Pain management with ultrasound-guided lidocaine-ropivacaine caudal block in hypospadias repair: A single-surgeon comparative study

Shuangbo Dai

Fujian Provincial Hospital

Min Chen

Fujian Provincial Hospital

Shaohua HE (✉ slyy2016@126.com)

Fujian Provincial Hospital <https://orcid.org/0000-0003-2468-0859>

Research article

Keywords: ultrasound-guided caudal epidural block, hypospadias, pain management, lidocaine, ropivacaine, genitourinary surgery

Posted Date: November 2nd, 2019

DOI: <https://doi.org/10.21203/rs.2.16538/v1>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License. [Read Full License](#)

Abstract

Background: Postoperative pain management in hypospadias surgery can be challenging, especially with the occurrence of postoperative penile erection, which is usually accompanied with bleeding and often interferes with wound healing. Ultrasound-guided caudal epidural block is easy to administer and can attenuate postoperative physiological stress response. In this study, we compared the effect of pain control among patients receiving standard general anesthesia (Group G) and among those receiving caudal analgesics of lidocaine-ropivacaine (Group GC).

Methods: A total of 100 patients needing hypospadias repair for the first time were consecutively enrolled; 50 patients received caudal analgesics depending on available anesthesiologists. All patients were operated on by the same experienced surgeon. Primary outcome included pain and sedation scores, and the incidence of painful erections within 24 hours following surgery. Heart rate (HR) and analgesic requirement were also compared.

Results: Baseline characteristics and vital statistics did not differ between the two groups. Postoperative erections were significantly less frequent in the GC than in the G group (22% vs. 64%, $P < 0.05$). The HRs and pain scores of the GC group were lower than those of the G group ($P < 0.05$) in the first 12 hours. Postoperative sedative effect was better and analgesic requirement less for the GC than the G group ($P < 0.05$) in the first 24 hours.

Conclusion : Caudal lidocaine + ropivacaine can provide effective pain management in the early postoperative period and reduce the occurrence of painful erections. Further volume dosing studies are needed to refine the strategy for optimal pain control.

Introduction

Hypospadias is one of the most of common congenital defects in boys, for which the true prevalence is difficult to estimate, partly due to the lack in standardized criteria and method of classification [1]. The etiology of hypospadias remains largely unknown though genetic and environmental inheritance is thought to play a role[2].

Guidelines on pediatric urology recommend that the corrective surgery be completed at the age of 6-18 months [3]. In our practice, however, pediatric patients needing hypospadias repair are usually presented at an older age (mostly as toddlers), and their tolerance for pain significantly diminishes as they grow out of infancy. Because of the large wound surface and intensive nerve distribution involved in hypospadias repair, pain can be severe and complications can occur as a result of adverse physiological stress response. Effective pain relief is often challenging, but critical, in patient care.

Outcome of the hypospadias surgery largely depends on the operating surgeon, and practices vary greatly with over 250 surgical techniques available for this procedure [4]. Almost as important yet easier to improve, is effective postoperative pain control, to achieve better surgical outcome and timely recovery.

Caudal epidural block is commonly used in pediatric anesthesia, applicable in sub-umbilical interventions in the pediatric population, including surgery of the lower abdomen (hypogastrium), perineum, and the lower limbs. A technique of epidural anesthesia, caudal block is usually performed by delivering the medications through the sacral foramen into the epidural cavity to block the sacral spinal nerve. The anatomy of the sacral canal varies greatly: reportedly 20% of the population have anatomic anomalies of the sacral canal, malformations of the sacral foramen or a closed hiatus [5]. The conventional landmark-based technique of caudal injection in children was reported with a success rate in the range of 75-96% [6, 7]. Performed with visualization tools such as the ultrasound, which is quickly becoming commonplace practice, caudal blocks can improve block efficacy and patient safety. Ultrasound can clearly show the sacral foramen, sacrococcygeal ligament and the sacral space; it also makes it possible for real-time monitoring of the spread of injectate and expansion of the epidural cavity upon injection of medication [6].

