# ORIGINAL PAPER

# Comparison between rectus sheath block with 0.25% ropivacaine and local anesthetic infiltration with 0.5% ropivacaine for laparoscopic inguinal hernia repair in children

Takahiro Tamura[1], Kenitiro Kaneko[2], Shuichi Yokota[3], Takashi Kitao[3], Masahiko Ando[4], Yoko Kubo[4], and Kimitoshi Nishiwaki[1]

[1]*Department of Anesthesiology, Nagoya University Graduate School of Medicine, Nagoya, Japan*
[2]*Department of Pediatric Surgery, Aichi Medical University Graduate School of Medicine, Nagoya, Japan*
[3]*Division of Anesthesia, Japanese Red Cross Nagoya Daiichi Hospital, Nagoya, Japan*
[4]*Center for Advanced Medicine and Clinical Research, Nagoya University Hospital, Nagoya, Japan*

## ABSTRACT

This randomized, observer-blinded prospective study aimed to compare the postoperative analgesic effects of ultrasound-guided rectus sheath block with those of local anesthetic infiltration of the surgical field in children undergoing inguinal hernia repair. Children aged 2 to 14 years, scheduled for elective single-incision laparoscopic percutaneous extraperitoneal closure, were randomly allocated to receive ultrasound-guided rectus sheath block (group R) or local anesthetic infiltration of the surgical field (group L). In group R, 0.5 ml/kg of 0.25% ropivacaine (per side) was administered after intubation. In group L, 0.4 ml/kg of 0.5% ropivacaine was administered after peritoneal closure. Postoperative pain was assessed using the Face Scale and Face, Legs, Activity, Cry, Consolability scale at various time points, including the primary endpoint of 2 h after leaving the operation room. Additional analgesic drugs were used according to the Face Scale scores. Patient characteristics, the amount of additional drugs, and complication rate were evaluated in both groups. The patient and surgical characteristics were comparable between groups. The Face Scale and Face, Legs, Activity, Cry, Consolability scale scores were not significantly different between group R (n = 38) and group L (n = 38) at 2 h after leaving the operation room. The amount of additional drugs administered at 2 h after leaving the operation room were also comparable between groups. Our findings suggest that the postoperative analgesic efficacy of ultrasound-guided rectus sheath block is not superior to that of local anesthetic infiltration of the surgical field for pediatric single-incision laparoscopic percutaneous extraperitoneal closure.

Keywords: rectus sheath block, local anesthetic infiltration, prospective study, regional anesthesia, inguinal hernia

Abbreviation:
UG-RSB: ultrasound-guided rectus sheath block
LAI: local anesthetic infiltration of the surgical field
SILPEC: single-incision laparoscopic percutaneous extraperitoneal closure
FS: Face Scale
FLACC: Face, Legs, Activity, Cry, Consolability

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OR: operation room
GA: general anesthesia

## INTRODUCTION

Pain control in patients undergoing day surgery is considered one of the most important parameters of postoperative management.[1] Single-incision laparoscopic percutaneous extraperitoneal closure (SILPEC) is a common day surgery performed for the repair of inguinal hernia in children. Generally, this procedure is performed with LAI for postoperative pain control. Ultrasound-guided rectus sheath block (UG-RSB) has also gained popularity for postoperative pain relief because it reportedly causes fewer side effects while providing an analgesic effect similar to that of local anesthetic infiltration of the surgical field (LAI).[2,3]

Recently, one study reported that UG-RSB was more effective than LAI for postoperative analgesia, while another study indicated that there was no significant difference in the analgesic effect between the two techniques.[4,5] Therefore, the findings for these two techniques remain controversial. The provision of analgesia before skin incision may result in the decreased use of intraoperative and postoperative opioids, although the efficacy of preanalgesia has been found to be ambiguous in a recent study.[6] In addition, one study[7] reported that the concentration of local anesthetic used for LAI was higher than that used for US-RSB, and the authors found that the analgesic effects of the two techniques were similar from 30 min after leaving operation room (OR). Therefore, further studies evaluating RSB and LAI with different anesthetic concentrations are necessary. We hypothesized that UG-RSB is more effective than LAI for pain control after SILPEC, even if a higher concentration of anesthetic is used for LAI than for RSB. To test this hypothesis, we designed a randomized, observer-blinded prospective study to compare the efficacy of UG-RSB with that of LAI for postoperative analgesia in children undergoing SILPEC for inguinal hernia repair. Postoperative pain was evaluated using Face Scale (FS)[8] scores, which were recorded by blinded parents, and Face, Legs, Activity, Cry, Consolability (FLACC) scale[9] scores, which were recorded by blinded nurses.

