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A RANDOMIZED CONTROL TRIAL TO EVALUATE EFFICACY BETWEEN BUPIVACAINE VERSUS ROPIVACAINE FOR POST OPERATIVE ANALGESIA FOR CAUDAL BLOCK IN PEDIATRIC PATIENTS

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ABSTRACT

Introduction: Pain has become the fifth vital sign and is now a critical focus of the patient. The relief of pain has always been part of anaesthesiologist's role in the most immediate postoperative period and extending beyond post-anaesthesia care unit. There is also increasing evidence that optimal pain management can impact outcome beyond the intra operative period.

Aims: To assess the quality of sensory and motor blockade, duration of Sensory & motor blockade and duration of postoperative analgesia.

Materials and Methods: This was a Prospective Double blinded Randomized Comparative Study conducted in GMERS Medical College and sola Civil Hospital Ahmedabad from July 2018 to August 2020. 60 patients were included in this study.

Result: Our study showed that a single pre-surgical caudal injection of ropivacaine after induction of anaesthesia provided good quality analgesia of sufficient duration following lower abdominal and perineal surgeries.

Conclusion: Caudal Ropivacaine 0.25%, 1ml/kg provided reliable and long lasting analgesia similar to 1ml/kg of 0.25% Bupivacaine in children undergoing sub-umbilical surgeries. Ropivacaine caused less motor blockade than bupivacaine with similar time for sensory recovery.

Keywords: Ropivacaine, Analgesia, Bupivacaine and Caudal block.

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INTRODUCTION

Pain is perhaps the most feared symptom of disease, which a man is always trying to alleviate and conquer since ages.

The world health organization defines pain as "unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage"[1]

Pain has become the fifth vital sign and is now a critical focus of the patient. The relief of pain has always been part of anaesthesiologist's role in the most immediate postoperative period and extending beyond post-anaesthesia care unit. There is also increasing evidence that optimal pain management can impact outcome beyond the intra operative period.

Children are special in this regard because, in them it is a very complex phenomenon. It is also very difficult to differentiate restlessness or crying due to pain from that of hunger or fear in the children. An effective pain therapy to block or modify the myriad physiologic responses to stress has become an essential component of modern paediatric anaesthesia and surgical practice. Single shot caudal block provides good quality pain relief during immediate post-operative period following infra-umbilical and lower limb surgeries in paediatric patients. Caudal blocks also decrease the intra-operative and post-operative IV drugs, narcotics and inhalational drugs requirement & decrease perioperative stress response.

The caudal epidural block involves placing a needle through the sacral hiatus to deliver medications into the epidural space. Caudal anaesthesia and analgesia is most widely used neural blockade in children for the management of post-operative pain following surgical procedure on lower abdomen, perineum, and lower extremity. Caudal anaesthesia/analgesia is simple to perform, reliable and safe[2]. Peridural administration of local anaesthetics significantly diminishes or abolishes nociceptive impulses from entering the central nervous system. Caudally, administration of local anaesthetic provides excellent analgesia.

The main limitation of caudal anaesthesia and analgesia is the short duration of action after a single shot injection. The use of caudal catheters to administer repeated doses or infusions of local anaesthetics is not popular, partly because of concerns about infection and cost concerns. Prolongation of caudal analgesia using a 'single-shot' technique has been achieved by the addition of various adjuvants[3] like Fentanyl, Magnesium, Morphine, Dexamethasone, Ketamine, Clonidine, Tramadol, Dexmedetomidine, and Neostigmine.

Administration of regional analgesia with Local Anesthetics remains a cornerstone of postoperative analgesia in children. This study is designed to evaluate and compare the duration of analgesia and side effects of 0.25% Ropivacaine (1ml/kg) and 0.25% Bupivacaine (1ml/kg) given through caudal epidural route in children undergoing lower abdominal general surgical procedures. To increase the specificity of the study we have included only herniotomy patients in our study.

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AIMS AND OBJECTIVE

- To assess the quality of sensory and motor blockade.
- Duration of Sensory & motor blockade.
- Duration of postoperative analgesia.

PRIMARY OBJECTIVE:

- Duration of analgesia as measured by time requirement of first dose of rescue analgesia.
- Quality of analgesia as measured by Objective pain score.
- Quality of motor block as measured by Motor power scale.

SECONDARY OBJECTIVES:

- Ease of performance.
- Any adverse reaction or complications.

MATERIALS AND METHODS

This was a Prospective Double blinded Randomized Comparative Study conducted in GMERS Medical college and sola Civil Hospital Ahmedabad from July 2018 to August 2020. After obtaining clearance from the Institutional Ethics Committee of GMERS Medical College,Ahmedabad, the study was explained in detail to the parents and written Informed Consent was obtained from them.

