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RESEARCH ARTICLE

COMPARATIVE STUDY OF POST-OPERATIVE CAUDAL ANALGESIA FOR PAEDIATRIC PATIENTS UNDERGOING LOWER ABDOMINAL SURGERY

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A B S T R A C T

Background Caudal epidural analgesia is commonly used in pediatric anesthesia. It is a safe and reliable technique that can be used with general anesthesia for perioperative analgesia in patients undergoing abdominal surgeries. The aim of the study to evaluate quality and duration of analgesia with various dosages of clonidine with levobupivacaine as an adjuvant.

Method Ninty children, age one to nine years, undergoing lower abdominal surgery, were comprises to three groups: caudal analgesia with 1 ml/kg of 0.25% levobupivacaine in normal saline (group I), 1 ml/kg of 0.25% levobupivacaine with 0.8 µg/kg of clonidine (group II) and 1 ml/kg of 0.25% levobupivacaine with 1.0 µg/kg of clonidine (group III). Post-operative pain was assessed by FLACC scale for 15 hours.

Result Pain of children was assessed on the Face, Legs, Activity, and Cry, FLACC scale. At 15 min. after the procedure score of all the subjects in Group I, Group II and Group III was found to be '0'. The score remained '0' at all time intervals up to 2 and 4 hours FLACC score. The difference in FLACC score among the groups was found to be statistically significant. Between group differences were found to be statistically significant between Group I & Group II and between Group II & Group III. No difference in FLACC score of Group I and Group III was found.

Conclusion Clonidine in a dose of 1 µg/kg added to 0.25% levobupivacaine for caudal analgesia, during lower abdominal surgeries, prolongs the duration of analgesia, and reduced the rescue analgesia without any adverse effects.

INTRODUCTION

Caudal epidural analgesia is very popular technique and frequently performed regional blocks in pediatric anesthesia [1, 2]. It is a safe technique and reliable that can be used with general anesthesia for perioperative analgesia in patients undergoing abdominal surgeries. Caudal analgesia can reduce the amount of inhaled and intravenous anesthetic administration, decrease the stress response to surgery, facilitate a smooth recovery rapid, smooth recovery, and provide good immediate postoperative analgesia [3]. The use of caudal catheters to administer repeated doses or infusion of local anesthetic solution is not popular, because of the risk of infection and delay in early mobilization. So to prevent these risks another way is to add an adjuvant to prolong the duration of analgesia by single shot technique [4]. Postoperative pain relief in an in pediatric age groups is a main concern to the anesthesiologist as pain not only distresses the patient, but also increases anxiety in which the parents can be comforted by good postoperative analgesia. Caudal block regional techniques is one of the most common used in pediatric anesthesia. Recently it has gained popularity, especially for surgical procedures below the umbilicus, as it is a safe, simple, and reliable technique [3, 4]. Caudal analgesia with levobupivacaine is very common in pediatric anesthesia for providing intra- and postoperative analgesia. Several adjuncts such as aphids, ketamine, midazolam, neostigmine and clonidine wear used with bupivacaine to prolong its action [5-9] and thus extend the duration of post-operative analgesia provided by the single dose caudal technique [10-13]. Amongst all adjuvants, clonidine is one of the most commonly used. Clonidine is a α-2 adrenergic agonist, has widely been used in neuraxial and peripheral nerve blocks prolong the action of levobupivacaine [14, 15]. Aim of the study to evaluate the efficacy of clonidine as an adjuvant to levobupivacaineused in caudal block for prolonging analgesia in children undergoing sub-umbilical surgery and the possible side effects.

MATERIALS AND METHODS

This is a prospective case study was performed after obtaining the approval of the institutional ethical committee. Patients were randomized into three groups (n=30 in each group) using a computer generated random number tables. These groups were further classified, based on the caudal block drug combination used.

