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The hTEE system for transoesophageal echocardiographic monitoring of haemodynamic instability

Medtech innovation briefing

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Summary

Effectiveness	Adverse events and safety
• Three studies were identified that used the haemodynamic transoesophageal echocardiography (hTEE) system to monitor haemodynamic instability in critical care: 1 prospective observational study (n=94), 1 case series (n=21) and 1 case report (n=1). None reported patient outcome measures and evidence on clinical effectiveness is currently lacking. • The observational study demonstrated that when used by suitably skilled and experienced operators, the hTEE system provided relevant haemodynamic monitoring information, which had a clinical impact in most patients. • No clinical studies have directly compared the hTEE system with conventional transoesophageal echocardiography. • Two clinical trials of the hTEE system were identified, 1 which has completed and 1 which is ongoing. Both focus on patient outcome measures.	• The observational study reported minor gastric bleeding without clinical consequence in 2 patients. In addition, 2 patients developed a mechanical ulceration of the superior lip, caused by prolonged contact with the probe. • The authors of the case series reported that, to date, they have used more than 200 individual ClariTEE probes (part of the hTEE system) in the cardiovascular intensive care unit and over 50 elsewhere with no complications.

Cost and resource use • The average cost of consumables per hTEE use is £750, with additional costs arising from capital investment in the system, training and maintenance. • Training needs for all intensive care physicians will have a cost and resource impact. However, no published evidence was found on the NHS costs of adopting the technology or resource consequences.	**Technical factors** • In the observational study, malfunction of the ClariTEE probe precluded further imaging in 2 patients who had already been monitored for 48 hours. • Haemodynamic evaluation was not possible in the observational study in 15% of patients. The authors attributed this to the technical limitations of the ClariTEE probe (its being single-patient use and miniature). • With appropriate training, intensive care physicians can conduct both qualitative and semi-quantitative hTEE assessment as an adjunct to conventional haemodynamic monitoring.

Introduction

Haemodynamic instability can be defined as perfusion failure, represented by clinical features of circulatory shock and advanced heart failure (Weil 2005). It may also be defined as 1 or more out-of-range vital sign measurements, such as low blood pressure. Impaired cardiac performance is a frequent cause of haemodynamic instability and circulatory failure in critically ill patients (Hütteman 2006). Other causes include: cardiac contusion, haemothorax, embolism (air or fat), spinal cord injury, cardiac tamponade, tension pneumothorax, rupture of the heart, aortic injury, uncorrected blood and fluid loss, myocardial ischaemia, arrhythmias, injury, adrenal insufficiency, anaphylaxis, acute severe brain injury, and metabolic causes (Ho 1998). People who have had major surgery, such as organ transplant, are also at risk of perioperative haemodynamic instability. Each of these causes of haemodynamic instability has its own incidence and survival rates. Consequently, there is no record of overall incidence of haemodynamic instability in the literature.

Cardiac output is the product of heart rate and stroke volume. Relevant haemodynamic measures of stroke volume include preload (delivery of adequate blood volume to the left ventricle), contractility and afterload. Preload depends on many factors, including volume and right ventricular function, which can be assessed by transoesophageal echocardiography (Hastings 2012).

In critical care, haemodynamic management options comprise fluid resuscitation to increase preload, administration of vasopressors to maintain systemic blood pressure, and administration of inotropes to increase contractility and cardiac output.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

The haemodynamic transoesophageal echocardiography (hTEE) system (ImaCor Inc.) is designed to be used for episodic monitoring of people who require advanced hemodynamic management in the critical care setting, such as cardiac intensive care units or general intensive care units. The hTEE system comprises an ultrasound recording console, which can be moved from bedside to bedside, and a disposable transoesophageal probe which remains in place in the patient for up to 72 hours.

Conventional transoesophageal echocardiography is a semi-invasive adjunct to conventional haemodynamic monitoring, providing real-time bedside information about structural and functional abnormalities of the heart such as contractility, filling status and cardiac output (Hütteman 2006). It has the important advantage of being able to visualise and assimilate dynamic information that can change the course of patient management (Prabhu et al. 2012).

CE marking

The hTEE system is a class IIa medical device that was CE marked to ImaCor Inc. in July 2011.

Description

The hTEE system visualises the structures of the heart and provides episodic assessment of cardiac filling and function in people who are haemodynamically unstable. The system comprises 4 main components:

- the Zura EVO ultrasound control and imaging console with touch screen 19-inch display mounted on a rolling stand
- ultrasound imaging software within the console
- the miniature single-patient use transoesophageal echocardiography probe (the ClariTEE probe)
- a control handle attached to the console for connecting to the ClariTEE probe.

Optional components are an uninterruptible power supply and a universal serial bus data transfer module.

The disposable ClariTEE probe is 5.5 mm in diameter. It uses a monoplane piezoelectric design operating at 7 MHz and 6 MHz, which provides an image penetration depth of up to 18 cm and an image sector angle of 70° or 90° (software version 2.3.0). The miniature design allows the probe to remain in position for up to 72 hours; the imaging console is attached and detached as needed.