Sixty children satisfying the selection criteria were randomized by computer generated randomization table into two groups of thirty each – Group B and Group R. The randomization sequence was prepared in double-blinded cancelled manner. The children in group B received 1 ml/kg of 0.25% Bupivacaine (0.5% solution diluted in equal volumes of distilled water) whereas those in group R received 1ml/kg of 0.25% Ropivacaine (0.5% solution diluted in equal volumes of distilled water)through the caudal route.

CRITERIA FOR PATIENT SELECTION

The criteria for including the children in the study were:

- Age 3-8 years
- ASA I or II physical status
- Elective Lower Abdominal Surgeries.
- Duration of surgery < 90 min.

EXCLUSION CRITERIA

The children with the following problems were excluded from the study:

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- ASA III & IV
- Local infection in the Caudal region
- Pre-existing Neuromuscular disease
- Congenital anomaly of the lower back
- Mental retardation, Delayed development
- Bleeding diathesis
- H/o Allergy to Local Anaesthetics
- H/o Cardiac , Liver & Renal Disease
- H/o Seizures & Epilesy.

RESULT AND DISCUSSION

Caudal block is a useful alternative to general- anaesthesia or total IV anaesthesia as it provides effective postoperative analgesia. Post-operative analgesia provides not only pain relief but also inhibits trauma induced nociceptive impulses to blunt autonomic reflexes. It allows the patients to breath and move freely to enhance early restoration of function.

Enteral and parenteral analgesics (both opioids and non-opioids), used for providing post-operative analgesia, are associated with risk of gastro-intestinal bleeding, precipitation of asthma, nausea and vomiting, thrombocytopenia, sedation, respiratory depression, hepatotoxicity, nephrotoxicity etc.

The regional techniques including the caudal block, spinal anesthesia or epidural anesthesia helps to avoid most of the complications and it is possible to achieve analgesia with minimum of drug dose and complications. Caudal block is easy to perform and has been found to be very effective in children due to their unique anatomy which facilitates extensive spread of local anaesthetic after giving caudal block in caudal epidural space.

Our study showed that a single pre-surgical caudal injection of ropivacaine after induction of anaesthesia provided good quality analgesia of sufficient duration following lower abdominal and perineal surgeries.

The mean age in the two groups was comparable - around five years with a minimum of 3 years and a maximum of 9 years. The mean weight (around 14 kg) and height (around111 cm) were also comparable in both the groups.

All the procedures were for inguinal hernia,the mean duration of surgery was short - around 32 min in both the study groups. All the children had stable hemodynamics intraoperatively. A marginal decrease in heart rate and blood pressure which was seen in our study could be explained by the fall in these parameters that is usually associated with induction of anaesthesia and a successful caudal block.

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Ropivacaine has been used in different concentrations for caudal block with varying efficacy. Da Conceicao et al[4] used ropivacaine 0.375% for caudal block and found that it produces sufficient analgesia for lower abdominal surgery in children. But, Ivani et al[5] in two different studies observed that 0.2% ropivacaine given through the caudal route in children is sufficient to provide sensory blockade for infra-umbilical surgeries. In our study, we used 0.25% ropivacaine that provided reliable and long duration analgesia. This finding is in conjunction with previous studies.

In our study, we used 1 ml/kg volume for caudal injection that was adequate for sub umbilical surgeries. Other studies have used 1ml/kg of local anaesthetic for thoracolumbar surgeries. Many anesthetist had observed that 1ml/kg of 0.2% ropivacaine and 0.25% bupivacaine by caudal block had similar onset and duration. They compared these concentrations in order to achieve equal volumes and to maintain blindness of the study. But, we used equal volumes of 0.25% concentration of both ropivacaine and bupivacaine, thereby achieving study blinding as done by Khalil et al[6] and others. Mereto et al[7] found that the mean onset time of caudal 0.2% ropivacaine was 9 min with that of 12 min for 0.25% bupivacaine whereas another study had observed that the mean onset time was 9.7 and 10.4 min respectively. Since our aim was not to compare the onset times, we used a fixed time of 10min after caudal block for incision for both the groups. In our study, this was found adequate for both ropivacaine and bupivacaine with no child requiring fentanyl supplementation.

T.L.Ala-Kokko et al[8] had evaluated that 1ml/kg of 0.2% ropivacaine (2mg/kg) and 0.2% bupivacaine (2mg/kg) given by caudal route in 30 children aged 2.3 to 8.7 years resulted in peak plasma concentrations of 1.22 µg/ml and 1.28 µg/ml respectively which is much less than the maximum tolerated venous concentrations of ropivacaine (2.2(0.8) and bupivacaine (2.1 +-1.2) in adult volunteers. They also observed that the time taken to achieve peak concentrations were significantly longer for ropivacaine than bupivacaine indicating slower absorption and tissue distribution of the former after caudal administration. This difference may be due to the intrinsic vasoconstrictor effect of ropivacaine at low concentrations and higher lipid solubility of bupivacaine. In our study, we used 1 ml/kg of 0.25% ropivacaine, i.e.1.875 mg/kg of ropivacaine that is much less than that used in the above study. This obviated the need for measuring plasma concentration in our study.

