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Original Article

Comparative Study of Levobupivacaine and Levobupivacaine with Tramadol in Pediatric Caudal Epidural Block

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Abstract

Introduction: Caudal block is the regional anesthetic technique that is used most frequently in pediatric surgery, and bupivacaine and levobupivacaine are widely utilized in this technique. Opioid drugs have been added to local anesthetic solutions to prolong the duration of analgesia, but ideal combination was not found.

Aim: The aim is to study the post-operative analgesic effects and other effects of tramadol when added to caudal levobupivacaine as an adjunct in children undergoing lower abdominal surgeries.

Materials and Methods: ASA I and II patients between 2 and 6 years of age undergoing lower abdominal surgeries were included in the study. Group LT (n = 30) received caudal 0.25% levobupivacaine 1 ml/kg with tramadol 2 mg/kg making the volume to 0.5 ml and Group L (n = 30) received caudal 0.25% levobupivacaine 1 ml/kg + 0.5 ml normal saline.

Results: The duration of post-operative analgesia recorded a mean of 5.5 ± 1.05 h in group L compared with 13.5 ± 2.3 h in Group LT, with a $P < 0.0001$. The dosage of paracetamol consumed was greater in the L group and is statistically significant with a $P < 0.0001$. The difference of mean sedation score between both groups was statistically insignificant ($P > 0.05$). No episodes of clinically significant post-operative complications such as post-operative nausea and vomiting, respiratory depression, urinary retention, pruritus, hypotension, and bradycardia were observed.

Conclusion: Levobupivacaine with tramadol provided effective post-operative analgesia with minimal side effects.

Key words: Anesthesia, Caudal, Levobupivacaine, Tramadol

INTRODUCTION

The quest for searching newer and safer anesthetic agents has always been one of the primary needs in anesthesiology practice. Ease of performance and reliability makes caudal block the most routinely performed block in pediatrics. Administration of caudal bupivacaine is a widely used regional anesthetic technique for both intra- and post-operative analgesia in lower limb, anoperineal, penoscrotal, and abdominal surgical procedures in pediatrics.[1] Unintentional intravascular injection of bupivacaine during caudal block placement may cause life-threatening cardiovascular and central nervous system complications.[2] There have been reports of death attributable to bupivacaine-induced cardiotoxicity in adults after accidental intravenous injection.[3] Even an epidural test, dose containing epinephrine does not reliably produce hemodynamic responses in children during inhalation anesthesia.[4] In this study, we have chosen levobupivacaine. Levobupivacaine in comparison to bupivacaine has a wider margin of safety, less motor blockade, less cardiovascular/neurological toxicity, and similar duration of analgesia. It can be safely used for regional anesthesia and analgesia in the ambulatory setting in pediatrics a newer drug with less toxicity profile instead of bupivacaine.[5]

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To overcome this problem as well as to increase the duration of analgesia, combining local anesthetic agents with other drugs as adrenaline, clonidine, ketamine, or various opioids have met with varying degrees of success. We used tramadol in this study as the adjuvant owing to its lesser respiratory depressant action compared to other opioids and its significance in prolonging post-operative analgesia as reported from other studies.

Aim

The aim is to study the post-operative analgesic effects and other effects of tramadol when added to caudal levobupivacaine as an adjunct in children undergoing lower abdominal surgeries.

