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Anesthesiology

EFFICACY OF CLONIDINE AS AN ADJUVANT TO BUPIVACAINE FOR CAUDAL ANALGESIA IN PAEDIATRIC PATIENTS

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ABSTRACT

Background

Local anesthetics have been routinely used for regional blocks in children. Clonidine an alpha2 adrenergic agonist, has been used as an adjunct to local anesthetics for caudal analgesia. This study was conducted to see the efficacy of clonidine as an adjunct to bupivacaine in post operative pain relief following caudal analgesia for subumblical surgeries in paediatric (age 1-3 years).

Aim

To assess the efficacy of combining clonidine with bupivacaine and comapare it with bupivacaine alone on duration of postoperative analgesia, in paediatric caudal anesthesia for children (1-3 years) coming for subumbilical surgery.

Materials and methods

This randomized double blind controlled trial in 100 pediatric patients undergoing We elective subumbilical surgery under general anesthesia in our institute between 2014 January to 2016 January for a period of 2 yrs

Results

We found that clonidine as an adjuvant to bupivacine enhanced postoperative analgesia compared to bupivacaine alonewithout deleterious side-effects

Conclusion

From our study, we conclude that there is significant difference in the duration of analgesia and post operative analgesia between two groups.

KEYWORDS : Bupivacine, clonidine, postoperative analgesia

INTRODUCTION

It is unconscionable to continue to neglect the safe application of analgesics in our young patients. The past decade has witnessed enormous evolution and specialization in studies and research pertaining to pediatric analgesia and pharmacotherapy. It is now accepted that acute post operative pain management is an integral part of the practice of pediatric anesthesia[1].

Considering the facts that biology of pain development of pain perception in children, assessment of pain, behavioral and psychological aspects of pain and pharmacology of analgesics are unique to this age group, the approach to a pediatric patient and the modalities to reduce pain should also be specialized. Local anesthetics have been routinely used for regional blocks in children. Clonidine, an alpha2 adrenergic agonist, has been used as an adjunct to local anesthetics for caudal analgesia[2] This study was conducted to see the efficacy of clonidine as an adjunct to bupivacaine in post operative pain relief following caudal analgesia for sub umbilical surgeries in pediatric (age 1-3 years). We compare postoperative pain relief as well as the requirement of rescue analgesia also looking for postoperative complications as compared to local anesthetics alone. Clonidine, and alpha-2 adrenergic agonist and can be safely administered is caudal analgesia and is being used as an adjunct to local anaesthetics to increase the duration of analgesia[3] We compared pain relief after surgery as well as requirement of rescue analgesiain this study. The successful use of clonidine in adults led to the evaluation in paedeatric analgesia[4]

Materials and methods

In our study we performed caudal analgesia in 2 groups of pediatric patients to compare the efficacy of clonidine as an adjuvant to bupivacaine versus bupivacaine alone in children undergoing sub umbilical surgery. The caudal analgesia remains the most popular and commonly used reliable and safe technique in pediatric analgesia. This is a randomized double blind controlled trial in 100 pediatric patients undergoing elective sub umbilical surgery under general anesthesia in our institute between 2014 January to 2016 for a period of 2 yrs.Sample size determined by power analysis.

INCLUSION CRITERIA

1. Age 1 to 3 years
2. ASA I & II patients
3. Patients undergoing elective sub umbilical surgery.

EXCLUSION CRITERIA

1. ASA grade > or = III
2. Infection at the site of caudal analgesia
3. Any sacral bone anomalies
4. Spina bifida
5. Coagulopathy

METHODS

100 patients under ASA –I and ASA – II scheduled to undergo elective sub umbilical surgery were included in this study. Preoperative examination was done and informed consent obtained. Subjects were premedicated with 0.5mg/kg oral midazolam prior to induction. The patients were randomly allocated into two groups by picking random lots from a sealed bag

Group 'A' received 1ml/kg of 0.25% bupivacaine in normal saline.

Group 'B' Received 1ml/kg of 0.25% Bupivacaine with Clonidine 1mcg/kg in normal saline.

The block was given post induction by a consultant anesthesiologist, and another anesthesiologist who was blinded to the injection monitored post operative scoreThe patients were assessed for 24 hours post operatively. Pain score was assessed using FLACC scale.

