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A COMPARATIVE STUDY OF CAUDAL BLOCK WITH BUPIVACAINE VERSUS BUPIVACAINE PLUS TRAMADOL IN INFRA UMBILICAL SURGERIES IN CHILDREN.

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ABSTRACT **Background and Aims:** Caudal analgesia is one of the most popular regional anaesthetic techniques employed in children. It is a relatively simple technique with a predictable level of blockade, and is by far the most common regional technique used in paediatric surgery for lower abdominal, urological, and lower limb operations. Various methods have been devised to prolong the duration of action of single shot caudal block. In this study the addition of an opioid agonist, TRAMADOL, 1mg/kg which lacks the effect of respiratory depression will be added to bupivacaine with regards to analgesic potency, quality, duration and side effects and will be compared with bupivacaine alone. **Material and Methods:** After approval from institutional ethical committee This study was conducted at Department of Anaesthesiology, Govt. Medical College Kota. This study included 60 children of ASA grade I and II aged between 1to 5 yrs undergoing various elective infra-umbilical surgical procedures such as herniotomies, circumcision, orchidopexy, perineal surgeries and minor lower extremity procedures. The patients were randomly devided into two groups of 30 patients each. Group A received 0.25% of bupivacaine 1 ml/kg. Group B received 0.25% of bupivacaine 1 ml/kg with tramadol 1mg/kg. The various parameters studied were intraoperative hemodynamic changes, duration of postoperative analgesia, postoperative sedation, postoperative analgesic requirement, and incidence of side-effects. Results: Both the groups were similar with respect to patient demoghraphic and clinical characteristics. The hemodynamic parameters like heart rate, systolic blood pressure & diastolic blood pressure were also comparable. The mean duration of analgesia was 247.16 ± 36.43 min in group A with a range of 180 to 355 min. In group B, the mean duration of analgesia was 433.5 ± 60.2 min with a range of 265 to 530 min. The difference in the mean duration of analgesia was statistically highly significant ($p<0.0001$). The incidence of nausea and vomiting was among 3(9%) children in group A compared to 2(6%) in group B. This was not statistically significant. There was no incidence of hypotension, bradycardia, dural or vessel puncture and respiratory depression in the two groups. **Conclusion:** This study showed that tramadol in a dose of 1 mg/kg, added to 0.25% bupivacaine for caudal analgesia and administered as a 1ml/kg mixture in children, for infraumbilical surgery, significantly prolongs the duration of post-operative analgesia when compared to 1ml/kg of 0.25% bupivacaine alone, without any side effects.

KEYWORDS : Bupivacaine, Tramadol, Caudal Block, Children

Introduction

Caudal analgesia is one of the most popular regional anaesthetic techniques employed in children. It is a relatively simple technique with a predictable level of blockade, and is by far the most common regional technique used in pediatric surgery for lower abdominal, urological, and lower limb operations[1,2]. However, the mean duration of surgical analgesia provided by single shot caudal procedure is limited by the duration of action of local anaesthetics.

Tramadol, an opioid agonist, is a synthetic analogue of codeine. It is a potent norepinephrine inhibitor. It also inhibits serotonin uptake with facilitation of its release. It has moderate affinity for mu receptor. Its analgesic potency is equal to that of pethidine and 1/5th to 1/10th potent as morphine. It has no respiratory depressant effect. The addition of tramadol also prolongs the duration of action of bupivacaine after intrathecal and epidural administration in adults. In this study the addition of an opioid agonist, TRAMADOL, 1mg/kg which lacks the effect of respiratory depression will be added to bupivacaine with regards to analgesic potency,quality,duration and side effects and were compared with bupivacain alone[3].

In this study we have added an opioid TRAMADOL with bupivacaine, which lacks the effect of respiratory depression as side effect and is added to bupivacaine with regard to analgesic potency.

Material and methods

After approval from institutional ethical committee this study was conducted at Department of Anaesthesiology, Govt. Medical College Kota. This study included 60 children of ASA grade I and II aged between 1to 5 yrs undergoing various elective infra-umbilical surgical procedures such as herniotomies, circumcision, orchidopexy, perineal surgeries and minor lower extremity procedures. The patients were randomly devided into two groups of 30 patients each. Group A received 0.25% of bupivacaine 1 ml/kg. Group B received 0.25% of bupivacaine 1 ml/kg with tramadol 1mg/kg.