In this study, we aimed to compare the early postoperative pain management, including incidence of painful erections, and sedative effect of ultrasound-guided caudal block (Group GC) to those of standard general anaesthesia (Group G) in paediatric patients of hypospadias repair.

Methods

The study was approved by the ethics committee of the Fujian Provincial Hospital. Written informed consent was provided by guardians of the patients prior to the enrollment.

We used one-sided analysis of variance of the mean values from our preliminary findings on postoperative pain scores to arrive at a sample size of 46 per group ($\alpha = 0.05$, $\beta = 0.1$, $m_1 = 3$, $m_2 = 5$, $s_1 = 1.8$, $s_2 = 2.0$, $\Delta = 1$). We aimed to enrol 50 patients per group, and recruitment ended when a total of 100 eligible patients were enrolled.

Routine surgical management of hypospadias repair was performed by SH, an experienced pediatric surgeon with an annual volume of hypospadias surgery of >40 cases. Between January 2017 and December 2018, patients who needed hypospadias repair for the first time (American Society of Anesthesiologist (ASA) Class I and II) in our hospital were consecutively enrolled. Exclusion criteria were: 1) coagulation disorders, 2) systemic infection or caudal site infection, 3) neurological abnormalities or disorders, and 4) allergy to local anaesthetics (lidocaine or ropivacaine). No one was excluded during the enrolment period.

Generally, in our practice, pediatric patients undergoing hypospadias repair would receive intravenous (IV) injection of sufentanil for general anesthesia. In this series, designated anesthesiologists received training prior to study commencement to administer ultrasound-guided caudal epidural blocks for children. Ultrasound-guided caudal analgesics were only administered when trained anesthesiologists were available (on alternative days of surgical schedule). As a result, 50 patients received caudal analgesics (the GC group), and 50 received standard general anesthesia (the G group). Recommended concentration of caudal ropivacaine is 0.1%-0.375% with 1-1.5 mL/kg

[ref]. Clinically, in pediatric surgery, 2 mg/kg of ropivacaine can suffice as local anesthetic method in sub-umbilical surgery. In this study, we used 1 mL/kg of 0.2% ropivacaine, equivalent to dosage of 2 mg/kg to body weight.

Before surgery, an IV line was obtained, and no sedative agent was administered for pre-medication. In the operating room, routine monitoring of patients, ie, electrocardiogram (ECG), non-invasive blood pressure (NBP), peripheral oxygen saturation (SpO₂), and end-tidal carbon dioxide pressure (P_{ET}CO₂), was started. Propofol 1mg/kg and atropine 0.01 mg/kg of body weight was given intravenously for induction, and 8% sevoflurane was administered as inhalation induction. Following loss of consciousness, with a laryngeal mask airway (LAM), the patient was intubated for breathing control.

In the GC group, the patient was placed in the left lateral decubitus position, with the hips and knees flexed, the caudal area sterilized. Examine the caudal end of the sacrum with ultrasound, place the transducer at the midline for a transverse view of the sacral hiatus. When locating the cornua and sacrococcygeal ligament (Fig. 1), rotate the transducer by 90 degrees to obtain the longitudinal view of the sacral hiatus. Applying the “in-plane” technique (Fig. 2a), insert the block needle directly into the sacral canal, through between the cornua, to deliver a mixture of 0.08% lidocaine hydrochloride and 2mg/kg of ropivacaine, spreading of which in the sacral space could be visualized on the ultrasound (Fig. 2b).

In the G group, IV injection of sufentanil of 1 ug/kg was administered prior to skin incision. For either group, during the operation, level of sevoflurane was maintained at 1.5% - 3.0%. The heart rate (HR), mean blood pressure (MBP), and P_{ET}CO₂, at times when placing and removing the LAM, upon and at 30, 60, 90, and 120 minutes of skin incision were recorded.

