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Title page

The Utility of Gastro-laryngeal Tube during Transesophageal Echocardiography: Prospective Randomized Clinical Trial

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Study Protocol

After approval from the Ethics Committee of Bezmialem Vakif University School of Medicine, study was performed for 42 patients scheduled for TEE under sedation and analgesia or general anesthesia. Patients with American Society of Anesthesiology (ASA) physical status I-II and aged 20-75 years old were included in this study. ts who were under 20 to over 75 years old, an allergy to anesthetic drugs, emergent procedure, uncontrolled cerebrovascular disease, drug and alcohol addiction, performed oropharyngeal surgery were excluded, as were all patients who refused written informed consent.

Preoperative evaluations were performed on all patients a day before procedure. Age, gender, height, weight, and ASA physical status were recorded. On the day of procedure, patients were taken to the procedure room after premedication with 0.003 mg/kg IV midazolam (Dormicum, Deva Holding Cor., Istanbul, Turkey). Standard monitoring procedures were used, including heart rate (HR), noninvasive blood pressure, electrocardiogram, peripheral oxygen saturation (SpO2).

Forty two patients were randomly assigned to either the Group 1 (n=22, sedation and analgesia without any airway instrumentation) or Group 2 (n=20, airway control provided by GLT after inducing sedation and analgesia). Also, randomization (1:1) was based on a computer generated random numbers table, using MedCalc v. 16 statistical software for Windows (medcalc.com.tr). All patients received standard intervention procedures determined by the same team of cardiologists and an anesthesiologist with experience in TEE. Standard intervention procedure protocol was not change in any way.

All patients received preoperative midazolam (0.01-0.02 mg/kg) before being taken to the procedure room. For patients in Group 1, a standardized sedation and analgesia was administered by an experienced anesthesiologist. After administration of lidocaine (1 mg/kg) and atropine sulfate (0.01 mg/ kg), and also preoxygenation (100% 4 L/min O2 for 3 min), patients were induced with propofol (1-2 mg/kg) and fentanyl (1-2 mcg/kg) via intravenous (IV) route at doses calculated according to ideal body weight. Anesthesia was maintained with propofol infusion (4 mg/kg/h). Repetitive IV boluses of propofol (0.1 mg/kg) were administered, if necessary. Patients received oxygen (100%, 3 L/min) through a nasal cannula during sedation and analgesia.

For patients in Group 2, after administration of lidocaine (1 mg/kg) and atropine sulfate (0.01 mg/ kg), and also preoxygenation (100% 4 L/min O2 for 3 min), patients were induced with propofol (1-2 mg/kg) and fentanyl (1-2 mcg/kg). After induction of anesthesia, supraglottic airway device named GLT (VBM Medizintechnik GmbH, Sulz, Germany) was inserted (Figure 3). Patients were ventilated mechanically with a tidal volume of 6–8 mL/kg

based on ideal body weight and a frequency of 12–14 breaths/min using a Dräger Primus ventilator (Dräger AG, Lübeck, Germany) after inserting the GLT. Repetitive IV boluses of propofol (0.1 mg/kg) were administered, if necessary. Also, GLT was then removed at the end of TEE procedure.

The anesthesiologist was responsible for patient comfort, hemodynamic stability, immobility, adequate analgesia and airway management.

We hypothesized that GLT, allowing passage of the TEE probe and ensuring supraglottic airway control, would provide more advantages in terms of hemodynamic stabilization, complications related airway management, cardiologist and patient satisfactions when used in a clinical setting. To date, there has been no detailed prospective clinical study analyzing the performance of the GLT during TEE. The present study sought to address this gap by performing a prospective clinical study to analyze the performance of the GLT during TEE. Our primary outcome measures were safety of airway management, and cardiologist and patient satisfactions. Our study also recorded demographic characteristics, intraoperative and postoperative hemodynamics, level of hypoxemia, and duration of procedure as secondary outcome measures.

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences program (SPSS 22.0; IBM). The Shapiro Wilk normality test was used to test whether quantitative variables showed a normal distribution. Differences between variables in two groups with normal distribution were compared with the paired t-test. Continuous variables distributed abnormally were compared between the groups using a Mann–Whitney U test. Differences between variables within the same group at different times were tested with the Friedman test, and significant variables had pairwise comparisons performed with the Dunn test. Categorical variables were summarized using frequencies and percentages, and were compared between the groups using a chi-square test or Fisher's exact test. Descriptive statistics are given as mean, standard deviation, median, Q1 (1st quartile), Q3 (3rd quartile), frequency and percentage (%). Results were evaluated at a 95% confidence interval at a significance level of $p < 0.05$. Consent to conduct the study was obtained from Local Ethic Committee of Bezmialem Vakif University.