

Comparison between Caudal Tramadol and Nalbuphine as Adjuvants to 0.2% Ropivacaine in Children Undergoing Hypospadias Surgery: A Randomised Clinical Trial

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Abstract: ***Background and Aims:** Providing perioperative analgesia has become imperative in paediatric anaesthesia practice to prevent long term behavioural changes. Caudal route though very safe and reliable way of providing analgesia for lower abdominal surgeries, has the drawback of short duration of action with single shot technique which can be overcome by adding different adjuvants. We compared the analgesic effects of caudal tramadol and nalbuphine added as adjuvants to 0.2% ropivacaine in children undergoing hypospadias surgery under general anaesthesia. **Methods:** 128 patients aged 2-7 years, ASA grade 1 and 2, were randomly allocated to 2 groups: Group T: patients received caudal 0.2% ropivacaine 0.75 ml/kg plus 1.5 mg/kg tramadol in 1ml saline. Group N: patients received caudal 0.2% ropivacaine 0.75 ml/kg plus 0.05 mg/kg nalbuphine in 1ml saline. Primary outcome was duration of absolute analgesia. Total analgesic requirement was recorded for 24 hours post surgery. Data analysis was done using Chi square, student t or Mann Whitney U test depending on normality of the variable. **Results:** The mean duration of analgesia was higher in Group T (12.5 ± 2.4 hours) as compared to Group N (6.7 ± 1.5 hours). Accordingly the requirement of rescue analgesic was lesser in group T as compared to group N. while no adverse effects were noticed in any group. **Conclusion:** Addition of tramadol to caudal ropivacaine significantly increased duration of postoperative analgesia as compared to nalbuphine.*

Keywords: Caudal block, hypospadias, tramadol, nalbuphine

1. Introduction

Pain is the conscious experience of sensorial information and a feeling of unpleasantness that manifests as a result of nociception. The impact of painful experience on young nervous system is so significant that long term effects can occur, including a lower pain tolerance and behavioural defects in later life [1] [2]. Therefore providing effective post op analgesia has become imperative in paediatric anaesthesia practice.

Caudal block is one of the most popular techniques for post operative analgesia [3] in infraumbilical surgeries as it is very safe and effective but with the drawback of short duration with single shot technique [4]. Caudal catheters are rarely used due to increased risk of soiling and infection. Prolongation of caudal analgesia has been achieved by addition of various adjuvants such as tramadol [5], ketamine, neostigmine, clonidine, dexmedetomidine [6] and dexamethasone [7]. Recently nalbuphine has been tried for this purpose. Tramadol is a synthetic opioid which when given epidurally has shown to provide effective, long-lasting analgesia with no significant respiratory depression in children.

Nalbuphine hydrochloride is a mixed k- agonist and u- antagonist opioid of the phenanthrene group. It leads to stimulation of spinal and supraspinal opioid receptors which leads to good analgesia with minimal sedation, minimal nausea and vomiting and less respiratory depression and stable cardiovascular functions

2. Methods

This prospective, randomized, double blind, interventional study was conducted on 128 paediatric patients aged 2-7 years of ASA grade I and II, undergoing elective hypospadias surgeries in the Department of Anesthesiology, SPMCHI, affiliated to SMS MEDICAL COLLEGE, Jaipur with due permission from institutional ethics committee and review board and after taking written informed consent from the parents.

The sample size required was 64 in each group at 95% confidence and 80% power to verify the expected difference of $360.25(\pm 720.50)$ minutes in duration of analgesia. Mean duration of analgesia for 1.5 $\mu\text{g}/\text{kg}$ tramadol is 720.50 and we assumed half of this duration of analgesia (360.25 minutes) with 0.05 mg/kg nalbuphine on the basis of our past clinical experience. The standard deviation was assumed double of the mean difference of duration of analgesia.

Group (T) n=64: patients received caudal 0.2% ropivacaine 0.75 ml/kg plus 1.5 mg/kg tramadol in 1ml saline.