After turning on the machine and entering patient information via an on-screen keyboard (for first assessment only), the user attaches the ClariTEE probe to the control handle. The probe is inserted down the oesophagus where the 4 chamber view, or superior vena cava view, can be obtained. For the trans-gastric short axis view, the probe enters the top of the stomach, where it is then flexed upward (anteflexed up to 90°) or downward (retroflexed to 20° minimum). The user then adjusts the position of the probe with the system in image mode to provide real-time views of cardiac filling and function. A 3-lead electrocardiogram cable may be used to assist the identification of images at end systole and end diastole.

The ultrasound imaging software performs 7 functions:

- recording and updating patient information
- real-time imaging
- cineloop acquisition

- image enhancement
- playback
- evaluation
- hTEE measurements.

Cineloops are 3 or 6 second ultrasound image files recorded and saved by the user during real-time imaging. Single-view or split-view screen modes allow real-time images and cineloops to be viewed, acquired, optimised and compared. On-screen imaging controls allow the user to adjust brightness (B-mode), colour flow, gain, filter, contrast and depth to optimise real-time images.

The system provides 3 cross-sectional views (transgastric short axis, mid-oesophageal 4 chamber and superior vena cava), allowing the user to assess different aspects of cardiac filling and function. Following assessment, the probe is detached from the umbilical control handle and remains in place for further episodic monitoring or assessment, as needed, for up to 72 hours.

Calculated hTEE parameters are made in measuring mode using stored cineloops which are recalled for review. On-screen playback and, if necessary, further image quality adjustment controls are combined with 2 measurement tools for area (tracing tool) and distance (measuring tape tool) to calculate cardiac filling and function parameters. Cineloops can be transferred from the Zura EVO console and synchronised with a local picture archiving and communication system server. Patient records can also be transferred between Zura EVO systems using a data transfer module connected to the USB port.

Intended use

The ClariTEE probe may remain inserted for up to 72 hours, allowing for the episodic assessment of cardiac filling and function using transoesophageal echocardiography. It is not a continuous monitoring device and is not indicated for use on patients under 18 years of age. As with conventional transoesophageal echocardiography, patients with known contraindications such as oesophageal or stomach varices, obstructive oesophageal pathology, recent surgery or radiation therapy in the oesophageal or gastric area should be evaluated by a clinician before having a hTEE procedure. There are no additional contraindications for hTEE compared with conventional transoesophageal echocardiography.

Setting and intended user

The hTEE system is intended for use on people who require advanced hemodynamic management in critical care settings including the cardiac intensive care unit and the general intensive care unit. After receiving device-specific training, intensive care physicians can conduct the qualitative and semi-quantitative hTEE assessment.

Current NHS options

Current NHS options for providing cardiac imaging in critical care settings include conventional transthoracic echocardiography and transoesophageal echocardiography ultrasound imaging systems.

Conventional transoesophageal echocardiography is understood to be available on most cardiac intensive care units for haemodynamic instability where it would be conducted by an anaesthetist or intensivist. However, on general intensive care units in the UK, it seems more likely that, if available, a transthoracic echocardiogram would be done for haemodynamic instability.

The European Society of Cardiology recommends that transoesophageal echocardiography be used if transthoracic examination is inconclusive and the clinical question is important enough to warrant the risk and moderate discomfort associated with the procedure (Flachskampf et al. 2010).

On a general intensive care unit, a cardiologist is likely to perform conventional transoesophageal echocardiography for diagnostic reasons. These may include identifying or excluding a cardiovascular cause of haemodynamic instability, including valve lesions, endocarditis and other consequences of sepsis, myocardial pump dysfunction, hypovolaemia, cardiac tamponade, aortic dissection, and intracardiac masses (Flachskampf et al. 2010). However, the European Society of Cardiology recommends a higher specification multiplane ultrasound probe for most of these applications, and the basic monoplane ClariTEE probe is not intended for conventional diagnostic use.

As part of the European Society of Cardiology recommendations, Flachskampf et al. (2010) state that transoesophageal echocardiography may be used on a critical care patient with severe or life-threatening haemodynamic disturbance who is unresponsive to treatment, or on patients in whom new or ongoing cardiac disease is suspected and who are not adequately assessed by transthoracic imaging or other diagnostic tests.

NICE is not aware of other CE-marked devices that have a similar function to the hTEE system. The ClariTEE probe is the only miniature, indwelling transoesophageal echocardiography probe intended for episodic monitoring for up to 72 hours.

Costs and use of the technology

The list prices of the hTEE system components, excluding VAT, are:

- Zura EVO console with control handle and imaging software: £41,600.
- ClariTEE sterile, single-patient use, disposable probe: £750.
- Optional uninterruptible power supply: £5850.
- Optional universal serial bus data transfer module: no additional cost.
- ImaCor annual maintenance plan: £4160 per year.

