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Original Research

Evaluation of laparoscopic-guided rectus sheath block in gynecologic laparoscopy: A prospective, double-blind randomized trial

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ABSTRACT

Background: Ultrasound-guided nerve blocks are effective; however, their use in the abdominal wall is reportedly associated with a risk of abdominal organ injury. Laparoscopic-guided nerve blocks are thought to be safer than ultrasound-guided nerve blocks. We evaluated the safety and effectiveness of the laparoscopic-guided rectus sheath block (LGRSB) for umbilical incisions after gynecologic laparoscopy.

Materials and methods: A single-center, prospective, randomized controlled trial of 210 women who underwent gynecologic laparoscopy was performed at a university teaching hospital in Japan. The intervention group underwent the LGRSB with ropivacaine hydrochloride at the end of laparoscopy under general anesthesia and received regular care. The control group received only regular care without a field block. The postoperative pain score (PPS) was recorded at 6 and 12 h and 1, 2, and 3 days postoperatively. The PPS and use of postoperative analgesics (loxoprofen, diclofenac, and pentazocine) were recorded by the floor nurses, who were blinded to the patients' data.

Results: In total, 107 women in the intervention group and 101 women in the control group were analyzed. No adverse events were encountered throughout this study. There was no evidence of differences in the PPS or use of perioperative opioids and postoperative analgesics.

Conclusion: The LGRSB for umbilical incisions after laparoscopic gynecology was easy and safe. However, this method did not significantly reduce the PPS at rest or during coughing in all postoperative conditions after gynecologic laparoscopy compared with the control.

1. Introduction

Laparoscopic surgery is considered a minimally invasive procedure and is associated with earlier recovery and discharge than traditional laparotomy. Despite their brief recovery time, laparoscopic surgeries are not pain-free in the immediate postoperative period and require a multimodal therapeutic approach [1–3]. Postoperative pain after laparoscopy is often the main factor that hinders patients' return to normal activities.

Effective analgesia is essential in postoperative management after laparoscopy. Ultrasound-guided nerve blocks are reportedly effective for relief of postoperative pain. These procedures, such as the transversus abdominis plane block and rectus sheath block (RSB), anesthetize the nerve of the anterior abdominal wall [4,5]. And these techniques are used more frequently than local infiltration because these techniques have tamponade of local anesthetics and prevent its oozing from sutured wound. In current practice, these techniques are carried out with ultrasound guidance. Because these techniques require intraperitoneal infiltration of a regional anesthetic, which requires specialized skill and ultrasound equipment, they are not easy for all surgeons to perform. Additionally, some reports have indicated that these techniques occasionally cause injury to organs [6–8]. Based on previous reports, we presumed that the laparoscopic-guided RSB (LGRSB) for umbilical incisions is safe and effective. We therefore measured the differences in postoperative pain between patients treated with the LGRSB at the umbilicus and patients who received usual care

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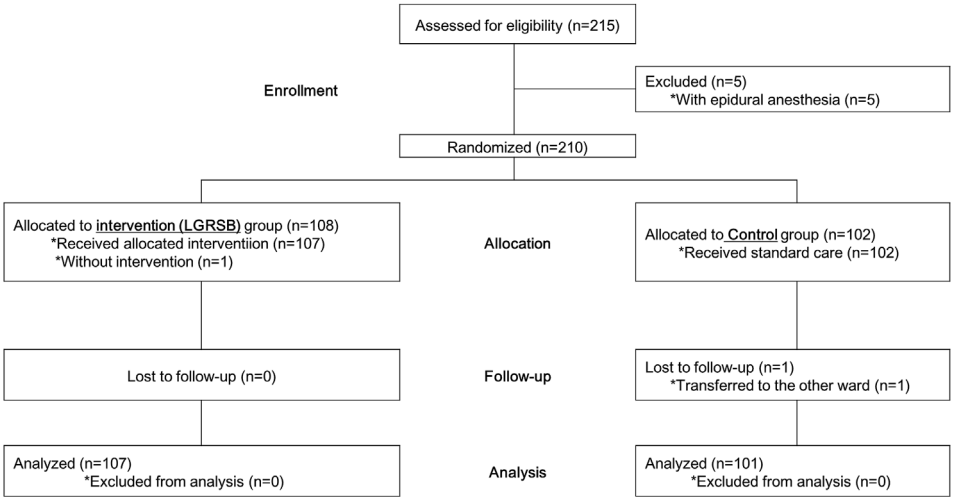


Fig. 1. CONSORT flow diagram. This diagram illustrates the flow of patients enrolled in the study. LGRSB, laparoscopic-guided rectus sheath block.

after gynecologic laparoscopy.