## METHODS

This prospective, observer-blinded randomized trial was approved by the institutional review board of our institution. The study protocol conformed to the tenets of the Declaration of Helsinki, and the study is registered through the University Hospital Medical Information Network (Study ID: UMIN000017919).

### Participants

Children aged 2 to 14 years who were scheduled for elective SILPEC with a 5-mm port between August 2015 and October 2016 were enrolled in this study. The exclusion criteria were as follows: American Society of Anesthesiologists class III or worse, use of analgesics before surgery, bleeding disorder, allergy to ropivacaine, and psychiatric illness.

### Randomization

After obtaining written informed consent from the parents or guardians and recording demographic data, we used a computer-generated randomization program to allocate the patients

to one of two groups: group R, where patients received US-RSB, and group L, where patients received LAI. An age-stratified permuted block method was incorporated to achieve optimal balance (patient age strata, 2–4, 5–9, and 10–14 years). The patients, parents or guardians, and ward staff were blinded to the group allocation. All patients received the same sterile dressings, which did not reveal the technique used.

*Anesthetic methods*

All patients received oral midazolam 0.1 mg/kg as premedication 30 min before surgery. GA was slowly induced using 5.0%–8.0% sevoflurane under standard monitoring in both groups. After intravenous access placement, followed by the administration of rocuronium 1 mg/kg and fentanyl 1.0 μg/kg, patients were intubated with a tracheal tube without a cuff; this was immediately followed by the administration of acetaminophen 15 mg/kg. GA was maintained using air, oxygen, and 2.5%–3.0% sevoflurane. After intubation in group R, an anesthesiologist administered 0.5 ml/kg of 0.25% ropivacaine (per side) via the lateral border of the rectus sheath at the level of umbilicus. The puncture area and the ultrasound probe were kept clean and sterile. The block procedures were performed with a 23-gauge short-bevel needle using an in-plane puncture technique under guidance from an ultrasound system with a 50-mm, 13-MHz linear ultrasound transducer (Venous50, GE Healthcare Japan K.K., Tokyo, Japan). The same procedure was repeated on the contralateral side. In group L, the surgeon administered a subcutaneous intradermal injection containing 0.4 ml/kg of 0.5% ropivacaine after peritoneal closure. The ropivacaine concentrations for the two groups were selected on the basis of a previous study[10] and are routinely used at our department. Sevoflurane inhalation was gradually decreased during subcutaneous suturing and was discontinued when surgery was complete. After natural awakening, we administered 2 mg/kg of sugammadex sodium, with neuromuscular monitoring to ensure a train-of-four count of >2.

*Data collection*

The blinded parents of each patient used FS (0–5) to assess postoperative pain at rest at 0.25, 0.5, 1, 2, 4, 8, 12, 18, and 24 h after leaving OR. In addition, blinded nurses used the FLACC scale[9] to evaluate pain at rest at 0.25, 0.5, 1, 2, and 4 h after leaving OR. The primary endpoint was postoperative pain at 2 h after leaving OR. Additional analgesic drugs were used at 4 h after the intraoperative administration of acetaminophen, in accordance with the FS score at 2 h after leaving OR: score 0 to 1, no additional drug; score 2 to 3, acetaminophen 10 mg/kg; and score 4 to 5, acetaminophen 15 mg/kg. After discharge from our hospital, additional analgesia with acetaminophen 10 mg/kg was prescribed for use at home as per the patient's or parent's demand. Patient characteristics, the amount of additional drugs required, and the incidence of complications were additionally recorded for both groups.

