

**Title: Continuous basal infusion versus programmed intermittent bolus for quadratus lumborum block after laparoscopic colorectal surgery: A randomized controlled, double-blind study**

**Yuki Aoyama<sup>1</sup>, Shinichi Sakura<sup>1</sup>, Aumjit Wittayapairoj<sup>1</sup>, Shoko Abe<sup>1</sup>, Saki Tadenuma<sup>1</sup>, Yoji Saito<sup>1</sup>**

1 Department of Anesthesiology, Faculty of Medicine, Shimane University, Izumo City, Shimane, Japan

**Corresponding author:** Shinichi Sakura

**Mailing address:** Department of Anesthesiology, Faculty of Medicine, Shimane University, 89-1 Enya-cho, Izumo City, Shimane 693-8501, Japan

**Tel:** +81-853-20-2295

**Fax:** +81-853-20-2292

**E-mail:** ssakura@med.shimane-u.ac.jp

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## **ABSTRACT**

**Background:** Quadratus lumborum block (QLB) has recently attracted attention as a part of multimodal analgesia after abdominal surgery. It has been shown that programmed intermittent boluses of local anesthetic can produce better analgesia and wider sensory blockade compared with continuous basal infusion with some peripheral nerve blocks. The present study was conducted to see if this theory holds true for QLB in patients undergoing laparoscopic colorectal surgery.

**Methods:** Fifty patients undergoing laparoscopic colorectal surgery were divided into 2 groups to receive continuous basal infusion (group C) or programmed intermittent boluses (group PIB) of local anesthetic. After surgery, patients received the posterior approach to QLB and a catheter was introduced bilaterally. Patients in group C received a continuous infusion of 0.15% levobupivacaine at 3 ml/hour, and those in group PIB received a bolus of 12 ml every 4 hours. All patients received intravenous patient-controlled analgesia using fentanyl. Measurements were taken for cumulative fentanyl consumption, pain scores, cutaneous sensory blockade, analgesic requirements and adverse events for 46 hours.

**Results:** The primary outcome of cumulative fentanyl consumption at 22 hours showed no significant difference between the groups [group C: 11.9 (11.2-15.5)  $\mu\text{g}/\text{kg}$  (median (interquartile range)) and group PIB: 12.3 (11.6-15.3),  $p=0.473$ ]. Pain scores, demands for rescue analgesics, and spread of cutaneous sensory blockade were similar for the two groups.

**Conclusion:** Programmed intermittent boluses of local anesthetic for continuous QLB did not produce better analgesia or wider sensory blockade compared with continuous basal infusion in patients undergoing laparoscopic colorectal surgery.

## INTRODUCTION

Colorectal surgery is among the most frequently conducted major abdominal surgical procedures. Although nowadays in most cases, colorectal surgery is conducted as laparoscopic surgery that is thought to be minimally invasive, postoperative pain can still be severe and preclude prompt patient recovery. Abdominal wall blocks, especially transversus abdominis plane block (TAPB), have been shown to reduce opioid consumption and improve recovery, and thus are recommended as a part of multimodal analgesia for laparoscopic colorectal surgery in a recent enhanced recovery after surgery (ERAS) society guideline [1]. Yet, the results of previous studies evaluating the benefits of TAPB are still inconclusive [2].

Quadratus lumborum block (QLB) is a newly developed technique which has been shown to produce better analgesia compared with TAPB for patients undergoing caesarean section [3], open hysterectomy [4], laparoscopic surgery [5,6] and lower abdominal surgery [7,8]. Continuous QLB with a catheter(s) has also been reported to provide effective and prolonged analgesia in patients after colorectal surgery [9,10], renal surgery [11–13] and liver resection [14]. However, few studies have focused on the difference in delivery methods including the difference between single shot and continuous infusion for QLB.

Recently, intermittent boluses of local anesthetic have attracted attention due to the development of devices with programmed delivery and have been used to produce wider sensory blockade and better analgesia compared with continuous basal infusion with epidural analgesia for labor [15,16] and some peripheral nerve blocks [17–21]. Since QLB is a fascial compartment block where a large volume of local anesthetics producing a wide spread is preferable, it is reasonable to presume that intermittent boluses contribute to maintaining the range of cutaneous

sensory blockade and thus, result in better analgesia compared with the same volume using continuous basal infusion.