2. Materials and methods

2.1. Design, setting, and enrollment

This prospective, double-blind randomized trial was performed at a university teaching hospital in Japan from August 2014 to December 2016. All benign gynecologic diseases were covered to assess gynecologic procedures without malignancy. Fig. 1 shows the flow diagram of this study. Women who had indications for gynecologic laparoscopy for benign gynecologic diseases were recruited until > 200 women were enrolled.

The work has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines.

2.2. Randomizing and blinding

The patients were randomized into one of two groups: those in the LGRSB group received a field block, and those in the control group received no field block. Patients in the control group received no injection of inactive fluids because the aim of this study was to evaluate the laparoscopic method rather than efficacy of anesthetic drugs. All women in both groups could take commonly used analgesics postoperatively and were not given sedative drugs throughout the postoperative period. The randomization was performed in the operation room after induction of general anesthesia. We used a numbered container method. The surgical nurses chose one of two sheets from an envelope ("field block" was printed on one sheet and "control" was printed on the other) and assigned a sheet to each patient. We performed the field block according to each patient's assignment. The surgical nurses, anesthesiologist, and surgeons did not inform the floor nurse or patients of the assignment. The floor nurses, who were still blinded to the patients' assignments, measured the postoperative pain scores (PPSs) using a pain rating scale during the first 3 postoperative days (PODs). We set the follow-up period of three postoperative days under Japanese health insurance system's order which give approval for three day hospitalizations. The patient eligibility criteria were an age of ≥20 years, provision of written informed consent for this study, and an appropriate medical status for laparoscopic surgery. The exclusion criteria are listed below (Table 1). We also excluded women who were likely to require laparotomy and epidural anesthesia and those with a possible malignancy that we could not rule out.

Table 1
Exclusion criteria.

Suspected to have malignant disease
Pregnancy
Allergy to the regional anesthetics
Severe liver dysfunction
Chronic hemodialysis
Clotting abnormality
Taking anticoagulant or antiplatelet regularly
Neuropathy disorder
Likely to require laparotomy and epidural anesthesia

2.3. Surgical procedures

All patients underwent general anesthesia by total intravenous anesthesia, which consisted of fentanyl citrate, remifentanil hydrochloride, propofol, and rocuronium bromide, and received preoperative antibiotic prophylaxis. The surgical approach was either a single-port technique or a multi-port technique involving insertion of three or four ports at or below the umbilicus. Periumbilical single-port surgery was performed with an EZ ACCESS™ and LAP PROTECTOR™ (Hakko, Nagano, Japan), which consist of a retractor component and cap component. Multi-port laparoscopy was performed with one 12-mm transumbilical trocar, two 5-mm ports inserted into the right lower quadrant and suprapubic region, and one 5- or 12-mm port inserted into the left lower quadrant. In every case, peritoneal access was obtained using an open transumbilical port placement technique. Pneumoperitoneum was created with pressure standardized from 8 to 10 mmHg. Only five gynecologists carried out the LGRSB. The LGRSB was performed at the end of the surgical procedure and immediately prior to extubation. In total, 3 mg/kg of 0.5% ropivacaine divided into equal aliquots was infiltrated into both sides of the posterior rectus sheaths and peritoneum laterally about 3 cm from umbilical incision using a 23-gauge, 10-cm needle under laparoscopic direct vision (Fig. 2). The use of laparoscopic visualization ensured that the needle tip did not penetrate the peritoneum (Fig. 3).

2.4. Outcome assessment and statistical analysis

The PPS was determined using a pain rating scale (0 = no pain, 5 = worst pain imaginable), with which the patients were asked to evaluate their maximal degree of pain. The PPS was recorded at 6 and 12 h and on PODs 1, 2, and 3 with the patient at rest and during coughing. The patients were instructed to use pain relief medications when their PPS was ≥3. Postoperative pain was managed as follows.

