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Does local infiltration anesthesia on laparoscopic surgical wounds reduce postoperative pain? Randomized control study

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Abstract

Purpose: Recently, endoscopic surgeries are widely performed in the gynecological field. Several studies on the use of local anesthesia for pain control after laparoscopic surgery have been conducted; however, its effects remain controversial. Herein, a randomized control study on gynecological laparoscopic surgeries was conducted to analyze the effectiveness of local anesthesia on postoperative pain.

Methods: Patients who underwent laparoscopic surgeries due to gynecologic benign diseases or endometrial cancer in the early stage were enrolled, and randomly divided into intervention (injected with levobupivacaine), and control (injected with saline) groups. The primary outcome was the dosage of analgesic consumption within 12 hours postoperatively.

Results: A total of 147 patients were enrolled in the intervention group and 147 in the control group. The outcome of local anesthesia was not significantly different between the two groups during the whole analysis. We analyzed the effects of local anesthesia in the laparoscopic surgery subgroup. The dosage of analgesic consumption within 12 h after a laparoscopic hysterectomy (TLH) or TLH with pelvic lymph node dissection (TLH+PLD) in the intervention group was significantly smaller than that in the control group.

Conclusion: Local infiltration anesthesia can effectively reduce postoperative pain in patients who underwent TLH or TLH +PLD.

KEYWORDS

hysterectomy, laparoscopic surgery, local infiltration anesthesia, salpingo-oophorectomy, VAS

1 | INTRODUCTION

In the last two decades, the prevalence of endoscopic surgeries has widely spread in the field of gynecology. The advantages of laparoscopic surgery are cosmetic beauty, shorter postoperative recovery time, less postoperative pain, shorter hospital stays, and decreased blood loss. Operative laparoscopy offers the benefit of a faster return to normal activity. In addition to the other benefits of laparoscopic surgeries, adhesions are less likely to form with laparoscopic surgeries than with laparotomies.[1] For pain relief after surgery, epidural anesthesia and patient-controlled analgesia (PCA) have been used after conventional laparotomies. However, after laparoscopic surgery these procedures were not used because of decreased postoperative pain. Postoperative pain in laparoscopic surgery is

believed to be lighter than laparotomy. If we can reduce postoperative pain after laparoscopic surgery, these methods will lead to increased patient satisfaction.

Various types of pain are experienced in laparoscopic surgery such as pain in the trocar wound, pain of the wound in the abdominal cavity, peritoneal irritation, and pain in the pneumoperitoneum.[2] Local infiltration anesthesia has been used for pain relief after laparoscopic surgery. Several studies on local anesthesia for pain control after laparoscopic surgery have been conducted. However, the results of pain relief with local anesthesia are still controversial. Meta-analysis on the intraperitoneal administration of local infiltration anesthesia published by Marks et al in 2012 was effective for 6 hours postoperatively, and no significant difference was observed 24 hours postoperatively, although the administration route of local infiltration anesthesia was different between this study and Marks et al.[3] Wheatley and Fiddes reported that they could reduce pain by administering local infiltration anesthesia directly to the fallopian tube during sterilization surgery.[4,5] In addition, Ke et al reported that patients desiring infertility and undergoing sterilization surgery were able to reduce postoperative pain by injecting local infiltration anesthesia into the port wounds preoperatively.[6] Pellico and Ceyhan reported that postoperative pain was reduced by administrating local infiltration anesthesia both intraperitoneally and directly to the port wound.[7,8] Parsanezhad et al reported that locally infiltrating anesthetics intraperitoneally administered when performing diagnostic laparoscopy for unexplained infertility can effectively relieve pain.[9] Jimenez et al reported that the combination of local infiltration anesthesia to the port wound site preoperatively and intraperitoneal administration postoperatively reduced postoperative pain and opioid usage.[10] In contrast, several studies demonstrated that administration of local infiltration anesthesia to the port wound did not reduce postoperative pain.[11-13]

In Japan, facilities expecting the analgesic effect after laparoscopic surgery and administering local infiltration anesthesia to the wound have already been found; however, studies on local anesthetics are limited in Japan.[14] In this study, we conducted a randomized control study of local anesthesia in gynecological laparoscopic surgery to analyze effects of local infiltration anesthesia on postoperative pain. We also investigated the effects of anesthesia in various kinds of laparoscopic surgeries in the field of gynecology.

