RESEARCH PAPER | Medical Science | Volume : 5 | Issue : 10 | October 2015 | ISSN - 2249-555X

Comparison of Ropivacaine with Bupivacaine for Caudal Block in Paediatric Patients Undergoing Infra Umbilical Surgery

KEYWORDS: Pediatric caudal; Ropivacaine; Bupivacaine

Anil Thakur
MD, Associate Professor Department Of Anesthesiology &Critical Care ESI, PGIMSR, Basaidarapur, New Delhi. Corresponding author

Kiranpreet Kaur
DNB, Assistant Professor Department of Anesthesiology and Critical Care, Pt. BD Sharma, PGIMS, Rohtak..

Rajesh Chetiwal
Associate Professor, Department. Of Medicine, ESI, PGIMSR, Basaidarapur, New Delhi.

Neeraj Gupta
MD, Ex Resident , Department Of Anesthesiology &Critical Care Pt. BD Sharma, PGIMS, Rohtak..

ABSTRACT

Background: *Regional anaesthesia produces excellent postoperative analgesia in infants and children. Bupivacaine as local anaesthetic has proven its efficacy in producing long lasting analgesia. Ropivacaine, an enantiomer of propivacaine, and is a long acting amide local anaesthetic agent, producing nerve block via reversible inhibition of sodium influx in nerve fibres. The aim of the present study was to evaluate and compare the perioperative analgesic effect of single shot caudal epidural 0.75 ml kg-1 of 0.25% bupivacaine versus 0.75mlkg-1 of 0.2% ropivacaine in paediatric patients undergoing infraumbilical surgery.*

Material and methods: *Sixty children in the age group of 2 to 8 years enrolled in the study were randomly divided into two groups of 30 each. Group B received 0.75 mlkg-1 of 0.25% bupivacaine and group R received 0.75 mlkg-1 of 0.2% ropivacaine. Patient's heart rate, respiratory rate, peripheral arterial oxygen saturation, objective pain scale (OPS), motor power score (MPS) and time for rescue analgesia were recorded. The data recorded was statistically analyzed using Student's unpaired t test. P value <0.05 was considered significant.*

Results: *Variations in OPS in both groups at different time intervals were comparable (p>0.05). Motor power scale was recorded in all the patients in both the Groups. In 90 minutes about 27 patients in group B and 29 patients in group R had MPS of 10. Patients in Group R required rescue analgesia earlier, at around 6 hours postoperatively as compared to 8 hours postoperatively in Group B*

Conclusion: *We conclude that both the drugs are similar in their properties and safe with minimal side effects, for perioperative pain relief in the form of caudal epidural block and 0.25% bupivacaine provides prolonged duration of analgesia when compared with 0.2% ropivacaine in the similar doses.*

Introduction:

Acute pain accompanies almost all surgical procedures. For patients undergoing surgery, postoperative pain is an anticipated and often feared consequence[1] Post-operative pain is easier to treat because the cause is known.

Poor pain control may result in increased morbidity and mortality. Adverse sequelae of uncontrolled postoperative pain include delayed postoperative recovery of normal physiological functions, restricted mobility, increased catecholamine release, decreased sputum clearance, atelectasis, hypoventilation and perfusion inequality.[4] Unfortunately the children have often been deprived of adequate perioperative analgesia due to fear of over dosage, delayed ambulation and discharge from the hospital.[5]

Regional anaesthesia techniques are preferred for relief of post operative pain.[7] It produces excellent post operative analgesia and attenuation of the stress response in infants and children.[8] It provides a longer duration of analgesia along with minimal side effects. Caudal epidural block remains the most versatile and popular block performed in children. [9]

Bupivacaine is the most commonly administered local anaesthetic for routine intraoperative analgesia in children. Bupivacaine as local anaesthetic has proven its efficacy in producing long lasting analgesia when administered in caudal epidural space.[10] Ropivacaine, is the pure S (-) enantiomer of propivacaine, and is a long acting amide local anaesthetic agent, producing nerve block via reversible inhibition of sodium influx in nerve fibres. A preliminary evaluation of ropivacaine for caudal analgesia in children suggested a quicker onset and a longer duration of action.[11]

We hypothesise that caudal block is most effective pain modality in pediatric patients undergoing infraumblical surgery and bupivacaine and ropivacaine are established drug used in caudal block so we evaluatedand compared the perioperative analgesic effect of single shot caudal epidural 0.75mlkg^{-1} of 0.25% bupivacaine versus 0.75mlkg^{-1} of 0.2% ropivacaine in paediatric patients undergoing infraumbilical surgery.