Group (N) n=64: patients received caudal 0.2% ropivacaine 0.75 ml/kg plus 0.05 mg/kg nalbuphine in 1ml saline.

Group randomisation was done by anaesthesia resident who was not participating further in this study. Anaesthetist who gave anaesthesia was different from the anaesthetist who recorded study variables. As patient was under general anaesthesia so he was not able to see what drug was given to him though his parents were told about adjuvant being given with caudal block.

One day prior to the surgery PAC was done and routine lab investigations were checked

On the day of surgery, on arrival in OT, routine non invasive monitors were attached and baseline parameters in form of respiratory rate, systolic, diastolic and mean BP, ECG, SpO₂ were noted. Patients were premedicated with Inj. Glycopyrrolate 0.005mg/kg, inj Midazolam 0.05mg/kg and Inj fentanyl 2µg/kg through already secured i/v line as per hospital protocols.

After preoxygenation with 100% O₂ for 3 minutes induction was done with Inj. Thiopentone 5mg/kg and Inj. Atracurium 0.6mg/kg i.v. Direct Laryngoscopy was done and patient was intubated with endotracheal tube of appropriate size.

Patients were placed in the lateral position, and a caudal block was administered using a 5 cm short bevelled 22G needle. The study drug prepared for that particular patient was injected epidurally through the caudal route and time of block was noted. Anaesthesia was maintained with N₂O: O₂ (60:40) and sevoflurane (1-2%) and Inj. Atracurium (0.15mg/kg i.v. sos). Hemodynamic parameters were recorded throughout the surgery at fixed time intervals.

At the end of surgery all anaesthetic agents were discontinued and patient was taken on 100% O₂. On regaining spontaneous respiration, patient was reversed with Inj. Neostigmine 0.05mg/kg and Inj. Glycopyrrolate 0.005mg/kg i.v. Patient was extubated when fully awake, breathing spontaneously and was shifted to recovery room. Duration of surgery was noted Primary outcome of study was duration of absolute analgesia which was measured as the time from the administration of caudal block to the first administration of rescue analgesic. Secondary outcome was total analgesic requirement.

Post operative pain was assessed using AIIMS'PAIN DISCOMFORT SCORE

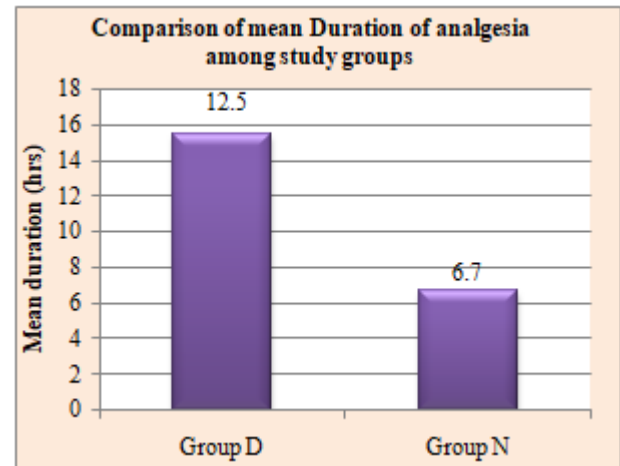
When pain discomfort score ≥ 4 rescue analgesia in the form of oral paracetamol (perfalgan) 10-15 mg/kg was given and if not enough diclofenac suppositories (1-2 mg/kg) were added. Time to first rescue analgesia was noted and was measured by time from caudal injection until the pain score was ≥ 4 and the demand for first analgesic was made. Total analgesic dose given in first 24hrs postoperative period was recorded.