2 | MATERIALS AND METHODS

2.1 | Patients and selection

Patients who underwent laparoscopic surgeries due to gynecologic benign diseases or endometrial cancer in the early stage in Kawasaki Medical School Hospital and Okayama Ofuku Clinic from June 2015 to January 2017 were enrolled in this study. All patients aged ≥18 years and had no allergies to local anesthesia; all agreed to participate in this study. As a result, patients who used epidural anesthesia in addition to general anesthesia, those who underwent laparotomy were not included in the study. This study was approved by the ethical review board of Kawasaki Medical School (No.2082). A clinical trial registration (number: UMIN000022412) was also obtained. Written informed consent was obtained from all patients enrolled in the study.

2.2 | Study protocol

We conducted a randomized controlled trial on the local infiltration anesthesia after a laparoscopic surgery in this study. The enrolled patients were divided into intervention and control groups using the envelope method. Patients in the intervention group were injected with 2 mL of 0.5% levobupivacaine (POPSCAINE®; Maruishi Pharmaceutical Co., Ltd., Osaka city, Japan) using a 25G needle per 1 cm of wound into the muscular fasciae at the end of the laparoscopic surgery. Patients in the control group were injected with 2 mL of saline. The pain evaluation after laparoscopic surgery was performed using a Visual Analogue Scale (VAS) at 1 hour and 2 hours postoperatively. VAS exhibits the strongest pain as 10 and the weakest pain as 0. The primary outcome is the dosage of analgesic consumption within 12 hours postoperatively because it can be measured objectively and we avoided to disturb the rest of the patient. Secondary outcomes are the VAS scores 1 or 2 hours postoperatively and analgesic use or nonuse. We also examined the adverse effects of local infiltration anesthesia, such as local bleeding, allergenic reaction, and damage to the organs.

Laparoscopic surgeries were performed under general anesthesia without an epidural or PCA. The location of trocars in total laparoscopic hysterectomy (TLH) or TLH with pelvic lymph node dissection (PLD), ovarian cystectomy, and salpingo-oophorectomy (SO) was one trocar (12 mm) from the umbilicus and three trocars (5 mm) at the right, left, and middle of the lower abdomen. The location of trocars in myomectomy was one trocar (12 mm) at the left lower abdomen and three trocars (5 mm) at the right lower abdomen, umbilicus, and beside the umbilicus. When patients had postoperative pain, intravenous acetaminophen, intravenous pentazocine, or anal diclofenac was administered.

We analyzed the effects of local anesthesia in the subgroups of laparoscopic surgeries. Gynecological laparoscopic surgeries were divided into four groups depending on the degree of operative invasion: laparoscopic surgery of the ovary and fallopian tube (Group1), laparoscopic myomectomy (LM; Group 2), laparoscopically assisted vaginal hysterectomy (LAVH; Group 3), and TLH or TLH+PLD (Group 4).

2.3 | Statistical analysis

The Student's *t* test was performed for the analysis of analgesic consumption within 12 hours postoperatively, VAS in 1 and 2 hours postoperatively, and the number of days of hospitalization. The chi-squared test was performed for analgesic use or nonuse. Statistical analysis was performed using the JMP version 9 program (SAS Institute Inc., Cary, NC, USA). Statistical significance was

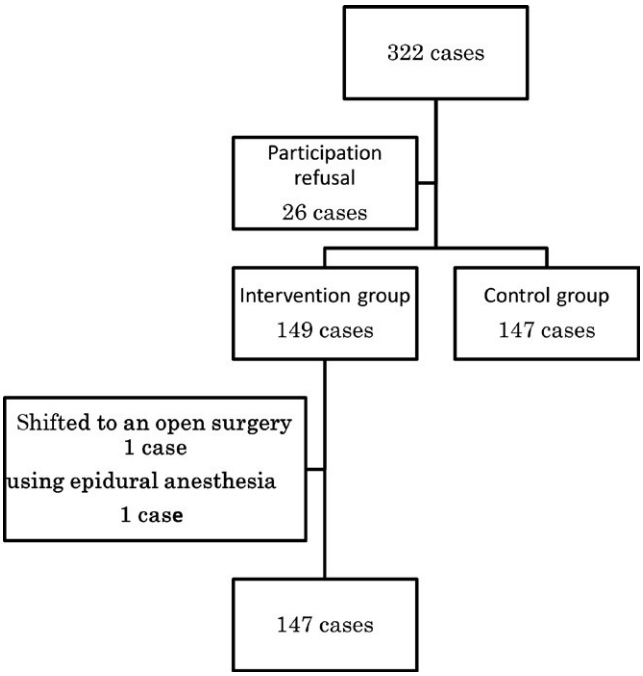

FIGURE 1 The study protocol. A total of 322 patients were enrolled in this study. They were divided into the intervention (147 patients) and control (147 patients) group. Two patients dropped out from the study: one was shifted to an open surgery and the other was treated with epidural anesthesia in the intervention group

considered if $P < 0.05$. The values were represented as mean ± standard deviation.

