A COMPARATIVE STUDY BETWEEN O.125% CAUDAL BUPIVACAINE AND 0.125% CAUDAL BUPIVACAINE WITH 0.5µg/kg FENTANYL AS CAUDAL ANALGESIA IN CHILDREN UNDERGOING ELECTIVE INFRAUMBILICAL SURGERIES

Dr. Kakani Janakibabu[1], Dr. T. V. V. S. V. Prasad[2], *Dr. Ranganadh. T[3], Dr. Shanthi jwala. U[4], Dr. G.Manju Bhargavi [5]

[1.2. 3.]Associate Professor, Department of Anaesthesiology and Critical Care, Government Medical college, Srikakulam, AP.

[4. 5.]Post graduate, Department of Anaesthesiology and Critical Care, Government Medical college, Srikakulam, AP.

*Corresponding Author: Dr. Ranganadh.T, Associate Professor, Department of Anaesthesiology and Critical Care, Government Medical college, Balaga, Srikakulam, AP 532001.

ABSTRACT:

Background: The goal is to reduce or eliminate perioperative pain with as few adverse effects as possible. The mode of anaesthesia that has been proven to be safe and effective in children is regional. In addition to extending analgesia to the postoperative period with minimal sedation [(2)], the use of inhalational and intravenous analgesics can be reduced. In childern caudal epidural is the regional block infra-umbilical procedures.

OBJECTIVES: This study was aimed at comparing Bupivacaine 0.125 % (1ml/kg) alone against Bupivacaine 0.125 % (1ml/kg) plus Fentanyl 0.5 µg/kg as a caudal block administered via single bolus in infra-umbilical procedures in children aged 1 to 8 years. Hemodynamic alterations, ie heart rate and blood pressure., and Duration of post operative analgesia after and Adverse reactions are the parameters noted

MATERIAL & METHODS: Study Design: A prospective, randomized, comparative study. **Study area:** Department of Anaesthesia and Critical care, Government Medical college ,Srikakulam ,AP. **Study Period:** 1 year. **Study population**: children, of both gender, posted for infraumbilical procedures of various types. **Sample size:** study consisted a total of 60 cases. **Sampling method:** Simple random method. A general, systemic examination, including the airway and spine, was done on the day of surgery also. Vital parameters such as systolic blood pressure, respiratory rate and pulse rate were noted. In addition, investigations such as blood and urine tests, bleeding and clotting times, a chest x- ray if necessary, and viral tests (HIV & HBsAg) were done. Informative and written consent was obtained from the parent. Prior to surgery, restriction was advised for solid foods for 6 hours, milk for 4-5 hours and clear fluids for 2-3 hours. All children were given 1 mg/kg of Promethazine syrup the night before the scheduled operation.

Results: The mean duration of analgesia at various time intervals in both the groups was statistically significant. The mean duration of analgesia in the B group (0.125% Bupivacaine) is 5.2 ± 0.85 hrs, the mean duration of analgesia in the BF group (0.125 % Bupivacaine + 0.5 mc/kg Fenyanyl) is 10.8 ± 1.24 hrs. This duration of analgesia is statistically significant as detected by using t test (p = 0.03, <0.05**)**

CONCLUSION: The present study demonstrated that caudal epidural block with Bupivacaine 0.125% (1ml/kg) plus Fentanyl (0.5 mcg/kg) resulted in analgesia of longer duration and postoperative analgesia when compared with 0.125% Bupivacaine (1ml/kg) alone, with no significant difference in the hemodynamic parameters and the occurrence of side effects.

Key words: Caudal; Bupivacaine; Fentanyl; children.

DOI Number: 10.14704/nq.2022.20.9.NQ44564 **Neuro Quantology 2022; 20(9):4871-4878**

*e*ISSN 1303-5150 www.neuroquantology.com

INTRODUCTION:

"Pain is the worst of ills, and when it is severe, it overturns all patience." Paradise Lost, by Milton. "The patient is the centre of our universe, the point around which all of our efforts revolve and all of our efforts are directed." J.B. Murph.

