A RANDOMIZED CLINICAL TRIAL COMPARING PLAIN BUPIVACAINE AND DEXMEDETOMIDINE AS ADJUVANT TO BUPIVACAINE IN PAEDIATRIC CAUDAL ANESTHESIA

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ABSTRACT :

Background Many local anesthetic drugs of variable concentration are used. Bupivacaine is a long-acting amide local anaesthetic that has provided reliable anaesthesia and analgesia with differential motor-sensory blockade for more than 40 years. Caudal opioid have advantages of prolonging duration of analgesia, but has side effects such as nausea, vomiting, pruritis and late respiratory depressionHence here is an attempt to study, addition of dexmedetomidine with striking lack of respiratory depressant effect, when given as adjuvant with caudal bupivacaine .

Methods: This was a Prospective Double blinded Randomized Comparative clinical trial conducted in mookambikai Hospital surgery department Chennai from April 2023 to August 2024. he randomization was done by assistant, using simple lot system. We wrote equal number of letter A and B (50 envelopes contained letter A and 50 envelopes letter B) in a closed envolopes. Patients were asked to pick up one envelope randomly. Patients were assigned in a group whichever letter the envelope contained.

Results: we conclude that dexmedetomidine is a safe and effective adjuvant to local anaesthetic bupivacaine for paediatric caudal anaesthesia. Dexmedetomidine 2mcg/kg with bupivacaine 0.25% 1ml/kg provided quality analgesia and extended duration of post operative analgesia compared to plain bupivacaine 0.25% in equal volumes and concentration when administered for caudal block for sub-umbilical surgeries. Dexmedetomidine provided hemodynamic stability and less incidence of shivering in the post operative period compared to plain bupivacaine.

Conclusion our study allow us to conclude that the addition of dexmedetomidine 2mcg/kg to caudal 0.25% bupivacaine significantly increases duration of post-operative analgesia in children of 2-7 years age undergoing elective sub umbilical surgeries.

Keywords: Dexmedetomidine, Bupivacaine, Caudal Anesthesia.

INTRODUCTION:

Pain is perhaps the most feared symptom of disease, which a man is always trying to alleviate and conquer since ages. Historically, children have been undertreated for pain and for painful procedures and are often unrecognized or neglected1.

The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.2 In children, even the definition of pain has been debated.3 Research over the past two decades has provided incontrovertible evidence that not only do neonates experience pain, but that unrelieved pain has adverse long-term consequences. They are harmful neuroendocrine responses, behavioral changes, disrupted eating and sleep cycles, and increased pain perception during subsequent painful experiences.4, 5, 6

Till date, various methods and medications have been tried to provide post operative pain relief in pediatric population. Side effects of the pain medication have limited their use in children. For example, narcotics could cause respiratory depression, pruritis. Oral analgesics cannot be given during immediate post-operative period after general anesthesia due to the risk of vomiting and aspiration. Fear of needle stick in the case of parenteral analgesics poses problem in pediatric population.

Pain management is an integral part of practice of pediatric anesthesiologists7.
Regional anesthesia in pediatric population is safe and effective. Along with providing post-operative analgesia, it reduces requirements of inhalational and intravenous agents with minimum sedation 7. Caudal epidural anesthesia is the most commonly practiced regional technique in children for abdominal and lower limb surgeries.

Many local anesthetic drugs of variable concentration are used. Bupivacaine is a long-acting amide local anaesthetic that has provided reliable anaesthesia and analgesia with differential motor-sensory blockade for more than 40 years.8, 9

But the mean duration of surgical analgesia provided by long acting local anesthetic drug is only for 4-8 hrs during single shot caudal procedure. For this reason prolongation is achieved by addition of various adjuvants like opioids, clonidine, midazolam etc. Caudal opioid have advantages of prolonging duration of analgesia, but has side effects such as nausea, vomiting, pruritis and late respiratory depression10.
Hence here is an attempt to study, addition of dexmedetomidine with striking lack of respiratory depressant effect, when given as adjuvant with caudal bupivacaine 8, 9.

AIM AND OBJECTIVES OF THE STUDY:

This study aims to compare plain bupivacaine and dexmedetomidine as adjuvant to bupivacaine in prolongation of post operative analgesia in pediatric caudal anesthesia.

