Original Research Article

Evaluation of spinal anaesthesia by bupivacaine heavy (0.5%) and bupivacaine heavy (0.5%) with midazolam in infra-umbilical paediatric surgeries

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Abstract

Background: Post-operative analgesia is very important factor in paediatrics surgery as pain is very complex and most feared phenomenon in children. Bupivacaine, a long-acting local anaesthetic agent provides only 4–8 h of analgesia. Midazolam has a shorter duration of action and high potency. **Aim:** To compare efficacy of spinal anaesthesia with 0.5% bupivacaine alone (Group A) and combination of bupivacaine with preservative free midazolam (Group B) in infra-umbilical paediatric surgeries. **Material and Methods:** Analytical longitudinal study conducted on 40 children of age 7 to 12 years undergoing infra-umbilical surgery in tertiary care hospital. **Results:** Mean age in Group A and B was 9.2 years and 9.6 years, respectively. Duration of motor blockade was 83.2 minutes and 103.9 minutes; average time of onset of sensory blockade was 5.14 minutes and 5.06 minutes; mean durations of post-operative analgesia were 1.34 hours and 2.9 hours; in group A and group B cases, respectively. Among group B cases, commonest complication was shivering (15%) followed by nausea and vomiting (5%) while among group A cases, commonest adverse effect was shivering (35%) followed by nausea and vomiting (25%). **Conclusion:** Spinal anaesthesia with Bupivacaine and Midazolam significantly increases duration of post-operative analgesia, the duration of motor blockade and time of two segment regression without any significant effect on height and time of onset of sensory blockade. Need of supplementary general anaesthesia was reduced by use of addition of Midazolam.

Key Words: Ketamine, Caudal block, Analgesia, Pain management, Adverse effects.

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INTRODUCTION

Post-operative analgesia is very important factor in paediatrics surgery as pain is very complex and most feared phenomenon in children. Post-operative crying due to pain, hunger or fear is very difficult to differentiate in children.[1,2] This one along with fear of respiratory depression are the reasons for withholding analgesia in children. Many studies consistently showed that children receive fewer, less frequent and smaller doses of potent opioids.[3,4,5] Many previous study studies stated higher levels of safety and efficacy of spinal anaesthesia over general anaesthesia in normal as well as high risk children.[6] Shorter duration of action after a single injection of local anaesthetic solution is the main drawback of spinal anaesthesia and administration of repeated doses is not preferred due to fear of iatrogenic infection.[7] Bupivacaine, a long-acting local anaesthetic agent provides only 4–8 h of analgesia.[6] Midazolam is newer and only benzodiazepine approved for use in neonates which has a shorter duration of action and high potency.[8] It modulate

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nociceptive responses by interacting with specific gamma-aminobutyric acid (GABA) receptors in the brain and spinal cord.[9] Many previous human trials showed caudal midazolam with bupivacaine produce more postoperative analgesic effect with minimal adverse effects.[10,11] Physiological and anatomical factors in children significantly affect pharmacodynamics of anaesthetic agents.[12,13] So, this study was conducted to compare post-surgical analgesia, requirement of post-operative rescue analgesics and adverse effects of spinal anaesthesia with 0.5% bupivacaine alone and combination of bupivacaine with preservative free midazolam in infra-umbilical paediatric surgeries.

MATERIAL AND METHODS

A hospital based prospective analytical study was conducted at operation theatre of paediatrics surgery and anaesthesia department of tertiary care hospital. Forty paediatrics cases in the age group of 7 years to 12 years undergoing infra-umbilical surgeries under spinal anaesthesia with Bupivacaine alone or with mixture of Bupivacaine and preservative free Midazolam were included in study. Cases having local infection or sepsis at the injection site, spinal deformity and congenital anomalies, any decompensated systemic disorder, bleeding disorders including anticoagulation therapy and not willing to participate (child or parents) were excluded. Institutional Ethics Committee (IEC) was taken before commencement of study. Written informed consent was taken from parents after explaining the details of study procedure, risk and advantages. Routine investigations were done. Pre-operative assessment of all cases was performed for anaesthetic fitness (ASA grading I and II). Cases were not allowed to take solid food for 6 hours and clear fluids for 2 hours before commencement of anaesthesia. 22G intravenous cannula was used to establish intravenous line (I.V). All cases were given injection intravenous midazolam (0.03 to 0.05 mg/kg body weight) for restraining and sedation during lumbar puncture (LP). Ringer Lactate and Dextrose 25% 25cc was given in the dose of 4ml/kg/hr for intra-operative period. *Group A* constituted of 20 cases who were going to receive spinal anaesthesia using Bupivacaine heavy 0.5% in the dose of 0.06 ml/kg body weight. *Group B* constituted of 20 cases who were going to receive spinal anaesthesia using spinal anaesthesia using bupivacaine heavy 0.5%-0.06ml/kg + preservative free midazolam 0.02 mg/kg body weight.

