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Research Article

CAUDAL ANAESTHESIA FOR SUB-UMBILICAL PAEDIATRIC SURGERY: A STUDY OF POST-OPERATIVE BUPIVACAINE WITH DIFFERENT DOSE OF CLONIDINE

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A B S T R A C T

Background: Caudal analgesia is frequently used as an paediatric anaesthesia. It is a safe and reliable technique that can be used with general anesthesia for perioperative analgesia in patients undergoing abdominal surgeries. Clonidine is an alpha2-adrenergic agonist, used for analgesic effects in different doses with 0.25% bupivacaine. The aim of the study to evaluate quality and duration of analgesia with various dosages of clonidine with bupivacaine as an adjuvant.

Method: A totalninetypaediatric patients were comprises to three groups(30 each group): caudal analgesia with 1 ml/kg of 0.25% bupivacaine in normal saline (group I), 1 ml/kg of 0.25% bupivacaine with 0.8 µg/kg of clonidine (group II) and 1 ml/kg of 0.25% bupivacaine with 1.0 µg/kg of clonidine (group III)undergoing lower abdominal surgery. FLACC scale was used for assessment of post-operative pain.

Result: At 15 min. after extubation the mean score were significantly lower in group III (0.89±0.370 as compared to group II (1.30±0.35) and group I (1.97±0.43). The mean duration of 1st time requirement of analgesia in the group III was significantly longer as compared to group II and group I. Moreover, the number of patients requiring rescue anaesthesia one dose or two dose were comparable in between groups.

Conclusion: our study showed that the clonidine 1 µg/kg with 0.25% bupivacaine for caudal analgesia was prolongs the duration of analgesia and lower the requirement of rescue analgesia.

INTRODUCTION

The most preferred paediatric regional anesthesia techniques are caudal and lumbar epidural blocks and ilioinguinal, iliohypogastric, and penile nerve blocks Markakis, 2000). When compared with adults, lower concentrations of local anesthetics are sufficient in children; rapid onset but the duration is usually less (Jöhr, 2015). The finding for the best adjuvant and local anesthetic in respect to efficacy, safety, and prolonged period of analgesia, till date continues (Lönnqvist, 2005). Bupivacaine was routinely used for caudal block because it decrease the risk of unwanted motor blockade (Ivani *et al*., 2005).

Bupivacaine is the most commonly used local anaesthetic for sub-umbilical paediatric surgery. The bupivacaine is the small duration of action (4-6hours) when administered as a 'single shot technique'. Numerous adjuncts such as opioids, midazolam, clonidine and ketamine have been used to prolong the action of bupivacaine (De Beer and Thomas, 2003; Ansermino et a., 2003; Kumar *et al*., 2005; Tsui *et al*., 2005; Sanwatsarkar *et al*., 2017; Priolkar *et al*., 2016). Therefore prolong the duration of post-operative analgesia provided by the Single dose injection in caudal anesthesia technique.

Clonidine is an alpha 2 agonist. It has been extensively used for neuraxial and peripheral nerve blocks to extend the action of bupivacaine. It is one of the most frequently used additives with bupivacaine for caudal analgesia in children (Yildiz *et al*., 2006). In various study reported that the clonidine is improving and prolonging the analgesia effects of caudal bupivacaine. Caudal clonidine, combined with bupivacaine has been used in different doses and it was found that increasing the dose of clonidine from 1 µg/kg to 2 µg/kg did not enhance its efficacy (Lönnqvist, 2005; Sanwatsarkar *et al*., 2017; Priolkar *et al*., 2016; Yildiz *et al*., 2006; Kehlet, 1989; Beauvoir *et al*., 1994). However, hypotension and bradycardia was seen as a side effect in a dose dependent manner, the incidence being less with 1µg /kg (Lönnqvist, 2005; Sanwatsarkar *et al*., 2017; Priolkar *et al*., 2016). Therefore, weaim to evaluate the analgesic properties of different dose of clonidine analgesic additive in caudal bupivacaine in children.

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MATERIALS AND METHODS

This prospective comparative study was carried out after obtaining the approval from the institutional Ethical Committee. A total of 90 paediatric patients 3-10 years old The American Society of Anesthesiologists status I, II scheduled for infra-umbilical surgicalsurgerieswere included in the study. Informed consent were obtained from all the patients. Children with local infection of the caudal area, history of allergic reactions to local anesthetics, bleeding diasthesis, preexisting neurological or spinal diseases, mental retardation, neuromuscular disorders were excluded from the study.Patients were randomized in to three groups (n= 30 in each group) using computer generated random number table.
Caudal analgesia with 1 ml/kg of 0.25% bupivacaine in normal saline (group I), 1 ml/kg of 0.25% bupivacaine with 0.8 µg/kg of clonidine (group II) and 1 ml/kg of 0.25% bupivacaine with 1.0 µg/kg of clonidine (group III).