Children with ASA grade III and IV, infection at the site of injection, coagulopathy or anticoagulation therapy, congenital abnormalities of lower spine and meninges, active disease of the CNS and history of allergy to local anaesthetics were excluded from stud Informed consent was obtained from the attendants before including the children in the study. Patients were induced with oxygen and halothane (in increasing concentration) using Jackson Reis circuit and intravenous line was secured. An infusion of Ringer Lactate was started and fluid was administered according to the calculated requirements. All patients monitored for NIBP, pulse oximetry, respiratory rate and ECG. After induction, patients were placed in the lateral Sim's position and sacral hiatus was identified by running the thumb up from coccyx towards the sacrum.

After identifying the sacral hiatus, a 23G hypodermic needle with its bevel facing anteriorly was inserted at an angle of 60-70° to the skin till the sacro-coccygeal membrane was pierced, when a distinct "pop" was felt. The needle was lowered to an angle of 20° and advanced 2-3 mm to make sure that the entire bevel is inside the space. Confirmation of the needle point being in the epidural space was done with the "whoosh" test and the lack of resistance encountered by injection of 2-3 ml of air. Aspiration was done to exclude dural puncture or vessel puncture and the drug was injected according to group Group A patients received 0.25% of bupivacaine 1 ml/kg and Group B patients received 0.25% of bupivacaine 1 ml/kg with tramadol 1mg/kg. Anaesthetic agents were discontinued at the beginning of skin closure. 100% oxygen through a face mask was administered for 3-5 minutes. Once the vitals were stable and the child will awake, the child was shifted and placed in semi-prone position in the recovery room. On arrival to the recovery room, the child was monitored for another 1 hour with SpO2, respiratory rate, NIBP and heart rate every 15 minutes. After that the child was shifted to the ward and monitored thereafter.

Parameters:

Hemodynamic parameters: Patients were monitored for heart rate, respiratory rate and blood pressure after administration of caudal block at 0,5,15,30,45,60,120 and 180 minutes and the values were recorded.

Duration of action: Duration of action of drug is defined as the time interval between the administration of caudal block and the first requirement of supplementary analgesia for the patient.

Post-operative analgesia: Post-operative analgesia is assessed by Paediatric Objective Pain Scale. The assessment was done for a period of 24 hours after caudal block. Whenever pain score was more than 6 points from 2 consecutive intervals of 10 minutes, then supplementary analgesia with rectal Paracetamol (15mg/kg) was given. These assessments were made at 1, 2,3,4,8,12,16,20 and 24 hours after caudal block.

Side effects: Patients were monitored for intra-operative and post-operative complications.
1} Nausea and vomiting: Any episodes noted and treated accordingly
2} Bradycardia: Defined as the decrease in the heart rate of more than 30% of the baseline value. It was subsequently treated with Inj. Atropine 0.01mg/kg.
3} Hypotension: Defined as a decrease in the mean arterial pressure of greater than 30% of the baseline value. It was treated with rapid infusion of IV fluids and if hypotension persist, then Inj. Phenylephrine 2-10µg/kg.
4}Respiratory depression: Defined as a decrease in the SpO2 of <93% that required aministration of supplemental oxygen via face mask or a respiratory rate of < 10 breaths per minute.
Statistical analysis:
The results of continuous variables are given as mean ± SD and proportion as percentage. The difference between the two groups was assessed by student's - t test and chi-square test. For all the tests a 'p' value of 0.05 and less was considered for statistical significance.

RESULTS

Age & Gender wise distribution of patients

Here, in group-A majority of patients (50%) were in age group 1-2 years followed by 33.3% patients in age group >4 years and 16.6% patients were in age group 3-4 years. The mean age of patients in group-A was 2.96±1.62. Similarly, in group-B majority of patients (43.3%) were in age group greater than 4 years followed by 36.7% patients in age group 3-4 years and 20% patients were in age group 1-2 years. The mean age of patients in group-BC was 3.86±1.2. The mean age was not statistically significant between two groups with p-value 0.178.

Also in group-A 90% patients were male children and 10% female children. In group-B 80% patients were male children and 20% female children.

