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Comparative Study of Injection Bupivacaine(0.25%)+ Injection Tramadol Versus Injection Plain Bupivacaine(0.25%) in Caudal Epidural Anaesthesia In Paediatric Patients for Lower Limb Orthopedic Surgeries

KEYWORDS: caudal ,tramadol ,bupivacaine ,post operative analgesia.

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ABSTRACT *To compare the effects of caudal Bupivacaine alone and Bupivacaine-Tramadol in young children for lower limb orthopedic surgeries.Aim of the study was to compare quality and duration of analgesia In a double blind study,40 paediatric patients of ASA I and II were randomly allocated in two groups to receive 1ml/ kg of either 0.25% Bupivacaine or 0.25%Bupivacaine+Tramadol via caudal route. There was no significant difference between the two groups in hemodynamic variables, onset of sensory and motor block, complications. The quality and duration of analgesia was more with Tramadol group.*

Bupivacaine+Tramadol is a safe and effective combination which provides prolonged postoperative analgesia following caudal block.

INTRODUCTION

Pain relief in paediatric patient is a challenging job for an anaesthetist as they are at risk of inadequate pain management with age related factors. Misconception exist that may contribute to paediatric patients receiving inadequate analgesia for procedures that would routinely be treated aggressively in adults. Although much is now known about pain management in children, improvements are needed to improve paediatric pain management effectively. so, well organised plan should be there before giving anaesthesia, adopting the idea of "managing pain before it occurs."

Many new techniques and methods applicable for post operative(post op.) pain management in paediatric patients depend on the patient, underlying medical condition, type of surgery, the patients disposition following surgery(inpatient versus outpatient) and physician's comfort level with a particular analgesic regime.

Caudal block Is the most common regional anaesthetic technique performed in children as it is safe, reliable, with a lower failure rate in an experienced hands[1]. Admistration of a single agent with a high dose may provide satisfactory anaesthesia and analgesia but may cause side effects like hypotension, respiratory depression etc[10]. To overcome this, two agents with low doses may prove superior in achieving prolonged effect with minimal side effects. Ketamine, Clonindine and various Opiods have been tried with Bupivacaine with varied degrees of success.

In present study, we have used injection(inj.) Tramadol along with inj.Bupivacaine for Caudal epidural block to study analgesic efficacy ,hemodynamic stability , duration of postoperative analgesia and any adverse effects in paediatric patients undergoing lower limb orthopedic surgeries.

AIMS AND OBJECTIVES

This study was conducted to see the effect of Tramadol when used along with Bupivacaine for Caudal epidural block regarding:-

1) Onset of sensory blockage.
2) Duration of analgesia.
3) Onset of motor blockage.
4) Duration of motor blockage.
5) No. of doses of rescue analgesics used during 24 hour post operative period.
6) Complications if any.

MATERIALS AND METHODS:-

Total 40 paediatric patients, aged 2 to 12 year posted for orthopedic lower limb surgery were studied. They were randomly divided in to two groups as, Group I and II

Group I: (Control group) received inj.Bupivacaine0.25%

Group II: (Study group) received inj.Bupivacaine0.25% + Inj Tramadol 1 mg/kg[4] .Total volume for caudal block being 1 ml/kg in both groups.(Not exceeding total volume over 20 ml.)

Selection of patients:

1) ASA I and II
2) Age group 2_ 12 years
3) Investigations:

1) HB %
2) BT, CT
3) Chest x-ray pa view
4) Other investigation as per the need of case

Exclusion criteria:

1) Local skin infection at the site of sacral hiatus.
2) Refusal by parents and patients.
3) Bleeding tendencies.
4) Major malformation of sacrum.
5) Previous history of convulsive disorder.

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Surgeries done under Caudal Block:-
1) Tibia ten nail
2) Femur ten nail
3) Foot k-wire
4) Removal of lower limb implant
5) TBW patella
6) Congenital telepus eqino varus deformity correction
7) Femur sequestration

After obtaining institutional approval, informed written consent of parents was taken. All these patients underwent pre-anaesthetic check up the day before surgery. All routine and specific investigations were noted .The children were kept nil by mouth for 6 hour .Before shifting the patient inside the operation theatre, anaesthesia machine and all the resuscitation equipments were kept ready. Access was taken with appropriate intracath infusion of Ringer lactate with 10% Dextrose started. Pulse oximeter and NIBP cuff were applied .Baseline Pulse, Blood pressure, Respiratory rate and SpO2 were recorded .Inj. Glycopyrrolate 4 mcg/Kg ,inj.Ondansetron 0.1mg/kg and inj. Ketamine 1-2mg/kg iv given.

After patient became calm ,caudal block was performed with full aseptic and antiseptic precautions with patient in left lateral position .A 22G hypodermic needle is inserted at about 45 degree to skin between sacral cornu and directed it cranially to penetrate sacrococcygeal ligament till contact is made with bony anterior wall of sacrum .Needle was then depressed almost up to skin covering the sacrum with bevel facing downward and advanced into Sacral canal up to 2-3cm.After negative aspiration of blood and CSF, we injected the prepared solution .Drug doses used were 1 ml/kg, according to Armitage formula[2]. The total amount of drug was injected over 60 to 90 seconds.

