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ORIGINAL ARTICLE

Analgesia after Lower Abdominal Surgery in Children Treated with Caudal Bupivacaine Versus a Bupivacaine-Tramadol Combination

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ABSTRACT

Background: Postoperative pain management in pediatric patients is essential in controlling pain and in improving recovery results. The technique of caudal epidural analgesia is widely used in pediatric lower abdominal surgeries and adding tramadol to bupivacine has been effective in producing increased analgesic effect.

Objective: To evaluate the efficacy of tramadol as an adjuvant to bupivacaine for caudal analgesia in pediatric patients undergoing lower abdominal surgeries.

Material and Methods: This randomized controlled trial was performed at the Fatima Hospital Baqai Medical University Karachi, from January 2023 to June 2023. Total 64 pediatric patients aged 2–12 years undergoing elective lower abdominal surgeries were randomly assigned into two groups of 32 patients each. In Group A, caudal bupivacaine (0.25 %, 1 mL/kg,) was administered while in Group B bupivacaine (0.25 %, 1 mL/kg) and tramadol (1 mg/kg.) in combination with each other. Evaluation of postoperative pain was performed using the FLACC scale at 1, 2, 4, 6, and 12, and 24 hours in the postoperative period. The primary result was the duration of analgesia, secondary results included the pain scores, requirements for rescue analgesia and adverse effects. The statistical analysis was done using SPSS version 24.

Results: Mean pain scores were significantly lower for the bupivacaine-tramadol group at all time points ($p < 0.001$) and the duration of analgesia in this group was longer (11.99 ± 2.00 hours versus 5.68 ± 0.95 hours, $p < 0.001$). The bupivacaine-tramadol group also had lower rescue analgesia requirements (0.56 ± 0.50 doses vs 2.78 ± 0.83 doses; $p < 0.001$). There was no significant increase in adverse effects.

Conclusion: For pediatric patients requiring caudal analgesia, the addition of tramadol to bupivacaine provides prolonged analgesia with a favorable safety profile, and results in improved postoperative pain management.

Keywords: Bupivacaine, Tramadol, Caudal analgesia, Pediatric surgery, Postoperative pain.

INTRODUCTION

Postoperative pain control in pediatric surgeries is of critical importance for a good recovery, to avoid psychological stress factors and to minimize complications. Use of the caudal route is a frequently chosen technique in pediatric anesthesia and is generally quite effective for intraoperative as well as postoperative pain relief. Bupivacaine, one of the local anesthetics, has been widely employed because of a long duration of action and a low systemic toxicity. Yet, many adjuvants, such as tramadol, have been added to bupivacaine in order to improve the analgesic efficacy and prolong time of pain relief[1].

A long acting, amide, Local anaesthetic[2], Bupivacaine, is specifically efficacious for caudal analgesia in infra umbilical surgeries. However, its prolonged action often falls short to manage prolonged postoperative pain management, Therefore investigation has been made on adjuvants that would enhance its effect[2,3]. Tramadol, with a unique mechanism of weak μ receptor agonism as well as inhibition of serotonin and noradrenaline reuptake, has been proven to be an adjuvant. Use in combination with bupivacaine for caudal blocks in pediatric patients has been associated with better analgesic outcomes and lower utilization of systemic analgesics[4,5].

The results of recent studies suggest that combination bupivacaine tramadols are likely to improve postoperative analgesia. As an example, one study showed that tramadol as an adjuvant to bupivacaine significantly lowered postoperative pain scores and increased the duration from initial analgesia until rescue analgesia was required when compared with bupivacaine alone[6]. Additionally, the combination appears to have a favorable safety profile with few adverse effects including nausea and sedation which are common with systemic opioids[7].

Now, tramadol also offers the benefits of combining with bupivacaine beyond its use for pain relief. This combination thus decreases the chances for additional opioid administration which is important as pediatric patients are more sensitive to opioid related adverse effects. A reduction in postop inflammation and improved patient satisfaction with this multimodal approach to analgesia has also been reported from other studies[8,9]. Nevertheless, neurotoxicity and systemic side effects of tramadol still need more research done because of these advantages[10].

Secondly, emerging evidence also suggests that the combination may have some specific benefits in specific surgical populations. The bupivacaine -tramadol combination has been shown to provide better analgesia than bupivacaine alone in pediatric patients undergoing lower abdominal surgeries where achieving effective pain control can be difficult[11]. Reduction of physiological stress associated with pain is crucial for faster recovery and earlier hospital discharge, which this improvement in analgesic quality allows.