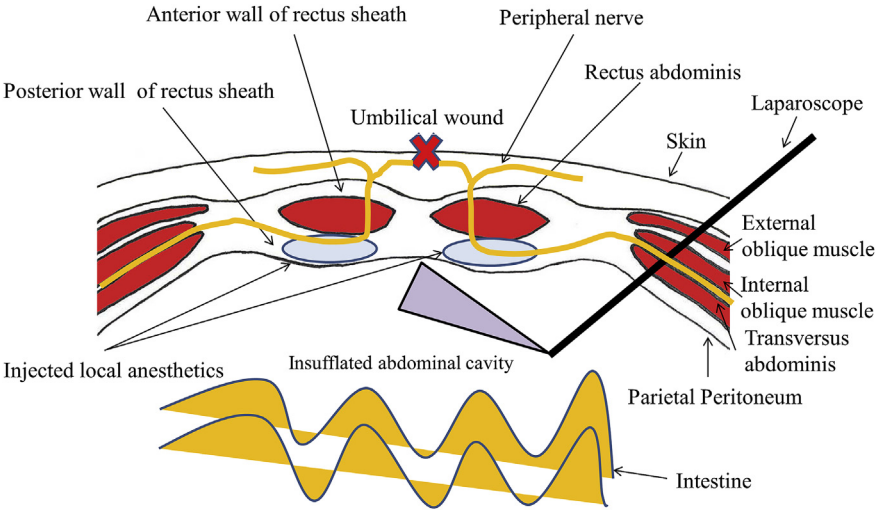


Fig. 2. Laparoscopic-guided rectus sheath block in transverse plane.

Before starting oral intake, the patients could first use a suppository (diclofenac sodium, 25 mg) and then receive an intramuscular injection (pentazocine, 15 mg) every 3–4 h if necessary. After starting oral intake, they could use an oral medication (loxoprofen sodium hydrate, 60 mg) every 6 h. In every case, postoperative measurements were performed by the floor nurses. Data analyses were performed to assess the mean PPS, the amount of perioperative opioids used per hour, and the number of postoperative pain relief medications used.

All patients' age, body mass index, surgical procedure, and postoperative diagnosis were recorded. Total blood loss was calculated from the volume of blood obtained by suction and gauze. The operation time was recorded from the first incision to completion of the final skin sutures. Operative complications associated with the field block were defined as injuries to the bowel, bladder, or ureter; intra-abdominal bleeding; and wound infection. The surgeons ensured that the puncture site was free from active bleeding and that a skin bulge was present on the abdominal wall by visual evaluation on POD 1. They also performed transvaginal ultrasound examination to rule out the development of intra-abdominal hemorrhage and ascites by POD 3.

This study was performed according to a research protocol approved by the Ethics Committee of Medical Research in our institute. The study conduct and data analysis were performed following the CONSORT criteria, and the study was registered in a clinical trials database before enrollment. This study was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki. All women planning to undergo laparoscopic surgery provided informed consent.

Recruitment continued until > 200 women were enrolled. Based on previous studies of abdominal field blocks in laparoscopic surgery and laparotomy, considering a mean PPS of 3.2 for the LGRSB and 3.9 for the control with a standard deviation of 1.7, α error of 0.05, and power (1 – β) of 0.08, 188 patients were required. Likewise, considering a mean of 2.5 postoperative pain relief medications used for the LGRSB and 3 used for the control with a standard deviation of 1, 128 patients were required. Each sample was set at 100 patients [4,9–11]. All statistical analyses were conducted using SPSS version 22 (IBM Corp., Armonk, NY, USA) at a 0.05 significance level. We used the Mann–Whitney test for the operative time and estimated blood loss and Student's *t*-test for the other parameters.

3. Results

In total, 215 women were approached for participation in this study. Among them, five women failed to meet the study criteria because they required epidural anesthesia with laparotomy. The remaining 210 women were randomly assigned to the 2 study groups so that each group comprised > 100 women. After allocation, one woman in the LGRSB group did not undergo the assigned intervention because of surgeon error. During the follow-up, one woman in the control group was transferred to another ward and did not undergo the postoperative measurements. Therefore, we analyzed the data of 208 women. Fig. 1 shows the progression of all women throughout the study.

The patients' characteristics are presented in Table 2. The two groups had similar demographic and perioperative data. There were no significant differences in age, height, weight, body mass index, operative time, or estimated blood loss. The surgical procedures, postoperative diagnoses, and performance of single-port laparoscopy are shown in Table 3. There were no significant differences in the surgical procedures between the two groups. No perioperative complications occurred in this study.