Methods

This prospective double blindrandomized study was approved by institutional ethical committee and institutional board. Sixty children of either sex in the age group of 2 to 8 years belonging to American Society of Anesthesiologists (ASA) physical status I or II, scheduled for lower abdominal surgery were included in the present study. Informed consent from parents of all the participants was obtained. The patients with known history of hypersensi-

Volume : 5 | Issue : 10 | October 2015 | ISSN - 2249-555X

tivity to local anaesthetics, coagulopathies, spinal cord deformity, mental retardation and refusal for block were excluded from the study..

All patients were examined preoperatively and were subjected to complete general physical as well as systemic examination. All routine investigations were carried out and informed written consent was obtained from the parents. Patients were kept fasting for six hours for solids and two hours for clear fluids before the procedure. No premedication was administered. All the children were randomly allocated to one of the two groups (n = 30 each) depending upon the drugs administered via caudal epidural route. Group B received 0.75 $mlkg^{-1}$ of 0.25% bupivacaine and group R received 0.75 $mlkg^{-1}$ of 0.2% ropivacaine.

Allocation to one of two combinations was done using sealed coded envelopes. The study drug was prepared by a fellow anaesthesiologist who was not involved in the study. Hence neither anaesthetist who was conducting study, nor the patient is aware of the drug administered, the study was conducted in double blind manner. Caudal block was administered by same consultant anaesthesiologist in all the patients. In the operation theatre patient was monitored continuously for pulse rate, ECG, non invasive blood pressure (NIBP) and peripheral arterial oxygen saturation (SpO2).

In all the patients after preoxygenation, general anaesthesia was induced with sevoflurane in O_2 by face mask. Tracheal intubation was facilitated by injection vecuronium bromide 0.1 $mgkg^{-1}$ anaesthesia was maintained with 33% O2 in 66% N_2O sevoflurane and maintenance dose of vecuronium bromide of 0.1 $mgkg^{-1}$.After induction of general anaesthesia child was turned in lateral position for administration of caudal block. Under all aseptic and universal precautions caudal epidural blocks was administered using 23 gauge hypodermic needle of length 25 mm. The local anaesthetic solution were prepared as per coded slips and kept ready prior to performing the caudal block. After negative aspiration, the study drug was administered.

Ten minutes were allowed to elapse after administration of the caudal block before surgical incision. Heart rate, blood pressure and peripheral arterial oxygen saturation (SpO2), was monitored continuously, just before incision T_{B10} (baseline), immediately after incision and thereafter recorded at every 5 minutes interval. Adequate intra-operative analgesia was defined by the haemodynamic stability, as indicated by absence of an increase in heart rate and/or systolic blood pressure greater than 20% as compared with base line values (T_{B10}). An increase in heart rate and/or systolic blood pressure (SBP) more than 20% at any stage was indicative of inadequate block and rescue analgesia was given in form of intra venous fentanyl 1μgkg^{-1} upto a maximum of 2μgkg^{-1}. At the completion of surgery, residual neuro-muscular block was reversed with 0.05 $mgkg^{-1}$neostigmine and 0.01 $mgkg^{-1}$ glycopyrrolate and patient was extubated. Patient was then be transferred to post-operative room and observed for 24 hours.

