

Research Journal of Pharmaceutical, Biological and Chemical Sciences

To Evaluate and Compare the Efficacy and Duration of Action of Caudal Fentanyl and Bupivacaine with Midazolam and Bupivacaine in Children during Post-Operative Period.

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ABSTRACT

We conducted study on a group of 40 children in the age of 1-10yr, both boys and girls Comparing the efficacy and duration of caudal fentanyl and bupivacaine with midazolam And bupivacaine combinations in children undergoing infraumbical and lower limb surgeries in their post operative period. We divided sample into 2 groups, group A received 0.25% 1ml/kg bupivacaine and 1mcg/kg fentanyl, group B receiving 0.25% 1ml/kg bupivacain and 50mcg/kg midazolam respectively. Postoperatively, quality of analgesia Was assessed by hanallahs Pain scale, duration of analgesia Was also assessed, sedation Score and activity of child was also checked Postoperatively. At the end of study we observed that quality and duration of analgesia was better and prolonged respectively in Group A children receiving bupivacaine and fentanyl combination.

Keywords: Fentanyl, Bupivacaine, Midazolam

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INTRODUCTION

The smile on the face of a child who is comfortable in his/her mother's arms in the post anaesthesia care unit is one of the greatest rewards any anaesthesiologist can receive. It is the responsibility of an anaesthesiologist to provide the analgesia, not the responsibility of the child to request pain relief [1].

Acute pain management in the pediatric patients poses a unique challenge to the anaesthesiologist. Regional anaesthetic techniques are now widely used in children undergoing surgery. Single shot caudal epidural anaesthesia with local anaesthetic is the most commonly used regional technique in children. Bupivacaine is the most commonly used local anaesthetic agent with duration of action of 4-6 hours. Various techniques have been devised to prolong the duration of postoperative analgesia. Placement of a catheter poses an inherent risk of infection and delays mobilization.

Many drugs including epinephrine, morphine, buprenorphine, neostigmine, clonidine, midazolam, tramadol etc. have been co-administered with caudal bupivacaine to maximize and extend the duration of postoperative analgesia.

Fentanyl and Midazolam in combination with Bupivacaine has been shown to prolong the duration of postoperative analgesia when administered caudally in children [1,3,5].

The present study was undertaken to compare the analgesic effectiveness of caudal administration of a combination of Fentanyl and Bupivacaine with Midazolam and Bupivacaine for postoperative pain relief [2].

AIM OF THE STUDY

To evaluate and compare efficacy and duration of caudal Fentanyl and Bupivacaine with Midazolam and Bupivacaine combination in children in the post-operative period.

- To compare the efficacy of the drugs
- To compare the vital parameters in terms of pulse rate, blood pressure and respiratory rate in each group.
- To compare the duration of analgesia.
- To compare the complications if any.

MATERIALS AND METHODS

A comparative study that included 40 patients of ASA Grade I between 1-10 years of age undergoing infra-umbilical surgeries (inguinal herniotomy, herniorrhaphy, orchidopexy and hypospadias repair) and lower limb procedures under general anaesthesia [1,3,5].

Inclusion Criterion

- Children between 1-10 years
- Posted for infra Umbilical Surgeries
- Physical status ASA I

Exclusion Criterion

- Parental unwillingness
- Body weight more than 25 KGs
- Children with pre existing 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 anaesthetics

After institutional approval and parental written informed consent were obtained healthy boys and girls aged 1-10 years with physical status ASA I posted for elective perineal lower abdominal or lower extremities surgeries were allocated to receive caudal anaesthesia with either Bupivacaine with Fentanyl or Bupivacaine with Midazolam after induction of general anaesthesia. [1,2,5] Patients were divided into two groups of twenty each.

Group A - Bupivacaine 0.25% 1ml / kg body.wt + Fentanyl 1µg / kg.body .wt
 Group B- Bupivacaine 0.25% 1ml / kg body.wt + Midazolam 50µg/ kg.body.wt

Each patient was visited the day before the surgery, history was noted and thorough clinical examination was done. The procedure was explained and informed written consent obtained from the attender of the child. [2,4]

The following investigations were done – Hb%, TC, DC, ESR, urine albumin and sugar, bleeding time and clotting time. All the operations were done under general anaesthesia.

