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A STUDY OF THE EFFICACY AND SAFETY OF CLONIDINE AS AN ADJUNCT TO BUPIVACAINE FOR CAUDAL ANALGESIA IN CHILDREN

Anaesthesiology

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ABSTRACT

Aim to assess the efficacy of 1µ|kg of Clonidine as a caudal adjunct to bupivacaine for postoperative pain relief in paediatric patients. To assess the safety of Clonidine, as a caudal adjunct to bupivacaine to increase the duration of analgesia. This prospective randomised study was conducted on 40 paediatric patients. 20 in each group of ASA-I,II were posted for lower abdominal surgeries. After induction of anaesthesia the patients were positioned in left lateral position with hips and knees flexed. With 22G hypodermic needle caudal epidural block given at sacral hiatus after confirming negative aspiration. Group B received 0.25% bupivacaine alone. Another group BC received 0.25% bupivacaine with Clonidine 1microgram/kg.

KEYWORDS

INTRODUCTION

Pain is a more terrible lord of mankind than even death itself" said nobel laureate ALBERT SCHWEIZER. Pain has become the fifth vital sign and is now a critical focus of the patient. The relief of pain has been the fundamental aspect of the practice of anaesthesiology. Proper management of pain remains one of the most important and pressing responsibilities of the anaesthesiologist.

There is increasing evidence that optimal pain management can impact outcome beyond the intraoperative period. Alleviation of postoperative pain may continue to improve clinical outcomes, hasten recovery, facilitate early mobilization and return to daily living. Children suffer pain in the same way as adults though they may be unable to describe the pain or their subjective experiences. Unfortunately, even when their pain is obvious, children frequently receive no treatment or inadequate treatment.

Appropriate pain management is of great importance when dealing with children, because the way the child is treated may influence the way he or she deals with pain for the rest of his or her life. Untreated pain can lead to physiological complications, psychological distress and personality changes in developing children, family disruption and prolongation of hospital stay with resultant increased expenses. In addition social withdrawal, temper tantrums and autistic behavior are also seen in these children.

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The role of clonidine as an analgesic administered by extradural route is now well established in children. Co administration of caudal clonidine in a dosage of 1µg|kg with 0.25% bupivacaine has been found to prolong analgesia without any adverse effects.

Extradural clonidine in a dose of 1 – 3µg|kg added with local anaesthetics intensifies the analgesia by approximately 50%. The sedative property of Clonidine reduces the requirements of hypnotics and is often a desirable feature. This study was conducted to assess the efficacy and safety of clonidine in low doses as an adjunct to bupivacaine for postoperative pain relief in paediatric patients.

MATERIAL AND METHODS

This is a prospective randomised comparative study which was done at MALLA REDDY INSTITUTE OF MEDICAL SCIENCES Suraram, Hyderabad with sample size of 40 for a period of 18 months January 2020 to june 2021.

Inclusion Criteria :

- Patients aged between 2-8yrs of either gender
- ASA-I & II

Exclusion Criteria :

- local infection in the caudal region,
- bleeding diathesis,
- preexisting neurological (or) spinal diseases
- congenital anomaly of the lower back.

A written consent was obtained from the parents after they were informed about the procedure to be performed, to give post operative analgesia for their children. The children were allocated randomly into two groups of 20 patients each. One group named group B received 0.75 ml/kg of 0.25% bupivacaine alone. Another group named group BC received 0.75ml/kg of 0.25% bupivacaine with 1microgram/kg clonidine.

All children were kept fasting for 6 hours. They were received by an anaesthesiologist inside the premedication room one hour before surgery. Preanaesthesia check up was done and the children were premedicated with syrup midazolam 0.5 mg/kg 45 minutes prior to the surgery.

Baseline cardio respiratory parameters such as pulse rate, noninvasive blood pressure, electrocardiogram, respiratory rate and oxygen saturation(SpO_2) were recorded and monitored continuously every 5 minutes intraoperatively.

