

# A Comparative Study of Dexmedetomidine and Tramadol as an Adjuvant to Levobupivacaine in Ultrasound Guided Transverse Abdominus Plane Block in Pediatric Patients Undergoing Laproscopic Orchidopexy

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## ABSTRACT

**Background:** Transverse abdominus plane (TAP) block is a regional anesthetic technique which provides an excellent analgesia without major adverse effects. The primary aim of this study was to evaluate the efficacy of dexmedetomidine in comparison to tramadol when added as adjuvant to levobupivacaine in TAP block on duration of post operative analgesia following laproscopic orchidopexy.

**Methods:** Sixty American Society of Anaesthesiologists (ASA) grade 1 pediatric patients undergoing laproscopic orchidopexy under general anaesthesia were randomized into two groups (GroupLD and Group LT). Group LD recieved ultrasound guided bilateral TAP block with 0.3 ml/kg 0.25% levobupivacaine with 1µg/ kg of dexmedetomidine on both sides and Group LT recieved TAP block with 0.3 ml/kg 0.25% levobupivacaine with 1mg/ kg of tramadol. During the first 24 h postoperatively, we assessed hemodynamic stability, respiratory depression, and postoperative pain using face, legs, activity, cry, consolability (FLACC) pain scale.

**Results:** Total duration of analgesia ( $986.67 \pm 47.29$  min vs.  $690 \pm 53.49$  min, P value- 0.000), and the total consumption of paracetamol in the first 24 hours postoperatively ( $324.28 \pm 35.5$  mg vs.  $580.14 \pm 38.23$ , P value – 0.000) were statistically highly significant in group LD in comparison to group LT. The FLACC score were lower in Group LD as compared to group LT and side effects profile were similar in both the groups.

**Conclusion:** Dexmedetomidine in a dose of 1 µg.kg-1 when added to levobupivacaine in ultrasound guided transverse abdominus plane block significantly prolongs the duration of postoperative analgesia as compared to tramadol with levobupivacaine without major side effects.

Laproscopic orchidopexy is a commonly performed surgery for nonpalpable undescended testis [1]. Various modes of analgesic technique like NSAIDs, opioids, regional analgesic techniques have been employed to attain adequate analgesia. But usage of systemic opioids are associated with various adverse effects like nausea, vomiting, respiratory depression, sedation and retention of urine and hyperalgesia [2]. Rafi

first reported transversus abdominis plane (TAP) block in 2001, which confers analgesia in the T7–L1 dermatomal region in the anterior abdominal wall. Utilization of ultrasound has made TAP block more safe and simple. Several adjuvants like dexmedetomidine, clonidine, fentanyl and dexamethasone have been used with local anesthetic agents to extend the duration of analgesia [3-4]. Tramadol, a synthetic analogue of codeine, is an

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agonist at opioid  $\mu$ -receptor and also a potent serotonin norepinephrine reuptake inhibitor [5]. Tramadol poses reduced risk of respiratory depression as compared to morphine and other opioids [6]. Dexmedetomidine, a selective alpha-2 adrenergic agonist has been used as an additive extensively in the regional techniques [7]. After extensive search we could not find any study which has compared the efficacy of dexmedetomidine and tramadol as adjuvants to levobupivacaine in TAP block for laparoscopic orchidopexy. Hence we conducted present study to compare the efficacy of dexmedetomidine and tramadol added as adjuvants to 0.25% levobupivacaine in ultrasound-guided TAP block for pediatric patients posted for laparoscopic orchidopexy under general anaesthesia.

## Methods

After obtaining hospital ethical committee approval (AIMS/IEC/2098/2021, Date: 11/01/2021) and informed consent from the parents, this prospective randomized double-blind study was conducted on 60 pediatric patients between the age groups 1 and 10 years with American Society of Anesthesiologists (ASA) status I, who were scheduled to undergo laparoscopic orchidopexy under general anaesthesia. Patients were randomized into two groups comprising of 30 members using sealed envelope technique.

