Original Article

Prospective Randomized Controlled Comparison of Caudal Bupivacaine and Ropivacaine in Pediatric Patients

Chipde SS, Banjare M, Arora KK, Saraswat M

Department of Anesthesiology, M.G.M. Medical College and M.Y. Hospital, Indore, Madhya Pradesh, India

Address for correspondence:
Dr. Surabhi Sudhir Chipde,
Department of Anesthesiology,
M.G.M. Medical College and
M.Y. Hospital, Indore,
Madhya Pradesh, India.
E-mail: drsurabhichipde@gmail.com

Abstract

Background: Bupivacaine and ropivacaine are commonly used agents for caudal anesthesia in pediatric patients. Several studies have shown different motor and cardiovascular effects of two drugs. **Aim:** The primary objective of this study was to evaluate the efficacy of both drugs and secondary objective was to compare motor blockade and hemodynamic effects caused by them. **Subjects and Methods:** This was a prospective randomized controlled study including 50 consecutive patients in the age group of 1-10 years, who underwent urogenital surgeries under general anesthesia. Caudal block was given with either bupivacaine (0.25%) 1 ml/kg (Group I) or ropivacaine (0.25%) 1 ml/kg (Group II). Heart rate (HR) and systolic blood pressure (SBP) were recorded as a baseline, before the anesthesia induction and then at 30, 60 and 90 min after incision. Pain scores were assessed post-operatively by a single observer at 30 min and then at 2, 4, 8 and 12 h with a 5-point observer pain score (OPS). Patients and observer were blinded to the medication given. The duration of absolute analgesia was defined as the time from caudal injection until the pain score was >2. Motor block was assessed by modified Bromage scale. Statistical analysis was performed with Chi-square test, Student's *t*-test and log-rank test. $P < 0.05$ were considered as significant. **Results:** HR and SBP measured at a specific time intervals showed no significant difference. All the patients had adequate intraoperative analgesia. Mean OPS were comparable between two groups. Duration of absolute analgesia was 276.8 (11) min in Group I and 284.8 (12) min for Group II. The only significant difference was the motor-block score at 2, 3 and 4 h after surgery, although the score was same 1 h post-operatively. **Conclusion:** The efficacy of both ropivacaine and bupivacaine is almost same in terms of onset and duration of analgesia. Therefore, the motor blockade caused by ropivacaine is less; there is no significant difference in cardiovascular events.

Keywords: Analgesia, Bupivacaine, Caudal block, Motor block, Ropivacaine

Introduction

Caudal block is a useful adjunct to the general anesthesia for lower abdominal surgery in children, as it reduces peri-operative narcotic requirement.[1] Bupivacaine has proven its efficacy in producing adequate analgesia, when given caudally.[2] Unfortunately, motor blockade resulting from it may be a cause of distress in the post-operative period and may lead to delayed hospital discharge.[3-5] Ropivacaine is another amide local anesthetic, which has been reported to cause less motor block and less cardiovascular events than bupivacaine.[2,6] However, some of the studies have shown similar motor and cardiovascular effects of two drugs.[1,7,8] It is also unclear, which drug causes more duration of analgesia.[3,9,10] This study has been carried out to evaluate the efficacy of caudal block with bupivacaine and ropivacaine in pediatric patients in a prospective randomized controlled trial (RCT) and to compare the motor blockade and hemodynamic effects caused by them.

Access this article online

Quick Response Code:

Website: www.amhsr.org

DOI: 10.4103/2141-9248.138025

Subjects and Methods

This is a prospective randomized study including 50 consecutive patients in the age group of 1-10 years, who

underwent elective unilateral inguinal herniotomy or urogenital surgeries from January 2011 to July 2011 in M.G.M. Medical College, Indore. The study was approved by the local ethics committee and written informed parental consent was obtained for each subject. All patients were American Society of Anesthesiologists (ASA) grade I. Patients were randomly allocated to one of the two groups by using a random number table, to receive caudal block with either bupivacaine (Group I) or ropivacaine (Group II). Patients and observer were blinded to the medication given. Patients having coagulopathy, spinal deformities, infection at the injection site or allergy to amide local anaestheticsanesthetics were excluded from the study.