Due to an underestimation of pain, children were given insufficient analgesics in the beginning. However, when more information about various pain pathways became available, the concept of analgesia in the post-surgical period in children gained attention[1]. "All of mankind's happiness can be attained in the release from pain, not in pleasure." Dryden, John.

The current goal is to reduce or eliminate pain with as few adverse effects as possible. The mode of anaesthesia proven to be safe and effective in children is regional. In addition to extending analgesia to the postoperative period with minimal sedation [2], the use of inhalational and intravenous analgesics is minimised For infra-umbilical procedures, caudal anaesthesia is the routinely used regional block in children. Caudal anaesthesia is a safe and dependable mode of anaesthesia. It can be coupled with general anaesthesia for efficient analgesia both intra and postoperatively.[3].

Local anaesthetic drugs can be used in variable concentrations. Continuous caudal is not routinely practiced due to fear of infection. Therefore, the mean duration of surgical pain relief provided by caudal through a single bolus is limited by the local anaesthetic agent used, in aspect of its duration [4].

The action of caudal block can be prolonged by using additives such as opioids, Clonidine, midazolam, neostigmine, ketamine when administered through a single bolus. Compared to Bupivacaine alone, caudal opioids have the advantage of increasing analgesia duration. Side effects include vomiting, pruritis, and late respiratory depression, which can be reduced by lowering the concentration [4].

Fentanyl is a synthetic opioid agonist .When delivered via the epidural route, the leading site of action is at the substantia gelatinosa [5] located in the dorsal horn of the spinal cord At the spinal cord, Fentanyl binds to mu, kappa, and delta receptors to produce spinal analgesia. It quickly passes through the lumbar dura and reaches the lipid phase of the underlying tissue of the cord with low opioid migration in the rostral direction, avoiding depression of the respiratory and cardiovascular systems.

OBJECTIVES:

This study is aimed at comparing Bupivacaine 0.125 % (1ml/kg) alone against Bupivacaine 0.125 % (1ml/kg) plus Fentanyl 0.5 µg/kg as a caudal block administered via single bolus, in infra-umbilical procedures ,in children aged 1 to 8 years,: Hemodynamics such as variations in heart rate ,blood pressure and duration of analgesia after surgery and adverse effects , if any, are the parameters noted.

MATERIAL & METHODS:

Study Design: A prospective, randomized, comparative study.

Study area: Department of Anaesthesia, GMC, Srikakulam.

Study Period: 1 year.

Study population: children, belonging to either gender, posted for infraumbilical procedures of various types.

Sample size: study consisted of 60 cases.

Sampling method: Simple random method.

Inclusion criteria:

- Age group of 1-8 yrs.
- ASA grade I and II.
- Children electively posted for infraumbilical procedures.

Exclusion criteria:

- ASA grade III and IV
- Infection involving the sacrum
- Coagulation abnormalities or on anticoagulants
- Congenital sacral anomalies
- Meningitis
- History of hypersensitive reaction to local anaesthetics and Immunocompromised patients

Ethical consideration: Institutional Ethical committee permission was taken prior to the commencement of the study.

Study tools and Data collection procedure:

a. 23G needle (hypodermic)

b. 5 cc syringe (for whoosh test)

c. Sterile gauze, bowl, sponge holding forceps, sterile spinal sheet and spirit.

d. Drugs – (0.5%) Bupivacaine vial, Fentanyl 100 mcg ampoule, Boyle's apparatus with Sevoflurane vaporizer, Jackson Rees circuit.

e. Patent i.v line with infusion of crystalloid.

f. Sterile water for drug dilution

g. Emergency equipment included:

The children were also seen on the day of surgery, and a general, systemic examination, including the airway and spine, was performed. Vital parameters such as systolic blood pressure, respiratory rate and pulse rate were noted. In addition, investigations such as blood and urine tests, bleeding and clotting times, a chest x- ray if necessary, and viral tests (HIV & HBsAg) were done. Informative and written consent was obtained from the parent. Prior to surgery, restriction was advised for solid foods for 6 hours, milk for 4-5 hours and clear fluids for 2-3 hours. All the children were given 1 mg/kg of Promethazine syrup ,the night before the scheduled operation.

