Ultrasonography-Guided Bilateral Rectus Sheath Block vs Local Anesthetic Infiltration After Pediatric Umbilical Hernia Repair
A Prospective Randomized Clinical Trial

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**IMPORTANCE** Regional anesthetic techniques can be used to alleviate postoperative pain in children undergoing pediatric surgical procedures. Use of ultrasonographic guidance for bilateral rectus sheath block (BRSB) has been shown to improve immediate pain scores and reduce use of postoperative analgesia in the postanesthesia care unit (PACU).

**OBJECTIVE** To compare efficacy of ultrasonography-guided BRSB and local anesthetic infiltration (LAI) in providing postoperative analgesia after pediatric umbilical hernia repair.

**DESIGN** Prospective, observer-blinded, randomized clinical trial.

**SETTING** Tertiary-referral urban children’s hospital.

**PARTICIPANTS** Eligible children 3 to 12 years of age undergoing elective umbilical hernia repair from November 16, 2009, through May 31, 2011.

**INTERVENTIONS** Ropivacaine hydrochloride administered at the conclusion of surgery as LAI by the surgeon (n = 25) or as ultrasonography-guided BRSB by the anesthesiologist (n = 27).

**MAIN OUTCOMES AND MEASURES** Scores on the FACES Pain Rating Scale measured at 10-minute intervals and all use of analgesic medications in the PACU.

**RESULTS** Median FACES scores in the PACU were lower in the BRSB group compared with the LAI group at 10 minutes (0 vs 1; \( P = .04 \)), 30 minutes (0 vs 1; \( P = .01 \)), and 40 minutes or later (0 vs 1; \( P = .03 \)). Fewer doses of opioid and nonopioid medications were given to the BRSB group compared with the LAI group (5 vs 11 doses for opioids; 5 vs 10 for nonopioids).

**CONCLUSIONS AND RELEVANCE** In the PACU, ultrasonography-guided BRSB after umbilical hernia repair in children is associated with lower median FACES scores and decreased use of opioid and nonopioid medications compared with LAI. Future studies could examine the use of longer-acting anesthetic agents with ultrasonography-guided BRSB.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT01015053
Regional anesthetic techniques have been used to alleviate postoperative pain in children undergoing outpatient surgical procedures since the mid-1990s. Bilateral rectus sheath block (BRSB) was initially described for use in pediatric patients undergoing umbilical hernia repair without ultrasonographic guidance, with a randomized pilot study demonstrating no advantage of BRSB over local anesthetic infiltration (LAI) for postoperative pain management. Use of ultrasonographic guidance for ilioinguinal and/or iliohypogastric nerve blocks in children was subsequently shown to reduce the volume of the local anesthetic used. This technical advancement was then used for BRSB to enhance identification of rectus sheath anatomy and was shown in a small study of 20 children undergoing elective umbilical hernia repair to provide sufficient pain control without the need for additional postoperative analgesia. Gurnaney et al recently conducted a randomized prospective study to compare ultrasonography-guided BRSB and LAI in providing postoperative analgesia after pediatric umbilical hernia repair. Although the timing of the placement of the local anesthetic was different between the 2 groups, they found that BRSB decreased the amount of opioid pain medication used during the perioperative period.

Before our study, the accepted regimen for postoperative pain management after elective umbilical hernia repair at our institution consisted of surgeon-administered LAI in the wound at the end of surgery followed by a combination of opioid and nonopioid medications in the postanesthesia care unit (PACU) and at home. We undertook this prospective, randomized, observer-blinded study to compare the efficacy of ultrasonography-guided BRSB and LAI in providing self-reported postoperative analgesia after umbilical hernia repair in children. Our primary objective was to compare patient-reported pain scores using the FACES Pain Rating Scale (FACES) developed by Wong and Baker at defined intervals in the PACU and at home within the first 24 hours after surgery. Our secondary aims were to compare the use of opioid and nonopioid medications between treatment groups in the PACU and at home and to obtain measures of parents’ perceptions of their child’s pain at 12 and 24 hours after surgery.

Methods

The study design was a prospective, randomized, observer-blinded trial with 2 parallel arms. Approval was obtained from the institutional review board of Boston Children’s Hospital before patient enrollment (09-08-0398). Consent was obtained from each patient’s legal guardian.

