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Original Research Article

A comparative study to compare the efficacy of hyperbaric bupivacaine alone and hyperbaric bupivacaine with clonidine in caudal block in paediatric lower abdominal surgeries

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ABSTRACT

Background: The aim was to compare the efficacy of addition of clonidine to hyperbaric bupivacaine and to compare it with plain hyperbaric bupivacaine for caudal analgesia in children aged 3 months to 3 years in term of analgesic duration, hemodynamic change and degree of sedation.
Methods: Sixty ASA I and II children undergoing lower abdominal surgeries were divided into two groups of 30 each, plain hyperbaric bupivacaine group (Group B) and hyperbaric bupivacaine with clonidine group (Group C). Group B received only bupivacaine and Group C received bupivacaine with clonidine in caudal block.
Results: Hemodynamic and demographic profiles were comparable between both the groups. Addition of clonidine significantly prolonged duration of caudal analgesia and significantly reduce the FLACC scores in group C as compared to group B. Mean sedation score immediately after postoperative period was higher in group C but after 4 hours of awakening, there was gradual fall in mean sedation score in both groups.
Conclusions: Addition of clonidine to bupivacaine in caudal analgesia significantly increases the duration of post-operative analgesia.

Keywords: Bupivacaine, Clonidine, Infraumbilical surgeries, Post op analgesia, Sedation score, FLACC score

INTRODUCTION

In children pain is underdiagnosed and not adequately understood as well as treated medical problem. Again we all know that pain is a subjective feeling.[1] Importance of adequate pain relief in pediatric patients is due to the fact that it may lead to long term adverse effects like disturb neuroendocrine responses, disrupted sleep pattern and food habits and decreases pain threshold to subsequent exposure in later life.

For paediatric pain relief various techniques have been employed and lots of studies have done. Among these, regional anaesthesia is the most widely used and most popular technique.[2] Now days caudal block is the most commonly performed regional anaesthesia technique used particularly in lower abdominal, urological and lower limb surgeries. Popularity of caudal block in paediatric surgeries is due to the fact that it is easy to perform and is relatively safe.[3]

Caudal block is a useful alternative/supplement to general anaesthesia to decrease the need of inhalation or IV agents during intraoperative period. This leads to early recovery from general anaesthesia with less postoperative complications thus allowing early resumption of oral

intake. Caudal blockage result in analgesia, sympathetic and motor blockage depending on concentration dose and volume of local anaesthetics used.

In paediatric surgeries for postoperative analgesia single dose bupivacaine is use safely and effectively but major disadvantage is relatively shorter duration of analgesia. To overcome this problem adjuvant like clonidine, dexmedetomedine, ephedrine, opioids, ketamine and neostigmine used for increasing the duration of caudal analgesia.[4]

Clonidine, is an α2 adrenergic agonist and its use now a day is not limited to its antihypertensive action but also widely used as an adjuvant and in premedication. When used as adjuvant in caudal block it increase the duration of analgesia without affecting hemodynamic profiles and give opportunity to use less amount of local anesthetic so total plasma concentration decreases and margin of safety increase. With the use of clonidine there may be few incidence of sedation but ultimate hospital discharge rate is unchanged.[5] Clonidine also has an antinociceptive action due to its effect on alpha 2 receptor located on brain stem and posterior horn of spinal cord, as α 2 receptors are implicated in pain management, so analgesia may be produced.

METHODS

After getting clearance from ethical committee and taking written and informed parental consent, 60 patients age 3 months to 3 years of ASA I and ASA II scheduled for elective lower abdominal surgery under general anaesthesia were recruited for the comparative study. The patients were assigned randomly into two groups; group B and group C, 30 patients in each group. Patient with anatomical abnormalities like spina bifida or scoliosis, with bleeding disorder or coagulopathy, with known allergy to any of study drugs, with history of developmental delay or mental retardation and with any signs of infection at the site of caudal block were excluded from study.