Premedication was done with intravenous (i.v.) glycopyrolate glycopyrrolate (0.01 mg/kg) and all procedures were performed under general anaesthesiaanesthesia. Induction was done with i.v. propofol 3 mg/kg and i.v. atracurium 0.5 mg/kg, followed by oro-tracheal intubation. AnaesthesiaAnesthesia was maintained with 70% of nitrous oxide in oxygen, isoflurane 0.2-0.4% and atracurium. Patients received caudal block with either bupivacaine (0.25%) 1 ml/kg or ropivacaine (0.25%) 1 ml/kg in left lateral position using a 23-gauge short-bevel needle (Dispovan, Ballabgarh, India) under aseptic condition. Neither sedatives nor opioids were administered intra-operatively.

Heart rate (HR) and systolic blood pressure (SBP) were recorded as a baseline, before the anesthesia induction and then at 30, 60 and 90 min after incision. During surgery, adequate analgesia was defined by hemodynamic stability, as indicated by the absence of an increase in SBP or HR by >15% of pre-incision baseline values, for which the child received fentanyl (2 μg/kg). Then patient was observed in every 5 min and fentanyl (0.5 μg/kg) was repeated as and when required. Isoflurane concentration was maintained between 0.2% and 0.4%. Fluid therapy was standardized during and after surgery. During surgery, children received lactated Ringer's solution 6 ml/kg/h, whereas 5% dextrose in 0.45% NaCl was infused at 4 ml/kg/h in the post-operative period. An intraoperative decrease of SBP or HR by >30% was defined as hypotension or bradycardia, respectively and was treated by fluid bolus, ephedrine, or atropine, as necessary.

Each patient was observed for 4 h in the recovery room before being transferred to the ward. HR and oxygen saturation (SpO_2) and SBP were monitored every 30 min. Pain scores were assessed post-operatively by a single person at 30 min and then at 2, 4, 8 and 12 h with a 5-point observer pain score (OPS): 1 = asleep or awake and laughing; 2 = awake, but no pain; 3 = mild pain (irritable/restless); 4 = moderate pain (crying, grimacing restless but consolable); and 5 = severe pain (crying/screaming/inconsolable). The duration of absolute analgesia was defined as the time from caudal injection until the pain score was > 2. Rescue analgesic was given for a pain score/4 in the form of paracetamol suppository (20 mg/kg), if necessary.

Motor block was assessed on awakening by using a modified Bromage scale that consisted of 4 points: 0 = full motor strength (flexion of knees and feet), 1 = flexion of knees, 2 = little movement of feet only, 3 = no movement of knees or feet. However, younger children who could not move their legs on command were stimulated by tapping on the legs and feet. The incidence of adverse effects such as nausea, vomiting and pruritus was evaluated by a yes/no survey. All evaluations were performed along with assessments of pain.

The sample size was determined with a target to have a power of 0.80 and *P* value of 0.05. All the statistical analysis was performed by SPSS 17 software (Chicago Inc. Illinois, USA). Data were expressed as mean (standard deviation). Analysis was performed with Chi-square test, Student's *t* test and log-rank test. *P* values of less than 0.05 were considered as significant.

Results

The two groups were comparable for age (mean 5.7 [1.5] in Group I vs. 5.4 [1.5] years in Group II), weight (mean 15.4 [2.6] in Group I vs. 15.2 [2.5] kg in Group II) and sex ratio (M: F = 24:1 in both groups), as well as in surgical procedures [Table 1]. HR and SBPs measured at a specific time intervals showed no significant difference [Figures 1 and 2]. All patients had adequate intraoperative analgesia. Fentanyl was required in 4 patients of Group I and 5 patients of Group II (*P* = 0.12). There was no episode of severe hypotension or bradycardia in any patient. Mean OPS at different time intervals post-operatively, was comparable for the two groups without a significant difference [Table 2]. Duration of absolute analgesia (OPS < 2) was 276.8 (11) min in Group I and 284.8 (12) min for Group II (*P* = 0.23). First rescue

Table 1: Surgical procedures performed in each group

Surgery	Group I (bupivacaine) (%)	Group II (ropivacaine) (%)
Inguinal hernia	10 (40)	10 (40)
Circumcision	6 (24)	5 (20)
Urethroplasty	5 (20)	6 (24)
Cystolithotomy	2 (8)	2 (8)
Orchidopexy	2 (8)	2 (8)

