Section: Anaesthesiology

Original Research Article

COMPARATIVE STUDY OF ANALGESIC EFFICACY OF CLONIDINE AND FENTANYL ADDED TO CAUDAL BUPIVICAINE IN CHILDREN UNDERGOING LOWER ABDOMINAL SURGERIES

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Abstract

Background: Pain, an unpleasant sensory or emotional experience, involves noxious input transmitted via A-delta and C fibres to the CNS. Targeted therapies, such as local anaesthetics, opioids, and NSAIDs, along with regional techniques, such as caudal anaesthesia, effectively relieve pain while reducing systemic analgesic needs. This study aimed to compare the clinical efficacy of fentanyl and clonidine as adjuvants to bupivacaine in caudal anaesthesia. **Materials and Methods:** This prospective randomised double-blinded study included 60 patients. Caudal blocks were administered under aseptic precautions with bupivacaine and either fentanyl or clonidine, followed by intra- and postoperative monitoring of vital signs and complications. Analgesia duration was assessed using pain scales, and rescue analgesia was provided if pain scores were ≥ 4. **Result:** Comparison between the fentanyl and clonidine groups revealed no significant differences in age, duration of surgery, or weight ($p>0.05$). The total duration of analgesia was significantly longer in the clonidine group (648.4±31.38) than in the fentanyl group (547.93±25.09; $p<0.0001$). There were no significant differences between the groups in baseline, intraoperative, or postoperative heart rate, SpO2, systolic and diastolic blood pressure, or mean arterial pressure. Clonidine had significantly lower pain scores than fentanyl at 4, 6, 8, and 12 hours post-procedure ($p<0.05$), with no differences observed at 2, 16, and 18 hours. **Conclusion:** When clonidine was added to bupivacaine, a comparatively greater analgesic effect was observed than when fentanyl was added to bupivacaine. The side effect profile of the clonidine group was also better than that of the fentanyl group.

INTRODUCTION

Pain is defined as an unpleasant emotional or sensory experience associated with tissue damage. Even preterm babies have the functional and anatomical components needed to perceive pain. The noxious input is transmitted to the central nervous system by A-delta and C fibres. Several sites in the pain pathway can be targeted for pain relief. At the peripheral level local anaesthetics, opioids and NSAIDS can be used to relieve pain. Alpha-2 agonists, opioids, and local anaesthetics can be used at the level of the spinal cord. Opioids can also be used at the cortical level. Commonly, combination therapies are used to relieve pain. The caudal route is a widely used regional anaesthetic technique because of its simplicity, reliability, and safety profile. It significantly decreases the requirement for systemic anaesthetics and analgesics.

Aim

This study aimed to compare the clinical efficacy of fentanyl and clonidine as adjuvants to bupivacaine in caudal anaesthesia.

MATERIALS AND METHODS

This prospective randomised double-blinded study included 60 children. This study was approved by the Institutional Ethics Committee before initiation, and informed consent was obtained from all patients.

Inclusion Criteria

ASA I and II children aged 1-6 years undergoing infraumbilical surgery were included.

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Exclusion Criteria

Children with ASA physical status III-IV, block site infection, known history of allergy to any of the drugs used, bleeding diathesis, skeletal deformities, pre-existing spinal or neurological disease, and patient refusal were excluded.

Methods

Pre-Operative Evaluation

In all children included in the study, a history of any previous anaesthesia or surgical procedures, significant medical diseases, and known allergies were recorded. Age, body weight and vital parameters were recorded. Complete physical examination and routine laboratory investigations were performed.

On the day of the surgery, a thorough preoperative examination of the patient was performed. After informing the advantages and disadvantages of the procedure to the parents, their consent was obtained. Vital parameters were recorded and intravenous access was performed using an appropriate IV cannula. Premeditation with injection of atropine 0.01 mg/kg IM was administered half an hour before anaesthesia. They were then pre-oxygenated with 100% oxygen for 3 min, and induction of anaesthesia was achieved with 50% N2O and oxygen and titrated doses of propofol, midazolam, and sevoflurane 2% with an appropriate face mask.

