Postoperative Pain Management: Efficacy of Caudal Tramadol in Pediatric Lower Abdominal Surgery: A Randomized Clinical Study

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Abstract

Background: One of the methods of pain control after pediatric surgical procedures is regional techniques, including caudal block, despite their limitations.

Objectives: In this study, the pain score and complications of caudal tramadol were evaluated in pediatrics following lower abdominal surgery.

Methods: In this study, 46 children aged 3 to 10 years were allocated into two equal groups (R and TR) for performing caudal anesthesia after lower abdominal surgery. The injectate contained 0.2% ropivacaine 1 mL/kg in the R group (control group) and tramadol (2 mg/kg) and ropivacaine in the TR group. The pain score, duration of pain relief, amount of paracetamol consumption, hemodynamic alterations, and possible complications at specific times (1, 2, and 6 hours) were evaluated in both groups.

Results: No considerable difference was observed in the pain score between the groups in the first and second hours (P > 0.05). However, in the sixth hour, the TR group had a significantly lower pain score than the R group (P < 0.05). Compared to the R group, the TR group had a longer period of analgesia and lower consumption of analgesic drugs (P < 0.05). Heart rate and blood pressure differences were not significant between the two groups (P > 0.05). Similarly, the duration of operation and recovery time were not remarkably different between the two groups (P > 0.05). Complications had no apparent differences between these two groups, as well (P > 0.05).

Conclusions: In this study, the addition of tramadol to caudal ropivacaine in pediatric lower abdominal surgery promoted pain relief without complications.

Keywords: Tramadol, Ropivacaine, Caudal Block, Pediatric, Lower Abdominal Surgery, Postoperative Pain

1. Background

For pain management after pediatric lower abdominal surgery, various methods have been used so far, including the administration of opioid and non-opioid drugs, as well as performing central and peripheral nerve blocks (1-5). As a neuraxial procedure, caudal is one of the popular techniques for pain management in children after lower abdominal surgeries, particularly orchidopexy, hernia, etc., within peri-operative care (6). The main drug in these cases is usually local anesthetics, which are not commonly sufficient to induce prolonged analgesia if administered alone in caudal; thus, much research has been done to examine the efficacy of caudal analgesia in pediatric groups (7-10). Being similar to bupivacaine in structure, ropivacaine is one of the most common local anesthetics for postoperative pain management, but its duration of motor block is shorter and has better cardiovascular stability and less neurotoxicity, thus allowing for faster discharge from the recovery room (11-14).

Tramadol is a synthetic opioid analgesic with a moderate potency whose effects vary depending on the type of opioid-specific receptors and can cause differences in the physiological parameters obtained (15). Administration of tramadol as an adjuvant for pain management or adding it to local anesthetics in various methods has enhanced their analgesic potency without increasing the incidence of adverse effects (16-19).

Despite some available research in this field, the appropriate dose of tramadol to be added to ropivacaine in caudal epidural in children has not yet been defined.
2. Objectives

Our aim in this study was to investigate the pain score and complications of tramadol as an adjuvant to caudal ropivacaine in the pediatric population scheduled for lower abdominal operation.

3. Methods

Following the Ethics Committee approval (Ref: IR.UMS.FMD.REC.1398.107) and receipt of the clinical trial registration code (Ref: IRCT20190929044924N1), written informed consent was obtained from the parents before the enrollment of children in this study. Forty-six pediatric patients (both sexes) aged 3 - 6 years, with ASA I-II, who were candidates for lower abdomen surgery, for 30 minutes to two hours under general anesthesia, were included in this double-blind, randomized clinical trial. The exclusion criteria for the study consisted of problematic surgeries (i.e., blood transfusion due to unacceptable bleeding), sacral deformities, hemorrhagic disorders, infections (local or systemic), history of drug hypersensitivity, and refusal of parents. The sample size of 46 patients was obtained using the following formula, who were randomly divided into two groups of 23:

\[ n = \frac{2[(z_1 - \alpha_2) + (Z_1 - b)]^2b^2}{d^2} \]

To double-blind the study, the children’s parents and the researchers were kept unaware of the group classification.

