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A Comparative Study of Caudal Analgesia with Bupivacaine Alone and Bupivacaine with Butorphanol in Pediatric Surgeries

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Abstract

Introduction: The assessment of pain in small children is often difficult to interpret as the most common sign of pain is crying which is also seen in a myriad of non pain full conditions. Epidural space in children favours rapid longitudinal spread of drugs and makes it effective in treating postoperative pain. *Aim:* The aim of this study was to evaluate the efficacy of caudal bupivacaine alone or in combination with butorphanol for postoperative analgesia in children undergoing infra-umbilical surgeries. *Materials and Methods:* A Simple Randamoized which includes 50 patients posted for urogenital operations such as herniotomy, orchidopexy, urethroplasty and CTEV Correction divided into two groups of 25 each. Group B received 0.25% plain bupivacaine and Group BB received 0.25% Bupivacaine with Butorphanol adjuvant. The effect of recovery from caudal blockade and duration of analgesia was compared and contrasted. *Results:* There were no significant changes in heart rate, blood pressure and oxygen saturation between two groups. Postoperative pain score was comparable in two groups in first eight hours, but it is significantly less in bupivacaine with butorphanol group which is statistically significant. There is a significant difference between the groups in the mean duration of analgesia with Group BB having a much longer duration compared to Group B. 3 patient in Group B and 5 patient in Group BB had nausea in postoperative period, which is statistically insignificant (p>0.05). No episodes of any other clinically significant postoperative complications were recorded. *Conclusion:* Butorphanol is considered to be a safe and effective adjuvant to Bupivacaine for caudal analgesia in children undergoing surgery below umbilicus.

Keywords: Bupivacaine; Butorphanol; Pediatric Surgeries

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Introduction

Pain, as defined by international association for study of pain, is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. The mechanism of pain perception in pediatric[1] population is different and is complex and is not often adequately understood rather than emphasizing on the clinical evaluation alone; biopsychosocial perspective needs to be looked deeply while managing pain in this special

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population. The assessment of pain in small children is often difficult to interpret as the most common sign of pain is crying which is also seen in a myriad of non painful conditions. There have been recent developments in the pediatric post operative pain management with emphasis of adequate treatment of pain early to prevent morbidity in this patient population. These developments are highly important in developing nations where the progress of anesthesia specialty has been non uniform and at a varied pace.

The various methods[2,3] of providing pain relief have some side effects which prohibit their use in children for eg. narcotics, because of their respiratory depression, the other analgesics which cannot be given for some time after general anesthesia due to the fear of vomiting and a spiration, the fear of the needles in the case of parentally administered analgesics. The regional anesthetic techniques significantly decrease post operative pain and systematic analgesic requirements. Caudal route was chosen for this study as it is one of the simplest and safest techniques in pediatric anesthesia with a high success rate. Epidural space in children favours rapid longitudinal spread of drugs and makes it effective in treating postoperative pain.

Caudal block is usually done after the introduction of general anesthesia an disused as an adjunct to intraoperative anesthesia as well as postoperative analgesia in children undergoing surgical procedures below the level of the umbilicus. Caudal analgesia can reduce the amount of inhaled and IV anesthetic administration, attenuates the stress response to surgery facilitates a rapid, smooth recovery, and provides good immediate post operative analgesia[1,3]. In order to decrease peri-operative analgesic requirements after single shot caudal epidural blockade, various additives, such as morphine, fentanyl, clonidine and ketamine with local anesthetics have been investigated.

The aim of this study was to evaluate the efficacy of caudal bupivacaine alone or in combination with butorphanol for postoperative analgesia in children undergoing infra-umbilical surgeries.

Materials and Methods

The present study is Simple Randamoized study at Osmania general hospital and Niloufer hospital, between August 2016-September 2017, who underwent lower abdominal and lower limb surgeries after obtaining institutional ethical committee and parental written informed consent.

Inclusion Criteria: Age groups 1-10 years, ASA grade I and II, Cases scheduled for operations such as urethroplasty, herniotomy, orchidopexy and CTEV correction.

