Reviewer's report

Title: A Prospective Study To Evaluate The Accuracy Of Pulse Power Analysis To Monitor Cardiac Output In Critically Ill Patients.

Version: 1 Date: 17 May 2007

Reviewer: Nick Linton

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General

PulseCO should track changes in CO within an individual patient. It is not an absolute method and requires calibration (e.g. with indicator dilution). Following the initial calibration, if there are no haemodynamic changes then the pulse contour will not change – and so PulseCO will not change. PulseCO is designed to estimate CHANGES in CO based upon changes in the arterial pressure waveform. You therefore need a group of patients in whom there are significant changes in haemodynamics (much greater than in this study) during the period of comparison. This allows CHANGES in CO estimated by pulse contour analysis to be compared with CHANGES estimated by the calibration method. Clinicians reading the paper might ask: 1) Is PulseCO better than assuming that CO remains the same as it was at calibration? 2) Is PulseCO also better than assuming that the SVR remains the same at calibration. I hope that the answer to both these questions is ‘yes’ – unfortunately there is no statistical evidence in the paper to demonstrate this.

In this paper, the method of statistical analysis is similar to most other papers evaluating pulse contour analysis. The ABSOLUTE CO values were pooled and then compared with a ‘Bland-Altman’ analysis. This has previously been demonstrated to be spurious and invalid (see Br J Anaesth 2002; 89: 336–9 (I am one of the authors)). The authors should have pooled CHANGES in CO. The data needs to be reanalysed and the current analysis discarded.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. "This study, therefore seeks to investigate the duration that the two methods remain sufficiently similar to be acceptable for clinical use."

The authors have previously stated that “the calibration will be valid so long as there are no significant changes in the haemodynamic status of the patients”. I agree that it is prudent to check the calibration of PulseCO at regular intervals. However, it is not the duration of use, per se, that influences accuracy – it is changes in the state of the patient, and these are more likely to occur in longer periods of time. A recommendation for recalibration based only upon time does not seem sufficient.

2. "Comparison between these measurements was performed by linear regression analysis and the technique described by Bland and Altmann [8]."

This is a fundamental error: the wrong variables are being compared. PulseCO estimates changes in cardiac output (absolute values being displayed after calibration). Therefore, changes in cardiac output estimated by LiDCO and by PulseCO should be compared - not the absolute values. Preferably, proportional changes should be assessed because a change from 2-4L/min is more clinically significant than a change from 12-14L/min.

In figure 1, the correlation coefficients are high because of the large variation in cardiac output between different patients rather than within individual subjects. The method of analysis used by the authors can yield ‘good results’ even with artificial PulseCO data, where changes in cardiac output have been generated randomly with a computer. See - Br J Anaesth 2002; 89: 336–9

3. "A total number of 54 pairs of data were available at the end of data collection." and "Six of the fourteen
patients had changes in their cardiac output of greater than 15% from their baseline value [Table2].”
This is a small number for a study of existing cardiac output techniques. 8/14 patients had minimal changes in cardiac output. Is there sufficient good quality data?

4. "The LiDCOplus monitor (LiDCO, Cambridge, UK) is a device that combines a pulse power algorithm (PulseCO) with an independent form of calibrating the pulse power algorithm via lithium dilution (LiDCO) [7].”
Reference [7] does not contain any information about the “pulse power algorithm”. Please include an appropriate reference.

5. "This error rate was quantified by dividing twice the standard deviation of the bias by the mean cardiac output for both techniques."
The bias is the mean of the differences. Did you intend: “This error rate was quantified by dividing the twice the standard deviation of the differences by the mean cardiac output for both techniques.”

6. "It has been demonstrated to be accurate so long as recalibration is performed whenever there is major haemodynamic change [1-6].”
References [2] and [5] are the same. They showed that the method was grossly inaccurate after phenylephrine infusion.

7. "At baseline the PulseCO was calibrated using the lithium dilution technique as previously described and according to manufacturer’s instructions [9].”
Reference [9] is a study on children and the dose of lithium was not always 0.3 mmol.

What next?: Reject because scientifically unsound
Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I have previously developed and published an alternative pulse contour method, and was funded by LiDCO Ltd (the manufacturer of the devices tested in this manuscript). I am an inventor on a number of patents relating to cardiac output measurement. I have previously owned shares in LiDCO Ltd.