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CRITICAL CARE IMPACT OF MONITORING CARDIAC FUNCTION VIA DIRECT VISUALIZATION USING A MINIATURIZED TEE PROBE: A PILOT STUDY

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Introduction

The purpose of this study was to determine the potential of a miniaturized TEE probe (the ImaCor ClariTEETM, approximately NG tube size) to perform hemodynamic monitoring in a variety of critical care settings (post cardiac surgery as well as general ICU patients).
TEE has been cited as especially appropriate for hemodynamic monitoring because hemodynamic abnormalities are multifactorial; causes include hypovolemia, left ventricular systolic dysfunction, and tamponade. The recently introduced ImaCor ZuraTM cardiac monitoring system uses this miniaturized, detachable, single-use TEE probe to obtain a variety of cardiac images, including the trans-gastric short axis view. In contrast to conventional TEE probes, the ImaCor system was designed for episodic hemodynamic monitoring over a time period of up to 72 hours. The ImaCor system was cleared by the FDA for this application.

Monitoring Hemodynamic Status and Cardiac Function

There is a critical need to assess and monitor hemodynamic status and cardiac function in patients following surgery and in intensive care situations such as the intensive care unit (ICU). Outside the ICU arena, cardiac specialists have found that directly visualizing the heart with ultrasound provides an accurate assessment of cardiac preload (volume) and performance. During open heart surgery, transesophageal echocardiography (TEE) is routinely employed to assess intravascular volume status and cardiac function, despite the availability of a wide variety of monitoring devices. Cardiac anesthesiologists have come to rely upon this ultrasound imaging information to make decisions with respect to fluid management and the use of pharmacotherapy, including pressors.

Until now, assessment of cardiac status using TEE has been difficult, expensive, and limited outside the cardiac OR. The large size of current TEE probes (typically 10-15 mm in diameter) leads to the need for anesthesia and precludes long term monitoring. Additionally, conventional TEE devices are complex, requiring dedicated personnel with specialty training. These limitations have led to the use of indirect methods, such as central venous pressure (CVP) monitoring, for the assessment of cardiac status, despite their inherent limitation: pressure and flow measurements cannot adequately describe volume status, pumping efficiency and factors such as wall motion abnormalities which may limit pumping efficiency. The ImaCor Zura system, including the ClariTEE probe - a miniaturized TEE probe – was designed to addresses the critical need for monitoring cardiac status episodically over periods up to 72 hours.

Limitations of indirect monitoring

The limitations of current indirect hemodynamic monitoring methods have been well studied over the past twenty-five years. A recent review of states that CVP should no longer be used to guide fluid management: *"The results of this systematic review are clear: (1) there is no association between CVP and circulating blood volume, and (2) CVP does not predict fluid responsiveness across a wide spectrum of clinical conditions. In none of the studies included in this analysis was CVP able to predict either of these variables. … Conclusions: This systematic review demonstrated a very poor relationship between CVP and blood volume as well as the inability of CVP/CVP to predict the hemodynamic response to a fluid challenge. CVP should not be used to make clinical decisions regarding fluid management."* (Marik, Baram and Vahid (2008).

The pulmonary capillary wedge pressure ('wedge', PCWP, PAOP) measured by the Swan-Ganz catheter *"has been shown to not correlate with other accepted methods of determining left ventricular filling or volume or intravascular volume and also does not help to generate cardiac function curves. Therefore, knowledge of it may actually lead to incorrect management more frequently than not."* (Liebowitz and Oropello, 2007). Kumar et al. (2004), Osman et al. (2007) and Chatterjee (2009) describe similar limitations.

Role of TEE

In a major review article for the *World Interactive Network Focused on Critical Ultrasound*, Price at al. (2008) describe ultrasound as the appropriate diagnostic tool in the ICU for many assessments, including

"• Systolic function and regional wall motion abnormalities
- *Diastolic function*
- *Hypovolemia and volume responsiveness*
- *Tamponade and pericardial disease*
- *The sepsis syndromes*
- *Effects of pre-load and afterload and assessment of filling status …*
- *Assessment of shock …*
- *Hemodynamic measurements"*

Poelaert and Schüpfer (2005) concluded that *"echocardiography permits a rational approach to the problem of hypotension"* and to overall hemodynamic management. Charon et al. (2006) add *"Echocardiography has been widely demonstrated to predict fluid responsiveness accurately. This is now a complete and noninvasive tool able to accurately determine hemodynamic status in circulatory failure."*
Our results support an expanding role for TEE in monitoring hemodynamic status and cardiac function in patients following surgery and in intensive care situations

Hypothesis

Cardiac monitoring with the ImaCor Zura imaging system can significantly impact clinical management in post-cardiac surgery and general ICU patients.