Exclusion criteria: H/o of central nervous disease, sacral abnormalities, H/o of drug allergy, H/o of bleeding disorder AND skin infection at the site of block.

Patients were allocated by randomly in to two groups of 25 patients each.

Group B receive 0.25% plain Bupivacaine 1 ml/kg for caudal block.

Group BB 25 mcg/kg added to 0.25% bupivacaine 1 ml/kg.

In all children, age, body weight, and baseline vital parameters were recorded. History regarding previous anesthesia, surgery, any significant medical illness, medications and allergy was recorded. Complete physical examination, airway assessment and local examination of lower back were done.

Hemoglobin percentage, bleeding time, clotting time, blood sugar, urea, serum creatinine and urine analysis, USG. Patients were fasted for 4 hours and pre medicated with oral Midazolam 0.5 mg/kg 30 minutes before surgery. After applying standard monitors, an intravenous cannula was secured and Isolyte-p solution was infused to provide fluid during surgery. Injection Glycopyrrolate 0.01 mg/kg was administered intravenously as premedicant. General anesthesia was induced with Thiopentone sodium 5 mg/kg, 2% sevoflurane and Nitrous oxide in oxygen via mask.

Endotracheal intubation was facilitated by administering injection vecuronium bromide 0.1 mg/kg intravenously. After securing Endotracheal tube, patients were placed in left lateral position.

Procedure

After placing lateral position, skin of the back over the sacrum was scrub using povidone iodine solution, Under aseptic precautions, a short beveled 22 G needle was introduced proper position of needle confirmed by the pop sensed during penetration of sacro-coccygeal membrane of caudal epidural space, which was followed by whoosh test done using 0.5 ml of air after needle insertion negative aspiration of blood and cerebrospinal fluid, then 1 ml/kg of local anaesthetic agent 0.25% bupivacaine given to Group B and 0.25% Bupivacaine with Butorphanol adjuvant to Group BB was administered slowly.

After deposition of the drug in epidural space, patients were placed in supine position and anesthesia was maintained by 1% sevoflurane, 50% of Nitrous oxide plus 50% oxygen and top up doses of vecuronium bromide ($1/5^{th}$ of the loading dose of 0.1 mg/kg).

HR and blood pressure were recorded just before and after surgical incision and then every 5 min interval till the end of surgery, residual neuromuscular blockade was reversed and patients were transferred to the post operative ward.

Using the paediatric observations FLACC (face, legs, activity, cry, consolability) pain scale with its 0-10 score range, each patients pain intensity was assessed at the end of surgery and then every 30 min interval until the patient became fit to discharge from postoperative ward.

If the FLACC pain scale was 4 or more, rectal Paracetomol 20 mg/kg was administered.

Observations were continued for 24 hours. Complications such as postoperative nausea and vomiting (PONV), respiratory depression, urinary retention, hypotension and bradycardia were also noted. Respiratory depression was defined as a decrease in SpO_2 of less than 95% requiring supplementary oxygen. Hypotension was defined as fall of 20% mean arterial pressure from base line. Bradycardia was defined as HR below 80 beats/min for age 1 year and 60 beats/min for ages above 1 year. The parameters were compared in two groups and results subjected to appropriate statistical analysis are Hemodynamic parameters and Quality of postoperative analgesia effect.

Stastistical Analysis

All recorded data were entered using MS Excel software and analysed using spss 16 version software for determining statistical significance. Numerical variables were presented as mean and standard deviation (SD) and categorical variables were presented as frequency (%).

Student's t test was used for between-group comparisons between categorical variables.

A p value of <0.05 was taken to be significant and a p value of <0.001 was considered highly significant.

Results

This study includes 50 patients posted for urogenital operations such as herniotomy, orchidopexy, urethroplasty and CTEV Correction divided into two groups of 25 each. Group B received 0.25% plain bupivacaine and Group BB received 0.25% Bupivacaine with Butorphanol adjuvant. The effect of recovery from caudal blockade and duration of analgesia was compared and contrasted.