Group I 1 ml/kg body weight levobupivacaine 0.25% with normal saline

Group II 1 ml/kg body weight levobupivacaine 0.25% ± 0.8 µg/kg clonidine

Group III 1 ml/kg bodyweight levobupivacaine 0.25% + 1 µg/kg clonidine

The effect of the anesthetic agent and its combination with various adjuvants on the duration was analyzed by the relevant statistical test. They are included in children between 1 to 9 years, posted for lower abdominal surgeries with informed written consent from their parents and ASA physical status-I and II and excluded in parental unwillingness, Body weight > 25 kg children with preexisting neurological or spinal disease, cardiovascular, respiratory, renal, hepatic or any other systemic disease; bleeding diathesis, infection at the site of block, abnormalities of the sacrum, allergic to local anesthetics, aspirin ingestion in the preceding week, chronic use of any anti-inflammatory drugs.

All children were fasted and were given midazolam 0.5 mg/kg PO 30 min before surgery in the preoperative room as premedication. After obtaining ivaccess, infusion of lactated ringer's solution was started. All the monitors were placed (i.e. pulse oximeter, NIBP and electrocardiogram). The patients were preoxygenated for 5 minutes with facemask. Anaesthesia was induced with propofol 2–4 mg/kg and endotracheal intubation facilitated by succinylcholine 1.5–2 mg/kg. Anaesthesia was maintained with 0.5 to 1% halothane and 60% nitrous oxide with atracurium and lungs were ventilated mechanically. The FLACC scale for pain assessment in children: There are five parameters, each given a score of 0–2 and the total score is taken to assess pain.

The study drugs were randomly prepared by an anesthetist, who was not involved in the study, in unlabeled syringes and handed to the Anaesthesiologist who was blind to the identity of the drug. All study drugs were kept at room temperature and used within 30 min of preparation. Paediatric patients undergoing lower abdominal surgery under general anaesthesia between age groups of 2–6 years. Baseline vitals were noted - pulse rate, SBP, DBP, MAP, heart rate, SpO2. 15 min before extubation caudal block was given to the patient and followed in post op period and pain was assessed based on FLACC scoring.

The time from arrival in the post anaesthesia care unit to the first time the FLACC score was greater than 4 was recorded And noted as the duration of adequate caudal analgesia.

Statistical analysis

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) version 15.0. The values were represented in number (%) and mean±SD.The student "t" test and analysis of variance (ANOVA) were used for analysis ofquantitative parametricdata. For non-parametric quantitative variable, Kruskall-Wallis H test and Mann Whitney U test were used. 'P value' less than 0.05 was considered to be significant.

RESULTS

The present study was carried out with an aim to evaluate the analgesic activity of different combinations of levobupivacaine and clonidine among children undergoing surgical procedures under the caudal block. Out of 90 patients, a total of 30 (33.3%) received levobupivacaine 0.25% alone in group I, levobupivacaine 0.25% with 0.8 µg/kg of clonidine in group II and levobupivacaine 0.25% with 1 µg/kg of clonidine in group III were enrolled in the study (Table 1).

Table 1 Group wise distribution of patients

S. No.	Group	Description	No. of patients	Percentage (%)
1.	I	Patients who received Levobupivacaine 0.25% alone	30	33.3
2.	II	Patients who received Levobupivacaine 0.25% with 0.8 µg/kg of clonidine	30	33.3
3.	III	Patients who received Levobupivacaine 0.25% with 1 µg/kg of clonidine	30	33.3

Pain of children was assessed on the face, legs, activity, and cry, consolability scale or FLACC scale. At 15 min. after the procedure score of all the subjects in group I, group II and group III was found to be '0'. The score remained '0' at all time intervals up to 2 hours. At 4 hours FLACC score of group I was found to be 1.37±0.49 while that of group II and group III remained to be 0.00±0.00. The difference in FLACC score among the groups was found to be statistically significant. Between group differences were found to be statistically significant between Group I and group II and between group I and group III. No difference in FLACC score of group II and group III was found (Table 2).