The patient was placed in the left lateral position, and a sacral hiatus was identified under strict aseptic precautions; a caudal block was performed in all patients. The caudal space was identified by the loss of resistance and swoosh test. Then, negative aspiration of blood and CSF was confirmed (to avoid intravascular or subarachnoid injection), and local anaesthetic was administered.

Group A (n=30) received 1 ml/kg 0.25% bupivacaine with preservative-free fentanyl 1mcg/Kg. Group B (n=30) received 1 ml/kg 0.25% bupivacaine with preservative-free clonidine 1mcg/kg. Intraoperative monitoring of heart rate, blood pressure, and SPO2 was recorded before and after induction and every 5 min until the completion of surgery. Postoperatively, the heart rate, blood pressure, and SPO2 were monitored along with any problems such as dry mouth, nausea and vomiting, retention of urine, and respiratory depression.

Respiratory depression is defined as a decrease in SPO2 levels of < 95% that requires supplemental oxygen. Bradycardia is defined as a heart rate of < 80/min for infants and < 60/min for children above 1 year of age. The duration of analgesia was assessed using a subjective pain scale in children aged > 3 years and an observational pain scale in children who cannot express pain. If the pain score was ≥ 4 or if the patient complained of pain, rescue analgesia with paracetamol suppository 15 mg/kg was administered.

Statistical analysis: Data were presented as mean, standard deviation, frequency and percentage. Continuous variables were compared using an independent-sample t-test. Categorical variables were compared using Pearson's chi-square test. Significance was defined as $p < 0.05$, using a two-tailed test. Data analysis was performed using IBM-SPSS version 21.0 (IBM-SPSS Corp., Armonk, NY, USA).

RESULTS

The comparison between the fentanyl and clonidine groups revealed no significant differences in age (3.32±1.49 vs. 3.77±1.72; p=0.28), duration of surgery (27.67±7.74 vs. 26.5±9.54; p=0.605), or weight (13.2±1.95 vs. 14.2±1.99; p=0.06). The total duration of analgesia was significantly longer in the clonidine group (648.4±31.38) than in the fentanyl group (547.93±25.09; p <0.0001). There was no significant difference in sex between the groups (p=0.476).

The most common surgery performed was hernia, with 16 and 12 patients in the fentanyl and clonidine groups, respectively. Circumcision was the least common, with 3 patients in the fentanyl group and 6 in the clonidine group. The postoperative complications were minimal. Nausea was the most frequent, occurring in 3 patients in the fentanyl group and 1 in the clonidine group [Table 1].

The majority of patients 49 (81.6%) weighed ≤ 15 kg, whereas only 11 (18.3%) weighed >15 kg. Regarding the duration of surgery, most procedures were completed within 30 min, with 41 (68.3%) surgeries, while 19 (31.6%) surgeries exceeded 30 min [Table 2].