Upon awakening, the LAM was removed. Time to awakening was recorded. The patient was sent to the recovery unit for post-anesthesia care and observation. In the recovery unit, a nurse clinician blinded to the anesthetic method evaluated the patient every 15 minutes for pain and sedative level, and recorded the HR, as well as the occurrence and treatment of painful erections (with observation and report by the caregivers). The Face, Leg, Activity, Cry and Consolability (FLACC) pain scale, with a range of score of 0-10 (higher scores indicate more pain), was used to assess postoperative pain [8]. The level of sedation was measured with the Ramsay Sedative Scale, which is composed of evaluation of the patient's responsiveness while awake (levels 1-3) and asleep (levels of 4-6, higher scores indicate deeper sedation) [9].

When stabilized, the patient was then lifted to the wards, and pain was evaluated by the same nurse clinician at 2, 4, 8, 12, 24 hours after surgery. When the patient's pain score reached 6 or above, intramuscular injection of midazolam 0.1 mg/kg of body weight was given and titrated to keep the pain score below 6. Postoperative analgesics were administered in standardized weight-based doses, and were thus measure by number of doses

received. Corresponding HRs were recorded at the same time points. The nurse clinician observed the occurrence of painful erection and also documented any incidents reported by the caregivers of the patient.

Statistical analysis

The SPSS software 13.0 was used. Histogramic analysis was used to assess normality of the data. Normally distributed data were reported as means and standard deviation (SD), and one-way analysis of variance was applied in between-group comparisons. Non-normally distributed interval data were reported as median with inter-quartile range, and analyzed with the two-tailed Mann-Whitney *U*-test. Ordinal data were analyzed with the chi-square test, and P values < 0.05 were used to indicate statistical significance.

Results

A total of 100 pediatric patients, aged 1-7 years (mean ± SD, 4.3 ± 2.0), were included in the analysis, 50 patients each group, determined by anesthesiologist availability. Demographic characteristics (age, height and weight) did not differ significantly between the two groups of patients (Table 1). Duration of surgery and time to awakening was also comparable between the two groups (Table 1). Hemodynamic measurements (HR, MBP, and P_{ET}CO₂) during the operation did not significantly differ between different time points in either group, or between the two groups (Table 2).

Table 1. General characteristics of patients by anesthetic groups (mean ± standard deviations).

Group	Age (years)	Weight (kg)	Height (cm)	Surgical time (min)	Wake time (min)
GC (n=50)	4.3±1.8	15±4	105±11	148±25	8±3
G (n=50)	4.2±2.1	15±5	108±15	150±30	10±4

Note: GC: General anesthesia with caudal epidural block; G: standard general anesthesia.

Table 2. Intraoperative hemodynamic comparisons between the two groups (mean ± standard deviations).

Measurements	Group	LAM placement	Skin incision	Time into surgery (min)				LAM removal
				30	60	90	120	
HR	GC	93±11	95±13	97±14	95±12	99±13	98±10	100±13
(pulse/min)	G	94±12	97±11	97±10	96±13	97±12	96±13	99±14
MBP	GC	62±7	66±8	65±10	67±9	66±7	69±8	68±8
(mmHg)	G	64±8	67±9	68±7	65±9	68±8	66±10	69±9
P _{ET} CO ₂	GC	34.7±2.5	35.3±2.4	34.8±1.8	35.1±2.2	34.8±1.8	35.0±2.8	35.2±2.4
(mmHg)	G	35.1±2.3	35.1±2.1	35.2±2.5	34.8±1.5	35.0±2.5	34.9±1.9	35.2±1.7

Note: GC: General anesthesia with caudal epidural block; G: standard general anesthesia.

Abbreviations: HR, heart rate; MBP, mean blood pressure; P_{ET}CO₂, end-tidal carbon dioxide pressure.

