

Ultrasound-guided rectus sheath block, caudal analgesia, or surgical site infiltration for pediatric umbilical herniorrhaphy: a prospective, double-blinded, randomized comparison of three regional anesthetic techniques

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Background: Umbilical hernia repair is a common pediatric surgical procedure. While opioid analgesics are a feasible option and have long been a mainstay in the pharmacological intervention for pain, the effort to improve care and limit opioid-related adverse effects has led to the use of alternative techniques, including regional anesthesia. The current study prospectively compares the analgesic efficacy of three techniques, including caudal epidural blockade, peripheral nerve blockade, and local wound infiltration, in a double-blinded study.

Patients and methods: A total of 39 patients undergoing umbilical hernia repair were randomized to receive a caudal epidural block (CDL), ultrasound-guided bilateral rectus sheath blocks (RSB), or surgical site infiltration (SSI) with local anesthetic. Intraoperative anesthetic care was standardized, and treatment groups were otherwise blinded from the intraoperative anesthesiology team and recovery nurses. Postoperatively, the efficacy was evaluated using Hannallah pain scores, Aldrete recovery scores, the need for intravenous fentanyl, and the time to discharge.

Results: Each cohort was similar in terms of age, weight, premedication dosing, length of case, intraoperative and postoperative fentanyl requirements, and time to tracheal extubation. Among the three cohorts, there were no significant differences noted in terms of pain scores or time to recovery.

Conclusion: All the three techniques provided effective analgesia following umbilical hernia repair. Our findings offer effective and safe analgesic options as alternatives to the neuraxial (caudal) approach.

Keywords: caudal, pediatric, rectus sheath, regional anesthesia, umbilical hernia

Background

Umbilical hernias develop commonly in infants and reach a maximal size by the first month of life. They make up 14% of abdominal hernias and occur in approximately one of six children.^{1,2} The incidence decreases to 2–10% in children older than 1 year of age, and while most umbilical hernias close spontaneously before this time, the incidence of incarceration or strangulation may be as high as 10–20%.^{2,3} Although umbilical herniorrhaphy is a common pediatric outpatient surgical procedure, it may be associated with significant postoperative pain. Historically, the mainstay of pediatric analgesia has been opioid-based therapy. While this approach is generally safe, its potential for adverse effects has prompted the use of alternative analgesic methods in

infants and children.⁴ Although caudal epidural blockade has been the most commonly used pediatric regional anesthetic technique, effective analgesia in a variety of circumstances is possible with the use of peripheral nerve blockade even in children.⁵⁻⁷ Additionally, peripheral nerve blockade may have a lower incidence of adverse effects when compared with neuraxial techniques, including caudal epidural analgesia.⁸

With respect to umbilical hernia repair in the pediatric population, the rectus sheath block (RSB) has been established as a modality for pain management.⁹⁻¹² Popularity of the RSB has increased both due to its opioid-sparing effects and minimizing adverse effects such as itching, nausea, and vomiting and due to the advent of ultrasound guidance, which has allowed for significant improvements in safety and accuracy of this procedure.^{9,13-17} Despite the demonstrated efficacy of neuraxial and peripheral nerve blockade with regard to opioid use, there are relatively few prospective, direct comparisons of the respective regional techniques in an otherwise standardized setting. In the adult population, continuous infusion into the rectus sheath may provide equivalent analgesia to epidural analgesia following laparotomy for colorectal surgery or even superior pain relief following laparoscopic cholecystectomy when compared to the intraperitoneal instillation of a local anesthetic agent.^{18,19} In children, significant differences have been noted between an RSB approach and surgical wound infiltration in the context of umbilical hernia repair, but the administration of the local anesthetic agent by the surgeon occurred at the end of surgery in these studies.^{20,21} This may have biased the results in favor of the RSB, based on anticipated differences in the intraoperative requirement of opioids. Our study is unique in that it provides a concurrent comparison of three separate regional anesthetic methods for pediatric umbilical hernia repair. After initiating the study with a pairwise comparison of RSB to the caudal epidural block (CDL), we expanded the study to include a third cohort as a further point of reference, which was treated with pre-incisional surgical site infiltration (SSI) of local anesthetic by the surgeon.