Methods

The ImaCor Zura imaging system was used to monitor cardiac dynamics in 40 patients (post cardiac surgery and general ICU) at 7 clinical centers. Images were assessed for cardiac function. Changes in patient management were recorded.

The ImaCor system

The ImaCor monitoring system includes the Zura, an optimized ultrasound engine designed for the intensivist, the miniaturized ClariTEE transesophageal echocardiography probe designed for improved assessment and management of hemodynamics and cardiac function, and a detachable handle which allows one ultrasound machine to monitor many patients. The ClariTEE probe allows direct imaging of the left ventricle, and may be left indwelling for up to 72 hours allowing periodic assessment of cardiac preload and left ventricular systolic function over a prolonged period of time.

Case report: Assessment of hypotension in the PACU following spinal fusion using ImaCor TEE monitoring

The limitations of current indirect hemodynamic monitoring methods have been well studied over the past twenty-five years. A recent review of states that CVP should no longer be used to guide fluid management:

Performed by Jesse Marymont, MD
Evanston Hospital, Evanston, IL

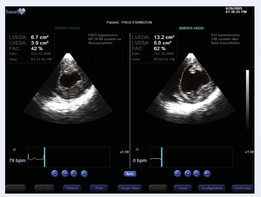
Objective: Diagnose source of post-surgical hypotension in the post-anesthesia care unit (PACU).

Background: 77 year-old, 48 kg female with multiple myeloma presented with a collapsed T-12 vertebrae. Hemoglobin on admission: 9.7. Additional medical history included hypertension, a prior coronary angioplasty, and a prior carotid endarterectomy.
During the operation the patient sustained a blood loss of 1700 mL with a urine output of 400 mL. During the procedure, the patient received 4500 mL IV fluids, 4 units PRBC, and 250 mL Hespan. In the PACU the patient was still found to be hypotensive (70-80 mm Hg systolic) after 750 mL IV fluid and neosynepherine were administered.

Methods: The attending physician ordered a bedside TEE using the ImaCor ClariTEE™ probe.The probe was successfully placed, and the transgastric short-axis view (TGSAV) of the left ventricle (LV) was obtained. Qualitative and quantitative analysis of the left ventricular size and function revealed hypovolemia, ventricular hypertrophy, and abnormal wall motion. With this information, additional fluids were aggressively administered and pressors were titrated and subsequently discontinued upon achieving normotensive blood pressure. The probe remained indwelling in the patient to enable further assessments.

Results: Patient was normotensive (140 mm Hg) in the intensive care unit the next morning.

Conclusion: Postoperative hemodynamic stability is a common complication following non-cardiac surgery. Empiric administration of IV fluids and plasma expanders is inadequate and may contribute to new problems. The ClariTEE™ probe is an effective tool for diagnosing causes of hemodynamic instability in the PACU environment due to the immediacy of the imaging and the actionable data provided to the intensivists.

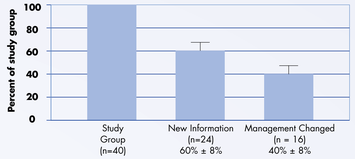


Results

The device was well-tolerated with no observed complications. Two patients were studied while fully conscious without sedation. New clinical information was obtained in 24 patients (60% of the 40 in the study). Clinical management was influenced in 16 of these 24 patients (67% of these 24, 40% of the 40 in the study). Management changes included fluid administration, adjustment to vasoactive and inotropic agents, and surgical decision making.

Please see two case studies below.

New information and influence on Clinical Management



Case report: Successful use of a novel, miniaturized transesophageal probe for diagnosing tamponade following coronary artery bypass

Performed by Michael Wall, MD
Barnes-Jewish Hospital, St. Louis, MO

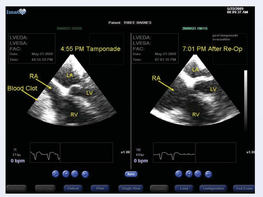
Objective: Diagnose source of hypotension in a patient immediately following coronary artery bypass in the CTICU environment.

Background: 86 year-old male with extensive medical history who had undergone elective CABG several hours earlier. In the CTICU, the patient was tachycardic and hypotensive (80–110 mm Hg) while on Levophed. SVO_2 was 32% and CVP was 25 mm Hg.

Method: Attending ICU physician ordered a transthoracic echo (TTE) and a transesophageal echo (TEE) with the ClariTEE™ probe. Both studies were performed at the bedside simultaneously in the ICU.