*Statistical analysis*

We estimated that a minimum of 76 patients would be required for the study to have a power of 80% for the detection of a significant between-group difference in the FS score at 2 h after leaving OR, with an effect size of 0.8 standard deviations for a significance level of 0.01. We thought that a difference in the FS score that was equivalent to a large size effect was clinically significant.[10] To compensate for unforeseen dropouts and potentially higher than expected variability, we planned to enroll 86 patients. FS and FLACC scale scores were analyzed using a linear mixed model including the treatment group, time, and interaction between these variables as covariates. Least-squares means and their 95% confidence intervals were calculated for each time point, and adjustments for multiple comparisons were made using the Tukey–Kramer test.

Qualitative variables and demographic data, including age, weight, and height, were compared using *t*-tests. Categorical data were analyzed using Pearson's chi-square tests. All data were analyzed by a statistician using SAS version 9.4 software (SAS Institute Inc., Cary, NC, USA).

## RESULTS

Between August 2015 and October 2016, 80 of the 86 enrolled patients were randomly allocated to one of the two treatment groups (n = 40 each). After allocation, two patients in each group withdrew from the study, and 38 patients per group were included in the final analysis (Fig. 1). Demographic data and surgical characteristics, including the surgical duration and the duration from the end of GA to exit from the operation room, were comparable between the two groups (Table 1). There was no significant difference in the interval between the end of surgery and discharge from OR between groups (data no shown). However, the duration of anesthesia was significantly different between the two groups (Table 1).
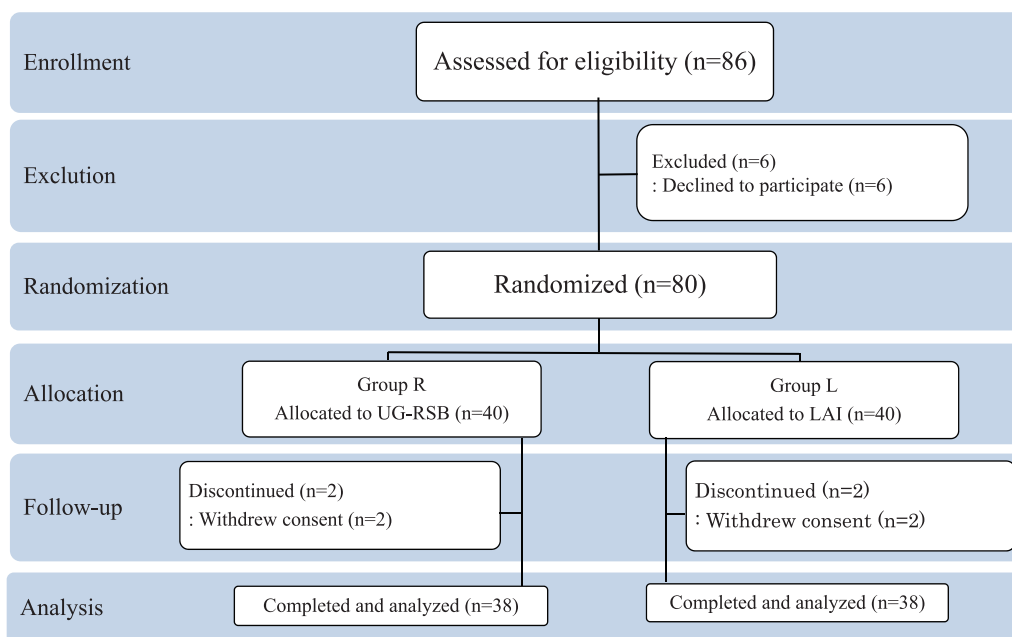


**Fig. 1** Flow chart showing the patient inclusion procedure

Of 86 patients initially screened for eligibility, six were excluded. The remaining 80 were randomly assigned to two equally sized groups: ultrasound-guided bilateral rectus sheath block (UG-RSB) group (Group R) and local anesthetic infiltration of the surgical field (LAI) group (Group L). Two patients in each group discontinued the study after group allocation. The final analysis was performed for 38 patients in each group.

