

Review

Equipment review: An appraisal of the LiDCO™plus method of measuring cardiac output

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Abstract

The LiDCO™plus system is a minimally/non-invasive technique of continuous cardiac output measurement. In common with all cardiac output monitors this technology has both strengths and weaknesses. This review discusses the technological basis of the device and its clinical application.

Keywords cardiac output, measurement

Introduction

This issue of *Critical Care* launches the first review in the new Health Technology Assessment section. As outlined in the editorial [1], the format is a combination of information from the developer and a balanced independent review. These articles should be read in conjunction as they are designed to assess the technology from two different perspectives.

The technology under review is a continuous cardiac output monitor based on lithium dilution (LiDCO™plus, LiDCO Ltd, Cambridge, UK). The first section is based on a structured questionnaire derived from the SCCM Working Group of HTA [2]. This provides answers from the manufacturer relating to the technology's background, usage and outcome

data. The responses are presented unaltered for the reader to form their own opinion. Clearly there is a potential for product promotion, but the formalised structure and narrow scope of the questions are designed to minimise this. There then follows a review by Dr Rupert Pearce, who has experience with the technology but no competing interests.

We hope this combination of articles will provide some added value in an area of our specialty where the truth often lies buried. The questionnaire-and-review structure of the assessment is intended as a template for development of the HTA section, and will be maintained as a consistent format for future device reviews.

Technology questionnaire

Kashif Ikram and John Barry

What is the science underlying the technology?

The PulseCO™ system calculates continuous beat-to-beat cardiac output by analyzing the arterial blood pressure trace following calibration with the absolute LiDCO cardiac output value. This system has been shown to be accurate and reliable in various clinical settings. It has been demonstrated that recalibration is unnecessary for at least 8 hours (Pittman *et al.*, Aronson *et al.*, and Jonas *et al.*, unpublished data) [3,4].

The LiDCO™ system provides a bolus indicator dilution method for measuring cardiac output and calibration of PulseCO™. A small dose of lithium chloride is injected via a central or peripheral venous line; the resulting arterial lithium concentration–time curve is recorded by withdrawing blood past a lithium sensor attached to the patient's existing arterial line. In terms of accuracy, clinical studies have demonstrated that the LiDCO method is at least as accurate as thermodilution over a wide range of cardiac outputs, and even

in patients with varying cardiac outputs [5–9]. In one study [9] LiDCO and thermodilution cardiac output were compared with an electromagnetic flow probe. The results of that study indicated that LiDCO was more reliable than conventional thermodilution cardiac output measurement. The dose of lithium needed (0.15–0.3 mmol for an average adult) is very small and has no known pharmacological effects [10,11].

The LiDCO™plus system combines LiDCO and PulseCO™, and provides a real-time and continuous assessment of a patient's haemodynamic status.

What are the primary indications for its use?

The LiDCO™plus Hemodynamic Monitor is intended for continuous monitoring of cardiac output, via blood pressure, in patients with pre-existing peripheral arterial line access. The system is safe, accurate and easy to use (Pittman *et al.*, Aronson *et al.*, and Jonas *et al.*, unpublished data) [3,4]. In acute care settings in which information on real-time haemodynamic changes are required, the LiDCO™plus system can be set up in under 5 min by a trained nurse or doctor. It can be used in a conscious patient and in preoperative, perioperative and postoperative settings. In many cases it averts the necessity for an invasive PAC and associated morbidity [12–29].

The primary indications for use include acute heart failure, Gram-negative sepsis, drug intoxication, acute renal failure, severe hypovolaemia, management of high-risk patients and patients with a history of cardiac disease, fluid shifts, complex circulatory situations and medical emergencies.

What are the common secondary indications for its use?

Following initial calibration, the LiDCO™plus system can provide a rapid 'early warning' of a significant change in haemodynamic status. Thus, in patients with conventional indications for invasive arterial blood pressure monitoring, the device is intended as a means to display continuous haemodynamic data in a comprehensive manner.