3 | RESULTS

A total of 322 patients were enrolled in this study and were divided into the intervention (147 patients) and control (147 patients) groups. Two patients dropped out of the study: one was shifted to an open surgery and the other was treated with epidural anesthesia in the intervention group (Figure 1). No serious complications were observed in either group. As shown in Table 1, differences in age, BMI, parity, operation time, and blood loss were not significant between the intervention and control groups. Table 2 demonstrates the operative methods of both groups. No significant difference was observed in the operative methods between the two groups. As shown in Table 3, no significant difference on the outcome of local anesthesia was found between the two groups. No adverse effects were also found in either group.

As shown in Tables 4 and 5, the difference on the effects of local anesthesia was not significant between Group 1 and Group 2. Table 6 demonstrates that local anesthesia has no positive effects in Group 3. Table 7A demonstrates the effects of local anesthesia in Group 4. The dosage of analgesic consumption within 12 hours postoperatively in the intervention group was significantly smaller

TABLE 1 Characteristics of patient background

	Overall (N = 294)	Intervention group (N = 147)	Control group (N = 147)	*P* value
Mean age (years old)	41.8 ± 10.1	40.8 ± 9.4	42.9 ± 10.7	NS
BMI (kg/m^2)	22.3 ± 4.3	22.8 ± 4.1	22.2 ± 3.6	NS
Parity	1.1 ± 1.2	1.0 ± 1.2	1.2 ± 1.2	NS
Operation time (min)	80.0 ± 50.8	84 ± 50.3	75.0 ± 51.0	NS
Amount of bleeding (mL)	112.0 ± 192.9	122.8 ± 235.8	100.9 ± 135.7	NS

TABLE 2 Operative methods of the intervention group and the control group

	Intervention group	Control group	*P* value
Number of cases	147	147	NS
Laparoscopic hysterectomy	8 (2.7%)	10 (3.4%)	NS
Laparoscopic myomectomy	49 (16.7%)	35 (11.9%)	NS
Laparoscopic oncological surgery	3 (1.0%)	5 (1.7%)	NS
Laparoscopic salpingo-oophorectomy	15 (5.1%)	20 (6.8%)	NS
Laparoscopic ovarian cystectomy	31 (10.5%)	29 (9.9%)	NS
Laparoscopic assisted vaginal hysterectomy	34 (11.6%)	43 (14.6%)	NS
Others	7 (2.4%)	5 (1.7%)	NS

TABLE 3 Results of all laparoscopic surgeries in this study

	Intervention group (N = 147)	Control group (N = 147)	*P* value
Analgesic consumption within 12 h after surgery (time)	1.6 ± 1.0	1.6 ± 1.0	0.481
Analgesic use or nonuse within 12 h after the surgery (use/overall)	124/147	123/147	0.873
VAS in 1 h after surgery	4.5 ± 3.2	4.3 ± 3.1	0.340
VAS in 2 h after surgery	2.8 ± 3.2	2.6 ± 2.7	0.230
Hospitalization (days)	3.6 ± 1.1	3.6 ± 1.2	0.451
Time to initial use of analgesic (min)	152.3 ± 246.9	160.5 ± 248.8	0.389

TABLE 4 Results of surgeries of the ovary or the fallopian tube (Group 1)

	Invention group (N = 54)	Control group (N = 54)	*P* value
Analgesic consumption within 12 h after surgery (time)	1.2 ± 0.8	1.1 ± 1.0	0.494
Analgesic use or nonuse within 12 h after surgery (use/overall)	41/54	35/54	0.206
VAS in 1 h after surgery	3.7 ± 2.4	4.1 ± 2.6	0.201
VAS in 2 h after surgery	2.1 ± 2.2	2.1 ± 2.2	0.498
Hospitalization (days)	3.3 ± 1.4	3.0 ± 1.1	0.085
Time to initial use of analgesic (min)	215.3 ± 292.3	288.4 ± 323.5	0.111

TABLE 5 Results of surgeries of laparoscopic myomectomy (Group 2)