MATERIALS AND METHODS

The prospective randomized comparative study was conducted in the Department of Anesthesia at Tirunelveli Medical College Hospital. ASA I and II patients between 2 and 6 years of age undergoing lower abdominal surgeries were included in the study. Exclusion criteria: Suspected coagulopathy, infection at the site of caudal block, history of developmental delay, neurological diseases, skeletal deformities, and allergy to local anesthetics. Group LT (n = 30) received caudal 0.25% levobupivacaine 1 ml/kg with tramadol 2 mg/kg making the volume to 0.5 ml and group L (n = 30) received caudal 0.25% levobupivacaine 1 ml/kg + 0.5 ml normal saline. All the patients were premedicated with injection atropine 0.02 mg/kg i.m. 45 min before anesthesia. Induction of anesthesia was achieved with 50% N_2O and 8% sevoflurane in oxygen in spontaneous ventilation. Appropriate size laryngeal mask airway (LMA) was inserted. After the insertion of LMA, sevoflurane concentration was reduced to 3% in 50% nitrous oxide, patients were left in spontaneous ventilation, and a caudal block was performed in all patients depending on the group. Hemodynamic parameters were maintained 30% below the baseline by adjusting the amount of sevoflurane that was inhaled. During the intraoperative period, narcotics, analgesics, or sedatives were not added. Standard monitors were utilized during the procedure. Recordings of heart rate, mean airway pressure, and SpO_2 were taken before the procedure and every 5 min till the procedure ended. During the procedure, recordings of any hypotension requiring crystalloid bolus, use of atropine for bradycardia, and maintenance requirement of sevoflurane were done. The occurrence of intraoperative hypotension requiring a fluid bolus, bradycardia requiring atropine, and the maximum maintenance concentration of sevoflurane was recorded. Pediatric observational Face, Legs, Activity, Cry, Consolability scale (FLACC) scale was used with its 0-10 score range. Each patient's pain intensity was determined at the end of surgery and then every 4 h for 24 h following the surgery. When FLACC score was 4 or more, syrup paracetamol 15 mg/kg was administered. The duration of analgesia (from the time of caudal injection to the time at which FLACC score, 4 or more) was also recorded. Sedation score was assessed using Ramsay's sedation scale. Complications such as post-operative nausea and vomiting (PONV), respiratory depression, hypotension, and bradycardia were also noted.

RESULTS

In this study, we encountered eight failed caudal blocks. Those cases were eliminated from the study. Age, weight of the children, and duration of surgery between both the groups were comparable and were not statistically significant ($P > 0.05$). In the LT group, 66.6% were male and the remaining 33.3% were females, compared to the L group which had 60% males and 40% females. Both groups were comparable with no statistical difference. The mean weight of the LT group was 13.100 ± 3.889 kg and L group was 12.907 ± 3.549. The difference of weight between the two groups was not statistically significant ($P > 0.05$). The type of surgeries between the both groups was also comparable but not statistically significant (Table 1). The pre-operative hemodynamic changes between the groups were comparable and were not statistically significant.

The end of surgery hemodynamic changes between the groups was comparable and was not statistically significant. The intraoperative hemodynamic changes between the groups were comparable and were not statistically significant.

The mean duration of surgery of L group was 35.667 ± 7.5 min and LT group was 37.6 ± 5.3 min. The difference between the means was not statistically significant ($P > 0.05$) (Table 2). The emergence from surgery is comparable in both groups.

Table 1: Comparison of procedure based on group

Type of surgery	L group	LT group
Herniotomy	16	13
Hydrocele	2	6
Circumcision	8	8
Orchiopexy	4	3
Total	30	30

Table 2: Comparison of the duration of surgery

Groups	Mean±SD	*P* value
L group	35.667±7.512	0.240
LT group	37.667±5.371	

SD: Standard deviation

The duration of post-operative analgesia recorded a mean of 5.5 ± 1.05 h in group L compared with 13.5 ± 2.3 h in Groups LT, with a $P < 0.0001$ (Table 3).

The dosage of paracetamol consumed was greater in the L group and is statistically significant with a $P < 0.0001$ (Table 4).

The difference of mean sedation score between both groups was statistically insignificant ($P > 0.05$) (Table 5).

There was a significant difference between the groups in the FLACC scores measured at 4th and 6th h in the post-operative period. Group L patients achieved significantly higher FLACC score in comparison to group LT, where 15 children reached a FLACC score of 4, at 6th h compared with 0 patient in group LT. Whereas, in group LT, children had FLACC score 4, only at 16th h of post-operative period (Table 6). No episodes of clinically significant post-operative complications such as PONV, respiratory depression, urinary retention, pruritus, hypotension, and bradycardia were observed.