The children were randomly divided into 2 groups, each containing 30 members. Group B had the caudal block with 1 ml/kg of 0.125% Bupivacaine. Group BF had the caudal block with 1 ml/kg of 0.125% Bupivacaine plus Fentanyl 0.5 mcg/kg. The child was monitored with anPrecordial stethoscope, Temperature, SpO2, Non-invasive blood pressure, ECG, and Respiratory rate. After receiving caudal block, patients' heart rate, respiratory rate, and blood pressure were measured and recorded at time intervals of 0,5,15,30,45,60,120, and 180 minutes. The time interval from which the caudal block was administered up to the first demand for supplemental analgesia for the patient is the drug's duration of action.

The Paediatric Objective Pain Scale is used to assess postoperative analgesia. After the caudal block, the assessment was carried out for 24 hours. If the pain score was more than 6 for two consecutive 10-minute intervals, additional analgesia of syrup Paracetamol (15 mg/kg) was administered. These measurements were taken at time intervals of 1, 2, 3, 4, 8, 12, and 24 hours after the caudal block.

Statistical analysis:

The results of continuous variables are given as mean ± SD and proportion as percentage. Assessment of difference between the two groups was done by student's t test and chi-square test. A 'p' value of < 0.05 was taken as value of significance in the tests.

OBSERVATIONS & RESULTS:

The children enrolled in this study were 60 in total , belonging to the age group 1-8 years. They belonged to ASA Grade I and **II.** They were categorized into two groups of 30 each. Group B received the caudal block with Bupivacaine 0.125% (1ml/kg). Children in group BF had the caudal block with Bupivacaine 0.125% (1ml/kg) plus Fentanyl (0.5mcg/kg). The demographic parameters such as gender, age and weight did not show any statistical significance.

Table 1: Types of surgeries

Surgery	Group				Total	
	Bupivacaine		Bupivacaine + Fentanyl		N	%
	N	%	N	%		
Circumcision	9	30	5	16.67	14	23.33
Rt. Hydrocele	4	13.33	3	10	7	11.67
Lt. Hydrocele	1	3.33	2	6.67	3	5
Colostomy closure	3	10	3	10	6	10
Rt. Herniotomy	4	13.33	6	20	10	16.67
Lt. Herniotomy	1	3.33	2	6.67	3	5

Stage 1 Urethroplasty	4	13.33	5	16.67	9	15
Thirsch stitch	1	3.33	1	3.33	2	3.33
B/l Orchidopexy	2	6.67	2	6.67	4	6.67
Rectal Polypectomy	1	3.33	1	3.33	2	3.33
Total	30		30		60	

Table 2: Mean age of patients

MEAN AGE OF PATIENTS						
	GROUP	**N**	**MEAN**	**SD**	**t**	**p**
Age	Bupivacaine	30	4.1	2.31	0.5	0.31
	Bupivacaine + Fentanyl	30	4.13	2		

The mean distribution of Age between the two groups was not statistically significant.

Table 3: Sex distribution

Group	**Sex**				**Total**
	Male		**Female**		
	N	**%**	**N**	**%**	
Bupivacaine	27	90	3	10	30
Bupivacaine + Fentanyl	26	92.5	4	7.5	30
Total	54		7		60

The mean Sex distribution of patients in both the groups was not statistically significant.

Table 4: Mean distribution of HR, SBP, DBP, RR

	Group	**N**	**Mean**	**SD**	**t**	**P**
HR	Bupivacaine	30	104.42	9.26	0.01	0.5
	Bupivacaine + Fentanyl	30	105.55	6.73		
SBP	Bupivacaine	30	104.8	6.07	0.003	0.49
	Bupivacaine + Fentanyl	30	105.8	6.28		
RR	Bupivacaine	30	26.51	3.37	0.004	0.48
	Bupivacaine + Fentanyl	30	26.04	4.22		

The mean heart rate in the B group (104.42 ± 9.26), the mean heart rate in the BF group (105.55 ± 6.73) which does not show any statistical significance. (p = 0.5)

The mean systolic BP in the B group (104.8 ± 6.07), the mean systolic BP in the BF group (105.8 ± 6.28), which does not show any statistical significance. (p = 0.49).

