Original Article

Vaginal Vault Infiltration with Bupivacaine for Postoperative Pain Control after Total Laparoscopic Hysterectomy: A Randomized control trial

Kallol Kumar Roy[1], Poojitha Kalyani Kanikaram[1], Nilanchali Singh[1]*, Vimi Riwari[2], Rinchen Zangmo[1], Jyoti Meena[1], Anamika Das[1], Deepika Kashyap[1], Archana Minz[1]

Departments of [1]Obstetrics and Gynaecology and [2]Anaesthesia, AIIMS, New Delhi, India

Abstract

Objectives: The objective of this study was to assess the effect of local infiltration of anesthetic to the vaginal vault on postoperative pain after total laparoscopic hysterectomy.

Materials and Methods: This was a single-center, randomized trial. Women assigned to laparoscopic hysterectomy were randomly divided into two groups. In the intervention group ($n = 30$), the vaginal cuff was infiltrated with 10 ml of bupivacaine, whereas the control group ($n = 30$) did not receive local anesthetic infiltration to vaginal vault. The primary outcome measure was to analyze the efficacy of bupivacaine infiltration in the study group by comparing the postoperative pain in both the groups at 1, 3, 6, 12, and 24 h using pain visual analog scale (VAS). The secondary outcome was to measure the need for rescue opioid analgesia.

Results: Group I (intervention group) had lesser mean VAS score at 1st, 3rd, 6th, 12th, and 24 h compared to Group II (control group). There was an additional requirement of opioid analgesia for postoperative pain in Group II than in Group I, which was statistically significant ($P < 0.05$).

Conclusion: Injection of local anesthetic into the vaginal cuff increased the number of women experiencing only minor pain after laparoscopic hysterectomy and decreased postoperative opioid usage and its side effects. Local anesthesia of the vaginal cuff is safe and feasible.

Keywords: Hysterectomy, laparoscopy, local analgesia, postoperative pain, vaginal vault

Introduction

Total laparoscopic hysterectomy (TLH) has emerged as a viable alternative to total abdominal hysterectomy. TLH offers advantages over the abdominal route in women requiring total hysterectomy for benign diseases, particularly with respect to minor perioperative complications, blood loss, and hospital stay.[1] Laparoscopy ensures faster recovery, fewer complications, and less pain as compared to laparotomy. This mode is still not devoid of pain and better pain control in postoperative period is still sought.

In addition to the discomfort at the port-site incisions, few authors report that 80% of the patients require opioid analgesia after laparoscopic surgery.[2,3] Opioid-related side effects might delay mobilization, increase the duration of hospital stay, and delay recovery, thereby diminishing the benefits of laparoscopic procedures. Therefore, the use of opioid analgesics should be minimized.[4] Excess use of nonsteroidal anti-inflammatory drugs (NSAIDS) is also not devoid of side effects. Systematic analgesics such as NSAIDs and opioids cannot directly block the visceral nociception despite dose regulation under patient-controlled analgesia. It is reasonable that direct block of the uterosacral plexus through injection of a prolonged half-life analgesic can improve pain relief

Article History:
Submitted: 26-Oct-2021
Revised: 04-Dec-2022
Accepted: 05-Dec-2022
Published: 18-May-2023

Access this article online

Quick Response Code:

Website: www.e-gmit.com

DOI: 10.4103/gmit.gmit_125_21

Address for correspondence: Dr. Nilanchali Singh, Department of Obstetrics and Gynaecology, AIIMS, Ansari Nagar, New Delhi - 110 016, India.
E-mail: nilanchalisingh@gmail.com

How to cite this article: Roy KK, Kanikaram PK, Singh N, Riwari V, Zangmo R, Meena J, *et al*. Vaginal vault infiltration with bupivacaine for postoperative pain control after total laparoscopic hysterectomy: a randomized control trial. Gynecol Minim Invasive Ther 2023;12:90-5.