Procedure:

Pre-operative heart rate, systolic and diastolic blood pressure, respiratory rate and other vitals were recorded. Lumbar puncture was done in the L4-5 interspace with 25 G spinal needle with stylette after placing children in the left lateral position and taking all aseptic precautions. Close monitoring of pulse rate and blood pressure was done throughout the procedure. Pin-prick was used to assess time of onset of sensory block and response noticed by face grimace. Observation of progress of paralysis in the legs and anterior or lateral abdominal muscles as the child cried or coughed was used to judge onset of motor block. Standard operating protocols, definitions and procedure were formulated before start of study and followed till end of complete data collection. Spinal anaesthesia was considered satisfactory if the child was free of pain during surgery and no supplementary agents other than midazolam intravenously were necessary for sedation. 'The time interval between injection of drug and the time of reappearance of the movements of the feet' was taken as duration of anaesthesia. Fall in heart rate more than 30% of baseline was considered as 'bradycardia'. Similarly fall in systolic blood pressure more than 30% of baseline was considered as 'a hypotension'. Postoperative heart rate, blood pressure and respiratory rate were monitored for every 30 mins. Pain relief was evaluated by using 10 cm linear visual scale. Duration of post-operative analgesia was recorded. Daily follow-up visits were given till discharge from hospital to assess development of any adverse effect.

Statistical analysis: Data was entered in Microsoft Excel and analysed with SPSS v.16. Tables and graphs used at appropriate places to present data in meaningful manner. Descriptive statistics like frequency, proportions, mean, range and standard deviation were used. Inferential statistics like chi-square test and student t test were used. Statistical significance was considered if $p<0.05$.

RESULTS

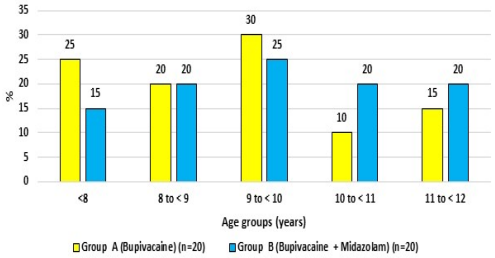

Figure 1: Age wise distribution of study participants among two groups

Table 1: Comparison of sensory and motor blockade between two groups

		Group A (Bupivacaine)		Group B (Bupivacaine + Midazolam)	
		Mean	SD	Mean	SD
Sensory blockade	Time of onset (min)	5.14	1.2	5.06	1.31
	Range	4 to 6		4 to 6	
Height (Thoracic segment) (Sensory blockade)	Height (Cm)	5.4	1.02	5.2	1.15
	Range	(T4-T10)		(T4-T10)	
Motor blockade	Duration (min)	83.2	8.2	103.9	9.31
	Range	75 to 100		100 to 115	

Table 2: Comparison of efficacy parameters between two groups

		Group A (Bupivacaine)		Group B (Bupivacaine + Midazolam)	
		Mean	SD	Mean	SD
Time to two segment regression (min)	Time (min)	84.2	8.2	100.1	7.31
	Range	75 to 100		90 to 110	
Post-operative analgesia	Duration (Hr)	1.34	0.52	2.9	1.31
	Range	1 to 2		2 to 6	
Requirement of general anaesthesia supplementation	No. of cases	4		0	

Table 3: Comparison of haemodynamic parameters between two groups

		Group A (Bupivacaine)		Group B (Bupivacaine + Midazolam)	
		Mean	SD	Mean	SD
Systolic Blood Pressure (mmHg)	Pre-operative	116.2	17.2	116.3	12.31
	Maximum Intra-operative fall (%)	90.6 (25.6%)	15.5	92.5 (23.8%)	14.41
	Post-operative	100.4	16.23	98.6	12.39
Heart rate (beats per min.)	Pre-operative	94.2	9.2	91.5	9.31
	Maximum Intra-operative fall (%)	78.6 (15.6%)	7.59	76.4 (15.1%)	8.91
	Post-operative	84.2	10.23	81.5	9.99