In addition to arterial blood pressure parameters and cardiac output, the LiDCO™plus haemodynamic monitor calculates a number of derived parameters, including the following: body surface area, systolic pressure variation, pulse pressure variation, cardiac index, stroke volume, stroke volume index, stroke volume variation, systemic vascular resistance and systemic vascular resistance index.

For management of volaemia, the 'preload response' measurements of pulse pressure variation and stroke volume variation can be useful in closed chest, mechanically ventilated patients [30–52]. These 'preload' measurements benefit from being dynamic, measured in real-time and available in a minimally invasive manner. One report recently published in *Anaesthesia and Analgesia* [37] showed that, 'a SVV [stroke volume variation] value of 9.5% or more, will predict an increase in the SV [stroke volume] of at least 5% in

response to a 100-ml volume load, with a sensitivity of 79% and specificity of 93%.'

What are the efficacy data to support its use?

The PulseCO™ haemodynamic monitor has been shown to be accurate and reliable in various clinical settings (Pittman *et al.*, Aronson *et al.*, and Jonas *et al.*, unpublished data) [3,4]. These studies were conducted both in patients undergoing off pump cardiac surgery and in the stopped heart. Cardiac output ranged from 2.7 to 21.3 l [4]. Data have also been presented validating use of LiDCO™plus in the medical intensive care unit in patients with a variety of diagnoses and in the pacing laboratory (Jonas *et al.*, unpublished data) [53]. It is clear that this system provides no incremental risk to the patient and could replace the insertion of a highly invasive PAC in many high-risk patients (Pittman *et al.*, Aronson *et al.*, and Jonas *et al.*, unpublished data) [3,4].

Are there any appropriate outcome data available?

There is a growing volume of evidence to suggest that optimizing flow (cardiac output) and oxygen delivery can lead to improved outcomes in terms of mortality and morbidity in suitable patients [54–57]. LiDCO™plus can permit patients' haemodynamic status to be 'optimized' in a safe, accurate and timely manner.

What are the costs of using the technology?

In order to use the technology, a monitor (LiDCO™plus) and disposable lithium sensor are required. The cost per patient of using the system is typically significantly less than that of a continuous cardiac output PAC. It is designed to work with any arterial catheter system. The LiDCO system does not require the use of special catheters, introducer trays, or x-ray information for verification of correct positioning. Savings can probably be realized on elimination of many of the comorbidities associated with PAC insertion [12–29].

Should there be any special user requirements for the safe and effective use of this technology?

The LiDCO™plus haemodynamic monitor system is suitable for patients who have undergone insertion of arterial and venous catheters (peripheral or central) and require monitoring. Use of lithium chloride is contraindicated in patients undergoing treatment with lithium salts, in patients who weigh less than 40 kg (88 lb) and in patients who are in the first trimester of pregnancy. Performance may be compromised in patients with severe peripheral arterial vasoconstriction, in those undergoing treatment with aortic balloon pumps and in those with aortic valve regurgitation.

All staff should be properly trained in the appropriate set up and use of the LiDCO system.

What is the current status of this technology, and, if it is not in widespread use, why not?

The LiDCO™ system consists of electro-medical equipment, sterile medical disposable elements and a sterile injectate.

These systems have US Food and Drug Administration and CE mark approval and have been marketed since July 2001. On continental Europe approval for the lithium chloride injectate has been received for Austria, Belgium, Czech Republic, Germany, the Netherlands and Spain. Italy is pending for early 2004. Over 80 key institutions in the USA and over 50 institutions in the UK are routinely using the LiDCO™ technology.

What additional research is necessary or pending?

A number of studies are currently either ongoing or pending. These include the following: studies employing stroke volume variation for optimal fluid management in risk patients; studies validating stroke volume variation, stroke volume and cardiac output in volume resuscitation as compared with current parameters (end-diastolic volume index, cardiac output, cardiac index) in a trauma setting; studies using LiDCO™plus to optimize high-risk surgery patients preoperatively and postoperatively with a view to reducing mortality/morbidity; and studies comparing LiDCO™plus with standard monitoring in terms of impact on patient management.

Competing interests

K Ikram is an employee of LiDCO Ltd and J Barry is a Director of LiDCO Plc.