The mean RR in the B group (26.51 ± 3.37), the mean RR in the BF group (26.04 ± 4.22), which does not show any statistical significance. (p = 0.48)

The mean distribution of HR, SBP, DBP, and RR between the two groups was not statistically significant.

Table 5: Pain incidence at various time intervals

	Group	N	Mean	SD	t	P
Pain1st hour	Bupivacaine	30	0.00	0.00	-	-
	Bupivacaine + Fentanyl	30	0.00	0.00		
Pain2nd our	Bupivacaine	30	0.00	0.00	-	-
	Bupivacaine + Fentanyl	30	0.00	0.00		
Pain3rd hour	Bupivacaine	30	4.53	0.9	5.2	<0.00001
	Bupivacaine + Fentanyl	30	0.3	0.46		
Pain 4th hour	Bupivacaine	30	4.7	0.87	2.3	0.0125
	Bupivacaine + Fentanyl	30	0.3	0.46		
Pain 8th hour	Bupivacaine	30	3.43	0.57	0.0001	0.5
	Bupivacaine + Fentanyl	30	2.77	0.73		
Pain12th hour	Bupivacaine	30	3.6	0.62	0.00015	0.5
	Bupivacaine + Fentanyl	30	3	0.59		
Pain24th hour	Bupivacaine	30	1.57	0.5	0.15	0.44
	Bupivacaine + Fentanyl	30	1.8	1.12		

The mean Pain incidence at various time intervals of patients in both the groups was statistically significant at 3 & 4 hours.

Table 6: Sedation scores at various time intervals:

	Group	N	Mean	SD	T	P
Sedation 1st hour	Bupivacaine	30	4	0	-	-
	Bupivacaine + Fentanyl	30	4	0		
Sedation 2nd hour	Bupivacaine	30	4	0	-	-
	Bupivacaine + Fentanyl	30	4	0		
Sedation 3rd hour	Bupivacaine	30	3.53	0.51	2.45	0.008
	Bupivacaine + Fentanyl	30	4	0		
Sedation 4th hour	Bupivacaine	30	3.47	0.51	1.71	0.046
	Bupivacaine + Fentanyl	30	4	0		
Sedation 8th hour	Bupivacaine	30	3.23	0.57	3.25	0.001
	Bupivacaine + Fentanyl	30	4	0		
Sedation 12th hour	Bupivacaine	30	2.9	0.75	3.87	0.0001
	Bupivacaine + Fentanyl	30	4	0		
Sedation 24th hour	Bupivacaine	30	2.6	0.49	1.92	0.029
	Bupivacaine + Fentanyl	30	4	0		

eISSN 1303-5150

Group BF showed a higher sedation score of significant value when compared to Group B after the 2nd hour in the period post-surgery.

Table 7: Duration of analgesia

Duration of analgesia	N	Mean	SD	t	P
Bupivacaine	30	5.2	0.85	1.9	0.03
Bupivacaine + Fentanyl	30	10.8	1.24		

The mean duration of analgesia at various time intervals of patients in both the groups was statistically significant. The mean duration of analgesia in the B group (0.125% Bupivacaine) is 5.2 ± 0.85 hrs, the mean duration of analgesia in the BF group (0.125 % Bupivacaine + 0.5 mc/kg Fenyanyl) is 10.8 ± 1.24 hrs. This duration of analgesia is statistically significant as detected by using t test (p = 0.03, <0.05**)**

Table 8: Incidence of complications

Complications	Group B	Group BF
Vomiting	4	6
Respiratory depression	0	0
Pruritis	0	2
Dural puncture	0	0
Hypotension	0	0
Urinary Retention	0	0
Bradycardia	0	0

In the B group the incidence of vomiting was 4 (10 %). In the BF group the incidence of vomiting was 6 (15 %) which was not statistically significant. The incidence of pruritus in the group B was 2 as compared to nil incidences in the group BF which had no value of significance. There was no incidence of respiratory depression, blood vessel puncture, dural puncture, hypotension or bradycardia in both the groups.

DISCUSSION:

The effects of 0.125 % Bupivacaine alone and 0.125 % Bupivacaine plus 0.5µg/kg Fentanyl for block via caudal route in paediatric patients were compared in the present study.