	Invention group (N = 49)	Control group (N = 35)	*P* value
Analgesic consumption within 12 h after surgery (time)	1.7 ± 0.9	1.5 ± 0.9	0.135
Analgesic use or nonuse within 12 h after surgery (use/overall)	44/49	29/35	0.223
VAS in 1 h after surgery	4.2 ± 3.4	2.8 ± 2.7	0.026
VAS in 2 h after surgery	2.3 ± 2.5	1.8 ± 2.1	0.184
Hospitalization (days)	3.7 ± 0.9	3.5 ± 1.4	0.167
Time to initial use of analgesic (min)	100.5 ± 190.3	145.4 ± 228.1	0.164

TABLE 6 Results of laparoscopically assisted vaginal hysterectomy (Group 3)

	Invention group (N = 34)	Control group (N = 43)	*P* value
Analgesic consumption within 12 h after surgery (time)	2.5 ± 0.9	2.3 ± 0.9	0.127
Analgesic use or nonuse within 12 h after surgery (use/overall)	33/34	43/43	0.257
VAS in 1 h after surgery	6.3 ± 3.3	5.4 ± 3.3	0.121
VAS in 2 h after surgery	4.4 ± 5.0	2.9 ± 3.1	0.047
Hospitalization (days)	3.8 ± 0.6	4.0 ± 0.8	0.147
Time to initial use of analgesic (min)	45.4 ± 60.4	35.0 ± 21.1	0.146

than that in the control group ($P = 0.003$). The difference on analgesic use or nonuse within 12 hours postoperatively was also significant between the two groups ($P = 0.003$) in Group 4. The VAS score at 1 hour and 2 hours postoperatively in the intervention group was lower than that in the control group in Group 4, but not significant. The time to initial use of analgesics in Group 4 in the control group was significantly shorter than that in the intervention group ($p = 0.003$). We divided Group 4 into TLH and TLH+PLD. Tables 7B and 7C demonstrate the effects of local anesthesia at on patients who underwent TLH and TLH+PLD, respectively. In

TABLE 7A Results of laparoscopic hysterectomy or hysterectomy including pelvic lymph node dissection (Group 4)

	Invention group (N = 11)	Control group (N = 15)	*P* value
Analgesic consumption within 12 h after surgery (time)	0.7 ± 0.8	1.6 ± 0.7	0.003
Analgesic use or nonuse within 12 h after surgery (use/overall)	6/11	15/15	0.003
VAS in 1 h after surgery	5.0 ± 3.2	6.3 ± 3.1	0.146
VAS in 2 h after surgery	3.2 ± 2.1	5.0 ± 3.0	0.05
Hospitalization (days)	3.6 ± 1.4	4.3 ± 2.1	0.194
Time to initial use of analgesic (min)	361.7 ± 344.3	94.7 ± 72.4	0.003

TABLE 7B Results of laparoscopic hysterectomy

	Invention group (N = 8)	Control group (N = 10)	*P* value
Analgesic consumption within 12 h after surgery (time)	0.8 ± 0.7	1.6 ± 0.7	0.01
Analgesic use or nonuse within 12 h after surgery (use/overall)	5/8	10/10	0.03
VAS in 1 h after surgery	5.3 ± 3.1	6.3 ± 3.1	0.27
VAS in 2 h after surgery	2.7 ± 1.5	5.3 ± 2.3	0.007
Hospitalization (days)	3.3 ± 0.9	3.8 ± 2.1	0.42
Time to initial use of analgesic (min)	299.1 ± 348.7	81.0 ± 75.8	0.04

TABLE 7C Results of laparoscopic hysterectomy including pelvic lymph node dissection

	Invention group (N = 3)	Control group (N = 5)	*P* value
Analgesic consumption within 12 h after surgery (time)	0.7 ± 1.2	1.6 ± 0.9	0.12
Analgesic use or nonuse within 12 h after surgery (use/overall)	1/3	5/5	0.03
VAS in 1 h after surgery	4.0 ± 3.9	6.4 ± 3.4	0.20
VAS in 2 h after surgery	4.5 ± 3.2	4.4 ± 4.3	0.49
Hospitalization (days)	4.7 ± 2.1	5.4 ± 1.7	0.30
Time to initial use of analgesic (min)	528.7 ± 331.4	122.0 ± 63.6	0.02

addition, we analyzed the time to initial usage of analgesics for the four groups in the control group. The time to initial use of analgesics in Group 1, Group 2, Group 3 and Group 4 in the control group were 288.4 ± 323.5 minutes, 145.4 ± 228.1 minutes, 35.0 ± 21.1 minutes, and 94.7 ± 72.4 minutes, respectively. The time to initial use of analgesics in Group 2 was significantly shorter than that in Group 1 ($P = 0.012$), and that in Group 4 was also significantly shorter than that in Group 1 ($P = 0.012$). The difference in the time to initial use of analgesics was not significant between Groups 3 and 4.