Patients were premedicated with midazolam 0.4mg/kg orally 30-40 min before surgery. All patients were given general anesthesia. Anesthesia were induced with oxygen, nitrous oxide 60% and halothane (2%-3%) through Jackson-Ree's modification of Ayre's T piece with appropriate size face mask and standard monitoring (heart rate, noninvasive blood pressure and pulse oximetry). After induction of anesthesia intravenous cannula was placed and Laryngeal Mask Airway (LMA) of appropriate size introduced. Anesthesia was maintained with O2-N_2O (1:2) and isoflurane (2%-3%) with respiration assisted manually with fresh gas flow of 2-3 L/min. Intra-operative, heart rate (HR), mean arterial blood pressure (MAP) and oxygen saturation (SpO2) were monitored.

Intraoperative the adequacy of analgesia was evaluated by haemodynamic stability, absence of a rise of heart rate (HR) and mean arterial pressure (MAP) of more than 15% of pre incision baseline values. If the more than 15% increase in HR or MAP, 20 minutes after administration, it was considered as failure of caudal anaesthesia and if HR, MAP increased after 45 minutes surgical incision it was considered as ainadequate analgesia. After failure of caudal or inadequate analgesia, patient was given fentanyl 2 µ/kg intravenously and was excluded from the study.

The patients were observed for 24 hours postoperatively. Pain score was assessed using the FLACC (F — face, L — leg, A — activity, C — cry, C — consolability) scale [Table 1](Merkel *et al*., 1997). Assessment of pain by FLACC scale was done at 0, 1, 2, 6, 12 and 24 hours postoperatively. The time from caudal placement of drug to the first recording of a FLACC score ≥4 was taken as the duration of analgesia. Sedation score was assessed by the – 4 point patient sedation score (Klimscha *et al*., 1998) at 2 hours, 4 hours and 6 hours postoperative. Side effects like nausea, vomiting, respiratory depression, pruritus hypotension, and bradycardia were also noted.

Statistical analysis

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) version 15.0. The data was presented as mean ± standard deviation for quantitative variables and in percentage for categorical ones. The student "t" test and analysis of variance (ANOVA) were used for analysis of quantitative parametric data. 'p-value' less than 0.05 was considered as a significant.

RESULTS

In the study none of the caudal blocks were considered as failed block in all 90 participants.In demographic data such as age, sex, weight, ASA grade and the duration of surgery were comparable in all three groups as shown in Table 2. Baseline of heart rate (pulse/min.) and MAP (mmHg) were also comparable in all three groups. The type of surgeries (Inguinal Hernia, Hypospadias, Undescended testis, Urethroplasty) were also compared between the three groups (Table 2).

Table 1 FLACC scale for pain assessment

Category	Scoring		
	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; Occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to; distractable	Difficult to console

Each of the five categories is scored from 0-2, resulting in total range of 0-10, FLACC = Face, Leg, Activity, Cry, Consolability; 0 = No pain, 1 - 3 = Mild pain, 4 - 7 = Moderate pain, 8 - 10 = Severe pain

Pain was assessed by FLACC scale. At 15 min. after extubation the mean score of all the subjects in group I, group II and group III was found to be 1.97±0.43, 1.30±0.35, 0.89±0.37. The mean FLACC score was significantly lower in Group III as compared to Group II and Group I [Table 2].

Table 2 Demographic characteristics of the patients

	Group I (n=30) Mean±SD	Group II (n=30) Mean±SD	Group III (n=30) Mean±SD
Age (month)	33.45±4.33	34.21±3.19	32.95±3.79
Sex			
Male	22 (73.33%)	23 (76.67%)	21 (70.0%)
Female	8 (26.67%)	7 (23.33%)	9 (30.0%)
Weight (kg)	13.71±2.11	13.83±2.03	14.01±2.27
ASA grade I/II	11/19	10/20	11/19
Duration of Surgery (min)	62±15	65±16	62±15
Baseline Heart Rate (pulse/min.)	109.04±6.45	109.68±7.14	110.17±7.88
Baseline MAP (mmHg)	78.32±7.20	80.41±7.67	79.56±7.43
Type of Surgery			
Inguinal Hernia	16 (53.33%)	14 (46.67%)	16 (53.33%)
Hypospadias	9 (30.0%)	10 (33.33%)	9 (30.0%)
Undescended testis	4 (13.33%)	4 (13.33%)	4 (13.33%)
Urethroplasty	1 (3.33%)	2 (6.67%)	1 (3.33%)

Data are represented as mean, ±SD, n (%) and ratio. SD=Standard deviation

Whereas the mean sedation score after 15 min extubation was also significantly greater in group III as compared to group receiving group II and control group I (Table 3). The mean duration of 1st time Analgesia requirement (min) in the group III was significantly longer as compared to group II and group I (Table 2). Moreover, the number of patients requiring rescue anaesthesia one dose or two dose were comparable in between groups (Table 3).