to enhance recovery and reduce opioid-related systemic side effects.[5] Infiltration of local analgesia intraoperatively has been found to reduce postoperative pain in several studies.[4,6,7] Intraperitoneal local anesthetic was introduced in the early 1950s, and it has since been used in various surgical procedures. In gynecologic laparoscopy, local anesthetic instillation into the intraperitoneal space and local injection into the incision site are common. After uterine surgery, visceral pain intensity is maximal, and most patients complain of lower abdominal pain. Visceral pain is transmitted by the pelvic visceral plexus, which is derived from the hypogastric plexus associated with the uterus, vagina, rectum, and bladder. The uterus receives primary innervation from the uterosacral plexus (Lee–Frankenhauser plexus), which is located near the lateral side of the uterine cervix within the uterosacral ligament and which plays an important role in pain transmission.

Infiltration of vaginal vault with 0.25% bupivacaine causes sensory blockade of uterosacral plexus and reduces postoperative pain. With this concept, vaginal vault infiltration with local anesthetic agent after TLH is expected to reduce postoperative pain and may decrease the requirement of opioid use. Therefore, this randomized control study was done to evaluate the efficacy of infiltration of bupivacaine in the vaginal vault after TLH to reduce postoperative pain.

Methodology

This was a prospective two-arm double-blinded randomized control trial conducted in the Department of Obstetrics and Gynecology at an Apical Center in North India. All patients who require TLH for benign condition were recruited from the gynecology outpatient department. Since there was no similar study conducted in this population, sample size could not be calculated. However, to ensure a minimum sample size of 30 in both the groups, the total sample size of 60 was kept. Ethical clearance was obtained from the institutional ethics committee (CTRI No.: CTRI/2020/05/024994.). Written informed consent was taken from all the participants. The patients were randomized into two groups using computer-generated randomization software. The allocation cards were sealed in a sequentially numbered envelope. The principal surgeon opened the envelopes in the operation theater prior to surgery. After randomization, patients were divided into two groups. Group I comprised the intervention group (n = 30), wherein patients received bupivacaine infiltration of vaginal vault after TLH. Group II comprised the control group (n = 30), who did not receive bupivacaine infiltration in vaginal vault.

The inclusion criteria for the study were patients requiring TLH with or without bilateral salpingo-oophorectomy (BSO) for benign conditions and uterine size ≤12 weeks of pregnancy. The exclusion criteria were presence of malignancy, contraindication to any medication that was used in the study (Bupivacaine, paracetamol, diclofenac), history of chronic pelvic inflammatory disease, and history of previous multiple surgeries. The primary outcome measure was the postoperative pain measured in both the groups at 1, 3, 6, 12, and 24 h, using visual analog score. The secondary outcome measure was need for rescue analgesia. The study consort diagram is depicted in Flowchart 1.

Preoperative workup

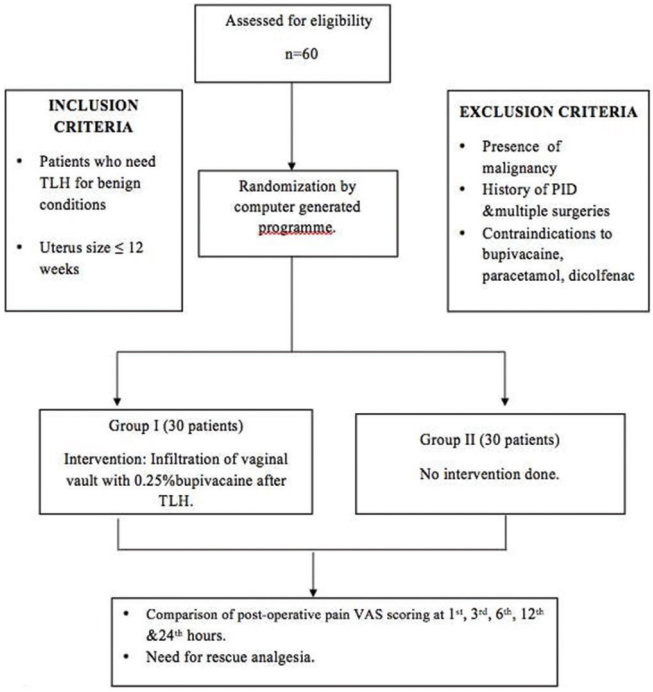
A complete workup of each patient in terms of demographic profile, body mass index (BMI), and eligibility criteria was performed. A complete general physical and gynecological examination was done. All the patients were interviewed and written informed consent was taken. In all the patients, preoperative investigations for fitness to general anesthesia were done. They underwent Papanicolaou test (PAP Smear) test and endometrial aspiration before surgery. All the surgeries were performed under general anesthesia as per the standard protocol.