4 | DISCUSSION

In this study, we investigated the effectiveness of local anesthesia in reducing postoperative pain in gynecological laparoscopic surgery. The difference on the outcomes of local anesthesia was not significant between the intervention and control groups in all gynecological laparoscopic surgeries in the study. The effect on pain relief of local anesthesia is controversial in gynecological laparoscopic surgery. Recently, a meta-analysis on local infiltration anesthesia demonstrated that it was effective 6 hours postoperatively, but not 24 hours postoperatively.[3] This meta-analysis was conducted mainly on patients who underwent adnexal surgeries, who generally had low surgical stress.[3] We divided gynecological laparoscopic surgeries into four groups depending on the degree of operative invasion. The results of the meta-analysis were different from those of this study, because the latter was conducted on patients who underwent ovarian or fallopian tube surgeries. The reason for the discrepancy was unknown; however, one possible reason is that it was difficult to make a significant difference between the intervention and control group because laparoscopic surgery in the ovary or fallopian tube might be less invasive and induce less pain.

Although local anesthesia did not affect VAS on postoperative pain, the dosage of analgesic consumption and the frequency of

analgesic use within 12 hours postoperatively in Group 4 in the intervention group were significantly lower than those in the control group. The time to initial use of analgesic in Group 4 in the intervention group was significantly longer than that in the control group. These data indicate that Group 1 experienced significantly less pain than Groups 3 and 4 had. In general, surgical stress is considered to be highest in Group 4 and minimally invasive in Group 1.

The results of our study demonstrate that local infiltration anesthesia might be more effective in reducing postoperative pain in more invasive laparoscopic surgeries such as HT and oncological surgery (Group 4). Although the reason is uncertain, local anesthesia might possibly reduce the pain in the skin and fascia of the port wound site, which may lead reduced analgesic consumption and number of analgesic users. Further investigations would be needed to demonstrate the mechanism of pain relief of local infiltration anesthesia in more invasive laparoscopic surgeries.

The dosage of analgesics used by the patients in the intervention group was significantly lower than that in the control group in laparoscopic hysterectomy and laparoscopic oncological surgeries; however, the difference in VAS between 1 and 2 hours postoperatively was not significant. This might be due to the fact that patients were treated with analgesic whenever they felt pain in this study. Patients may possibly use an analgesic 1 hour and 2 hours postoperatively. The difference in the number of days of hospitalization was not significant between the two groups in the laparoscopic hysterectomy/oncological surgery. Because hospitalization days for laparoscopic surgery have already become shorter, making it shorter than they are at the current condition is difficult.

After a meta-analysis report in 2012, several studies on local infiltration anesthesia have been conducted. The bupivacaine infiltration to the trocar wound after a laparoscopic surgery did not reduce the pain score significantly compared with the non-administrated group.[13] The administration of peritoneal ropivacaine nebulization was effective to reduce postoperative pain.[15] Studies on pain control by local infiltration anesthesia were still controversial. Further investigations will be necessary to reveal the effects of local anesthesia in gynecological surgeries.

In conclusion, the local infiltration anesthesia can effectively reduce postoperative pain after laparoscopic hysterectomy and laparoscopic oncological surgery. In addition to a conventional analgesic, using local infiltration anesthesia may improve the patient's quality of life.

A meta-analysis demonstrated effectiveness of local anesthesia on minimally invasive surgery, however, this study could not confirm the effect of local infiltration anesthesia on minimally invasive surgery. Further investigations would be necessary to clarify the usefulness of local anesthesia in laparoscopic surgeries.

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DISCLOSURES

Conflict of interests: Mika Sugihara, Takahito Miyake, Yasunari Miyagi, Takashi Oda, Yukiko Hazama, Rikiya Sano, Takafumi Nakamura, Mitsuru Shiota, and Koichiro Shimoya, declare to have no conflict of interest. *Human rights statements and informed consent*: This article does not contain any studies with human and animal subjects performed by the any of the authors. *Animal studies*: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the 1964 Helsinki Declaration and its later amendments. Informed consent was obtained from all patients for being included in the study. The protocol for the research project including human subjects has been approved by a suitably constituted Ethics Committee.

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