Analgesia for umbilicus in children

**Table 1** Demographics and surgical characteristics of children

| | Group R | Group L | P-value |
|---|---|---|---|
| **Age (years)** | 5.03 ± 2.5 | 4.92 ± 2.3 | 0.77 |
| **Height (cm)** | 108.4 ± 15.9 | 106.4 ± 15.3 | 0.49 |
| **Body weight (kg)** | 19.0 ± 7.0 | 18.1 ± 5.7 | 0.48 |
| **Sex, Male:Female (number of patients)** | 18:20 | 16:22 | 0.57 |
| **Surgery** | | | |
| Duration of anesthesia (min)* | 83.3 ± 23.7 | 73.1 ± 18.9 | 0.04 |
| Surgical duration (min) | 42.3 ± 14.9 | 42.8 ± 18.3 | 0.91 |
| Duration from the end of general anesthesia to exit from the operation room (min)** | 14.6 ± 7.8 | 14.4 ± 5.0 | 0.88 |
| **The number of patients with additional drugs** | | | |
| Face scale score at 2 h after surgery, 0–1 | 20 | 18 | 0.89 |
| Face scale score at 2 h after surgery, 2–3 | 17 | 19 | |
| Face scale score at 2 h after surgery, 4–5 | 1 | 1 | |
| **The total amount of perioperative acetaminophen (mg/4 h)\*\*\*** | 378.9 | 377.6 | |

Group R: Ultrasound-guided rectus sheath block. Group L: Local anesthetic infiltration of the surgical field
*Time from the initiation of oxygenation to extubation. **Extubation marked the end of general anesthesia.
***4 h after leaving OR
Data are expressed as means ± standard deviations (n = 38)
The statistical significance of differences between the two groups was assessed using two-tailed $t$-tests (differences in sex were assessed using a chi-square test).

There were no statistically significant differences between the two groups with regard to postoperative pain; both FS scores (Fig. 2-a, c) and FLACC (Fig. 2-b) scale scores for groups R (n = 38) and L (n = 38) showed no significant differences throughout the observation period. The amount of additional drugs administered at 2 h after leaving OR was also comparable between groups (Table 1).

Postoperative vital signs were similar in both groups (data not shown). One patient in each group experienced postoperative nausea and vomiting (n = 1, 2.63%). No adverse events associated with the surgical intervention and UG-RSB procedure were recorded, and all patients left the hospital at 5–7 h after leaving OR.

**(a)**

**(b)**

**(c)**
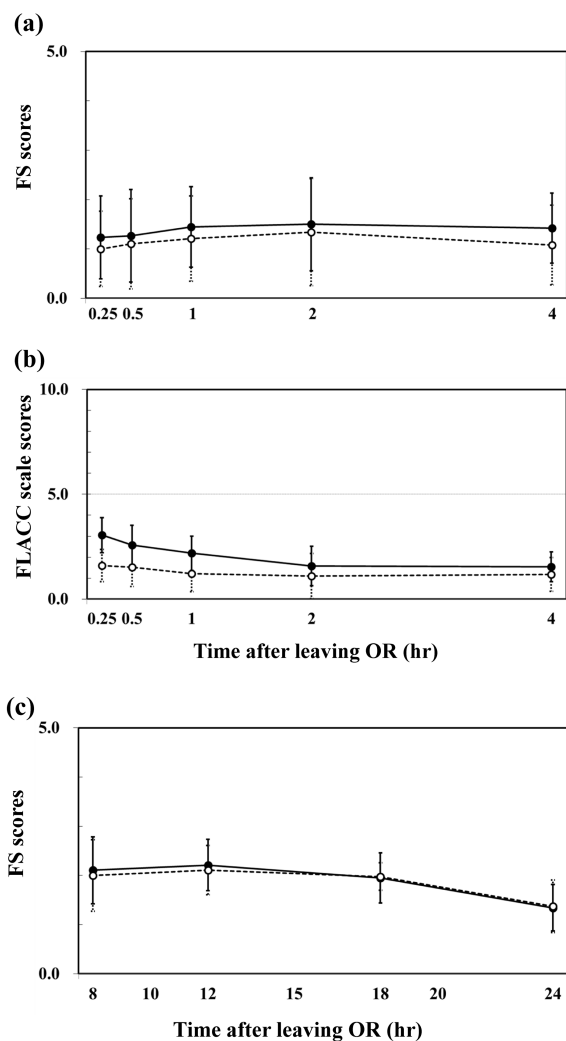


**Fig 2.** Comparison of the analgesic effects of ultrasound-guided bilateral rectus sheath block (UG-RSB) with those of local anesthetic infiltration of the surgical field (LAI) in children undergoing inguinal hernia repair
There are no statistically significant differences between the two groups with regard to postoperative pain; both Face Scale scores (a, c) and Face, Legs, Activity, Cry, Consolability scale scores (b) for groups R (○: n = 38) and L (●: n = 38) are comparable throughout the observation period.