Preanesthetic checkup was the done 1 day before surgery. On the day of surgery fasting status was confirmed before the procedures, written and informed consent was taken. Intravenous fluids was started after securing an IV line. Basal HR, SPO_2 and NIBP were noted and measured throughout the procedures. Inj. glycopyrrolate 4µg/kg were given as premedication to all children. Pre-oxygenation was done by a facemask and JR circuit with fresh gas flow of 6 L/min oxygen. Anaesthesia was induced with 4-5 mg/kg Inj. Thiopentone sodium i.v. and Inj. Succinylcholine 1.5-2 mg/kg i.v. After intermittent IPPV, trachea was intubated with appropriate size ET tube. Maintenance of anaesthesia was done by oxygen, nitrous oxide and sevoflurane. inj. atracurium i.v. was used as a muscle relaxant. Intravenous fluid was given according to weight of the child and estimated fluid loss depending on type of surgery. No other narcotics, analgesics, sedatives or antiemetics were administered intra-operatively. For caudal block after induction patients were turned to left lateral position. All antiseptic and aseptic precaution were taken and caudal block was given with 23 G hypodermic needle after confirmation of space and after negative aspiration of CSF. Bupivacaine group received 1ml/kg of 0.25% bupivacaine with 1ml of saline and Clonidine group received 1ml/kg of 0.25% bupivacaine with clonidine 1µg/kg in 1 ml saline. Dressing was applied at injection site and patient was turn back to supine position. All vital parameters were noted after giving position and then every 20 minutes throughout the procedure. Sufficient level of analgesia was decided on the basis of increase in heart rate not more than 20% from base line value and from need of inhalation agents during intra-operative period. Hypotension defined as decrease in MBP > 20% from base line value, was managed by giving fluids intravenously. Perioperative bradycardia defined as heart rate below 20% of basal and was treated with Inj. Atropine 0.01 mg/kg.

All patients were reversed with Inj neostigmine 0.05 mg/kg and injection Glycopyrrolate 8µg/kg after surgery was completed. Trachea was extubated after oral and endotracheal suction. Pulse, blood pressure, SpO_2, respiratory rate were continuously monitored and sedation score and FLACC score were noted every 1 hour for next 4 hours in the presence of a staff nurse in PACU. Postoperative respiratory depression, defined as oxygen saturation less than 93 % was treated by oxygen with ventimask at the rate of 4 L/minute. Postoperative nausea and vomiting were treated with i.v. ondansetron 0.15 mg/kg. Postoperative pruritus was treated with i.v. diphenhydramine 0.2 mg/kg. Postoperatively patients were monitored for 24 hours. Analgesia was assessed using FLACC pain scale and sedation was assessed by sedation score. Children who had a pain score of more than 4 were administered acetaminophen 10mg/kg i. v.

The sample size was calculated by taking the help of statistician with a goal of clinically meaningful prolongation of caudal blockade of 15 to 20 %, ensuring power of the study being 0.80 with alpha error of 0.05. This results in sample size of 23–26 patients in each group but expecting 10 % dropout rate, total 60 patients were considered in the study. After collecting all the relevant data from both groups, mean and standard deviation were calculated using MS EXCEL software for age, weight, duration of analgesia, sedation score, FLACC score, hemodynamic parameters and incidence of adverse effect. Analyses of results were done by using Epi-info7.0 and SPSS software. ANOVA (Analysis of Variance) test and Kruskel Wallis H test (equivalent to chi square test) was performed for the data evaluation.

RESULTS

This study was a randomized, single blinded study, done on 60 pediatric patients of ASA physical status I and II,

aged 3 months to 3 years, undergoing routine lower abdominal surgeries like hypospadias repair, orchidopexy, herniotomy etc.

Group B

Control group - bupivacaine 0.25 % (1ml/kg) with 1 ml normal saline

Group C

Clonidine group - bupivacaine 0.25 % (1ml/kg) with clonidine at a dose of 1 mcg/kg in 1 ml of saline. As per the table, two groups were comparable in respect to age, weight and sex ratio without any significant difference ($p > 0.05$).

Table 1: Demographic data.

Variables	Group B (n = 30)	Group C (n = 30)	P value
Age (months) mean±SD	19.4±14.67	22.83±18.54	0.4301
Weight (Kg) mean±SD	9.6±2.66	10.43±3.91	0.3395
Sex ratio (M:F)	22:8	27:3	0.39

Table 2: Duration of analgesia in hours.

Duration of analgesia (hours)	Group B	Group C	P-value
Mean±SD	4.41±0.63	7.93±0.69	0.001

Table 2 shows the duration of analgesia in two groups. By adding Clonidine to bupivacaine (group C) there were notable prolongations of analgesia in comparison to bupivacaine alone (group B). So prolongation of duration of caudal analgesia between both the groups ($p<0.05$) were significant.