With a p-value of 0.31, the mean age distribution between the Groups B & BF was not statistically significant. With a p-value of 0.31, the mean distribution of Weight between the Groups B & BF was not statistically significant. Three patients in Group B (10%) and four in Group BF (7.5%) were females, whereas 27 patients in Group B (90%) and 26 in Group BF (92.5%) were males, with no statistical significance (p- value > 0.05). When the demographic profiles of the two groups B and BF were compared, there was no statistically significant difference. Campbell et al. [6] discovered similar results.

In each group, the changes in preoperative, intraoperative, or postoperative hemodynamic parameters were of no significant value. The B group's mean heart rate is (104.42 ± 9.26), while

the BF group's mean heart rate is (105.55 ± 6.73), neither of which is statistically significant. (p = 0.5) The mean systolic blood pressure in the B group is (104.8 ± 6.07), and the mean systolic blood pressure in the BF group is (105.8 ± 6.28), both of which are statistically insignificant. (p = 0.49) The mean RR in the B group (26.51 ± 3.37), as well as the mean RR in the BF group (26.04 ± 4.22), are not statistically significant. (p = 0.48)

Similar findings were found in other studies. Desai et al. [7] found no significant differences in hemodynamic and respiratory parametres ,when comparing Bupivacaine 0.25% with two different dosages of Fentanyl (1mcg/kg and 0.5mcg/kg) with adrenaline in caudal.

In a paediatric age range, Gharshallah A et al. [8] evaluated two different dosages of Fentanyl, 0.5mcg/kg and 1mcg/kg, with 0.25 percent Bupivacaine in caudal. They also discovered no significant alterations in hemodynamic or respiratory variables. [7] In their study of a single caudal injection of 0.125 percent Bupivacaine with Fentanyl (1mcg/kg), Campbell et al. [9] discovered hemodynamic stability.

In the B group (0.125 % Bupivacaine), the mean value of the duration of analgesia is 5.2 ± 0.85 hours, while the mean duration of analgesia in the BF group (0.125 % Bupivacaine + 0.5 mc/kg Fentanyl) is 10.8 ± 1.24 hours. This duration of analgesia is statistically significant as detected by the t-test (p = 0.03, <0.05)

Desai et al. [7] discovered in their study that the extent of analgesia was 5.04 ± 0.35 hours in Group Fentanyl (1mcg/kg) and 3.30 ± 0.57 hours in Group Fentanyl (0.5mcg/kg), indicating that group Fentanyl (1mcg/kg, had a more significant duration of analgesia than group Fentanyl (0.5mcg/kg). Constant et al. [9] studied the impacts of Fentanyl or Fentanyl with Clonidine on the extent of analgesia after a single-shot caudal block. They found that it was 253 ±105 minutes with Fentanyl (1mcg/kg) and 287 ±130 minutes with Fentanyl (0.5mcg/kg) and Clonidine (0.75mcg/kg), indicating that Clonidine prolonged the analgesic effect of 0.5mcg/kg of Fentanyl. When the dose of Fentanyl in the mixture was raised, Rucci et al. [10] discovered that analgesic blockade occurred quickly. In their research of caudal Bupivacaine (0.5%) with Fentanyl (1mcg/kg), Moine et al. [11] discovered more than 24 hours of postoperative analgesia. In their investigation, Lomessy A et al. [12] found that the extent and quality of analgesia post-surgery was improved by Fentanyl.

In their study, Campbell et al. [6] compared postoperative analgesia with caudal Bupivacaine (0.125%) and Fentanyl (1mcg/kg) to Bupivacaine alone. They came to the conclusion that adding Fentanyl to the mix did not improve or prolong postoperative analgesia. Gharsallah et al. [8] also observed similar findings. In contrast to the above two studies, analgesia in the Bupivacaine- Fentanyl group was of a longer duration than in the Bupivacaine alone group in this study.

Nausea and vomiting were reported by 10% of participants in Group B and 15% of patients in Group BF in this study. Despite the fact that individuals receiving Fentanyl had a higher rate of vomiting, the results were not statistically significant. Respiratory depression, or urinary retention was not present in any of the patients in our study. Desai et al. [7] and Gharsallah et al. [8] reported similar observations.

