

COMPARATIVE STUDY OF CAUDAL BUPIVACAINE WITH DEXAMETHASONE AND BUPIVACAINE WITH CLONIDINE IN INFRAUMBILICAL SURGERIES IN CHILDREN

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Abstract

Background: Caudal block is a dependable approach for paediatric urogenital surgery. Bupivacaine's effectiveness has been improved by the use of a variety of analgesics. Dexamethasone has gained popularity as an adjuvant because of its safety profile. The main goal of this study is to assess and compare the analgesic effectiveness and adverse effects of dexamethasone and clonidine when used combination with bupivacaine during paediatric urogenital surgeries. **Materials and Methods:** This comparison study in 60 children aged 5 to 10 years of ASA grade I and II, were divided into Groups D and C. Group D received 1 mL/kg of 0.25% bupivacaine with dexamethasone 0.1 mg/kg (maximum volume 20 ml) while Group C received 1 mL/kg of 0.25 % bupivacaine with clonidine 1.5 g/kg (maximum volume 20ml). After the caudal block patients' blood pressure, heart rate, and respiration rate were checked at 0, 5, 15, 30, 45, 60, and 180 minutes. **Result:** There is hemodynamic stability in both groups. Postoperatively, Group D offers an analgesia that lasts longer. **Conclusion:** The effectiveness of bupivacaine can be increased by dexamethasone and clonidine. Dexamethasone performs better than clonidine in the postoperative period at delivering long-lasting analgesia without the requirement for rescue analgesia.

INTRODUCTION

Ineffective pain management in children can have long-term psychosocial, physical, and behavioural consequences.^[1] Opioid-induced respiratory depression and difficult pain evaluations on very young children caused undertreatment pain in children which is widespread. Because of newer procedures and the availability of newly marketed medications, the provision of adequate perioperative analgesia in children has improved over time.^[2] This improvement is also a result of people being more aware of the negative effects of untreated pain. Single-shot caudal blockade is one of the regularly utilised perioperative pain management methods in children. Single shot caudal block has straightforward blocking ability, which makes it a reliable analgesic in the early postoperative period. It has become a safe, widely accepted, and often used technique.^[3] However, caudal block offers temporary analgesia. To prolong the single-shot caudal block, adjuvant such opioids, ketamine, adrenaline, and 2 agonists have been utilised. These

substances are used to lengthen the analgesic effect and improve block quality, but they can have negative effects that depend on the type and quantity of additives employed.^[4] For example, prolonged sadness and bradycardia are linked to clonidine, alpha 2 agonists, and dexmedetomidine. Ketamine causes analgesia after epidural administration and prolongs and enhances Bupivacaine's caudal block analgesia however it is neurotoxin to children.^[5] Dexamethasone is a commonly used analgesic that is administered via a variety of routes. It exerts direct action by eliciting local analgesic effect and also works by inhibiting the nervous system's nuclear factor-kB (NF-kB) expression. Because it inhibits central sensitization and operates on NF-kB, its capacity for epidural action is greater.^[6] The best adjuvant is still up for debate, and researchers are currently looking for a best medication that treats caudal block in children with prolong analgesia and reduce adverse effects. When combined with local anaesthetics in the epidural area, the long-acting corticosteroid dexamethasone, which has anti-inflammatory effects, revealed a reduced need for

postoperative rescue analgesics following orthopaedic surgeries and abdominal. Similar to this, numerous studies have shown that the alpha agonist Clonidine has analgesic benefits during local, spinal, and epidural anaesthesia when used in conjunction with a local anaesthetic such as bupivacaine. Research on analgesic effects in the periphery has been sparked by the discovery that clonidine has analgesic effects at the spinal level. It directly affects the nerve itself locally and supports local anaesthetic activity.^[2] Furthermore, clonidine appears to have analgesic effects without causing significant side effects. This study compares bupivacaine 0.25% (1 ml/kg) with dexamethasone (0.1 ml/kg) and 0.25% (1 ml/kg) with clonidine (1.5 µg/kg) as a single-shot caudal block during infraumbilical procedures on children (5-10 years).