The distributions of pain scores were skewed, and therefore the values were expressed with median and interquartile range. In the recovery unit, the pain scores and HRs were significantly lower, and sedative levels deeper, for the GC group than for the G group at all time points (evaluated every 15 minutes for an hour) (Table 3). In the following hours, the pain scores for both groups escalated with time, but significantly lower for the GC than for the G group, until 12 hours later when the significance level became non-significant. The pain scores for the two groups became equivalent at the 24th hour post surgery (Tables 3 & 4). HRs were significantly lower for the GC than for the G group, for 12 hours, and the differences wore off afterwards (Table 4). Postoperative painful erections were significantly less frequent in the GC than the G group (22% vs. 64%), so was the use of midazolam (Table 4).

Table 3. Postoperative comparisons on pain, sedation, and hemodynamic measurements of the two groups in the post-anesthesia recovery unit.

Measurements	Groups	Time in recovery unit (min)			
		15	30	45	60
Pain scores [M(Q)]	GC	1±1*	2±2*	2±1*	3±2*
	G	3±1	5±1	5±1	6±2
Sedation scores [M(Q)]	GC	3±0	3±1*	2±1*	2±0*
	G	3±1	2±1	1±0	1±0
Heart rate [pulse/min, ± SD]	GC	105±11*	106±7*	107±9*	110±8*
	G	112±12	115±8	117±9	120±10

Note: GC: General anesthesia with caudal epidural block; G: standard general anesthesia; M(Q): median (inter-quartile range); SD: standard deviation.

* Comparisons with Group G were statistically significant with $P < 0.05$.

Table 4. Comparisons of postoperative erections and pain management of the two groups in the first 24 hours.

Measurements	Group	Post-operation time (hours)				
		2	4	8	12	24
Pain scores [M(Q)]	GC	3 (2) *	3 (1) *	4 (2) *	4 (2) *	5 (1)
	G	5 (2)	6 (2)	6 (2)	5 (2)	5 (2)
Heart rate [pulse/min, $\pm$ SD]	GC	100 $\pm$ 10*	101 $\pm$ 8*	102 $\pm$ 7*	98 $\pm$ 10*	97 $\pm$ 12
	G	109 $\pm$ 12	112 $\pm$ 8	110 $\pm$ 9	108 $\pm$ 11	100 $\pm$ 13
Postoperative midazolam use [N (%)]	GC	8 (16) *				
	G	25 (50)				
Postoperative erections [N (%)]	GC	11 (22) *				
	G	32 (64)				

Note: GC: General anesthesia with caudal epidural block; G: standard general anesthesia; M(Q): median (inter-quartile range); SD: standard deviation.

*Comparisons with Group G were statistically significant with $P < 0.05$.

Discussion

The goal for hypospadias repair is to restore normal function and cosmetics. Information on the long-term result of the surgery is not usually available as few studies followed the patients into adulthood. Anecdotally, rates of complications (including unsatisfactory surgical outcome) when patients were followed into their teens were as high as 40% in China (personal communications). Despite unclear methodological issues, this is alarming and speaks to the needs for better patient care, aside from surgical techniques.

We included painful penile erections in describing the pain profile of patients in the early postoperative period, as it is a different component of pain in patients' experiences, and more importantly, likely to result in tearing of tissue around the wound and interfere with healing. Although current guidelines, from European and North American medical associations, suggest that the optimal age for hypospadias repair is somewhere between 6 and 18 months [3, 4], the majority of pediatric patients presented for surgical management in our practice is well beyond infancy. The reasons behind this are multifactorial, and, in part, may have to do with the social-economic status of the family, psychology of the guardians as well as the children, and a cultural view of genital surgery for boys, which is beyond the scope of our investigation. The increased age at surgery can, however, affect the patients' tolerance for pain and physiological stress response, thus presenting new challenges for effective postoperative pain control.