Fig. 4 shows a comparison of the mean PPS between the two groups

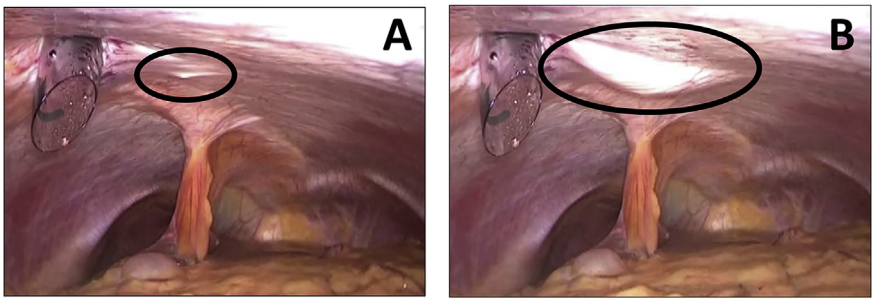


Fig. 3. Laparoscopic-guided rectus sheath block. (A) Laparoscopic view of the peritoneal surface prior to administration the rectus sheath block. (B) Laparoscopic view of the bulge following the rectus sheath block.

Table 2
Demographic and perioperative data.

	LGRSB (n = 107)	Control (n = 102)	*P* value
Age(y), mean (SD)	39.2(10.3)	41.6(13.3)	0.145
Height(cm), mean (SD)	157.8(5.3)	156.8(5.5)	0.164
Weight(cm), mean (SD)	53.9(8.3)	53.6(7.4)	0.831
BMI (kg/m2), mean (SD)	21.6(3.2)	21.8(3.0)	0.615
Operative time (min), median (range)	120(55-352)	113.1(44-275)	0.450
Estimated blood loss (ml), median (range)	35(5-1100)	5(5-1200)	0.140

Age, height, weight, and body mass index are expressed as mean (standard deviation), and operative time and estimated blood loss are expressed as median (range). Statistical analysis was performed using Student's *t*-test and the Mann–Whitney test. LGRSB, laparoscopic-guided rectus sheath block; BMI, body mass index.

Table 3
Laparoscopic surgical procedures among the randomized patients.

Laparoscopic surgery	LGRSB (n = 107)		Control (n = 101)		*P* value
	n	%	n	%	
Hysterectomy	25	23.4	23	22.5	> 0.99
(Myoma)	(13)	(52)	(12)	(52)	
(Cervical intraepithial neoplasia)	(8)	(32)	(7)	(30)	
(Adenomyosis)	(3)	(12)	(2)	(9)	
(Endometrial hyperplasia)	(1)	(4)	(2)	(9)	
Myomectomy	**13**	**12.1**	**9**	**8.8**	**0.504**
Salpingo oophorectomy	**21**	**19.6**	**23**	**22.5**	**0.614**
(Endometriotic cyst)	(7)	(33)	(6)	(26)	
(Mature teratoma)	(4)	(19)	(3)	(13)	
(Mucinous adenoma)	(1)	(5)	(2)*1	(9)	
(Serous adenoma)	(9)*1	(43)	(12)*2	(52)	
Cystectomy	**42**	**39.3**	**44**	**43.1**	**0.675**
(Endometriotic cyst)	(27)*1	(64)	(24)	(55)	
(Mature teratoma)	(11)	(26)	(13)	(30)	
(Mucinous adenoma)	(1)	(2)	(3)	(7)	
(Serous adenoma)	(3)	(7)	(4)	(9)	
Salpingectomy	**6**	**5.6**	**3**	**2.9**	**0.499**
(Ectopic pregnancy)	(6)		(3)		

