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Research Article

Synergistic effects of Paracetamol and Dexamethasone with Lidocaine in Intravenous regional anesthesia (IVRA) of upper limbs: A randomized clinical trial

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KEYWORDS

Intravenous regional anesthesia;
Lidocaine;
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Abstract *Background and aim:* Post-operative pain is considered an important complication of Intravenous regional anesthesia (IVRA) which is gaining popularity especially for surgeries on upper limbs.

Methods: The present double blind randomized clinical trial was conducted on 60 candidates of upper limb surgeries aged between 20 and 60 years who were of ASA classes 1 or 2. Subjects were randomly assigned to 4 groups: the first group was treated solely with 3 mg/kg of Lidocaine. The second and third groups received the same amount of Lidocaine plus 8 mg of Dexamethasone or 300 mg of Paracetamol respectively and for the fourth group a combination of all medications was used. For all patients, Lidocaine was diluted with normal saline until a total volume of 40 cc was reached. Onset of Sensory and motor nerve blocks, severity of post-operative pain and amount of mepridine consumption in the first 24 h after surgery were assessed.

Results: Onset of Sensory and motor nerve block was significantly accelerated in the fourth group ($p < 0.01$). Post-operative pain and analgesic consumption were significantly reduced in the fourth group when compared with the other groups ($p < 0.05$).

Conclusion: A combination of Paracetamol and Dexamethasone significantly enhances the analgesic effect of Lidocaine in IVRA by accelerating the establishment of both the sensory and motor nerve blocks and prolonging the period of analgesia as well as improving the quality of analgesia and reducing the need for analgesic medications during and after the operation.

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1. Introduction

Many orthopedic surgeries may be performed under nerve blocks or other alternatives of GA such as Intravenous regional anesthesia (IVRA). Named after the German Surgeon August Bier who developed the IVRA or the Bier method in 1908, this technique is still deemed useful for limb surgeries [1], especially when GA is highly associated with risks such as difficult intubation or aspiration. The advantages of this technique include cost effectiveness, rapid achievement of anesthesia feasibility at a variety of settings such as day case or the A&E department, desirable site of operation and reduced risk of hemorrhage [2]. However, this technique is also associated with a number of untoward reactions which include toxicity of the local anesthetic agent, obtunded onset of anesthesia, fatigue and hypotonia of muscles and the pain of applying the tourniquet application discomfort and the pain that afflicts the limb following deflation of the tourniquet [3]. The anesthetic agent that is to be used in IVRA should ideally yield short onset, long lasting anesthesia with a low dose and minimal side effects. Efforts are currently underway to optimize the effect of local anesthetics and minimize their side effects by using a combination of drugs including opioids such as fentanyl [4,5], Mepridine [6,7], Morphine, Sufentanil and Tramadol [1]; NSAIDs such as Ketorolac [1,8], Tenoxicam and Acetyl Acetate [1]; α2 agonists such as Clonidin [1,9,10] and Dexmedetomidine [1,11]; Muscle relaxants such as Pancronium [4], Atracurium, cis-Atracurium and Mivacurium [1], Neostigmin [12,13], Ketamin [14], Magnesium [15] and Bicarbonate [1].

Among a host of trials on a wide range of agents to optimize the quality and quantity of anesthesia, some suggest that addition of Dexamethasone [16] or Paracetamol [17,18] may be conducive to the effect of Lidocaine in achieving a desirable state of anesthesia. In the absence of any study to compare the independent effect of Paracetamol and Dexamethasone and their combined effect on IVRA with Lidocaine, particularly in the upper limb, and in view of the increasing use of IVRA for operations in the upper limb, this study was conducted to evaluate the effect of those medications on the depth and duration of IVR anesthesia in upper limbs.