Table 2: Post-operative OPS at different time intervals

Post-operative duration (h)	Mean OPS score		*P* value
	Group I (bupivacaine)	Group II (ropivacaine)	
0.5	1.35	1.25	0.06
2	1.56	1.45	0.07
4	2.24	1.97	0.07
8	3.12	2.99	0.08
12	4.12	4.02	0.09
24	5	4.84	0.08

OPS: Observer pain score

analgesic (at OPS > 4) was given after 7.6 (1.2) h in patients with Group I and after 8.0 (0.9) h in Group II ($P = 0.16$). The only significantly different finding between two groups was motor block score on the Bromage scale after 2, 3 and 4 h after surgery, although the score was same 1 h post-operatively in both groups (P = 0.23, 0.04, 0.02, 0.01 at 1, 2, 3, 4 h post-operatively) [Figure 3]. There were no adverse effect such as nausea, vomiting and pruritus between the two groups.

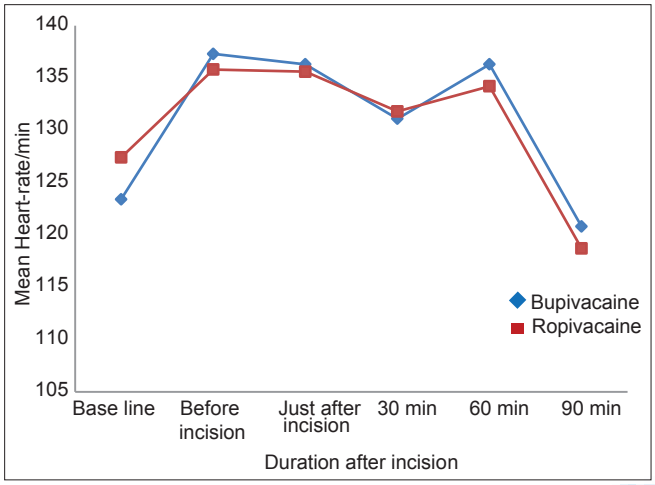

Figure 1: Mean heart rate at different time intervals

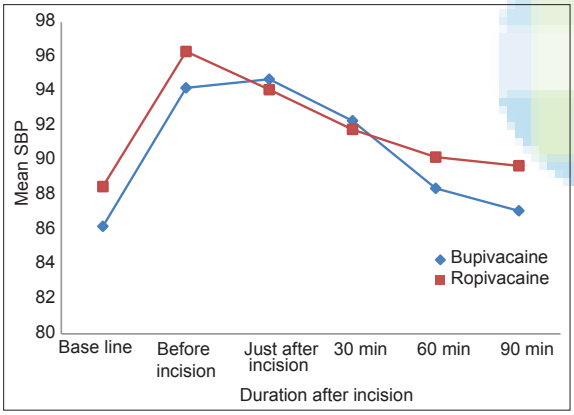

Figure 2: Mean systolic blood pressure at different time intervals

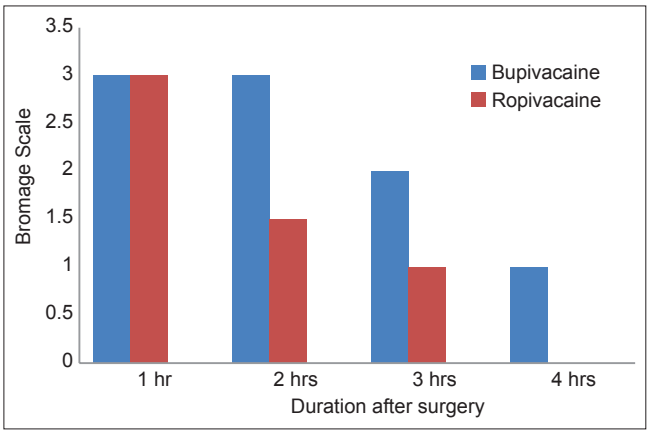

Figure 3: Motor blockade (mean bromage score)