Patients and methods

Study design

We conducted a prospective, double-blinded, randomized comparison of three patient cohorts following registration at www.clinicaltrials.gov (NCT01394523, TBhalla, 07/11/2011). The study was performed with ethical approval by the Institutional Review Board of the Nationwide Children's Hospital, OH, USA. Written informed consent was obtained from the parents of all children involved in the

study, and where appropriate, assent was obtained from the child. To be included in the study, pediatric patients presenting for umbilical hernia repair needed to be of American Society of Anesthesiologists (ASA) physical status I or II. Patients with comorbid cardiac, pulmonary, or neurological diseases or those having concomitant procedures (circumcision, orchidopexy, etc.) were excluded from the study. The time period for inclusion had no set end point initially, but was to end when reaching 25 subjects per group based on the power analysis and inclusion of a third experimental group as detailed below. Treatment was standardized with exception of the experimental variable, which was based on one of the three treatments groups: CDL, RSB, or SSI. The primary outcome measured was postoperative observational pain score, obtained using a Hannallah pain scale, and we also compared length of surgical procedure, anesthesia time (induction to tracheal extubation), recovery scores using the Aldrete system, and postoperative requirement for analgesics.^{22,23} Other secondary measurements included time from case completion to endotracheal extubation, intraoperative end-tidal inhalational agent, intraoperative requirement for supplemental fentanyl, and time to discharge. Demographic data such as patients' age, sex, and weight were also collected. The respective Hannallah and Aldrete scores were assessed at 5, 10, 20, and 30 minutes after tracheal extubation.

Anesthetic management

Premedication with oral midazolam was provided at the discretion of the attending anesthesiologist in the preoperative holding area. All patients underwent standard mask induction with nitrous oxide and sevoflurane in oxygen followed by placement of an intravenous cannula. For blinding purposes, in the absence of the primary anesthesiology providers, a specialized regional anesthesiology team took over patient care in the operating room (OR) after induction of anesthesia until draping of the patient for surgery. During this time, the regional anesthesiologist or surgeon performed the CDL, RSB, or SSI, respectively, based on a computer-generated random assignment. Maintenance anesthesia consisted of isoflurane titrated to keep heart rate and blood pressure within 10% of baseline values. If these parameters could not be maintained with an isoflurane end-tidal concentration of $\leq 2\%$, supplemental fentanyl (1 $\mu\text{g}/\text{kg}$) was administered. Upon completion of the surgical procedure, the patient's trachea was extubated and patient care was transferred to a provider in the post-anesthesia care unit (PACU). An independent observer, who was blinded to the type of regional anesthesia that was provided in the OR,

assigned the appropriate Hannallah and Aldrete scores at the allotted times. A standardized fentanyl dose of 1 µg/kg was provided in the PACU for pain scores >4 and reassessed until they dropped below this level. Patients were then discharged upon achieving an Aldrete score of ≥9.

Regional treatments

Patients who weighed up to 20 kg in the CDL group received 1.5 mL/kg of 0.2% ropivacaine and those who weighed >20 kg received 1.2 mL/kg to a maximum of 30 mL/kg. The relatively higher volumes used for the CDL were designed to provide more cephalad spread for coverage of the surgical procedure, but remained in line with established dosing guidelines for these blocks. Following a previously described technique, the RSB group was treated bilaterally with 0.1 mL/kg of 0.2% ropivacaine per side and administered at the T9–T10 level under ultrasound guidance.¹⁵ For those patients who were randomized into the SSI cohort, the surgeon injected either 0.5 mL/kg of 0.5% bupivacaine or 1 mL/kg of 0.25% bupivacaine based on the surgeon's discretion in line with his or her standard practice. All the aforementioned local anesthetic preparations contained 5 µg/mL of epinephrine.