Operative procedure

Patients were placed in the lithotomy position for the standardized laparoscopic procedure. A uterine manipulator was used to expose the uterus and pelvic structures. Pneumoperitoneum was created using a Veress needle through the umbilicus, and a 10 mm umbilical trocar and three 5 mm secondary ports were used. TLH was performed stepwise using LigaSure and harmonic scalpel as energy sources. The vaginal cuff was closed using a continuous barb suture laparoscopically. After vault closure, 10 ml of 0.25% bupivacaine was infiltrated laparoscopically using a fine tipped aspiration needle into the vaginal vault at two different points 2–3 cm apart, 5 ml at each point, and at a depth of 3–4 mm, in the study group. In the control group, the latter step was omitted. Figure 1 shows infiltration of bupivacaine into the vaginal vault laparoscopically using aspiration needle.

Postoperative management

Postoperative pain was treated using intravenous paracetamol 1 g six hourly for 24 h. All the patients were given NSAIDS (Diclofenac) three times a day for 5 days. Additional requirement of analgesics (opioids and NSAIDS) was recorded. The women were asked to scale their pain with VAS score. The severity of incisional pain using VAS score (0 indicated no pain and 10 indicated unbearable pain) at 1, 3, 6, 12, and 24 h after surgery was recorded. They received tramadol 50 mg IM if they report a VAS score >4 in the postanesthesia care unit and surgical ward. The operative time, amount of operative bleeding, uterine weight, and any complications were recorded. The length



Flowchart 1: Consort diagram of the study

of hospital stay was counted from the end of surgery till discharge.

Pain assessment

Pain visual analog scale (VAS) was used to assess postoperative pain in our study. The VAS is a validated, subjective measure for acute and chronic pain. Scores were recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" and "worst pain."

Statistical analysis

Descriptive statistics such as standard deviation and range values were computed for normally distributed data and the mean value was compared using "*t* independent" tests. Frequency of categorical data was compared using "Chi-square/Fisher's exact" tests. Nonnormal data, median values, and interquartile range were computed using nonparametric "Mann–Whitney tests." All statistical analyses were carried out using STATA software version 12.0 (STATA CORP, Texas, US). For all statistical tests, probability of $P < 0.05$ was considered statistically significant.

Results

In this study, 60 patients requiring TLH were randomized into two groups using a computer-generated randomization program. Group I (intervention group) received bupivacaine infiltration to vaginal vault after TLH, and Group II (Control group) did not receive bupivacaine infiltration to vaginal vault. The patients in the two groups were comparable in terms of age, BMI, parity, and other baseline