Accordingly, we conducted the present study to see if programmed intermittent bolus (PIB) of local anesthetic might produce better analgesia and a wider sensory blockade compared with continuous basal infusion for the posterior approach to QLB in patients undergoing laparoscopic colorectal surgery.

## **METHODS**

This single-center, prospective, randomized, double-blind study was approved by the Shimane University Hospital ethical committee on July 24, 2017 and was registered in the University Hospital Medical Information Network Clinical Trials Registry on August 17, 2017 (UMIN000028511). Patients aged 20-80 years, classified as American Society of Anesthesiologists physical status I-II, and scheduled for laparoscopic colorectal surgery were recruited. Exclusion criteria included contraindication to peripheral nerve block, allergy to study medication, preoperative use of opioids and steroids and apparent neuropathy. Written informed consent was obtained from all patients who were subsequently randomly divided into two groups to receive either continuous basal infusion (group C) or programmed intermittent boluses (group PIB) of local anesthetic for QLB. Our institutional clinical trial center conducted randomization and informed an investigator which group the patient would be assigned to on the day before surgery.

### **Study Protocol**

Anesthetists who were blinded to the group assignment cared for each patient. In the operation room, a standard monitor was applied and an intravenous line was secured. After induction of general anesthesia with propofol, fentanyl and rocuronium, the trachea was intubated. During surgery, general anesthesia was maintained with propofol titrated to maintain bispectral index of 40-60 and remifentanyl was infused for intraoperative analgesia. Fentanyl 2 µg/kg and acetaminophen were intravenously injected during skin closure. After surgery, but prior to extubation, all patients received the bilateral posterior approach to QLB under ultrasound guidance according to the technique previously described [3,22]. All the blocks and catheter

placement were performed by an experienced regional anesthesiologist who was familiar with this block. A 1-5 MHz convex transducer (LOGIQ e Premium; GE Healthcare, Japan) and an 18G Tuohy needle attached to extension tubing was used with a standard aseptic technique. The blocks were performed with the patient in either the supine or a slightly wedged position. The transducer was positioned at the lateral abdomen between the iliac crest and costal margin to observe the external oblique, internal oblique, and transversus abdominis muscles. The ultrasound view was adjusted posteriorly to show the quadratus lumborum muscle and the lumbar interfascial triangle between the quadratus lumborum, erector spinae and latissimus dorsi muscles. The needle was inserted from the lateral abdomen to reach either the posterolateral aspect of the quadratus lumborum muscle or the lumbar interfascial triangle. After injection of 20 ml of 0.25% levobupivacaine through the needle over approximately 10 sec, a catheter was inserted bilaterally. To confirm the correct catheter tip position, a small amount of air was injected through the catheter and observed under ultrasound image. The catheter was fixed with sterile tape (Sorba View SHIELD Medium; CENTURION, MI, USA). Immediately thereafter, bilateral infusion of 0.15% levobupivacaine was started according to the assigned protocol. Patients in group C received a continuous infusion at 3 ml/hour, and those in group PIB received a bolus of 12 ml over 57.6 sec every 4 hours using CADD-Solis PIB (Smiths Medical; Tokyo, Japan) until 46 hours after block. The pump was covered with a bag to ensure that neither patient nor anesthetist were aware of the infusion protocol. Rescue analgesia with bolus of local anesthetics via the catheter was not applied.

The trachea was extubated when each patient was fully awake and breathing adequately. After extubation, all patients were transferred to a postsurgical ward where they were kept for two postoperative days. All patients also received intravenous patient-controlled analgesia (PCA)

with fentanyl (0.5 µg/kg/hour and on-demand bolus of 0.5 µg/kg, 15-minute lockout time, maximum dose of 2000 µg for 46 hours) using I-Fusor Plus (JMS; Hiroshima, Japan) for 46 hours postoperatively. Acetaminophen or flurbiprofen axetil was intravenously injected for rescue analgesia.

