline (control group, n = 77) at the 3 and 9 o'clock positions of the uterine cervix. The primary outcome was the visual analog scale score (VAS) determined 1 h (h) postoperatively.
Results: The 152 patients did not differ in their baseline demographics or perioperative characteristics. The mean VAS 1 h postoperatively was significantly lower in the study group than in controls (5.7 ± 1.2 vs. 6.8 ± 1.1, P < 0.001). The average VAS at 30 min, 3 h, and 6 h postoperatively was also significantly lower in the study group. Patients in the study group had a significantly lower analgesic requirement than did controls during the first 24 h postoperatively (6 [7.8 %] vs. 16 [21 %], P = 0.021). Total QoR-40 questionnaire scores were higher in patients who received bupivacaine.
Conclusion: Paracervical bloc with 0.5 % bupivacaine just before TLH is an effective and safe method to reduce pain and lower postoperative analgesic requirement.
URL link that leads directly to the trial registration: https://clinicaltrials.gov/ct2/show/NCT05341869?cond=NCT05341869&draw=2&rank=1.

Introduction

Total hysterectomy is one of the most common surgical procedures in gynecology. Total laparoscopic hysterectomy (TLH) has several advantages over open surgery, such as better cosmetic outcomes, faster recovery, and an earlier return to normal activities and work, and has thus become the preferred approach [1–3]. Nonetheless, postoperative pain (PP) remains an issue of concern [1–3].

The reported incidence of PP after TLH ranges from 35 % to 63 % [4–7]. The origin of PP after laparoscopy is multifactorial, arising from several perioperative factors, including pneumoperitoneum, stretching of the intraabdominal cavity, blood left in the abdomen, and dissection of the pelvic region [6,7]. A prospective trial found more intense pain and greater analgesia requirement in the immediate postoperative period associated with laparoscopic surgery than with laparotomy [8]. Methods to decrease the severity of PP are required before TLH can be confidently recommended. Women undergoing TLH experience both incisional pain and visceral pain during the first postoperative hour [9]. The pain is most intense during the first 30 min after TLH but then gradually subsides during by 72 h postoperatively [9]. Because a high level of acute postoperative pain (APP) increases the risk for chronic postsurgical pain, its control during the immediate postoperative period should be prioritized.

Among the strategies to control APP after TLH are transverse abdominal plane blocks, superior hypogastric plexus blocs, local anesthetic injection on the port side, and reduced port caliber [10–12]. Paracervical block (PCB) blocks the Frankenhouser nerve plexus, which supplies the visceral sensory fibers to the uterus, cervix, and top of the vagina. The effect of PCB in TLH was evaluated

Synopsis: Paracervical bloc with 0.5% bupivacaine just before laparoscopic hysterectomy is an effective and safe method to reduce pain and lower postoperative analgesic requirement.

* Corresponding author. Erciyes University, Faculty of Medicine, Department of Obstetrics and Gynecology, Division of gynecologic oncology, Erciyes University Faculty of Medicine Kiosk, Faculty Cluster Houses No: 30, 38030 Melikgazi, Kayseri, Turkey.
E-mail address: drvarolgulseren@gmail.com (V. Gülseren).

https://doi.org/10.1016/j.tjog.2024.01.013

in two randomized studies but their limitations precluded drawing conclusions on PP after TLH [4,5]. A recently published meta-analysis cited the need for high-quality studies [6]. Thus, the primary goal of this randomized clinical trial was to determine whether PCB at the onset of surgery, as a part of an enhanced recovery protocol, improves patient recovery after TLH.

Materials and method

This prospective randomized study was approved by the University Clinical Research Ethics Committee and the Ministry of Health, and was registered at ClinicalTrials.gov (NCT05341869). The study was carried out between 1 May 2022–31 December 2022. It was performed in accordance with the tenets of the Declaration of Helsinki, and all patients provided written informed consent on the day before surgery. The CONSORT guidelines for randomized trials were followed.

Patients who underwent type A TLH with or without additional surgery, such as salpingo-oophorectomy or salpingectomy, were eligible for study participation. Exclusion criteria were age <18 years, refusal to provide consent, inability to understand the study questionnaire, severe psychiatric or mental disorder, American Society of Anesthesiologists (ASA) physical status classification > III, history of regular narcotic use within 6 months of surgery and planned concomitant procedures, such as sacrocolpopexy, sling surgery, or for deep infiltrating endometriosis. After recruitment, patients were excluded from the trial if the duration of surgery was >90 min, if an additional operation was needed such as lymphadenectomy, if any type of anesthesiologic complication occurred (e.g., admission to the intensive care unit), or if conversion to laparotomy was required.