The manufacturer offers system training when 30 ClariTEE probes are initially purchased with the Zura EVO console. Training typically takes 3 to 4 days as part of a user-agreed implementation programme, after which trained staff should be able to provide local training for additional users. The manufacturer offers training for additional users at a cost of £990 per day, excluding probes.

The manufacturer's annual maintenance plan includes unlimited software upgrades for 12 additional months, on-site preventative maintenance every 6 months and, if needed, an on-site technician to maintain a 95% system uptime. The anticipated lifespan of the Zura EVO system is 5 years.

The ClariTEE probe would typically be used for up to 6 assessments over a 24-hour period, with each assessment taking between 5 and 15 minutes. This results in a cumulative imaging time of 1.5–4.5 hours. Based on this, the monitoring cost per patient would be £750 for the ClariTEE probe, with additional costs arising from the capital investment in the system, training and maintenance costs.

Costs for conventional transoesophageal echocardiography systems on the Capital Medical Imaging National Framework Agreement are available to NHS organisations from the NHS Supply Chain.

Likely place in therapy

The hTEE system is intended to be used as an adjunct to continuous monitoring in people who require advanced hemodynamic management in critical care. Given that the hTEE system's design allows episodic monitoring for up to 72 hours, its most likely use is guiding therapeutic management of people in intensive care units who are haemodynamically unstable.

Specialist commentator comments

Examination with the hTEE system would generally be restricted to sedated and intubated patients in critical care settings.

One specialist commentator advised that limited trials of the hTEE system in their local NHS trust suggested its ability to obtain diagnostic images was very poor compared with conventional transoesophageal echocardiography.

The paper by Vieillard-Baron et al. (2013) was published by a group of international experts in transoesophageal echocardiography, working in a French system of training fellowships, and one specialist commentator stated that their success rates may not translate into UK practice.

With regard to cost and resource consequences, 1 specialist commentator advised that the Cioccari et al. (2013) study conducted in Europe does not match the UK, where there is a rapid turnaround of junior staff, increasing both training demands and costs. Furthermore, training in critical care transoesophageal echocardiography in the NHS is more complex and lengthy than described in this paper.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women, and
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance. (NB these are protected characteristics under the Equality Act (2010).

No equalities considerations were identified for the ImaCor hTEE system.

Evidence review

Clinical and technical evidence

Three clinical studies were identified in which the hTEE system was used as an intervention for people who are haemodynamically unstable. These were a prospective observational study (Vieillard-Baron et al. 2013), a case series (Maltais et al. 2013) and a case report (Mykytenko et al. 2012).

The prospective observational study was a multicentre investigation of 94 patients with haemodynamic instability of any cause, across 4 intensive care units during a 4-month period (Vieillard-Baron et al. 2013). The primary outcomes were feasibility of insertion, complications, image quality and influence on management. No failure of probe insertion was observed, however, in 17% of cases the nasogastric tube had to be removed to enhance probe insertion. Two patients had minor, self-limited gastric bleeding that was reported to have negligible clinical consequence. In 1 of these patients, endoscopy revealed oesophageal ulceration. An additional 2 patients developed a mechanical ulceration of the superior lip, caused by prolonged contact with the probe. Image quality was judged as 'adequate or optimal' in 91/94 (97%) of cases in the superior vena cava view, 89/94 (95%) of cases in the 4 chamber view, and 86/94 (91%) of cases in the short axis view. However, all superior vena cava, mid-oesophageal 4 chamber and transgastric short axis views were optimal in only 45% of patients. Haemodynamic assessment was not possible in 15% of patients, which the authors attributed to the technical limitations of the single-patient use, miniature probe. The authors expressed the opinion that the ClariTEE probe had lower overall imaging quality than that usually obtained with a conventional transoesophageal echocardiography probe, although no direct comparisons were made. The mean duration for which the probe remained in place was 32 ± 23 hours, allowing for a mean of 2.8 ± 1.6 haemodynamic evaluations per patient (which led to a mean of 1.4 ± 1.5 therapeutic changes per patient). Of the 263 haemodynamic assessments made, 132 (50%) had a direct therapeutic effect in 62 patients (66%). A summary of this study is presented in table 1.

Table 1 Summary of the Vieillard-Baron et al. (2013) prospective observational study

Study component	Description

Objectives/ hypotheses	To evaluate the haemodynamic monitoring capability and safety of the ImaCor single-use miniaturised TEE probe, when left in place for up to 72 hours in mechanically ventilated ICU patients being assessed for a cardiorespiratory compromise.
Study design	Prospective observational study.
Setting	Multicentre study during a 4-month period with 4 participating ICUs.
Inclusion/ exclusion criteria	Inclusion criteria: all patients requiring mechanical ventilation for circulatory failure or acute lung injury/acute respiratory distress syndrome and who needed TEE for diagnosis and management. Circulatory failure was defined as the presence of sustained hypotension (systolic blood pressure less than 90 mmHg or a mean arterial pressure less than 65 mmHg) associated with clinical evidence of tissue hypoperfusion which needed the use of vasopressors or inotropes. Exclusion criteria: at least 1 of the following: <18 years old, pregnant, contraindication for a TEE study.
Primary outcomes	Feasibility of probe insertion Complications Image quality Influence on patient management.
Statistical methods	Continuous variables expressed as mean ± standard deviation.
Participants	n=94 ventilated, critically ill patients. Of these: n=57 in septic shock, n=7 in cardiogenic shock, n=13 with post-resuscitation syndrome, n=4 in haemorrhagic shock, n=13 on ventilation for acute lung injury/acute respiratory distress syndrome.