Statistical analysis

Our initial study design was powered to detect a one standard deviation difference in postoperative pain scores between CDL and RSB, which yielded a sample size requirement of 18 patients in each group to achieve 80% power for a 95% confidence level with an unpaired *t*-test. To include the interests of our surgical colleagues, we added a third group (SSI) to the design prior to study initiation with plans to enroll 25 patients in each group to account for possible attrition from the study or missing data. A relatively low rate of enrollment prompted an interim review 5 years into the study. During this time, 78 patients met criteria for the study based on preliminary screening and were approached accordingly. Half of these patients were excluded from the study (*n* = 39), mostly

due to refusal to participate (*n* = 27, 69.2%) and also due to the presence of comorbidities (*n* = 4, 10.3%), inappropriate patient weight (*n* = 4, 10.3%), or surgical factors (*n* = 4, 10.3%). Subsequent conditional power analysis, using data on the Hannallah pain score in the PACU, yielded an anticipated power of 6.8% for demonstrating a significant difference in this outcome between the CDL and RSB groups if the study were to proceed as planned. Given the statistical futility and impracticality of continuing the study, we concluded with a total of 39 patients, distributed equally among the three cohorts. Data were analyzed using GraphPad Prism version 7.00 for Windows (GraphPad Software, Inc., La Jolla, CA, USA; www.graphpad.com). We compared baseline patient characteristics and perioperative measurements using one-way analysis of variance (ANOVA) and the chi-square test for continuous and categorical data, respectively. Hannallah and Aldrete scores were compared using the Kruskal–Wallis rank sum test. Pairwise comparisons were corrected for multiple comparisons using the Tukey and Dunn's tests for ANOVA and Kruskal–Wallis rank sum, respectively. Statistical significance would be considered at a *P*-value of ≤0.05.

Results

Each group consisted of 13 patients, all of whom contributed to the analysis with exception of one failed block in the CDL group. There were no significant differences between groups in terms of age, weight, and sex distribution (Table 1). Length of surgery, anesthesia time, and the time to tracheal extubation were also similar. All groups required comparable amounts of intraoperative opioid and inhaled anesthetic agent, as well as having an equivalent need for postoperative fentanyl. As a whole, fewer than half of the patients in our study required analgesic intervention in the PACU, ranging from 38.4% to 53.8% when considering the treatment groups separately. While the only parameter left to the discretion of the primary anesthesiology team was provision of oral midazolam, we ruled this out as a factor insofar as all groups

Table 1 Patient demographics and perioperative details

	CDL (n = 12)	RSB (n = 13)	SSI (n = 13)	Total (n = 38)	P-value
Age (years)	4.2 ± 1.5	4.3 ± 1.6	4.6 ± 1.2	4.4 ± 1.4	0.746
Weight (kg)	16.5 ± 3	17.5 ± 3.6	18.1 ± 2.1	17.4 ± 2.9	0.400
Sex (F/M), n (%)	6/6 (27.3/37.5)	10/3 (45.5/18.8)	6/7 (27.3/43.8)	22/16 (100/100)	0.226
Duration of surgery (minutes)	21.8 ± 7.3	25.8 ± 5.5	27.8 ± 7.7	25.2 ± 7.1	0.099
Duration of anesthesia (minutes)	56.3 ± 10.6	63 ± 26.5	60.3 ± 18.5	60 ± 19.5	0.704
Time to tracheal extubation (minutes)	11 ± 9.6	8.2 ± 11	13.3 ± 11.8	10.8 ± 10.8	0.497
Analgesia required, n (%)	5 (41.7)	7 (53.8)	5 (38.4)	17 (44.7)	0.709
Time to discharge (hours)	2.5 ± 0.8	2.7 ± 1.2	2.5 ± 1.0	2.6 ± 1.0	0.876

Note: Data presented as mean ± standard deviation, unless otherwise stated.

Abbreviations: F, female; M, male; CDL, caudal epidural block; RSB, rectus sheath block; SSI, surgical site infiltration.

received similar quantities of premedication. A regrouped analysis based on administration of premedication showed no significant difference between groups for any of the measured parameters, so the provision of midazolam preoperatively did not demonstrate an influence on the results of this study.