F- Face, L – Leg, A – Activity, C – Cry, C – Consolability

O – no pain
1- 3 mild pain
4- 7 moderate pain
8- 10 severe pain

The follow up in PACU and ward for FLACC scale was noted separately by anesthesiologist in the PACU and a nurse in the ward who were blinded, and the date was analyzed at the end of the study by a blinded statistician. The post operative follow up times were 15, 30,45,60,90,120 minutes for heart rate and systolic blood pressure. The FLACC scale was noted for 0,1,2,6,12 and 24 hrs post operatively. In the post operative unit, the necessity for rescue medicine was decided by the pain score > or = 4. Rescue medication was provided with paracetamol suppository with a loading dose of 30-40mg/kg followed by 15-20mg/kg sixth hourly

In the post operative period patients were also monitored for adverse effects including respiratory depression, hypotension and bradycardia.

RESULTS

In our study we compared the effectiveness of clonidine as an adjuvant to bupivacaine in caudal analgesia for pediatric patients coming for sub umbilical surgery.There was no difference in demographic analysis.

The mean age of the two groups were compared using independent T-test. Group A has a mean age of 20.72 month. Group B had a mean age of 19.32months. It was found to be insignificant with a p value of 0.253

Table 1

Age in months	Mean	SD
Group A	20.72	5.89
Group B	19.32	6.27

The sex distribution between the two groups was compared with Persons Chisquare test. There was no significant difference between the two groups with a p value 1.0

Table2

SEX	Group A	Group B
MALE	47	47
FEMALE	3	3

The mean weight of the patient in the two groups were compared using independent. I test and it was found that there was no significant difference between the two groups, with a p value of 0.118

Table 3

WEIGHT (KG)	MEAN	SD
GROUP A	10.06	2.14
GROUP B	8.56	2.28

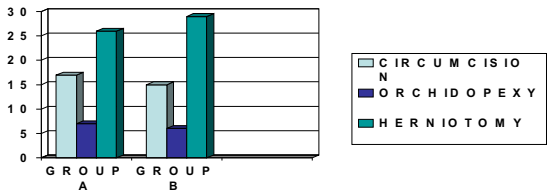
TYPE OF SURGERY

The type of surgery between the two groups was compared using Pearsons Chiquare test and it was insignificant with a p value of 0.833

Table4

TYPE OF SURGERY	GROUP A	GROUP B
CIRCUMCISION	17	15
ORCHIDOPEXY	7	6
HERNIOTOMY	26	29

Chart 1



DURATION OF SURGERY

The duration of surgery between the two groups was compared using independent. T test. Group A had a mean age of 28.9 minutes. It was found to be insignificant with a p value of 0.438

Table 5

DURATION OF SURGERY	MEAN
GROUP A	28.9
GROUP B	25.5

DURATION OF ANALGESIA

The duration of analgesia between the two groups were compared using Mann-whitney test. It was found that there was a significant difference between Group A and B with a p value of <0.05 with a mean of 288.7 minutes in Group A and 593.4 minutes in Group B.Aruna parameswari et al also found similar results in their study.

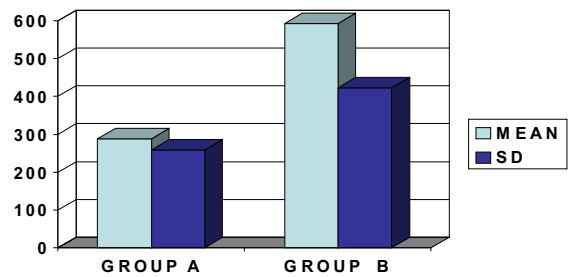
Table 6

DURATION OF ANALGESIA (MIN)	GROUP A	GROUP B
MEAN	288.7	593.4
SD	259.1	423.3

Yildiz et al, examined the effects of clonidine with 0.125% bupivacaine on the duration of postoperative analgesia in caudal anesthesia in 60 children aged 1-10 years undergoing elective inguinal hernia repair and found that the duration of postoperative analgesia was significantly longer (10hurs + 50minutes) in the group given bupivacaine and 2 ug/kg clonidine.

In our study, in the clonidine Group B, there was prolonged analgesia for a period of 9hours + 53 minites (SD 7 hours + 3minutes) in the post operative period when compared to groups A where patients had analgesia only for a period of 4hours +48 minutes (SD 4 hours + 19 minutes

Chart2



RESCUE MEDICATION

The requirement of rescue medicine was compared between the two groups using Pearsons Chisquare test and it was found to be significant with a p valu <0.05 with 9 children not requiring rescue analgesia for 24 hours postoperatively in group B compared to 2 children in group A

Table 7

NUMBER OF DOSES	GROUP A	GROUP B
ZERO	2	9
ONE	29	34
TWO	15	7
THREE	4	0

NUMBER OF RESCUE ANALGESIC DOSES

In group A, 2 children did not require rescue analgesia for the first 24 hours postoperative period where as in group B 9 children did not require rescue analgesia. iv morphine during the initial 24 hours postoperative period. In our study the number of patients who received rescue medications was much less in group B than in group A. In group A, 2 children did not require rescue analgesia for the first 24 hours postoperative period where as in group B 9 children did not require rescue analgesia.