### **Measurements**

Patients were blinded to their group assignment, and anesthetists who were also blinded to the group assignment conducted measurements. Measurements were obtained at 4, 16, 22, 34 and 46 hours after blocks for all of the following: postoperative fentanyl consumption, demands for PCA and other analgesics, pain scores on visual analogue scale (VAS: 0, no pain; 100, worst pain imaginable) at rest and while coughing, dermatomal sensory blocked levels as determined by loss of cold and pinprick sensation, and adverse events such as nausea and vomiting. In addition, occurrence of complications related to blocks including local anesthetic toxicity, hematoma and visceral organ injury, if any, was recorded. Cutaneous sensory blockade was assessed bilaterally on the middle axillary line. A small ice cube and a slightly dulled needle were used for sensory assessment. Nausea, vomiting and other complications were assessed dichotomously.

### **Statistical analysis**

The primary endpoint was cumulative fentanyl consumption at 22 hours after block. The secondary endpoints included demands for PCA and rescue analgesics, VAS at rest and while coughing, the number of dermatomes with sensory blockade and adverse events.

We conducted power analysis based on data of our preliminary (unpublished) study using 12 patients who underwent gynecological open abdominal surgery. In that study, the cumulative fentanyl consumption at 22 hours was less in patients receiving intermittent boluses of levobupivacaine than in those receiving continuous basal infusion [continuous basal infusion group: 20.6 (9.8)  $\mu\text{g}/\text{kg}$  (mean (SD)) and intermittent bolus infusion group: 13.8 (4.4)]. Assuming  $\alpha = 0.05$  and  $\beta = 0.2$  (80% power), 42 patients (21 in each group) were required in each group and the number was raised to 50 (25 in each group) to allow for drop-outs.

Statistical analysis was performed using the SPSS 23.0 software (SPSS, Inc., Chicago, IL, USA). The two-tailed Student's t-test was applied for parametric statistics and values were expressed as mean (SD). Generalized estimating equations and the Mann-Whitney U-test were used for non-parametric statistics including fentanyl consumption and VAS pain scores between groups over time and between groups at each time point, respectively, and the results were expressed as median values with the interquartile range. The chi-square test or Fisher's exact test were used for categorical data. A p-value  $< 0.05$  was considered statistically significant.

## RESULTS

Patients scheduled for laparoscopic colorectal surgery between August 2017 and February 2019 were enrolled in the study and randomly allocated to two groups. Out of 50 patients who gave consent, nine patients were excluded, and 41 patients (21 and 20 patients for group C and group PIB, respectively) completed the study (Figure 1). One patient in group PIB was excluded from analysis because the catheter inserted for QLB was obstructed between 16 and 22 hours. Baseline and perioperative characteristics of the patients were similar between the two groups (Table 1).

The primary outcome of cumulative fentanyl consumption at 22 hours showed no significant difference between the groups (Table 2). No significant difference was observed in fentanyl consumption, demands for PCA and other analgesics, or VAS pain scores at rest or while coughing at any time point. Adverse events including postoperative nausea and vomiting were also comparable (Table 3).

Loss of cold and pinprick sensation at 16 hours was observed between T6 and L4 in either group, and more than 50% of patients in each group developed cutaneous sensory blockade at the T11-L1 dermatomes (Figure 2). One patient in each group failed to develop any sensory blockade on one side (1 out of 42 and 1 out of 40 in group C and group PIB, respectively). Comparably for both groups, the median number of dermatomes with sensory blockade was 1 to 3 at any time point up to 46 hours (Figure 3). Cutaneous sensory blockade remained similar in both groups up to 46 hours (52.4% and 52.5% in group C and group PIB, respectively,  $p=1.000$ ). No serious complication related to the blocks including local anesthetic toxicity, hematoma and visceral organ injury was observed.

## DISCUSSION

In this prospective, randomized controlled study, we compared the analgesic effect and cutaneous sensory blockade of PIB and continuous basal infusion of local anesthetic for the posterior approach to QLB. As opposed to our hypothesis, we observed no superiority of PIB over continuous basal infusion for either postoperative opioid consumption, postoperative pain scores or levels of cutaneous sensory blockade. To the best of our knowledge, this is the first prospective comparative study evaluating the analgesic effect and sensory blockade of different delivery methods for continuous QLB.