Table 1: Changes in heart rate

Heart Rate (in min)	Group-A		Group-B		P-value	Remarks
	Mean	SD	Mean	SD		
Base Line	110.46	15.09	112.8	10.6	0.47	NS
0	107.6	14.81	112.6	11.5	0.14	NS
5	106.7	12.67	111.1	10.61	0.15	NS
15	105.46	11.34	108.7	9.1	0.22	NS
30	103	11.75	106.26	8.98	0.23	NS
45	100.8	11.35	106.26	10.24	0.06	NS
60	99.9	11.56	104.06	10.15	0.14	NS
120	99.4	11.41	104.13	11.05	0.1	NS
180	99.53	11.57	105.8	12.41	0.047	Sig

In group A, the mean baseline heart rate was 110.46±15.09 per minute which decreased to 105.46±11.34 at 15 min. The mean baseline heart rate in group B was 112.8±10.6 per minute which decreased to 108.7±9.1 at 15 minutes. However, there was no significant difference in the heart rate between the two groups at any time interval ($p > 0.05$), except at 180 min (0.047)

Table 2: Changes in systolic blood pressure.

SBP	Group A		Group B		P Value	Remark
	Mean	SD	Mean	SD		
Base line	97.66	7.16	100.73	5.64	0.07	NS
0 min	98.13	6.25	100.53	5.55	0.12	NS
5 min	105.66	7.26	102.4	6.85	0.07	NS
15 min	103.06	7.46	101.4	6.19	0.35	NS
30 min	99	6.36	99.73	5.16	0.62	NS
45 min	96.6	6.01	98	3.36	0.27	NS
60 min	95.53	6.63	96.93	4.32	0.33	NS
120 min	94.2	6.52	96.26	3.59	0.13	NS
180 min	94	6.36	96.06	3.76	0.13	NS

In group A, the mean baseline systolic blood pressure was 97.66±7.16 per minute which increased to 103.06±7.26 at 15 min. The systolic blood pressure gradually decreased to 94±6.4 per minute at 180 minutes. The mean baseline systolic blood pressure in group B was 100.7±5.6 per minute which increased to 101.4±6.2 at 15 minutes and gradually decreased to 96.1±3.8 at 180 minutes. However, there was no significant difference in the systolic blood pressure between the two groups at any time interval ($p > 0.05$)

Table 3: Changes in diastolic blood pressure.

DBP	Group A		Group B		P Value	Remark
	Mean	SD	Mean	SD		
Base line	62.26	4.6	61.73	6.68	0.72	NS
0 min	62.4	4.65	62.26	7.21	0.93	NS
5 min	68.6	4.73	65.2	7.21	0.03	Sig
15 min	68.33	5.38	66.26	6.07	0.16	NS
30 min	63	5.52	64.13	6.07	0.45	NS
45 min	62.33	5.75	62.33	6.43	0.99	NS
60 min	60.46	5.93	59.4	6.5	0.5	NS
120 min	59.26	4.74	59.23	11.66	0.98	NS
180 min	59.86	5.63	82.33	110.41	0.27	NS

In group A, the mean baseline diastolic blood pressure was 62.26±4.6 per minute which increased to 68.33±5.4 at 15 min. The diastolic blood pressure gradually decreased to 59.86±5.63 per minute at 180 minutes. The mean baseline diastolic blood pressure in group B was 61.7±6.7 per minute which increased to 66.26±6.1 at 15 minutes. However, there was no significant difference in the diastolic blood pressure between the two groups ($p > 0.05$).

Table 4: Sedation score at various time intervals.

Time interval(hr)	Sedation score	Group -A		Grou p-B		P-value	Remarks
		No.	%	No.	%		
1hr	<3	30	100	30	100	1	NS
	≥3	0	0	0	0		
2hr	<3	30	100	30	100	1	NS
	≥3	0	0	0	0		
3hr	<3	9	30	30	100	0.0001	S
	≥3	21	70	0	0		
4hr	<3	0	0	15	50	0.0001	S
	≥3	30	100	15	50		
8hr	<3	0	0	0	0	1	NS
	≥3	30	100	30	100		
12hr	<3	0	0	0	0	1	NS
	≥3	30	100	30	100		
24hr	<3	0	0	0	0	1	NS
	≥3	30	100	30	100		

The sedation Score in group-A and group-B were below 3 at the end of first and second hour. At the end of third hour, 9(30%) of the patients in group-A had a sedation score below 3 and 21 (70%) patients had sedation score of ≥3. In group-B all patients had pain score was below 3. The differences were found statistically significant with p-value equal to 0.0001

At the end of fourth hour, all the patients in group A had a pain score of ≥3 and In group-B 15 (50%) sedation score was below 3 and 15 (50%) patients had pain score of ≥3. The differences were found statistically significant with p-value equal to 0.0001.

The sedation score was ≥3 in all the patients in group A and all the patients in group B had a score was ≥3 by the end of eight hour 12th and 24th hour which was statistically non-significant.

