



## Dose Addition of Tramadol to Levobupivacaine Femoral Nerve Block Prolong Its Analgesic Efficacy in Patients Undergoing Anterior Cruciate Ligament Reconstruction?

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### Abstract

*This study was designed to evaluate the effect of addition of tramadol to levobupivacaine femoral nerve block in patients undergoing anterior cruciate ligament reconstruction under general anaesthesia. 60 male patients ASA I-II aged 18-45 years, scheduled for anterior cruciate ligament reconstruction under general anaesthesia, patients were randomly allocated into two equal sized groups using closed envelope technique: Group L: (n= 30) femoral nerve block with levobupivacaine (0.5%) 20ml. Group LT: (n= 30) femoral nerve block with levobupivacaine (0.5%) 20ml +2mg/kg tramadol. Time to first request of postoperative analgesia, severity of postoperative pain at rest using VAS, dose of pethidine consumed in 24 h were recorded. There were no statistical significant differences between the two studied groups as regard to patient characteristics, time to first request of postoperative analgesia, postoperative pethidine consumption and 24 hours VAS at rest between the two studied group. The addition of tramadol 2mg/kg did not improve postoperative analgesic efficacy of levobupivacaine (0.5%) femoral nerve block in patients undergoing anterior cruciate ligament reconstruction under general anaesthesia.*

**Key Words:** Femoral nerve block , levobupivacaine, tramadol, knee surgery

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## **Introduction**

Pain after anterior cruciate ligament (ACL) reconstructions is significant, it can be controlled by intraarticular local anaesthetics, opioids, or a combination of the two, and regional anaesthesia [1]. Femoral nerve block is used for anaesthesia and analgesia for lower limb orthopaedic surgeries eg. total knee arthroplasty, repair of the anterior cruciate ligament, and patellar surgery [2-4]. Many additives can be used for prolongation of the duration of regional blockade. eg, dexamethasone, magnesium sulphate, clonidine, nitroglycerin [5-8]. Tramadol hydrochloride is an analgesic drug acting at central and peripheral  $\mu$ -opioid and monoaminergic receptors [9]. It has local anaesthetic properties [10], possibly by blocking  $K^+$  channels [11].

Levobupivacaine, is an amino amide type of local anaesthetic the pure S(-) enantiomer of racemic bupivacaine, has less cardiotoxic and neurotoxic potentials [12]. Previous studies showed conflicting results about the efficacy of tramadol as adjuvant to local anaesthetics some studies not prove its efficiency [13-15] and others documented that it has a beneficial effect [16,17].

The aim of this study was to evaluate the effect of addition of high dose tramadol to levobupivacaine femoral nerve block in patients undergoing anterior cruciate ligament reconstruction under general anaesthesia.

## **Patients and Methods**

After approval of the ethical committee in Beni Suef university hospital (Egypt) a written informed consent was obtained from 60 male ASA I-II patients aged 18-45 years, scheduled for anterior cruciate ligament reconstruction under general anaesthesia from January 2013 to January 2014.

Patients were excluded if they had any contraindication to regional anaesthesia (patient refusal, acquired or congenital coagulopathy, local infection, neurological disease affecting the lower limbs) and if there is a known allergy to the study drugs.

The study protocol; and the visual analogue scale (VAS) for pain assessment were explained to each patient during the preoperative visit.

In the operating room, an intravenous cannula was inserted, ringer solution was started. Standard monitors including electrocardiography, pulse oximetry, and non-invasive blood pressure cuff were applied.

The patients were randomly assigned using closed envelope technique to two equal size groups (30 each):

Group (L): Femoral nerve block was performed with 20 ml of levobupivacaine 0.5% (levobupivacaine HCL, Chirocaine Abbott laboratory, manufactured by Nycomed Pharma AS, Norway). injected slowly in increments after negative aspiration for blood.

Group (LT): Femoral nerve block was performed with 20 ml of levobupivacaine 0.5% + 2mg/kg tramadol injected slowly in increments after negative aspiration for blood

The study drugs were prepared by an anesthesiologist who was unaware to the study design.

Femoral nerve block was performed while the patient in the supine position with both legs extended, under strict antiseptic technique, using a peripheral nerve stimulator (EZstimII, Life-Tech TX USA, 1.0 mA, 2 Hz, 100  $\mu$ sec), 50-mm 25-gauge insulated needle was introduced 1 cm lateral to the femoral artery and 1.5 cm below the inguinal ligament. When a current <0.3 mA elicited contractions of the quadriceps femoris muscle with a visible cephalic movement of the patella (dancing patella sign; patella twitch) the study drugs were injected slowly in increments after negative aspiration for blood.

After confirmation of adequate sensory block, general anaesthesia was induced in all patients with i.v. propofol 2-2.5 mg/kg, fentanyl 2  $\mu$ g/kg, atracurim 0.5mg/kg, oral cuffed endotracheal tube was inserted, anaesthesia was maintained with oxygen 100%, sevoflurane, atracurium, mechanical ventilation with maintenance of endtidal carbon dioxide 35-40mmHg.

At the end of surgery neuromuscular blockade was reversed with IV neostigmine 0.04mg/kg and atropine 0.02mg/kg and the trachea was extubated when the patient respond to commands, all patient were transferred to the post anaesthesia care unit (PACU) On arrival in the PACU, the patients were connected to the standard monitors, face oxygen masks were applied. The postoperative pain at rest was assessed using VAS, where zero score corresponds to no pain and 10 to the maximum or worst pain, If patient reported a VAS at rest of 3 or

higher pethidine 50 mg im was given. All patients received 1 g i.v. acetaminophen (Perfalgan® laboratories UPSA) every 8 hours.