Table 1: Patient characteristics and clinical parameters

Patient details	Group B	Group BB
Age (in years)	3.72	3.70
Weight (in Kg)	12	12
Gender M:F Ratio	23:02	23:02
Duration of Anesthsisa (in min)	35	31
Baseline Heart Rate (Beats per min)	106.8	104
Baseline map	72.9	75

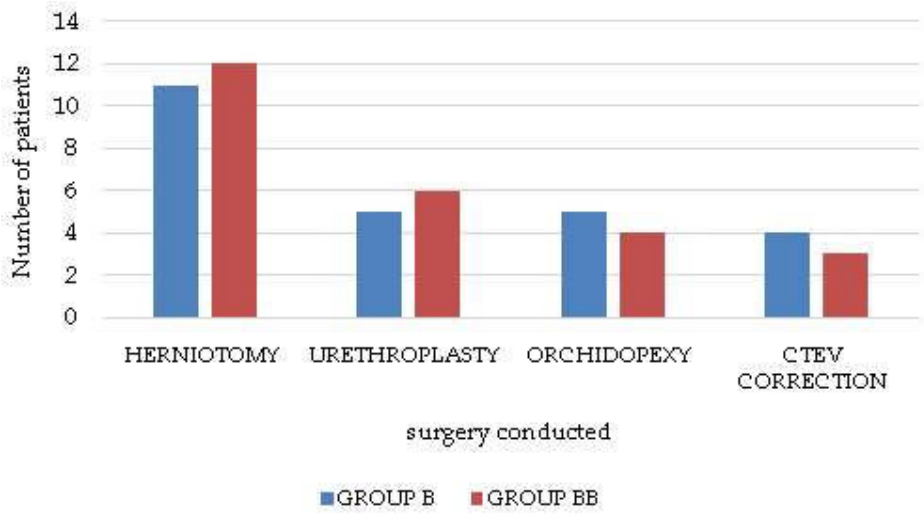

Fig. 1: Nature of Operations

Table 2: Haemodynamic changes during surgery

	Group B		Group BB		Standard deviation for B group		Standard deviation for BB group		*p* value	
	HR	MAP	HR	MAP	HR	MAP	HR	MAP	HR	MAP
Base line	104	75	106.80	72.90	8.3	4.6	8.1	5.7	>0.10	>0.10
After incision 5 min	91	70	97.7	68.9	7.7	4.3	8.3	4.6	>0.05	>0.10
10 min	91.3	70	93.5	68.1	6.9	4.9	6.8	5.1	>0.06	>0.07
20 min	89	71.	91.2	68.2	6.48	5.3	6.01	5.5	>0.07	>0.10
30 min	88	71	89.5	68.2	5.5	5.8	5.45	5.7	>0.10	>0.10
60 min	85	70	86.5	70	5.3	4.4	5.25	4.7	>0.06	>0.07
90 min	82	72	85	68.1	5.1	5.9	5.1	5.2	>0.05	>0.10

Table 3: Postoperative pain scoring in two groups FLACC (face, legs, activity, cry, consolability) Score

Post Operation	Group B		Group BB		*p* Value
	Mean	SD	Mean	SD	
0 hour	0	0	0	0	
2 hour	1.4	0.49	1.12	0.33	0.0219
4 hour	2.8	0.9	2.2	0.41	0.0039
6 hour	4.38	1.35	3.72	0.79	0.0401
8 hour	7.2	0.76	5.44	1.04	< 0.0001

Table 4: Post operative complications

	PONV	Respiratory Depression	Urinary Retention	Hypotension	Bradycardia
Group B	3	Nil	Nil	Nil	Nil
Group BB	5	Nil	Nil	Nil	Nil