MATERIALS AND METHODS:

This was a Prospective Double blinded Randomized Comparative clinical trial conducted in mookambikai Hospital surgery department Chennai from April 2023 to August 2024. The randomization was done by assistant, using simple lot system. We wrote equal number of letter A and B (50 envelopes contained letter A and 50 envelopes letter B) in a closed envolopes. Patients were asked to pick up one envelope randomly. Patients were assigned in a group whichever letter the envelope contained. The drug preparation was made by the assistant based on selected patients group. Caudal block was performed by the investigator, Intra operative monitoring and post operative observations were made by the SameBlinding: The patient's parents/guardians were not aware, to which group the child belongs to. and the investigator was also blinded as the randomization and drug preparation was done by assistant who was not involved in the study.

Before the start of the study ,Pilot study was done with a sample size of 10 patients in each group, to decide on sample size. The mean and standard deviation of duration of post operative analgesia was calculated from pilot study. The sample size was calculated based on the formula given in NTI Bulletin 2006. (Sample size determination in health studies, V. K. Chadha,, National Institute Bulletin 2006 children were selected based on criteria:2-7 years age,either male or female sex,belonging to ASA I or II physical status,

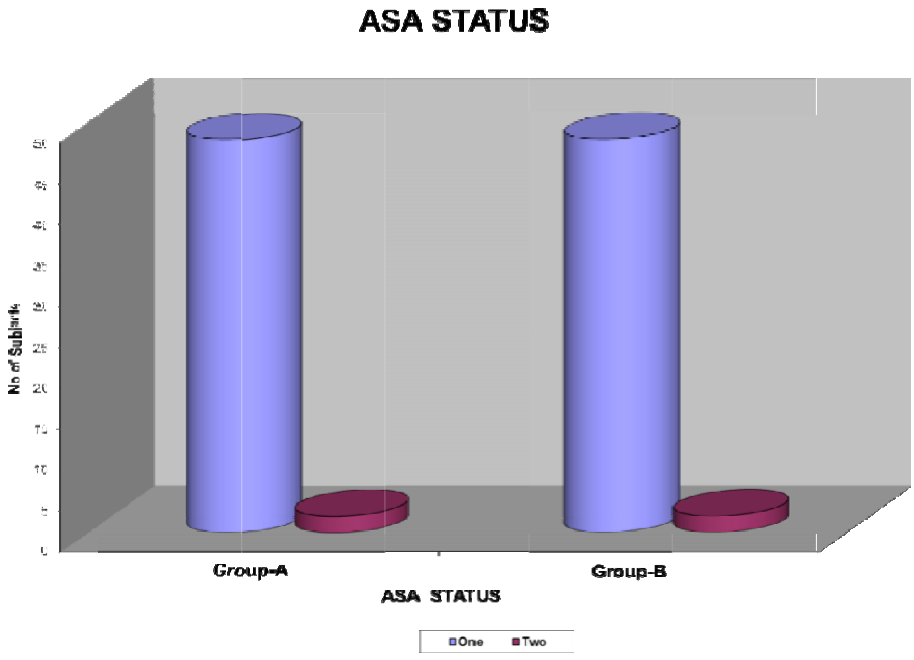
The children with the following problems were excluded from the study:Local infection in the Caudal region,Preterm neonate,Pre-existing Neuromuscular disease,Congenital anomaly of the lower back,Mental retardation, Delayed development,Bleeding disorders or coagulopathy,Parent refusal for the procedure.

Statistical analysis was done using the statistical package for social sciences (SPSS).Different statistical methods were used as appropriate. Mean ± SD was determined for quantitative data and frequency for categorical variables. The independent t- test was performed on all continuous variables. The normal distribution data was checked before any t-test. The Chi-Square test was used to analyze group difference for categorical variables. A p- value < 0.05 was considered significant

RESULTS:

ASA Status

	Group-A		Group-B	
	N	**%**	**N**	**%**
1	48	96	48	96
2	2	4	2	4
Total	**50**	**100**	**50**	**100**
Chi square Value *	**0**			
Df	**1**			
Significant	**1.000 (Not Significant)**			



DURATION OF SURGERY:

There was no difference in the duration of surgery between the two groups with a maximum duration of 50 min. The average duration of surgery was around 32 min in both groups.

	Group-A	Group-B
Mean	31.9	32.4
Sd	11.95	13.02
t-Value	**0.2**	
Df	**98**	
p-value	**0.84 (Not Significant)**	

TYPE OF SURGERY:

Type of surgery between two groups were similar .The level of blockade required was similar in both groups.