**The following parameters were evaluated and recorded:**

1. Patient characteristics
2. Time to first request of postoperative analgesia
3. The severity of postoperative pain at rest over 24 hours.
4. Postoperative pethidine consumed

***Statistical analysis:***

Data are presented as mean (SD) or median (and range) or numbers, student t- test was used for comparison between means of two groups, nominal data were analysed with Fisher's exact test, P values <0.05 were considered statistically significant. Statistical package for social science (SPSS) software version 17 was used. Sample size was calculated similar to a previous study [18] on 20 patient per group, we increase the number to 30 in each group to compensate if any case excluded due to failure or inadequate block. The a-error level was fixed at 0.05 and the power was set at 90%.

**Results**

All patients completed the study, there were no statistical significant differences between the two studied groups as regard to patient characteristics (age, weight, height and ASA status, duration of surgery) (Table 1).

There were no statistically significant differences in the time to first request of postoperative analgesia, postoperative pethidine consumption and 24 hours VAS at rest between the two studied groups (Table 2,3).

**Table 1.** Patient characteristics and operative data in the studied groups. Data presented as mean  $\pm$ SD or numbers

| Variables                    | Group L<br>(n=30) | Group LT<br>(n=30) |
|------------------------------|-------------------|--------------------|
| Age (years)                  | 28.1 $\pm$ 8.0    | 29.1 $\pm$ 8.1     |
| ASA physical status (I/II)   | 18/2              | 19/1               |
| Weight (Kg)                  | 90.8 $\pm$ 6.1    | 90.2 $\pm$ 7.0     |
| Height (cm)                  | 178.3 $\pm$ 7.2   | 179.9 $\pm$ 5.2    |
| Duration of surgery<br>(min) | 95.3 $\pm$ 9.0    | 96.5 $\pm$ 8.4     |

No statistical significant differences between the studied groups.

Group L =femoral nerve block with levobupivacaine 0.5%.

Group LT= femoral nerve block with levobupivacaine 0.5% + 2mg/kg tramadol

**Table 2.** Postoperative time to first request of analgesia (minutes), pethidine requirements. Data presented as mean  $\pm$ SD.

| Variables          | Group L (n=30)   | Group LT (n=30)  |
|--------------------|------------------|------------------|
| TFA (min)          | 154 $\pm$ 3.0    | 156 $\pm$ 2.10   |
| Pethidine (mg/24h) | 180.0 $\pm$ 49.3 | 173.3 $\pm$ 53.0 |

No statistical significant differences between the studied groups.

TFA= Time to first request of analgesia

Group L =femoral nerve block with levobupivacaine 0.5%.

Group LT = femoral nerve block with levobupivacaine 0.5% + 2mg/kg tramadol

**Table 3.** Postoperative Visual Analogue Scale(VAS)

| Time | Group L<br>(n=30) | Group LT<br>n=(30) |
|------|-------------------|--------------------|
| 1 h  | 3(3-4)            | 3(3-4)             |
| 8 h  | 3(3-4)            | 3(3-4)             |
| 16 h | 4(3-5)            | 3(3-5)             |
| 24 h | 5 (4-5)           | 4 (4-5)            |

No statistical significant differences between the studied groups

Group L = femoral nerve block with levobupivacaine 0.5%.

Group LT = femoral nerve block with levobupivacaine 0.5% + 2mg/kg tramadol

## **Discussion**

The results of present study showed that addition of tramadol 2mg/kg did not prolong the analgesic duration and efficacy of levobupivacaine (0.5%) femoral nerve block in patients undergoing anterior cruciate ligament reconstruction under general anaesthesia. Previous study in patients undergoing hip and knee arthroplasty showed that tramadol does not provide a clinically significant analgesic effect as an adjunct to 0.25% bupivacaine for continuous psoas compartment block [13]. It was reported that the use of systemic or perineural tramadol 1.5 mg /kg as adjunct to levobupivacaine psoas compartment block did not support a clinically important local anesthetic or peripheral analgesic effect [14].

In our study we used a higher dose of tramadol 2mg/kg and we did not found any clinical significant effect. Robaux et al [15] failed to demonstrate an increase in sensory or motor block when tramadol was added to mepivacaine 1.5% for brachial plexus block. But Kapral et al [16] demonstrated that the addition of tramadol 100 mg to mepivacaine 1% for axillary plexus block prolonged sensory and motor block compared with mepivacaine alone or axillary block with tramadol 100 mg i.v.

Previous study showed that the addition of tramadol 200mg to 30 ml lidocaine 1.5% (1/200,000 epinephrine) for axillary brachial plexus block prolonged the sensory and motor block duration and reduced the severity of postoperative pain [17], and that tramadol 100 mg added to ropivacaine 0.5% for interscalene block improved the quality of post-operative analgesia with fewer side effects than intravenous bolus [18].

## **Conclusion**

The addition of tramadol 2mg/kg did not improved postoperative analgesic efficacy of levobupivacaine (0.5%) femoral nerve block in patients undergoing anterior cruciate ligament reconstruction under general anaesthesia.

## **Conflict of Interest**

The authors declare no conflicts of interest.

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