MATERIALS AND METHODS

This study compares the effects of dexamethasone (Group D) and clonidine (Group C), each of which is given to 30 children of either sex. Various elective infraumbilical surgical procedures such as herniotomies, circumcision, orchidopexy, perineal surgeries, and minor lower extremity have been used. This study is approved by the institutional ethics committee. Informed consent was obtained from the parent before the inclusion of children in the study.

Inclusion Criteria

- The age group of 5-10 years and ASA grade I and II
- Patients for elective infraumbilical surgeries

Exclusion Criteria

- ASA grade III and IV
- Infection at the site of injection
- Coagulopathy or anticoagulation
- Congenital abnormalities of lower spine and meninges
- The active disease of the CNS
- History of allergy to local anesthetics

Procedure

Patients were induced with oxygen and sevoflurane (in increasing concentration) using the Jackson Rees circuit, and the intravenous line was secured. Injection atropine 0.02mg/kg was given intravenously after securing IV access. An infusion of Ringer Lactate was started, and fluid was administered.

Caudal Block

The patient's vital signs, including their capacity for spontaneous breathing, were once more evaluated as they were gently positioned in the left lateral position. Sevoflurane (2%) and oxygen were used to maintain anaesthesia. The sacral hiatus was found by sliding the thumb up first from coccyx towards

the sacrum under strictly aseptic conditions. After identifying the sacral hiatus, a 23G hypodermic needle was inserted into the skin at a 60° to 70° angle. The children was placed in the supine position after the injection was finished, the needle was removed. No analgesia was administered before the operation or while it was being performed. Throughout the procedure, the patient's spontaneous breathing and sevoflurane (2%) anaesthesia were maintained.

Drug & Dosage

Group D: received 1mL/kg of 0.25% bupivacaine with dexamethasone 0.1mg/kg (maximum volume 20ml).

Group C: received 1 mL/kg of 0.25% bupivacaine with clonidine 1.5 µg/kg (maximum volume 20ml).

Monitoring

Monitoring included pulse-oximetry, precordial stethoscope, respiratory rate, NIBP and ECG. Both the caudal block time and the duration of the surgery were recorded.

Recovery

At the start of skin closure, anaesthetic drugs were stopped being administered. For 3-5 minutes, 100% oxygen was supplied. The children were transferred to recovery room when their vitals were stabilised, they positioned in a semi-prone posture. Every 15 minutes, SpO₂, NIBP, respiratory rate, and heart rate were measured.

Patients were monitored for respiration, heart rate, and blood pressure after caudal block at 0, 5, 15, 30, 45, 60, 120, and 180 minutes. The time between the delivery of caudal block and the initial need for supplemental analgesia is referred to as the duration of analgesia. The pain score was monitored with Faces Legs Activity Cry Consolability tool ([FLACC], 0 –10). After caudal block the examination will continue for 24hr.

Statistical Analysis

In order to conduct the analysis, SPSS version 21.00 was used. The mean SD and average as a percentage are used to express the results of continuous variables. The student's t-test and chi-square test were used to see whether there was a difference between the two groups.

RESULTS

A total number of 60 children in the age group of 5 – 10 years belonging to ASA grade I and II were enrolled in this study.

Demography

The demographic data of group D and group C were comparable in terms of age, weight, surgery duration and types of surgery. There were insignificant differences between the two groups [Table 1].

Surgical Procedures

Different types of surgeries were carried out in both groups of the current study. Where 13 cases (43%) in group D and 14 cases (46%) in group C accounted for 50% of the hemiotomy. However, orchidopexy was done in two cases in each group [Table 2].

Heart Rate

The baseline HR in Group D was 92.5 ± 5.6 beats/min which decreased to 92 ± 1.9 beats/min over the 3 h. In Group C, the baseline HR decreased from 92.9 ± 3.1 to 92.5 ± 1.6 beats/min. There was no significant difference in the heart rate between the two groups at any time interval ($p > 0.05$).