Continuous infusion of local anesthetic through a catheter at a set volume per hour has conventionally been used to extend the duration of analgesia with various kinds of regional anesthesia techniques. Theoretically, this method can work as long as local anesthetic is in contact with the target nerve(s). However previous studies have shown that the spread of local anesthetic solution gradually decreases when administered in an epidural space, resulting in decreased analgesic effect. For example, Kanai et al. showed that the number of anesthetized dermatomes decreased from 16 to nearly 0 over the course of 15 hours of continuous epidural infusion of 0.5% lidocaine at 6 ml/hour [23]. Therefore, it is plausible that a local anesthetic solution continuously infused for a peripheral nerve block similarly recedes as time passes. Effects of this decrease in volume may not change analgesic effects when the target is a nerve or nerve fibers in a confined space. However, this does not apply when the target of a peripheral nerve block is in an unconfined space.

Intermittent bolus injections of local anesthetic may benefit patients because high injection pressure can produce a wider and more uniform spread of the solution. Previous studies have shown that PIB in labor epidural analgesia provides higher sensory block levels, better patient

satisfaction and decreased local anesthetic consumption compared with continuous basal infusion [15,16]. Similar results have been shown with some lower-extremity peripheral nerve blocks when the two delivery methods are compared [17,18,24]. For example, Hillegass et al. showed preferable effects of PIB for femoral block in pain scores and opioid requirements [18]. Other researchers have shown that PIB for thoracic paravertebral block produced wider dermatomal sensory blockade and improved analgesia [19–21]. However, benefits of PIB on abdominal wall blocks have not been apparent [25–27]. For example, Khatibi et al. conducted a volunteer study in which each volunteer received bilateral continuous TAPB using PIB (0.2% ropivacaine 24 ml every 3 hours) on one side and continuous basal infusion (0.2% ropivacaine at 8 ml/hour) on the other side. The authors found that PIB produced a wider sensory blockade both horizontally and vertically at early time points, but the difference disappeared after 6 hours [27].

In the present study, neither postoperative opioid consumption and pain scores, nor levels of cutaneous sensory blockade differed between PIB and constant basal infusion of local anesthetic. The exact mechanism of how the posterior approach to QLB works is still unknown. A solution injected posterior to the transversalis fascia and around the quadratus lumborum muscle may spread into the paravertebral space, resulting in blockade of thoracic spinal nerves and sympathetic trunk. If this is how this block works most effectively, it could theoretically take a large volume of local anesthetic to produce a wide spread. A recent cadaver study showed that as much as 30 ml of dye injected posterior to the quadratus lumborum muscle at L3-4 consistently reached T11-L1 inside the thoracic paravertebral space [28]. A volunteer study using magnetic resonance imaging showed that 0.7 ml/kg (about 42 ml for the present study population) of 0.2% ropivacaine mixed with gadolinium administered for the posterior approach to QLB spread into the T10-T12 vertebral levels [29]. In the present study, however, despite the use of small volume

or slow infusion, the majority of patients in both groups developed sensory blockade at the T11-L1 dermatomes at 16 hours. Thus, it appears that effects of the PIB and constant basal infusion used in the present study were nearly and similarly as good as they get.

This study has several limitations. First, the sample size calculation for this study was conducted based on the data of patients undergoing open laparotomy instead of laparoscopic surgery. It is possible that the intensity and characteristics of postoperative pain differ between the two distinct surgical procedures and that the number of patients was not large enough to prove the hypothesis of this study if surgical procedure in the present study caused less severe pain. Second, every patient received continuous basal infusion of fentanyl which has been common practice at our institution. However, considering that a small number of demands for additional fentanyl were made in both groups, the use of no basal infusion of fentanyl would have yielded different results in our primary outcome. Third, nobody knows with certainty the exact best way to administer continuous QLB. With regard to continuous basal infusion as well as PIB, use of other settings, such as a different rate of infusion and/or a larger volume as a bolus, may lead to different results. Fourth, our study blocks were performed after surgery. Pre-incisional blocks have been shown to have a preemptive analgesic effect and might have affected postoperative pain levels [30]. In addition, pneumoperitoneum often produces subcutaneous emphysema which might make it difficult to conduct abdominal wall block using ultrasound. However, preoperative catheter insertion for QLB has a number of problems because the catheter insertion site is close to the surgical site and insufflation of the abdominal cavity during laparoscopic surgery may result in withdrawal or dislodgement of the catheter. Fifth, it is possible that some of the results including cutaneous sensory blockade and VAS pain scores in Group PIB were influenced by the difference in time between an intermittent bolus and