Patients received preoperative educational information and counseling (by KG), including written information in the form of pamphlets on laparoscopy and hysterectomy. An explanatory surgical video was shown prior to the procedure to reduce anxiety. The pre-procedural anxiety level was assessed using the Hospital Anxiety and Depression Scale (HADS), which includes seven items that determine the anxiety score. Each item is answered by the patient using a 4-point (0–3) scale [13].

Before surgery, the patients were randomized by a project doctor without knowledge of the allocation, resulting in two comparable groups. Patients in the study group received 10 mL 0.5 % bupivacaine and those in the control group received 10 mL normal saline. The allocation sequence was computer-generated using random block sizes and the results were kept in an opaque sealed envelope, to be opened by a medical nurse not involved in the study but charged with preparing the infiltrating solutions, which were identical in appearance.

After enrollment, according to our clinical protocol, all patients underwent preoperative carbohydrate loading in the form of a carbohydrate-rich (~50 g) beverage provided 2–6 h before the induction of anesthesia. All patients also received low-molecular-weight heparin, and at anesthesia induction, received prophylactic intravenous antibiotics. No patients received any form of preoperative analgesia, such as nonopioid or opioid adjuncts. A standardized anesthesiology protocol was used for all patients. None of the patients underwent simultaneous epidural analgesia. Anesthesia was induced via an intravenous (IV) injection of atropine (10 μg/kg), propofol (2 mg/kg), fentanyl (2 μg/kg), and rocuronium (0.6 mg/kg). After endotracheal intubation, anesthesia was maintained by the inhalation of sevoflurane in a mixture of 60 % oxygen and 40 % nitrous oxide, to obtain a minimal alveolar concentration of 0.8–1.3 %, and the continuous infusion of propofol (0.5–4 μg/kg/h) and remifentanil (2–15 μg/kg/h) to maintain hemodynamic variation within 20 % of baseline. Alveolar recruitment maneuvers (+30 cmH_2O positive airway pressure sustained for 30 s) were performed every 30–60 min during surgery. Special care was taken to maintain normothermia and to control glycemia. A regimen of fluids and electrolytes was established to ensure normovolemia.

All surgical procedures were performed by the highly experienced surgeon (>1000 laparoscopic gynecological surgeries, KG) using a diamond port configuration to improve access and surgical efficiency. After general anesthesia, the patients received either 10 mL 0.5 % bupivacaine with epinephrine (study group) or normal saline (control group), administered by the study surgeon (KG). The 5 mL solution was syringe-injected into the cervical stroma at 3 and 9 o'clock and to a depth of 2–3 cm and then the uterine manipulator was inserted. No other anesthetic blocks were administered during the procedure. Surgery was performed with the patient placed in the Trendelenburg position (30°) and under a 12 mmHg pneumoperitoneum, using CO_2 gas as the distention medium at a standard temperature of 19–21 °C, 0 % relative humidity, a 6 L/min flow rate, and maintenance at a rate of 1 L/min. The use of surgical instruments was standardized. At the end of the procedure, the ports were opened to release intra-abdominal CO_2 and the abdomen was manually compressed by the operator to evacuate residual CO_2. The neuromuscular block was antagonized with neostigmine and atropine and then the patients were transferred to the post-anesthesia care unit. Paracetamol (10 mg/kg) and tramadol (1 mg/kg) were administered intravenously to all patients during desufflation for pain relief, and 4 mg ondansetron was administered to prevent nausea and vomiting.

On the day of surgery, all patients were managed according to a standard postoperative analgesia protocol consisting of two intravenous doses of 75 mg diclofenac sodium (Voltaren; Novartis, Istanbul, Turkey) at 12 h intervals, administered in the postoperative ward. Patients who requested additional pain relief were given tramadol hydrochloride (Contramal; Abdi İbrahim, İstanbul, Turkey) at a dose of 100 mg IV (up to 3 times per day) usually along with 10 mg IV metoclopramide. Our postoperative care protocol is described in detail in a previous report [14]. A nonsurgical member of the research team (LT) collected data on the patients' demographics and surgical outcomes. The patients were instructed to use etodolac 100 mg (max dose 200 mg) at home if necessary for the first 7 days following discharge and to visit the clinic if it was not beneficial. However, no patient visited the clinic for this reason. Patients were requested to attend a follow-up appointment after 1 and 2 weeks for counseling on the pathology results and treatment decision-making. During the follow-up visits, they were also asked about their symptoms and average etodolac use.