Intubation is facilitated with Inj.suxamethonium chloride 2mg/kg. Patients were intubated with an appropriate size uncuffed endotracheal tube orally. No opioids were used intraoperatively. Under controlled ventilation, muscle relaxation was maintained with Inj.vecuronium 0.08mg/kg. Anaesthesia was maintained with halothane 0.5 – 1% and 70 % nitrous oxide in oxygen mixture. Under strict aseptic precautions, a 22 G hypodermic needle was inserted in the sacral hiatus at 45 degree angle to the skin. Once the sacrococcygeal membrane was penetrated and loss of resistance obtained the angle was changed and needle was directed up the canal further 2-3mm the injection was made after gentle aspiration to rule out any intrathecal or intravascular placement. Group B received 0.25% Bupivacaine alone. Another Group BC received 0.25% Bupivacaine with Clonidine 1micro grams/ Kg .

The dosage of local anaesthetic injected into the caudal space was calculated according to the MODIFIED ARMITAGE formula .

On completion of surgery, the residual effect of the muscle relaxant

was reversed with Inj.neostigmine 50 microgram/kg and Inj.atropine 20 microgram/kg and patients were extubated when fully awake.

The recovery was assessed using MODIFIED ALDRETE SCORE (27) and children were shifted to the post operative ward, where monitoring of respiratory rate, oxygen saturation (SpO2), pulse rate and blood pressure were continued. The quality of analgesia was assessed hourly, for the first 6 hours and then every 2 hours for the next 6 hours.

The intensity of pain was measured using the OBJECTIVE PAIN SCALE SCORE devised by HANNALLAH RS.(28). Each parameter was awarded a score of 0-2 accordingly. The sum total of the awarded score was taken at each time interval. A log was kept at the bedside for noting the occurrence of possible complications including hypotension, bradycardia and respiratory depression. Patients were administered rescue analgesia with Syrup paracetamol 10mg/kg on evidence of pain (i.e) if the OBJECTIVE PAIN SCALE reached a value of 5. The duration of analgesia was calculated from the time of injection of the drug in the epidural space to the time when OPS reached 5.

Postoperative sedation score was done using RAMSAY SCALE every one hour for first 6 hours and then every 2 hours for the next 6 hours. Respiratory depression was defined as decrease of (SpO2) less than 93% or a decrease in respiratory rate less than 10/min. Excessive sedation was defined as a RAMSAY SEDATION SCORE of V or VI Caudal block and monitoring of scores for pain and sedation were performed by anaesthesiologists blinded to the study allocations.

OBSERVATION AND RESULTS

They were randomly divided into two groups of 20 patients each to receive caudal block as mentioned below. One group (group BC) received a mixture of 0.75ml / kg of 0.25% bupivacaine and 1microgram/kg clonidine, 20 minutes before surgery. Other group (group B) received 0.75ml / kg of 0.25% .bupivacaine alone 20 minutes before surgery. The patients were assessed by a blinded observer in the postoperative period.

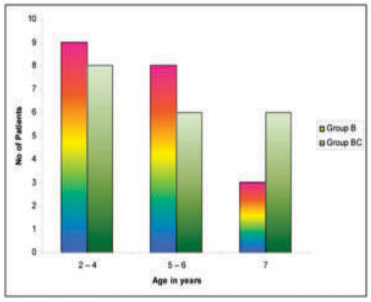
Age And Sex Distribution

The age distribution in both groups ranged from 2-8 years as follows.

AGE IN YEARS	GROUP B		GROUP BC	
	MALE	FEMALE	MALE	FEMALE
2 – 4	6	3	6	2
5 – 6	5	3	4	2
7	2	1	4	2
	13	7	14	6

From this table it is clear that the number of children in 2 – 4 yrs, 5 – 6 yrs and 7 years interval is not much different between the two groups. This shows age was not a confounding factor.

Age Distribution



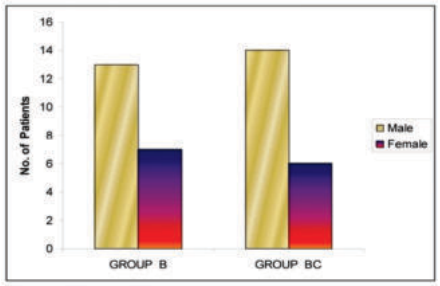
In this bar diagram, the horizontal axis represents age in years and vertical axis represents the number of patients. The age distributions in both groups are not much different.

Mean Age in years + S.D	GROUP B	GROUP BC	P VALUE
	4.8 + 1.44	5.15 + 1.63	0.48

S.D (Standard deviation)

There was no statistically significant difference in age distribution (P > 0.05).

Hence there is no bias in the age distribution.