Mean Arterial Pressure

Over 3 hours, MAP decreased in both groups. Within three hours, the MAP in group D dropped from 74.9 ± 3.23 mmHg to 63.9 ± 7.318 mmHg. MAP dropped from 64.83 ± 2.80 mmHg to 62.63 ± 2.37 mmHg in group C. However, there was no statistically significant difference in the mean MAPs between the two groups.

Systolic and Diastolic Blood Pressure

The average systolic blood pressure at baseline in group D was 98 ± 6.2 mm Hg. After the operation, the pressure rose to 105 ± 6.5 mm Hg after 5 minutes, then it gradually fell to 97 ± 8.2 mm Hg after 180 minutes. The average systolic blood pressure in group C was 99 ± 2.5 mm Hg. Following surgery, the blood pressure was 105 ± 6.0 mm Hg at 5 minutes and dropped to 96 ± 3.8 mm Hg at 180 minutes. At each time point, the variations in systolic blood pressure were negligible.

The mean baseline diastolic blood pressure in group D was 63 ± 4.2 mm Hg, and after 5 minutes, it maximally climbed to 69 ± 4.2 mm Hg, before declining to 60 ± 4.2 mm Hg after 180 minutes. The mean diastolic blood pressure in group C was 63 ± 5.8 mm Hg at baseline; it increased to 68 ± 4.4 mm Hg at its maximum after 5 minutes, and then decreased to 62 ± 5.8 mm Hg after 180 minutes.

Duration of Post Operative Analgesia (hours)

In our study, caudal analgesia lasted for 13–20 hours in the dexamethasone group and 10–14 hours in the

clonidine group during the postoperative period. Between groups C and D, the average post-operative analgesic duration was 9 ± 4.2 hr and 16.5 ± 7.2 hr, respectively. It is found to be statistically significant with the p value of < 0.001 .

Total analgesic top-ups required in first 24 hrs (hours)

The median of total analgesic top ups required in the first 24 h was significantly lower in Group D (1.3) when compared to Group C (2.5) [$P < 0.001$].

Pain score: Mean hourly FLACC pain scores in both groups were similar up to 6 hours after injection. Thereafter, the mean score in group C was significantly higher than that in group D. The duration of analgesia was 10-14 hours for group C and 13-20 hours for group D. The mean score was lower in group D than in group C with the difference statistically significant at 6, 8, 10, 12, 15, and 18 hours ($*P < 0.05$). Data are presented as mean \pm SD

Sedation Score

Ramsay sedation score was assessed every 15 min till 3 h postoperatively. Sedation score 2 in group C and in group D it was 1 by 3hrs. All children were able to open their eyes to speech from immediate postoperative period in group C. Group C had slightly higher mean sedation score, up to 3, compared to mean sedation score of 2 in group D, in the immediate postoperative period. Ramsay sedation score was higher in Group C than group D over a period of 3 hours but it is not statistically significant with $P > 0.05$. All children were awake and alert by the end of 12 hours in both groups.

Adverse Effect

The incidence of nausea and vomiting was among 1(3.3%) children in group D compared to 1(3.3%) in group C. This was not statistically significant. There was no incidence of hypotension, dural or vessel puncture and respiratory depression in the two groups.

Table 1: demography data of different variables

	Group D	Group C	P value
Age(years)	7.35 ± 2.55	7.175 ± 2.417	0.638
Weight(Kg)	26.97 ± 4.21	25.47 ± 4.51	0.5279
Height(Cm)	112 ± 44.21	110.6 ± 39.5	0.6
Duration of surgery(minutes)	49.33 ± 8.58	50.67 ± 8.68	0.51

Table 2: Different types of surgeries conducted in two groups

Types of surgery	Group D(%)	Group C(%)
Circumcision	6 (20)	8 (26)
Herniotomy	13 (43.33)	14 (46)
Orchidopexy	2 (7)	2 (7)
Anorectal surgeries	5(16)	4 (14)
Others	4 (14)	2 (7)

