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Original Article

Comparison of Analgesic Efficacy of Nalbuphine with Tramadol as Adjuvant to Local Anaesthetic in Caudal Block in Children

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ABSTRACT

Objective: To compare the mean time of first rescue analgesia with Nalbuphine versus Tramadol as an adjuvant to Bupivacaine given for caudal block in children.

Study Design: Quasi-experimental study

Place and Duration of Study: Anesthesiology Department, Bolan Medical Complex Hospital, Quetta Pakistan, from Feb to Aug 2019.

Methodology: The study included 60 patients, of either gender, aged 3-12 years. Group-A included patients who received 0.125% Bupivacaine 1ml/kg with Tramadol 2mg/kg body weight caudally. Group-B included patients who received 0.125% Bupivacaine with Nalbuphine 0.1mg/kg body weight caudally. The time required for the first rescue analgesia call was noted in all patients. Paracetamol 10 mg/kg intravenous was given as a rescue analgesic in all patients.

Results: The mean age of patients was 8.30±3.03 years, and mean weight of patients was 23.33±6.92 Kg. There were 26(43.33%) female and 34(56.67%) male patients. The mean pain score was 3.53±1.43 in the Tramadol-Group and 1.86±1.25 in the Nalbuphine-Group (p-value<0.001). The mean time of first rescue analgesia showed significant prolongation in the Nalbuphine-Group compared to the Tramadol-Group.

Conclusion: A single dose of Nalbuphine as an adjunct to Bupivacaine is superior to Tramadol in reducing post-operative pain when given caudally in paediatric patients. It also significantly prolongs the duration of analgesia in children.

Keywords: Caudal Block, Children, Nalbuphine, Pain, Post-operative pain, Tramadol

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INTRODUCTION

Although the declaration of Montreal includes pain relief as a basic human right, post-surgical pain relief is not sufficient in 80% of the population, including children, the mentally incapacitated, the elderly, and pregnant females.[1] Despite multimodal analgesia, 40% of hospitalised children continue to suffer moderate to severe pain. Caudal block is used as an adjunct to general anaesthesia and has an opioid-sparing effect, which enables fast and smooth recovery from anaesthesia.[2] A single-shot caudal block increases efficacy and the duration of post-operative analgesia.[3] In ambulatory surgeries like herniotomy and circumcision in children, caudal block is used to reduce the pain.[4] Different drugs have proved useful in improving the duration in addition to enhancement of the quality of analgesia of the local anaesthetic used in caudal block dispensed as a single shot, such as opioids, clonidine and ketamine.[5,6] Using two different low-dose agents can avoid using a single agent in high doses and prevent its untoward side effects.[7] Nalbuphine is a synthetic analogue of codeine, which is almost as potent as pethidine but does not cause respiratory depression.[8] It is utilised for the management of moderate to severe pain. Nowadays, Nalbuphine is gaining access as an adjuvant with Bupivacaine to increase the analgesic activity in the caudal block.[9] Therefore, the rationale of this study is to determine the analgesic efficacy of Tramadol versus Nalbuphine given as an additive to Bupivacaine for caudal block in paediatric patients. The results of this study will help us to decide whether Nalbuphine is more effective than Tramadol or not. If Nalbuphine is found to be equally effective as Tramadol, then we will use only Nalbuphine in future as an additive to Bupivacaine for caudal in the paediatric age group because

METHODOLOGY

The quasi-experimental study was conducted at the Anaesthesiology Department, Bolan Medical Complex Hospital, Quetta Pakistan, from February to

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August 2019, after permission from the Research Ethics Committee (Number: 2825). The sample size was calculated by taking the time of requirement of first analgesia 6.5±0.57 hours in the Nalbuphine Group versus 5.3±1.77 hours in the Tramadol Group.[10]

Inclusion Criteria: Children of either gender, aged 3 to 12 years, with the American Society of Anesthesiology Status, I or II, who were planned to undergo infra umbilical surgeries, were included.

Exclusion Criteria: Children having any respiratory or cardiac morbidity were excluded.

After getting informed written consent from parents and guardians, 60 children were included. All children who planned for the caudal block were split into Groups A and B using the lottery method.

A caudal epidural block was given under general anaesthesia immediately after surgery for post-operative analgesia. A consultant anaesthetist gave all caudal blocks with at least two years of post-fellowship experience. Group-A participants received Bupivacaine (0.125%)1ml/kg with Tramadol 2mg/kg body weight. Group-B participants received 0.125% Bupivacaine with Nalbuphine 0.1mg/kg body weight caudally. After patients had recovered from general anaesthesia, pain scores were recorded at 3, 6, and 10 hours postoperatively. A Wong-Baker FACES pain rating scale was used to measure the pain. The time of requirement of the first analgesia was noted in all patients. All patients received Paracetamol 10 mg/kg as a rescue analgesic. Data regarding the patient's age, weight, gender, and pre-op ASA status was also collected, and all information regarding the study variables was noted on a pre-designed proforma.

The data was processed through the Statistical Package of Social Sciences (SPSS) version 26. Mean±SD deviation was computed for quantifiable variables. Frequency and percentage were calculated for discrete variables. The independent sample t-test was employed to for inferential statistics. The *p*-value≤0.05 was considered statistically significant.