Anesthetic Plan

General anaesthesia with caudal block was performed Post operatively,

- Quality of the pain relief was recorded using hanallah pain score
- The duration of pain relief (time from caudal placement till the first dose of post-operative analgesic)
- Requirement of rescue medication.
- Side effects of the drugs if any.
- Sedation scoring

HANALLAH PAIN SCORE

S.No.	Observation	Criterion	Points
1	Arterial Pressure	> 10% pre op	0
		> 20% pre op	1
		> 30% pre op	2
2	Crying	No Crying	0
		Crying respond to tender love in care	1
		Crying not responding to tender love in care	2
3	Movement	None	0
		Restless	1
		Thrashing	2
4	Agitation	Asleep/Calm	0
		Mild	1
		Hysterical	2
5	Posture	No special posture	0
		Flexing legs and thighs	1
		Holding groin	2
6	Complains of pain	Asleep/ No Pain	0
		Cannot localize	1
		Can localize	2

Sedation scoring was done as follows

- Eyes open spontaneously – 1
- Eyes open in response to verbal stimulation – 2
- Eyes open in response to physical stimulation – 3
- Unresponsive – 4

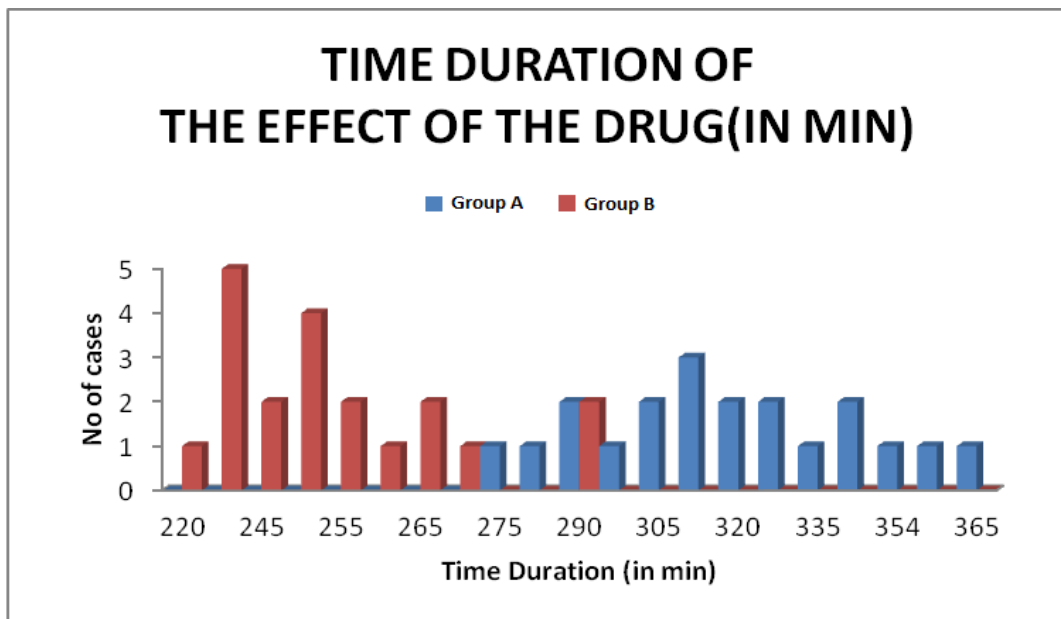
The data was analyzed for statistical significance by ANOVA test. p ≤ 0.05 was considered as significant. The results were expressed as frequency, percentages and mean ± standard deviation.

OBSERVATIONS AND RESULTS

Study Design: A Comparative anesthesia clinical study with 40 patients randomized into two groups, 20 in Group A (Bupivacaine 0.25% 1ml / kg body.wt + Fentanyl 1µg / kg.body .wt) and 20 in Group B (Bupivacaine 0.25% 1ml / kg body.wt +Midazolam 50µg/ kg.body.wt) is undertaken to study the total number of analgesia doses, sedation score and hemodynamics.

Time duration of the effect of the drug (in Minutes)

S.No.	TIME DURATION (IN MIN)	Group A	Group B
1.	220	0	1
2.	235	0	5
3.	245	0	2
4.	250	0	4
5.	255	0	2
6.	260	0	1
7.	265	0	2
8.	270	0	1
9.	275	1	0
10.	285	1	0
11.	290	2	2
12.	295	1	0
13.	305	2	0
14.	310	3	0
15.	320	2	0
16.	330	2	0
17.	335	1	0
18.	340	2	0
19.	354	1	0
20.	355	1	0
21.	365	1	0
	Total	20	20



Time duration of the effect of the drug (in min)

NULL HYPOTHESIS: The drug Fentanyl has the same effect when compared to the drug Midazolam.

Paired Samples Statistics

TIME DURATION	Mean	N	Std. Deviation	Std. Error Mean
Group A	.95	21	.921	.201
Group B	.95	21	1.431	.312

Paired Samples Correlations

TIME DURATION	N	Correlation	Sig.
FENTANYL & MIDAZOLAM	21	-.571	.007

Since the p value = 0.007 (< 0.05) the test is significant.

RESULT: The drug Fentanyl shows significant effect when compared to Midazolam.

NULL HYPOTHESIS: The drugs Fentanyl and Midazolam have the same effect on the patients.

