Cover Page

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Insertion of a Transoesophageal Echocardiography Probe Using the McGRATH Video Laryngoscope in Cardiac Surgery Patients: A Randomized Controlled Trial

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Location and Expected Duration of the Study:

Location: Prince Sultan Cardiac Center, Riyadh, Saudi Arabia

Cairo University, Cairo, Egypt

Expected Duration: From January 2026 to June 2026

RESEARCH PROPOSAL

Project Summary

Transoesophageal echocardiography (TEE) is an essential intraoperative monitoring tool in cardiac anesthesia. Despite its utility, TEE probe insertion can cause complications such as oropharyngeal injuries and esophageal perforation. Reported rates of oropharyngeal injury range from 0.2% to 1.2%, and esophageal perforation occurs in 0.01% to 0.09% of patients. Most injuries are located at the upper esophagus, particularly near the esophageal inlet. Assisting probe insertion using a conventional Macintosh laryngoscope has been suggested to reduce such injuries. However, its limited visualization of the esophageal inlet remains a challenge. The McGRATH video laryngoscope provides a superior view of upper airway anatomy, including the glottis and esophageal inlet, and may therefore offer safer and more efficient TEE probe placement.

Project Objectives

Primary objectives:

•To compare the incidence of pharyngeal mucosal injury during TEE probe insertion between patients using the McGRATH video laryngoscope and those using the Macintosh laryngoscope.

Secondary Objectives:

• To compare the visibility of the oesophageal inlet during insertion.

• To measure the duration of TEE probe insertion.

• To assess the number of insertion attempts.

Literature Survey/Background

Although transoesophageal echocardiography (TEE) is considered a well tolerated technique, rare but serious complications have been reported.[1-6] In anaesthetised patients, the total incidence of oropharyngeal injury associated with insertion of a TEE probe ranges from 0.2 to 1.2%,[1,3,5] and orogastric tract perforation, the most feared complication, occurs in 0.01 to 0.09% of both ambulatory and anaesthetized patients.[1-4] When orogastric tract perforation occurs, it most commonly affects the hypopharynx and the oesophagus, the incidence of which are 0.01 and 0.02%, respectively.[7-9] Oesophageal perforation occurs more frequently in the upper oesophagus including the oesophageal inlet than in the middle to lower oesophagus.[1,2,4] This is probably because the crossing of fibres from the constrictor muscle of the pharynx and the cricopharyngeus muscle make this portion of the oesophagus particularly susceptible to injury and perforation.[4] The incidence of minor adverse effects related to TEE probe insertion such as oropharyngeal mucosal injury seems to be more frequent in anaesthetized patients, but data is lacking and there is just a single study that puts the incidence of mucosal injury after blind TOE probe insertion at 55%, a relatively high figure.[10] Perforation of the hypopharynx and upper oesophagus after TEE probe insertion is likely to be caused by difficulties introducing the probe into the inlet of the oesophagus, generating undue pressure at the tip of the probe. Mucosal injury in the pharynx and oesophageal inlet per se is not serious but would also result from excessive pressure exerted by the probe tip. Prevention of these complications requires that force during insertion is avoided, and for this, direct visualization of the inlet of the oesophagus is desirable. Insertion under direct vision with a Macintosh laryngoscope (Macintosh) can reduce the high incidence of oropharyngeal injury from 55 to 5%.[10] The presence of an endotracheal tube prevents direct visualisation of the oesophageal inlet even when using the Macintosh, and it may sometimes be difficult to observe the passage of a TEE probe, creating conditions for pharyngeal injury.

The McGRATH MAC (McGRATH; Aircraft Medical Ltd., Edinburgh, UK) is a video laryngoscope that provides a better view of the glottis, piriform fossa and oesophageal inlet in tracheal intubation than the Macintosh.[11,12] We hypothesize

that the McGRATH will provide better visualization of the oesophageal inlet and will reduce the incidence of pharyngeal injury related to insertion of a TEE probe.