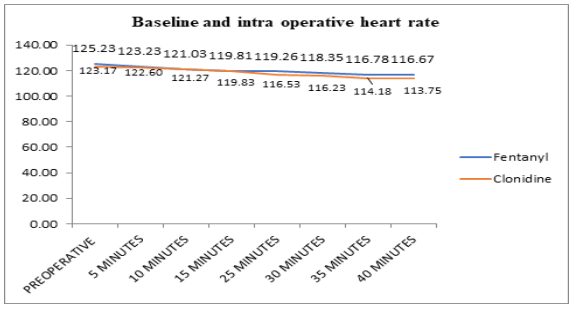

Figure 1: Baseline and intraoperative heart rate

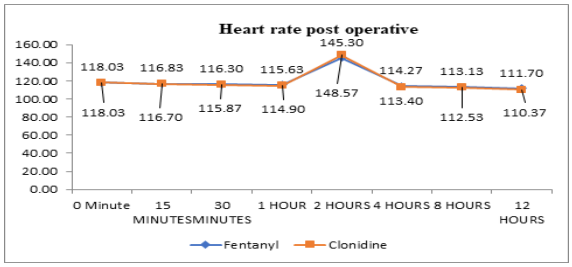

Figure 2: Post-operative of heart rate

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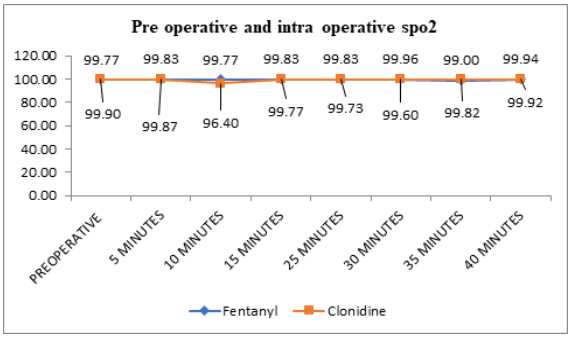