measurements; measurements taken immediately before the designated time point that was before each intermittent bolus might have underestimated the effects of intermittent boluses. On close examination of individual data in the present study, however, measurements at 16 hours after blocks were conducted before the injection in 2 of 20 patients, and the values of these two patients were similar to the results reported for Group PIB. Finally, no measurements were conducted after 46 hours. Thus, there was no denying the possibility that two infusion techniques differed in effects after the infusion.

### **Conclusion**

In conclusion, PIB of local anesthetic for continuous QLB did not produce better analgesia or a wider sensory blockade compared with continuous basal infusion in patients undergoing laparoscopic colorectal surgery. Further studies are needed to confirm these results.

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None.

### **Conflicts of Interest Statement**

Smiths Medical ASD Inc. provided research funding, infusion pumps and tubing, but the company had no involvement in the study design, data collection, analysis, interpretation of the data, or preparation of the manuscript.

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**Author contributions:**

All authors contributed to the study conception and design. Data collection and analysis were performed by Yuki Aoyama, Shinichi Sakura, Shoko Abe. The first draft of the manuscript was written by Yuki Aoyama and Shinichi Sakura, and all authors commented on the manuscript.

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**Table 1**

Baseline and perioperative characteristics of the patients.

	Group C (n=21)	Group PIB (n=20)
Sex (male/female), n	13/8	15/5
Age, yr	69 (64-77)	74 (68-77)
Height, cm	160 (7)	153 (22)
Body weight, kg	60 (13)	58 (9)
ASA-PS (I/II), n	3/18	0/20
Surgical time, min	333 (100)	334 (91)
Anesthetic time, min	449 (103)	453 (90)
Surgical procedure (under laparoscopy), n (%)		
Ileocecal resection	2 (9.5%)	1 (5.0%)
Right hemicolectomy	4 (19.0%)	4 (20.0%)
Left hemicolectomy	1 (4.8%)	3 (15.0%)
Sigmoidectomy	11 (52.4%)	9 (45.0%)
Anterior resection	3 (14.3%)	3 (15.0%)
Remifentanil dose, mg	4.5 (1.9)	4.4 (1.8)

Data are presented as mean (SD), median (interquartile range) or number of patients (%).

**Table 2**

Postoperative patient data regarding fentanyl consumption and analgesic requirements.

	Group C (n=21)	Group PIB (n=20)	P value
Cumulative fentanyl consumption, $\mu\text{g}/\text{kg}$			0.957*
4 hours	2.5 (2.0-3.2)	2.5 (2.0-3.4)	0.907
16 hours	8.9 (8.1-10.3)	8.7 (8.3-11.5)	0.734
22 hours	11.9 (11.2-15.5)	12.3 (11.6-15.3)	0.473
34 hours	18.5 (17.9-22.4)	18.8 (18.0-22.4)	1.000
46 hours	24.5 (23.7-27.5)	25.0 (24.0-27.9)	0.593
PCA bolus of fentanyl at time intervals, time			0.779*
4 hours	1 (0-2)	1 (0-3)	0.768
16 hours	1 (0-3)	1 (0-6.5)	0.730
22 hours	0 (0-3)	1 (0-2.75)	0.311
34 hours	1 (0-4)	1 (0-3)	0.467
46 hours	0 (0)	0 (0-1.75)	0.125
Rescue analgesics, time	0 (0-2)	0.5 (0-1)	0.944

PCA, patient-controlled analgesia. Data are presented as median (interquartile range) or number.

\*The P-value of generalized estimating equation.

**Table 3**

Postoperative patient data regarding pain scores and postoperative nausea and vomiting.

