Prospective randomized observer-blinded study comparing the analgesic efficacy of ultrasound-guided rectus sheath block and local anaesthetic infiltration for umbilical hernia repair

H. G. Gurnaney 1*, L. G. Maxwell 1, F. W. Kraemer 1, T. Goebel 1, M. L. Nance 2 and A. Ganesh 1

1 Department of Anesthesiology and Critical Care Medicine and 2 Department of Surgery, The Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine, 34th St and Civic Center Blvd, Philadelphia, PA 19104-4399, USA
* Corresponding author. E-mail: gurnaney@email.chop.edu

Background. Umbilical hernia repair, a common day-surgery procedure in children, is associated with considerable postoperative discomfort. Possible modes of postoperative analgesia for umbilical hernia repair are rectus sheath block (RSB) and local anaesthetic infiltration of the surgical site (LAI).

Methods. We undertook an observer-blinded, randomized, prospective, observational study to compare the efficacy of ultrasound-guided RSB and LAI in providing postoperative analgesia for umbilical hernia repair. Our primary objective was to compare the use of opioid medication between patients who receive RSB and those who receive LAI. Our secondary objectives were to compare the duration of analgesia based on time to first rescue analgesic, to compare the quality of analgesia based on revised FACES scale, and to determine the incidence of side-effects.

Results. Fifty-two patients (26 in each group) completed the study. There was a statistically significant difference in the perioperative opioid medication consumption between the LAI group [mean: 0.13 mg kg⁻¹, confidence interval (0.09–0.17 mg kg⁻¹)] and the RSB group [mean: 0.07 mg kg⁻¹, confidence interval (0.05–0.09 mg kg⁻¹)] (P=0.008). When we compared the postoperative opioid consumption between the LAI group [mean: 0.1 mg kg⁻¹, 95% confidence interval (0.07–0.13 mg kg⁻¹)] and the RSB group [mean: 0.07 mg kg⁻¹, 95% confidence interval (0.05–0.09 mg kg⁻¹)] (P=0.09), there was a trend towards statistical significance between the two groups. The difference in time to rescue analgesic administration between the RSB group [49.7 (36.9) min] and the LAI group [32.4 (29.4) min] was not statistically significant (P=0.11).

Conclusions. This study demonstrates that ultrasound-guided RSB provides superior analgesia in the perioperative period compared with infiltration of the surgical site after umbilical hernia repair. In comparing only the postoperative period, analgesia provided by an ultrasound-guided RSB showed a trend towards statistically significant improvement compared with infiltration of the surgical site.

Keywords: paediatric anaesthesia; regional anaesthesia; ultrasound guidance; umbilical hernia repair
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Editor’s key points

• Umbilical hernia repair in children is associated with considerable postoperative discomfort.
• Rectus sheath blocks (RSBs) and local anaesthetic infiltration of the surgical site (LAI) are used for providing postoperative analgesia for umbilical hernia repair.
• Ultrasound-guided RSB provides superior analgesia in the perioperative period compared with LAI for umbilical hernia repair in children.
close to the lateral edge of the rectus muscle in the plane between the rectus abdominis muscle and the posterior rectus sheath as the nerves travel from a lateral to the medial direction in the plane between the posterior rectus sheath and the rectus abdominis muscle. With the help of high-resolution ultrasound guidance, the practitioner can directly visualize relevant structures which are essential landmarks for a successful execution of nerve blocks. This direct visualization improves the success rate of nerve blocks and avoids complications.

Providing analgesia before the surgical incision may decrease the amount of intraoperative and postoperative opioid use and the side-effects of the opioid medications, though the role of pre-emptive analgesia has been found to be equivocal in a recent metaanalysis. Nerve blocks can be placed before the surgical incision but infiltration of the surgical field is usually performed at the end of the procedure to avoid distortion of the surgical field.

We undertook an observer-blinded, randomized prospective study to compare the efficacy of RSB and LAI in providing postoperative analgesia. Our primary objective was to compare the use of opioid medication between patients who receive RSB and those who receive local infiltration of the surgical site. Our secondary objectives were to compare the duration of analgesia based on time to first rescue analgesic, to compare the quality of analgesia based on the revised Bieri FACES pain scale, and to determine the incidence of side-effects.

Methods

The Institutional Review Board at The Children’s Hospital of Philadelphia, Philadelphia, PA, approved this prospective, randomized, observer-blinded study. Written informed consent was obtained from the parents of all children. ASA classification I or II patients between 5 and 18 yr of age who were scheduled to undergo an umbilical hernia repair at The Children's Hospital of Philadelphia were approached for inclusion in the study. Patients with developmental delay that the parents believed would interfere with postoperative pain score assessment, and those with allergy to bupivacaine were excluded from the study. The trial is registered in a public trial register (clinicaltrials.gov) under the identification number NCT00578136.

After obtaining written informed consent, the study patients were assigned using computer-generated random numbers to either the RSB group or the LAI group. Data regarding the patient’s age, gender, race, ethnicity, and weight were collected from the patient’s chart.