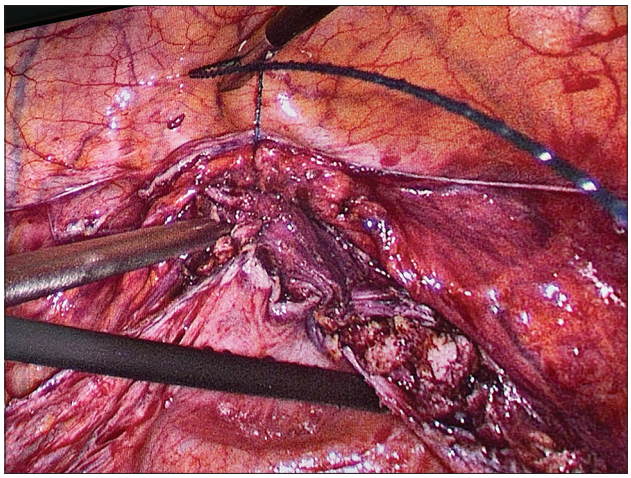


Figure 1: Infiltration of bupivacaine in to the vaginal vault laparoscopically using aspiration needle

characteristics. The baseline characteristics of both the groups are mentioned in Table 1.

Most of the patients were operated for abnormal uterine bleeding with failed medical management, classification based on POLYP, Adenomyosis, Leiomyoma, Malignancy and hyperplasia, Coagulopathy, Ovulatory dysfunction, Endometrial, Iatrogenic, and Not yet classified (PALMCOEIN) given by International Federation of Gynecology and Obstetrtics (FIGO), as mentioned in Table 1.

There are nine categories, which are arranged according to the acronym PALM-COEIN. One patient was operated for cervical intraepithelial neoplasia-3. The difference between mean values of estimated blood loss and operating time was not statistically significant in both the groups ($P > 0.005$). The operative characteristics in both the groups are depicted in Table 2.

All the patients in Group I (intervention group) had a pain VAS score <4 when compared to around 93% of the patients in Group II (control group) at 1 h postsurgery ($P = 0.49$). Similarly, all the patients in Group I had a VAS score <4 when compared to 86.6% of the patients in Group II at 3 h postsurgery ($P = 0.112$). The VAS score was <4 in significantly more number of patients, in the intervention group as compared to the control group at 6 h postsurgery (97% vs. 30%), with the $P = 0.001$. Similarly, the VAS score of less than 4 was significantly more common in Group I (96.7%) as compared to patients in Group II (10%) at 12 h postsurgery ($P = 0.001$). 36.7% of the patients in Group I had a VAS score <4 when compared to 3.3% of the patients in Group II ($P = 0.002$) at 24 h postsurgery. The number of patients having VAS score <4 at 6th, 12th, and 24th h of postoperative period was significantly more in the intervention group [Table 3]. Hence, infiltration with local

analgesia effectively reduced the intensity of postoperative pain in postoperative period.

The mean value of VAS score at 1st h after completion of surgery in Group I was 1.53 ± 0.507, whereas in Group II was 2.17 ± 0.74 ($P < 0.001$). Similarly, the mean values of VAS score at 3rd, 6th, 12th, and 24th h were calculated and compared between the two groups and found to be statistically significant at all these times ($P < 0.001$). Thus, the intervention group had lesser mean VAS scores at 1, 3, 6, 12, and 24 h [Table 4]. The additional procedure that is BSO did not affect the VAS score ($P > 0.05$).

Five patients in the intervention group (I) received additional opioid analgesia in the postoperative period, whereas 27 patients in the control group (II) required the same in postoperative period ($P < 0.05$). In Group I, although there was an increase in the mean value of VAS score from 3rd to 6th, 12th, and 24th h, the mean value was <4 for most of the patients. Hence, Group I received lesser additional opioid analgesics for postoperative pain in the first 24 h of surgery. In contrast, more number of patients had a mean VAS score >4 in Group II. Thus, additional requirement of opioid analgesia for postoperative pain was more in Group II as compared to Group I ($P < 0.05$) [Table 5].

Discussion

TLH was established from 1989 onward.[8] While contemporary changes such as a shift to minimally invasive modalities have resulted in improved outcomes, it is still associated with significant postoperative discomfort. Recently, there have been multiple attempts to institute strategies that reduce postoperative pain after a hysterectomy.