Participants

Children 3 to 12 years of age who underwent elective umbilical hernia repair from November 16, 2009, through May 31, 2011, at our institution were eligible for this study (Figure 1). Exclusion criteria consisted of the following: American Society of Anesthesiologists classification of III or greater, history of a complex regional pain syndrome, history of long-term analgesic use, use of any analgesic (eg, an opioid medication, acetaminophen, or a nonsteroidal anti-inflammatory agent) within 24 hours before surgery, history of renal insufficiency or a bleeding disorder, concurrent additional surgery at another anatomic site, being a ward of the state, a non–English- or non–Spanish-speaking patient or primary caregiver, inability to document postoperative pain level using FACES scores, and inability of the primary caregiver to comply with home instructions.

Randomization and Treatment Allocation

Randomization proceeded after written informed consent was obtained in the preoperative area and was assigned by a research team member (L.M.B.) blinded to the group allocation. The randomization scheme was created using a uniform (0 or 1) random number generator in commercially available statistical software (SAS, version 9.2; SAS Institute, Inc) incorporating an age-stratified permuted block method of size 4 to achieve optimal balance (patient age strata, 3-7 and 8-12 years). Sealed envelopes for each age stratum containing the random allocations were opaque and tamperproof.

Blinding

The surgeon (including C.C.), regional pediatric anesthesiologist (R.S.D., H.K.C., D.J.C., and C.S.L.), and operating room staff (anesthesiologists and nurses) were not blinded to the treatment group. However, the patient and family, recovery room nurses, and study coordinator who collected the data from families were blinded. All patients received 2 uniform sterile dressings that were applied to the surgical site as well as the potential regional block sites regardless of randomization.

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**Figure 1. CONSORT Flow Diagram**

This diagram uses the criteria of 133 patients with umbilical hernia aged 3 to 12 years who underwent surgical repair at Boston Children’s Hospital from November 16, 2009, through May 31, 2011. BRSB indicates bilateral rectus sheath block; LAI, local anesthetic infiltration.
Interventions
Thirteen staff surgeons enrolled their patients in the study and performed umbilical hernia repairs using standard umbilical incisions. Four pediatric anesthesiologists with expertise in regional anesthesia performed the BRSB. Patients were randomized to one of the following 2 treatment arms using equivalent, volume-adjusted doses of ropivacaine hydrochloride: (1) LAI injected at the site of incision by the surgeon or (2) ultrasonography-guided BRSB administered by the pediatric regional anesthesiologist at the conclusion of surgery.

Study Protocol
Anesthetic Technique
Patients received no acetaminophen or midazolam before surgery. Anesthesia was induced via a mask using inhalational anesthetics and oxygen. After peripheral intravenous (IV) placement, general anesthesia was maintained via laryngeal mask airway or endotracheal tube depending on the intraoperative anesthesiologist’s preference. Intravenous fentanyl citrate (1 μg/kg) was administered before incision for intraoperative analgesia. All study patients received IV ketorolac tromethamine, 0.5 mg/kg, at the end of the case. Before emergence, patients received IV ondansetron hydrochloride, 0.1 mg/kg.

Description of Treatment Arms
At the conclusion of surgery, patients in the BRSB underwent cleansing of the periumbilical abdominal wall beyond the lateral border of the rectus muscle with the external oblique muscle bilaterally using a 2% concentration of chlorhexidine gluconate. A ultrasonographic probe (M-Turbo with the L25x transducer; SonoSite, Inc) was used to image the lateral border of the rectus sheath cephalad to the level of the umbilicus. A 22-g short-bevel needle was used to introduce 0.2% ropivacaine hydrochloride, 0.5 mL/kg, between the posterior rectus sheath and the rectus muscle with spread of the anesthetic agent monitored by ultrasonography guidance. This procedure was repeated on the opposite side.

For the LAI arm, patients received a subcutaneous and/or intradermal injection of 0.5% ropivacaine hydrochloride, 0.4 mL/kg, at the surgical site at the conclusion of the surgical procedure.

Data Collection
Demographics and clinical data were collected from patients’ medical records. Race was obtained from hospital records and was defined by the patient. Preoperative vital signs and a baseline FACES score were documented in the preoperative area before induction of anesthesia. Surgical start and stop times (which includes time required for LAI by the surgeon or BRSB by the anesthesiologist) were documented.

