18.04.2018

Title Page

A Comparison of Two Different Anesthetic Application (Sedation / Analgesia & LMA) on Anxiety Level and Patient Satisfaction in Patients with in Vitro Fertilization: Prospective Randomized Clinical Trial

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

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

Abdullah Karaer, Prof. Dr. Division of Reproductive Endocrinology, Department of Obstetrics and Gynecology, Inonu University Faculty of Medicine, Malatya, Turkey.

Gorkem Tuncay. Asst Prof. Division of Reproductive Endocrinology, Department of Obstetrics and Gynecology, Inonu University Faculty of Medicine, Malatya, Turkey.

Address all correspondence to:

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

Mail: drsedatakbas@gmail.com

Phone Number: +905058263912

Fax Number: +904223410728

A short title: **Anesthesia Management of in Vitro Fertilization**

Conflict of Interest:

The authors declare that they have no conflict of interest.

Funding Information:

None

18.04.2018

Study Protocol

This trial was approved by the Local Ethic Committee of Inonu University (Protocol no: 2018/56, Approval Date: 18.04.2018). We conducted a prospective, randomized controlled clinical trial with 140 female patients undergoing in vitro fertilization (IVF) at an university hospital.

Patients with American Society of Anesthesiology (ASA) scores of I-II and who were aged 18–55 years old will be included in our study. Patients will be interviewed before surgery to obtain informed consent. Patients with ASA III-IV, under 18 years of age, over 55 years of age, uncontrolled diabetes mellitus, cardiovascular, pulmonary disease, cerebrovascular events, patients with an allergy to anesthetic drugs pregnant were excluded. Patients who refused informed consent will be also excluded.

All of the patients one day before surgery; hemoglobin, hematocrit, prothrombin time, active partial thromboplastin time, aspartate aminotransferase, alanine aminotransferase will be evaluated. Electrocardiography and preoperative anesthetic evaluations will be performed. The patients who will agree to participate in the study will fill the demographic data form and STAI TX-1 (State Anxiety Scale Scale) form 2 hours before the procedure. Standard monitoring procedures will be used, including heart rate (HR), noninvasive blood pressure (NIBP), electrocardiogram (ECG), and peripheral oxygen saturation (SpO_2).

Age, gender, height, weight, body mass index (BMI), ASA scores, laboratory values, duration of anesthesia, duration of the procedure, concomitant diseases, preoperative symptoms, anesthetic drugs and doses used, causes and duration of infertility, anesthesia and complications of surgery will be recorded. HR (heart rate), SAB (systolic arterial pressure), DAB (diastolic arterial pressure), MAP (mean arterial pressure), DSS (respiratory rate), peripheral oxygen saturation (SpO_2) values will be recorded at preoperative, peroperative and postoperative

periods. Patients, who will not experience complications during the procedure, will be transferred to the post-anesthesia care unit (PACU) after the procedure. VAS score (Visuel Analog Scale) and RAMSEY sedation score will be recorded for the patients followed up in the PACU. Patients will be transferred to the 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). In all patients, postoperative analgesia will be achieved IV analgesic medication using appropriate doses of paracetamol (1 gr, IV). Patients will complete the QoR-40 questionnaire, which is a Patient Satisfaction Survey, 24 hours after discharge.

Randomization was performed with the MedCalc for Windows (medcalc.com.tr.), version 16 statistical software. 140 patients will be randomly allocated to two study groups: Sedation Analgesia group (Group S, *n = 70*) and Maryngeal Mask Airway, LMA (Group L, *n* = 70). Midazolam 0.05 - 0.1 $mg.kg^{-1}$ IV will be performed for premedication before the procedure in both groups. No inhalation anesthetics will be used in groups. In both groups, Anesthesia will be induced and maintained with propofol 1-2 $mg.kg^{-1}$ IV, remifentanil 0.05 - 0.1 mcg kg^{-1} IV or fentanyl 1-2 mcg kg^{-1} IV.

Statistical Analysis:

Data will be analyzed using the Statistical Package for the Social Sciences program (SPSS 22.0, IBM). As some pre and anesthetic characteristics of patients will be distributed abnormally nonparametric statistics will be used. Quantitative data are presented as mean or standard deviation and categorical data are shown as numbers or percentages. Continuous variables will be compared between the groups using Mann-Whitney U-test. Categorical variables will be summarized using frequencies and percentages (%) and compared between the groups using Chi-Squared Test. The results will be evaluated at a 95% confidence interval at a significance level of $p<0.05$.