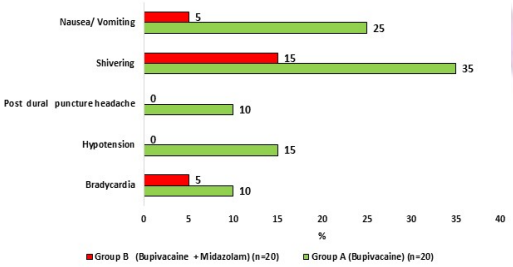

Figure 2: Complication rate among two groups

Age wise distribution of 40 study participants have shown in *figure no.1*. Out of 40 paediatrics cases, 20 cases were administered with Bupivacaine alone (Group A) and 20 cases were administered with Bupivacaine and Midazolam (Group B). Among both groups, most of cases were of age between 9 to 10 years i.e. 30% in group A and 25% in group B. Mean age in Group A and B was 9.2 years and 9.6 years, respectively. The variation in distribution of age among groups was not statistically significant. Comparison between parameters of sensory blockade and motor blockade of 2 groups is shown in *Table no.1*. Duration of motor blockade was 83.2+/-8.2 minutes and 103.9+/-9.31 minutes in group A and group B cases, respectively. This difference was statistically highly significant (t=12.48; p<0.001). Average time of onset of sensory blockade in group A (Bupivacaine) was 5.14+/-1.2 minutes while that in group B was 5.06+/-1.31 minutes. This difference was statistically not significant. Average height of sensory blockade (thoracic segment) was 5.4+/-1.02 cms. in group A cases ranging from T4 to T10 vertebrae. While in group B cases, mean height of sensory blockade (thoracic segment) was 5.2+/-1.15 cms., ranging from T4 to T10 vertebrae. But, this difference was statistically insignificant. *Table no.2* highlights comparison of efficacy parameters of two modalities. Mean durations of post-operative analgesia were 1.34+/-0.52 hours and 2.9+/-1.31 hours for group A and group B cases, respectively. The difference between these two durations was statistically highly significant (t=8.31; p<0.001). Out of 20 cases each in group I and II, 4 cases of group A required general anaesthesia supplementation and no one from group B required such supplementation. In group A cases, average time required for two segment regression was 84.2+/-8.2 minutes ranging from 75 to 100

minutes. In group B cases, average time required for two segment regression was 100.1+/-7.31 minutes ranging from 90 to 110 minutes. This difference was statistically highly significant (t=2.87; p<0.001). Comparison between haemodynamic parameters of both groups is shown in *table no.3*. Pre-operative mean heart rate was 94.2+/-9.2 bpm and 91.5+/-9.31 bpm, for group A and B, respectively. This difference was statistically insignificant. Intra-operatively maximum fall in heart rate was 78.6+/-7.59 bpm (15.6%) and 76.4+/-8.91 (15.1%) bpm, for group A and B, respectively. Post-operative mean heart rate was 84.2+/-10.23 mmHg and 81.5+/-9.99 bpm, for group A and B, respectively. Pre-operative mean systolic blood pressure (SBP) was 116.2+/-17.2 mmHg and 116.3+/-12.31 mmHg, for group A and B, respectively. This difference was not statistically significant. Intra-operatively maximum fall in SBP was 90.6+/-15.5 mmHg (25.6%) and 92.5+/-14.41 (23.8%) mmHg, for group A and B, respectively. Post-operative mean systolic blood pressure (SBP) was 100.4+/-16.23 mmHg and 98.6+/-12.39 mmHg, for group A and B, respectively. Complications rates are shown in *figure no.2*. Among group B cases, commonest complication was shivering (15%) followed by nausea and vomiting (5%) and bradycardia (5%). Hypotension and post-dural puncture headache were not seen in group B cases. High or complete spinal blockade was not noted in any case of both groups. Among group A cases, commonest adverse effect was shivering (35%) followed by nausea and vomiting (25%), hypotension (15%), bradycardia (10%) and post-dural puncture headache (10%).