Gender Distribution

In group B 65% are male and 35% are female and in group BC 70% are male and 30% are female. The sex distribution in both the group is also not much different. Hence there is no bias in the sex distribution.

Weight Distribution

Mean Wt in kgs + S.D	GROUP B	GROUP BC	P VALUE
	22.1 + 5.18	18 + 5.41	0.46

S.D (Standard deviation) There was no statistically significant difference in weight distribution (P > 0.05).

Hence there is no bias in the weight distribution.

Types Of Surgical Procedures

The various surgical procedures performed are shown below.

SURGICAL PROCEDURES	GROUP B	GROUP BC
Herniotomy	12	12
Pvsac ligation	5	4
Hypospadias	3	4
Total	20	20

From this table it is clear that the type of surgical procedures between the two groups is not much different. Hence there is no bias in the type of surgical procedures

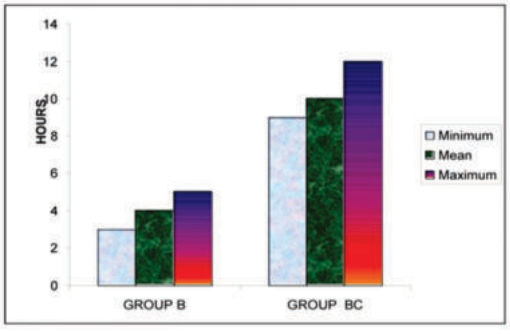
Duration Of Analgesia

Duration of analgesia in group B (0.25% Bupivacaine) ranged from 3 to 5 hours with a mean duration of 4.3 hours. Duration of analgesia in group BC (0.25% Bupivacaine and 1microgram/kg clonidine) ranged from 9 to 12 hours with a mean duration of 10.2 hours.

Duration Of Analgesia

Mean duration of Analgesia in hrs + S.D	GROUP B	GROUP BC	P VALUE
	4.3 + 0.73	10.2 + 1.01	0.0001

S.D (Standard deviation)



Duration Of Analgesia

The mean duration of analgesia in group BC is 10.2 hours, whereas in group B it is only about 4.3 hours. This means that group BC has got extended duration of analgesia when compared with group B. This duration of analgesia is also statistically significant as detected by using student 'T' test, by which the probability value is less than 0.05 (P < 0.0001). This P value means that it is highly significant.

DISCUSSION

The past decade has witnessed many advances in the understanding and treatment of pain in children. Recently regional blocks are being used for pain relief in children. Local anaesthetic agents have been routinely used for regional blocks in children. The use of adjuncts can effectively help in reduction of the dose and an increase in duration of the local anaesthetic agents.

This study was undertaken to assess the efficacy and safety of clonidine with bupivacaine in paediatric patients undergoing lower abdominal surgeries under caudal analgesia. KLIMSCHA.W et al carried out a similar study and concluded that clonidine 1microgram/kg and 2microgram/kg can be safely added to bupivacaine caudal blockade in small children for ambulatory hernia repair to achieve an increased duration of analgesia (median [range]) was (360 [270-360] minutes and 360 [355-360] minutes respectively). The major drawback of their study was the limited time of post operative assessment because of early discharge (6 hours.). In our study, the duration of post operative assessment was 12hours to assess the maximum duration of analgesia provided by clonidine and local anaesthetic combination.

In a study by JAMALI .S et al on the advantage of the use of clonidine in paediatric regional analgesia, the dose of bupivacaine used was 1ml/kg of 0.25% bupivacaine and duration of analgesia was 16 hours. In the present study however, 0.75 ml/kg of 0.25% bupivacaine was used. The dose of clonidine used was 1microgram/kg and the duration of analgesia was 10.2 hours. This may be explained by the fact that the quality, level and duration of the caudal blockade is depends on the dose, volume and concentration of the injected drugs as per SILVANI, CAMPORESI, AGOSTNO, SALVO study (14). They compared the duration of post operative analgesia in children undergoing hypospadiasis repair when two different volumes and concentrations of fixed doses of ropivaccaine were used. They concluded that high volume low concentration regimen produces prolonged analgesia as compared to low volume high concentration regimen.

CONCLUSION

This study concludes that the addition of clonidine in the doses of 1microgram/kg to 0.75ml/kg of 0.25% bupivacaine for caudal blockade significantly prolongs the duration of analgesia in pediatric patients.

This dose is safe for use in pediatric patients without any additional risk.

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