Caudal administration of an opioid analgesic with local anaesthetics is safe, effective, and dependable in postoperative pain management. Fentanyl provides analgesia faster and has fewer adverse effects such as nausea and vomiting. Fentanyl 0.5mcg/kg combined with Bupivacaine offers a longer duration of analgesia than Bupivacaine alone.

CONCLUSION:

The present study demonstrated that caudal block with Bupivacaine 0.125% (1ml/kg) plus Fentanyl (0.5 mcg/kg) resulted in a longer duration of intra operative and postoperative analgesia when compared to 0.125% Bupivacaine (1ml/kg) alone, with no significant difference in the incidence of hemodynamic parameter variations and occurrence of side effects.

REFERENCES:

1. Frank HK. The society of Paediatric Anaesthesia: 15th annual meeting, New Orleans, Louisiana. Anaesthesia Analgesia 2002; 94:1661-1668.

2. Wolf AR. Development and evaluation of pain and the stress response. In: Bissonette B, Dalens BJ, editors. Paediatric Anaesthesia principles and practice. Nework: McGraw-Hill; 2002.p.187-200.

3. Langlade A, Kriegel I. Treatment of acute postoperative pain. Ann Chir 1997; 51:1013-1021.

4. El Hamamsy M, Abd-Elrahman A, Abd-Elaziz Essa M, Zakaria D. Prolongation of caudal analgesia in pediatric surgery: Comparison between dexmedetomidine, clonidine, tramadol, and fentanyl. Kasr EL Einy Med J 2008; 14:1-10.

5. Shukla U, Prabhakar T, Malhotra K. Postoperative analgesia in children when using clonidine or fentanyl with ropivacaine given caudally. J Anesthesiol Clin Pharmacol 2011; 27:205-10.

6. Campbell FA, Yentis SM, Fear DW, Bissonnette B (1992) Analgesic efficacy and safety of a caudal bupivacaine fentanyl mixture in children. Can J Anesth 39(7): 661- 664.

7. Desai DJ, Swadia VN, Gupta KK. Comparative Study of Two Different Doses of Fentanyl with 0.25% Bupivacaine through Caudal Route for Paediatric Anaesthesia and Postoperative Analgesia. J Anaesth Clin Pharmacol 2008; 24(1): 31-34.

8. Gharsallah A, Atallah T, Hmouda H. Evaluation of two dosage of fentanyl in caudal anaesthesia. Can J Anaesth 1996; 44(5): 419-421.

9. Constant I, Gall O, Gauyet L, Chauin M, Murat I. Addition of clonidine or fentanyl to local anaesthetic prolongs the duration of surgical analgesia after single shot caudal block in children. Br J Anaesth 1998; 80: 294-298.

10. Rucci FS, Cardarone M, Miloglori P. Fentanyl and bupivacaine mixtures for extradural blockade. Br J Anaesth 1985; 57: 275-284.

11. Moine P, Ecoffey C. Bupivacaine caudal block with fentanyl in children. Anesthesiology 1998; 3A: V71.

12. Lomessy A. Magna C. Clinical advantages of fentanyl given epidurally for post-operative analgesia. Anesthesiology 1984; 61; 466-69.

13. Polaner D.M., Taenzer A.H., Walker B.J. Paediatric Regional Anesthesia Network (PRAN): a multi-institutional study of the use and incidence of complications of pediatric regional anesthesia. Anesth Analg. 2012; 115:1353–1364.

14. Mirjalili S.A., Taghavi K., Frawley G., Craw S. Should we abandon landmark- based technique for caudal anesthesia in neonates and infants. Paediatr Anaesth. 2015; 25:511–516.

15. Solanki N M, Engineer S R, Jansari D B, Patel R J. Comparison of caudal tramadol versus caudal fentanyl with bupivacaine for prolongation of postoperative analgesia in pediatric patients. Saudi J Anaesth 2016; 10:154-60

16. Kannojia UK, Meena RK, Paswan AK, Meena K, Prakash S, Loha S. Comparison of caudal dexmedetomidine and fentanyl combined with bupivacaine in pediatric patients undergoing urogenital surgery. Anaesth Pain & Intensive Care 2017;21(2):204-211