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Equipment review

Rupert M Pearse

Introduction

Measurement of cardiac output and its role in clinical management remains a controversial topic. Although the pulmonary artery catheter (PAC) has not been shown to cause excess mortality [1], concerns remain about the morbidity associated with such an invasive technique.

Some practitioners do not accept a role for cardiac output measurement in clinical practice. Others believe fluid and/or inotropic therapies should be guided by flow measurements wherever possible. This debate is beyond the scope of the present review. Any data provided by a monitoring device should be interpreted with care and used in conjunction with other physiological and biochemical parameters. Clinical estimation of cardiac output, even by an experienced physician, is unreliable [2], whereas the use of flow monitoring has proved beneficial in various patient groups both with [3,4] and without the use of targets for oxygen flux [5-8].

The LiDCO™plus™ system (LiDCO Ltd, Cambridge, UK) is one of several cardiac output measurement devices that are now

commercially available. This review provides a critical analysis of the technological basis for the product and discusses its clinical applications. The aim is to equip the reader with an understanding of the strengths and limitations of the system (Table 1), thereby allowing safe and more effective use.

Scientific basis

The LiDCO™plus system employs two technologies. Initial cardiac output measurement is performed by lithium indicator dilution. A bolus of lithium chloride is injected intravenously and then detected by a lithium-sensitive electrode attached to an arterial cannula. This measurement is then used to calibrate pulse contour analysis software, which provides continuous cardiac output data by analyzing the arterial pressure waveform. The technique is minimally invasive, requiring only arterial and venous cannulae. A peripheral venous cannula may be used although a central venous catheter is preferable. Patients in whom cardiac output monitoring is useful generally require invasive arterial and central venous pressure monitoring, and the use of this system does not usually require additional cannulation.

Table 1

Strengths and weaknesses of the LiDCO™plus method of measuring cardiac output

Strengths	Weaknesses
May be used in conscious and unconscious patients May be calibrated by nursing or medical staff in 10 min Provides dynamic markers of fluid responsiveness	Arterial waveform artefact may significantly affect data accuracy Irregular pulse rate may affect data accuracy Nondepolarizing muscle relaxants interfere with calibration

The underlying technology is similar to that employed by the PiCCO™ (Pulsion systems, Munich, Germany) system, which uses transpulmonary thermodilution to calibrate pulse contour analysis software. Both systems allow minimally invasive measurement of cardiac output in conscious and unconscious patients for as long as necessary. This allows wider clinical application than oesophageal Doppler, which is poorly tolerated in conscious patients, or the PAC, the duration of use of which is limited by infection risk.

Lithium indicator dilution

Several studies have evaluated the lithium dilution technique of cardiac output measurement, most frequently in comparison with thermodilution using the PAC. Only three studies in humans have been published in peer-reviewed journals, two in cardiac surgical patients [9,10] and one in critically ill paediatric patients [11]. The accumulated evidence in animal and human studies does suggest a good correlation with thermodilution using the PAC. However, whether thermodilution can be regarded as a 'gold standard' of cardiac output measurement is doubtful. It is estimated that a 22% change in cardiac output is necessary before any difference is detected by this technique [12]. It is reasonable to accept the body of evidence for the accuracy of the lithium dilution technique for the time being, but further validation in a general population of critically ill adults would be helpful.

The pharmacokinetics of intravenous lithium have been described [13]. No additional side effects of the administration of lithium by this route have been reported. The recommended dose of lithium required for calibration may be used on 10 successive occasions in a 40 kg anephric patient without exceeding the therapeutic range for oral lithium therapy. The use of intravenous lithium chloride is not recommended in patients who weigh under 40 kg, those who are pregnant and those receiving oral lithium therapy.

Pulse contour analysis

The various features of the arterial pressure waveform are determined by the physiology of both the heart and the peripheral circulation. Any complex waveform may be analyzed by separation into a number of contributory waveforms or harmonics. PulseCO™ (LiDCO Ltd) calculates change in stroke volume by power analysis of the first harmonic of the arterial pressure waveform. This approach differs slightly from that of the PiCCO™ system; PulseCO™

analyses the arterial waveform throughout the cardiac cycle whereas PiCCO™ utilizes only the area under the systolic portion of the curve. There are no published reports directly comparing these two approaches of pulse contour analysis.