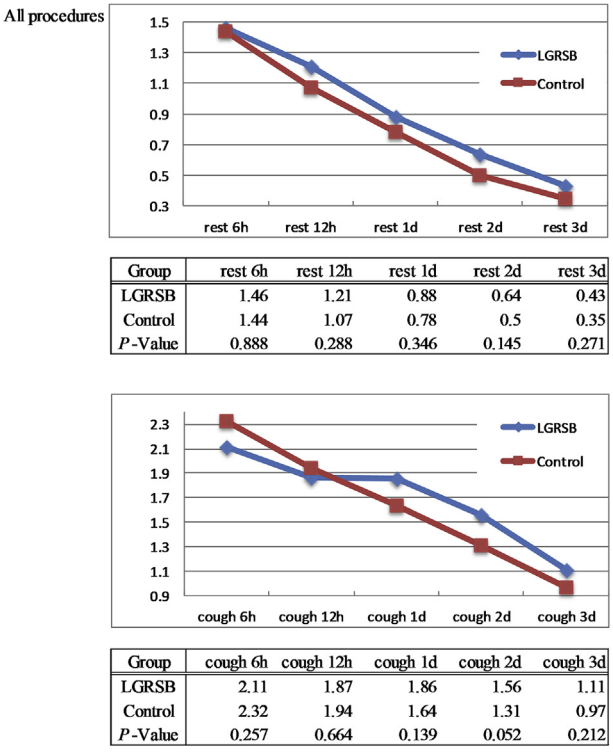
LGRSB, laparoscopic-guided rectus sheath block.
*1One case of single-port laparoscopy.
*2Two cases of single-port laparoscopy.

for all surgical procedures. There were no significant differences in all postoperative conditions. At rest, the mean PPS was higher in the LGRSB than control group. During cough, the mean PPS was lower in the LGRSB than control group at 6 and 12 h postoperatively; later, this relationship reversed.

Table 4 shows an analysis of the consumption of perioperative opioids and analgesics. There were no significant differences in the amounts of these medications between the two groups.

4. Discussion

This is the first prospective, double-blind, randomized controlled trial to assess the LGRSB for gynecologic laparoscopy. The only similar randomized study of this method for gastroenterological surgery was published in 2017 [12]. Like the previous study, the present study indicates that this method can be safely performed. All gynecologists performed this technique with ease by following another clinician's performance without strict training, and no complications occurred. Therefore, we believe that the LGRSB is adequately safe. However, this study differs from the previous study in that the LGRSB did not significantly reduce the PPS at rest and during coughing in all postoperative conditions compared with the control. This conclusion



Group	rest 6h	rest 12h	rest 1d	rest 2d	rest 3d
LGRSB	1.46	1.21	0.88	0.64	0.43
Control	1.44	1.07	0.78	0.5	0.35
P-Value	0.888	0.288	0.346	0.145	0.271

Group	cough 6h	cough 12h	cough 1d	cough 2d	cough 3d
LGRSB	2.11	1.87	1.86	1.56	1.11
Control	2.32	1.94	1.64	1.31	0.97
P-Value	0.257	0.664	0.139	0.052	0.212

Fig. 4. Pain data of all procedures. Comparison of mean postoperative pain score at rest and during coughing after all laparoscopic procedures between the LGRSB and control groups. LGRSB, laparoscopic-guided rectus sheath block; rest 6 h, at rest 6 h postoperatively; cough 1d, during coughing 1 day postoperatively.

Table 4
Postoperative analgesics and perioperative opioids.

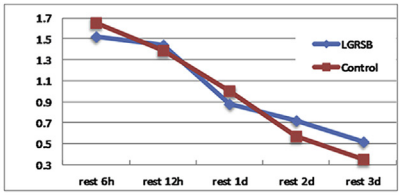
	LGRSB	Control	*P* value
Diclofenac Na Suppository	1.18	1.19	0.938
Pentazocine Hydrochloride Injection	0.33	0.33	0.997
Loxoprofen Na Tablet	2.01	2.19	0.602
Fentanyl (μg/min)	103.11	105.98	0.731
Remifentanil (μg/min)	100.36	108.89	0.307

Mean doses of analgesics and opioids for all laparoscopic procedures. LGRSB, laparoscopic-guided rectus sheath block.

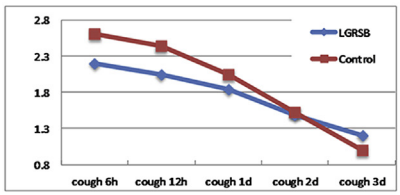
regarding efficacy of the LGRSB is both a limitation and a new finding.