Patients with a history of delayed milestones development or mental retardation, known hypersensitivity to local anaesthetics, coagulation disorders, and injection site infection were excluded from the study. After elaborative pre anaesthetic check and necessary investigations, patients were kept nil by mouth 6 hours for solid food and 2 hours for clear liquids. After shifting to operation theatre (OT), we attached standard monitors (electrocardiogram, non-invasive blood pressure, and pulse oximetry) and intravenous line was secured. Baseline heart rate and mean arterial blood pressure were recorded before induction of anaesthesia and every 5 min till the surgery is finished. All patients were induced using 8% sevoflurane in fifty percent air and fifty percent O<sub>2</sub>. After intubating dose of atracurium we intubated the patients with age appropriate endotracheal tube. Anaesthesia was maintained with sevoflurane, atracurium, fentanyl, O<sub>2</sub> and air and calculated amount of intravenous fluids were infused. After the end of the surgery and before extubation, TAP block was administered. Ultrasound-guided TAP block was administered on either sides in supine position. A linear probe with 10–12 MHz frequency was placed in transverse plane to the lateral abdominal wall in the midaxillary line in between the iliac crest and lower costal margin. A 27 G spinal needle was inserted in plane in relation to the ultrasound probe and advanced into the fascial plane lying between the internal oblique and transversus abdominis muscles and study drug was meticulously injected after careful aspiration to exclude

vascular puncture. The local anaesthetic solution of isobaric levobupivacaine 0.25% (0.3 ml/kg) was prepared, dexmedetomidine (1  $\mu$ /kg) was added for group LD and tramadol 1 mg/kg was added for group LT, and thus prepared drug was divided into two equal volumes to be injected on each side. After reversing the neuromuscular blockade, patients were extubated and shifted to postanaesthesia care unit. They were monitored for thirty minutes in PACU and then shifted to ward. Any untoward events like hypotension, bradycardia, nausea and vomiting were recorded as adverse effects.

A blinded observer assessed the intensity of the pain using FLACC pain scale with its 0–10 score range at the time of discharge PACU and then every 2 h for 24 h after the operation. Rescue analgesics in the form of intravenous paracetamol 15 mg/kg/dose was administered if the FLACC pain scale was more than 3. We considered the time of first request of analgesia in minutes as primary outcome and the FLACC pain scale score, total analgesic doses (oral acetaminophen) required during the first 24 h postoperatively, and postoperative haemodynamic parameters were the secondary outcomes measured.

Based on the previous studies and literature review, we calculated the sample size and we recruited 60 patients, with  $\alpha$  error of 0.05 and statistical power of 80%. We utilized statistical package SPSS Version 20.0 (Armonk, NY: IBM Corp) for the analysis of data.

Parametric data were analysed using an independent t-test and a paired t-test and nonparametric data were analyzed using Mann - Whitney U-test and the P values lesser than 0.05 was considered as statistically significant.

## Results

Pertaining to demographic data, both the groups were statistically similar (Table 1). Pediatric FLACC score (Table 2) were statistically similar between either groups at arrival to 12 h follow-up with P value > 0.05. There was a significant increase in FLACC score in group LT at 12 h, 14 h and 16 h (P value 0.001, 0.001 and 0.000 respectively). FLACC score were comparable between the two groups at 18 h and 24 h. Total duration of analgesia was significantly prolonged in group LD (986.67  $\pm$  47.29) than in group LT (690  $\pm$  53.49) with a P value - 0.000 with a statistically significant decrease in a total dose of acetaminophen in group LD (324.28  $\pm$  35.5) than in group LT (580.14  $\pm$  38.23) with a P value -0.000 (Table 3). The mean blood pressure, heart rate, EtCO<sub>2</sub> and oxygen saturation were comparable between two groups and were statistically non-significant throughout the study period and none of them required any intervention. Sedation scores were comparable between two groups and were statistically non-significant. There were no significant adverse effects among either groups.

**Table 1- Demographic data of group LD and LT**

		Group LD	Group LT	P value
Age	Mean $\pm$ SD	2.80 $\pm$ 1.45	2.83 $\pm$ 1.36	0.934
Sex	Male	16	14	0.573
	Female	14	16	
Duration of surgery	Mean $\pm$ SD	124.47 $\pm$ 7.8	124.79 $\pm$ 7.6	0.923
Weight	Mean $\pm$ SD	13.67 $\pm$ 6.4	13.50 $\pm$ 5.8	0.947