In comparing caudal bupivacaine with and without the addition of tramadol, varying results serve to highlight the need for standardized protocol for dosing to reduce risks. Elucidation of the mechanisms and clinical outcomes of this combination will allow clinicians to tailor analgesic strategies to the individual needs of pediatric patients undergoing lower abdominal surgeries.

MATERIALS AND METHODS

This study was designed as a randomized controlled trial and conducted in the Fatima Hospital Baqai Medical University Karachi, from January 2023 to June 2023, after obtaining approval from the institutional ethical review board. Informed consent was secured from the parents or guardians of all enrolled children. The study included 64 children, aged 2 to 12 years, scheduled for elective lower abdominal surgeries. The sample size was determined using a 95% confidence interval (CI) and 90% power, based on data from a previous study that reported mean postoperative pain scores of **3.5 ± 4.62** in the bupivacaine-

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tramadol group compared to **7.6 ± 5.42** in the bupivacaine-only group[12].

Participants were randomly divided into two groups of 32 each using computer-generated random numbers. Group A was administered caudal bupivacaine alone (0.25%, 1 mL/kg), while Group B received a combination of bupivacaine (0.25%, 1 mL/kg) and tramadol (1 mg/kg). Caudal blocks were performed under sterile conditions following the induction of general anesthesia. Children with contraindications such as allergies to local anesthetics, bleeding disorders, spinal abnormalities, or pre-existing neurological issues were excluded.

Postoperative pain was evaluated using the FLACC scale (Face, Legs, Activity, Cry, Consolability) at 1, 2, 4, 6, 12, and 24 hours after surgery. Data collected included demographic details (age, weight, and gender), surgical parameters (type and duration of surgery), and pain scores at the specified time points. The duration of effective analgesia, defined as the time from caudal block to the first rescue analgesic requirement, and the number of rescue analgesia doses administered within 24 hours were also recorded. Subgroup analyses were performed to compare outcomes by gender, age groups (<6 years, 6–9 years, >9 years), and weight categories (<15 kg, 15–20 kg, >20 kg). Side effects such as nausea, vomiting, itching, and sedation were noted as well.

The primary outcome of the study was the duration of effective analgesia, while secondary outcomes included the number of rescue analgesia doses and pain scores at different intervals. Statistical analysis was performed using SPSS version 24. Continuous variables were summarized as mean ± standard deviation (SD), and group comparisons were conducted using independent samples t-tests. A p-value <0.05 was considered statistically significant.

RESULTS

The average age of the study participants was 6.98 ± 2.98 years, and their average weight was 19.38 ± 5.99 kg. The surgeries lasted for an average of 59.29 ± 17.57 minutes, and the mean duration of analgesia was found to be 8.83 ± 3.54 hours. Postoperative pain scores, measured at specific intervals, demonstrated a steady decrease over time. The mean ± SD pain scores were 5.31 ± 1.98 at 1 hour, 4.87 ± 2.12 at 2 hours, 4.29 ± 1.84 at 4 hours, 3.81 ± 1.83 at 6 hours, 3.27 ± 2.15 at 12 hours, and 2.67 ± 2.00 at 24 hours.

Table 1 compares the pain scores between the two groups. Across all time points (1, 2, 4, 6, 12, and 24 hours), the pain scores were consistently lower in the Bupivacaine-Tramadol group when compared to the Bupivacaine-only group ($p < 0.001$). For instance, at the 1-hour mark, the mean pain score in the Bupivacaine group was 7.05 ± 0.92, while it was significantly lower in the Bupivacaine-Tramadol group (3.57 ± 0.92). Similarly, at 2 hours, the scores were 6.69 ± 1.12 and 3.05 ± 1.03 for the Bupivacaine and Bupivacaine-Tramadol groups, respectively. By 24 hours, the mean scores had dropped to 4.39 ± 1.12 in the Bupivacaine group and 0.95 ± 0.89 in the Bupivacaine-Tramadol group.

The duration of analgesia was significantly longer in the Bupivacaine-Tramadol group, with a mean of 11.99 ± 2.00 hours, compared to 5.68 ± 0.95 hours in the Bupivacaine group ($p < 0.001$). Additionally, the Bupivacaine group required more rescue analgesia doses, averaging 2.78 ± 0.83 doses, compared to 0.56 ± 0.50 doses in the Bupivacaine-Tramadol group ($p < 0.001$). These findings highlight the superior efficacy of the bupivacaine-tramadol combination in providing prolonged pain relief and reducing the need for additional analgesics (Table 2).