TEST APPLIED: ANOVA

Time	Group A			Group B			P value F Vs M
	N	Mean BP	HR	N	Mean BP	HR	
Base Line	20	69 ± 02	134 ± 10	20	65 ± 04	129 ± 06	0.0143
5	20	68 ± 02	133 ± 08	20	65 ± 01	126 ± 06	0.0325
10	20	67 ± 02	129 ± 08	20	64 ± 03	124 ± 06	0.0223
15	20	67 ± 03	127 ± 08	19	64 ± 02	120 ± 06	0.0213
20	20	66 ± 02	125 ± 08	20	62 ± 03	118 ± 05	0.0156
25	20	66 ± 02	121 ± 08	20	63 ± 02	113 ± 04	0.0000
30	18	65 ± 02	118 ± 07	17	63 ± 02	110 ± 04	0.0003
35	13	64 ± 03	117 ± 07	03	64 ± 01	109 ± 03	0.0032
40	08	64 ± 03	116 ± 04	03	64 ± 02	109 ± 03	0.0000
45	03	65 ± 03	111 ± 03	02	63 ± 01	108 ± 00	0.0000
50	02	66 ± 00	111 ± 01	01	66 ± 00	102 ± 00	0.0000

(Test applied: ANOVA)

(P < 0.05 is significant)

The test applied here is ANOVA and the result shows that Fentanyl has significant effect when compared to Midazolam. (Since the mean and standard deviation values of fentanyl is more than midazolam).

DISCUSSION

Caudal anaesthesia is a useful adjunct to General Anaesthesia for infra umbilical surgeries in children as it provides post-operative analgesia and reduces peri-operative narcotic requirements.

Our data demonstrated that addition of Fentanyl or Midazolam to a mixture of local anaesthetics prolonged analgesia provided by single shot caudal block. In paediatric anaesthesia, extradural analgesia via the caudal approach is used widely for many surgical procedures. The main disadvantage of this safe and reliable technique is short duration of action after a single injection of local anaesthetic. To avoid extradural catheter placement and yet prolong the duration of single shot caudal anaesthesia, various additives to local anaesthetic solutions have been used.

In a study conducted by S.Yaddanapudi, V.K.Grover in children undergoing genitourinary and herniotomy surgeries with addition of Fentanyl 1µg/kg to Bupivacaine in caudal block concluded that caudal Fentanyl addition prolonged the duration and quality of analgesia by mean duration of 324 ± 13.4 minutes. In our study there is prolongation of duration of analgesia by mean duration of 318.20 ± 24.49 minutes with addition Fentanyl to Bupivacaine.

In a study conducted by Mohammed Naugib in children undergoing unilateral inguinal herniotomy surgeries with addition of 50µg/kg to Bupivacaine in caudal block concluded that caudal Midazolam addition

prolonged the duration and quality of analgesia. In our study there is prolongation of analgesia by mean duration of 247.25 ± 12.19 minutes with addition of Midazolam to Bupivacaine.

In our study we compared the efficacy of two differential drugs Fentanyl $1\mu\text{g}/\text{kg}$ and Midazolam $50\mu\text{g}/\text{kg}$ in combination with Bupivacaine 0.25%, 1ml/kg. Duration of analgesia was found significantly more in group using Fentanyl with mean duration of 318.20 ± 24.49 minutes compared to Midazolam with mean duration of 247.25 ± 12.19 minutes.

The haemodynamics parameters showed no significant differences between the two groups both intra-operatively and post-operatively.

Side effects of Fentanyl like vomiting, pruritis, respiratory depression was not seen in children after caudal administration of Fentanyl. There was no much sedation in children after caudal administration of Midazolam.

SUMMARY

Caudal analgesia with Bupivacaine is used commonly for pain relief in children. Fentanyl or Midazolam have shown to potentiate the analgesic effects of local anaesthetics when administered caudally in children. We did the study to evaluate the efficacy of Fentanyl or Midazolam adding to Bupivacaine in prolonging the duration of analgesia in caudal blockade in children.

Our study comprised of 40 children of either sexes aged 1-10 years, belonging to ASA-I, who were randomly allotted to two groups of 20 each. Group A received 0.25% Bupivacaine with $1\mu\text{g}/\text{kg}$ of Fentanyl whereas Group B received 0.25% plain Bupivacaine with $50\mu\text{g}/\text{kg}$ of Midazolam. Duration of analgesia is significantly more with Fentanyl ($P=0.007$) than with Midazolam. None of the children had motor blockade with either of the groups studied. Both the groups had good analgesia. All the children were calm and quiet post-operatively.

CONCLUSION

We conclude from our study that combination of Fentanyl with Bupivacaine for caudal epidural blockade resulted in longer duration and better quality of post-operative analgesia with minimum requirement of additional post-operative analgesics when compared to Bupivacaine with Midazolam.

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