

# Assessment of efficacy of spinal anaesthesia by bupivacaine heavy (0.5%) and bupivacaine heavy (0.5%) with ketamine in infra-umbilical surgeries in children

Khushboo R Damani<sup>1</sup>, Shrikant M Upasani<sup>2\*</sup>

<sup>1,2</sup>Assistant Professor, Department of Anaesthesiology, SMBT Institute of Medical Sciences and Research Centre, Dhamangoan, Nashik, Maharashtra, INDIA.

Email: [shrikantupasani77@gmail.com](mailto:shrikantupasani77@gmail.com)

## Abstract

**Background:** Spinal anaesthesia allows use of small dose with a low risk of systemic toxicity. Epidural administration of preservative free Ketamine with has profound analgesic effects at spinal cord level without having any systemic adverse effects. **Aim:** To evaluate the efficacy of spinal anaesthesia with 0.5% bupivacaine alone and combination of bupivacaine with preservative free ketamine. **Material and Methods:** Analytical follow-up study conducted on 40 paediatrics cases (7 to 12 years of age) undergoing infra-umbilical surgery under spinal anaesthesia by Bupivacaine (Group I) and Bupivacaine with Ketamine (Group II). **Results:** Most of cases were of age between 9 to 10 years with mean age of 9.2 years. Duration of motor blockade was 83.2 minutes and 120.1 minutes; average time of onset of sensory blockade was 5.14 minutes and 4.98 minutes; mean durations of post-operative analgesia were 1.34 hours and 6.2 hours; in group I and group II cases, respectively. Among both groups, commonest adverse effects were shivering and nausea and vomiting. Four cases of group I required general anaesthesia supplementation and no one from group II required such supplementation. **Conclusion:** Addition of Ketamine to Bupivacaine significantly increases the duration of motor blockade, time of two segment regression and duration of post-operative analgesia. Requirement of supplementation of general anaesthesia was reduced by use of Ketamine.

**Key Words:** Midazolam, Postoperative analgesia, Pain management, Racemic Ketamine.

## \*Address for Correspondence:

Dr Shrikant M. Upasani, Assistant Professor, Department of Anaesthesiology, SMBT Institute of Medical Sciences and Research Centre, Dhamangoan, Nashik, Maharashtra, INDIA.

Email: [shrikantupasani77@gmail.com](mailto:shrikantupasani77@gmail.com)

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## INTRODUCTION

Pharmacokinetics and pharmacodynamics of anaesthetic agents in paediatrics surgeries significantly affects neural

blockade due to physiological and developmental factors in children.<sup>1</sup> Action of local anaesthetic agent in children is favoured by better penetration into partially myelinated nerve fibre, as it takes almost 12 years of age for complete myelination and myelination considerably affect pharmacodynamics of local anaesthetic agents.<sup>2</sup> Safety and efficacy profiles of spinal anaesthesia have been examined by previous studies which suggested it as a potent alternative to general anaesthesia in normal as well as high risk paediatrics surgeries.<sup>3-6</sup> The amide local anaesthetic (bupivacaine/ lidocaine) are used regularly and spinal anaesthesia allows use of small dose with a low risk of systemic toxicity. Ketamine is an analgesic as well as anaesthetic agent with a wide range of applications in paediatric surgeries.<sup>7,8</sup> Racemic ketamine is not

recommended due to neurotoxicity of preservative agents. Epidural administration of preservative free Ketamine has profound analgesic effects at spinal cord level without having any systemic adverse effects. Addition of preservative free ketamine to bupivacaine has been shown to prolong the duration of postoperative analgesia in infra-umbilical paediatrics surgeries.<sup>9,10</sup> So, this study was planned to compare the efficacy of spinal anaesthesia with 0.5% bupivacaine alone and combination of bupivacaine with preservative free ketamine in terms of duration of post-operative analgesia, requirement of supplementation of anaesthesia in case of failure or inadequacy of effects and complications rates in infra-umbilical paediatric surgeries.