DISCUSSION

Total 40 cases in whom spinal anaesthesia by either Bupivacaine heavy 0.5% in dose of 0.06 ml/kg (Group A) or Bupivacaine with Midazolam 0.02 mg/Kg (Group B) was administered. Study done by Kumar *et al.*.[4] reported mean age as 6 years and 5.8 years for group A and B, respectively. Current study reported comparable findings with, highest number of cases were below the age of 10 years (75% for gr. A and 60% for gr. B). Mean age of cases was 9.2 years and 9.6 years for group A and B respectively. Study done by Himabindu *et al.*[14] reported 6.12 years and 5.68 years as mean age of group A and B, respectively. Sadhana *et al.*[15] reported 6.64 years and 6.16 years as mean age of group A and B cases, respectively. Kumar *et al.*[4] reported statistically significant difference between mean duration of onset of group A (7.6 mins) and group B (16.8 mins). Present study findings differed from this as mean time of onset of sensory blockade of group B (5.06 mins) was slightly less than group A (5.14 mins) and the difference was insignificant statistically. Height of thoracic blockade was T4 to T10 for both groups with 5.4 cms. and 5.2 cms. for group A and B, respectively. Duration of motor blockade was higher for group B (103 mins) than group A (83 mins) and difference was statistically significant. Kokki *et al.*[6] reported T1 to T7 as height of sensory blockade. Nishiyama *et al.*[17] and HO KM *et al.*[17] reported similar findings in their studies. Study done by Kumar *et al.*[4] reported mean duration of complete analgesia as 238 mins and 376 mins for group A and B, respectively and this difference was significant. Himabindu *et al.*[14] reported up to 68% of children in the bupivacaine group were pain free until 3 hours after surgery while 80% of children were pain free in bupivacaine and midazolam group up to 3 hours indicating longer duration of analgesia. Comparable findings were reported by present study which reported average higher duration of analgesia in group B (2.9 hours) than group A cases (1.34 hours) and this difference was statistically highly significant. Kokki *et al.*[6] reported 83 mins as time for two segment regression which was similar to present study findings (84.2 mins). Sadhana *et al.*[15] reported 101.72 mins and 100.58 mins as mean duration of anaesthesia. They also reported 295 mins and 605 mins as mean duration of analgesia for group A and B. More cases of group A required supplementary anaesthesia than group B. These findings were comparable with present study findings. Bano *et al.*[10], Ghai *et al.*.[18] and Mahajan *et al.*[11] reported comparable findings in their study. Study done by Kumar *et al.*[4] reported pre-operative mean arterial pressure (MAP) as 91.5 mmHg and 89.4 mmHg for group A and B, respectively. They also reported mean heart rate as 110 bpm and 112 bpm for group A and B, respectively. Similar findings were reported by current study, as pre-operative heart rate and systolic blood pressure (SBP) of group A (94.2 bpm; 116.2 mmHg) was almost similar to that of group B (91.5 bpm; 116.3 mmHg), respectively. Himabindu *et al.*[14] did not found statistically significant difference in intraoperative vital parameters, pulse rate and blood pressure of group A and B. This was comparable with current study findings. Sadhana *et al.*[15] reported intra-operative HR and SBP as (92.6 bmp; 95.92 mmHg) and (99.6 bpm; 95.2mmHg) for group A and B, respectively. They also reported post-operative HR and SBP as (97.92 bmp; 97.2 mmHg) and (100.2 bpm; 99.76 mmHg) for group A and B, respectively. Difference between vitals were not significant at any time for both groups. This findings were similar to present study findings. Pradhan *et al.*[19] reported no significant differences in quality of pain relief, postoperative behaviour or analgesic requirements between two group. Kokki *et al.*[6] reported nausea (20%), shivering (13%), bradycardia (5%) and hypotension (2%) as complications of Bupivacaine group. Present study reported comparable findings as commonest adverse effect was shivering (35%) followed by nausea and vomiting

(25%) in group A. While among group B cases, commonest complication was shivering (15%) followed by nausea and vomiting (5%). Arbabi *et al.*[20] reported similar findings. Chaudhary *et al.*[21] reported vomiting and motor weakness as common complications of both groups. Sadhana *et al.*[15] reported nausea and vomiting, respiratory depression and hypotension as complications of group B while no complications in group A. Tsui *et al.*[22] and Menzies *et al.*[9] reported concurrent study findings with that of current study.

CONCLUSION

Spinal anaesthesia with Bupivacaine and Midazolam significantly increases duration of post-operative analgesia, the duration of motor blockade and time of two segment regression without any significant effect on height and time of onset of sensory blockade. Both Bupivacaine and Bupivacaine with Midazolam affect haemodynamic parameters but complications rates in Bupivacaine and Bupivacaine with Midazolam administered groups were not similar. Need of supplementary general anaesthesia was reduced by use of addition of Midazolam.

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