Preoperative transverse abdominis plane blocks, injection of local anesthetic to port sites, and reduced port caliber are few examples to control postoperative pain. Most of these approaches are focused on decreasing discomfort on the abdominal wall. However, anatomical sites that also undergo significant tissue manipulation, such as the vaginal cuff and pelvic dissection sites, are often overlooked for targeted pain control despite the presence of nociceptors in the region. We propose the vaginal cuff and parametria as sites for targeted pain control with the objective of reducing noxious stimuli from the pelvic dissection and vaginal cuff closure. The present study was a randomized controlled trial performed to assess the efficacy of bupivacaine, a long-acting amide local anesthetic, infiltration in the vaginal vault in reducing postoperative pain after TLH and to see if it decreases the requirement of opioid use.

Severity of pain was recorded using VAS score (0 indicating no pain and 10 indicating unbearable pain) at 1st, 3rd, 6th, 12th, and 24th h after surgery. It was reported that the vaginal vault infiltration with bupivacaine is effective in reducing postoperative pain and bypassing the requirement of opioid analgesia, thereby preventing opioid-related side effects in early postoperative period. Kilpiö *et al*. performed a single-center, randomized trial, in which women assigned to laparoscopic hysterectomy were randomly divided into

Table 1: Patient characteristics in both the groups

Characteristics	Group I ($n=30$)	Group II ($n=30$)	*P*
Mean age (years)	43.10	43.03	0.967
Mean BMI (kg/m^2)	26.04	27.42	0.11
Median parity	2	2	0.164
Occupation			
Home-maker	29	30	0.138
Skilled worker	1	0	
Educational status			
Secondary level	24	23	0.35
Graduate	6	7	
Medical disorder			
Diabetes mellitus	4	2	>0.05
Hypertension	0	1	
Hypothyroidism	2	2	
Asthma	1	0	
Rheumatic heart	1	0	
Disease			
Others	0	1	
PBAC	439	502	0.0397
Indication of hysterectomy as per FIGO classification, *n* (%)			
AUB-O (n=8)*	6 (20)	2 (6.7)	>0.05
AUB-E (n=1)	0	1 (3.3)	
AUB-A (n=9)	5 (16.7)	4 (13.3)	
AUB-L (n=32)	15 (43.3)	17 (53.3)	
AUB-P (n=7)	3 (10)	4 (13.3)	
AUB-M (n=2)	0	2 (6.7)	
CIN-3 (n=1)	1 (3.3)	0	

*Failed medical management. BMI: Body mass index, PBAC: Pictorial blood assessment chart, AUB: Abnormal uterine bleeding, FIGO: International federation of gynecology and obstetrtics, CIN: Cervical intraepithelial neoplasia

Table 2: Intra operative findings in both the groups

	P	Group I ($n=30$)	Group II ($n=30$)
Uterine size			
Uterus 12 weeks size (n=10)	>0.05	5	5
Uterus 10 weeks size (n=5)		3	2
Uterus 8 weeks size (n=14)		5	9
Uterus 6 weeks size (n=8)		5	3
Uterus normal size (n=23)		12	11
Operating time (min)	0.685	65	67.7
Blood loss (ml)	0.047	99.17	89.67
Surgery performed			
TLH	>0.05	28	28
TLH with bilateral salpingo-oophorectomy		2	2

TLH: Total laparoscopic hysterectomy

Table 3: Comparison of number of patients having visual analog scale score <4 in both the groups

	Group I (n=30)		Group II (n=30)		*P*
	Number of patients with mean VAS <4	Number of patients with mean VAS >4	Number of patients with mean VAS <4	Number of patients with mean VAS >4	
VAS 1	30	0	28	2	0.49
VAS 3	30	0	26	4	0.11
VAS 6	29	1	9	21	0.001
VAS 12	29	1	3	27	0.001
VAS 24	11	19	1	29	0.002