Results: An echo technologist performed the TTE from the patient's left side and was unable to assess the right atrium. The attending ICU physician, performing the TEE exam from the right side of the bed easily placed the probe without complication and was quickly able to obtain a four-chamber view of the heart. From this view, the physician noticed a large blood clot pressing on the right atrium and concluded that localized tamponade was the cause of the patient's deterioration. Based on this new information, the patient was taken directly back to the operating room for an immediate reoperation and the clot was removed. The patient's status immediately stabilized, and he returned to the ICU. Shortly after the patient's return, the physician performed a second assessment with the ClariTEE™ probe and determined that the right atrium was filling normally. The patient's blood pressure was no longer labile (140-150 mm Hg), Levophed was discontinued, and the patient was hemodynamically stable (HR: 70 beats/minute and CVP: 8 mm Hg).

Discussion: The published incidence of tamponade following cardiac surgeries is 0.5%-5.8% (Russo et al., 1993), and re-operation due to tamponade is costly and associated with increased mortality and prolonged hospital stay. While the use of TEE is well documented as an effective tool in the cardiac O.R. for monitoring patients, there is currently no effective method of monitoring these patients outside the O.R. where serious complications often occurs. In this specific case, as often occurs in the ICU, the TTE was unable to provide the critical information required to make this diagnosis.

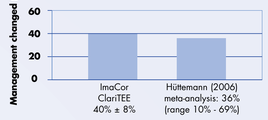


Conclusion: The ClariTEE™ probe can be an effective and useful tool in diagnosing tamponade in post-cardiac surgery cases. Moreover, the ClariTEE™ probe allows physicians to establish a continuity of care in the ICU that heretofore has not been available.

Conclusions

The impact of the ImaCor Zura imaging system with the miniaturized ClariTEE probe was equivalent to the impact reported by Hüttemann's (2006) large review of studies with conventional TEE probes. The ImaCor system influenced clinical management in 40% ± 8% of patients; this compared well with Hüttemann's reported 36% (range 10% - 69%). We conclude that monitoring cardiac function via direct visualization with a miniaturized TEE probe has significant clinical utility.

Influence On Clinical Mamagement



Discussion

Summary of results

A miniaturized TEE probe can be used to easily and safely monitor hemodynamic status and cardiac function in a critical care setting.

TEE and sepsis

Our present results also suggest that a user-friendly and patient-friendly TEE system will prove useful in monitoring the fluid status and cardiac function of sepsis patients, and thus overcome remaining barriers to implementing early goal directed therapy (EGDT) for sepsis.

Review of EGDT for sepsis

Sepsis mortality is extraordinarily high and directly linked to hemodynamic instability resulting in tissue hypoxia, but can be reduced from 46.5% to 30.5% through the use of *"early goal directed therapy."* (Rivers et al., 2001). Prompt, accurate fluid resuscitation in an important component of EGDT. One key component of early goal-directed therapy is the critical need to assess hemodynamic status and cardiac function in patients with sepsis (c.f. Zanotti Cavazzoni and Dellinger, 2006; Dellinger et al., 2008). Moreover, in a recent 6,000 patient review, Rivers, Coba and Whitmill (2008) found that early goal-directed therapy (GDT) in severe sepsis could *"save the lives of one in six [sepsis] patients"* and calls strongly for "overcoming logistical, institutional, and professional barriers to implementation."

Given its success, why is GDT not more widely implemented? Cost is not a valid reason: Trzeciak et al. (2006) found *"a reduction in median hospital facility charges [with GDT] of approximately $53,000 per patient."* Moreover, Shorr et al. (2007) found that GDT also reduced length of stay by 5 days (p = .023), consistent with other studies beginning with Rivers (2001).

Carlbom and Rubenfeld (2007) found key *"barriers to implementing protocol-based sepsis resuscitation in the emergency department …. More than half of all respondents recognized a critical shortage of nursing staff, problems in obtaining central venous pressure monitoring, and challenges in identification of patients with sepsis as the largest roadblocks to overcome in implementing early goal-directed therapy."* In addition, we note *"a very poor relationship between CVP and blood volume as well as the inability of CVP/DeltaCVP to predict the hemodynamic response to a fluid challenge. CVP should not be used to make clinical decisions regarding fluid management."* (Marik, Baram and Vahid 2008.)

Role of TEE

In a major review article for the *World Interactive Network Focused on Critical Ultrasound*, Price at al. (2008) write *"Echocardiography can play a key role in the management of the septic ICU patient both by excluding cardiac causes for sepsis, and by guiding haemodynamic management of those patients in whom sepsis reaches such a severity to jeopardize cardiovascular function and survival."*

A user-friendly and patient-friendly TEE system offers the potential to overcome these barriers. Vieillard-Baron et al. (2003) found *"bedside echocardiography can identify the precise cause of hemodynamic instability in septic shock, which may be hypovolemic, cardiogenic, or distributive. … Repeated bedside echocardiography can also assess the adequacy and efficacy of therapies implemented."*

Please see also the *Role of TEE* in the section *Monitoring Hemodynamic Status and Cardiac Function* above.

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