

A novel transesophageal ultrasound imaging system for the assessment and monitoring of cardiac function in ICU over a prolonged period of time: A proof of concept study

Paul Boucher, M.D.*, Rakesh Arora, M.D., Gurmeet Singh, M.D., Yanick Beaulieu, M.D.,
Deirdre Hennessy, M.Sc, and Christopher Doig, M.D.
Foothills Medical Centre (University of Calgary), Calgary, AB, Canada

Purpose:

Echocardiography is becoming the standard of care in the ICU as a diagnostic and monitoring tool of physiologic function. While transesophageal (TEE) imaging is superior in the critically ill patient, its use as a monitor is limited by the size of the probe. The purpose of this study was to assess the effectiveness of a novel miniaturized (17Fr, 5.5mm) TEE imaging system to capture transgastric short axis views of the left ventricle in critically ill patients over time.

Methods:

In this product development, proof of concept study, a miniaturized monoplane articulating TEE probe (ImaCor) was assessed for its ability to provide clinically useful transgastric images in critically ill patients over time without requiring probe removal. The trial was done in two parts. The first was to test the prototype of the probe in 10 patients for 4 hours. The second part was to test a disposable probe in patients for up to 72 hours. Images were obtained episodically

but on a regular schedule using the indwelling probe. An assessment of the images was made by 3 blinded reviewers. Inter-observer agreement was compared using a Kappa statistic.

Results:

25 patients were enrolled in the study; 10 in the first part and 15 in the second part. The average time the probe remained in-situ was 41.2 hours. Clinically useful images were obtained from 24/25 patients. 90.3% of all images obtained were clinically useful. In 21/25 patients these images were considered to have no clinical limitations, whereas in 4 patients at least one series of images was considered to have some technical limitations. The inter-rater agreement between the 3 reviewers was 0.59, with the majority of disagreement regarding technically limited studies.

Conclusion:

The miniaturized TEE system was able to provide clinically useful images over time in 96% of patients. No complications were experienced during this study.

*Paul Boucher, grant monies (from industry related sources). This study was undertaken with a grant from ImaCor, the developer of the imaging system. None of the authors received a salary from the company nor does anyone own shares; Product/procedure/technique that is considered research and is NOT yet approved for any purpose. The imaging device described in this study has not yet been approved for use. Submission of the 510K to the FDA has occurred.