Postoperatively Patients heart rate, respiratory rate, peripheral arterial oxygen saturation, objective pain scale (OPS),[12] motor power score (MPS) were recorded at 0, 15, 30, 60, 90, 120 min and thereafter hourly or until OPS ≥6. This time was recorded as T_{Res} and rescue analgesia was given as per surgical unit protocol. Thereafter continuous haemodynamic monitoring of patients vital parameters were done for 24 hours and any deviation ≥ ± 20% was recorded. Objective pain assessment was done by using Hannallah Objective Pain Scale (OPS)[12] (Table - 1). Child was not disturbed if sleeping comfortably and was assumed to be pain free.

Residual motor block in the lower extremity was assessed using motor power scale immediately after arrival in the recovery room. Thereafter at regular interval of time, till the MPS reached the score of 10 (Table 2). Patient sedation was assessed and recorded hourly for 24 hours by using an objective sedation score of Mackenzie and Grant (Table 3).[13] Side effects, like respiratory depression, vomiting, and urinary retention -if any were recorded and treated accordingly.

The uncoding of drug solution was done at the end of study. The data recorded was statistically analyzed using unpaired student t test. p value >0.05 was considered non significant and p value<0.05 was considered significant.

Results

Data of all 60 patients enrolled in the study were included in the analysis. The mean age and weight of the children were comparable in both the groups (Table 4). Average duration of surgery in our study was 30 minutes. In group B 90% and in group R 97% were males and rest were females.

Hemodynamic parameters were recorded and transient non significant (p>0.05) rise in pulse rate was observed just after incision (T_{B10}) in both the groups. No significant change in pulse rate was observed postoperative period. SBP and DBP were compared in both the groups intraoperatively as well as postoperatively and when statistically compared p value was found to be non significant (>0.05). No evidence of desaturation was observed at any single moment in both the groups intraoperatively well as postoperatively.

Objective pain score (OPS) recorded at different time intervals in both groups is shown in FIG 1.Variations in OPS in both groups at different time intervals were comparable (p>0.05). The time of rescue analgesia in both groups is shown in table 5. It was significantly delayed in Group B than Group R. This was clinically as well as statistically significant (p< 0.05). Patients in Group R required rescue analgesia earlier, at around 6 hours postoperatively as compared to 8 hours postoperatively in Group B (Table 2).

Motor power scale was recorded in all the patients in both the Groups. By 60 minutes MPS reached 10 in 21 patients in group B and 25 patients in group R. In 90 minutes about 27 patients in group B and 29 in group R had MPS of 10 (Fig 2). The variations in Sedation score at different time intervals in both groups were comparable (p>0.05). No patient in any of the groups had sedation score more than four at any time interval (fig 3).

Complications like vomiting, pruritus, urinary retention, respiratory depression etc was observed throughout the study period in both the groups. Incidence of these complications are shown in table 6.

Discussion

Post operative pain assessment and relief have become an integral part of paediatric anaesthesia.[14] Caudal anaesthesia is a useful adjunct to general anaesthesia for lower abdominal surgery in children as it provides good post-operative analgesia and reduces perioperative narcotic re-

Volume : 5 | Issue : 10 | October 2015 | ISSN - 2249-555X

quirements.[15] Unfortunately, motor blockade resulting from caudal block may be a cause of distress to children in the postoperative period and could lead to delayed hospital discharge.[16] Bupivacaine has a well defined role in regional anaesthesia and analgesia for several years. However, ropivacaine allegedly offers a wider margin of safety, less motor blockade, less neuro/cardiotoxicity and similar duration of analgesia in comparison to bupivacaine.[17]

The objective of this study was to compare ropivacaine 0.2% or bupivacaine 0.25%, for the quality of caudal block, Hannallah objective pain score (OPS)[12], Motor power scale, sedation score[13] and complications.

Both the groups were comparable with respect to age, weight, ASA physical status and duration of surgery. All blocks were successful, and there was no complication or clinical evidence of local anaesthetic toxicity.

Ivani et al[11], Khalil et al[18] and Ray et al[19], and documented non significant rise in pulse rate and no change in systolic and diastolic blood pressure following surgical incision. Stability in RR and SpO_2 was observed similar to our study which can be because of effective pain relief in the postoperative period. Singh et al[20] showed that a high baseline RR declined gradually over three hours after receiving caudal bupivacaine.