The primary endpoint was the difference in the 1 h postoperative Visual Analog Scale (VAS) pain score. Secondary outcomes included Faces Pain Scale-Revised Score (FPS-R), the quality of postoperative recovery according to the Quality of Recovery-40 questionnaire (QoR-40) scores 24 h postoperatively [15], and additional analgesia requirement. In the VAS, a 10 cm line was used and the patient was asked to mark the corresponding level of experienced pain. Before the study began, the participants were instructed on how to judge their pain intensity using the VAS (0 cm = no pain, 10 cm = worst pain imaginable). Pain was assessed using the VAS at six timepoints during the postoperative period (30 min, 1, 3, 6, 12, and 24 h) by a clinical assistant (LT) blinded to patient allocation. Patients were also asked to assess their pain using the FPS-R, by the same assistant, at 2, 4, 6, and 12 h postoperatively (Fig. 1). We assess the VAS and FPS scores at different times that have been chosen to find the best result and minimize the bias [7].

Prior to the full trial, we conducted a non-blinded pilot trial consisting of 20 patients per group and performed a power analysis. The mean VAS 1 h after surgery was 6.3 ± 2 in the saline group and 5.9 ± 2.3 in the PCB group. According to this result, a sample size of 146 patients per group was required for a power of 95 % and a

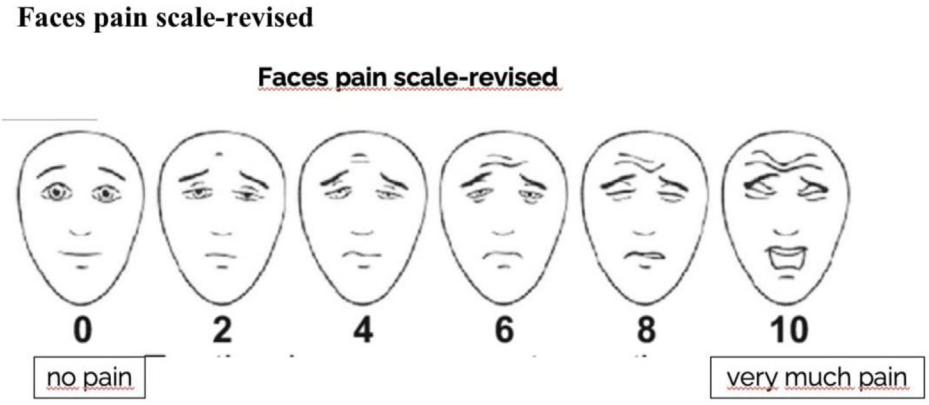

Fig. 1. Faces pain scale-revised.