Surgery	Group A		Group B		Total	
	N	%	N	%	N	%
PVSL	2	4	3	6	5	5
URETHROPLASTY	6	12	6	12	12	12
HERNIOTOMY	16	32	13	26	29	29
PVSL+CIRCUMCISION	7	14	7	14	14	14
CIRCUMCISION	3	6	2	4	5	5
ORCHIDOPEXY	13	26	14	28	27	27
Others	3	6	5	10	8	8
TOTAL	50	100	50	100	100	100

Chi-square 1.78 DF=6 significant value =0.94 (Not Significant)

DURATION OF ANALGESIA:

There was a significant difference in duration of analgesia between twogroups. Group A has post operative analgesia of (4.22+/_1.09) hours and group B has average (13.64+/_4.12) hours analgesia. Difference was statistically significant(p=0.0002)

Duration of Analgesia

	Group-A	Group-B
Mean	4.22	13.64
Sd	1.09	4.12
t-Value	15.64	
Df	98	
p-value	0.0001 (Significant)	

Duration of Analgesia:

The number of times patients received analgesia was more in group A compare to group B. 68% patients in group B required only once supplementation of paracetamol. 48% patients in group A received paracetmol 15mg/kg analgesia three times in 24 hour compare to only 3(6%) patients in group B.7(14%) patients in group B did not required paracetamol supplementation in 24 hours versus all patients in group A required analgesic supplementation . Number of times the additional analgesia required was more in group A and hence the total analgesia consumed is more in group A.

Post operative analgesia requirement

No of times Analgesia given	Group-A		Group-B	
	N	**%**	**N**	**%**
0	0	0	7	14
1	6	12	34	68
2	20	40	6	12
3	24	48	3	6
Total	**50**	**100**	**50**	**100**

DISCUSSION:

Bupivacaine is a long acting amide local anesthetic. It is most frequently used for caudal anaesthesia in children that provides effective analgesia and motor blockade.
Dexmedetomidine is a potent alpha 2 agonist, widely used to provide analgesia sedation and anxiolysis. It is a safe adjuvant to to bupivacaine in pediatric caudal anaesthesia.

In our study we evaluated the effect of combination of bupivacaine and dexmedetomidine in prolongation of post operative analgesia in children. Incidentally hemodynamic changes and side effects like nausea vomiting and shivering was also compared between plain bupivacaine group and combination of bupivacaine and dexmedetomidine group, in children undergoing lower abdominal and perineal surgeries.

In a double-blinded comparative study, 100 children aged 2-7 years of ASA I and II physical status were randomly allocated to receive a single pre-surgical caudal injection of 1ml/kg of 0.25% bupivacaine and 1ml normal saline (Group A) or 0.25% Bupivacaine and 1ml of 2mcg/kg dexmedetomidine (Group B), after induction of general anaesthesia. Apart from monitoring the vital parameters likr, heart rate, blood pressure, spo2, all children were assessed for postoperative analgesia by FLACC pain scale. Incidence of side effects like nausea vomiting and shivering was noted.
The two groups were comparable for age, sex, weight, vital signs, duration and type of surgery. The following results were noted at the end of study.

Thequality and duration of analgesia was significantly prolonged in group B(14+/-69 HOURS) compared to group A (4.22 hour).

Total number of analgesic administered after rescue analgesia in group A was very high compared to group B.3, hemodynamic changes between two groups were not significant in both groups. There was no bradycardia or hypotension either intra operatively or post operatively.
Incidence of shivering was high in group A compared to group B.

From above results we conclude that dexmedetomidine is a safe and effective adjuvant to local anaesthetic bupivacaine for paediatric caudal anaesthesia. Dexmedetomidine 2mcg/kg with bupivacaine 0.25% 1ml/kg provided quality analgesia and extended duration of post operative analgesia compared to plain bupivacaine 0.25% in equal volumes and concentration when administered for caudal block for sub-umbilical surgeries. Dexmedetomidine provided hemodynamic stability and less incidence of shivering in the post operative period compared to plain bupivacaine.

CONCLUSION:

From above observations, our study allow us to conclude that the addition of dexmedetomidine 2mcg/kg to caudal 0.25% bupivacaine significantly increases duration of post-operative analgesia in children of 2-7 years age undergoing elective sub umbilical surgeries. Addition of dexmedetomidine provides stable hemodynamics and lesser incidence of shivering in paediatric patients.

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