Anaesthetic technique

Each subject before operation received midazolam 0.5 mg kg\(^{-1}\) orally (maximum 10 mg) and acetaminophen 15 mg kg\(^{-1}\) (maximum 650 mg) orally. Standard vital sign monitors were placed. Anaesthesia was induced using sevoflurane with oxygen and nitrous oxide. After i.v. catheter placement, the patient was administered fentanyl 1 \(\mu\)g kg\(^{-1}\) at induction, the patient’s airway was secured, and a volatile anaesthetic agent was used for maintenance of anaesthesia. Ondansetron 50 \(\mu\)g kg\(^{-1}\) (maximum 4 mg) was given within the last 30 min of the procedure. Local anaesthetic placement was performed based on the randomization schedule. Each haemodynamic change (>20% increase in systolic arterial pressure and heart rate above pre-incision levels) observed during surgery was treated by increasing the level of inhalation anaesthetic. Patients with persistent tachycardia received a dose of morphine (0.05 mg kg\(^{-1}\)).

Study protocol

RSB group

For patients randomized to receive RSB, the area of the abdomen at the lateral border of the rectus muscle and ~1 cm cephalad to the umbilicus was prepped and draped bilaterally. A sterile probe cover was placed over a Sonosite HFL38 ultrasound probe (Sonosite Inc., USA). An anaesthesiologist placed a 22 g needle using an in-plane technique under ultrasound guidance. The needle tip was placed close to the lateral border of the rectus sheath between the posterior rectus sheath and the rectus muscle. Spread of local anaesthetic was visualized between the rectus sheath and the rectus abdominis muscle under ultrasound guidance. The same procedure was repeated on the opposite side. A predetermined volume of 0.25% bupivacaine was injected for the RSB (Table 1).

Local anaesthetic infiltration

For patients randomized to receive LAI, after the completion of the surgical procedure, the surgeon infiltrated the surgical site with a predetermined volume of 0.25% bupivacaine (Table 1).

Postoperative period

Standard post-anaesthesia care unit (PACU) monitoring, consisting of pulse oximeter, non-invasive arterial pressure, temperature, and ventilatory frequency, were performed per PACU protocol for Phase 1 and Phase 2 recovery. The PACU team was blinded to the method of administering local anaesthetic. A blinded member of the research team made the initial assessment of postoperative pain using the revised Bieri FACES pain scale. The revised FACES pain scale excludes smiles and tears and is designed to facilitate the scoring on a 0–10 scale of pain in children older than 4 yr. Its use has been validated in children 5 yr of age.

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Volume of local anaesthetic used</th>
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<tr>
<td>&lt;12</td>
<td>0.5 ml kg(^{-1})</td>
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<td>12 to &lt;30</td>
<td>12 ml</td>
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<td>30 to &lt;40</td>
<td>16 ml</td>
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<tr>
<td>≥40</td>
<td>20 ml</td>
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Table 1: Total volume of local anaesthetic used by weight
and older. When a patient woke in the PACU, the patient’s pain score was recorded by a blinded observer both at rest and (if the patient was comfortable) with an attempt to sit up to 90°. Subsequent assessments were made at hourly intervals while the patient was in the hospital. For patients with a pain score of 4 or more on the revised FACES pain scale, morphine i.v. 0.05 mg kg\(^{-1}\) per dose, repeated every 10 min up to a maximum of 0.3 mg kg\(^{-1}\), or oral oxycodone 0.1 mg kg\(^{-1}\) (maximum=5 mg) was administered to bring the pain score below 4. The decision between i.v. vs oral pain medication was based on the severity of pain and the patient’s ability to take oral medications. Total amount of analgesic medications administered, time to first rescue analgesic administration and any supplemental antiemetic medications administered were documented. The total amount of opioid medication use was converted to morphine equivalents by body weight (mg kg\(^{-1}\)) for comparison between the groups (1 mg of i.v. morphine=2 mg of oral oxycodone). The incidence of nausea, vomiting, and pruritus were recorded.

Statistical analysis

Sample size calculation

The primary objective of this study is to compare the total amount of i.v. and oral opioid used between the patients who receive RSB and those who receive LAI for postoperative analgesia. Assuming the opioid requirement [mean (SD)] in the LAI group to be 0.2 (0.1) mg kg\(^{-1}\) and in the RSB group to be 0.1 (0.1) mg kg\(^{-1}\), a sample size of 44 patients (22 patients in each group) will have a power of 80% to detect a difference in means of 0.1 mg kg\(^{-1}\) with a 0.05 two-sided significance level.

The opioid use in the study population did not have a normal distribution using the Kolmogorov–Smirnov test (\(P<0.01\)), so the Wilcoxon rank-sum test was used to compare the total opioid use between the two groups of patients. Similarly, the Wilcoxon rank-sum test was used to determine the duration of analgesia based on time to first rescue analgesic (oral or parenteral), because the data were not normally distributed. The Kaplan–Meier curves were generated to display time to rescue analgesic (oral or parenteral). Quality of analgesia based on the revised Bieri FACES scale pain scores was considered to be a non-continuous variable and a generalized estimating equation (GEE) model was used to test the difference in pain scores between the two groups. Fisher’s exact test was used to compare the incidence of side-effects between the two groups.