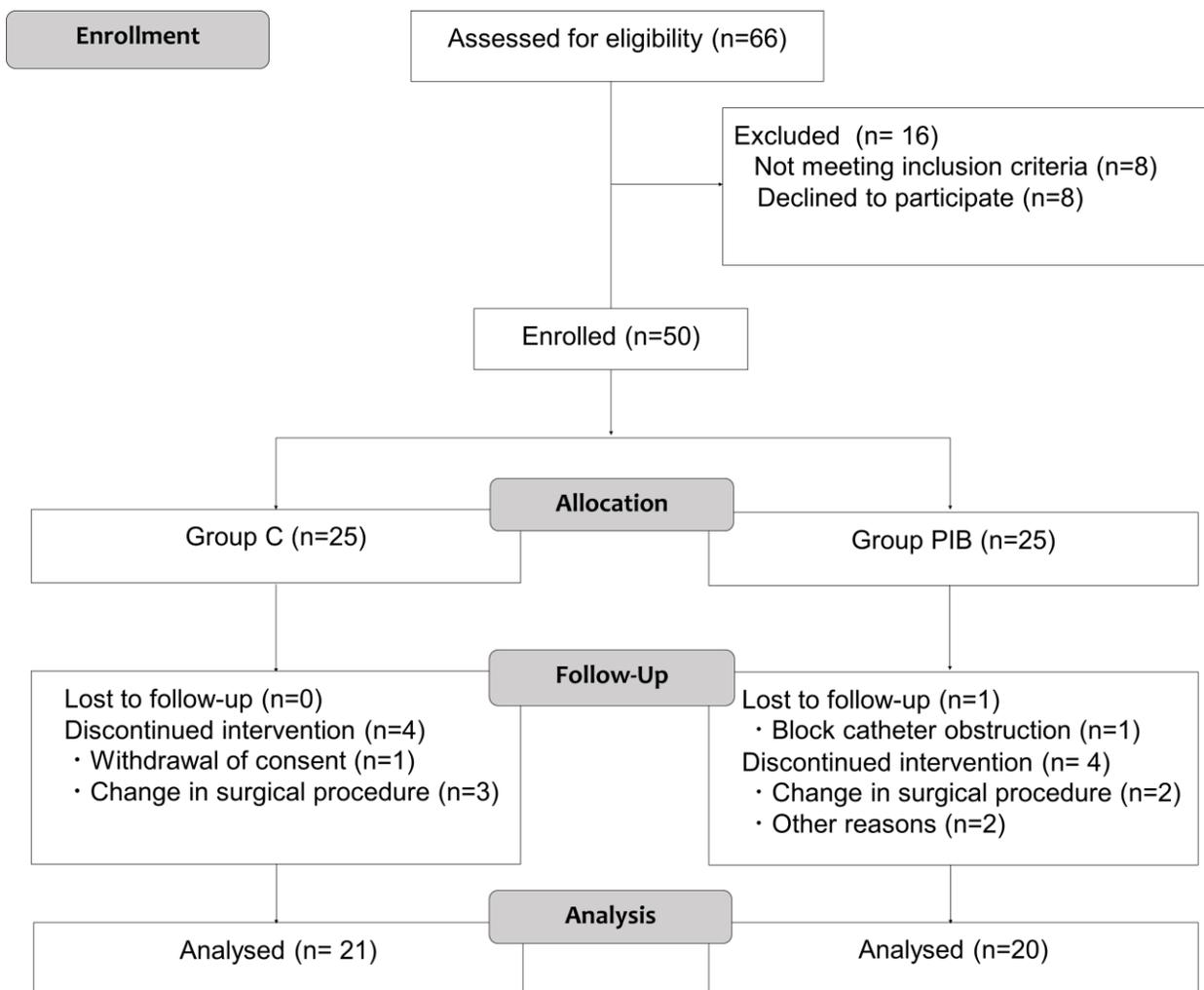
	Group C (n=21)	Group PIB (n=20)	P value
VAS at rest, mm			0.878*
4 hours	7 (0-40)	20 (6-38)	0.305
16 hours	19 (6-32)	12 (2-26)	0.343
22 hours	10 (0-20)	10 (1-20)	0.979
34 hours	11 (0-25)	15 (9-25)	0.668
46 hours	6 (0-10)	10 (0-22)	0.366
VAS while coughing, mm			0.529*
4 hours	30 (19-40)	40 (32-54)	0.369
16 hours	50 (34-71)	48 (32-72)	0.201
22 hours	40 (32-55)	48 (33-63)	0.583
34 hours	54 (44-59)	46 (26-62)	0.307
46 hours	35 (20-51)	45 (26-52)	0.657
Nausea, n (%)	8 (38.1%)	7 (35.0%)	1.000
Vomiting, n (%)	3 (14.3%)	3 (15.0%)	1.000
Antiemetic drug use, n (%)	7 (33.3%)	6 (30.0%)	1.000

VAS, visual analogue scale. Data are presented as the median (interquartile range) or number of patients. \*The P-value of generalized estimating equation.