A limitation of this study is that uniformity of abdominal invasion could not be preserved because of application the LGRSB to all gynecological procedures. Because the various procedures involved different degrees of surgical invasion (especially intra-abdominal invasions which could not be covered by this method), subgroup analyses were performed with reference to reports about field blocks in laparoscopic surgery [13–17]. Two subgroup analyses of each procedure and port setting were performed to allow for separate consideration of intra-abdominal and abdominal wall invasion. The first subgroup analysis involved four categories corresponding to each specific procedure: total laparoscopic hysterectomy, laparoscopic myomectomy, surgery for endometriosis, and adnexal surgery for benign adnexal diseases other than endometriosis. Because endometriosis is associated with deep pelvic pain, we distinguished endometriosis from other ovarian tumors. The second subgroup analysis involved two categories: single-port and multi-port laparoscopy. Consequently, all subgroup analyses also showed that the LGRSB did not significantly reduce the PPS compared with the control (Figs. 5 and 6). Although surgical invasion was standardized based on each procedure and port setting, a significant reduction of the PPS was not shown.

TLH

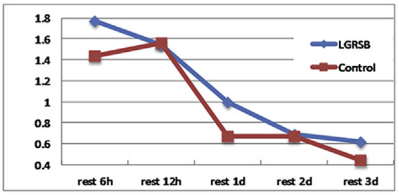


Group	rest 6h	rest 12h	rest 1d	rest 2d	rest 3d
LGRSB	1.52	1.44	0.88	0.72	0.52
Control	1.65	1.39	1	0.57	0.35
P-Value	0.703	0.882	0.617	0.373	0.304

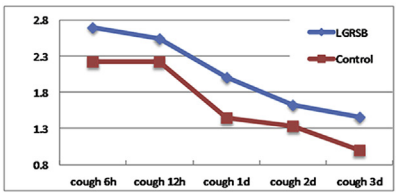


Group	cough 6h	cough 12h	cough 1d	cough 2d	cough 3d
LGRSB	2.2	2.04	1.84	1.48	1.2
Control	2.61	2.44	2.04	1.52	1
P-Value	0.269	0.304	0.524	0.879	0.404

LM

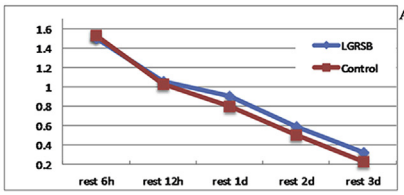


Group	rest 6h	rest 12h	rest 1d	rest 2d	rest 3d
LGRSB	1.77	1.54	1	0.69	0.62
Control	1.44	1.56	0.67	0.67	0.44
P-Value	0.455	0.971	0.21	0.936	0.458

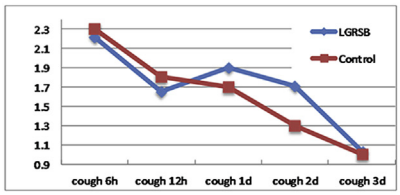


Group	cough 6h	cough 12h	cough 1d	cough 2d	cough 3d
LGRSB	2.69	2.54	2	1.62	1.46
Control	2.22	2.22	1.44	1.33	1
P-Value	0.305	0.518	0.214	0.514	0.209

Surgeries for endometriosis

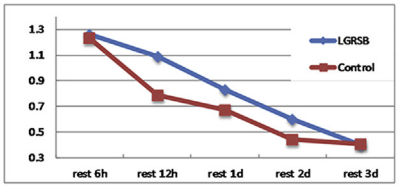


Group	rest 6h	rest 12h	rest 1d	rest 2d	rest 3d
LGRSB	1.5	1.06	0.9	0.59	0.32
Control	1.53	1.03	0.8	0.5	0.23
P-Value	0.906	0.905	0.633	0.535	0.428

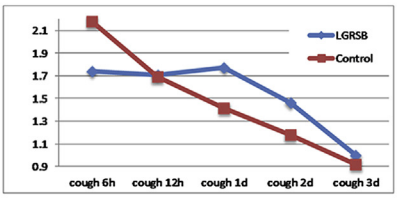


Group	cough 6h	cough 12h	cough 1d	cough 2d	cough 3d
LGRSB	2.21	1.65	1.9	1.71	1.03
Control	2.3	1.8	1.7	1.3	1
P-Value	0.773	0.559	0.443	0.123	0.886

Adnexal surgeries excluding endometriosis



Group	rest 6h	rest 12h	rest 1d	rest 2d	rest 3d
LGRSB	1.26	1.09	0.83	0.6	0.4
Control	1.23	0.79	0.67	0.44	0.41
P-Value	0.924	0.181	0.352	0.342	0.941