Results	**Feasibility of probe insertion** No failure of probe insertion was observed. It was inserted at the first attempt in 78/94 patients (83%) and the nasogastric tube had to be removed in the remaining 17 % of cases. No additional sedation or paralysis was necessary. **Complications** Two patients had minor, self-limited gastric bleeding without relevant clinical consequence. In 1 of these, upper endoscopy revealed an oesophageal ulceration. An additional 2 patients developed a mechanical ulceration of the superior lip, due to prolonged contact of the probe. Technical dysfunction of the probe precluded further imaging in 2 patients who had already been monitored for 48 hours. **Image quality** Image quality was judged as adequate or optimal in 91/94 (97%) of patients in the superior vena cava transverse view, 89/94 (95%) in the mid-oesophageal 4 chamber view, and 86/94 (91%) in the transgastric short axis view. However, all views were optimal in only 45% of patients and haemodynamic assessment was not possible in 15% of patients. **Influence on patient management** The mean duration of probe insertion was 32 ± 23 hours, allowing for a mean of 2.8 ± 1.6 haemodynamic evaluations per patient (which led to a mean of 1.4 ± 1.5 therapeutic changes per patient). Among the 263 haemodynamic assessments, 132 (50%) had a direct therapeutic effect in 62 patients (66%).
Conclusions	In expert hands, the probe provided relevant information for the haemodynamic monitoring of ventilated ICU patients with cardiorespiratory compromise and had a therapeutic effect in most patients.
Abbreviations: ICU, intensive care unit; n, number of patients; TEE, transoesophageal echocardiography.	

The case series by Maltais et al. was conducted in a single-institution university hospital setting during a 9-month period in 21 postoperative, cardiac surgery adult patients who were haemodynamically unstable (Maltais et al. 2013). The primary outcomes were fluid volume responsiveness, and agreement between echocardiographic and standard haemodynamic assessments. Two patients needed reoperation for bleeding and tamponade physiology. Right ventricular dysfunction was diagnosed by episodic transoesophageal echocardiography monitoring in 7 patients (33%), and hypovolaemia was documented in 12 patients (57%). Volume responsiveness was documented in 11 patients (52%). Discordance between haemodynamic

monitoring and episodic transoesophageal echocardiography was qualitatively observed in 14 patients (66%), meaning that there was a change in treatment as a result of echocardiographic findings. A summary of this study is presented in table 2.

Table 2 Summary of the Maltais et al. (2013) case series

Study component	Description
Objectives/ hypotheses	Objective: to assess whether episodic monoplane TEE with a limited examination would help guide the postoperative management of high-risk cardiac surgery patients. Hypothesis: that episodic monoplane TEE guides assessment of intravascular/ myocardial volume, inotrope need, vasopressor use, and assessment of pericardial effusions in critically ill, postoperative, cardiac surgery patients.
Study design	Prospective, consecutively enrolled, non-blinded, descriptive case series.
Setting	Single institution in a university hospital setting during a 9-month period (June 2010 to February 2011).
Inclusion/ exclusion criteria	Inclusion criteria: haemodynamically unstable at any time in the ICU (defined as persistent systolic BP < 100 mmHg, cardiac index < 2.2 l/min/m^2, SvO_2 < 60%, suspected pericardial effusion with tamponade physiology, base deficit >8 mEq/l, or lactate >5 mg/dl despite persistent inotropic, vasopressor, and/or volume resuscitation, and concern for or known right ventricular failure). Exclusion criteria: none defined.
Primary outcomes	**Fluid volume responsiveness** Concordance/discordance between echocardiographic data and standard haemodynamic data, with discordance defined as a change in direction of management as a result of echocardiographic findings.
Statistical methods	Descriptive statistics for categorical variables were reported as frequency and percentage, and continuous variables were reported as mean (standard deviation) or median (range) as appropriate.
Participants	n=20 unstable postoperative cardiac surgery patients and n=1 in septic shock (mitral valve endocarditis) for surgical evaluation.