Table 3: FLACC score

FLACC score	Group B Mean±SD	Group C Mean±SD	P value
At 1 hour	2.16±0.45	1.83±0.37	0.003
At 4 hour	4.03±0.60	2.86±0.33	0.0001

The above table shows the comparison of FLACC scores at 1 and 4 hours post operatively. Adding clonidine significantly reduce the FLACC scores in group C as compared to group B. Higher FLACC scores were observed in plain bupivacaine group (group B).

There was notable difference in FLACC scores at 1 and 4 hour between group B and group C ($p <0.05$). Mean sedation score immediately after postoperative period was higher in group C. At 4 hours after awakening, there was gradual fall in mean sedation score in both groups.

Table 4: Postoperative mean sedation score.

Time (hours)	Mean sedation score		P value
	B group	C group	
0	1.76±0.42	2.5±0.5	0.0001
1	1.5±0.5	1.83±0.37	0.0052
2	0.96±0.40	1.66±0.47	0.0001
3	0.33±0.47	1.06±0.62	0.0001
4	0.16±0.37	0.6±0.48	0.0002

Table 5: Hemodynamic parameters.

Hemodynamic parameters	Group B	Group C	P value
Preoperative vitals (mean±sd)			
Pulse	116.4±3.261901	114.3333±4.91483	0.0593
MBP	89.33333±3.486482	90.23333±3.007583	0.304
Intraoperative vitals (mean±sd)			
Pulse	109.0778±0.711473	108.9667±0.245656	0.4549
BP	87.34444±0.498478	87.61111±2.744341	0.6020
Postoperative vitals (mean±sd)			
Pulse	106.8867±0.53355	106.76±0.299641	0.096
BP	87.65425±0.69836	87.38667±0.291566	0.0597

The above table shows the comparison of hemodynamic parameters during preoperative, intraoperative and postoperative period. We can see that hemodynamic parameters were not significant between the groups at any point during the study. This may be due to the fact that clonidine at a dose of 1 mcg/kg does not cause much alteration in the hemodynamic parameters. Above table shows there was higher incidence of nausea and vomiting

in group C compare to group B but the result was not significant (p = 0.23). One case of bradycardia was observed in group C. No episodes of respiratory depression and hypotension were observed in any of the groups.

Table 6: Postoperative complication.

Post-op complication	Group B	Group C
Nausea and vomiting	1 (3.3 %)	4 (13.3%)
Bradycardia	0	1 (3.3 %)
(<80/min for age<1 year and<60/min for age>1 year)		
Respiratory depression (SPO_2< 93%)	0	0
Hypotension (decrease in MAP >20%)	0	0

DISCUSSION

For children pain is only experienced and for them it is very difficult to express. Routinely used methods for pain relief is not appropriate for pediatric patients as there is chances of respiratory depression with use of narcotics, danger of aspiration and vomiting with the use of oral analgesic shortly after GA and with use of parentral analgesic fear of needle stick. But now days in paediatric patients the concept of postoperative pain relief has dramatically improved with the increasing popularity of regional anaesthesia. Requirement of systemic analgesic and postoperative pain is noticeably reduced with the use of regional techniques. Caudal block is a useful alternative to general anaesthesia and total I.V. anaesthesia as it provides an excellent means for post-operative analgesia. Unfortunately, motor blockade produced by caudal blockade may be a cause of distress to children in the postoperative period. There is always a continuing search for perfect combination of drugs for caudal block.

Various adjuvants have been used to prolong the duration of caudal analgesia. A alpha 2 agonist, clonidine, when combined with local anaesthetic noticeably increases the duration of analgesia with decrease in total anaesthetic concentration thus increasing margin of safety and reducing incidence of motor block. Cost of block and morbidity is reduced by avoiding catheter placement with the use of clonidine. In this study we compared bupivacaine and bupivacaine with clonidine in term of duration of analgesia and efficacy in pediatric patients posted for lower abdominal surgeries. Sharpe P et al, demonstrate that bupivacaine when used in small volume (0.5 ml/kg) may not be sufficient to deliver clonidine at the site of action.[1]