An assessment of pain in the PACU using the Hannallah scoring system revealed little to no pain in the first 5–10 minutes after tracheal extubation (Table 2). The highest median pain scores were achieved at the 20-minute assessment period in all groups, with a possibility of an increase in pain scores relatively sooner in the RSB and SSI groups when compared to the CDL cohort. However, there were no statistically significant differences overall between the treatment groups. While the uncorrected confidence interval for difference of medians between CDL and SSI Hannallah scores at the 20-minute time point did not include zero, correction for multiple comparisons suggested a lack of statistical significance. Similarly, each cohort displayed a similar recovery profile, all reaching a median Aldrete score high enough for discharge by 20 minutes after tracheal extubation (Table 3). In absolute terms, 78.9% of all patients had an Aldrete score ≥ 9 by 30 minutes after tracheal extubation, ranging from 76.9% to 83.3% when considering the groups separately. Of note, there were no significant differences between groups in terms of analgesic requirements, the bulk of which were nonopioid based, and between the 30-minute time point and time to discharge, and there were also no significant differences between groups in terms of length of stay in the hospital.

Discussion

Our study provides a direct, concurrent comparison of three separate regional anesthetic modalities that were provided

preoperatively in the context of superficial abdominal wall surgery in a pediatric population. Because the studied interventions were performed at the same time relative to surgical incision, this permits a fair assessment of both the respective intraoperative and postoperative impacts of these techniques. Despite difficulty in enrolling the planned number of patients for this study, the lack of variability between treatment groups provides fundamental implications for the postoperative care of these patients.

Our data are in alignment with previous work that reported adequate and equivalent analgesia between the RSB and neuraxial route as well as with other investigators who found no difference in postoperative opioid use and pain scores when comparing the RSB to local anesthetic infiltration into the surgical wound.^{11,18} Investigators who have used ultrasound guidance advocate the increased accuracy and safety of this approach with the RSB, thereby making it superior and more efficacious than SSI with local anesthetic. However, these distinctions were made in the context of differential timing of drug administration in these studies (pre-incision for the RSB versus postsurgical manipulation for the SSI). The lack of variability between treatment groups in our study supports the idea that deposition of local anesthetic at one of the multiple sites along the nociceptive pathway could provide a similar analgesic effect when applied pre-incision in the context of minor surgical procedures. In recognition that SSI may have a relatively quick onset, the relevance of timing administration could be probed further by comparison to a postsurgical SSI group. An important consideration is whether or not the lingering effects of premedication and/or use of inhaled anesthesia may have lessened any apparent differences between our studied groups. To address the former, we ruled out the influence of midazolam

Table 2 Hannallah scoring at specified postoperative time periods

Time (minutes)	Hannallah score	CDL	RSB	SSI	Multiple comparisons	CDL vs. RSB	CDL vs. SSI	RSB vs. SSI
5	Mean \pm SD	0 \pm 0	1.2 \pm 3	0.2 \pm 0.6	Δ of medians	0	0	0
	Median	0	0	0	95% CI	-0.4, 0.4	0, 0	-0.5, 0.5
	IQR	0, 0	0, 0	0, 0	P-value	0.220	0.480	0.525
10	Mean \pm SD	1.3 \pm 2.5	2.3 \pm 2.9	2.5 \pm 3.5	Δ of medians	1	0	1
	Median	0	1	0	95% CI	-3.9, 1.9	-3.2, 3.2	-2.5, 4.5
	IQR	0, 1	0, 4	0, 5	P-value	0.242	0.309	0.950
20	Mean \pm SD	3.8 \pm 3.5	3.6 \pm 3.8	2.2 \pm 2.9	Δ of medians	4	5	1
	Median	5	1	0	95% CI	-0.8, 8.8	0.8, 9.2	-3.6, 5.6
	IQR	0, 7	0, 7	0, 5	P-value	0.813	0.216	0.151
30	Mean \pm SD	2.9 \pm 3.3	3.1 \pm 3.1	2.1 \pm 2.7	Δ of medians	1	1	2
	Median	1	2	0	95% CI	-5.5, 3.5	-3.2, 5.2	-2.2, 6.2
	IQR	0, 6.3	0, 5	0, 3	P-value	0.839	0.570	0.407

Note: P-values are calculated by unpaired Mann–Whitney U test.