3. Results

Comparison of Pain Discomfort score among study groups

| Time | Group T | Group N | P value |
|---------|-----------|-----------|------------|
| 0 hour | 0 | 0 | - |
| ½ hour | 0 | 0 | - |
| 1 hour | 0.3 ± 0.6 | 0.6 ± 0.8 | 0.014 (S) |
| 2 hour | 0.9 ± 1 | 1.8 ± 1 | <0.001 (S) |
| 4 hour | 1.8 ± 0.8 | 2.6 ± 0.8 | <0.001 (S) |
| 6 hour | 2.5 ± 0.6 | 3.7 ± 1.2 | <0.001 (S) |
| 9 hour | 2.7 ± 0.5 | 5.5 ± 1 | <0.001 (S) |
| 12 hour | 3.5 ± 1 | 6.1 ± 0.5 | <0.001 (S) |
| 18 hour | 4.1 ± 1.1 | 6.4 ± 0.6 | <0.001 (S) |
| 24 hour | 5.7 ± 0.8 | 6.9 ± 0.3 | <0.001 (S) |

Table illustrates the pain discomfort score among study groups. The mean pain discomfort score at one hour was higher in Group N (0.6) as compared to Group T (0.3) and this difference was found to be statistically significant ($p=0.014$). The mean pain discomfort score increased significantly with time in both the groups. On intergroup comparison the pain discomfort score was found to be significantly lower in Group T as compared to Group N at all follow up times till 24 hours after surgery ($p<0.001$)



The mean duration of analgesia was higher in Group T 12.5 ± 2.4 hrs as compared to Group N 6.7 ± 1.5 hrs. This difference in mean duration of analgesia between study groups was found to be statistically significant ($p<0.001$).

4. Discussion

Increasing expertise in regional anaesthesia coupled with the realization that infant and children do suffer from pain, its use is in vogue for post operative pain relief in paediatric age group. While the lack of cooperation by paediatric patients can never be eliminated, improved sedative agents and recognition that regional anaesthesia with light general anaesthesia is both safe and efficacious has allowed more children to receive benefit of this approach to balanced anaesthesia. A caudal block is a popular, reliable and safe technique for paediatric pain management and is usually placed after the induction of general anaesthesia as an adjunct to both intra operative and postoperative analgesia in children undergoing surgical procedures below the level of the umbilicus. Caudal block facilitates a rapid, smooth recovery and provides good postoperative analgesia but with the limitation of short duration of action. Various adjuvants such as opioids, ketamine, $\alpha 2$ agonists have been used with local anaesthetics to increase the duration and quality of analgesia. The present study was designed to compare the duration of postoperative analgesia between caudally administrated tramadol and nalbuphine added to ropivacaine

Prosser *et al.* [8] observed that caudal tramadol produced useful analgesia for up to 12 h after hypospadias surgery.

References

[1] Andrews K, Fitzgerald M. Cutaneous flexion reflex in human neonates: A quantitative study of threshold and

- stimulus response characteristics after single and repeated stimuli. *Dev Med Child Neurol* 1999;41(10):696-703
- [2] Taddio A, Katz J , Ilerisch AI, Koren G. Effect of neonatal circumcision on pain response during subsequent routine vaccination. *Lancet* 1997; 349 (9052):599-603.
- [3] Silvani P, Camporesi A, Agostino M R et al. Caudal analgesia in paediatrics: an update, *Minerva anaesthesiology* 2006;72:453-9.
- [4] Lloyd-Thomas AR. Pain management in paediatric patients. *Br J Anaesth* 1990;64:85-104.
- [5] Dogra N, Rajat D et al. A study to compare caudal levobupivacaine, tramadol and a combination of both in paediatric inguinal hernia surgeries 2018;62(5):359-65
- [6] Bharti N, Praveen K, Bala I. A dose response study of caudal dexmedetomidine with ropivacaine in pediatric day care patients undergoing lower abdominal and perineal surgeries: A randomized controlled trial. *Pediatr Anaesth* 2014;24(11):1158-63.
- [7] Chaudhary S, Dogra N: Evaluation of caudal dexamethasone with ropivacaine for post-operative analgesia in paediatric herniotomies: A randomised controlled study, *Indian Journal of Anaesthesia* 2016;60:30-33
- [8] Prosser DP, Davis A, Booker PD, Murray A. Caudal tramadol for postoperative analgesia in pediatric hypospadias surgery. *Br J Anaesth* 1997;79:293-6.