Caudal analgesics are commonly used in pediatric operations, including hypospadias, though

the practice of caudal epidural block in children varies greatly by regions, and even from one medical center to another [10, 11]. In China, caudal blocks for pediatric populations are often available in large hospitals where anesthesiologists are afforded the necessary training. General anesthesia, on the other hand, is the standard of care as pain management and available to all in almost any medical setting with an anesthesiologist. Postoperative pain in hypospadias operations, however, can be severe, especially when the sensory nervous system has developed. Systemic toxicity in children also continues to be a topic of concern. The consensus is that the traditional method of general anesthesia can be improved with reduced use of opioids or opioid-free therapy [6, 12, 13].

In the current study, we observed a cohort of hypospadias patients, one group administered with opioid-free caudal analgesics and the other with standard general anesthesia, and compared the intraoperative vital indices and early postoperative pain and sedation levels of the patients. This was made possible with the available technique of ultrasound guidance, as the conventional caudal methods, including the landmark technique, presented uncertainties with variable sacral anatomy and was therefore deemed unfeasible in our practice (with overworked anesthesiologists).

The perioperative vital indices of the two groups were comparable, suggesting that the caudal lidocaine-ropivacaine mixture can offer sufficient intraoperative anesthesia. Ropivacaine is a long-acting amide local anesthetic agent, which produces less motor blockade than bupivacaine [14]. Reportedly, it is associated with reduced central nervous system toxicity and cardiotoxicity [15].

Limitations

We acknowledge that, though of a prospective design, this was an observational study, as the application of ultrasound-guided caudal anesthesia was only available on a limited basis depending on surgical schedule due to the limited number of anesthesiologists who could perform this method. For the rest of the study, all the procedures were performed with routine care, and we applied no preferential selection of patients to receive either method. As a result, the two groups of patients were comparable by demographic characteristics.

All the operations were performed by the same experienced pediatric surgeon, which minimized operator variation but at the same time limited the representativeness of our sample. However, we successfully recruited the targeted number of patients to sufficiently demonstrate any potential differences in the two methods of pain management. Though short of randomization, the resulted group assignment was found to indicate no selection bias.

Our assessment of postoperative pain scores was based on evaluation by a clinician designated for the study, facilitated with a simple measurement scale which is easy to administer but depends on the judgement of the evaluator. However, as stated earlier, all the procedures in the study were routine care practices and we made no change to any existing protocol except for the administration of anesthetics for the GC group. We also included a number of other measurements in order to demonstrate a complete profile of patients' pain experience, including HRs, postoperative analgesic requirement, and painful erections.

Conclusions

The use of ultrasound-guided caudal analgesia with lidocaine-ropivacaine combination was effective in early postoperative pain control for hypospadias patients (ASA class I & II). In particular, the occurrence of postoperative painful erections was significantly reduced in the first 24 hours post operation, which is critical for a satisfactory surgical outcome and patient care. Whether the concentration and/or dosing needs to be adjusted, or other auxiliary agents need to be co-administered to improve pain management, are topics for further investigations.

Abbreviations

GC – general anesthesia with caudal epidural block

G – standard general anesthesia

IV – intravenous

ECG – electrocardiogram

NBP – non-invasive blood pressure

SpO₂ – peripheral oxygen saturation

HR – heart rate

MBP – mean blood pressure

P_{ET}CO₂ – end-tidal carbon dioxide pressure

LAM – laryngeal airway mask

Declarations

Ethics Approval

The study was approved by the ethics committee of the Fujian Provincial Hospital. Written informed consent was provided by guardians of the patients prior to the enrollment.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analyzed in the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

Not applicable.

Authors' contributions

All authors participated in the design and implementation of the study. SH performed all the hypospadias surgery in the study. SD performed data analysis and was a major contributor in writing the manuscript. MC also contributed to the analysis and writing of the manuscript. All authors read and approved the final manuscript.

