

Assessment of the clinical utility of an ultrasonic monitor of cardiac output (the USCOM) and agreement with thermodilution measurement

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Cardiac output (CO) is traditionally measured with a pulmonary artery catheter, but several studies have demonstrated that use of these catheters does not reduce mortality and may be associated with increased morbidity.¹⁻³ This has led to interest in less invasive methods of monitoring.

A non-invasive device for measuring CO — USCOM (Ultrasonic Cardiac Output Monitor, USCOM Ltd, Sydney, NSW) — was introduced for clinical use in 2001. It operates by measuring red cell velocity using continuous-wave Doppler ultrasound.⁴ The device provides non-invasive transcutaneous measurement of CO using an ultrasound transducer to obtain a Doppler flow profile (velocity–time graph) from either the aortic (suprasternal notch) or pulmonary (left of sternum, below second intercostal space) windows. The CO is calculated from the product of the velocity–time integral and the cross-sectional area of the target valve.⁵ Aortic and pulmonary valve areas are estimated from regression equations that relate valve diameter to height.⁶

The advantages of this portable CO monitor are obvious and include its non-invasiveness and the potential to reduce associated complications. The USCOM device is reported to provide rapid, repeatable measurements of cardiac output, its use is simple to learn, and the same device can be used in multiple patients.⁷⁻¹⁰ Other studies have suggested that it provides a rapid, accurate and safe measure of CO and that it may aid the introduction of early goal-directed therapy by emergency physicians, even in the retrieval setting.¹¹ However, published reports have differed in their conclusions about the acceptability of the agreement between ultrasonic measurements of CO and the clinical standard (thermodilution measurement).^{4,8,10,12,13}

Although the acceptability of the agreement between ultrasonic and thermodilution CO measurements is uncertain, a non-invasive device would be clinically useful if able to reliably identify low, normal and high CO, and to track changes in CO. We compared ultrasonic and thermodilution measurements of CO to assess these features.

Methods

Patient selection

The study was approved by the Prince of Wales Hospital Research Ethics Committee, Sydney, NSW. The study

ABSTRACT

Objective: To assess the clinical utility of an ultrasonic monitor of cardiac output (USCOM), its reliability in tracking cardiac output (CO) changes and agreement with thermodilution (TD) measurements of CO.

Design: Prospective comparison study.

Setting and participants: 55 adults undergoing thermodilution (TD) CO monitoring in a cardiothoracic or general intensive care unit between December 2006 and December 2007.

Main outcome measures: USCOM and TD measurements of CO on two occasions in each patient were compared by Bland–Altman analysis for bias and limit of agreement. A mean percentage error < 30% was considered acceptable. Per cent change in cardiac index (CI) was determined by each method. Doppler profiles obtained by the USCOM were assessed against an ideal standard (“acceptable”).

Results: 55 patients had measurements on 110 occasions, but Doppler waveforms were not obtained on 18 of these (16%), leaving 39 patients with paired comparisons for analysis (including 27 men; mean age, 64.7 [SD, 14.5] years). Mean TD CI was 3.4 ± 1.0 L/min/m² (range, 2.0–6.0 L/min/m²). The bias was 0.6 L/min/m² (95% confidence limits [CLs], 0.4–0.8 L/min/m²), and the mean percentage error was 56% (95% CLs, 45%–65%). Twenty-two Doppler profiles (28%) were classed as acceptable; the mean percentage error for these was 62% (95% CLs, 38%–65%). On 15/19 occasions (74%) where TD CI changed > 15%, USCOM CI also changed > 15%, but three of these changes (16%) were in the opposite direction. USCOM CI changed > 15% on 9/20 occasions (45%) when TD CI did not.

Conclusions: Poor agreement with TD and a substantial rate of failure to obtain an USCOM measurement suggest that this device is unsuitable as a monitoring tool in intensive care.

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included a convenience sample of adult patients in a general intensive care unit and a cardiac surgical unit who had either a pulmonary artery catheter or a thermistor-tipped arterial catheter in place for thermodilution meas-

urement of CO. The study was conducted between December 2006 and December 2007.

Apparatus and data collection

Thermodilution cardiac output

Thermodilution (TD) measurements of CO were obtained either by pulmonary artery thermodilution (TDpa), using a pulmonary artery balloon-tipped flotation catheter, or by transpulmonary thermodilution (TDtp), using a femoral or axillary artery catheter (Pulsiocath, Pulsion Medical Systems, Sydney, NSW). Measurements were made using triplicate bolus injections of 0.9% saline (10 mL at room temperature for TDpa; or 15 mL [20 mL if body weight > 100 kg] chilled for TDtp) administered at random over the respiratory cycle. Three good-quality thermodilution curves were averaged to obtain TD CO.

USCOM cardiac output

All USCOM measurements of CO were made by one investigator (MB), who had received standardised training from USCOM and had undertaken at least 65 ultrasonic CO assessments before the study.

The ultrasound probe was placed initially on the suprasternal angle (aortic-valve view) and manipulated to obtain the best waveform and audible signal. The pulmonary-valve view (left sternal edge starting at the second intercostal space) was assessed if the aortic-valve view produced a poor-quality waveform or access was difficult (eg, in the presence of a sternotomy wound or central venous line). Doppler waveforms were averaged over a respiratory cycle to calculate the USCOM CO. The time to obtain an acceptable signal was limited to 15 minutes.

Procedure

Cardiac output and cardiac index (CI) were determined on two occasions in each patient. For post-cardiac surgery patients, measurements were taken within the first 4 postoperative hours and between 08:00 and 10:00 on the first postoperative

day (12–24 hours later). For general ICU patients, measurements were taken on a convenience basis and repeated within 24 hours. USCOM measurements were made before TD measurements, with the USCOM operator blinded to the TD measurement by covering the bedside monitor.

