Study Title

Does Transesophageal Echocardiography Along With an Orogastric Tube Improve the Image Quality Intraoperatively?

NCT03454399

01/10/2017

Study protocol

Objectives:

Assess the echocardiography image quality before and after suctioning orogastric tube attached to transesophageal echocardiography (TEE) probe.

Study Design:

Clinical trial with two-point evaluation at a single tertiary care medical center.

Methods:

Study population include surgeries which meet intraoperative TEE indication.

Preoperatively, the investigators attach a 16 French OG tube (COVIDIEN llc, Mansfield, MA. USA) to X7 TEE probe (Philips Medical Systems, Andover, MA) using a silk surgical suture (OGT-TEE probe). All patients give their written consent to participate in this study preoperatively. All patients receive general anesthesia with endotracheal intubation, standard American Society of Anesthesiologists monitoring, arterial blood pressure monitoring, central venous pressure monitoring, pulmonary artery pressure monitoring, and TEE. The demographics and characteristics of these patients are collected from our computerized patient database.

Data Acquisition

TEE images are collected using an iE33 echocardiographic machine (Philips Medical Systems, Andover, MA, USA) with an OGT-TEE probe. After induction of general anesthesia, regular OG tube is placed and removed after suctioning stomach. Then OGT-TEE probe is inserted. Transgastric left ventricle short axis view (TG LV SAX) and midesophageal 4 chamber views (ME 4CV) are captured for 5 consecutive beats before and after suctioning OGT-TEE probe. Images with significant wall motion abnormality are excluded from assessment. For open heart surgeries, this is when coming off cardiopulmonary bypass (CPB); while for OLT cases, this is done when reperfusion or surgeons complained about distended stomach. Suction is performed for 1 minute at > -110 cm H_2O, and amount and characteristics of suction content is recorded. While acquiring these views, TEE device setting is not changed and iSCAN button is used before movie acquisition.

Measurements

Three investigators A, B and C, working independently, evaluate LV FAC and RV FAC for all images. Thus, 47 x 3 sets of images for each are investigated to obtain inter-observer variability. Subsequently, following an interval of between 6 and 8 months, investigator C again analyze all images to obtain intra-observer variability. In addition, these 3 investigators are asked to categorize image quality as numbers based on each investigator's impression (1: very bad, 2: bad, 3: acceptable, 4: good, and 5: very good) before and after suctioning.

Statistical Analysis

Continuous variables with normal distribution are displayed as the mean ± standard deviation, while those variables with non-normal distribution as median and interquartile range. Categorical variables are presented as proportions and absolute numbers. For continuous variables, the normality test is performed using the Kolmogorov-Smirnov test. The differences between the 2 groups are investigated using the chi-square test or Fisher's exact test if any of the expected frequency <5 for categorical variables, and unpaired and paired Student t-test or the Mann-Whitney U test for continuous variables. The differences between the 3 groups are investigated using Fisher's exact test for categorical variables, and one-way ANOVA test or Kluskal-Wallis test for continuous variables. Intraclass correlation coefficient (ICC) is a widely used reliability index in intrarater and interrater reliability analyses. Intraobserver and interobserer reliability analyses of LV FAC and RV FAC are performed using ICC. We obtain consistency ICC for inter-observer variability using all three investigators, and absolute-agreement ICC for intraobserver variability using investigator C, who measure all images twice with an interval between 6 and 8 months. All the statistical analyses are performed with R (version 3.4.3). A p-value of less than 0.05 is considered statistically significant