Table 5: Pain score at various time intervals.

Pain Score	Group A		Group B		P Value	Sig
	Mean	SD	Mean	SD		
1hr	0	0	0	0	0	-
2 hr	0	0	0	0	0	-

3 hr	1.33	0	0	0	0.001	Sig
4 hr	4.466	1.93	1.93	1.33	0.0001	Sig
8 hr	4.66	5.26	5.26	0.98	0.0394	Sig
12 hr	4.2	4.16	4.16	1.44	0.928	NS
24 hr	4.8	4.3	4.3	1.51	0.151	NS

The Paediatric Objective Pain Score in group-A and group-B were below 6 at the end of first and second hour and did not require any analgesia. At the end of third hour, 29 of the patients in group-A had a pain score below 6 and 1 (3.33%) patients had pain score of 6. In group-B all patients had pain score was below 6.

At the end of fourth hour, 16 of patients in group A had a pain score below 6 and 14 (46.7%) patients had pain score of 6 In group-B 96.7% had pain score below 6 and 3.33 had pain score of 6. The differences were found statistically significant with p-value equal to 0.0001.

The pain score was 6 in 12(40%) of patients in group A and 19(63.3%) in group B by the end of eight hour which was not statistically non-significant. At the end of 12th and 24th hour, group A had 9(30%) and 13(43.3%) patients with pain score of 6 and in group-B 9 (30%) and 11(36.7%) with similar pain score respectively. The differences were found statistically insignificant.

Table 6: Duration of analgesia.

Duration of Analgesisa	N	Mean	SD	P Value
Group A	30	247.16	36.429	<0.0001
Group B	30	433.5	60.189	

The mean duration of analgesia was 247.16 ± 36.43 min in group A with a range of 180 to 355 min. In group B, the mean duration of analgesia was 433.5 ± 60.2 min with a range of 265 to 530 min. The difference in the mean duration of analgesia was statistically highly significant (p<0.0001).

Table 7: Incidences of complications

COMPLICATIONS	Group A	Group B
Hypotension	0	0
Vomiting	3 (9%)	2 (6%)
Dural puncture	0	0
Blood vessel puncture	0	0
Respiratory depression	0	0
Pruritis	0	0

The incidence of nausea and vomiting was among 3(9%) children in group A compared to 2(6%) in group B. This was not statistically significant. There was no incidence of hypotension, bradycardia, dural or vessel puncture and respiratory depression in the two groups. The incidence of vomiting is shown in graph.

DISCUSSION

Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in pediatrics anesthesia. It is a reliable and safe technique that can be used with general anesthesia for intra and post-operative analgesia in pediatric patients undergoing lower abdominal and limb surgeries. The use of adjuncts can effectively help in reduction of the dose and an increase in duration of the local anesthetic agents 4. Our study was undertaken to assess the efficacy and safety of tramadol with bupivacaine in paediatric patients undergoing lower abdominal and lower limb surgeries under caudal analgesia.

Age & sex

In present study in group-A majority of patients (50%) were in age group 1-2 years followed by 33.3% patients in age group greater than 4 years and 16.6% patients were in age group 3-4 years. The mean age of patients in group-A was 2.96±1.62. Similarly, in group-B majority of patients (43.3%) were in age group greater than 4 years followed by 36.7% patients in age group 3-4 years and 20% patients were in age group 1-2 years. The mean age of patients in group-B was 3.87±1.2. The mean age was not statistically significant between two group with p-value 0.178. In consistent with this study by S Prakash et al 5 also found no significant difference in mean age of patients.

In present study in group-A90% patients were male children and 10% female children. In group-B 80% patients were male children and 20% female children. In study by S Prakash et al 5 also found in both the groups, sex distribution was equal, constituting 80% males and 20%females.

Changes in hemodynamic parameters:

In our study in group A the mean baseline heart rate was 110.46±15.09 per minute which decreased to 105.46±11.34 at 15 min. The heart rate gradually decreased to 99.53±11.57 per minute at 180 minute. The mean baseline heart rate in group B was 112.8±10.6 per minute which decreased to 108.7±9.1 at 15 minutes and gradually decreased to 105.8±12.41 at 180 minutes. However, there was no significant difference in the heart rate between the two groups (p > 0.05). In study by S Prakash et al 5 there were no significant changes in heart rate. Also in study by Meena Doda et al6 there were also no significant haemodynamic changes.

