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Effects of Preemptive Intravenous Paracetamol and Ibuprofen on Headache and Myalgia in Patients after Electroconvulsive Therapy

Erol Karaaslan, Asst. Prof. Department of Anesthesiology and Reanimation, Inonu University Medical Faculty, Malatya, Turkey

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

Esra Porgalı Zayman, Asst. Prof. Department of Anesthesiology and Reanimation, Inonu University Medical Faculty, Malatya, Turkey

Address all correspondence to:

Erol Karaaslan, Asst. Prof. Department of Anesthesiology and Reanimation, Inonu University Medical Faculty, Malatya, Turkey

Mail: erkara44@hotmail.com

Phone Number: +905322034830

Study Protocol

After approval from the Ethics Committee of Inonu University Medical Faculty, study was performed for 60 patients scheduled for an elective Electroconvulsive Therapy (ECT) under general anesthesia. Patients with American Society of Anesthesiologists (ASA) scores I or II and between 18-65 years were randomized to receive ECT 3 times a week for treatment of major depression to complete an average of 6 to 12 ECT sessions. The first 3 ECT sessions were included in the study. Patients with ASA scores III/IV, under the age of 18, over the age of 65, myocardial infarction, congestive heart failure, pulmonary disease, stroke history, bleeding disorder, hepatic and renal dysfunction, pregnant, migraine history, allergy of nonsteroidal anti-inflammatory drugs, parasetamol, propofol, neuromuscular disease, peptic ulcer disease, intracranial hypertension, glaucoma and patients who did not give informed consent were excluded from the study. After obtaining written informed consent from the patients, the study was conducted in accordance with the Declaration of Helsinki. The patients were divided randomly and double blind into three groups: Group K (control, saline, n=20), Group P (paracetamol, n=20) and Group I (ibuprofen, n=20).

All patients were informed about the study procedure and the visual analog scale (VAS: a 10-cm scale where 0 = no pain and 10 = unbearable pain). No premedication was given to the patients. Preemptive analgesics (ibuprofen 800 mg IV, paracetamol 20 mg.kg-1 mg IV) were administered to the patients 60 minutes prior to the ECT procedure. 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, standard anesthesia protocol was performed by experienced anesthesiologist to all patients via intravenous route; propofol 2-2,5 mg/kg, succinylcholine 1 mg/kg. A bite block was inserted prior to treatment to prevent tongue bite and to protect the patient's teeth.

Atropine (0.015 mg kg-1) was administered in patients with severe bradycardia during and after ECT, and esmolol (0,5 mg kg-1, bolus) was administered in patients with severe hypertension and tachycardia.

In patients who did not experience complications after the procedure, patients were transferred to the postoperative care unit. Patients with hemodynamically stable and adequate spontaneous breathing (saturation> 97%) were taken to the post-anesthesia care unit. ECG, pulse oximetry and NIBP monitoring were performed. 100% O2 (5-6L / min) was given by nasal cannula. After following up for approximately 1 hour, patients were transferred to the psychiatry service when they achieved a score of 9 or higher on the Modified Aldrete score (range 0 –12; scores of 9 and above indicate that the patient can be discharged from the PACU).

Patients were evaluated for pain intensity using a visual analogue scale (VAS) score (from 0 to 10, 0=no pain and 10=the worst pain imaginable). Heart Rate (HR), Systolic Arterial Pressure (SAB), Diastolic Arterial Pressure (DAB), Mean Arterial Pressure (OAB), and Respiratory rate (RR/min) were perioperatively recorded at T0 (5 min before the procedure), T1 (3 min after the anesthesia induction), T2 (post-seizure), T3 (5 min after the procedure). Postoperative side effects (presence of nausea, vomiting and pruritus), VAS (myalgia) and VAS (headache) were postoperatively recorded by trained nurses at T4 (postop 2nd hour), T5 (postop 4th hour), T6 (postop 6th hour), T7 (postop 12th hour), T9 (postop 24th hour). The duration and severity of seizure were also recorded.

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