Results	**Fluid volume responsiveness** Volume responsiveness was documented by echocardiography in 11 patients (52%), with no response in 10 patients (48%). **Concordance/discordance between echocardiographic data and standard haemodynamic data** Discordance between standard haemodynamic monitoring and episodic transoesophageal echocardiography was qualitatively observed in 14 patients (66%), meaning that there was a change in direction of management of these patients as a result of echocardiographic findings. **Additional results reported** Mean number of imaging sessions was 3.28, median 3 per patient. Two patients (10%) needed reoperation for bleeding and tamponade physiology. Right ventricular dysfunction was diagnosed by episodic TEE monitoring in 7 patients (33%), and hypovolaemia was documented in 12 patients (57%).
Conclusions	The authors demonstrated the ImaCor hTEE system's ability to change the clinical management of unstable, postoperative, cardiac surgery patients. Patients considered to be fluid responsive by echocardiography were more likely to be appropriately resuscitated 6 hours after initiation of imaging. Haemodynamic monoplane TEE assessment was judged a useful adjunct, extending the haemodynamic assessment capabilities of TEE from the operating room to the ICU. Additionally, the authors reported that they have used more than 200 probes in the cardiovascular ICU and more than 50 elsewhere with no complications to date.
Abbreviations: hTEE, haemodynamic transoesophageal echocardiography; ICU, intensive care unit; n, number of patients; SvO_2, mixed venous oxygen saturation.	

The retrospective case report Mykytenko et al. describes a single patient who developed septic shock complicated by right ventricular dysfunction and underwent hTEE to guide fluid resuscitation, vasopressor, and inotropic therapy (Mykytenko et al. 2012). Invasive haemodynamic monitoring with an arterial line and central venous line was started, as the patient was given a 5 litre fluid resuscitation and multiple vasopressors. Subsequently, hTEE demonstrated a range of clinically abnormal cardiac anatomical and functional features. A summary of this study is presented in table 3.

Table 3 Summary of the Mykytenko et al. (2012) case report

Study component	Description
Objectives/ hypotheses	To review a single patient with septic shock complicated by right ventricular dysfunction, in which hTEE guided fluid resuscitation, vasopressor, and inotropic therapy.
Study design	Retrospective descriptive case report.
Setting	Postoperative ICU.
Inclusion/ exclusion criteria	None defined.
Primary outcomes	Response to fluid resuscitation, vasopressor, and inotropic therapy.
Statistical methods	None.
Participants	n= 1; a 48-year old man who had an uneventful off-pump coronary artery bypass graft and 2 days later developed septic shock from pneumonia complicated by right ventricular dysfunction.

Results	Invasive haemodynamic monitoring with an arterial line and central venous line was initiated as the patient was administered with a substantial 5 litre fluid resuscitation and multiple vasopressors. Subsequently, hTEE demonstrated a range of clinically abnormal cardiac anatomical and functional features, with resultant images reproduced as 3 figures in the paper: shortly after the onset of septic shock, 12 hours later and 2 days later. hTEE demonstrated new RV dysfunction with apical sharing, grossly decreased thickening of the RV free wall, paradoxical septal motion with grossly normal left ventricular function. Low-dose epinephrine at 2 microgram/min was chosen in the setting of hypotension for inotropy and RV support with improvement of RV function over time. Subsequent to the initiation of epinephrine and initial improvement in RV function, a random cortisol level suggested relative adrenal insufficiency, so stress dose hydrocortisone was also added. Over the next 24 hours, the patient's haemodynamics improved dramatically, and they were weaned off all vasopressors except for low-dose epinephrine, which was stopped a few hours later based on resolution of RV dysfunction. The patient's ventilator was weaned over the next several days as they had diuresis and continued clinical improvement.
Conclusions	This study highlights the rapid interval development of RV dysfunction in a previously normal heart over the course of 48 hours secondary to septic shock and the utility of direct assessment of cardiac function with hTEE.
Abbreviations: hTEE, haemodynamic transoesophageal echocardiography; ICU, intensive care unit; n, number of patients; RV, right ventricle.	

Two appropriate ongoing or in-development trials on the ImaCor hTEE system for haemodynamically unstable patients were identified in the preparation of this briefing.

The EVENT retrospective, matched-pair, case-control study was completed in January 2014, although results have not yet been published. Its primary hypothesis was patient outcomes and secondary measures were hospital expenses.

The ImaCor II randomised controlled trial commenced in January 2014 and aims to recruit 500 participants. It is scheduled to complete in September 2016. This trial, in collaboration with the system manufacturer, is designed to measure patient outcomes, thereby demonstrating the efficacy of hTEE monitoring compared with standard monitoring.

Costs and resource consequences

The manufacturer stated that 45 ClariTEE single-use, disposable probes have been sold to NHS customers, for use with 3 Zura imaging systems on loan. No Zura EVO imaging systems have yet been sold to the NHS (figures correct at May 2014).