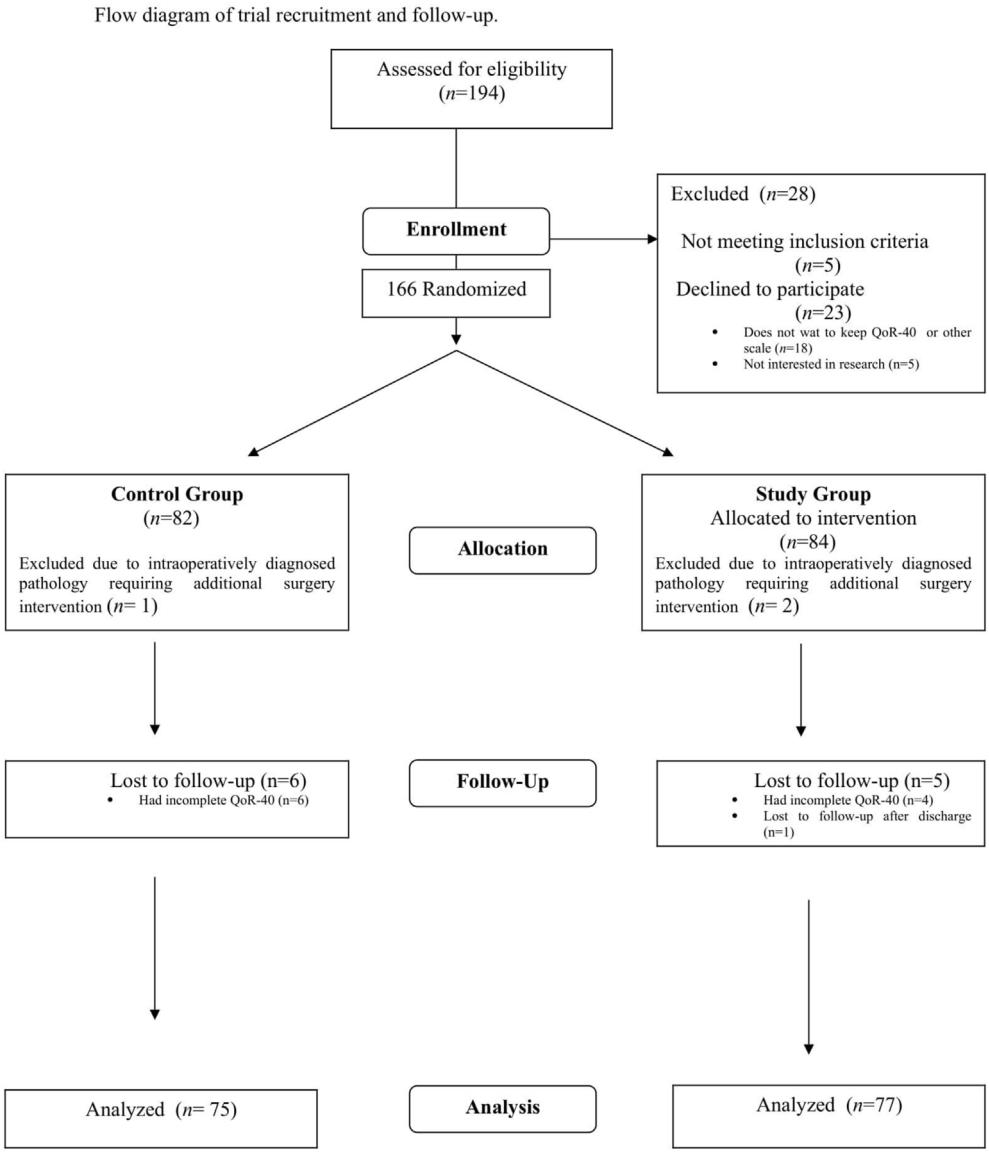

Fig. 2. Flow diagram of trial recruitment and follow-up.

significance level of 0.01. An additional 10 patients were recruited to account for possible attrition.

Categorical variables are presented as frequencies and percentages, and quantitative variables are given as the mean ± standard deviation and 95 % confidence interval, unless otherwise stated. Continuous variables were compared using Student's *t*-test or the Mann–Whitney U test. Normally distributed variables and dependent variables were compared using a paired *t*-test, and categorical variables were compared using a χ^2 test. All statistical analyses were performed using MedCalc software (version 14.0 for Windows; Mariakerke, Belgium). A P value < 0.05 was considered to indicate statistical significance.

Results

The patient flow is described in the consort diagram shown in Fig. 2. In total, 152 women were assigned to either the control group (n = 75) or the study group (n = 77). Their demographics and surgical characteristics did not significantly differ (Tables 1 and 2).

The study outcomes are described in Table 3. The mean VAS 1 h postoperatively was significantly lower in the study group than in controls (5.7 ± 1.2 vs. 6.8 ± 1.1, P < 0.001). The average VAS at 30 min, 3 h, and 6 h postoperatively was also significantly lower in the study group whereas the differences in the VAS score at 12 and 24 h postoperatively were not. The FPS score was significantly higher in controls at 2 h (7.5 ± 0.9 vs. 6.4 ± 0.9, P < 0.001), 4 h (6.1 ± 0.6 vs. 5.2 ± 1.0, P < 0.001), and 6 h (4.5 ± 0.9 vs. 3.7 ± 1.1, P < 0.001) but not at 12 h postoperatively.

Additional analgesic requirement during the first 24 h postoperatively was significantly lower in the study group than in controls (6 [7.8 %] vs. 16 [21 %], P = 0.021). Total QoR-40 questionnaire scores were higher in the study group but the two groups did not differ in the mean number of oral etodolac pills used after discharge. No complications or adverse effects related to the use of bupivacaine were reported.

Discussion

Patients administered PCB with bupivacaine just before TLH experienced less postoperative pain during the first 6 h postoperatively than did patients in the saline control group. Patients who received bupivacaine PCB also had less need for additional analgesic treatment and a better quality of recovery than those receiving saline.

Table 1
Preoperative patient demographics.