### MATERIAL AND METHODS

An observational analytical hospital based prospective study was conducted at paediatrics surgery operation theatre of tertiary care hospital. Institutional Ethics Committee (IEC) was taken before commencement of study. 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 Ketamine were enrolled for 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. Standard operating protocols, definitions and procedure were formulated before start of study and followed till end of complete data collection. Written informed consent was taken from parents after explaining the details of study procedure, risk and advantages. Pre-operative assessment of all cases was performed for anaesthetic fitness (ASA grading I and II). Routine investigations were done. 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). *Group I* 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 II* constituted of 20 cases who were going to receive spinal anaesthesia using bupivacaine heavy 0.5%-0.06ml/kg and preservative free ketamine 0.5 mg/kg body weight. Baseline 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. Spinal anaesthesia was considered satisfactory if the child was free of pain during surgery and no supplementary agents other than ketamine 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. Duration of post-operative analgesia was recorded. Daily follow-up visits were given till discharge from hospital to assess development of any adverse effect. Data was entered in Microsoft Excel and analysed with SPSS v.16. Descriptive statistics like frequency, proportions, mean, range and standard deviation were used. Chi-square test and Student t test were used to draw inference at 5% level of significance. Tables and graphs used at appropriate places to present data in meaningful manner.

### RESULTS

**Table 1:** Age wise distribution of study participants among two groups

Age in Years	Group I (Bupivacaine)		Group II (Bupivacaine + Ketamine)	
	No.	%	No.	%
<8	5	25	4	20
8 to < 9	4	20	5	25
9 to < 10	6	30	6	30
10 to < 11	2	10	3	15
11 to < 12	3	15	2	10
<b>Total</b>	<b>20</b>	<b>100</b>	<b>20</b>	<b>100</b>

**Table 2:** Comparison of sensory and motor blockade between two groups

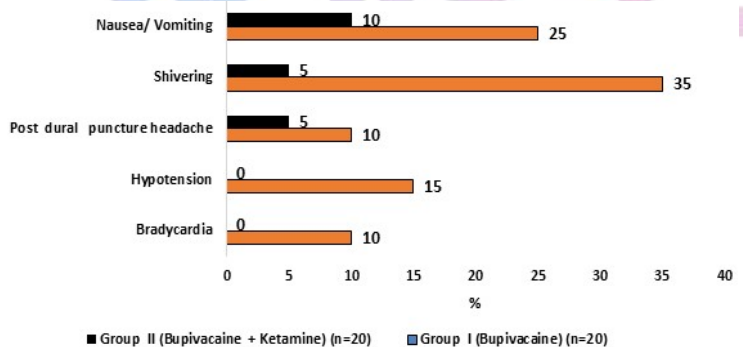
		Group I (Bupivacaine)		Group II (Bupivacaine + Ketamine)	
		Mean	SD	Mean	SD
		<b>Sensory blockade</b>	<b>Time of onset (min)</b>	5.14	1.2
	<b>Range</b>	4 to 6		3 to 6	
<b>Height (Thoracic segment) (Sensory blockade)</b>	<b>Height (Cm)</b>	5.4	1.02	5.8	1.11
	<b>Range</b>	(T4-T10)		(T5-T10)	
<b>Motor blockade</b>	<b>Duration (min)</b>	83.2	8.2	120.1	7.01
	<b>Range</b>	75 to 100		110 to 130	

**Table 3:** Comparison of efficiency between two groups

		Group I (Bupivacaine)		Group II (Bupivacaine + Ketamine)	
		Mean	SD	Mean	SD
		<b>Time to two segment regression (min)</b>	<b>Time (min)</b>	84.2	8.2
	<b>Range</b>	75 to 100		100 to 120	
<b>Post-operative analgesia</b>	<b>Duration (Hr)</b>	1.34	0.52	6.2	1.2
	<b>Range</b>	1 to 2		4 to 12	
<b>Requirement of general anaesthesia supplementation</b>	<b>No. of cases</b>	4		0	

**Table 4:** Comparison of haemodynamic parameters between two groups

		Group I (Bupivacaine)		Group II (Bupivacaine + Ketamine)	
		Mean	SD	Mean	SD
		<b>Systolic Blood Pressure (mmHg)</b>	<b>Pre-operative</b>	116.2	17.2
	<b>Maximum Intra-operative fall (%)</b>	90.6 (25.6%)	15.5	104.6 (8%)	14.4
	<b>Post-operative</b>	100.4	16.23	110	12.3
<b>Heart rate (beats per min.)</b>	<b>Pre-operative</b>	94.2	9.2	93.62	11.2
	<b>Maximum Intra-operative fall (%)</b>	78.6 (15.6%)	7.59	88.6 (5.02%)	9.44
	<b>Post-operative</b>	84.2	10.23	92.3	9.3