Table 3: Comparison of heart rate in two groups

Pulse Rate at	Group D	Group C	P value
Pre operative	92.5±5.6	92.9±2.1	0.638
Intra-Operative			
5 min	92.1±2.2	92.2 ±2.2	0.900
10 min	90.2 ±2.5	91.2 ±1.9	0.226
15 min	92.5±2.6	92.6 ±2.1	0.905
20 min	92.6 ±2.2	91.2 ±2.0	0.054
30 min	92.2 ±2.0	92.0 ±1.6	0.587
40 min	91.5 ±2.6	92.2 ±1.5	0.254
60 min	92.6±2.6	92.2 ±1.1	0.624
Post operative			
15 min	92.5 ±1.1	92.9±1.7	0.236
30 min	91.9 ±1.1	92.5± 1.1	0.095
60 min	92.8 ±1.2	91.9 ±1.1	0.068
90 min	92.2 ±1.2	92.8 ±1.2	0.060
120 min	92.5 1.6	92.2 1.2	0.550
150 min	91.6 ±1.5	92.2± 1.2	0.550
180 min	92.0 ±1.9	92.5 ±1.6	0.087

Table 4: Mean arterial pressure comparison of two groups.

MAP at	Group D	Group C	P value
Pre operative	74.9± 3.6	75.0± 2.9	0.8971
Intra-Operative			
5 min	74.0± 1.4	74.0± 1.4	0.9212
10 min	74.6 ± 1.2	74.5 ± 1.2	0.7305
15 min	73.5± 1.2	73.5 ± 1.2	1.0
20 min	73.4± 1.3	74.0 ± 1.4	0.1478
30 min	73.2± 1.2	73.5 ± 1.3	0.3655
40 min	74.6± 1.6	74.6 ± 1.7	0.8662
60 min	74.0± 1.0	74.1± 1.3	0.7166
Post operative			
15 min	74.0± 1.4	74.1± 1.3	0.8386
30 min	74.6 ±1.2	74.5 ±1.2	0.7305
60 min	73.5 ±1.2	73.9 ±1.2	0.2104
90 min	73.4 ±1.3	73.3 ±1.3	0.7424
120 min	73.2 ±1.2	73.6 ±0.8	0.1392
150 min	74.2 ±1.2	74.3± 1.2	0.907
180 min	74.3± 1.0	74.4 ±1.1	0.8937

Table 5: Respiratory rate comparison in group D and group c

SPO2 at	Group D	Group C	P value
Pre operative	98.48± 0.71	98.72± 0.61	1
Intra-Operative			
5 min	98.16 ±0.55	98.16± 0.55	1
10 min	98.44± 0.51	98.44± 0.51	1
15 min	98.19 ±0.58	98.11 ±0.58	0.61
20 min	98.28 ±0.54	98.36 ±0.57	0.56
30 min	98.68 ±0.48	98.65± 0.5	0.83
40 min	98.32± 0.69	98.36 ±0.7	0.81
60 min	98.24 ±0.6	98.23± 0.58	0.80
Post operative			
15 min	98.4 ±0.58	98.44 ±0.58	0.79
30 min	98.16 ±0.55	98.12 ±0.53	0.79
60 min	98.44 ±0.51	98.4 ±0.58	1
90 min	98.0± 0.58	98.0 ±0.58	1
120 min	98.32± 0.56	98.32± 0.56	0.60
150 min	98.64 ±0.49	98.56 ±0.58	0.83
180 min	98.32±0.69	98.36±0.7	0.89

No significant difference in SPO2 between the two group's pre op, intra op and post op.

Table 6: duration of post operative analgesia in both groups.

Duration of post operative analgesia	Range	Mean ±SD
Group C	10-14	9 ± 4.2
Group D	13-20	16.5 ± 7.2
p'VALUE <0.001 Significant		

Table 7: Total analgesic required in 24Hr

Total analgesic required in 24Hr	Range	Median
Group C	2.3- 2.7	2.5
Group D	1.1- 1.5	1.3