It is only possible to calculate changes in stroke volume rather than absolute values, hence the requirement for calibration by lithium dilution. Because lithium dilution measures cardiac output rather than stroke volume, significant change in heart rate during the calibration process will result in misleading data.

Recalibration is recommended every 8 hours. This technique of pulse contour analysis has been validated by comparison with lithium dilution and thermodilution techniques [14]. Once again this raises the question of whether there is a reliable standard against which a new technology can be compared. This concern applies to all cardiac output measurement techniques. The system has been used successfully with arterial cannulae in various sites, although not all have been scientifically validated. The PiCCO™ system may only be used with a cannula placed in the femoral or axillary artery.

Changes in the damping coefficient of the arterial pressure transducing system may profoundly alter cardiac output measurements. While air bubbles or blood clots in the arterial cannula may be removed, kinking of the cannula may necessitate recalibration or even replacement of the arterial cannula followed by recalibration. As circulatory compliance changes in response to primary physiological changes or vasoactive drugs, the morphology of the arterial waveform alters. Although studies do not report measurement error as a result of this phenomenon, this must be an inherent risk in any form of pulse contour analysis. Regular scrutiny of the arterial pressure waveform for changes in morphology is necessary, and recalibration may be required. Because cardiac output is estimated every cardiac cycle, atrial fibrillation, and occasionally other arrhythmias, may result in irregular data output, limiting clinical usefulness. This is not problematic unless the pulse rate is particularly irregular. Adjustments to the system may improve data quality.

Prediction of fluid responsiveness

One indication for the use of flow monitoring is the prediction of fluid responsiveness. The LiDCO™plus system also calculates the pulse pressure, systolic pressure and stroke volume variations that occur through the respiratory cycle.

These dynamic markers of fluid responsiveness are more reliable than traditional techniques [15] and more practical to use than fluid challenges guided by stroke volume change. This feature combined with more traditional parameters permits more appropriate fluid management in the ventilated patient. However, variations in stroke volume or pulse pressure may not be as readily attributed to hypovolaemia in the spontaneously breathing patient or in the presence of an irregular cardiac rhythm. As a result, these parameters may not be reliable in a large proportion of critical care patients.

Clinical application

The equipment provides a valuable guide to fluid and inotropic therapy in high-risk patients in the intensive care unit, operating theatre and other critical care areas. Because of the minimally invasive nature of the technology, the device may be used more readily than the PAC.

Training in the use of the system is necessary, but with practice it is possible to perform an initial calibration within 10 min and subsequent recalibrations within 5 min. This is faster than pulmonary artery catheterization and comparable to the PiCCO™ system but slower than the oesophageal Doppler. Any error in the calibration process once the lithium bolus is injected will result in a delay of approximately 15 min while the background plasma lithium concentration subsides. The use of muscle relaxants may interfere with calibration (although not continuous measurement) for up to 45 min. Lithium chloride is safe in the doses used and the maximum dose is rarely a limiting factor. The equipment is generally reliable, although there have been manufacturing problems with the lithium sensors in the past.

There are as yet no published interventional studies utilizing the LiDCO™plus system but a randomized trial of postoperative goal-directed haemodynamic therapy is under way. The benefits of cardiac output measurement using various devices have been repeatedly demonstrated [3–8]. What is important in any new method of cardiac output measurement is its accuracy and reliability rather than validation in interventional studies.

It is not clear whether data provided by the LiDCO system are accurate during the use of the intra-aortic balloon pump. Use is also not recommended in the presence of aortic regurgitation; whether mild valve dysfunction has any clinically relevant effect on data accuracy is unclear. Further validation in these two areas may allow wider use of the technology.

Conclusion

The new generation of cardiac output measurement techniques include the LiDCO™plus system, oesophageal Doppler and PiCCO™, as well as other technologies. Each device provides a safe and reliable alternative to the PAC. The choice of monitor depends mainly on the clinical application. The advantages of the LiDCO™plus system are that it is minimally invasive and may be used in conscious and unconscious patients.

Competing interests

None.

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