**Figure 1:** Complication rate among two groups

Study was conducted on 40 paediatrics cases, out of which 20 cases were administered with Bupivacaine alone (Group I) and 20 cases were administered with Bupivacaine and Ketamine, both (Group II). As indicated in *table no.1*, among both groups, maximum number of cases were of age between 9 to 10 years. By applying Chi-square test there was no significant variation in the distribution of age among groups. Mean age in Group I and II was 9.2 years. *Table no.2* depicts comparison between parameters of sensory blockade and motor blockade of 2 groups. Average time of onset of sensory blockade in group I (Bupivacaine) was 5.14+/-1.2 minutes while that

in group II was 4.98+/-1.01 minutes. This difference was not statistically significant. Average height of sensory blockade (thoracic segment) was 5.4+/-1.02 cms. in group I cases ranging from T4 to T10 vertebrae. While in group II cases, mean height of sensory blockade (thoracic segment) was 5.8+/-1.11 cms., ranging from T5 to T10 vertebrae. But, this difference was not statistically significant. Duration of motor blockade was 83.2+/-8.2 minutes and 120.1+/-7.01 minutes in group I and group II cases, respectively. This difference was statistically highly significant (t=15.31; p<0.001). Comparison of efficacy parameters of two modalities is shown in *table no.3*. In

group I cases, average time required for two segment regression was 84.2 $\pm$ 8.2 minutes ranging from 75 to 100 minutes. In group II cases, average time required for two segment regression was 106.6 $\pm$ 7.01 minutes ranging from 100 to 120 minutes. This difference was statistically highly significant ( $t=9.21$ ;  $p<0.001$ ). Mean durations of post-operative analgesia were 1.34 $\pm$ 0.52 hours and 6.2 $\pm$ 1.2 hours for group I and group II cases, respectively. The difference between these two durations was statistically highly significant ( $t=16.75$ ;  $p<0.001$ ). Out of 20 cases each in group I and II, 4 cases of group I required general anaesthesia supplementation and no one from group II required such supplementation. Haemodynamic changes of both groups are compared in *table no.4*. Pre-operative mean systolic blood pressure (SBP) was 116.2 $\pm$ 17.2 mmHg and 112.6 $\pm$ 18.2 mmHg, for group I and II, respectively. This difference was statistically insignificant. Intra-operatively maximum fall in SBP was 90.6 $\pm$ 15.5 mmHg (25.6%) and 104.6 $\pm$ 14.4 (8%) mmHg, for group I and II, respectively. Post-operative mean systolic blood pressure (SBP) was 100.4 $\pm$ 16.23 mmHg and 110 $\pm$ 12.3 mmHg, for group I and II, respectively. Pre-operative mean heart rate was 94.2 $\pm$ 9.2 bpm and 93.62 $\pm$ 11.2 bpm, for group I and II, respectively. This difference was statistically insignificant. Intra-operatively maximum fall in heart rate was 78.6 $\pm$ 7.59 bpm (15.6%) and 88.6 $\pm$ 9.44 (5.02%) bpm, for group I and II, respectively. Post-operative mean heart rate was 84.2 $\pm$ 10.23 mmHg and 92.3 $\pm$ 9.3 bpm, for group I and II, respectively. Rate of various complications are shown in *figure no.1*. Among group I cases, commonest adverse effect was shivering (35%) followed by nausea and vomiting (25%), hypotension (15%), bradycardia (10%) and post-dural puncture headache (10%). Among group II cases, commonest complication was nausea and vomiting (10%) followed by shivering (5%) and post-dural puncture headache (5%). Hypotension and bradycardia were not seen in group II cases. High or complete spinal blockade was not noted in any case of both groups.