2. Materials and methods

The present double blind randomized clinical trial was conducted on 60 candidates of upper limb surgeries who were referred to the Shahid Bahonar Hospital in the city of Kerman. The study was endorsed by the research council of Kerman University of Medical Sciences and was approved by its ethical committee (Ethical code No. k/90/462). Before recruitment of first subject, study protocol was registered in Iran Registration of Clinical Trials (IRCT) database under the ID:

IRCT201209053104N2.[1]

Informed consent was obtained from all subjects who aged between 20 and 60 years and were of ASA classes 1 or 2. Subjects were randomly assigned to 4 groups: the first group was treated solely with 3 mg/kg of Lidocaine. The second and third groups received the same amount of Lidocaine plus 8 mg of Dexamethasone or 300 mg of Paracetamol respectively and for the fourth group a combination of all medications was used. For all patients, Lidocaine was diluted with normal saline until a total volume of 40 cc was reached. Subjects who were suspected of any substance or drug abuse, those who were allergic to Lidocaine or had sustained open fractures of upper limb or had a history of hepatic disease, those cases who were complicated by infection and those who had received any other anesthetic or analgesic medicament prior to the operation were excluded from the study. Blood pressure, heart rate and arterial oxygen saturation were monitored for all patients in the operation theater and IV canula was fitted to the healthy limb of all subjects as a route of fluid or drug administration. Using a pink venflon, another IV line was secured at the distal end of the affected limb. After applying Smarch bandage for the purpose of blood evacuation, the limb was elevated for 2 min and then the proximal tourniquet was inflated to reach a pressure of 250 mmHg. Medications were administered by an anesthesiologist who was unaware of their content in a period of 90 s. Then, using a 22 gauge needle, sensory function was evaluated in the dermatomes pertaining to the Ulnar, Median and Radial nerves. Motor function was also assessed by flexion and extension of the wrist and fingers. Absence of any movement was regarded as completion of motor nerve block. Upon completion of both sensory and motor nerve blocks, the distal tourniquet would be inflated up to 250 mmHg and the proximal tourniquet would be deflated. Bp, heart rate and arterial O2 saturation readings were recorded before and after application of the tourniquet as well as at 5, 10, 15, 20, 30, 40 and 50 min past the start of the operation. The pain that was associated with tourniquet application was measured by using the Visual Analog Scale (VAS) at 5, 10, 15, 20, 30, 40 and 50 min after inflation of the tourniquet. Once the VAS score exceeded 4, 1 μg/kg of Fentanyl would be administered to the patient. During the surgery, each time the BP dropped to lower than 90 mmHg, it was treated with 5 mg of IV Ephedrin and when the heart rate dropped to lower than 50 b/min, the patient would receive 0.5 mg of IV Atropine. At the end of the operation, an anesthesiologist who was unaware of the group the patient was assigned to, would label the quality of the patient's anesthesia as poor (in need of further analgesia), moderate (patient often complaining of minor pain but no need for analgesia), Good or Excellent (no complain of pain).

Tourniquets would remain inflated for no shorter than 30 min and no longer than 2 h. Following the deflation of the tourniquet, the restoration of the sensory function was assessed every 30 s with the pin prick test. The re-activation time of the motor function was also recorded once the patient was able to voluntarily move fingers. For two h past the operation when the patient was moved to the recovery room or the ward, he/she was monitored for development of untoward effects such as Nausea, Vomiting, skin rash, Tachycardia, bradycardia, Hypotension, hypertension, vertigo, tinnitus and hypoxia. Any VAS score of higher than 20 was treated with 4 mg of IV Mepridine.

Based on the results of the Sen et al.'s trial [29], sample size was calculated by assuming that $m_1 = 1.8$, $m_2 = 0.2$, $sd_1 = 2$, $Sd_2 = 1$, $\alpha = 0.05$ and $\beta = 0.8$. Accordingly, the size of the sample was equal to 60. Data analysis was performed by means of the SPSS 17. The Post Hoc Tukey test and the Repeated Measure ANOVA were employed for comparing the mean period of time that was required for the establishment of sensory

[1] http://www.irct.ir/searchen.php?keyword=IRCT201209053104N2&field=a&lang=en.