Discussion

Post-operative pain relief in pediatric patients needs special attention due to their inability to express the severity and type of pain. Therefore, a pragmatic practical approach of pediatric pain management has been used in recent years with the introduction of safe and effective techniques.[1] Ropivacaine is increasingly used in the place of bupivacaine for the single shot caudal analgesia in children because of so called lower side-effects.[1-3]

Several authors have described that efficacy of analgesia produced by ropivacaine is same as bupivacaine.[4,5,9] In this study, we have demonstrated that efficacy of analgesia by caudally administered bupivacaine and ropivacaine were equal in both groups. These results are comparable with other studies.[3,5,9,10] In our study, the mean duration of analgesia was 276.8 min for bupivacaine and 284.8 ± 24 min in the ropivacaine group. Ray *et al*. found similar duration of analgesia in both groups (398 ± 23 in bupivacaine vs. 405 ± 18 in ropivacaine group).[11] On the contrary Locatelli *et al*. found that analgesic block lasted significantly longer in patients receiving bupivacaine (P = 0.03).[2] However, other authors didn't support this view and found that the average duration of analgesia is same for both drugs.[5,9]

Some older studies showed that ropivacaine causes less cardiovascular events than bupivacaine.[12] In our study, hemodynamic parameters, when measured at a specific time intervals, showed no significant difference between two groups. There was no significant cardiac event. In the study of Koinig *et al*., hemodynamic effects of ropivacaine were compared with bupivacaine.[13] Both groups showed a significant decrease in mean arterial blood pressure and HR from baseline values, but differences between groups were not observed. In the study of Da Conceicao *et al*., the HR and arterial pressure were measured every 5 min after administration of local anesthetic.[7] They found no difference between the two groups. These results are comparable with our findings.

Various studies have stated the prolonged motor blockade associated with bupivacaine in comparison with ropivacaine.[2,3,5,7] Locatelli *et al*. performed a randomized, double-blind, phase III, controlled trial comparing levobupivacaine 0.25%, ropivacaine 0.25% and bupivacaine 0.25% by the caudal route in children.[2] Bupivacaine produced a significant incidence of residual motor block compared with levobupivacaine or ropivacaine at wake-up ($P < 0.01$). Similarly, Da Conceicao *et al*. studied 60 children, randomly allocated in a double-blind manner, to receive one of two local anesthetics: 0.375% of ropivacaine 1.0 ml/kg or 0.375% bupivacaine 1.0 ml/kg.[7] The extent of motor block in the recovery room was scored as 1-3. The ropivacaine group showed a shorter duration of motor block than the bupivacaine group ($P < 0.05$).

In the evidence based clinical update published by Dobereiner *et al*., statistical analysis was performed between seventeen

RCTs.[3] It was found that, the incidence of motor blockade was higher with bupivacaine, so they advised that this drug should be administered if motor block is desired and ropivacaine is preferred if motor block is to be minimized. On the contrary, Khalil *et al*. found that ropivacaine (0.25%, 1 ml/kg) provided adequate post-operative analgesia with no difference from bupivacaine (0.25%, 1 ml/kg) in motor and sensory effects.[9] Ivani *et al*. performed a double-blind multicenter study involving 245 children and found no motor block in either group.[10]

Similarly, Tan *et al*. designed a study to compare the quality of caudal analgesia and incidence of motor blockade produced by these two drugs in pediatric patients scheduled for elective circumcision.[8] Post-operative pain and motor blockade were assessed by visual analogue and modified Bromage scales respectively. There were no significant differences in pain intensity and degree of motor blockade.

Some authors showed that ropivacaine undergoes slower systemic absorption from the caudal epidural space in children than does bupivacaine.[14,15] This can attribute to the lower systemic toxicity of ropivacaine.

There are some limitations of our study. First, it had a small sample size. Though the study is related to pain relief, we couldn't evaluate other problems of caudal analgesia like retention of urine, which is of concern, because of a large portion of patient mainly who undergone urethroplasty and cystolithotomy were catheterized post-operatively. ASA-1 might be another limitation of the study, because the cardiovascular effects are more pronounced or easier to see with children having heart disease and a higher ASA grade.

Nevertheless, this study confirms that ropivacaine is an effective local anesthetic when given by caudal route in pediatric patients. It produces sensory block similar to bupivacaine but motor block of shorter duration. This finding is useful for children for early post-operative recovery.