In group A, the mean baseline systolic blood pressure was 97.66±7.16 per minute which increased to 103.06±7.46 at 15 min. The systolic blood pressure gradually decreased to 94±6.4 per minute at 180 minutes. The mean baseline systolic blood pressure in group B was 100.7±5.6 per minute which increased to 101.4±6.2 at 15 minutes and gradually decreased to 96.1±3.8 at 180 minutes. However, there was no significant difference in the systolic blood pressure between the two groups at any time interval (p > 0.05).

In group A, the mean baseline diastolic blood pressure was 62.26±4.6 per minute which increased to 68.33±5.4 at 15 min. The diastolic blood pressure gradually decreased to 59.8±5.6 per minute at 180 minutes. The mean baseline diastolic blood pressure in group B was 61.7±6.7 per minute which increased to 66.26±6.1 at 15 minutes and gradually decreased to 59.23±11.66 at 120 minutes. However, there was no significant difference in the diastolic blood pressure between the two groups (p > 0.05). Hemodynamic changes appear to be less pronounced in children than in adults.

Post-operative analgesia:

Pain assessment is the most important and critical component of pain management. Assessing pain in children is an ever challenging as well as a difficult task, mainly because so far no reliable, universal method of assessing and measuring child's pain is available. In our study, we have used Pediatric Objective Pain scale which is a valid, objective and reliable method of pain assessment in children between 5 to 10 years. There was no incidence of pain score in group-A and group-B above 6 at the end of first and second hour and did not require any analgesia. At the end of third hour, 29(96.6%) of the patients in group-A had a pain score below 6 and 1 (3.33%) patients had pain score of 6. In group-B all patients had pain score was below 6. At the end of fourth hour, 16(50%) of patients in group A had a pain score below 6 and 14 (46.7%) patients had pain score of 6. In group-B 96.7% had pain score below 6 and 3.33 had pain score of 6. The differences were found statistically significant with p-value equal to 0.0001. The pain score was 6 in 12(40%) of patients in group A and 19(63.3%) in group B by the end of eight hour which was not statistically non-significant. At the end of 12th and 24th hour, group A had 9(30%) and 13(43%) patients with pain score of 6 and in group-B had 9 (30%) and 11(36.7%) with similar pain score respectively. The differences were found statistically insignificant. The duration of analgesia was significantly prolonged in bupivacaine-tramadol group (433.5±60.2 min) compared to bupivacaine alone group (247.16±36.4 min) in our study.

S. Prakash et Al5 studied 80 children, aged 2 and 8 yr undergoing inguinal herniotomy found that mean duration of postoperative analgesia was significantly increased on adding tramadol 1 mg/kg (720 ±90min) to plain bupivacaine 0.25%(1 ml/kg) (480± 90min).

Sedation score:

In our study, the sedation Score in group-A and group-B were below 3 at the end of first and second hour. At the end of third hour, 9(30%) of the patients in group-A had a sedation score below 3 and 21 (70%) patients had sedation score of ≥3. In group-B all patients had pain score was below 3. The differences were found statistically significant with p-value equal to 0.0001 At the end of fourth hour, all the patients in group A had a pain score of ≥3 and In group-B 15 (50%) sedation score was below 3 and 15 (50%) patients had pain score of ≥3. The differences were found statistically significant with p-value equal to 0.0001.

The sedation score was ≥3 in all the patients in group A and all the patients in group B had a score was ≥3 by the end of eight hour 12th and 24th hour which was statistically non-significant.

The duration of sedation corresponded closely with the duration of analgesia. It was difficult to distinguish between sedation and analgesia as we found that all the subjects were asleep provided they were comfortable and became restless or awake only when they were in pain and required analgesia.

Complications:

In our study, 3 of the children in group A and 2 of them in group B had an episode of vomiting which was treated with Inj Metaclopramide (0.1 - 0.2 mg/kg) IV. The incidence of vomiting was comparable in both groups, 9% and 6% in group A and B respectively. The addition of tramadol to bupivacaine in our study did not result in an increase in the incidence of side effects. The main side-effects of epidurally administered tramadol are bradycardia, hypotension and sedation. In our study, bradycardia or hypotension, warranting treatment, did not occur. Sedation, as mentioned earlier, correlated well with the duration of analgesia.

CONCLUSION

We conclude that tramadol in a dose of 1 mg/kg, added to 0.25% bupivacaine for caudal analgesia and administered as a 1ml/kg mixture in children, for infraumbilical surgery, significantly prolongs the duration of post-operative analgesia when compared to 1ml/kg of 0.25% bupivacaine alone, without any side effects.

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Nil.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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