Based on these finding they concluded that there is limited value with use of clonidine in dose of 2 µg/kg to low volume local anaesthetics. Manickamet A, et a1 had suggested that dose of 1ml/kg of 0.1% ropivacaine should be used with clonidine 1 µg/kg for caudal analgesia. So in our study we used in both the groups standard doses of 1ml/kg of 0.25% bupivacaine.[2] Klimscha W et al, studied the effect of clonidine 2 µg/kg in place of 1 µg/kg and found that it only increases the chances of side effects like bradycardia, hypotension and respiratory depression and no benefits in term of analgesic effect. Epidural dose of clonidine is 1-5 µg/kg, so considering all this factors we used a dose of 1µg/kg of clonidine in these study. Patients in our study were demographically similar in both the groups.[3]

There were no statistically significant variations regarding age, body weight and gender. All children were posted for lower abdominal surgeries like inguinal hernia repair, orchidopexy, hypospedias etc. Childrens in group C demonstrate a longer duration of analgesia which was similar to the study done by Neogi et al, who used clonidine at a dose of 1µg/kg with 0.25% ropivacaine in caudal analgesia.[4] Due to difference in doses, premedication, volatile anaesthetics, type of surgery and assessment of pain there was a wide variation in duration of action of clonidine. In this study, duration of caudal analgesia in group B was (mean±sd) 4.41±0.63 hours, which was increased by adding clonidine in group C to 7.93±0.69 hours (p < 0.05, significant). Aruna Parameswari et al demonstrate the mean duration of analgesia was significantly longer in group-B (bupivacaine+clonidine) (Mean±SD) 593.4±423.3 minutes than in group - A (bupivacaine) (Mean±SD) 288.7±259.1 minutes.[5] In a study by Hennaway AM, Elwahab AM et al, suggested that, there was significant difference in duration of caudal analgesia in plain bupivacaine group compared to bupivacaine+clonidine group but they had used 2µg /kg dose of clonidine.[7]

Different scores to assess the pain in children have been used. They include modified OPS (objective pain scale), CHEOPS (Children's Hospital Eastern Ontario Pain Scale), maunuksela score, poker chip tool instruction sheet and FLACC scale. To evaluate postoperative pain we choose FLACC score. FLACC score at 1 hour after surgery were (mean±SD) 2.16±0.45 hours and 1.83±0.37 hours in groups B and C respectively. FLACC score at 4 hour after surgery were (Mean±SD) 4.03±0.60 hours and

2.86±0.33 hours in groups B and C respectively. In this study sedation was longer in group C. But it is difficult to differentiate between sedation and analgesia as because when comfortable young children use to fell asleep but when they feel pain they became awake and agitated. Thus the effect of clonidine as analgesic is confused with sedation or vice versa. So longer duration of sedation in group C was may not be only due to sedative effects of clonidine. In support of our conclusion Negri DP et al, also demonstrate that postoperative sedation score was higher in clonidine group.[7]

But in our study no patients was deeply sedated and all were arousable during the study period. Our study shows that addition of 1 µg/kg of Clonidine to Bupivacaine slightly reduces pulse rate and MAP (3 - 10%) after 15-30 minutes of caudal administration but does not have significant effect on the patient's hemodynamic status. Jamali S, et al and Archna K et al also noted in their result a slight decrease in pulse rate and MAP after administration of clonidine.[8,9] Side effects like nausea-vomiting was slightly more in patients who received clonidine (13.3%). It was treated with I.V. Inj. ondansetron 0.15 mg/kg. Joshi W, Connelly NR, Fremann K et al also reported in their study that nausea, vomiting was seen more frequently in clonidine group. Incidence of bradycardia was higher in group C compared to group B.[10]

It was treated with injection atropine 0.01 mg/kg I.V. Mean time of first micturation was comparable in both the groups and there was no significant difference in both the groups ($p < 0.05$). Hennaway AM, Elwahab A et al in their study found that the time of first micturation was comparable in both bupivacaine and clonidine group.[6] In this study, there was no incidence of respiratory depression or hypoxia requiring oxygen supplementation and no incidence of hypotension which was similar to study done by Lee JJ, Rubin AP et al, who noted that there was no incidence of respiratory depression and hypotension requiring intervention during their study.[11]

CONCLUSION

Addition of clonidine to caudal bupivacaine significantly prolongs the duration of post-operative analgesia, arousable sedation and does not produce significant hemodynamic fluctuations or major side effects. Thus clonidine (1 µg/kg dose) is safe and effective adjuvant to bupivacaine in caudal block.

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