In our study, the mean time from caudal block to first dose of diclofenac administration was comparable for both the groups with the average being slightly less than 6 hours. A similar trial using 0.25% bupivacaine or 0.25% ropivacaine showed that postoperative analgesia was required at a mean time of 11hours for both drugs whereas another study using 0.375% bupivacaine or ropivacaine revealed that the mean time for first analgesia was around 5 hours in both drugs. On the contrary, Ivani compared 0.2% ropivacaine with 0.25% bupivacaine and observed that first requirement of rescue analgesia was 253 and 520 min for bupivacaine and ropivacaine groups respectively($P<0.05$). But this finding was not replicated by other studies.

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Our study showed that significant motor block was demonstrated in all our study children in the recovery room, with the ropivacaine group having a statistically significant greater motor power score than bupivacaine group. This faster resolution of motor blockade in the ropivacaine group continued in the post-operative ward also. This is in conjunction with other studies that recorded quicker motor recovery with 0.25% ropivacaine than 0.25% bupivacaine. Khalil also found delayed motor recovery in both the groups and found that those who received 0.25% ropivacaine had slightly higher mean motor score at the end of 3 hours than those who had received 0.25% bupivacaine. Conceicao used a higher concentration (0.375%) of ropivacaine and bupivacaine and observed that there was significant difference between ropivacaine and bupivacaine groups in motor block postoperatively with lesser blockade in the former. This quicker motor recovery in ropivacaine group may be due to its less lipid solubility as determined by the N-heptane/buffer partition coefficient of 2.9 as against that of 10 for bupivacaine. This low lipid solubility and high pKa (8.1) of ropivacaine causes blockade of A – delta and C fibers supplying pain and touch sensation to a greater extent than that of the A-Į and A-ù fibers supplying motor sensation. Other workers had observed that there were no significant differences in the quality or duration of sensory blockade between equal doses and concentrations of bupivacaine and ropivacaine and reported that sensory block resolved earlier than motor block. Our study also supported their views.

Due to the smaller study group, we did not encounter any instance of intravenous or intraosseous injections that could have resulted in local anaesthetic toxicity, thereby conferring an added advantage for ropivacaine in terms of increased safety profile. Our study and others have compared the effects of caudal ropivacaine and bupivacaine when administered along with volatile anaesthetics intraoperatively. Ingelmo in their study observed that without the effects of volatile anaesthetics 0.2% ropivacaine is less effective during surgical stimulation than 0.2% bupivacaine and 0.2% levobupivacaine when used for caudal block. They reasoned out this finding based on the observation that all volatile anaesthetics depress the spinal alpha- motor neuron activity and may potentiate caudal ropivacaine. But they too observed that there was no difference in the analgesic onset times or residual analgesia indicating ropivacaine is an effective local anaesthetic.

CONCLUSION

Ropivacaine is a safe and effective local anaesthetic for paediatric caudal anaesthesia. Ropivacaine 0.25% 1ml/kg provided good quality and adequate duration of analgesia similar to bupivacaine in equal volumes and concentration when administered for caudal block for sub umbilical surgeries. Ropivacaine produced significantly faster motor recovery than bupivacaine giving a distinct advantage over the latter by allowing the children to be discharged earlier.

In conclusion, Caudal Ropivacaine 0.25%, 1ml/kg provided reliable and long lasting analgesia similar to 1ml/kg of 0.25% Bupivacaine in children undergoing sub-umbilical surgeries. Ropivacaine caused less motor blockade than bupivacaine with similar time for sensory

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recovery. These along with the lower intrinsic toxicity of ropivacaine make it an effective and safe drug for day care surgery in paediatric patients.

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Table: Time required for first Rescue Analgesia

Time Required for first rescue Analgesia	Group B	Group R
Range	255 - 475	245 - 455
Mean	346.66	338.83
Standard Deviation	51.06	44.75

Table: MOTOR POWER SCALE

	GROUP B	**GROUP R**
	MEAN ± SD	MEAN ± SD
PRE OP	10	10
30 MIN	2.63 ± 0.55	3.66 ±0.71
60 MIN	4.13 ± 1.00	5.1 ± 0.60
2 HR	9.43 ±0.72	9.76 ± 0.43
4 HR	10	10
6 HR	10	10
12 HR	10	10
24 HR	10	10

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Table: SEX DISTRIBUTION

VARIABLE	GROUP B		GROUP R		P VALUE
	MEAN	SD	MEAN	SD	
AGE	5.6	2.04	5.7	1.68	0.42*
HEIGHT	109.6	5.49	112.06	5.33	0.39*
WEIGHT	14.23	3.46	14.3	2.38	0.46*

Table: DURATION OF SURGERY

DURATION OF SURGERY	GROUP B	GROUP R
Mean time of surgery	33.83 ± 6.39	33.33 ± 6.47