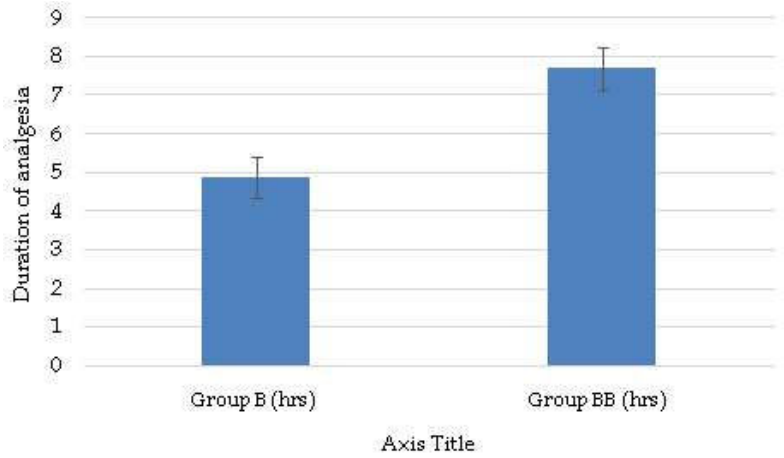

Fig. 2: Duration of analgesia

The calculated *p* value is >0.10, so this is statistically not significant. There were no differences between the two groups in age, weight, gender, duration of anesthesia, baseline blood pressure and heart rate (Table 1).

The preoperative, intraoperative and postoperative haemodynamic changes between the groups were comparable and were not statistically significant and therapeutic interventions were not required. The calculated *p* value is < 0.01 to 0.05. Hence, it is significant (Table 2).

Postoperative pain score was comparable in two groups in first eight hours, but it is significantly less in bupivacaine with butorphanol group which is statistically significant (Table 3).

There is a significant difference between the groups in the mean duration of analgesia with Group BB having a much longer duration compared to Group B [*p* value <0.0001] (Fig. 2).

The table 4 shows 3 patient in Group B and 5 patient in Group BB had nausea in postoperative period, which is statistically insignificant (*p*>0.05).

No episodes of any other clinically significant postoperative complications were recorded.

Discussion

Over the recent years, the concept of providing adequate postoperative analgesia in pediatric patients is well established, however, various methods showed side-effects limiting their use such as respiratory depression with IV opioids. With a high success rate, caudal analgesia was proved to be a simple and effective technique in children.

Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in pediatric anesthesia. It is a reliable and safe technique that can be used with general anesthesia for intra and postoperative analgesia in patients undergoing abdominal and lower limbsurgeries. The main disadvantage of caudal anesthesia is the short duration of action after a single injection of local anesthetic solution. Specific character of caudal block in pediatric age group.

Increased fluidity of epidural fat Increased diffusion of local anesthetic up to 6-7 Year of age.Excellent blockade after caudal anesthesia can be achieved up to 6-7 Year of age. The volume prescription scheme of Armit age that was published many years ago still remains the most dependable, asfollows: 0.5 mL/kg: All sacral dermatomes are blocked. The upper limit of anesthesia is at least Midthoracic. When 1.25 mL/kg is injected, excessive rostral spread (above T4) canoccuritis therefore preferable not to administer more than 1 mL/kg of local anesthetic. In present study both patients receive 0.25% bupivacaine 1 ml/kg as per armitage formula. An ideal combination of local anesthetic and adjuvant should provide adequate intraoperative anesthesia, good extended postoperative analgesia without prolonging the motor blockade or producing adverse hemodynamic or respiratory consequences.

Different additives have been used in order to improve the duration of action as well as the quality of analgesia of the local anesthetic used in the single shot caudal block technique such as opioids, epinephrine, clonidine, ketamine and neostigmine. The aim of this randomized control study was to compare the duration of postoperative analgesia, sedation, as well as the incidence of any side effect of caudally administered butorphanol to bupivacaine in pediatric patients undergoing lower abdominal and lower limb surgeries.