Acknowledgement

The authors thank LQ Editing Service for their assistance in language editing.

Conflict of interest

The authors declare that they have no conflict of interest.

References

- [1]. Springer, A., M. van den Heijkant and S. Baumann, Worldwide prevalence of hypospadias. J Pediatr Urol, 2016. 12(3): p. 152.e1-7.
- [2]. Brouwers, M.M., et al., Risk factors for hypospadias. Eur J Pediatr, 2007. 166(7): p. 671-8.

- [3]. Riedmiller, H., et al., EAU guidelines on paediatric urology. *Eur Urol*, 2001. 40(5): p. 589-99.
- [4]. Keays, M.A. and S. Dave, Current hypospadias management: Diagnosis, surgical management, and long-term patient-centred outcomes. *Can Urol Assoc J*, 2017. 11(1-2Suppl1): p. S48-S53.
- [5]. Johr, M. and T.M. Berger, Caudal blocks. *Paediatr Anaesth*, 2012. 22(1): p. 44-50.
- [6]. Wiegele, M., P. Marhofer and P.A. Lonnqvist, Caudal epidural blocks in paediatric patients: a review and practical considerations. *Br J Anaesth*, 2019. 122(4): p. 509-517.
- [7]. Ahiskalioglu, A., et al., Ultrasound-guided versus conventional injection for caudal block in children: A prospective randomized clinical study. *J Clin Anesth*, 2018. 44: p. 91-96.
- [8]. Merkel, S.I., et al., The FLACC: a behavioral scale for scoring postoperative pain in young children. *Pediatr Nurs*, 1997. 23(3): p. 293-7.
- [9]. Ramsay, M.A., et al., Controlled sedation with alphaxalone-alphadolone. *Br Med J*, 1974. 2(5920): p. 656-9.
- [10]. Suresh, S., et al., The European Society of Regional Anaesthesia and Pain Therapy/American Society of Regional Anesthesia and Pain Medicine Recommendations on Local Anesthetics and Adjuvants Dosage in Pediatric Regional Anesthesia. *Reg Anesth Pain Med*, 2018. 43(2): p. 211-216.
- [11]. Lonnqvist, P.A., et al., The European society of regional anesthesia and pain therapy and the American society of regional anesthesia and pain medicine joint committee practice advisory on controversial topics in pediatric regional anesthesia I and II: what do they tell us? *Curr Opin Anaesthesiol*, 2017. 30(5): p. 613-620.
- [12]. Johr, M., Regional anaesthesia in neonates, infants and children: an educational review. *Eur J Anaesthesiol*, 2015. 32(5): p. 289-97.
- [13]. Zhu, C., et al., Caudal and intravenous dexamethasone as an adjuvant to pediatric caudal block: A systematic review and meta-analysis. *Paediatr Anaesth*, 2018. 28(3): p. 195-203.
- [14]. Sharma, J., et al., A Comparative Study of 0.25% Levobupivacaine, 0.25% Ropivacaine, and 0.25% Bupivacaine in Paediatric Single Shot Caudal Block. *Anesthesiol Res Pract*, 2018. 2018: p. 1486261.
- [15]. Shah, R.D. and S. Suresh, Applications of regional anaesthesia in paediatrics. *Br J Anaesth*, 2013. 111 Suppl 1: p. i114-24.

Figures

Figure 1

Transverse ultrasound view of the SC: scaral cornua; SCL: sacrococcygeal ligament; and SH: sacral hiatus.

Figure 2a: Longitudinal ultrasound view of the sacral hiatus, inset showing position of the block needle.

Figure 2b: Longitudinal ultrasound view of the sacral hiatus, showing the analgesic liquid spreading into the epidural space.

Figure 2

2a: Longitudinal ultrasound view of the sacral hiatus, inset showing position of the block needle. 2b: Longitudinal ultrasound view of the sacral hiatus, showing the analgesic liquid spreading into the epidural space.