Conclusion

This study showed similar efficacy of both ropivacaine and bupivacaine in terms of onset and duration of analgesia. Although the motor blockade caused by ropivacaine is less than bupivacaine, there is no significant difference in cardiovascular events between two groups.

References

1. Marhofer P, Koinig H, Kapral S. The choice of drugs for caudal anesthesia in children. An overview. Anaesthesist 2003;52:55-67.
2. Locatelli B, Ingelmo P, Sonzogni V, Zanella A, Gatti V, Spotti A, *et al*. Randomized, double-blind, phase III, controlled trial comparing levobupivacaine 0.25%, ropivacaine 0.25% and bupivacaine 0.25% by the caudal route in children. Br J Anaesth 2005;94:366-71.
3. Dobereiner EF, Cox RG, Ewen A, Lardner DR. Evidence-based clinical update: Which local anesthetic drug for pediatric caudal block provides optimal efficacy with the fewest side effects? Can J Anaesth 2010;57:1102-10.
4. Breschan C, Jost R, Krumpholz R, Schaumberger F, Stettner H, Marhofer P, *et al*. A prospective study comparing the analgesic efficacy of levobupivacaine, ropivacaine and bupivacaine in pediatric patients undergoing caudal blockade. Paediatr Anaesth 2005;15:301-6.
5. Ivani G, DeNegri P, Conio A, Grossetti R, Vitale P, Vercellino C, *et al*. Comparison of racemic bupivacaine, ropivacaine, and levo-bupivacaine for pediatric caudal anesthesia: Effects on postoperative analgesia and motor block. Reg Anesth Pain Med 2002;27:157-61.
6. Luz G, Innerhofer P, Häussler B, Oswald E, Salner E, Sparr H. Comparison of ropivacaine 0.1% and 0.2% with bupivacaine 0.2% for single-shot caudal anesthesia in children. Paediatr Anaesth 2000;10:499-504.
7. Da Conceicao MJ, Coelho L. Caudal anesthesia with 0.375% ropivacaine or 0.375% bupivacaine in paediatric patients. Br J Anaesth 1998;80:507-8.
8. Tan JS, Choo SM, Chiu JW. Caudal ropivacaine versus bupivacaine for paediatric day-case circumcision procedures. Internet J Anesthesiol 2000;4:4.
9. Khalil S, Campos C, Farag AM, Vije H, Ritchey M, Chuang A. Caudal block in children: Ropivacaine compared with bupivacaine. Anesthesiology 1999;91:1279-84.
10. Ivani G, Lampugnani E, Torre M, Calevo Maria G, DeNegri P, Borrometi F, *et al*. Comparison of ropivacaine with bupivacaine for paediatric caudal block. Br J Anaesth 1998;81:247-8.
11. Ray M, Mondal SK, Biswas A. Caudal analgesia in paediatric patients: Comparison between bupivacaine and ropivacaine. Indian J Anaesth 2003;47:275-8.
12. Reiz S, Häggmark S, Johansson G, Nath S. Cardiotoxicity of ropivacaine – A new amide local anaesthetic agent. Acta Anaesthesiol Scand 1989;33:93-8.
13. Koinig H, Krenn CG, Glaser C, Marhofer P, Wildling E, Brunner M, *et al*. The dose-response of caudal ropivacaine in children. Anesthesiology 1999;90:1339-44.
14. Ala-Kokko TI, Partanen A, Karinen J, Kiviluoma K, Alahuhta S. Pharmacokinetics of 0.2% ropivacaine and 0.2% bupivacaine following caudal blocks in children. Acta Anaesthesiol Scand 2000;44:1099-102.
15. Karmakar MK, Aun CS, Wong EL, Wong AS, Chan SK, Yeung CK. Ropivacaine undergoes slower systemic absorption from the caudal epidural space in children than bupivacaine. Anesth Analg 2002;94:259-65.

How to cite this article: Chipde SS, Banjare M, Arora KK, Saraswat M. Prospective randomized controlled comparison of caudal bupivacaine and ropivacaine in pediatric patients. Ann Med Health Sci Res 2014;4:115-8.

Source of Support: Nil. **Conflict of Interest:** None declared.