## DISCUSSION

A comparative study of spinal anaesthesia by Bupivacaine heavy 0.5% in dose of 0.06 ml/kg (Group I) and Bupivacaine with Ketamine 0.5 mg/Kg (Group II) was conducted on 40 paediatrics cases. In current study, highest number of cases were below the age of 10 years (75%) in both groups. Mean age of cases was 9.2 years in both groups. Study done by Kumar *et al.*<sup>11</sup> reported mean age as 6  $\pm$  0.6 years and 6.2  $\pm$  0.5 years for group I and II, respectively. Study done by Nafiu *et al.*<sup>12</sup> reported 3.5 years and 3.6 years as average age of cases in their study as their study group was of age between 2 to 8 years. Singh *et al.*<sup>13</sup> reported 6.10 years and 5.3 years as mean age of

group I and II cases, respectively in their study. In current study, mean time of onset of sensory blockade of group II was less than group I but the difference was insignificant statistically. Kumar *et al.*<sup>11</sup> reported statistically significant difference between mean duration of onset of group I (7.6 mins) and group II (11.6 mins). In study done by Choudhury *et al.*<sup>14</sup>, time required for first analgesia was 6.5 hrs. and 9.2 hrs. for group I and group II, respectively. This difference was statistically significant. They reported 68 mins and 67 mins as duration of anaesthesia in group I and II respectively. Comparable findings were reported by studies done by Debbarma *et al.*<sup>15</sup> and Patel *et al.*<sup>16</sup> in their studies. In present study, average duration of analgesia was more in group II (6.2 hours) than group I cases (1.34 hours) and this difference was statistically highly significant. Study done by Kumar *et al.*<sup>11</sup> reported mean duration of complete analgesia as 238 mins and 336 mins for group I and II, respectively and this difference was significant. So these findings were comparable with present study findings. Study done by Nafiu *et al.*<sup>12</sup> reported, caudal injection of bupivacaine plus ketamine produced superior postoperative analgesia compared with Bupivacaine alone. They also reported fewer patients in the bupivacaine plus ketamine group required supplemental analgesia which was comparable with present study findings as none of group II cases required general anaesthesia supplementation. Singh *et al.*<sup>13</sup> reported duration of analgesia was significantly high in group II than group I. Choudhury *et al.*<sup>14</sup> reported higher mean duration of complete analgesia in group II (329 mins) as compared to group I (212 mins) and this difference was statistically significant. Marhofer *et al.*<sup>2</sup> reported 300 mins and 203 mins as duration of analgesia for group I and II, respectively. They also reported 30% cases required additional analgesia in both groups. Kaur *et al.*<sup>17</sup> and Koshfetrat *et al.*<sup>18</sup> reported similar findings in their studies. In current study, pre-operative heart rate and systolic blood pressure (SBP) of group I (94.2 bpm; 116.2 mmHg) was higher than that of group II (93.62 bpm; 112.6 mmHg) but this difference was not statistically significant. Study done by Kumar *et al.*<sup>11</sup> reported pre-operative mean arterial pressure (MAP) as 91.5  $\pm$  5.6 mmHg and 90.6  $\pm$  5.6 mmHg for group I and II, respectively. They also reported mean heart rate as 110  $\pm$  11 bpm and 118  $\pm$  12 bpm for group I and II, respectively. Panjabi *et al.*<sup>19</sup> reported similar findings in their study. Marhofer *et al.*<sup>2</sup> reported no significant change in HR and MAP during intra-operative period in any group. In present study Among only Bupivacaine cases, commonest adverse effect was shivering (35%) followed by nausea and vomiting (25%) while among group Bupivacaine with Ketamine cases, commonest complication was nausea and vomiting (10%) followed by shivering (5%) and post-dural puncture

headache (5%). High or complete spinal blockade was not noted in any case of both groups. Nafiu *et al.*<sup>12</sup> reported post-operative nausea and vomiting, delayed micturition and prolonged motor weakness as common complications among both groups. Singh *et al.*<sup>13</sup> reported, post-operative nausea and vomiting in 15% and 5% of the patients in the group I and group II, respectively. They did not find other complication like respiratory depression, hypotension, bradycardia and constipation in any groups.

## CONCLUSION

Addition of Ketamine to Bupivacaine did not significantly alter height and time of onset of sensory blockade but it significantly increases the duration of motor blockade, time of two segment regression and duration of post-operative analgesia. Also haemodynamic changes as well as occurrence of complications by Bupivacaine were not significantly altered by use of addition of Ketamine. Requirement of supplementation of general anaesthesia was reduced by use of Ketamine.

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