Tramadol Versus Low Dose Tramadol-paracetamol for Patient Controlled Analgesia During Spinal Vertebral Surgery

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Pain intensity may be high in the postoperative period after spinal vertebral surgery. The aim of the study was to compare the effectiveness and cost of patient controlled analgesia (PCA) with tramadol versus low dose tramadol-paracetamol on postoperative pain. A total of 60 patients were randomly divided into two groups. One group received 1.5 mg/kg tramadol (Group T) while the other group received 0.75 mg/kg tramadol plus 1 g of paracetamol (Group P) intravenously via a PCA device immediately after surgery and the patients were transferred to a recovery room, Tramadol was continuously infused at a rate of 0.5 mL/h in both groups, at a dose of 10 mg/mL in Group T and 5 mg/mL in Group P. The bolus and infusion programs were adjusted to administer a 1 mL bolus dose of tramadol with a lock time of 10 minutes. In Group P, 1 g of paracetamol was injected intravenously every 6 hours. The four-point nausea scale, numeric rating scale for pain assessment, Ramsey sedation scale, blood pressure, heart rate, respiration rate, peripheral oxygen saturation values and side effects were recorded at 0, 15 and 30 minutes, and at 1, 2, 4, 6, 12, 18 and 24 hours. The time to reach an Aldrete score of 9 was also recorded. A cost analysis for both groups was performed. In Group P, the numeric rating scale scores were significantly lower than that in Group T at 0 and 15 minutes. The number of side effects, additional analgesic requirement and the total dose of tramadol were lower in Group P than in Group T. However, the total cost of postoperative analgesics was significantly higher in Group P than in Group T ($p < 0.001$). We conclude that PCA using tramadol-paracetamol could be used safely for postoperative pain relief after spinal vertebral surgery, although at a higher cost than with tramadol alone.

Key Words: paracetamol, patient controlled analgesia, postoperative analgesia, spinal vertebral surgery, tramadol
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Postoperative pain is a nociceptive type of pain that develops as a result of tissue damage after surgical trauma, and is accompanied by central and peripheral sensitization. Approximately, 30–75% of patients experience moderate to severe pain in the postoperative period [1,2]. Inadequate analgesia in this period may

lead to functional deterioration caused by the pathophysiology of acute pain, and may trigger a sensitization process in the central and peripheral nervous systems, leading to chronic pain [1–5]. This ultimately increases the cost and the length of stay in a hospital [6,7]. Patient controlled analgesia (PCA) allows patients to administer their own analgesic medications when necessary. This reduces their anxiety and stress, both of which are major factors associated with postoperative pain [8].

The ideal analgesic agent used in PCA should have a rapid onset and a moderate duration. Furthermore, the agent should be free of side effects such as a ceiling dose, nausea, vomiting, respiratory depression and intestinal motility disorder. Opioids are commonly used as analgesics in intravenous (IV) PCA [9]. Nonsteroidal anti-inflammatory drugs (NSAIDs) are also commonly used for postoperative analgesia to avoid the side effects of opioids [10,11].

The aims of this study were to identify the effects of IV paracetamol on PCA tramadol use after spinal vertebral surgery and estimate the costs of the two types of treatment.

Methods

This prospective, randomized and controlled study was conducted after obtaining the approval of the Medical School Ethics Committee and informed consent from the patients.

A total of 60 patients who were scheduled for spinal vertebral surgery, and who were classified in the American Society of Anesthesiologists risk group I–II were admitted to the study. Their ages ranged from 18 to 60 years. Patients meeting any of the following criteria were excluded: (1) use of analgesics during the 24-hour period before surgery; (2) known allergy to any of the study drugs; (3) inability to use the PCA device due to lack of communication or muscle strength; (4) severe cardiopulmonary, renal or liver disease, morbid obesity (body mass index > 30 kg/m^2), or history of postoperative nausea and vomiting; (5) history of migraines; (6) current pregnancy, (7) history of alcohol abuse and convulsion anamnesis; (8) use of monoamine oxidase or serotonin reuptake inhibitors; or (9) history of complications during and after surgery.

In the preanesthetic evaluation, all patients were informed about the anesthesia method to be used. They were also trained on how to use the patient controlled analgesia device (Pain Management Provider, Abbott Laboratories, Chicago, IL, USA) and the 10-point numeric rating scale. We also collected verbal and written consent at this time. Thirty minutes before the patients were taken to the operation room, they were administered with 0.01 mg/kg atropine sulfate and 0.1 mg/kg midazolam intramuscularly.

In the operating room, patients were administered with 2 L/min oxygen (O_2) via a nasal cannula. Electrocardiograph, heart rate (HR), mean blood pressure (MBP) and peripheral O_2 saturation (SpO_2) were monitored using a Datex Ohmeda Cardiocap 5 (General Electric, Helsinki, Finland). Anesthesia was induced by 2 mg/kg propofol and 0.1 mg/kg vecuronium bromide. For analgesia, 0.05–2 μg/kg/min remifentanil hydrochloride was infused IV. Anesthesia was maintained with 50% O_2, 50% air and 1–1.5 minimum alveolar concentration (MAC) desflurane. Muscle relaxation was maintained by administering 0.03 mg/kg vecuronium bromide as needed.

In the study, hypotension (> 20% from the baseline systolic arterial blood pressure) was treated with IV boluses of 5 mg ephedrine repeated every 3 minutes, and bradycardia (heart rate <55 bpm) treated with atrophine 0.5/mg if occurs.

Patients were randomly divided into two groups using a random samples table. Group T received 1.5 mg/kg tramadol (100 mg/mL; Contramal ampoule, Abdi Ibrahim, Istanbul, Turkey) via one arm after remifentanil infusion via another arm, and Group P received 0.75 mg/kg tramadol plus 1 g paracetamol (Perfalgan®; Bristol-Myers Squibb, Istanbul, Turkey) intravenously via one arm, 15 minutes after stopping remifentanil infusion via another arm. Control values were recorded before the administration of the study drugs**.** The patients' vital signs were also taken and recorded afterwards. The duration of the surgical procedure and the total amount of remifentanil administered were recorded. Muscle relaxation was reversed by 0.05 mg/kg neostigmine and 0.01 mg/kg atropine.

The PCA device was inserted immediately after the patients were transferred to the postanesthesia recovery room and extubation. The tramadol dose for Group T was 10 mg/mL and continuous infusion was given at 0.5 mL/hr. In Group P, the tramadol dose was 5 mg/mL and continuous infusion was given at 0.5 mL/hr. In both groups, the bolus dose was 1 mL and the lockout time for the bolus and infusion