A blinded research team member assessed postoperative pain using FACES scores once the patient was awake and able to respond to questions and continuing at 10-minute intervals. Analgesics in the PACU were administered according to the patient’s self-reported FACES scores as described for the PACU protocol. Sleeping children were not awakened because they were assumed to be resting comfortably. All other medications (natural or chemical) given during the 24-hour home period were also documented. Caregivers also completed the Parent’s Postoperative Pain Measure (PPPM)\(^\text{10,11}\) at 12 and 24 hours after discharge. The PPPM is a 15-item instrument validated for children aged 1 to 12 years that examines the relationship between parent reports of child behaviors and child-rated pain in the postoperative period after minor surgery. Caregivers were contacted by telephone 24 hours after discharge, and families were asked to return the study journals by mail.

Sample Size and Statistical Analysis
A sample size of 25 in each treatment group provided 80% power to detect an effect size of 0.80 in the difference between FACES scores using the Mann-Whitney test with a Bonferroni-corrected 2-tailed significance level of .01\(^\text{12,13}\) (nQuery Advisor, version 7.0; Statistical Solutions). The effect size that we were sensitive to with the sample sizes was a difference in median FACES scores of 1 point or more between the 2 groups.

We used the Mann-Whitney test to compare FACES scores at the first obtainable score and at 10, 20, 30, and 40 or more minutes in the PACU and the PPPM scores at home. We compared the proportion of patients who had FACES pain scores of 0 between the groups using the 2-tailed Fisher exact test. Subsequent FACES scores were obtained every 4 hours (4, 8, 12, 16, 20, and 24) at home. Multivariable logistic regression was used to establish independent predictors of pain with age, body mass index (calculated as weight in kilograms divided by height in meters squared), and duration of surgery included as covariates.\(^\text{14}\) Vital signs (heart rate, mean arterial pressure, respiratory rate, and oxygen saturation level) were compared by the 2-tailed t test. Statistical analysis was performed using commercially available software (SPSS, version 19.0; SPSS Inc/IBM).

Results
Characteristics of Study Population
Among the 133 patients undergoing umbilical herniorrhaphy at Boston Children’s Hospital from November 2009 through May 2011, 100 were deemed eligible for inclusion in the study (Figure 1). Thirty-three patients did not meet inclusion criteria owing to the need for additional concomitant surgery (n = 14), a coexisting medical condition categorized as American Society of Anesthesiologists classification of III or IV (n = 4), a history of a bleeding disorder (n = 1), being a ward of the state (n = 6), being non–English or non–Spanish speaking (n = 3), receiving preoperative analgesics within 24 hours before sur-
FACES scores obtained at 10 minutes in the PACU; this difference of 28% has a 95% CI of 5% to 50%. At 30 minutes, 6 of 20 patients in the LAI group (30%) vs 15 of 21 in the BRSB group (71%) had no pain (41% difference [95% CI, 15%-62%]). At 40 minutes or longer, 10 of 19 patients in the LAI group (53%) and 9 of 10 in the BRSB group (90%) had no pain (38% difference [95% CI, 12%-57%]).

FACES and PPPPM Scores Reported at Home
We found no significant differences in FACES scores obtained at any of the 4-hour intervals within the first 24 hours after discharge between the 2 groups (Table 2). Table 2 also shows no significant group differences in PPPPM scores obtained at 12 and 24 hours after discharge.

Opioid and Nonopioid Medications
We found no significant differences in use of opioid and nonopioid medications between the treatment groups at any time in the PACU or at home (data not shown). However, when examining total use of analgesic medications in the PACU, we found fewer doses of opioid and nonopioid (acetaminophen) medications given to the BRSB group (5 opioid and 5 nonopioid) compared with the LAI group (11 opioid and 10 nonopioid) (data not shown). This trend was not noted at home, where 65 total doses of analgesics (20 opioid and 45 nonopioid) were given to the LAI group, and 63 total doses of analgesics (24 opioid and 39 nonopioid) were given to the BRSB group. We examined compliance with the study protocol for analgesic use at home; of 63 analyzable data points, 30 (48%) were compliant, 26 (41%) received stronger analgesics than indicated, and 7 (11%) received weaker analgesics than indicated. All data points with a FACES score of 0 (n = 2) or 1 (n = 12) at home received stronger analgesics than indicated.
Patients’ perceptions of their hospital care have been extensively studied, especially in adults, with an important finding that improvements are needed in pain management. These studies have led to the creation of acute pain management services in many tertiary hospitals with the aim of increasing patient satisfaction by providing adequate pain relief, cutting costs by reducing the length of hospitalization due to adverse side effects associated with increased opioid analgesic use, and decreasing the incidence of chronic pain. Similar data on parents’ perceptions of postoperative pain control in children are not well known.