After the sensory and motor onset was established and confirmed, inj.Midazolam 0.03-0.05mg/kg was given iv slowly.

Observations noted:
1) Onset of sensory block.
2) Duration of analgesia.
3) Onset of motor block.
4) Duration of motor blockade.
5) No. of doses of rescue analgesics used during 24 hour post operative period.
6) Complications if any

Pulse, Mean Arterial pressure, Respiratory rate, SPO2 were noted every 5 min up to the end of surgery. Then every 15 min for 2 hours . Then 1 hourly till wearing off of analgesic effect .When patient complain of pain or cry in post operative period , inj.Tramadol 1mg/kg iv given as rescue analgesic .Total no. of doses of inj.Tramadol required during 48 hours post op.were also noted.

Onset of sensory block was noted as the time from injection of drug to loss of response to pin prick over suprapubic area.[6]

Onset of motor block was noted as time from injection of drug to loss of lower limb movement to pin prick above the umbilical area.[6]

Duration of analgesia was noted as the time from injection of drug to first complaint of pain by patient or parent or cry.[6]

Duration of motor block was noted as the time from injection of drug to regaining of lower limb movement, spontaneously or to pin prick stimuli.[6]

RESULTS:-
The table 1 and 2 show the demographic data of patients, and are comparable in both the groups.

TABLE-1:-

	Gr. I Bupivacaine	Gr. II Bupivacaine + Tramadol
MALE	14	16
FEMALE	6	4
TOTAL	20	20

TABLE-2:-

Age in year	Gr. I Bupivacaine	Gr. II Bupivacaine + Tramadol
2 to 6	10	8
>6 to <10	7	8
>10 to 12	3	4
Total	20	20

The onset of sensory and motor block and the duration of analgesia and motor block are as shown in

TABLE-3:-

Parameters	Gr. I Bupivacaine	Gr.IIBupivacaine+Tramadol	P value
Average onset time for sensory block(min)	10.5 ± 1.0	10.3 ± 1.0	>0.05
Average onset time for motor block(min)	13.5 ± 1.2	13.2 ± 1.1	>0.05
Average duration of analgesia in hrs.	4.75 ± 0.8	7.3 ± 1.0	<0.05
average duration of motor block (minutes)	60 ± 3.2	62.5 ± 3.5	>0.05

No.of doses of rescue analgesic during 48 hours post op.period shown in

Table-4:-

No.of doses	Gr. I Bupivacaine	Gr.IIBupivacaine+Tramadol
0	0	0
1	0	15(75%)
2	2 (10%)	5 (25%)
3	16(80%)	
4	2 (10%)	0

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Table-5 :-complications

	Gr. I Bupivacaine	Gr.IIBupivacaine+Tramadol
Vomiting	2 (10%)	3(15%)
Convulsion	0	0
Respiratory Depression	0	0
Purities	0	0
Urinary Retention	0	0

DISCUSSION:-

Pain is a common human experience as a symptom frequently encountered in clinical practice. It is usually associated with actual or impending tissue damage .Post operative pain is an acute pain and should be treated adequately to decrease morbidity and hospital stay.

Ease of performance and reliability makes the caudal block the most commonly performed technique in children. Caudal administration of Bupivacaine is wide spread regional anaesthetic technique for intra and post op. analgesia for lower limb orthopedic, anoperineal, penoscrotal and lower abdominal surgical procedures in children[5,15].

Bupivacaine used alone in high dose also increases side effects and unintentional intravascular injection of Bupivacaine may lead to life thereating cardiovascualar and neuro toxicity[7,13].

To overcome this we have used combination of low doses of inj.Bupivacaine and Tramadol in caudal block for lower limb orthopedic surgeries. Adding Tramadol to Bupivacaine not only increases the duration of analgesia but markedly decreases the dose of both agents thereby decreasing the incidence of side effects i.e. respiratory depression, vomiting, pruritus and flushing in young children.

Bupivacaine is an amide local anesthetic with a slow onset but longer duration of action as compared to

Lignocaine. Its mechanism of action is similar to other local anesthetics i.e. prevention of transmission of nerve impulses (conduction blockade) by inhibiting the passage of sodium ions through ion selective sodium channels in nerve membranes.

Tramadol is a centrally acting analgesic that has a low affinity for opioid receptors but is only 5-10 times less potent than Morphine as an analgesic. An atypical opioid,Tramadol is a racemic mixture of two enantiomers (+) Tramadol and (-) Tramadol.It is synthetic analogue of Codeine that has an analgesic potency approximately equal to that of Pethidine but without respiratory depressant effect[14].

Demographic data:-

Patients in our study were demographically similar in both groups .There were no statistically significant variations regarding age ,weight and gender distribution .Duration and type of surgery was also similar in both groups and statistically not significant.

Hemodynamic changes:-

Pulse rate and mean arterial pressure remained within 20% of base line in all patients of both groups.