P value >0.05 not significant, P value <0.05 significant

**Table 2- FLACC score**

Time	Group LD	Group LT	P value
At arrival in PACU	2.32 $\pm$ 0.7	2.38 $\pm$ 0.6	0.876
At discharge from PACU	2.24 $\pm$ 0.6	2.25 $\pm$ 0.8	0.865
1 h	2.38 $\pm$ 0.8	2.38 $\pm$ 0.7	0.943
2 h	2.45 $\pm$ 0.4	2.46 $\pm$ 0.8	0.886
6 h	2.46 $\pm$ 0.9	2.48 $\pm$ 0.8	0.883
8 h	2.50 $\pm$ 0.5	2.54 $\pm$ 0.9	0.872
10 h	2.52 $\pm$ 0.3	2.56 $\pm$ 0.8	0.832
12 h	2.86 $\pm$ 0.7	4.67 $\pm$ 0.6	0.001
14 h	2.98 $\pm$ 0.5	4.98 $\pm$ 0.8	0.001
16 h	2.96 $\pm$ 0.7	5.36 $\pm$ 0.4	0.000
18 h	5.14 $\pm$ 0.2	5.23 $\pm$ 0.6	0.821
24 h	4.34 $\pm$ 0.3	4.65 $\pm$ 0.7	0.689

P value >0.05 not significant, P value <0.05 significant

**Table 3- Comparison between group LD and group LT regarding total duration of analgesia and total dose of analgesia**

	Group LD	Group LT	P value
Total duration of analgesia (min)	986.67 $\pm$ 47.29	690 $\pm$ 53.49	0.000
Total dose of paracetamol (mg)	324.28 $\pm$ 35.5	580.14 $\pm$ 38.23	0.000

P value >0.05 not significant, P value <0.05 significant

## Discussion

In this present study, patients belonging to the dexmedetomidine group had significantly prolonged analgesia in comparison to tramadol group. Group LD demonstrated statistically significant decrease in FLACC score at 12, 14, and 16 h postoperatively. The total dose of paracetamol consumption over 24 h post surgery was also reduced in group LD. The transversus abdominis plane (TAP) block is a novel, easy to perform and safe regional anaesthesia technique which can be used as an alternative mode of anaesthesia to neuroaxial blockade for abdominal surgeries [8]. But using local anaesthetics (LAs) alone in regional blocks provide a short duration of postoperative analgesia [9]. Hence, several studies used various adjuvants to prolong the duration of

postoperative analgesia. In support of our study, various studies have used dexmedetomidine and tramadol as adjuvants to local anaesthetics and found them useful and safe. Mostafa MF et al. compared the efficacy of dexmedetomidine and clonidine as adjuvants to levobupivacaine in ultrasound guided TAP block in pediatric patients undergoing laparoscopic orchiopexy [10]. They concluded that both dexmedetomidine and clonidine are useful adjuvants though dexmedetomidine is better among them. Abdelaal et al. studied the efficacy of dexmedetomidine as an adjuvant to levobupivacaine in pre-emptive TAP block for postoperative pain management after abdominoplasty surgery [11]. They concluded that dexmedetomidine and Levobupivacaine group had significantly lower pain score and reduced mepiridine consumption in comparison to control group. Varhney A et al. studied the efficacy of adding dexmedetomidine to levobupivacaine for postoperative analgesia following cesarean delivery [12]. They concluded that Dexmedetomidine as an adjuvant to levobupivacaine enhance analgesia and patient satisfaction. Rehab AbdelRaof et al. studied the efficacy of addition of dexmedetomidine to levobupivacaine for postoperative analgesia [13]. They observed when dexmedetomidine is added to bupivacaine, it improved postoperative analgesia in pediatric patients undergoing herniotomy. Kiran S et al. studied the efficacy of dexamethasone and tramadol as adjuvants to ropivacaine in subcostal TAP block [14]. They concluded that both dexamethasone and tramadol are useful adjuvants though dexamethasone is better among them. El-Kabariety R studied the efficacy of tramadol as an adjuvant to levobupivacaine in TAP block in women undergoing hysterectomy [15]. They concluded that addition of tramadol to levobupivacaine resulted in prolonged duration of postoperative analgesia and reduced morphine consumption.

These are few limitations of our study. First, our study lacked a control group. So, we could not evaluate the analgesic efficacy of TAP block by comparing it with control group. Second, onset of abdominal wall sensory block could not be assessed as patients were under general anaesthesia. Third, our study population was small, and they were assessed for 24 h only. Hence, further studies are warranted with larger study population to

evaluate the optimal doses of dexmedetomidine and tramadol as adjuvants to levobupivacaine for TAP block.

## Conclusion

Dexmedetomidine when added as an adjuvant to Levobupivacaine in a dose of 1 µg.kg<sup>-1</sup> in ultrasound guided transverse abdominus plane block significantly prolongs the duration of postoperative analgesia in comparison with tramadol with levobupivacaine without any major adverse effects.

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