'p'VALUE <0.001* Significant

Table 8: shows pain score in both groups

Time(in minutes)	Group C	Group D	P value
30	0.12±0.05	0.1±0.07	>0.05
60	0.18 ±0.07	0.15±0.08	>0.05
90	0.21±0.1	0.19±0.1	>0.05
120	0.30±0.18	0.21±0.1	>0.05
150	0.45±0.2	0.35±0.19	>0.05
180	0.85±0.522	0.42±0.25	>0.05
4 hr	0.92±0.522	0.52±0.41	>0.05
6 hr	1.0±0.82	0.85±0.72	< 0.05
8 hr	1.5±0.92	0.9±0.85	< 0.05
10 hr	1.8± 1.2	1.1±0.90	< 0.05
12 hr	2.8± 1.8	1.5±1.0	< 0.05
15 hr	3.11±2.1	1.9±1.5	< 0.05
18 hr	3.8±2.5	2.1±1.7	< 0.05
24 hr	4.0±2.8	3.5± 2.8	>0.05

Table 9: adverse effect in both groups.

Complications	Group D	Group C
Hypotension	0	0
Bradycardia	0	0
Nausea & Vomiting	1(3.3%)	1(3.3%)
Dural puncture	0	0
Blood vessel puncture	0	0
Respiratory depression	0	0
Pruritis	0	0

DISCUSSION

Caudal epidural anaesthesia is safe, easy to administer, and provides highly good postoperative analgesia for children undergoing sub umbilical surgery. Since longer acting local anaesthetics have a limited ability to prolong caudal analgesia, numerous medications have been tested in an effort to do so with the fewest possible side effects.^[8]

Opioids are a popular caudal block adjuvant that prolong the analgesic action's durability. However, the use of opioids in children has been constrained due to adverse side effects such pruritus, respiratory depression risk, vomiting, and nausea.^[9]

Ansermino et al. conducted a systematic evaluation of 12 studies, and 8 of them demonstrated that the analgesic effect can be prolonged by blocking the caudal nerve with clonidine (1–5 mg/kg), which can be added to local anaesthetics. Less than 2 mg/kg is the acceptable amount, which is beneficial for children and has few adverse effects including moderate sedation.^[10]

We have not reported discernible difference between the groups' heart rates. Our findings agreed with those of Ganeshnavar et al. and El-Hennawy et al. They also found that the participants Heart rate had not changed significantly either.^[11,12]

We have also noted decrease in MAP. This decrease in MAP was similar to the findings by Parameswari et al., and Raval and Kartik , who also reported insignificant changes in MAP among their study groups.^[13,14]

Shukla et al, studied postoperative analgesia duration with clonidine or fentanyl to ropivacaine and reported that both agents prolong the duration of analgesia after single-shot caudal epidural anesthesia. In contrast to fentanyl, clonidine showed an advantage because it does not produce any major clinically significant side effects such nausea, bradycardia, or depression. On the basis above finding authors has recommended that clonidine can be a better additive to ropivacaine in children with minimal side effect.^[15] In the current study, we used caudal Bupivacaine as an adjuvant with low-dose Dexamethasone 0.1 mg/kg to provide a sufficient block with no incidence of side effects. For individuals in the dexamethasone group, the analgesia lasted up to 16 hours. There are several studies which shown variation in the analgesia duration. The possible reason behind this is used of different dose of additive drugs, types of surgery, nature of aesthetic solution use, pain assessment and statistical analysis.

Dexamethasone's overall impact in reducing pain in children has been previously described. Dexamethasone is helpful in surgical pain because of its anti-inflammatory effects. Following juvenile orchidopexy, 0.5 mg/kg of intravenous dexamethasone administered in conjunction with a ropivacaine prolonged analgesia duration. Children undergoing orchidopexy and inguinal hernia repair demonstrated sustained analgesia with 0.1 mg/kg dexamethasone to ropivacaine for cadual block without any adverse side effects.^[16]

El-Feky et al found that the sedation score with caudal dexamethasone is lower than bupivacaine alone it but in the level.^[17]

CONCLUSION

Clonidine (1.5g/kg) is excellent caudal block analgesia due to less postoperative sedation, improved pain management, and stable hemodynamics; and can be a better alternative for dexamethasone (0.1mg/kg). Dexamethasone and Clonidine can improve the effectiveness of bupivacaine. In the postoperative period, dexamethasone performs better than clonidine at providing long-lasting analgesia without the need for rescue analgesia.

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