## DISCUSSION

SILPEC is typically a day surgery, and the optimization of analgesia and facilitation of timely discharge are important considerations. In the present study, we found that UG-RSB did not provide better postoperative analgesic effects than did LAI with a higher concentration of anesthetic in children who underwent SILPEC. Thus, the study hypothesis was rejected. A strength of our study was that the analgesic efficacy of UG-RSB was compared with that of LAI using a higher concentration of ropivacaine. The large sample size was another strength, considering that more accurate results with adequate statistical strength could be achieved with the increased patient number.

Previous studies indicated that UG-RSB provided better postoperative analgesia than did LAI in patients who underwent SILPEC.[3,11] However, the concentration or total amount of local anesthetic used for LAI was the same as or lower than that used for UG-RSB, respectively, in these previous studies. In one study where the same concentration of ropivacaine was used, the analgesic effects of UG-RSB and LAI in the early postoperative stages were significantly different.[3,11,12] In the present study, we were not sure whether the efficacy of LAI would be inferior to that of UG-RSB if we used a higher concentration of local anesthetic. Uchinami et al reported that the analgesic effects of the two techniques were similar from 30 min after leaving OR,[7] although the effects throughout the early postoperative period remained unclear. In truth, we found a trend for a lower postoperative FS score in the UG-RSB group than in the LAI group in the present study. However, the difference was not statistically significant. The findings of the previous studies and the present study indicate that the postoperative analgesic effect would be compromised if a higher concentration of local anesthetic was used for LAI.

In our study, blinded parents assessed postoperative pain using FS; these assessments could be less accurate than those made by medical staff members.[9] However, a previous study reported a strong correlation between FLACC scale scores determined by trained parents and those determined by nurses.[13] The FLACC scale has been validated for use in children and is recommended for the evaluation of postoperative pain in children because of its simplicity and validation over a broad age range.[14] In our study, we used not only FS but also the FLACC scale in order to ensure accurate readings for the small children. Both FS and the FLACC scale scores were not significantly different between the two groups throughout the observation period in our study.

This study has some limitations. First, the use of premedication may have enhanced the quality of nerve blockade and pain control, and the analgesic evaluations in the early postoperative stage may be different from those in previous studies. Second, local anesthetic injection before surgery is reportedly more effective than that after surgery.[15] However, another study showed that there were no significant differences between preoperative and postoperative local anesthetic injection[16]; therefore, this topic remains controversial. Although RSB before the surgical intervention supports the former, our results support the latter findings with regard to SILPEC. Third, we could not check the time of initiation of both techniques; however, our results indicated that LAI was satisfactorily effective at the first assessment time point. Fourth, we adopted the postoperative analgesic protocol to change the dose of acetaminophen, because the package insert for acetaminophen recommended a dosage of 10–15 mg/kg every 4–6 h, and we do not normally use postoperative analgesic protocols involving opioids for children at our hospital. Further studies are necessary to clarify the findings of this study. Finally, the total LA dose differed for the two groups because of the accurate subcutaneous injection for LAI and ease in suturing the skin of the umbilicus. The LA dose to be administered in group L was decided by the surgeon before the study was performed.

In conclusion, our results suggest that UG-RSB (0.5 ml/kg of 0.25% ropivacaine per side) is

Takahiro Tamura et al

not superior to LAI (0.4 ml/kg of 0.5% ropivacaine) for the management of pain after pediatric SILPEC. We do not believe that UG-RSB is the best approach for postoperative analgesia for SILPEC. Although LAI is a classical method, it is also very useful for SILPEC. We would like to provide a take-home message for anesthesiologists that both techniques are multimodal analgesic techniques and selection of the most appropriate technique should be made based on the consideration of time, cost, and the facilities at each institution.

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## DISCLOSURE STATEMENT

None of the authors has any conflicts of interest to declare in relation to this work.

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