Table 3 provides a subgroup analysis of pain scores at the 24-hour mark. Among male participants, the mean pain score was 4.32 ± 0.98 in the Bupivacaine group and 0.95 ± 0.78 in the Bupivacaine-Tramadol group ($p < 0.001$). A similar pattern was observed in female participants, where the mean scores were 4.44 ± 1.25 and 0.95 ± 1.12, respectively ($p < 0.001$).

This trend of lower pain scores in the Bupivacaine-Tramadol group persisted across all age and weight categories. For children under 6 years, the mean pain score in the Bupivacaine group was 4.89 ± 1.43, compared to 0.95 ± 0.72 in the Bupivacaine-Tramadol group ($p < 0.001$). Similarly, children in the 6–9 years and >9 years age groups showed significantly lower scores in the Bupivacaine-Tramadol group. Weight-based analysis revealed that children weighing less than 15 kg had mean scores of 4.59 ± 1.40 (Bupivacaine group) versus 0.70 ± 0.69 (Bupivacaine-Tramadol group, $p < 0.001$). Comparable reductions were noted in the 15–20 kg and >20 kg weight categories.

In summary, the combination of bupivacaine and tramadol demonstrated superior analgesic efficacy, offering prolonged pain relief and reduced rescue analgesia requirements compared to bupivacaine alone.

Table 1: Comparison of Postoperative Pain Scores (Mean ± SD) Between the Bupivacaine and Bupivacaine-Tramadol Groups

Variable	Group	N	Mean ± SD	p-value
Pain_1h	Bupivacaine	32	7.05 ± 0.92	<0.001
	Bupivacaine-Tramadol	32	3.57 ± 0.92	
Pain_2h	Bupivacaine	32	6.69 ± 1.12	<0.001
	Bupivacaine-Tramadol	32	3.05 ± 1.03	
Pain_4h	Bupivacaine	32	5.84 ± 1.13	<0.001
	Bupivacaine-Tramadol	32	2.74 ± 0.76	
Pain_6h	Bupivacaine	32	5.42 ± 0.72	<0.001
	Bupivacaine-Tramadol	32	2.20 ± 0.97	
Pain_12h	Bupivacaine	32	5.15 ± 1.08	<0.001
	Bupivacaine-Tramadol	32	1.39 ± 0.99	
Pain_24h	Bupivacaine	32	4.39 ± 1.12	<0.001
	Bupivacaine-Tramadol	32	0.95 ± 0.89	

Table 2: Comparison of Duration of Analgesia and Rescue Analgesia Between Groups

Variable	Group	N	Mean ± SD	p-value
Duration of Analgesia	Bupivacaine	32	5.68 ± 0.95	<0.001
	Bupivacaine-Tramadol	32	11.99 ± 2.00	
Rescue Analgesia	Bupivacaine	32	2.78 ± 0.83	<0.001
	Bupivacaine-Tramadol	32	0.56 ± 0.50	

Table 3: Comparison of Pain Scores (Pain_24h) Across Gender, Age Groups, and Weight Groups

Variable	Group	N	Mean ± SD	p-value
Gender				
Male	Bupivacaine	14	4.32 ± 0.98	<0.001
	Bupivacaine-Tramadol	21	0.95 ± 0.78	
Female	Bupivacaine	18	4.44 ± 1.25	<0.001
	Bupivacaine-Tramadol	11	0.95 ± 1.12	
Age Group				
<6 years	Bupivacaine	8	4.89 ± 1.43	<0.001
	Bupivacaine-Tramadol	15	0.95 ± 0.72	
6-9 years	Bupivacaine	15	4.04 ± 0.92	<0.001
	Bupivacaine-Tramadol	11	0.75 ± 0.99	
>9 years	Bupivacaine	9	4.52 ± 1.05	<0.001
	Bupivacaine-Tramadol	6	1.32 ± 1.13	
Weight Group				
<15 kg	Bupivacaine	10	4.59 ± 1.40	<0.001
	Bupivacaine-Tramadol	9	0.70 ± 0.69	
15-20 kg	Bupivacaine	6	4.42 ± 0.62	<0.001
	Bupivacaine-Tramadol	9	1.72 ± 0.79	
>20 kg	Bupivacaine	16	4.24 ± 1.11	<0.001
	Bupivacaine-Tramadol	14	0.62 ± 0.80	

DISCUSSION

Results of this study are consistent with those of earlier studies which showed the advantages of adjuvant use of tramadol with bupivacaine for caudal analgesia in pediatric patients subjected to

lower abdominal surgeries. Tramadol remarkably improves both the quality and duration of postoperative analgesia with minimal requirement for rescue analgesia and associated side effects.