In 2012/13, Hospital Episode Statistics Online recorded 33,405 transoesophageal echocardiograms in admitted NHS patients treated in England (code U20.2), of which 31,655 were adults. In 63.5% of all patients, transoesophageal echocardiography was recorded as a supplementary procedure during an admission, which would include its use for episodic haemodynamic monitoring in critical care. Health and Social Care Information Centre also recorded 48,577 adult critical care episodes in 2012/13 that were associated with cardiac surgery and primary cardiac conditions. However, in the UK most transoesophageal echocardiography is performed in the UK in the cardiology inpatient population for diagnosis and in cardiac surgery theatres for diagnosis and monitoring by cardiac anaesthetists. Therefore, it is difficult to determine the proportion of scans conducted in the specific population of people who are haemodynamically unstable and for episodic monitoring of cardiac function.

The ImaCor hTEE system is promoted as an adjunct to continuous haemodynamic monitoring, as an alternative to conventional transoesophageal echocardiography examination in the critical care setting. The Zura EVO imaging system, which is used in conjunction with the disposable ClariTEE probe, is kept in the critical care setting, rather than being in the echocardiography or radiology department of the hospital. Because of this, adoption of the hTEE system requires users within the intensive care unit to be trained to insert the ClariTEE probe and interpret the haemodynamic assessment images. The ImaCor website describes a tailored training programme that provides a wide range of educational materials. In current UK practice, the conventional transoesophageal echocardiogram would normally be conducted in the cardiac intensive care unit by an anaesthetist or intensivist, with training and accreditation available through a joint venture between the Association of Cardiothoracic Anaesthetists and the British Society of Echocardiography.

Cioccari et al. (2013) published a study on the feasibility of haemodynamic monitoring using the hTEE system in critically ill patients after a brief operator training period of 6 hours. They assessed 14 intensive care unit staff specialists over 148 hTEE examinations in 55 patients. They concluded that echocardiographic examinations after brief bedside training were feasible and of sufficient quality in most patients, with substantial inter-rater reliability between hTEE operators and an expert cardiologist. Results on relevant patient outcomes were not reported.

Training needs specific to the hTEE system will therefore have a measureable cost and resource impact, but no published evidence on resource consequences was identified.

Strengths and limitations of the evidence

The 3 studies are observational pilot studies of the hTEE system. In general, qualitative methods were used to report primary outcome measures, although the case series by Maltais et al. (2013) did capture some semi-quantitative data on the assessment of left ventricular end-diastolic area. The critical care settings of all 3 studies match the intended use of the hTEE system.

Although the study designs of all 3 identified papers are regarded as low quality in the conventional hierarchy of evidence, the study by Vieillard-Baron et al. (2013) was high quality as a prospective multicentre observational study with 94 patients across 4 centres. Its main strength was that the authors had previously validated their haemodynamic assessment test protocol against a more comprehensive and quantitative method and all 3 views of the heart were explored and assessed. However, the reliability of the analysis remains uncertain because blinding was not addressed. Another limitation is that inter-observer reproducibility was not tested.

The case series by Maltais et al. (2013) involved fewer participants. One of the key strengths of this study was the methodology where patients received intraoperative conventional transoesophageal echocardiography, and were continuously haemodynamically monitored postoperatively via a pulmonary artery catheter. When patients became haemodynamically unstable, the hTEE system was used as an adjunct to the pulmonary artery catheter to elucidate the pathology. This highlights the intended use for hTEE in clinical practice, and demonstrates its utility within the patient pathway. Incidental findings were also reported, such as average length of stay in the intensive care unit and observed in-hospital or 30-day mortality. However, a notable limitation of the study is that the authors obtained information from only the mid-oesophageal 4 chamber and transgastric short axis views; they did not address the absence of the superior vena cava view. It is important to note that this was an observational non-blinded case series, which leaves the results open to observer bias.

The third study was a retrospective case report on a single patient with right ventricular dysfunction (Mykytenko et al. 2012). Although this paper reports some interesting clinical observations in a single patient, the case report cannot be considered representative of the patient population in general.

Relevance to NICE guidance programmes

NICE has issued clinical guidelines on the use of conventional transoesophageal echocardiography for The management of atrial fibrillation (NICE clinical guideline CG180), as well as guiding treatment and therapy during 6 interventional procedures:

- Thoracoscopic exclusion of the left atrial appendage (with or without surgical ablation) for non-valvular atrial fibrillation for the prevention of thromboembolism (NICE interventional procedure guidance IPG400).
- Percutaneous mitral valve annuloplasty (NICE interventional procedure guidance IPG352).
- Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism (NICE interventional procedure guidance IPG349).
- Percutaneous mitral valve leaflet repair for mitral regurgitation (NICE interventional procedure guidance IPG309).
- Transmyocardial laser revascularisation for refractory angina pectoris (NICE interventional procedure guidance IPG301).
- Endoaortic balloon occlusion for cardiac surgery (NICE interventional procedure guidance IPG261).

However, this guidance does not specifically cover the use of transoesophageal echocardiography in critical care.

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Search strategy and evidence selection

Search strategy

In order to maximise sensitivity, the search strategy consisted of only 1 concept: the intervention. The strategy excluded animal studies and non-English language publications. The results were limited to those published since 2008, because this is the year of the first FDA 510k certificate for the device. The final strategy was peer reviewed by an independent information specialist.