In none of the cases the fluctuation was more than 20% from the baseline value. Average change in pulse rate was (-1.5 + 4.0) in Bupivacaine and (-1.0+ 3.2) in Bupivacaine+Tramadol group which is statistically insignificant.

Average change in MAP was in Bupivacaine group (-0.8 + 2.5) and (-0.5 + 2.5) in Bupivacaine+Tramadol group, which is statistically insignificant.

Sanna S. et al[12] in their study used the Bupivacaine+Tramadol vs Bupivacaine alone and found that there were no significant changes in HR and Blood pressure, intra and post operatively.

Ozkan S et al[11], in their study found that there was no significant difference in HR, MAP, SPO2 and RR in Bupivacaine group compared to Bupivacaine + Tramadol group.

In none of the cases respiratory depression was seen and SpO2 was maintained above 95% in all the cases intra and postoperatively.

Onset of sensory block:-

In our study,average onset time for sensory block was 10.5+1.1 in Bupivacaine group and 10.3+1.1 in Bupivacaine + Tramadol group. Ivani et al[8] and Dongare H.,Dongare D. et al[6]studied the same drugs and found the results compairable to our studies.

Duration of analgesia:-

Average duration of analgesia in Bupivacaine group was 4.75 + 0.8hours.While it was 7.3 + 1.0 hours in Bupivacaine + Tramadol group. Statistically, the duration of analgesia is significantly prolonged in Bupivacaine + Tramadol group. ($p<0.05$). Thus by adding Tramadol there was an increased in duration of analgesia in post operative period.

Ozkan S.et al[11] compared Bupivacaine with Tramadol in Caudal block for postoperative pain relief. They studied 20 pediatric patient randomized into two groups. After giving General anesthesia, caudal block was given. Patients from Group I in their study received 0.25% Bupivacaine 2 mg/kg while from Group II received 5% Tramadol 2 mg/kg.They found that pain and sedation score was significantly lower in Tramadol group as compared to Bupivacaine group. Also they reported that duration of analgesia in Bupivacaine group was 6.34 + 0.8 hours.While it was 10.09 + 0.9 hours in Tramadol group.

A.c. Senel et al[3]Studied Caudal Bupivacaine + Tramadol for postoperative analgesia in pediatric herniorrhaphy .They studied 60 cases aged 12 to 84 months, undergoing unilateral herniorrhaphy. All patients were randomly divided in 3 groups. Patients from group B received 0.25% Bupivacaine, from group B+T received 0.25 Bupivacaine+Tramadol 1.5 mg/kg and form group T received Tramadol 1.5 mg/kg in NS. Volume of drug in all three groups was 1ml/kg. They found duration of analgesia in group B+T was significantly longer (13.5 + 2.2 hours) than in the other two groups.

The mean duration of analgesia of caudal Bupivacaine and Bupivacaine + Tramadol in this study is shorter than that found in previous studies .Differences in the operations performed as the orthopedic operations are most painful and noisy ,method of pain scoring, Bupivacaine dose and volume ,and calculation of analgesia time probably ac-

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count for this discrepancy.

No. of doses of rescue analgesics in the 48 hour post operative period:-

In our study the Bupivacaine+Tramadol group required significantly less number of rescue analgesics as compared to plain Bupivacaine group .In plain Bupivacaine group all patients required 2 or more than 2 doses of rescue analgesic within 48 hour post operative period . In Bupivacaine+Tramadol group 75% patients required single rescue analgesic and 25% required 2 rescue analgesics.

Majid y. Mohammad K. et al[9]. studied that the requirement of rescue analgesia after 8 hours in group A (Bupivacaine 0.25%) was noted in 64% of the patients while as in group B (Bupivacaine 0.25% + inj.Tramadol 1mg/kg) this requirement was noted in only 16% of the patients. Similarly, after 12 hours rescue analgesic was required in 92% of patients in group A whereas it was only 48% in group B. The reduced incidence of need for rescue analgesics at the end of 8 & 12 hours post awakening was statistically significant i.e. ($p< 0.05$) in group B. Our results are comparable with them.

Complications:-

In our study 2 pts in Bupivacaine group and 3 pts in Bupivacaine+Tramadol group had nausea & vomiting..

Sanna S.et al[12],in their study observed incidence of emesis in Bupivacaine group was slightly less than (10%) & in Bupivacaine + Tramadol group it was (25%).

AC Senel et al[3],in their study observed that the incidence of nausea and vomiting was not different in Bupivacaine and Bupivacaine+Tramadol group.

Limitations of our study:-

-We have studied a small number of patients.

-Lack of a single test for quantitative assessment of pain as we have selected patients of varied age group(2-12years). so,in younger age group we have to rely on indirect evidence like cry or limb movment or on parents for pain.

CONCLUSION:-

Tramadol as an adjunct to Bupivacaine may prove more useful in young children and infants than other opioids because of its lack of respiratory depressant and powerful analgesic effect.

Tramadol prolongs the duration of analgesia when given along with Bupivacaine for caudal block in a paediatric patient for orthopedic lower limb surgery without any hemodynamic instability or serious complications.

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