There has been a study by Lawhorn CD, Stoner JM, Schmitz ML, Brown RE Jr, Stewart FW, Volpe P, Shirey R4 in the literature of butorphanol use for caudal anesthesia/analgesia in pediatric population undergoing genitourinary procedure. It was found that requirement of rescue analgesia in post anesthesia care unit and total numbers of morphine doses administered were significantly less in patients in whom butorphanol 30 µg/ kg was added to bupivacaine in caudal epidural analgesia. Our study's findings are consistent with their findings but the differences from the present study were: they had used 0.25% bupivacaine with 1:200,000 epinephrine and caudal epidural analgesia along with general anesthesia.

In another study, by Ohta K, Katsuno M, Kawana S, Namiki A5 butorphanol has also been used in patients of cerebral palsy undergoing elective orthopedic operations and it was found to be safe and useful for postoperative pain control in children.

One of the interesting findings of the present study is the paucity of side effects associated with caudal butorphanol as mentioned in the literature. Its high lipid solubility and high affinity for opioid receptors are additional factors that contribute to the paucity of side effects with its use.

High lipid solubility increases diffusion in the spinal cord and limits the amount of drugs remaining in the CSF, capable of reaching the brainstem where side effects are detected. In a recent trial it has been demonstrated that there were less chances of complication or side effects with caudal analgesia as compared to parenteral use of analgesics or penile block in patients for circumcision.

For the pediatric caudal epidural analgesia, other opioids like morphine, buprenorphine, fentanyl and tramadol have been used. In a study by Gaitini LA, Somri M, Vaida SJ, Yanovski B, Mogilner G *et al.* added fentanyl to bupivacaine in caudal epidural block to observe changes in plasma catecholamine levels in postoperative period. Addition of fentanyl citrate to bupivacaine in caudal epidural block in children did not influence the stress response to surgery, nor did it improve the analgesic intensity of the caudal block as described in literature.[6]

Drug like clonidine has also been used in a study by Lee JJ, Rubin AP but its use in caudal analgesia resulted in significant prolongation of duration of postoperative analgesia, with the side effects like bradycardia and urinary retention.[7] Veena Chatrath, Sarabjit Kaur. compared efficacy of caudally

administered clonidine with that of butorphanol, the mean duration of analgesia was statistically longer (p value < 0.01) in the group Butorphanol (822.0 ± 217.41 min) than Clonidine group (745.4 ± 216.69 min). The total number of 'rescue' analgesic doses required in the first 24 hrs was lesser in group B (0.80 ± 0.41) and C (0.96 ± 0.45).[8]

Caudal epidural use of morphine, buprenorphine or butorphanol in a study by Ohta K, Katsuno M, Kawana S, Namiki A. did not increase the frequency of side effects such as nausea, vomiting etc., and need for rescue analgesia was also less in these patients within 24 hours after operation.[5]

The use of tramadol in combination with 0.25% bupivacaine resulted in a significant increase in the analgesia time in study by Senel AC, Akyol A, Dohman D, Solak M. In a study by R. Pauranik, P. Gupta., added ketamine 5 mg/kg caudally and compared it with butorphanol 20 µg/kg. The study concluded the butorphanol provided superior analgesia for a longer duration than with ketamine.[10]

In our study, a total of 50 patients in the age group of 2-8 years were divided randomly in two groups (n=25). There were no differences between two groups with regard to demographic profile. Mean age in group B (receiving bupivacaine alone) was 3.72 and in group BB (receiving bupivacaine plus butorphanol) was 3.70. Sex ratio was also comparable, in both group B and group BB M:F=23:02.

During the study in both groups heart rate, blood pressure (SBP, DBP, MAP) were measured. The preoperative, intraoperative and postoperative haemodynamic changes between the groups were comparable and were not statistically significant (p value >0.05) and therapeutic interventions were not required.

The post operative pain score was comparable in two groups at 0,2,4,6,8 hrs, rescue analgesia was given with FLACC score more than 4. The score in butorphanol group was significantly lower with mean (5.44 ± 1.04) at 8 hrs while group B has mean (7.2 ± 0.76) with p value<0.0001.