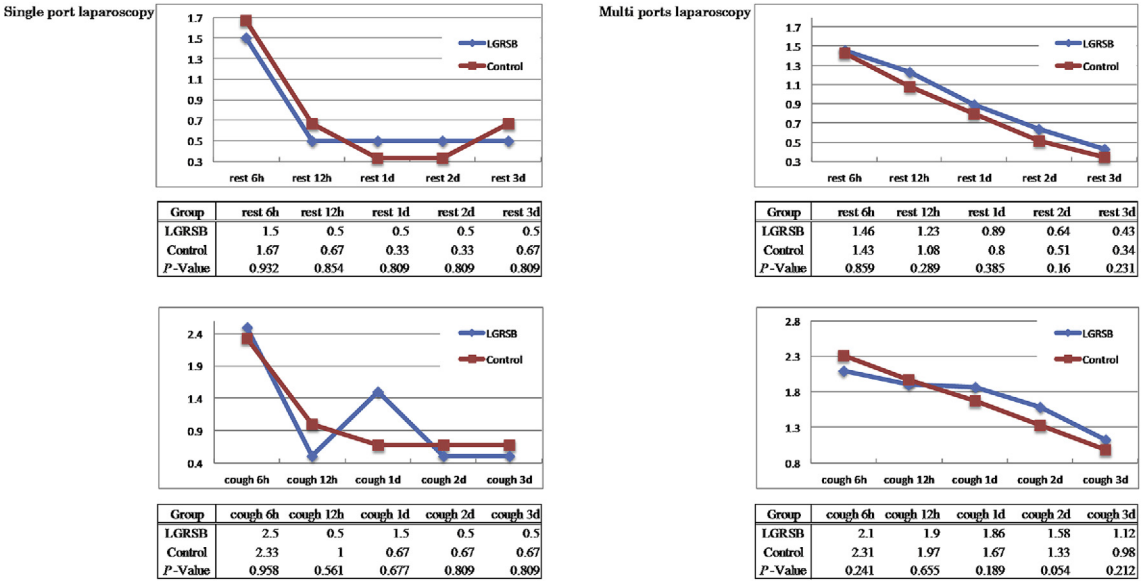
Group	cough 6h	cough 12h	cough 1d	cough 2d	cough 3d
LGRSB	1.74	1.71	1.77	1.46	1
Control	2.18	1.69	1.41	1.18	0.92
P-Value	0.187	0.936	0.101	0.163	0.682

Fig. 5. Pain data of each specific procedure. Comparison of mean postoperative pain score at rest and during coughing after each laparoscopic procedure divided into four categories between the LGRSB and control groups. LGRSB, laparoscopic-guided rectus sheath block; rest 6 h, at rest 6 h postoperatively; cough 1d, during coughing 1 day postoperatively; TLH, total laparoscopic hysterectomy; LM, laparoscopic myomectomy.

When surgical invasion excluding abdominal wall incision was considered, most of the previous studies in gastroenterological laparoscopy showed that field blocks were effective [11121617]. The differences in surgical invasion and pain between gastroenterological surgery and gynecologic surgery may be associated with differences in the operative site between intra-abdominal and retroperitoneal organs. In contrast, few previous gynecologic studies showed this efficacy [13,18]. Gynecologic laparoscopy may be less effective than gastroenterological laparoscopy in terms of umbilical pain.

With respect to the umbilical incisions performed in this study, the only transumbilical insertion technique applied was the open port placement technique regardless of whether single-port or multi-ports laparoscopy was performed. However, we could not perform a standard scar-length umbilical incision and adequately evaluate the difference in port setting. This is because fewer patients underwent single-port laparoscopy and the umbilical incisions were frequently extended to eviscerate the specimen when total laparoscopic hysterectomy or laparoscopic myomectomy was performed for women who had never delivered. Differences in postoperative pain have been suggested between single-port and multi-port gynecologic laparoscopy because single-port laparoscopy requires more analgesia than multi-port laparoscopy [19–21].