Among the various methods for assessment of pain in children Hannallah objective pain scale (OPS)[12] is used to assess the severity of pain. The pain assessment score i.e. OPS was observed to be easily applicable, widely used, validated, practical and well understood by children and parents. We achieved good pain relief with low OPS in both the groups in immediate post operative period. However OPS remained low for a longer period of time on an average of 481.33$\pm$134.59 min in the caudal bupivacaine group as compared to 377.11 $\pm$ 116.89 min in the ropivacaine group.

Ivani et al[11] used similar concentrations but higher volume (1ml/kg) of both the drugs and reported mean time for first rescue analgesia after bupivacaine and ropivacaine as 233.2 min (3.8 hours) and 271.9 min (4.54 hours) respectively which was far less than what we reported. The mean time required for rescue analgesia was 481.33 min (8 hrs) in bupivacaine group and 377.11 min (6 hrs) in ropivacaine group in our study ($p<0.05$). Ivani et al also reported longer duration of analgesia with ropivacaine over bupivacaine which is in contrast to our study and no further analgesia was required in 40% patients in each group. Fifty percent of children in the Group B and 36.67% Group R required no additional pain medication during our 24-h study period. However differing results can be due to administration of slightly higher volume.

Khalil et al[18], used same drugs in concentration 0.25% (1ml/kg) and documented time for the first administration of pain medication as 680 min (11.33 hours) in both groups which is extremely longer duration as observed in our study. This can be because of higher volume of drugs used by the authors in their study.

A significant difference between the two drugs in the mean time of requirement of additional analgesia i.e. 253 min for bupivacaine and 520 min for ropivacaine was reported by Ivani et al[21]. Duration of analgesia that Ray et al[19] recorded with bupivacaine and ropivacaine was 398 min and 405 min respectively. Locatelli et al[22] recorded the mean time of first administration of analgesic medication as 2.45 hours for bupivacaine and 1.6 hours for ropivacaine, which is comparable to our study but duration of analgesia was significantly less in both the groups than our study. Thus we reached an inference that there is lot of variation regarding duration of analgesia of both the drugs.

Motor weakness is shorter with ropivacaine as compared to bupivacaine in our study. Most authors reported return of motor power with in 3 hours after single shot caudal in either group as observed by Khalil et al,[18] . While Ivani et al,[11] observed no motor block in either group on awakening. Motor block recovery was slower in bupivacaine group in our study. Ray et al[19] and Locatelli et al[22], also observed longer motor block with bupivacaine group as compared to ropivacaine group.

Sedation scores in our study were comparable in the both groups at all the time intervals of the study period.

Local anaesthetics are generally quite safe and effective, but they may produce systemic toxic reactions affecting heart and brain.[23] No incidence of toxic reaction and any other significant side effects pertaining to drug was observed in any of the group in our study. Shaikh et al[24], used similar concentration and volume of bupivacaine and reported incidence of vomiting with bupivacaine to be 7% versus 6.6% in our study and urinary retention to be 1.4%.

We conclude that 0.25% bupivacaine provides prolonged duration of analgesia when compared with 0.2% ropivacaine in the similar doses i.e. 0.75 $mlkg^{-1}$. Ropivcaine does not provide an additional benefit over bupivacaine except for slightly less motor block. This additive property of ropivacaine can be beneficial in day care surgeries. But in other surgeries, bupivacaine can be the better alternative due to prolonged duration of analgesia. However both the drugs are similar in regards to their properties and safe with minimal side effects, for perioperative pain relief in the form of caudal epidural block.

