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Title page

Efficacy of Intravenous Paracetamol and Ibuprofen on Postoperative Pain and Morphine Consumption in Lumbar Disc Surgery; Prospective, Randomized, Placebo-Controlled Clinical Trial

Sedat Akbas, Asst. Prof. Department of Anesthesiology and Reanimation, Inonu University Medical Faculty, Malatya, Turkey

Ahmet Selim Ozkan, Asst. Prof. Department of Anesthesiology and Reanimation, Inonu University Medical Faculty, Malatya, Turkey

Mehmet Akif Durak, Asst. Prof. Department of Anesthesiology and Reanimation, Inonu University Medical Faculty, Malatya, Turkey

Address all correspondence to:

Sedat Akbas, Asst. Prof. Department of Anesthesiology and Reanimation, Inonu University Medical Faculty, Malatya, Turkey

Mail: sedat.akbas@inonu.edu.tr

Phone Number: +905058263912

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Study Protocol

After approval from the Ethics Committee of Inonu University Medical Faculty, study was performed for 60 patients scheduled for an elective lumbar surgery (hemilaminectomy and/or laminectomy and/or discectomy) under general anesthesia. Patients with American Society of Anesthesiologists (ASA) scores 1 or 2 and between 18-65 years were included in this study. Patients with ASA scores III/IV, under the age of 18, over the age of 65, peptic ulcer disease, hepatic and renal dysfunction, severe cardiovascular and pulmonary disease, allergic history to propofol, fentanyl, rocuronium, paracetamol, ibuprofen and morphine, emergency surgery and refused informed consent form were excluded from the study.

All patients were instructed to use intravenous patient-controlled analgesia (IV PCA). After premedication patients were taken to the operating room. Standard monitoring with noninvasive blood pressure (NIBP), heart rate (HR), peripheral oxygen saturation (SpO2) and electrocardiography (ECG) was performed to all. After opening the peripheral vein, anesthesia induction was administered to all patients via intravenous route; propofol 2-2.5 mg/kg, fentanyl 1 µg/kg, rocuronium 0.6 mg/kg. Anesthesia was maintained with sevoflurane (%2-2.5) and 40% oxygen in oxygen-air mixture during the surgery.

The patients were divided randomly and double blind into three groups: Group C (control, saline, n=20), Group P (paracetamol, n=20) and Group I (ibuprofen, n=20). Analgesic drugs were administered 30 minutes before the end of surgery with 250 ml saline for group C, 1 g paracetamol for group P and 800 mg ibuprofen (diluted with 250 ml saline). After the neuromuscular block was returned at the end of the surgery, patients were tarnsfered to postoperative care unit. All patients received morphine with intravenous patient controlled analgesia (IV PCA) device during postoperative 24 hours. The PCA solution was prepared with 100 mg morphine in 200 mL of saline (0.5 mg/ml). The PCA device was adjusted as infusion: 0 ml/h, bolus: 1 ml/h, lockout period: 7 min. After following up for approximately 1 hour in the postoperative care unit, patients were transferred to neurosurgery service.

All drug administrations were applied through IV infusion over 30 minutes. The first drug administration of each group was given at the time of wound closure and then repeated every 6 hours in all groups for postoperative 24 hours. HR, systolic arterial pressure (SAP), diastolic arterial pressure (DAP), mean arterial pressure (MAP), respiratory rate (RR), VAS score, RAMSEY sedation score, demand, delivery and total morphine consumption of PCA, presence of nausea-vomiting, pruritus, rash and urine retention were recorded postoperatively at after awakening of anesthesia, 1th, 2th, 6th, 12th and 24th hours. Patients were not administered with antiemetic

prophylaxis. Patients were treated with ondansetron (0.15 mg/kg, IV) if the presence of nausea-vomiting in the postoperative period. If VAS scores of the patients were above 4 in the postoperative period, 2 mg morphine was administered via IV.

Statistical Analysis

Statistical analysis were carried out by using SPSS program (SPSS for Windows version 22). ANOVA Test were used for the comparison between groups. Correlation analysis was based on the calculation of Pearson's rank correlation coefficients. Value of p below 0.05 was considered as statistically significant. Consent to conduct the study was obtained from Local Ethic Committee of Inonu University.