Table 2 Intergroup and between group comparisons of FLACC scale at different time intervals

	Group I (n=30)		Group II (n=30)		Group III (n=30)		Statistical Significance				
							Intergroup comparison (Kruskall-Wallis H test)		Between group Comparison (Mann Whitney U test)		
									I Vs. II	I Vs. III	II Vs. III
	Mean	SD	Mean	SD	Mean	SD	H	p	p	p	p
15 min after	0.00	0.00	0.00	0.00	0.00	0.00	0.000	1.000	1.000	1.000	1.000
30 min	0.00	0.00	0.00	0.00	0.00	0.00	0.000	1.000	1.000	1.000	1.000
45 min	0.00	0.00	0.00	0.00	0.00	0.00	0.000	1.000	1.000	1.000	1.000
1 h	0.00	0.00	0.00	0.00	0.00	0.00	0.000	1.000	1.000	1.000	1.000
2 h	0.00	0.00	0.00	0.00	0.00	0.00	0.000	1.000	1.000	1.000	1.000
4 h	1.37	0.49	0.00	0.00	0.00	0.00	85.684	<0.001*	<0.001*	<0.001*	1.000
6 h	4.60	1.16	0.00	0.00	0.00	0.00	84.789	<0.001*	<0.001*	<0.001*	1.000
8 h	4.60	1.16	1.33	1.12	1.10	0.76	58.394	<0.001*	<0.001*	<0.001*	0.492
10 h	.	.	5.10	0.66	3.30	0.47	43.441	<0.001*	-	-	<0.001*
12 h	.	.	6.43	0.77	4.70	0.92	32.591	<0.001*	-	-	<0.001*
15 h	.	.	8.43	0.50	7.60	0.77	17.414	<0.001*	-	-	<0.001*

*= Significant (p<0.05)

At 6 hours FLACC score of group I was found to be 4.60±1.16 while that of group II and group III remained to be

0.00±0.00. The difference in FLACC score among the groups was found to be statistically significant. Between group differences were found to be statistically significant between group I And group II and between group I and group III. No difference in FLACC score of group II and group III was found. At 8 hours FLACC score of was found to be 4.60±1.16 in group I, 1.33±1.12 in group II and 1.10±0.76 in group III. The difference in FLACC score among the groups was found to be statistically significant. Between groups differences were found to be statistically significant between group I and group II and between group IAndgroup III. The difference in FLACC scores of group II and group III was not found to be statistically significant. At 12 hours and 15 hours FLACC scores of group III was found to be significantly higher than that of group I and group II (Table 2). No pain was observed in patients of all the groups from 15 minutes before to 2 hours. Start of pain was early in group I (at 4 hours), change was found to be statistically significant at all time periods i.e. 4 hours, 6 hours and 8 hours. In group II and group III, start of pain was observed at 8 hours and change was found to be statistically significant at all time periods, i.e. 8 hours, 10 hours, 12 hours and 15 hours (Table 3).

Table 3 Intragroup change in FLACC from 15 minutes before procedure at different time intervals (Wilcoxon signed rank test)

	Group I				Group II				Group III			
	Mean change	SD	Z	'p'	Mean change	SD	't'	'p'	Mean change	SD	't'	'p'
15 min before	–	–	–	–	–	–	–	–	–	–	–	–
15 min after	–	–	–	–	–	–	–	–	–	–	–	–
30 min	–	–	–	–	–	–	–	–	–	–	–	–
45 min	–	–	–	–	–	–	–	–	–	–	–	–
1 h	–	–	–	–	–	–	–	–	–	–	–	–
2 h	–	–	–	–	–	–	–	–	–	–	–	–
4 h	1.37	0.49	4.964	<0.001*	–	–	–	–	–	–	–	–
6 h	4.60	1.16	4.843	<0.001*	–	–	–	–	–	–	–	–
8 h	4.60	1.16	4.843	<0.001*	1.33	1.12	4.069	<0.001*	1.10	0.76	4.332	<0.001*
10 h					5.10	0.66	4.903	<0.001*	3.30	0.47	5.007	<0.001*
12 h					6.43	0.77	4.995	<0.001*	4.70	0.92	4.898	<0.001*
15 h					8.43	0.50	4.939	<0.001*	7.60	0.77	4.903	<0.001*

*= Significant (p<0.05)

In group III rescue analgesia was required between 10 to 11 hours of the start of the procedure while in group II between 9.50 to 11 hours and in group I between 4 to 5.25 hours. The difference in mean duration of the requirement of analgesia among the groups was found to be statistically significant (F=2680. 280; p<0.001). Between groupsthe duration of the requirement of analgesia was found to be statistically significant between group I andgroup II and between group I andgroup III. The difference in mean duration of analgesia between group II and group III was not found to be statistically significant.