Figure 3: Preoperative and intraoperative of Spo2

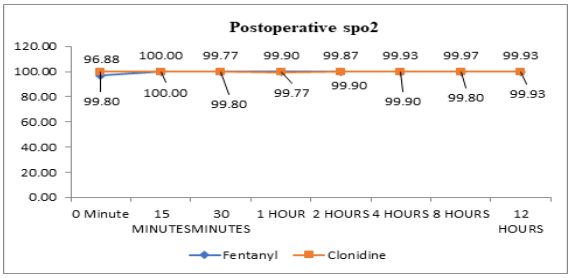

Figure 4: Postoperative of Spo2

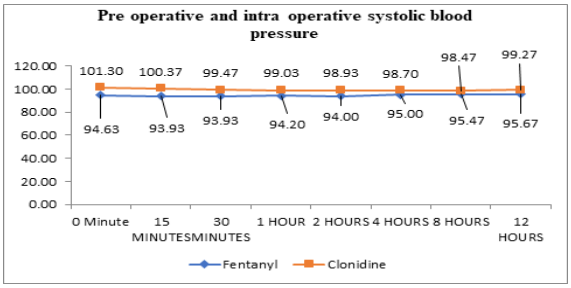

Figure 5: Preoperative and intraoperative of systolic blood pressure

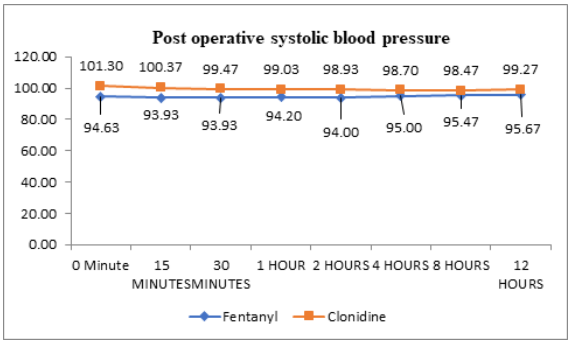

Figure 6: Postoperative of systolic blood pressure

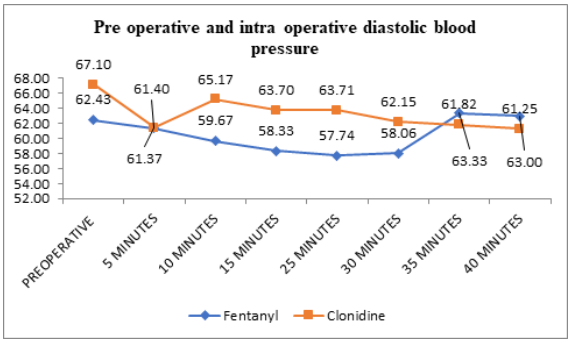

Figure 7: Preoperative and intraoperative of diastolic blood pressure

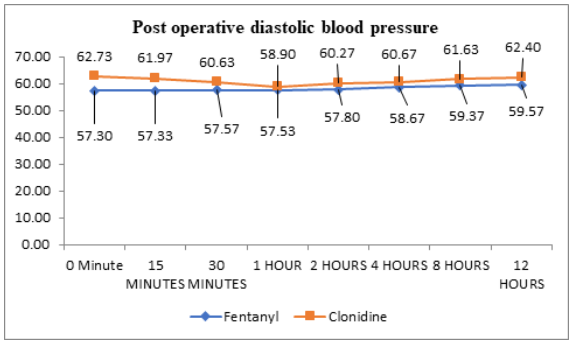

Figure 8: Postoperative of diastolic blood pressure

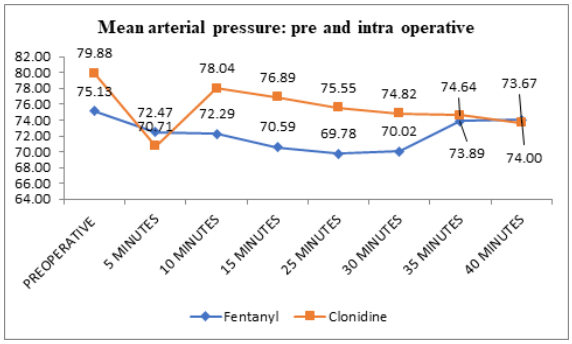

Figure 9: Pre- and intra-operative of mean arterial pressure

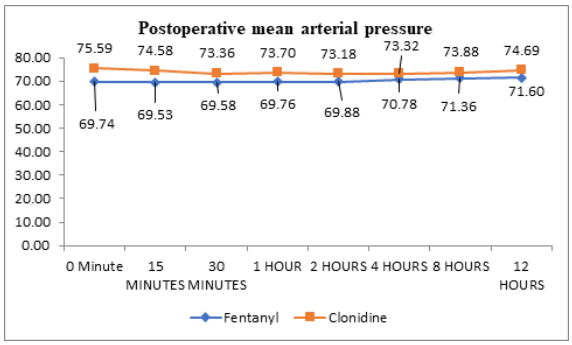

Figure 10: Postoperative of mean arterial pressure

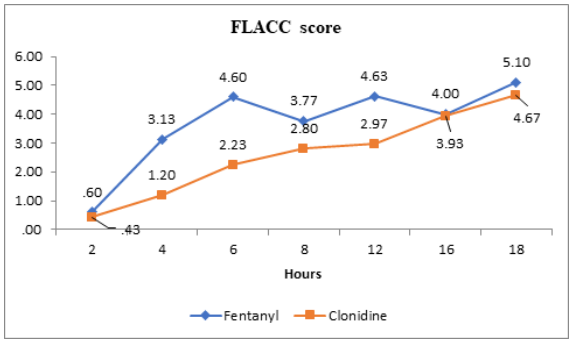

Figure 11: FLACC score

There was no significant difference in postoperative heart rate between the two groups [Figure 2].

There was no significant difference in the preoperative and intraoperative Spo2 levels between the two groups [Figure 3].

There was no significant difference in postoperative Spo2 between the two groups [Figure 4].

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There was no significant difference in preoperative and intraoperative systolic blood pressure between the two groups [Figure 5].
There was no significant difference in postoperative systolic blood pressure between the two groups [Figure 6].
There was no significant difference in preoperative and intraoperative diastolic blood pressure between the two groups [Figure 7].
There was no significant difference in postoperative diastolic blood pressure between the two groups [Figure 8].
There was no significant difference in mean arterial pressure: pre- and intraoperative between the two groups [Figure 9].
There was no significant difference in the postoperative mean arterial pressure between the two groups [Figure 10].
Clonidine had significantly lower pain scores than fentanyl at 4, 6, 8, and 12-hours post-procedure ($p<0.05$). However, no significant differences were observed at 2, 16, and 18 h [Figure 11].