VAS: Visual analog scale

Table 4: Visual analog scale score at 1st, 3rd, 6th, 12th and 24th h in both the groups

Groups	VAS 1	VAS 3	VAS 6	VAS 12	VAS 24
Group I (n=30) mean VAS score	1.53±0.507	2±0.587	2.27±0.691	2.67±1.06	3.63±0.148
Group II (n=30) mean VAS score	2.17±0.747	2.93±0.64	3.93±0.980	4.63±0.80	5.47±0.238
P	<0.001	<0.001	<0.001	<0.001	<0.001

VAS: Visual analog scale

Table 5: Patients requiring rescue analgesia in both the groups

VAS (at time interval in hours)	Group I (n=30) Number of patients who received rescue analgesia	Group II (n=30) Number of patients who received rescue analgesia
1	0	0
3	0	0
6	1	21
12	4	6
Total	5	27
P	<0.05	

VAS: Visual analog scale

two groups.[9] In the intervention group (n = 41), the vaginal cuff was infiltrated with 10 ml of ropivacaine (7.5 mg/ml) at four points, in addition to trocar-site anesthesia. In the control group (n = 40), only trocar incisions were infiltrated with local anesthetic. The primary outcomes were postoperative opioid (oxycodone) use and record postoperative pain at 1, 3, 6, 12, and 24 h of surgery using VAS. Secondary outcomes were emesis, bleeding, operative time, time to discharge, and complications. VAS scores for pain were less than 3 during the entire postoperative study period in 17 patients in the intervention group and 8 patients in the control group, which was statistically significant (P = 0.04). Otherwise, there were no significant differences between the groups in VAS scores for pain, the use of opioids, or in any other variables. In contrast to this, our study showed significantly decreased requirement of additional analgesia apart from less VAS scores at all times in postoperative period in the intervention group.

Kwack Young *et al.* compared postoperative pain intensity at 2 h after administration of ropivacaine or placebo solution into uterosacral ligaments at the end of laparoscopic-assisted vaginal hysterectomy.[5] The mean pain scores in the ropivacaine group (n = 20) were significantly less as compared to the saline group (P = 0.023). The patients who received saline required more opioid analgesia in comparison to those who received ropivacaine (P = 0.025). Radtke *et al*.[10] performed a paracervical block before laparoscopic hysterectomy and compared postoperative pain scores.

Postoperative pain scores (VAS scores) were significantly lower in the treatment group at 30 and 60 min (P < 0.001). Other interventions which have been found to be effective are infiltration of the muscular fasciae at the wound side, by the end of the laparoscopic surgery with levo-bupivacain, as reported by Sugihara *et al*.[11] bupivacaine block after the trocar incision closure by Tam *et al*.;[12] cold nebulization with ropivacaine before and after surgery by Somain *et al*.;[13] and intraperitoneal bupivacaine infiltration by Roy *et al*.[14]

Few patients could not reliably confirm their VAS score in 1st h as the effect of general anesthesia took time to wean off. However, the mean VAS score at 1st h postsurgery calculated in our study was statistically significant. Hence, this study shows that pain control is effective even in the first few hours of surgery, better than our anticipation. Similar studies performed by various authors like Radtke *et al*.[10] calculated VAS score at 30 and 60 min interval postsurgery and found to be statistically significant.

All patients in group I required low quantities of postoperative opioid analgesics when compared to Group II (P < 0.05).

Therefore, this study highlights the beneficial use of local vault infiltration with bupivacaine after TLH in improving pain control from early postoperative hours till 24 h. The results are especially encouraging as this is the period when maximum additional analgesics are required. The results were similar whether or not, the additional procedure of BSO was performed. Hence, local vault infiltration with bupivacaine is recommended for TLH with or without BSO.