Table 4 Intragroup and between group comparison of duration of rescue analgesia

Group	No. of patients	Min	Max	Mean	S.D.	Statistical significance				
						Inter group		I Vs. II	I Vs. III	II Vs. III
						F	p	p	p	p
Group I	30	4.00	5.25	4.48	0.38	2680.280	<0.001*	<0.001*	<0.001*	0.74
Group II	30	9.50	11.00	10.18	0.29					
Group III	30	10.00	11.00	10.39	0.38					

*= Significant (p<0.05)

During the post-operative period, patients were also monitored for adverse effects, including respiratory depression, vomiting, hypotension and bradycardia. Respiratory depression was defined as a decrease in oxygen saturation less than 93%, requiring oxygen by face mask. Hypotension was defined as systolic blood pressure less than 70 mm Hg and bradycardia was defined as a heart rate less than 75 beats/min. (Table 4). In our study, no cases in any group had bradycardia (heart rate 75 beats/min), hypotension (SBP <70 mm Hg), or respiratory depression (SpO2 <93%) in 24 hours of postoperative analgesia monitoring.

DISCUSSION

Levobupivacaine is considered as an effective agent for caudal anesthesia in children at a recommended dose of 2.5 mg·kg [1]. It appears to be of equivalent potency to racemic bupivacaine in children requiring lower abdominal surgery [16]. In our study, we have used in. levobupivacaine 0.25%, 1 ml/kg for caudal block as it is a pure S (-) -enantiomer of bupivacaine due to its lower cardiovascular side effect and decreased chances of central nervous system toxicity [17]. In this study, baseline and till 2 hours FLACC score were not significantly different in between all three groups. At 4 hours FLACC score of group I was found to be raised while that of Group II and group III remained the same. Start of pain was earlier in group I (at 4 hours) in comparison to group II and group III and the change was found to be statistically significant at 8 hours. In group II and group III, start of pain was observed at 8 hours and change was found to be statistically significant at all time periods i.e. 8, 10, 12 and 15 hours. Similarly, Parameswari *et al*. (2010), reported that the clonidine as an adjuvant to bupivacaine for caudal analgesia in children and it was seen that the duration of analgesia in the clonidine group in their study was 10 hours, while that in the plain bupivacaine group was 4.5 hours, which was similar to other studies [18]. El-Hennawy A *et al*. (2009), shows that the clonidine or dexmedetomidine to bupivacaine prolongs caudal analgesia in children and concluded that addition of dexmedetomidine or clonidine to caudal bupivacaine significantly promoted analgesia time (16 and 12 hours, respectively) than the use of bupivacaine alone (5 hours) [19]. Clonidine 1 µg/kg with 0.1% ropivacaine provided increased duration (590.25±83.93 minutes) and better quality of pain relief with no motor blockade and sedation compared to plain 0.1% ropivacaine (243.7±99.29 minutes) and 0.2% ropivacaine (388.5±82.35 minutes) [20].

In our study, the duration of analgesia requirement was more in group III and II as compared to group I. Meghani *et al*.

(2014), reported that the required rescue analgesics were lower in bupivacaine with clonidine group as compared to plain bupivacaine group [21]. In paediatric age group, a combination of 0.25% bupivacaine with 1- 2 µg/kg clonidine has foundto enhance the duration and quality of rescue analgesia [22].

In this study, the adverse effects were not significantly different between all three groups. Similarly, Parameswari *et al*. (2010), reported that the clonidine as an adjuvant to bupivacaine for caudal analgesia in children did not shows any adverse effects [18]. Contradictory, the frequency of side effects like bradycardia, hypotension and respiratory depression increased with increasing dose clonidine [23].

CONCLUSION

We conclude that the combination of levobupivacaine with clonidine was significantly prolongs the duration of post-operative analgesia and reduce the requirement of rescue analgesia, without any adverse effects.

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