Table 1: Comparative analysis of fentanyl and clonidine groups

		Group		P value
		Fentanyl	Clonidine	
Age (years)		3.32 ± 1.49	3.77 ± 1.72	0.28
Duration of surgery (min)		27.67 ± 7.74	26.5 ± 9.54	0.605
Weight (kg)		13.2 ± 1.95	14.2 ± 1.99	0.06
Total duration of analgesia (min)		547.93 ± 25.09	648.4 ± 31.38	<0.0001
Sex	Female	8	6	0.476
	Male	22	24	
Surgery	Hernias	16	12	-
	Urethroplasty	5	5	
	Circumcision	3	6	
	Others	6	7	
Postoperative complication	Nausea	3	1	-
	Vomiting	3	0	
	Urinary retention	2	1	
	Hypotension	0	0	
	Respiratory depression	0	0	

Table 2: Weight and duration of surgery

		Frequency (%)
Weight (kg)	≤15	49 (81.6%)
	> 15	11 (18.3%)
Duration of surgery (min)	≤ 30	41 (68.3%)
	>30	19 (31.6%)

DISCUSSION

Caudal anaesthesia is a very popular means of postoperative analgesia in the paediatric age group. The use of caudal catheters for administering repeated doses or infusions of local anaesthetic is not suitable because of concerns about infection. Thus, prolongation of the duration of single-shot caudal analgesia with adjuvants such as fentanyl and clonidine are preferable. These adjuvants also reduce the general anaesthesia requirements. They decrease the risk associated with deeper planes of anaesthesia. They provide comfortable and faster wake-up times, quicker discharge and thus fast turn overrate in the post anaesthetic care unit. In the short duration of surgery, they can help avoid airway instrumentation.
From this study conducted on 60 patients who underwent elective caudal block anaesthesia, we compared the effect of adjuvants like fentanyl and clonidine on the duration and quality of analgesia; along with the intraoperative and postoperative hemodynamics. It can be seen that the mean duration of analgesia in the clonidine group (648.4 minutes) was significantly higher than the mean duration of analgesia in the fentanyl group (547.9 minutes).
The FLACC score at 4 h revealed that in the fentanyl group, nearly half of the children (43.31%) needed rescue analgesia with paracetamol, whereas none of the children in the clonidine group had an FLACC score of 4 or more. However, by the end of 18 hours, all the children in both groups had received rescue analgesia, and the pain score was comparatively lower in the clonidine group. Intraoperative and postoperative hemodynamic monitoring did not reveal any statistically significant differences. The incidence of postoperative complications such as nausea, vomiting, and urinary retention was higher in the fentanyl group than in the clonidine group.
Yang et al. performed a systematic review and meta-analysis of clonidine versus other adjuvants used for paediatric neuraxial blocks. The results of the study showed that clonidine added to local anaesthetics in these blocks had a longer duration of postoperative analgesia along with fewer side effects, such as postoperative nausea and vomiting.[1] Thus, the present study correlates with the meta-analysis study in terms of duration of analgesia being more in the clonidine group and fewer side effects.

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CONCLUSION

Caudal anaesthesia is a frequently performed regional block for intraoperative and postoperative analgesia in children. In the present study, when clonidine was added to bupivacaine, there was a comparatively greater analgesic effect than when fentanyl is added to bupivacaine. The side effect profile of the clonidine group was also better than that of the fentanyl group.

REFERENCES

1. Yang Y, Yu L-Y, Zhang W. Clonidine versus other adjuncts added to local anesthetics for pediatric neuraxial blocks: A systematic review and meta-analysis. J Pain Res 2018; 11:1027–36. https://doi.org/10.2147/jpr.s158264.

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