

A Comparison of the Effects of Desflurane and Total Intravenous Anesthesia (TIVA) on Antioxidant System in Morbidly Obese Patients Undergoing Bariatric Surgery: A Randomized Trial

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Conflict of Interest:

The authors declare that they have no conflict of interest.

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None

Study Protocol

This trial was approved by the Local Ethic Committee of Inonu University (Protocol no: 2018/30, Approval Date: 07.03.2018). We conducted a prospective, randomized controlled clinical trial with 70 adult morbidly obese patients undergoing laparoscopic bariatric surgery at a university hospital.

Study Participants:

Morbidly obese patients with American Society of Anesthesiology (ASA) scores of III-IV, who aged 18–65 years old, and had a BMI>40 will be included in our study. Patients will be interviewed before surgery to obtain informed consent. Patients with pregnant or uncontrolled diabetes mellitus, cardiovascular disease, pulmonary disease, cerebrovascular disease, or drug and alcohol addiction were excluded. Patients who refused informed consent will be also excluded.

Preoperative Procedures:

All of the patients one day before surgery; hemoglobin, hematocrit, prothrombin time, active partial thromboplastin time, aspartate aminotransferase, alanine aminotransferase will be evaluated. Electrocardiography, posterior-anterior chest X-ray and preoperative anesthetic evaluations will be performed. Age, gender, height, weight, BMI, ideal body weight (IBW), ASA physical status and type of the surgery will be recorded in preoperative evaluation. On the day of surgery, patients will be taken to the operating room without premedication. Standard monitoring procedures will be used, including heart rate (HR), noninvasive blood pressure (NIBP), electrocardiogram (ECG), peripheral oxygen saturation (SpO2), and body temperature monitoring by esophageal probe. After the standard monitoring, invasive arterial monitorization will be performed to right radial artery under local anesthesia. BIS (Bispectral Index,

VISTATM Monitoring System) monitoring will perform to all patients. Two cerebral BIS sensors will glue to areas under the hairline and covered with tape to prevent exposure to light.

General Anesthesia:

A standardized general anesthesia protocol either desflurane or TIVA will be administered in all patients by an experienced anesthesiologist. After preoxygenation (100% 4 L/min O₂ for 3 min), propofol (1–2 mg/kg), rocuronium (0.8 mg/kg) and fentanyl (0.1 µg/kg) will be administered during the induction of anesthesia via intravenous (IV) route at doses calculated according to ideal body weights. End-tidal carbon dioxide (EtCO₂) will be continuously monitored after intubation. Tidal volume and ventilation rate will be adjusted to maintain EtCO₂ partial pressure of arterial blood at 35–45 mmHg. Rocuronium will be intermittently injected according to need based on Train of Four (TOF; Dräger AG, Lübeck, Germany) values. TOF responses will be assessed by ulnar nerve stimulation and adductor muscle response. 0.1–0.2 µg/kg fentanyl will be titrated for analgesia, as needed, if HR and/or mean arterial pressure (MAP) increased by 20% above baseline during surgery. Anesthesia will be maintained in desflurane group at inhalation in a 0.5 O₂ oxygen-air mixture (target MAC: 1-1.5, BIS values: 40 – 60, at the same times). Also anesthesia will be maintained in TIVA group with propofol and remifentanil infusion at inhalation in a 0.5 O₂ oxygen-air mixture (BIS values: 40 – 60). Desflurane or TIVA will be discontinued with the beginning of the skin sutures and the fresh gas flow was changed to 4 L/min of oxygen for both groups. In patients who will not experience complications during the surgery, sugammadex (IV, 2–4 mg/kg, Bridion®, MSD, Greenville, USA) will be then administrated to reverse residual muscle relaxation at the end of surgery.

Randomization:

Randomization was performed with the MedCalc for Windows (medcalc.com.tr.), version 16 statistical software. Seventy patients will be randomly allocated to two study groups:

Desflurane group (Group D, $n = 35$) and TIVA group (Group T, $n = 35$). Patients in both groups will be received a fresh gas flow of 4 L/min for the first 10 minutes and were then maintained with a fresh gas flow of 2 L/min. All patients will be mechanically ventilated with a tidal volume of 8 mL/kg based on ideal body weight and a frequency of 12–14 breaths/min using a Dräger Primus ventilator (Dräger AG, Lübeck, Germany). Age-related minimum alveolar concentration values will be determined and expressed as a percentage of volume. All patients will be received the standard surgical procedures determined by the same team of surgeons with experience in gastroenterology surgery. Pneumoperitoneum pressure will be ranged between 10 – 12 mmHg. Also pneumoperitoneum level will be 30 – 45 degrees. Surgical management of sleeve gastrectomy won't be changed in any way.

Outcome Measures:

HR, SpO₂, EtCO₂, mean arterial pressure (MAP), and BIS values will be recorded perioperatively. Blood samples will be taken for oxidative stress analysis at 15 minutes before anesthesia (T₀), perioperative period (1 hour after anesthesia induction) (T₁), and postoperative period (1 hour after awakening from anesthesia) (T₂). The blood samples will be kept in the biochemistry tubes under appropriate conditions (after centrifugation at -80 °C). Also anesthesia and surgery times, perioperative and postoperative complications will be recorded.

Postoperative Management:

Patients will be transferred to the post-anesthesia care unit (PACU) after surgery. Patients will be transferred to the general surgery intensive care unit 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 tramadol (0.5-1 mg/kg, IV) and paracetamol (1 gr, IV) at the time of beginning skin sutures.

Statistical Analysis:

On the basis of Han's study and using the power calculation method (OpenEpi, Version 3), assuming an alpha of 0.05 and a beta of 0.80, we calculated that 20 patients per group should be included in this study. 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 will be presented as mean or standard deviation and categorical data will be 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 $p<0.05$.