Table 3 Post-operative clinical data

	Group I (n=30) Mean±SD	Group II (n=30) Mean±SD	Group III (n=30) Mean±SD	p-Value
FLACC score (15 min after extubation)	1.97±0.43	1.30±0.35	0.89±0.37	<0.001*
Sedation score (15 min after extubation)	1.63±0.47	2.25±0.52	2.61±0.55	<0.001*
1st time Analgesia requirement (min)	278.13±19.50	465.17±21.21	512.10±29.27	<0.001*
No. of patients requiring rescue anaesthesia one dose (%)	17 (56.67%)	18 (60.0%)	18 (60.0%)	0.071
No. of patients requiring rescue anaesthesia two dose (%)	12 (40.0%)	7 (23.33%)	4 (13.33%)	0.057

Data presented as mean ± SD, *=Significant (p <0.01)

Intraoperative and postoperative heart rate were statistically similar in between group I, group II and group III. However the mean arterial pressures were also comparable in group I, group II and group III (Table 4).

Table 4 Heart rate (pulse/min) and Mean arterial blood pressure (mmHg) in all the study groups

Variable	Group I (n=30) Mean±SD	Group II (n=30) Mean±SD	Group III (n=30) Mean±SD	p-value
Heart Rate (pulse/mins)				
Intra-operative	115.85±7.88	114.12±8.48	113.7±8.12	0.98
Postoperative	107.03 ±8.72	105.64±52	102.19±8.76	0.96
MAP (mm of Hg)				
Intra-operative	74.14±8.14	73.09±7.82	74.02 ±8.35	0.95
Postoperative	73.15 ±8.12	71.34±7.48	71.28 ±9.26	0.89

Data presented as mean ± SD

The incidence of postoperative side effects such as sedation and respiratory depression were present in clonidine groups but there was comparable with controls group.

DISCUSSIONS

Bupivacaine has been used with various techniques in children, such as caudal injection, the lumbar epidural route for anesthesia during operation, continuous epidural infusion for pain control after operation, and for spinal anesthesia (Kehlet, 1989). Clonidine is a α_2 agonist, used as additive to local anesthetics such as bupivacaine (Beauvoir *et al*., 1994; Jamali1 *et al*., 1994; Ingelmo *et al*., 2005). Its addition increases duration and quality of local anesthesia.

Our study shows that addition of 0.8 µg/kg and 10 µg/kg clonidine with bupivacaine are safe and effective, prolonging the duration of postoperative analgesia via the caudal route in sub-umbilical paediatric surgery. But, 10 µg/kg clonidine with bupivacaine is more effective as it provides an extended duration of postoperative analgesia. Moreover, the requirements of postoperative rescue analgesic are significantly lower than 0.8 µg/kg clonidine and controls groups. The clonidine as an adjuvants are related with minimal side-effects. Our results are supported by similar findings of various previous studies (Sanwatsarkar *et al*., 2017; Priolkar *et al*., 2016; Jamali *et al*., 1994; Lee and Rubin, 1994; Tripi *et al*., 2005; Yildiz *et al*., 2006; Cook *et al*., 1995; Luz *et al*., 1999; Motsch *et al*., 1997). They reported that the caudal analgesia, a mixture of 1-2 µg/kg clonidine with 0.25% bupivacaine has been improve the duration and quality of analgesia in children. While various previous study shows the widely differ results, the duration of analgesia from 6.3 hrs (Luz *et al.,* 1999) to 16.4 hrs (Jamali *et al*., 1994) range for 1 µg/kg clonidine with 0.25% bupivacaine. In this study the 1µg/kg clonidine with 0.25% bupivacaine group was required significantly reduced number of analgesic doses postoperatively as compared to 0.8 and normal saline with 0.25% bupivacaine (control group). Similarly, Sanwatsarkar *et al*. (2017), Priolkar and D'Souza, 2016 and Cook *et al*. (1995), found that the number of doses of postoperative analgesics required were significantly lower in group containing bupivacaine and clonidine together as compared to bupivacaine alone group.

Our observations are supported by Parameswari *et al*. (2010) and Sanwatsarkar *et al*. (2017), who reported that the number of patients requiring 2 or 3 doses of rescue analgesic was more in the bupivacaine group compared to patients in clonidine with bupivacaine group.

In this study, we observed that the incidence of postoperative side effects respiratory depression and sedation were present in clonidine groups but there was comparable with controls group. Respiratory depression is a predictable but unwanted side effect of extradural opioid (Cook *et al.,* 1995; Parameswari *et al*., 2010). Several previous studies shows that in paediatric patients, there was not present any respiratory depression after caudal administration of clonidine with bupivacainee (Beauvoir *et al*., 1994; Jamali *et al*., 1994; Lee and Rubin, 1994; Motsch *et al*., 1997; Campbell *et al*., 1992; Moine *et al*., 1992). A sedative effect was observed after epidural clonidine in adults and to a lesser degree in children (Jamali *et al*., 1994; Lee and Rubin, 1994; Penon *et al*., 1991).

CONCLUSION

Caudal clonidine 1 µg/kg added with 0.25% bupivacaine is significantly prolongs the duration and quality of postoperative analgesia as compared to 0.8 µg/kg clonidine and plain bupivacaine with minimum side effects for sub-umbilical paediatric surgery.

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