	Control group (n = 75)	Study group (n = 77)	*P*
Age, mean (SD)	53.9 ± 10.0	56.3 ± 9.3	0.126
Postmenopausal n (%)	49 (65.3)	53 (68.8)	0.646
BMI, mean (SD)	28.6 ± 3.1	27.7 ± 3.3	0.081
Parity, median (min–max)	1 (0–3)	1 (0–3)	0.364
Number of vaginal deliveries median (min–max)	1 (1–3)	2 (1–3)	0.173
ASA n (%)			0.068
I	51 (68.0)	53 (68.8)	
II	15 (20.0)	7 (9.1)	
III	9 (12.0)	17 (22.1)	
Smoking history, n (%)	17 (22.7)	12 (15.6)	0.267
History of abdominal surgery, n (%)	16 (21.3)	17 (22.1)	0.911
Diabetes n (%)	12 (16.0)	8 (10.4)	0.306
Hypertension n (%)	12 (16.0)	14 (18.2)	0.721
HADS-A, median (min–max)	4 (2–8)	5 (2–8)	0.160
Indication for surgery n (%)			0.067
Leiomyomas	25 (33.3)	43 (55.8)	
Abnormal uterine bleeding	26 (34.7)	16 (20.8)	
Microinvasive cervical cancer	4 (5.3)	5 (6.5)	
Adnexal mass	10 (13.3)	6 (7.8)	
Endometrial hyperplasia	10 (13.3)	7 (9.1)	

ASA American Society of Anesthesiologists, BMI body mass index, HADS-A hospital anxiety and depression scale-anxiety.

Table 2
Surgical variables.

	Control group (n = 75)	Study group (n = 77)	*P*
Operation time, min median (min–max)	56 (42–75)	53 (40–71)	0.266
Estimated blood loss, ml median (min–max)	78 (46–230)	78 (9–230)	0.381
Uterus weight, g median (min–max)	109 (58–230)	106 (43–234)	0.197
Surgical procedure n (%)			0.409
THL + BS	52 (69.3)	58 (75.3)	
THL + BSO	23 (30.7)	19 (24.7)	
Intraoperative adhesions n (%)	15 (20.0)	12 (15.6)	0.476
Volume of inflated CO_2 (L) median (min–max)	198 (110–450)	190 (110–405)	0.392
Transfusion rate n (%)	–	–	–
Intraoperative complications n (%)			–
Bowel injury	–	–	
Bladder injury	–	–	
Ureter injury	–	–	
Drain insertion after surgery n (%)	7 (9.3)	5 (6.5)	0.516
Hospital stay (days), mean (SD)	1 ± 0	1 ± 0	1.00
Mortality n (%)	–	–	–

TLH Total laparoscopic hysterectomy, BS Bilateral salpingectomy, BSO salpingo-oophorectomy.

Table 3
Study outcomes.

	Control group (n = 75)	Study group (n = 77)	*P*
Post-op 30 min VAS mean (SD)	7.1 ± 1.2	5.9 ± 1.4	<0.001
Post-op 1 h VAS mean (SD)	6.8 ± 1.1	5.7 ± 1.2	<0.001
Post-op 3 h VAS mean (SD)	6.1 ± 0.9	5.4 ± 1.0	<0.001
Post-op 6 h VAS mean (SD)	5.1 ± 0.7	4.5 ± 0.8	<0.001
Post-op 12 h VAS mean (SD)	3.6 ± 0.9	3.3 ± 0.7	0.087
Post-op 24 h VAS mean (SD)	2.1 ± 0.8	1.9 ± 0.5	0.206
Post-op 2 h FPS-R mean (SD)	7.5 ± 0.9	6.4 ± 0.9	<0.001
Post-op 4 h FPS-R mean (SD)	6.1 ± 0.6	5.2 ± 1.0	<0.001
Post-op 6 h FPS-R mean (SD)	4.5 ± 0.9	3.7 ± 1.1	<0.001
Post-op 12 h FPS-R mean (SD)	1.9 ± 0.9	1.8 ± 1.2	0.556
Post-op 24 h FPS-R mean (SD)	1.1 ± 0.9	0.9 ± 1.0	0.104
Total additional analgesic[a] n (%)	16 (21.3)	6 (7.8)	0.021
First 8 h after surgery[b]	16 (21.3)	6 (7.8)	0.021
8–16 h after surgery[b]	9 (12.0)	3 (3.9)	0.077
16–24 h after surgery[b]	4 (5.3)	–	0.057
QoR-40 score mean (SD)			
Total	161.9 ± 13.3	166.6 ± 11.9	0.022
Physical comfort	49.4 ± 6.8	50.2 ± 7.0	0.503
Emotional state	33.9 ± 7.0	35.5 ± 6.3	0.158
Physical independence	19.0 ± 4.0	19.4 ± 4.3	0.514
Psychological support	28.9 ± 4.9	29.5 ± 4.8	0.405
Pain	30.5 ± 4.2	31.9 ± 3.6	0.036
Number of oral etodolac pills used after discharge	7.3 ± 1.8	7.0 ± 1.3	0.233
Readmission n (%)	–	–	–