Table - 1 : Hannallah Objective Pain Scale (OPS)

No	Observation	Criteria	Points
1	Systolic blood pressure	+10% pre op	0
		>20% pre op	1
		>30% pre op	2
2	Crying	no crying	0
		Crying, respond to tender loving care	1
		crying not responding to TLC	2
3	Movement	None	0
		Restless	1
		Thrashing	2
4	Agitation	asleep/calm	0
		Mild	1
		Hysterical	2
5	Posture	no special posture	0

Volume : 5 | Issue : 10 | October 2015 | ISSN - 2249-555X

		flexing legs and thighs	1
		holding groin	2
6	Complains of pain	asleep / states no pain	0
		cannot localize	1
		can localise	2

Table – 2 : MOTOR POWER SCALE

Motor Power Scale			
Muscle Tone Muscle Power (Flexion)	Flaccid 0 Unable	Hypotonia 1 Partial	Normal 2 Normal
Ankle	0	1	2
Knee	0	1	2
Thigh	0	1	2
Ability to stand	0	1	2

Table - 3 : SEDATION SCORE

Clinical status	**Score**
Fully awake and oriented	1
Drowsy	2
Eyes closed but rousable to command	3
Eyes closed but rousable to mild physical stimulation (ear lobe tug)	4
Eye closed but unrousable to mild physical stimulation	5

Table 4 Demographic profile of the two group

		Age	**Weight**
Group- B	Mean	4.58	15.47
	± **s.d.**	±1.75	±4.14
Group- R	Mean	5	15.7
	± **s.d.**	±1.82	±3.22
	p-value	0.18	0.40
	Inference	NS	NS

Table 5
Time of rescue analgesia in both groups

	RESCUE ANALGESIA (MINUTES)	
	Descriptives	
Group-B	**-**	-
	mean	481.3333
	±s.d	±134.5955
Group-R	**-**	-
	Mean	377.1053
	±s.d	±116.8964
	p-value	0.01081
	Inference	S

Table 6
Complications

	Group B (n=30)	Group R (n=30)	Statistical significance
Vomiting	2		NS
Pruitis	0		
Urinary retention	0	1	NS
Respiratory depression	0		

Fig 1 Objective pain score at different time intervals in two groups

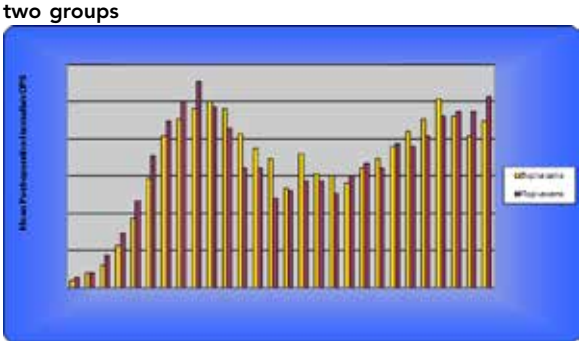


Fig 2 Motor power scale (MPS) at different time intervals in two groups.

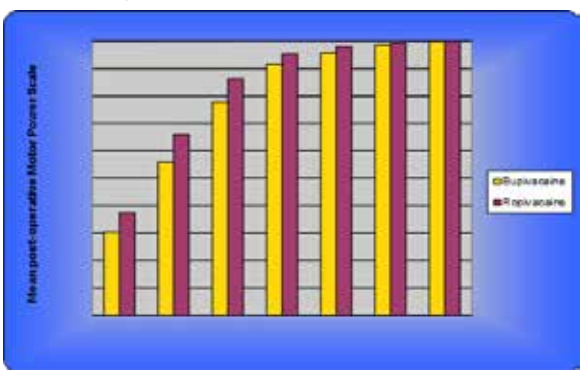
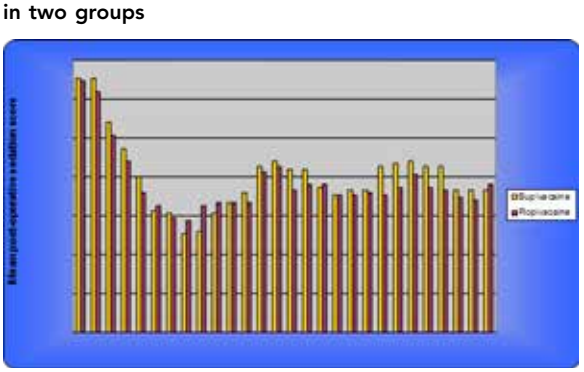