Abbreviations: CDL, caudal epidural block; RSB, rectus sheath block; SSI, surgical site infiltration; SD, standard deviation, CI, confidence interval; IQR, interquartile range.

Table 3 Aldrete scoring at specified postoperative time periods

Time (minutes)	Aldrete score	CDL	RSB	SSI	Multiple comparisons	CDL vs. RSB	CDL vs. SSI	RSB vs. SSI
5	Mean ± SD	7.5 ± 1.7	7.2 ± 1.4	7.4 ± 1.9	Δ of medians	1	1	0
	Median	7	8	8	95% CI	-2.9, 0.9	-2.9, 0.9	-1.9, 1.9
	IQR	6, 9	6, 8	6, 9	P-value	0.715	0.983	0.711
10	Mean ± SD	8.1 ± 1.4	8.1 ± 1.5	8 ± 1.5	Δ of medians	0.5	0.5	1
	Median	8.5	9	8	95% CI	-2.4, 1.4	-1.4, 2.4	-0.9, 2.9
	IQR	7.5, 9	7, 9	8, 9	P-value	0.883	0.894	0.824
20	Mean ± SD	8.5 ± 1.5	9 ± 1	8.6 ± 1.4	Δ of medians	0	0	0
	Median	9	9	9	95% CI	-1.3, 1.3	-1.3, 1.3	-1.3, 1.3
	IQR	8, 9.3	8, 10	8, 10	P-value	0.557	0.815	0.715
30	Mean ± SD	8.9 ± 1.1	9.2 ± 0.8	9.1 ± 0.8	Δ of medians	0	0	0
	Median	9	9	9	95% CI	-1, 1	-1, 1	-1.3, 1.3
	IQR	9, 9.3	9, 10	9, 10	P-value	0.457	0.867	0.640

Note: P-values are calculated by unpaired Mann-Whitney U test.

Abbreviations: CDL, caudal epidural block; RSB, rectus sheath block; SSI, surgical site infiltration; SD, standard deviation; CI, confidence interval; IQR, interquartile range.

based on a regrouped analysis. Of note, no significant differences were apparent between groups in our study throughout the entire length of stay, which averaged 2.6 hours, and in another study that reported significance between two of the regional techniques (RSB vs. SSI), all patients were premedicated with midazolam and all received inhaled anesthesia.²⁰ In view of this and given that the inhaled anesthetic was titrated reactively in our study, the effect of any residual general anesthetic in our study is likely negligible. The ramifications of our results could be meaningful in changing clinical practice by expanding the options that are available to anesthesiologists and surgeons. SSI with local anesthetic may be an appropriate alternative in those patients who refuse to undergo peripheral nerve blockade, in the same way that the RSB may be a good alternative for those patients in whom a neuraxial modality is contraindicated.

Conclusion

In summary, our study demonstrated equivalent opioid requirements and similar efficacy in analgesia between three regional anesthetic techniques. With the advancements in imaging technology and improved accuracy of peripheral nerve blockade, these techniques have become increasingly popular, and our data support that RSB may be used in lieu of caudal analgesia for umbilical herniorrhaphy in children. Of note, the volume of injectate required for the RSB is 60–87% smaller when compared to the CDL or SSI approach, making the former the most amenable to minimizing quantities of administered drug, which could reduce the chances of local anesthetic systemic toxicity. In cases where preoperative SSI is feasible without excessive anatomical distortion that would interfere with surgery, SSI with a local anesthetic would be an alternative means to potentially limit intraoperative opioid requirements and provide effective postoperative analgesia while limiting

the time required for neuraxial or peripheral nerve blockade. Limiting the amount of opioid that is needed postoperatively and the ability to minimize the quantity of prescription medication upon discharge could also improve patient safety.

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Disclosure

The authors report no conflicts of interest in this work.

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