VAS Visual analog scale, FPS-R faces pain scale-revised score, QoR-40 quality of recovery-40 questionnaire.
[a] Tramadol hydrochloride requirement.
[b] Calculated according the dose of tramadol hydrochloride.

Total hysterectomy is one of the most common gynecologic procedures performed worldwide. In these patients, adequate pain control after surgery is a primary concern. Preemptive analgesia, defined as an intervention administered before the onset of the painful stimulus, may intercept or substantially decrease subsequent pain or analgesic requirements [16]. To date, there are no clear recommendations for the preemptive treatment of postoperative pain in TLH patients [16]. Anesthetic infiltration of the paracervical tissues is among the preemptive analgesic methods used in gynecologic surgery because the paracervical tissue and cervix are anatomical landmarks for pain control [5].

In two-randomized control trials in patients undergoing TLH with or without salpingo-oophorectomy, the administration of PCB using bupivacaine before the procedure significantly reduced APP [4,5]. Unfortunately, both studies had several limitations, including a small sample size and the fact that the pain score was evaluated only during the first hour after surgery. Moreover, pain was assessed using only the VAS score, which is a subjective measurement [17,18].

In the present trial, pain was assessed using both the VAS and FPS-R. The latter is an objective method of pain assessment in which the facial expressions of the patient are evaluated by the medical staff [19]. The use of the FPS-R might in international trials facilitates comparisons of findings between countries [20]. Although a recent systematic review concluded that the beneficial effects of PCB last up to 4 h after surgery [7], in our study, the mean VAS and the FPS-R score were lower in patients treated with bupivacaine PCB for as long as the first 6 h after surgery. This result is not surprising because bupivacaine hydrochloride is a targeted block, with demonstrated effects for up to 9 h [4,5]. The QoR-40 was found to be the best measure of recovery following ambulatory procedures [21]. No randomized controlled trials have investigated the effect of PCB on the quality of patient recovery for laparoscopic gynecological surgery whereas we found a higher QoR-40 score in patients who received bupivacaine PCB and a direct correlation with adequate pain control after surgery.

Currently, there is no universally recommended anesthetic agent for use with PCB. In our trial, we used bupivacaine hydrochloride rather than liposomal bupivacaine, which provides analgesia for up to 72 h, because the latter formulation is not available in Turkey. The use of long acting bupivacaine may further decrease the analgesic requirement and the need for oral painkiller safter discharge.

Our study also had several limitations. First, during the study period, preoperative analgesia, which is strongly recommended to enhance recovery in patients undergoing minimally invasive surgery, was not provided to the patients. Second, the gynecologic surgeon preforming minimally invasive gynecologic surgery had a high patient volume, which may have influenced postoperative pain. Third, the patients included in the study had benign conditions and thus underwent only type A TLH, such that the results may not be generalizable to patients undergoing major gynecologic surgery. However, the strengths of our study included its large, randomized, double-blind, placebo-controlled design, the use of standardized protocols, and the similar clinical features of the two groups. Moreover, to the best of our knowledge, this is the first published evaluation of patient QoR-40 score after TLH.

In conclusion, our study demonstrates that bupivacaine PCB administered preemptively in patients undergoing TLH improves postoperative pain scores, reduces additional analgesic requirements, and increases patient satisfaction. Hence, PCB can be considered part of an enhanced recovery protocol.

Author contributions

To write: Kemal Güngördük.
Edited by: İsa Aykut Özdemir.
Literature research: Varol Gülseren, Leyla Taştan.
Statistical analysis: Varol Gülseren.
Data collecting: Leyla Taştan.
Evaluation: İsa Aykut Özdemir, Kemal Güngördük.

Funding

None.

Declaration of competing interest

The authors declare that they have no conflict of interest.

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