The following databases were searched:

- Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley).
- Cochrane Database of Systematic Reviews (Cochrane Library, Wiley).
- Database of Abstracts of Reviews of Effect (Cochrane Library, Wiley).

- Embase (Ovid SP).
- Health Technology Assessment Database (Cochrane Library, Wiley).
- MEDLINE and MEDLINE in Process (Ovid SP).
- NHS Economic Evaluation Database (Cochrane Library, Wiley).

The manufacturer's webpages were also searched for published evidence not retrieved by the database searches. The search strategies used for each of the databases are presented below (A1 to A7).

A1. Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R). Ovid SP. 1946 to present. Search date: 4 April 2014.

1 Echocardiography, Transesophageal/is (386)

2 Echocardiography, Transesophageal/ and (Miniaturization/ or Disposable Equipment/) (25)

3 exp Hemodynamics/is (653)

4 (imacor* or htee* or mtee* or htoe* or mtoe* or claritee* or clari-tee* or zura*).ti,ab,kf. (53)

5 ((hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam*) and (transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or tee or toe)).ti,ab,kf. (1784)

6 ((in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniature*) adj5 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag*)).ti,ab,kf. (229)

7 or/1-6 (3025)

8 ((in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniature*) adj5 (gaug* or instrument* or measure* or monitor* or sensor* or device*1 or system or systems or probe*1)).ti,ab,kf. (23279)

9 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or echo-cardiograph* or echocardiograph*).ti,ab,kf. (238085)

10 Echocardiography, Transesophageal/ (14921)

11 9 or 10 (242862)

12 8 and 11 (433)

13 7 or 12 (3357)

14 exp animals/ not humans/ (3917953)

15 13 not 14 (2895)

16 limit 15 to (english language and yr="2008 -Current") (601)

A2. Database: Embase. Ovid SP. 1974 to 3 April 2014. Search date: 4 April 2014.

1 (imacor* or htee* or mtee* or htoe* or mtoe* or claritee* or clari-tee* or zura*).ti,ab,kw. (92)

2 ((hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam*) and (transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or tee or toe)).ti,ab,kw. (2535)

3 ((in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniature*) adj5 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag*)).ti,ab,kw. (290)

4 1 or 2 or 3 (2846)

5 ((in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) adj5 (gaug* or instrument* or measure* or monitor* or sensor* or device*1 or system or systems or probe*1)).ti,ab,kw. (26071)

6 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or echo-cardiograph* or echocardiograph*).ti,ab,kw. (319745)

7 *Echocardiography, Transesophageal/ (6322)

8 6 or 7 (320019)

9 5 and 8 (571)

10 4 or 9 (3289)

11 (animal experiment/ or animal model/ or nonhuman/) not human/ (3755217)

12 10 not 11 (2987)

13 limit 12 to (english language and yr="2008 -Current") (1069)

A3. Database: Cochrane Database of Systematic Reviews. The Cochrane Library, Wiley. Issue 4 of 12, April 2014. Search date: 4 April 2014.

#1 MeSH descriptor: [Echocardiography, Transesophageal] explode all trees 363

#2 (imacor* or htee* or mtee* or htoe* or mtoe* or claritee* or clari-tee* or zura*):ti,ab 1

#3 ((hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam*) and (transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or tee or toe)):ti,ab 154

#4 ((in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag*)):ti,ab 6

#5 #1 or #2 or #3 or #4 456

#6 ((in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (gaug* or instrument* or measur* or monitor* or sensor* or device* or system or systems or probe*)):ti,ab 450

#7 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or echo-cardiograph* or echocardiograph*):ti,ab 19878

#8 #6 and #7 24

#9 #8 or #5 475

#10 #9 Publication Date from 2008 to 2014, in Cochrane Reviews (Reviews and Protocols) 1

A4. Database: Database of Abstracts of Reviews of Effect. The Cochrane Library, Wiley. Issue 1 of 4, January 2014. Search date: 4 April 2014.

#1 MeSH descriptor: [Echocardiography, Transesophageal] explode all trees 363

#2 imacor* or htee* or mtee* or htoe* or mtoe* or claritee* or clari-tee* or zura* 116

#3 (hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam*) and (transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or tee or toe) 244

#4 (in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag*) 14

#5 #1 or #2 or #3 or #4 626

#6 (in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (gaug* or instrument* or measur* or monitor* or sensor* or device* or system or systems or probe*) 944

#7 tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or echo-cardiograph* or echocardiograph* 26214

#8 #6 and #7 61

#9 #8 or #5 678

#10 #9 Publication Date from 2008 to 2014, in Other Reviews 8

A5. Database: Cochrane Central Register of Controlled Trials. The Cochrane Library, Wiley. Issue 3 of 12, March 2014. Search date: 4 April 2014.