Tripi et al, showed in their study that clonidine given caudally with bupivacaine 0.125% in a group of children aged 1-10 years undergoing uretero neocystostomy required significantly less iv morphine during the initial 24 hours postoperative period.

PAIN SCORE ANALYSIS

The pain score was assessed using FLACC scale, and the two groups were compared using Pearsons Chisquare test. It was found that there was a significant difference between group A and B from 2 hours to 12 hours with a p value <.05. Thus pain scores in Group B were significantly less when compared with group A.

PAIN SCORE 2HRS	0-3	4-10
GROUP A	37	13
GROUP B	47	3
PAIN SCORE 6HRS		
GROUP A	12	38
GROUP B	33	17

DISCUSSION

The present study was designed to evaluate the effectiveness of clonidine as an adjuvant to bupivacaine for caudal analgesia. A total of 100 patients were randomized into two groups A and B. Group A received 1ml/kg of 0.25% Bupivacaine, while Group B received Clonidine 1ug/kg with 1ml/kg of 0.25% Bupivacaine. Both the groups were then monitored for duration of postoperative analgesia. All the groups were comparable with respect to demographic details lke age, sex, and weight.In our study, the postoperative analgesia was

evaluated using the FLACC scale for the first 24 hours. In our study, as assessed by FLACC scale the postoperative pain was found to be significantly lower in the Group B which received clonidine as an adjuvant to bupivacaine than Group A which did not receive clonidine. This results consistant with similar other studies[5]

There are several mechanisms by which clonidine prolongs the analgesia produced by local anesthetic[6]. Firstly it interferes with the vascular reabsorption of the local anesthetic by causing vasoconstriction, secondly it might have a direct action on neural tissue and thirdly, it might induce analgesia through systemic mechanism after vascular reabsorption and redistribution to the brainstem also by direct stimulation of pre and postsynaptic alpha 2 receptors in the dorsal horn grey matter of the spinal cord, thereby inhibiting the release of nociceptive neurotransmitters.[7] Bernard et al, evaluated the effect of varying doses of clonidine with local anesthetics in axillary nerve blocks in patients coming for carpal tunnel release and showed that there was significant reduction in postoperative pain and also prolonged duration of analgesic effect with the use of clonidine..Per-Arne Lonnqvist et al, in his study has proved that the use of Clonidine as an adjunct to local anaesthetic enhances the quality of pain relief and substantially prolongs the duration of analgesia after caudal and epidural blockade in children Jamali et al, demonstrated in their study that the addition of 1 ug/kg of clonidine to a caudal block with 0.25% bupivacanie, as compared with bupivacaine alone, increases the duration of postoperative analgesia in paediatric patients by 15 hours. The sedation effect of clonidine was not assessed in this study as it was difficult to distinguish between sedation and analgesia in this age group. Hennawy et al, in his study of addition of clonidine to bupivacaine in caudal analgesia did not assess for sedation though it is a common side effect for the same reason.

No adverse effects were noticed in both the groups. There was no incidence of bradycardia or hypotension in both groups till 2 hours postoperatively. Jamah et al, in their study of clonidine added to bupivacaine in caudal blocks found no difference in heart rate among the groups during the first 3 hours after caudal anesthesia. The systemic arterial pressure in the clonidine group was lower then in the bupivacaine group. In our study the heart rate and systolic blood pressure was monitored till 2 hours postoperatively and was found to be stable. Wheeler et al, found in his study that addition of clonidine 2 ug/kg does not enhance the postoperative analgesia of a caudal block using 0.125% bupivacaine in children.[8]Though certain studies have found that clonidine did not enhance local anaesthetic effect in regional anaesthesia, our study substantiated its use as an adjunct to local anaesthetics in paediatrics to provide postoperative analgesia without deleterious side-effects. Clonidine in addition prolongs duration of analgesia without any increase incidence of adverse side effects like pruritis, respiratory depression commonly seen in opioids. Although many studies stress the benefits, some studies differ.[9]Though side effects less common than in adults they may be dose dependant.[10]

CONCLUSION

From our study we conclude that Clonidine as an aduvant to local anesthetics results in

1. Prolonged duration of analgesia.
2. Lesser need for rescue medication.
3. stable hemodynamics
4. No adverse effects.

From our study, we conclude that there is significant difference in the duration of analgesia between two groups. Clonidine 1ml/kg ,added to bubivacaine for caudal in paedeatric patients undergoing subumbilical surgery significantly alters the duration of post operative analgesia favourably, when compared to bupivacine alone.

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