Use of regional anesthesia techniques for abdominal operations in children is being increasingly used with sparse data about efficacy. Previous studies since the 1980s have examined regional anesthesia for pediatric inguinal and scrotal procedures with variable postoperative analgesia after ilioinguinal nerve block. Our study differs from previous trials examining related questions in similar patient populations in that 1 prior pilot study by Isaac et al did not include ultrasonographic guidance to perform BRSB. A more recent study by Gurnaney et al examined analgesic use between the treatment groups as a primary objective; the BRSB group received the block before the incision, whereas the LAI group received a local anesthetic after wound closure. We compared FACES pain scores at defined intervals in the PACU and at home within the first 24 hours after surgery.

Our study has shown that the BRSB group has a significantly higher percentage of patients with a FACES score of 0 (ie, no pain) and lower FACES scores at multiple time points in the PACU compared with the LAI group. We also found that the total use of analgesic (opioid and nonopioid) medications in the PACU was reduced in the BRSB group compared with the LAI group. At each time point in the PACU and at home, we did not find a significant difference in opioid or nonopioid medication use. The clinical significance of these findings is encouraging with regard to efficacy of ultrasonography-guided BRSB in providing short-term postoperative analgesia after umbilical hernia repair. We presume that 1 benefit of the BRSB from the patient’s and the family’s standpoints is that no pain (FACES score of 0) is more desirable than any level of pain (any FACES score >0). Differences in FACES scores between the study groups may have been minimized by the routine use of intraoperative ketorolac for all patients at our institution, which was mandated by the surgeons. Lack of prolonged analgesic effects of the BRSB at home is unfortunate, but these findings may be owing partly to additional

### Table 2. Comparison of Pain Scores Between the Treatment Groups

<table>
<thead>
<tr>
<th>Measure, Defined Interval</th>
<th>LAI Group</th>
<th>BRSB Group</th>
<th>P Value*</th>
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<tbody>
<tr>
<td>Preoperative FACES</td>
<td>0 (0-0) 25</td>
<td>0 (0-0) 27</td>
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<td></td>
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<td>First obtainable</td>
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<td>0 (0-4) 27</td>
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<td>10 min</td>
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<td>0 (0-5) 24</td>
<td>.04</td>
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<tr>
<td>20 min</td>
<td>1 (0-4) 18</td>
<td>0 (0-5) 26</td>
<td>.34</td>
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<tr>
<td>30 min</td>
<td>1 (0-5) 20</td>
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<td>≥40 min</td>
<td>1 (0-4) 19</td>
<td>0 (0-1) 10</td>
<td>.03</td>
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<tr>
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</tr>
<tr>
<td>4</td>
<td>2 (0-5) 22</td>
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<td>.36</td>
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<tr>
<td>8</td>
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<td></td>
</tr>
<tr>
<td>12</td>
<td>7 (2-13) 21</td>
<td>9 (0-13) 25</td>
<td>.54</td>
</tr>
<tr>
<td>24</td>
<td>5 (0-12) 21</td>
<td>5 (0-11) 25</td>
<td>.96</td>
</tr>
</tbody>
</table>

Abbreviations: BRSB, bilateral rectus sheath block; FACES, FACES Pain Rating Scale; LAI, local anesthetic infiltration; PACU, postanesthesia care unit; PPPM, Parent’s Postoperative Pain Measure.

* Statistically significant P values are given in boldface (calculated by nonparametric Mann-Whitney test).
methodologic challenges. Unsworth et al.\textsuperscript{19} used a similar self-reported pain scale strategy for administration of postoperative analgesics at home in children undergoing adenotonsillectomy. When FACES scores were obtained at defined times in the first 3 days after surgery, a similar amount of analgesic was administered to the children when compared with parent administration of analgesics without the use of FACES scores. They noted that analgesic administration was concordant with children’s pain scores in 68% of administrations, which is higher than the 48% noted in our study. These findings underscore the complicated dynamics involved in parental perception of their child’s postoperative pain and their subsequent attempts to address that pain. Compliance is altered if some parents, regardless of pain scores, prefer to administer stronger opioids or forgo opioid use for fear of possible adverse effects. We observed both scenarios in our study.

Our study findings may be generalizable to patients undergoing single-incision laparoscopic surgery (SILS) for abdominal operations using an umbilical port. A recent prospective, randomized trial by St Peter et al.\textsuperscript{20} noted that the SILS group received a greater total dose of analgesics during their hospital stay compared with the 3-port group. Two meta-analyses comparing conventional laparoscopic cholecystectomy with SILS cholecystectomy suggest that considerable postoperative pain remains after SILS cholecystectomy.\textsuperscript{21,22} Future studies examining the role of ultrasonography-guided BRSB in reducing postoperative pain after adult and pediatric SILS abdominal surgery may provide additional evidence.