Research Design

Prospective, randomized controlled study

Methods

This study will be conducted between January 2026 and June 2026. Written informed consent will be obtained from each patient, who will agree to be enrolled in the study.

Inclusion criteria:

• Adults (male or female), aged above 18

• ASA physical status II or III

• Scheduled for elective cardiac surgery under general anesthesia requiring intraoperative TEE

• Provide written informed consent

Exclusion criteria:

Patients with any of the following will be excluded:

•Dysphagia or sore throat

•oropharyngeal infection

•cervical spine pathology

Randomization and group allocations:

Randomization will be done by online random number generator software (https://www.sealedenvelope.com/simple-randomiser/v1/lists) into either a Macintosh (C group) or a McGRATH (M group) group using blocks of random sizes of 4. The group allocations will be contained in sealed envelopes that will be opened in the operating theatre suite after the enrolment procedure had been completed.

Three cardiac anaesthesiologists with more than 5 years of experience intraoperative TEE will participate in this study and will insert the TEE probe.

All patients will be assessed preoperatively using the Mallampati classification, and after induction of general anesthesia; the patients of both groups will have tracheal intubation.TEE probe assisted insertion with Macintosh or McGRATH will be done with the patient head in neutral position. External laryngeal manipulation and repositioning of the blade will not be allowed in the first trial. The esophageal inlet visibility will be assessed, and the time of insertion will be recorded.

Measurements:

The endpoints will include: each patient's demographics, Mallampati classification (MP), esophageal inlet visibility, numbers of insertion trials, duration for TEE probe insertion, vital signs pre and during the insertion (heart rate, blood pressure, and oxygen saturation), and presence of complications after removal of the probe and anesthesiologist satisfaction.

We defined the duration of TEE probe insertion as the time, measured in seconds, from the moment the mouth will be opened until the TEE probe will be fully inserted. The range of a single trial will be delineated from the insertion of the TEE probe into the mouth to its removal or insertion into the esophagus. The total time for TEE probe manipulation will be calculated by summing the durations of multiple trials, excluding the intervals between manipulations. We will evaluate pharyngeal injury as a trauma-related factor. Pharyngeal injury will be defined as observation of laceration and/or hematoma with the McGRATH after the TEE probe has been removed by a blinded observer to the group allocation. Also, he will record the presence or absence of laceration and/or hematoma in the posterior pharyngeal wall, postcricoid area, lateral and medial wall of the piriform sinus and the inlet area to the esophagus.

Sample size Calculation:

A preliminary study (internal data) showed:

• Visibility of oesophageal inlet: 40% (Macintosh) vs. 80% (McGRATH)

• Pharyngeal injury: 2% (Macintosh) vs. 0.7% (McGRATH)

To detect a reduction in mucosal injury from 2% to 0.7% with 80% power and alpha = 0.05, 50 patients per group (total n = 100) are required.

Statistical analysis

The Shapiro–Wilk test will be used to assess continuous variables for normality. Normally distributed continuous data will be analyzed by Student's t test. The Mann-Whitney U test will be used for analysis of the number of TEE insertion attempts. The x2 test will be used for analysis of the incidence of pharyngeal mucosal injury and visibility of the oesophageal inlet. All analyses will be performed using GraphPad Prism version 6.0 (GraphPad Software, San Diego, California, USA). Data will be presented as mean ±SD. A P value less than 0.05 will be considered statistically significant.

Interim Analysis and Safety Monitoring

An interim safety analysis will be conducted after 50 patients (50% enrolment). The study will be paused if:

• The rate of mucosal injury in either group exceeds 25%

• A statistically significant increase in complications is detected by The Data Safety Monitoring Board (DSMB) will review interim results and recommend continuation, modification, or early termination. The study will follow an intention-to-treat analysis approach.

Ethical Considerations

• Informed consent will be obtained from all participants.

• Confidentiality will be maintained in accordance with institutional and national standards.

• Adverse events will be recorded and reported promptly to the IRB.

• No financial compensation or inducements will be provided to participants.

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