A new finding was obtained in the subgroup analyses of each procedure. Especially in the analyses of the three categories (total laparoscopic hysterectomy, surgery for endometriosis, and adnexal surgeries excluding those for endometriosis), the mean PPS during coughing showed an uncommon trend in that the score reversed after 12 h postoperatively (Fig. 5). Two previous papers indicated that the duration of the sensory blockade provided by 0.5% ropivacaine was 13 ± 2 and 11 h, respectively [22,23]. According to these findings, we may presume that the efficacy of 0.5% ropivacaine lasts for around 11–13 h. This reverse trend occurred because the loss of anesthetic efficiency induced a rebound phenomenon. Unfortunately, we were unable to record the PPS before 6 h postoperatively and perform an



Group	rest 6h	rest 12h	rest 1d	rest 2d	rest 3d
LGRSB	1.5	0.5	0.5	0.5	0.5
Control	1.67	0.67	0.33	0.33	0.67
P-Value	0.932	0.854	0.809	0.809	0.809

Group	rest 6h	rest 12h	rest 1d	rest 2d	rest 3d
LGRSB	1.46	1.23	0.89	0.64	0.43
Control	1.43	1.08	0.8	0.51	0.34
P-Value	0.859	0.289	0.385	0.16	0.231

Group	cough 6h	cough 12h	cough 1d	cough 2d	cough 3d
LGRSB	2.5	0.5	1.5	0.5	0.5
Control	2.33	1	0.67	0.67	0.67
P-Value	0.958	0.561	0.677	0.809	0.809

Group	cough 6h	cough 12h	cough 1d	cough 2d	cough 3d
LGRSB	2.1	1.9	1.86	1.58	1.12
Control	2.31	1.97	1.67	1.33	0.98
P-Value	0.241	0.655	0.189	0.054	0.212

Fig. 6. Pain data corresponding to port setting. Comparison of mean postoperative pain score at rest and during coughing after division of the port setting into single-port and multi-port laparoscopy between the LGRSB and control groups. LGRSB, laparoscopic-guided rectus sheath block; rest 6 h, at rest 6 h postoperatively; cough 1d, during coughing 1 day postoperatively.

objective evaluation by ultrasound to detect whether the regional anesthetics had been delivered to the adequate layer.

Finally, although the safety of this method was confirmed, the efficacy was not strictly confirmed. Otherwise, postoperative pain after use of this technique might be accentuated by a rebound phenomenon that induces the loss of anesthetic efficacy in the late postoperative period. Considering the recommendation to start early postoperative ambulation in that period, we cannot strongly suggest introducing this method.

5. Conclusion

This is the first prospective randomized controlled trial to assess the LGRSB for gynecologic laparoscopy. This study showed that the LGRSB was easy and safe; however, it did not significantly reduce the PPS at rest or during coughing in all postoperative conditions compared with the control.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Declarations of interest

None.

conflicts of interest

The authors explicitly state that there is no conflict of interest in connection with this article.

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Ethical Approval

The Ethics Committee of Medical Research, University of Occupational and Environmental Health, Japan (approval date: 1 August 2014, reference no. H26066)

Research Registration Unique Identifying Number (UIN)

Before starting this trial, we registered The University hospital Medical Information Network (UMIN CTR) at http://www.umin.ac.jp/ctr/. The UMIN CTR is one registries of Japan Primary Registries Network (JPRN) and appeared at http://www.who.int/ictrp/network/jprn2/en/. We got Research Registration Unique Identifying Number (UIN) as UMIN; no. UMIN000014746.

Author contribution

Kinjo and Kurita planning and conducting this trial acquired and analysed the data in general. At an initial stage, Kawasaki from the perspective of an anesthesiologist built the design of this trial and advised surgeons on nerve block. Fujino from the perspective of a hygienist instructed us to analyse and interpret data. Finally, Yoshino and Hachisuga checked this paper.

Guarantor

The Guarantors are Yasuyuki Kinjo and Tomoko Kurita.

CRediT authorship contribution statement

Yasuyuki Kinjo: Conceptualization, Methodology, Validation, Investigation, Resources, Data curation, Writing - original draft, Visualization. **Tomoko Kurita:** Conceptualization, Methodology, Validation, Investigation, Resources, Data curation, Writing - original draft, Visualization. **Yoshihisa Fujino:** Methodology, Software, Formal analysis, Data curation. **Takashi Kawasaki:** Conceptualization, Methodology. **Kiyoshi Yoshino:** Methodology, Writing - review & editing, Supervision. **Toru Hachisuga:** Methodology, Writing - review & editing, Supervision.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2019.01.004.

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