Our study has some limitations. First, although we used a randomized clinical trial design, the treatment groups are not large and power is thus limited in assessing differences in opioid use between the groups. Second, postoperative pain after umbilical hernia repair may be widely variable, making detection of small changes in FACES scores difficult to capture. Third, our compliance data with administration of postoperative analgesia at home by parents based on the study protocol suggest that more work is needed to understand the complexities of parental perception of their child’s postoperative pain, some of which may be mitigated by improved parental education.

Future studies could examine the use of longer-acting local anesthetic agents for use with ultrasonography-guided BRSB. We chose ropivacaine, which has been shown to have superior postoperative analgesic effects compared with lidocaine when administered as a pediatric ilioinguinal nerve block.\textsuperscript{23} Longer-acting local anesthetic agents still in development, such as neosaxitoxin,\textsuperscript{24,25} may demonstrate improved postoperative analgesia at home and in the PACU. The addition of clonidine hydrochloride to the ropivacaine blocks may further extend the analgesic effects.\textsuperscript{26} In addition, administering the anesthetic before surgical incision for both treatment arms would allow one to study the role of preemptive analgesia in reducing postoperative pain in the PACU after each of the treatment arms. As newer pediatric regional anesthetic techniques are developed, studies should be performed to examine the efficacy of ultrasonography-guided BRSB with ultrasonography-guided bilateral transversus abdominis plane blocks\textsuperscript{27} in reducing postoperative pain after open and laparoscopic pediatric abdominal surgical procedures requiring midline and lateral incisions.

Finally, as with all new technologies, whether the cost of the BRSB justifies the clinical benefit it provides needs further study. The current methods used for this study, however, are not suitable for this analysis. First, we originally hoped to administer the anesthetic before surgical incision for both treatment arms to study the role of preemptive analgesia in reducing postoperative pain in the PACU. However, because surgical preference required the local anesthesia be delivered at the conclusion of surgery, we designed the BRSB arm to mirror this, thereby inflating the total length of surgery for the BRSB arm because the block could only be performed after the surgical dressings were applied. Second, patients were not billed for the BRSB in this study, and we therefore do not have any accurate cost data for that arm. Third, a future study comparing BRSB with LAI in providing preemptive analgesia could compare postoperative opioid use and frequency of opioid-induced adverse effects that may prolong recovery. Decreased PACU stay or avoidance of hospital admission could reduce costs.
Pain Control After Umbilical Hernia Repair

Invited Commentary

How Difficult Can We Make It?

Brad W. Warner, MD

Important to the overall experience for a child undergoing elective surgery is effective pain management. In this excellent study by Dingeman et al,1 a randomized prospective trial compared infiltration of local anesthetic with an ultrasonography-guided bilateral rectus sheath block (BRSB) after umbilical hernia repair. The authors report that the overall pain scores were better with fewer supplemental pain medications needed in the BRSB group.

This report has some limitations. Given the frequency with which umbilical hernia repair is performed, this study would be more convincing if a larger number of patients were enrolled. Further, although statistically significant, the pain score differences between the 2 groups were generally on the order of a single point. Therefore, whether these differences were biologically important remains unclear. Because preemptive analgesia is recognized to be more effective in minimizing postoperative pain, an even greater effect of the BRSB is likely if administered before the incision. Thus, a better study design would compare preincision BRB with the traditional postreperfusion infiltration of local anesthetic.

The cost difference between local anesthesia and BRSB was not mentioned and warrants justification, especially in face of the modest difference in pain scores between groups. Injecting local anesthetic is easy and does not require specific equipment. The BRSB procedure requires an
ultrasonographic machine and specific training to perform this technique successfully. Cost may therefore be higher as a result of the purchase and maintenance of the machine. An anesthesiologist charge for providing a regional anesthetic may be added. Further, the technique and training required for BRSB will undoubtedly add to operative time. Finally, risks unique to BRSB need to be monitored. All these factors must be considered because they undoubtedly add complexity to a straightforward and typically well-tolerated procedure.

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**Published Online:** June 12, 2013. doi:10.1001/jamasurg.2013.1453.

**Conflict of Interest Disclosures:** None reported.

**REFERENCE**