Study Title

TEE Image Quality Improvement With Our Devised Transesophageal Echocardiography Probe Cover and Its Effect on Surgical Decision Making

NCT03812185

Date: 01/18/2019

Study Design

This study was designed as a two-point evaluation at a single tertiary care medical center. This study was approved by the Henry Ford Health System Institutional Review Board (IRB #11958), and written consent was obtained from patients before enrollment. Additionally, this study was registered at ClinicalTrial.gov (NCT 03812185). This was a prospective, observational study of a cohort of adult patients who underwent surgeries requiring intraoperative TEE between January 2019 and December 2019 at Henry Ford Hospital in Detroit, MI. TEE data were collected from intraoperative TEE images as part of a prospective echocardiographic protocol using 2-dimensional (2D) TEE views. The demographics, perioperative clinical information, and postoperative outcomes of these patients were collected from our computerized patient database.

Patient Cohort

Adult patients undergoing surgeries requiring intraoperative TEE between January 2019 and December 2019 were included. The exclusion criteria were patient refusal to participate in the study, absolute contraindication to TEE, significant wall motion abnormality that hindered measurement of the left ventricular fraction area change (LV FAC), and inability to advance the OG tube through the TEE probe cover. All patients received general anesthesia with endotracheal intubation, standard American Society of Anesthesiologists monitoring, arterial blood pressure monitoring, central venous pressure monitoring, pulmonary artery pressure monitoring, and a comprehensive TEE examination with a designated protocol. Intraoperative management with anesthetics, mechanical ventilation, vasopressors, inotropic agents, and fluids/transfusions was performed based on department protocols, such as maintaining a mean arterial pressure > 65 mmHg, tidal volume 6-8 ml/ideal body weight (kg), and positive end-expiratory pressure 5-7 cmH2O.

Data Collection

After general anesthesia induction, our newly designed TEE probe cover (FIGURE 1; Fuji Medical, Tokyo, Japan) was attached to the X7 TEE probe (Philips Medical Systems, Andover, MA) and inserted into the patient's esophagus, and an OG tube (Salem Sump nasogastric tube, 16 Fr., Covidien, Minneapolis, MN) was advanced through the second lumen of the TEE probe cover. The length of advanced OG tube was adjusted so that the tip of OG tube would be 2-3 cm out of the second lumen. TEE images were intraoperatively collected by National Board of Echocardiography (NBE)-certified advanced

perioperative echocardiographers, who are blinded to this study design, using an iE33 echocardiographic machine (Philips Medical Systems, Andover, MA) and stored in Syngo Workflow (Siemens Medical Solution, Malvern, PA, USA). The designated views for TEE images were as follows: midesophageal 4-chamber view (ME4C), midesophageal 2-chamber view (ME2C), midesophageal aortic valve short-axis view (ME AV SAX), midesophageal long-axis view (ME LAX), midesophageal bicaval view (ME BIC), transgastric midpapillary short-axis view (TG Mid SAX), and deep transgastric long-axis view (DTG LAX). Image acquisition was performed twice, before and after OG tube suctioning, when the baseline TEE assessment was performed after general anesthesia induction. Suction was performed for 1 minute at > -110 cm H2O, and the amount and characteristics of the suctioned content were recorded. While acquiring these views, the TEE device setting was not changed, and the iSCAN button was pressed before video acquisition.10-13

Image quality assessment

TEE image quality was assessed in 2 different ways based on the TEE images acquired before and after suctioning. In the first method (method #1), the investigators categorized the quality of all acquired images on a numeric scale based on each investigator's impression (1: very poor, 2: poor, 3: acceptable, 4: good, and 5: very good). In the second method (method #2), the reproducibility of the LV FAC and right ventricular fraction area change (RV FAC) was assessed, assuming that better TG Mid SAX and ME4C image quality would yield better LV FAC and RV FAC reproducibility, respectively.18 LV FAC was calculated using TG Mid SAX, while RV FAC was calculated using ME4C.

Three investigators (A, B, and C), who were also NBE-certified advanced perioperative echocardiographers, assessed the quality of all TEE images post hoc. Thus, 50 x 3 sets of images for each were evaluated to determine the interobserver variability. Subsequently, following an interval of between 6 and 8 months, investigator C again analyzed all images to determine the intraobserver variability. To minimize selection bias, all investigators were blinded to the hypothesis of the study. Additionally, all investigators were blinded to which images were obtained before or after suctioning.

Outcomes

The quality of images obtained before and after pinpoint suctioning with our newly designed TEE probe cover was assessed using the following views: ME4C, ME2C, ME AV SAX, ME LAX, ME BIC, TG Mid SAX, and DTG LAX. As described in method #1, post hoc assessments were performed using image quality

categorized as discrete numbers based on each investigator's impression (1: very poor, 2: poor, 3: acceptable, 4: good, and 5: very good) before and after suctioning. Image quality improvement was defined as an increase in this number. Additionally, as described in method #2, the LV FAC was also assessed post hoc for intraclass correlation coefficient (ICC) analysis. Furthermore, we assessed the occurrence of TEE probe-related complications (postoperative severe sore throat, dysphagia, bloody aspirate from the OG tube) and the suctioned volume.

Statistical Analysis

Continuous variables with a normal distribution are displayed as the mean ± standard deviation, while those variables with a nonnormal distribution are displayed as the median and interquartile range. Categorical variables are presented as proportions and absolute numbers. For continuous variables, normality was tested using the Kolmogorov-Smirnov test.

The differences between 2 groups were investigated using the chi-square test or Fisher's exact test if any of the expected frequencies were <5 for categorical variables and unpaired and paired Student's ttests or the Mann-Whitney U test for continuous variables. Differences among 3 groups were investigated using Fisher's exact test for categorical variables and one-way ANOVA or the Kruskal-Wallis test for continuous variables.

Intraobserver and interobserver reliability analyses of the LV FAC and RV FAC were performed using the ICC20-22. We obtained consistency ICCs for interobserver variability using all three investigators and absolute-agreement ICCs for intraobserver variability using investigator C, who measured all images twice at an interval between 6 and 8 months. The proportion of cases showing improvement using the numeric scale and the occurrence of TEE probe-related complications (severe sore throat, dysphagia, and bloody aspirate from the OG tube) are also reported for descriptive assessment. The change in image quality according to the numeric scale (method #1) was averaged for the same case, and its association with the suctioned volume was assessed using Pearson's or Spearman's rank correlation test. All statistical analyses were performed with R (version 4.0.2). A p-value of less than 0.05 was considered statistically significant.