The induction and maintenance of anesthesia were performed in the same manner for both groups (including propofol, fentanyl, and atracurium for induction and isoflurane for maintenance). After surgery and before extubation, a caudal epidural block was performed under an aseptic situation, by lateral decubitus position, using a 20 G needle (Pajunk, Germany) under ultrasonography with a high frequency (6 - 13 MHz) linear probe (Sonosite, USA). When the exact location of the needle tip was confirmed by the sonographic view, 2 - 4 mL was slowly administered. If there were not any blood pressure and heart rate alterations, the remainder of the injectable solution was administered slowly.

Patients were randomly divided into two equal groups, R and TR. The injectable solution was 0.2% ropivacaine 1 mL/kg (Ropivacaine, Molteni, Italy) up to the highest volume of 15 mL in the R group and 0.2% ropivacaine 1 mL/kg plus tramadol 2 mg/kg (Ultram; Vertical Pharmaceutical, USA) in the TR group. Following the caudal block, the neuromuscular blockade was reversed (by atropine and neostigmine) and tracheal extubation was performed.

The patients were assessed at determined times (1, 2, and 6 hours after the operation), and if the pain score was more than 3, acetaminophen 15 mg/kg (Paracetamol Zolben, Switzerland) would be i.v. injected. Before and after the caudal injection, the pain scores were assessed using CHEOPS (Children’s Hospital of Eastern Ontario Pain Scale), and non-invasive blood pressure and heart rate monitoring were observed (Table 1). Moreover, the length of analgesia (pain score less than three), total acetaminophen used, post-anesthetic care unit stay (recovery time), and complications were evaluated.

Data were analyzed by SPSS 25. The results were expressed as the mean ± standard deviation (SD) for parametric data (weight, age, pain score, length of pain relief, surgery duration, amount of acetaminophen consumption, blood pressure, and heart rate) and percentage for non-parametric data (sex, complications). Parametric data were compared using the independent t test if the data distribution was normal; alternatively, the comparison was carried out employing the Mann-Whitney U test if there was an abnormal distribution. Non-parametric data were also compared using the χ² test or Fisher’s exact test. A p value of less than 0.05 was considered statistically significant.

4. Results

Demographic data and other information considered in the study are given in Table 2. As can be seen, the mean pain score assessed in the first and second hours was not significantly different between the two groups (P > 0.05); however, it was significantly lower in the TR group than in the R group in the sixth hour (P < 0.05).

The TR group also proved to have prolonged analgesia and less analgesic consumption compared to the R group (P < 0.05). There was no significant difference in the heart rate and blood pressure (systolic and diastolic) between the two groups (P > 0.05). Regarding the adverse effects, the difference between these two groups was not significant (P > 0.05). Furthermore, the differences in the duration of surgery and recovery time between these groups were not significant (P > 0.05).

5. Discussion

This study showed that adding tramadol (2 mg/kg) to caudal epidural ropivacaine increased pain relief and reduced acetaminophen consumption without affecting the incidence of complications in pediatric patients following lower abdominal surgery under general anesthesia.

To date, several studies have been conducted on the addition of adjuvant drugs to local anesthetics in regional...
Table 1. Modified CHEOPS (Children's Hospital of Eastern Ontario Pain Scale)

| Score | 0 | 1 | 2 |
|-------|---|---|---|
| Cry   | No cry | Crying, moaning | Scream |
| Facial| Smiling | Composed | Grimace |
| Verbal| Positive | None or other complaints | Pain complaint |
| Torso | Neutral | Shifting, tense, upright | Restrained |
| Legs  | Neutral | Kicks, squirm, drawn up | Restrained |

Table 2. Demographic Data, Pain Score, Analgesia, Acetaminophen Consumption, Heart Rate, Blood Pressure Alterations, and Complications