RESULTS

The study included 60 patients, the mean age of participants included in the study was 8.30±3.03 years. The minimum age was 03 years, and the maximum was 12 years. The mean weight of patients was 23.33±6.92 Kg. Regarding gender, 26(43.33%) female and 34(56.67%) male patients were in this study. The mean post-operative face pain score after surgery was 2.70±1.57. The minimum pain score was 0.0, and the maximum was 6. First rescue analgesia was given at a mean time of 5.08±1.49 hours. The minimum time of analgesia was 2 hours, and the maximum time of analgesia was 8 hours. In comparing postoperative pain scores between the groups, the mean pain score was 3.53±1.43 in the Tramadol-Group and 1.86±1.25 in the Nalbuphine-Group (Table-I). The mean time of first rescue analgesia was significantly protracted in the Nalbuphine Group; the mean time was 6.13±1.07 hours in the Nalbuphine Group versus 4.03±1.03 hours in the Tramadol Group (*p*-value<0.001) (Table–II).

Table-I: Comparison of Post-Operative Pain Between the Groups (n=60)

	Group A (n=60) Mean±SD	Group B (n=60) Mean±SD	*p*-value
Postoperative Pain Scores	3.53±1.43	1.86±1.25	<0.001

Table-II: Comparison of Time of First Rescue Analgesia Between the Groups (n=60)

	Group A (n=60) Mean±SD	Group B (n=60) Mean±SD	*p*-value
Time for first Rescue Analgesic	4.03±1.03 hours	6.13±1.07 hours	<0.001

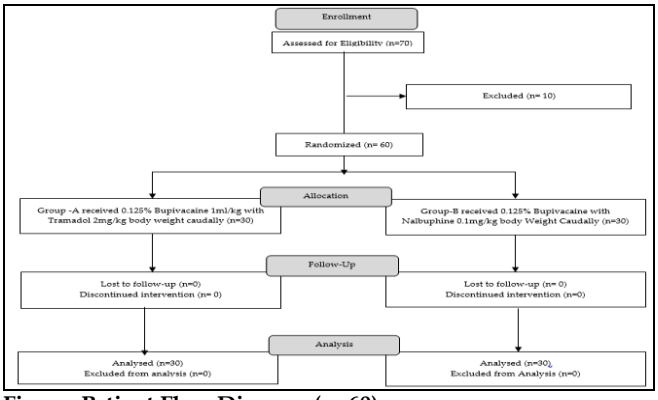

Figure: Patient Flow Diagram (n=60)

DISCUSSION

Pain management modalities are the same in the paediatric population as for the adult population, including opioid analgesics, infiltration of local anaesthetics and regional blocks.[11] Intravenous opioid analgesics are mostly employed for major surgeries. They have also been used as adjuvants to peripheral and neuraxial anaesthesia with varying degrees of success. Opioid use is often limited by their side effects, including pruritus, nausea, and respiration depression.[12] In the daycare paediatric surgery, analgesics causing sedation and respiratory depression are not very practical. Regional anaesthesia for post-operative pain relief is becoming more popular

for same-day surgery due to its advantages of simplicity, low rate of complications and safety.[13] Clonidine is a useful adjunct which provides prolonged pain relief in the neuraxial block but has prolonged motor blockade and is associated with increased incidences of hypotension, fainting, bradycardia, and sedation, likely due to systemic absorption.[14] Tramadol is a centrally-acting synthetic opioid that causes less respiratory compromise, provides good post-operative analgesia, and has the advantage of not having preservatives. As a review article recommends, Nalbuphine is a useful additive for intrathecal administration, causing analgesia without causing respiratory compromise.[15]

Hicks *et al*. computed the effects of Nalbuphine in obstetric analgesia when given in epidural space. Response to 100 µg/kg of Nalbuphine was recorded and evaluated at 5, 15, 30, 60, 90, and 120 min after injection by a visual analogue scale (VAS). In addition, the presence of untoward effects such as pruritus, urinary retention, respiratory compromise, hypotension, vomiting, or bradycardia was recorded. It was concluded that using Nalbuphine, in doses of 100 µg/kg epidurally, is effective in obtaining adequate analgesia during labour and is also clinically safe for both the mother and the newborn.[16] In another randomised control trial, Nalbuphine proved effective in lowering the pain scores in paediatric patients undergoing surgeries on the lower half of the body when given in caudal epidural space along with Levobupicaine.[17] Our study reinforced that Nalbuphine is a safe choice in the recommended dosage and does not induce respiratory failure. Compared with other opioids, Nalbuphine also results in fewer incidences of nausea and vomiting.[18] Finding the right drug and route in the right doses can help get adequate analgesia for paediatric age groups. The reluctance for regional anaesthesia has delayed adequate pain relief in our paediatric population for a long. However, now caudal analgesia is being used frequently, and it is resulting in early recovery and early ambulation in patients with sub-umbilical interventions.[19] With experience, caudal epidural blocks are technically much simpler in anaesthetised children than in adults, and the blockade produced is much more predictable.[20] The caudal epidural block provides excellent intra- and post-operative analgesia for almost all surgical interventions on the lower part of the abdomen and lower limbs, especially in neonates, infants, and certain high-risk children.

Effective paediatric pain management is as important as adult pain management. The lack of awareness, inadequate research, and reluctance to use opioids in children due to fear of respiratory depression and excessive sedation have resulted in significant morbidity and even mortality after surgical trauma in paediatric patients. Accurate assessment of pain and rational use of opioids can lead to successful pain management in paediatric patients.

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CONCLUSION

A single dose of Nalbuphine as an additive to Bupivacaine is superior to Tramadol in reducing post-operative pain. It causes significant prolongation in the duration of analgesia in paediatric patients.

Conflict of Interest: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MIK & MR: Data acquisition, critical review, approval of the final version to be published.

UK & KM: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SM & HMT: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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