Table 3: Comparison of the duration of analgesia

Groups	Mean±SD	*P* value
L group	5.533±1.050	<0.0001
LT group	13.567±2.388	

SD: Standard deviation

Table 4: Comparison of the number of doses of paracetamol taken

Groups	Mean±SD	*P* value
L group	2.867±0.571	<0.0001
LT group	1.233±0.430	

Table 5: Comparison of sedation score

Hours	Mean±SD		*P* value
	L group	LT group	
2	2±0	2±0	1.000
3	1.600±0.498	1.667±0.479	0.599
4	1±0	1±0	1.000
5	1±0	1±0	1.000
6	1±0	1±0	1.000

SD: Standard deviation

Table 6: Comparison of FLACC score

Hours	Mean±SD	
	L group	LT group
2	0.467±0.629	0±0
4	2.433±0.817	0.367±0.615
6	3.615±0.496	1.033±0.850
8	4.000±0	2.000±0.910
12	0±0	2.821±0.945
16 h	0±0	3.900±0.308
20 h	0±0	4.000±0.000

FLACC: Face, Legs, Activity, Cry, Consolability scale

DISCUSSION

In this study, the caudal block was performed in 60 children, 24-72 months of age, to compare the effects of levobupivacaine alone with a low dose combination of 0.25% levobupivacaine with 2 mg/kg tramadol for lower abdominal surgeries.

Yildiz *et al.*[6] compared the analgesic efficacy and duration post-operatively in children undergoing inguinal hernia repair following caudal block with levobupivacaine 0.125% or caudal tramadol 1.5 mg/kg and a mixture of both. They noticed no hemodynamic variations during the intraoperative period following surgical incision. Duration of analgesia was significantly prolonged in group LT than in group L and group T (9.1 ± 2.6 h vs. 5.4 ± 3.1 h and 4.1 ± 3.1 h, respectively) ($P < 0.01$). There were no significant differences between the group L and group T for the duration of analgesia ($P > 0.05$). There was no significance among the groups in the number of patients requiring analgesia following surgery ($P = 0.7$). In this study, the duration of post-operative analgesia was significantly longer in the LT group (813.6 ± 138). This may be due to the higher concentration of levobupivacaine (0.25%) used in this study.

Prakash *et al.*[7] evaluated the efficacy of analgesia following three doses of tramadol, given along with caudal bupivacaine, in providing post-operative pain relief for pediatric inguinal herniotomy. In their studies, when they used 2 mg/kg of tramadol with caudal bupivacaine 0.25% (0.75 ml/kg) in pediatric inguinal surgeries, they got a mean duration of post-operative analgesia of (mean [standard deviation] 12 (0.9) h). In this study, we used tramadol 2 mg/kg with 0.25% 1 ml/kg and we observed a post-operative analgesia of 13.5 ± 2.3 h. This increased duration of analgesia may be due to the higher volume of 1 ml/kg of levobupivacaine that we used in our study. However, the post-operative sedation scores in our study were insignificant and comparable to the above study. Furthermore, like the above study, the time to 1st void was significantly prolonged in the tramadol group. Only one study reported that the addition of tramadol did not significantly prolong the action of caudal bupivacaine.[8]

Engelman and Marsala[9] suggested that there could be a synergistic effect between the local anesthetics and the additives, such as tramadol, rather than simply an additive

effect, as the higher the dose of local anesthetics, the greater the additional anesthetic effect. In the literature, there are studies in rats exploring a synergistic interaction between intrathecal clonidine and lidocaine.[10]

In short, the results of this study were comparable with most of the previous studies. Caudal administration of tramadol to levobupivacaine seems to produce a dose related but definite increase in post-operative analgesia. There was no difference in post-operative sedation between the groups as evident by the time to spontaneous eye opening and sedation scores. Its still doubt whether the action of tramadol is due to delayed systemic absorption of the drug or due to a direct action at the spinal level, owing to the fact that it is one of the few drugs that have the same dose i.v and epidurally. In a study conducted in rats, it was found that tramadol depresses the spinal nociceptive responses in a similar way to morphine.[11]

CONCLUSION

Low-dose combination of 0.25% levobupivacaine and caudal tramadol 2 mg/kg body weight injected caudally for lower abdominal surgeries in young children had an additive effect and provided effective post-operative analgesia with minimal side effects. The duration of post-operative analgesia was significantly prolonged as compared to 0.25% levobupivacaine.

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