In the present study the duration of analgesia is significantly longer in group BB. The mean duration of analgesia of group B was (4.875 ± 0.54 hrs) and that of group BB was (7.7 ± 0.55 hrs) with p value <0.0001 which is highly significant. In a study by Vinita Singh, Ashish Kanaujia and G. P. Singh. Compared efficacy of bupivacaine plus butorphanol with plain bupivacaine and plain butorphanol, in this study Sixty ASA physical status I and II patients of either sex aged 1–10 year were randomized to one of three groups. Group L received 1 ml/kg of 0.25% bupivacaine; Group B received 1 ml/kg of 25 µg/kg butorphanol diluted in normal saline; and Group LB received 1 ml/kg of 25 µg/kg butorphanol in combination with 0.25% bupivacaine, in caudal epidural anesthesia. Hemodynamic variables (HR and MAP) and respiratory rate were monitored in all patients. Sedation score, pain score and requirement of rescue analgesia were recorded at preset time intervals along with postoperative complications.[4] There was no difference among the groups regarding sedation scores, requirement of rescue analgesia and postoperative complications. Mean duration of analgesia was maximum in group BL (14.5 ± 3.5 hr, p<0.001), than in group L (8.8 ± 4.8 hr) and group B (6.8 ± 2.9 hr). Conclusion of this study is comparable with our study, addition of 25 µg/kg butorphanol to bupivacaine resulted in superior analgesia with a longer period compared with caudal bupivacaine and butorphanol alone, without an increase of side effects.

Kundan Gosavi, Nilam Virkar *et al*. Compared caudal Butarphanol and Clonidine as an Adjuvant to Bupivacaine.[5] This study compared duration of analgesia and side effects of butorphanol and clonidine in caudal block along with general anesthesia in this double blind, randomised, controlled prospective study. 60 ASA grade I children of 20 to 10 years posted for infraumbilical abdominal or genitor urinary surgeries were randomly divided in three groups to receive bupivacaine 0.25% 1 ml/kg with either normal saline 1 ml (group B, control) or with butorphanol 25 mcg/kg (group BB) or clonidine 1 mcg/kg (group BC) in 1 ml by caudal route. Intraoperative and postoperative haemodynamic and respiratory parameters were recorded. Quality of analgesia was assessed using modified objective pain score. Results were analysed using Student's t test and chi- square test. Both BB and BC group showed better haemodynamic profile than group B. bradycardia and hypotension were at minimum at this dose of clonidine. Clonidine group had duration of analgesia (460.6 ± 45.86 mins) significantly longer than BB (378.8 ± 13.31 mins) and B group but also had higher sedation score in immediate postoperative period and can be a good option in paediatric neuraxial blockade. Though we did not compare with clonidine our results are similar to group B, group BB where duration of analgesia is significantly longer in group with butorphanol.

Complications such as postoperative nausea and

vomiting (PONV), respiratory depression, urinary retention, hypotension and bradycardia were also noted. Respiratory depression was defined as a decrease in SpO_2 of less than 95% requiring supplementary oxygen. Hypotension was defined as fall of 20% mean arterial pressure from base line. Bradycardia was defined as HR below 80 beats/min for age 1 year and 60 beats/min for ages above 1 year. In present study 3 patient in Group B and 5 patients in Group BB had nausea in postoperative period, which was statistically in significant ($p > 0.05$). There has been no other side effects like respiratory depression, hypotension, bradycardia or urinary retention. Although the children in butorphanol group has higher sedation than with plain bupivacaine group.

Conclusion

Caudal Butorphanol 25 µg/kg, combined with 0.25% Bupivacaine 1 ml/kg, provides longer duration of postoperative analgesia, less requirement of rescue analgesia, stable intraoperative vitals, in significant changes in hemodynamics intraoperatively and fewer postoperative side effects. Hence Children remained calm, quiet and minimally sedated but easily arousal. Thus, Butorphanol is considered to be a safe and effective adjuvant to Bupivacaine for caudal analgesia in children undergoing surgery below umbilicus.

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