Conclusion

Overall, the present randomized control trial demonstrates that vaginal cuff infiltration with local anesthetic is a feasible and safe option for postoperative pain relief. Infiltration of the vaginal vault with 10 ml of 0.25% bupivacaine, at the end of laparoscopic hysterectomy, significantly increases the number of women who experience minimal postoperative pain for the first 24 h after surgery, with no impairments in surgical outcome. It also diminishes the requirement of additional analgesia/opioid usage.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Mouton WG, Bessell JR, Otten KT, Maddern GJ. Pain after laparoscopy. Surg Endosc 1999;13:445-8.
2. Aarts JW, Nieboer TE, Johnson N, Tavender E, Garry R, Mol BWJ. *et al*. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane database of systematic reviews 2015;(8).
3. Walsh CA, Walsh SR, Tang TY, Slack M. Total abdominal hysterectomy versus total laparoscopic hysterectomy for benign disease: A meta-analysis. Eur J Obstet Gynecol Reprod Biol 2009;144:3-7.
4. Rattanalappaiboon D, Werawatakul Y, Tharnprisan P, Prasit M. Intraperitoneal lidocaine for decreasing intra-operative pain during postpartum tubal resection in Srinagarind hospital. J Med Assoc Thai 2012;95:477-81.
5. Kwack JY, Kwon YS. Immediate postoperative pain control with ropivacaine following laparoscopic-assisted vaginal hysterectomy: A randomized double-blind pilot study. Taiwan J Obstet Gynecol 2018;57:654-8.
6. Gupta N, Dadhwal V, Mittal S. Combined intraperitoneal instillation and port site infiltration of local anaesthetic (bupivacaine) for postoperative analgesia in women undergoing daycare diagnostic gynaecological laparoscopy. Eur J Obstet Gynecol Reprod Biol 2012;161:109-10.
7. Hristovska AM, Kristensen BB, Rasmussen MA, Rasmussen YH, Elving LB, Nielsen CV, *et al.* Effect of systematic local infiltration analgesia on postoperative pain in vaginal hysterectomy: A randomized, placebo-controlled trial. Acta Obstet Gynecol Scand 2014;93:233-8.
8. Schindlbeck C, Klauser K, Dian D, Janni W, Friese K. Comparison of total laparoscopic, vaginal and abdominal hysterectomy. Arch Gynecol Obstet 2008;277:331-7.
9. Kilpiö O, Härkki P, Mentula M, Pakarinen PI. Vaginal Cuff Infiltration with a Local Anesthetic for Postoperative Pain after Laparoscopic Hystertomy: A randomized control trial. Clinics of Surgery 2019;4:2489.
10. Radtke S, Boren T, Depasquale S. Paracervical block as a strategy to reduce postoperative pain after laparoscopic hysterectomy: A randomized controlled trial. J Minim Invasive Gynecol 2019;26:1164-8.
11. Sugihara M, Miyake T, Miyagi Y, Oda T, Hazama Y, Sano R, *et al.* Does local infiltration anesthesia on laparoscopic surgical wounds reduce postoperative pain? Randomized control study. Reprod Med Biol 2018;17:474-80.
12. Tam T, Harkins G, Wegrzyniak L, Ehrgood S, Kunselman A, Davies M. Infiltration of bupivacaine local anesthetic to trocar insertion sites after laparoscopy: A randomized, double-blind, stratified, and controlled trial. J Minim Invasive Gynecol 2014;21:1015-21.
13. Somaini M, Brambillasca P, Ingelmo PM, Lovisari F, Catenacci SS, Rossini V, *et al.* Effects of peritoneal ropivacaine nebulization for pain control after laparoscopic gynecologic surgery. J Minim Invasive Gynecol 2014;21:863-9.
14. Roy KK, Subbaiah M, Naha M, Kumar S, Sharma JB, Jahagirdar N. Intraperitoneal bupivacaine for pain relief after minilaparoscopy in patients with infertility. Arch Gynecol Obstet 2014;289:337-40.