ID Search Hits

#1 MeSH descriptor: [Echocardiography, Transesophageal] explode all trees 363

#2 imacor* or htee* or mtee* or htoe* or mtoe* or claritee* or clari-tee* or zura* 116

#3 (hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam*) and (transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or tee or toe) 244

#4 (in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag*) 14

#5 #1 or #2 or #3 or #4 626

#6 (in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (gaug* or instrument* or measur* or monitor* or sensor* or device* or system or systems or probe*) 944

#7 tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or echo-cardiograph* or echocardiograph* 26214

#8 #6 and #7 61

#9 #8 or #5 678

#10 #9 Publication Date from 2008 to 2014, in Trials 176

A6. Database: Health Technology Assessment Database. Cochrane Library, Wiley. Issue 1 of 4, January 2014. Search date: 4 April 2014.

#1 MeSH descriptor: [Echocardiography, Transesophageal] explode all trees 363

#2 imacor* or htee* or mtee* or htoe* or mtoe* or claritee* or clari-tee* or zura* 116

#3 (hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam*) and (transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or tee or toe) 244

#4 (in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag*) 14

#5 #1 or #2 or #3 or #4 626

#6 (in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (gaug* or instrument* or measur* or monitor* or sensor* or device* or system or systems or probe*) 944

#7 tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or echo-cardiograph* or echocardiograph* 26214

#8 #6 and #7 61

#9 #8 or #5 678

#10 #9 Publication Date from 2008 to 2014, in Technology Assessments 3

A7. Database: NHS Economic Evaluation Database. Cochrane Library, Wiley. Issue 1 of 4, January 2014. Search date: 4 April 2014.

ID Search Hits

#1 MeSH descriptor: [Echocardiography, Transesophageal] explode all trees 363

#2 imacor* or htee* or mtee* or htoe* or mtoe* or claritee* or clari-tee* or zura* 116

#3 (hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam*) and (transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or tee or toe) 244

#4 (in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag*) 14

#5 #1 or #2 or #3 or #4 626

#6 (in-dwell* or indwell* or in-situ or single-use or disposable or monoplane or mono-plane or single-plane or miniatur*) near/5 (gaug* or instrument* or measur* or monitor* or sensor* or device* or system or systems or probe*) 944

#7 tee or toe or hemodynam* or haemodynam* or hemo-dynam* or haemo-dynam* or transesophag* or trans-esophag* or transoesophag* or trans-oesophag* or echo-cardiograph* or echocardiograph* 26214

#8 #6 and #7 61

#9 #8 or #5 678

#10 #9 Publication Date from 2008 to 2014, in Economic Evaluations 12

Evidence selection

Initial scoping work on the topic, with NICE, informed the inclusion and exclusion criteria for the final evidence selection.

This first sift removed evidence based on the following exclusion criteria:

- articles of poor relevance against search terms
- publication types that were out of scope:
    - non-English language studies
    - conference abstracts
    - review protocols (for example, Cochrane review protocols)
    - articles if neither the abstract nor full text is freely available online.

A total of 1872 records were retrieved from the literature search. After de-duplication, 1367 remained. An initial 409 records were excluded as being animal studies, bench research and irrelevant interventions. The 958 remaining articles were sifted on title and abstract and 942 records were excluded, comprising: conventional transoesophageal echocardiography technologies; populations and settings out of scope (such as intraoperative use in cardiac surgery, hypothermia after cardiac arrest, and measuring haemodynamic effects of weaning off therapies);

conference abstracts; and non-original research. Full articles were retrieved for the remaining 16 records.

Full text assessment of the 16 records was done at second sift to identify relevant primary research addressing the use of the medical technology within the defined indication under review (people who are haemodynamically unstable). The conventional evidence hierarchy applies and the best available evidence was selected for inclusion within the evidence tables and for critical appraisal.

During the second sift, 13 records were excluded for the following reasons: 10 were conference abstracts not previously identified from title and abstract; 1 was a general review article; 1 was an initial experience case report with strong likelihood of also being reported in the subsequent case series from the same institution (Maltais et al. 2013); and 1 had a primary outcome concerning training of operators, which was out of the defined scope of this briefing, but contributed to the narrative on training in this briefing (Cioccari et al. 2013).

This left 3 articles on the application of hTEE to transoesophageal echocardiographic monitoring of people who are haemodynamically unstable in the critical care setting, for inclusion within the evidence tables and critical appraisal (1 prospective observational study, 1 case series and 1 case report; tables 1 to 3 respectively).

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Newcastle and York External Assessment Centre. The Interim Process & Methods Statement sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

Project team

Newcastle and York External Assessment Centre

Medical Technologies Evaluation Programme, NICE

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Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Dr Nick Fletcher, Consultant Anaesthetist for Cardiothoracic Surgery, St George's Healthcare NHS Trust.
- Dr Craig Morris, Consultant Intensivist and Anaesthetist, Derby Hospitals NHS Foundation Trust.
- Dr Marcus Peck, Consultant Intensivist, Frimley Park Hospital NHS Foundation Trust.

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