Results

A total of 54 patients (27 in each group) were enrolled, and 52 patients (26 in each group) completed the study (Fig. 1). The two groups were similar with respect to their age, gender, weight, and size of umbilical hernia defect (Table 2).

There was a statistically significant difference in the perioperative opioid medication consumption between the LAI group [mean: 0.13 mg kg\(^{-1}\), 95% confidence interval (0.09–0.17 mg kg\(^{-1}\))] and the RSB group [mean: 0.07 mg kg\(^{-1}\), 95% confidence interval (0.05–0.09 mg kg\(^{-1}\))] (\(P=0.008\)) (Table 3). Six patients (three in each group) did not receive any supplemental opioid in the perioperative period. Fourteen patients needed a dose of morphine during the intraoperative period secondary to persistent tachycardia not controlled by increasing the depth of anaesthesia. Eleven of these patients were in the LAI group and three were in the RSB group. When we compared the postoperative opioid consumption between the LAI group [mean: 0.1 mg kg\(^{-1}\), 95% confidence interval (0.07–0.13 mg kg\(^{-1}\))] and the RSB group [mean: 0.07 mg kg\(^{-1}\), 95% confidence interval (0.05–0.09 mg kg\(^{-1}\))] (\(P=0.09\)), there was a trend towards statistical significance between the two groups (Table 4).

The difference in time to rescue analgesic administration between the RSB group (49.7 (36.9) min) and the LAI group (32.4 (29.4) min) was not statistically significant (\(P=0.11\)) (Table 5). The Kaplan–Meier curves were used to generate a display of time to rescue by treatment group (Fig. 2). The pain scores at rest and with movement between the RSB group and the LAI group did not show a statistically significant difference (\(P=0.30\)) (Figs 3 and 4). Difference in the incidence of nausea in the RSB group (\(n=2, 8\%\)) and the LAI group (\(n=1, 3.85\%\)) was not statistically significant (\(P=0.610\)). Difference in the incidence of vomiting in the RSB group (\(n=2, 8\%\)) and the LAI group (\(n=1, 3.85\%\)) was not statistically significant (\(P=0.610\)). One patient in the RSB group complained of pruritus that resolved without treatment.

Discussion

This study demonstrates that for umbilical hernia repair, ultrasound-guided RSB provides superior analgesia compared with LAI in the perioperative period. Comparing only the immediate postoperative period between ultrasound-guided RSB and LAI, there was a trend towards a statistically significant difference between the two groups.

A previous study compared RSB with LAI and found no difference in postoperative opioid use and pain scores (2). One of the differences between this study and our study is the use of ultrasound guidance to perform the RSB. The use of ultrasound guidance provides real-time information about the needle tip location and the local anaesthetic delivery to the desired location. The use of ultrasound guidance has been shown to improve the success rate for the placement of RSB, ilioinguinal block, and transversus abdominis plane block. The RSB is a field block with a need to cover multiple nerves (branches of T10 nerve and also T9 and T11 nerves) to provide complete analgesia of the periumbilical area. Because it is possible that a single injection may not cover all the nerve segments, it is not unreasonable for the patients in the RSB group to need supplemental opioid analgesia.
Our study found a trend towards decreased postoperative opioid consumption in the recovery room for ultrasound-guided RSB compared with LAI. This improvement in postoperative analgesia needs to be balanced against the equipment requirements, the need for training to perform the ultrasound-guided RSB, and the time required to perform...
There is also the remote potential for perforation of intra-peritoneal structures and epigastric blood vessels when performing a traditional RSB without ultrasound guidance.

The timing of the placement of the local anaesthetic was different between the two groups. This is in keeping with general practice of performing regional anaesthesia techniques before the start of surgery. Surgical infiltration of the site is performed towards the end of the procedure (before incision closure) under direct visualization. This difference in the timing of local anaesthetic delivery may allow for pre-emptive analgesia in the rectus sheath group, but a recent meta-analysis of diverse surgical settings did not find a benefit from pre-emptive analgesia. Presurgical delivery of local anaesthetic into the surgical site is not favoured by some surgeons because it can cause distortion of the surgical field.

In our study, we used the modified Bieri FACES pain scale to assess the severity of pain in the postoperative period. As this scale has been validated for children 5 yr or older, we limited our inclusion criteria to this age group. As a result, our findings can only be generalized to patients 5 yr and older having umbilical hernia repair.

In summary, our study concludes that ultrasound-guided RSB decreases the amount of opioid pain medications used in the perioperative period. This benefit needs to be balanced against the time needed to perform this block and the training needed to use the ultrasound to perform the RSB. Further investigation is needed to assess the duration of this analgesic effect beyond the immediate postoperative period.

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Conflict of interest
None declared.

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