| Variables                      | R    | TR   | P Value |
|--------------------------------|------|------|---------|
| Age (y)                        | 6.04 ± 1.8 | 6.26 ± 1.7 | 0.542   |
| Sex (male: female) (n)         | 12: 11 | 14: 9 | 0.546   |
| Operation time (min)           | 45.6 ± 16.9 | 44.7 ± 15.8 | 0.664   |
| Pain score                     |       |       |         |
| First hour                     | 2.61 ± 0.72 | 2.57 ± 0.66 | 0.832   |
| Second hour                    | 3.0 ± 0.95 | 3.11 ± 0.92 | 0.639   |
| Third hour                     | 6.87 ± 1.98 | 4.65 ± 1.47 | 0.001   |
| Duration of analgesia (h)      | 2.83 ± 0.78 | 4.13 ± 0.76 | 0.001   |
| Acetaminophen (mg)             | 80.33 ± 28.43 | 61.87 ± 28.11 | 0.034   |
| Blood pressure (mmHg)          |       |       |         |
| Systolic                       | 94.5 ± 9.6 | 95.8 ± 5.6 | 0.604   |
| Diastolic                      | 62.2 ± 1.8 | 63.2 ± 3.1 | 0.237   |
| Heart rate (bpm)               | 103.1 ± 8.3 | 102.2 ± 9.2 | 0.844   |
| Recovery time (min)            | 126 ± 102 | 138 ± 84 | 0.337   |
| Complications                  |       |       |         |
| None                           | 19 (82.6) | 20 (88.8) | 0.778   |
| Hypotension                    | 1 (4.3) | 2 (8.66) | 0.884   |
| Tachycardia                    | 1 (4.3) | 1 (4.33) | 1.000   |
| Nausea/vomiting                | 1 (4.3) | 1 (4.33) | 1.000   |

*Values are expressed as mean ± SD or No. (%) .

Anesthesia in children and adults, which have produced different results in some cases, partly due to the dose of drugs, various concentrations of local anesthetics and adjuvants, and the type of surgery (20-24). Compared to ketamine, the addition of tramadol or fentanyl to local anesthetics in the axillary plexus block has accelerated the onset of sensory and motor blockade and reduced its duration and pain score, as well (25, 26).

To manage post-operative pain in pediatric lower abdominal surgery, tramadol and dexmedetomidine were separately added to caudal ropivacaine, and the results showed that the combination of caudal ropivacaine with dexmedetomidine had longer analgesia than its combination with tramadol, but the side effects were similar in the two groups (27). In our study, there existed no third group for further comparison, but it could be a good topic for future research. In a study, Jarineshin et al. conducted caudal block following anesthesia induction, and compared the addition of 2 µg/kg dexmedetomidine and 2 µg/kg fentanyl to caudal epidural bupivacaine 0.25% (28). The findings showed that dexmedetomidine was more effective than fentanyl in enhancing caudal analgesia for postoperative pain control without causing notable complications or hemodynamic alterations.

In some studies, non-opioid drugs such as ketamine and dexmedetomidine have been used to control pain in these cases, which have had considerable effects on postoperative pain management (29, 30), and its addition to...
caudal bupivacaine has also increased postoperative analgesia in children (31). In another study, the addition of tramadol, as compared with ketamine, to pediatric caudal ropivacaine was investigated, and the results indicated prolonged analgesia and reduced analgesic consumption in the tramadol group although it was associated with a high incidence of postoperative nausea and vomiting (32).

In our study, on the contrary, the amount and the type of complications between the two groups were not different.

In a study conducted by Singh et al., adding tramadol (2 mg/kg) to ropivacaine increased the pain relief without hemodynamic side effects (33), which is consistent with the results of the present study. Furthermore, the addition of tramadol to bupivacaine, as compared with caudal levobupivacaine, did not make any change in the severity of pain, duration of analgesia, and side effects, which raises the question of whether the type of local anesthetic can influence the effects of adding tramadol (34).

In a study on pain management in infra-umbilical cord surgery in children, 2 mg/kg tramadol was added as an adjuvant to caudal ropivacaine 0.2% (1 mL/kg), which increased pain relief, though not associated with considerable effects on sedation and motor block (35), and thus is in line with the results obtained in our study.

5.1. Conclusion

Overall, although the addition of tramadol to caudal ropivacaine in children increased the effects of the caudal epidural blockade in children, such as increasing the duration of analgesia and reducing the dose of analgesics, it did not raise the adverse effects; thus, it could be recommended for administration with caudal ropivacaine. However, the most common problem in these patients was, of course, the dissatisfaction of some parents and their fear of performing a caudal blockade.

Footnotes

Authors’ Contribution: Study concept and design, RFR, FI, AE, and RS; Analysis and interpretation of data, RFR, FI, AE, RS, and ARG; Drafting of the manuscript, FI, RS, and ARG; Critical revision of the manuscript for important intellectual content, FI and ANS.

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