It is well documented, from several studies, that the mixture of bupivacaine and tramadol proves superior for pain relief when compared with bupivacaine alone. In the view of this, Shamsuddin et al. reports that the bupivacaine-tramadol combination significantly reduced postoperative pain scores, prolonged the duration of analgesia, and resulted in less rescue analgesia and minimal side effects[12]. Likewise, Soomro et al. also reported that tramadol when combined with bupivacaine, produced a more prolonged analgesia in all age groupsthis RPV combination in pediatric patients found to be effective and safe[13]. Our results were consistent with these findings, as the bupivacaine–tramadol group had significantly lower pain scores and longer analgesia duration compared with the bupivacaine group.

Further results by Zubair et al. and Angasa et al. concur with the role of tramadol as an adjuvant. According to Zubair et al., the duration of analgesia was significantly longer in the tramadol group (11.12 ± 1.86 hours), compared to the group receiving bupivacaine alone (7.37 ± 1.96 hours), with lower pain scores throughout the 24 hour period[14]. A prolonged duration of analgesia (14 hours vs. 5 hours in the bupivacaine only group) and reduced postoperative analgesic consumption was shown by Angasa et al.[15]. However, these findings underscore the synergistic effect of tramadol in potentiating the analgesic properties of bupivacaine.

Studies such as Aggarwal et al. observed dose dependent prolongation of analgesia with tramadol without increasing the incidence of side effects[16] with the highest dose of tramadol (2mg/kg) resulted in the longest duration of analgesia. Similar to this, Regmi and Sapkota found that adding 1 mg/kg tramadol to bupivacaine significantly improved analgesia duration (467.5 ± 164.5 min versus 240.5 ± 69.4 min), with no significant adverse effects, making it safe to administer in pediatric populations[17]. Our results of decreased rescue analgesia requirement as well as prolonged analgesia in the bupivacaine – tramadol group are in keeping with this finding.

In addition, several studies have also commented on the reduction in total analgesic consumption in the tramadol group. For example, there was significantly lower consumption of paracetamol in the tramadol group compared to the bupivacaine-only group according to Angasa et al.[15]. This is in agreement with Nisa et al. who reported the addition of tramadol significantly improved sedation scores and decreased pain intensity without inducing additional adverse effects[18]. However, further analysis in our study also confirmed that the bupivacaine-tramadol group required fewer rescue analgesia doses.

The tramadol bupivacaine co-administration was consistently supported in the literature for safety profile. Rahman et al. and Wadood et al. reported that tramadol at a dose of 1 mg/kg significantly prolongs the duration of analgesia without causing sedation or emesis[19,20]. These results are supported by our findings showing no significant increase in adverse effects in the bupivacaine-tramadol group.

Regardless, the evidence favors use of tramadol as an add on to bupivacaine for caudal analgesia in pediatric patients. On the strength of the combination, it offers prolonged and superior postoperative pain relief, reduced need for additional analgesics and a favorable safety profile. This combination has clinical utility for providing optimal pain management for children undergoing lower abdominal surgeries as these findings show.

CONCLUSION

This is a prospective randomized controlled trial that shows the addition of tramadol to bupivacaine does significantly decrease postoperative pain and extend duration of postoperative analgesia in pediatric patients administered caudal analgesia for lower abdominal surgeries. Contrary to the tramadol-bupivacaine combination, the bupivacaine-tramadol combination caused prolonged analgesia, lower postoperative pain scores at all time points, and less rescue analgesics compared to bupivacaine alone. Importantly, the treatment exhibited efficacy in all demographic subgroups (by gender, age, and weight), and the safety profile remained favorable without significant increases in the occurrence of adverse effects. These findings support the use of bupivacaine tramadol as a safe and superior alternative for caudal analgesia in pediatric surgical practice and will help prevent the occurrence of discomfort to children and improve perioperative practice care.

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