Fig 3 Sedation score recorded at different time intervals in two groups



Volume : 5 | Issue : 10 | October 2015 | ISSN - 2249-555X

REFERENCE

1. Morgan GE, Mikhail MS, Murray MJ, editors. Pain management. In: Clinical Anesthesiology. New York: Lange medical books. 2002:p.309-58. 2. Anand KJ, Mickey PR. Pain and its effects in the neonate and fetus. N Engl J Med 1987; 317(21):1321-9. 3. Wolf A. Pain, nocicecption and the developing infant. Paediatr Anaesth 1999; 9:7-17. 4. Stoelting RK, Miller RD. Acute pain management . In: Stoelting RK , Miller RD, editors. Basics of anaesthesia. 4th ed. Philadelphia: Churchill Livingstone; 2003. p. 424-6. 5. Mather L, Mackie J. The incidence of post-operative pain in children. Pain 1983; 15: 271-82. 6. Anderson BJ. What we do not know about paracetamol in children . Paed Anaesth 1998.;8:451-60. 7. Litman RS. Paediatric anaesthesia. Paediatric anaesthesia- the requisites in anaesthesiology. 1st ed. Philadelphia(USA): Elsevier Mosby; 2004 : 160-5. 8. Boserberg A. Paediatric regional anaesthesia update. Paediatr Anaesth 2004; 14: 398-402. 9. Saunders JC. Paediatric regional anaesthesia : a survey of practice in the united kingdom. Br J Anaesth 2002; 89(5):707-10. 10. Tobias JD, Schrock C. Epidural management in paediatric anaesthesia. Anestesia paediatrica e neonatale 2008 Feb; 6(1):239-44. 11. Ivani G, Lampugnani E, Torre M, Calevo MG, DeNegri P, Borrometi F, et al : Comparison of ropivacaine with bupivacaine for paediatric caudal block. Br J Anaesth 1998; 81(2):247-8. 12. Broadman LM, Rice LJ, Hannallah RS. Testing the validity of an objective pain scale for infants and children. Anaesthesiology 1988; 69(3A): A770. 13. McKenzie I, Grant. Sedation score in paediatric patients. Paediatr Anaesth 2006; 16: 213-5. 14. Schechter NL. The undertreatment of pain in children : an overview. Pedia Clin N Am 1989; 36: 781-94. 15. McClure J. Ropivacaine. Br J Anaesth 1996;76:300–7. 16. Murat I, Delleur MM, Esteve C et al. Continuous extradural anaesthesia in children, clinical and haemodynamic implications. Br J Anaesth 1987; 59: 1441-50. 17. Scott DB, Lee A, Fagan D et al. Acute toxicity of ropivacaine compared with that of bupivacaine. Anesth Analg 1989; 69: 563-9. 18. Khalil S, Campos C, Farag AM, Vije H, Ritchey M, Chuang A. Caudal block in children, ropivacaine compared with bupivacaine. Anesthesiology 1999; 91(5):1279-84. 19. Ray M, Mondal SK, Biswas A. Caudal analgesia in paediatric patients: comparison between bupivacaine and ropivacaine. Indian J Anaesth 2003; 47(4):275-8. 20. Singh RJ, Gautam PL, Kaul TK, Kangotra V. Comparative study of caudal block for postoperative analgesia in paediatric patients with 0.25% bupivacaine and 0.25% bupivacaine with adrenaline. Ind J Anaesth 1997;40:43-6. 21. Ivani G, Mereto N, Lampugnani E, De Negri P, Torre M, Mattioli G, Jasonni V, Lonnqvist PA : Ropivacaine in paediatric surgery : Preliminary results. Paediatr Anaesth 1998; 8: 127-29. 22. Locatelli B, Igelmo 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 caudal route in children. Br J Anaesth 2005; 94(3):366-71 . 23. Berde CB. Convulsions Associated With Pediatric Regional Anesthesia. Anesth Analg 1992;75:164-7. 24. Shaikh NM, Mughal SA, Shaikh SM, Siddiqui FG, Memon A. Caudal epidural for postoperative analgesia in male children. J Liaquat Uni Med Health Sci 2006; 5:110-3.