## Figure Legends

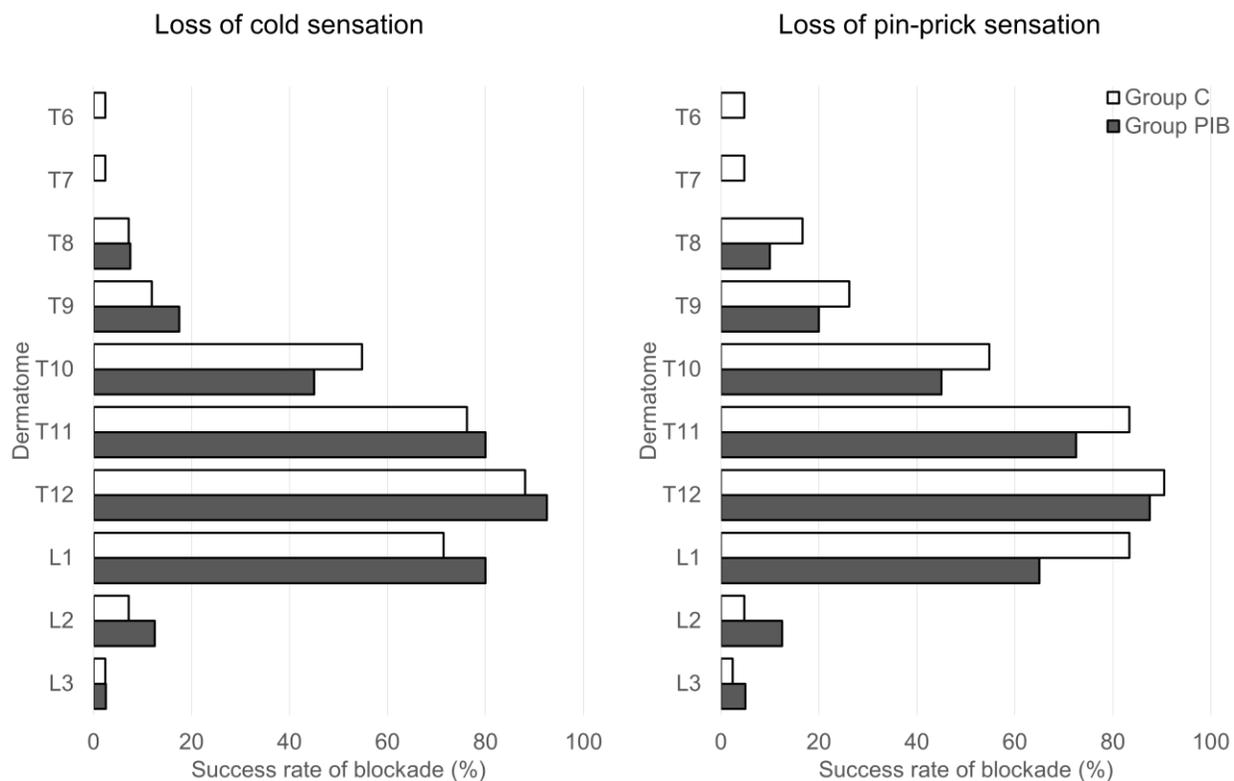
**Figure 1:**

CONSORT 2010 flow diagram.



**Figure 2:**

Cutaneous sensory blockade observed at 16 hours after blocks. The bar shows the success rate of blockade at each dermatome. Results are presented as a percentage.



**Figure 3:**

Number of dermatomes with cutaneous sensory blockade.

The box represents the 25<sup>th</sup>-75<sup>th</sup> percentiles, and the median is represented by the solid line.

Error bars above and below the box mark the minimum and maximum.