If a patient was receiving inotropic or vasoactive infusions, these were not adjusted during the observation period.

Data analysis

Continuous data were expressed as mean and standard deviation (SD). Data were analysed using the statistical package StatView 5 (SAS Institute, Cary, NC, USA). Statistical significance was set at $P < 0.05$.

The Bland–Altman method was used to assess bias and limits of agreement (LOA) of the two methods.¹⁴ The precision (95% confidence interval) of the estimated LOA was also determined.¹⁴ The mean percentage error was calculated as $\text{LOA}/\text{mean CI} \times 100$,¹⁵ where CI is the cardiac index. We considered agreement acceptable where mean percentage error was $< 30\%$.¹⁵

Body surface area determined by the Du Bois formula was used to calculate cardiac index for both TD and USCOM methods. Percentage change in cardiac index (ΔCI) was calculated as:

$$\Delta\text{CI} = (\text{TD CI}_2 - \text{TD CI}_1) / \text{TD CI}_1 \times 100.$$

Correlations between ΔCI values determined by different methods were assessed by the Pearson product moment correlation coefficient (R^2); and $\Delta\text{CI} > 15\%$ was considered clinically meaningful.

Doppler waveforms were printed and assessed for waveform quality by an USCOM expert (B Jacobson, Head of Clinical Marketing, USCOM Ltd). Doppler profiles met an ideal standard and were “acceptable” if they had full systolic width and continuous (or mostly continuous) sides forming a peak. Doppler profiles did not meet this ideal standard (“unacceptable”) if the sides were continuous (or mostly continuous) and formed a peak but did not have full systolic width. If profiles were not quite adequate, but the peak velocity was > 1.5 m/s, in association with a normal to high heart rate, then they were classed as “acceptable”.

Receiver operator characteristics (ROC) analysis (SPSS version 14.0, SPSS, Chicago, Ill, USA) was used to assess the agreement between USCOM CI and TD CI with respect to low (< 2.5 L/min/m²), normal (2.5–3.6 L/min/m²), and high (> 3.6 L/min/m²) CI values as determined by TD.

Data obtained when the cardiac rhythm was atrial fibrillation were identified post hoc and analysed as a subgroup.

Results

Between December 2006 and December 2007, data were obtained on 110 occasions for 55 patients. Doppler wave-

Table 1. Patient characteristics

	Cardiac surgical (n = 19)	General (n = 20)
Age in years (SD)	68.4 (8.9)	61.2 (17.9)
Sex (M/F)	14/5	13/7
APACHE II score	–	24 (7.8), 12–40
Clinical classification	CABG, 63% TVR, 5% MVR + TVR, 11% CABG + AVR, 16% CABG + MVR, 5%	Sepsis, 45% Other medical, 35% Surgical, 20%

CABG = coronary artery bypass graft. TVR = tricuspid valve replacement. MVR = mitral valve replacement. AVR = aortic valve replacement.

forms were unable to be obtained on 18 of these occasions (16%). Data were analysed only for patients with two measurements available, resulting in a final sample of 39 comparisons in 39 patients.

The patients were predominantly men (27, 69%) and had a mean age of 64.7 years (SD, 14.5 years). They comprised 20 general ICU patients and 19 post-cardiac surgery patients. Their characteristics are shown in Table 1. An intra-aortic balloon pump (IABP) was present for 10 measurements (in six post-cardiac surgery patients). The cardiac rhythm was regular (sinus rhythm, sinus tachycardia or paced) for 68 measurements (87%) and atrial fibrillation for the remaining 10 measurements.

Thermodilution measurements

Mean TD CI was 3.4 L/min/m² (SD, 1.0 L/min/m²) with a range of 2.0–6.0 L/min/m². Thermodilution CI was measured by TDpa on 40 occasions (52%) (all post-cardiac

surgery patients) and by TDtp on 38 occasions (all general ICU patients). The coefficients of variation for TDpa and TDtp triplicate measurements were 6% and 5%, respectively (18% and 6%, respectively, for TD measurements in the presence of atrial fibrillation).

USCOM measurements

The aortic-valve view was used for 47 USCOM CI measurements (60%) and the pulmonary-valve view for 31 (40%).

USCOM CI was significantly correlated with TD CI ($R^2 = 0.33$, $P < 0.001$). The bias was 0.6 L/min/m² (95% confidence limits [CLs], 0.4–0.8 L/min/m²), and the mean percentage error was 56% (95% CLs, 45%–65%) (Figure 1 and Table 2). For the 10 measurements made with an IABP present, bias was –0.05 L/min/m², and LOA was –1.25 L/min/m². Of the Doppler profiles, 22 (28%) were assessed as acceptable. The bias for this subgroup was 0.7 L/min/m² (95% CLs, 0.2–1.2 L/min/m²), and the mean percentage error was 62% (95% CLs, 38%–65%).

Ten datasets were obtained while the cardiac rhythm was atrial fibrillation. Analysis of the remaining 33 dataset pairs taken in the absence of atrial fibrillation showed a mean percentage error >30%, although the 95% confidence interval for the subgroup with acceptable Doppler profiles and no atrial fibrillation included 30% (95% CLs, 22%–67%) (Table 2).

For USCOM CI determination of low, normal and high CI levels, the area under the ROC curve was significantly different from 50% for the sample as a whole ($P = 0.01$) but not for the subgroups (Table 3). The area under the ROC curve for the whole sample was 67% (Table 3 and Figure 2).

Change in cardiac index over time

The mean change in TD CI was a decrease of 0.04 (SD, 0.8) L/min/m², with a maximum decrease of 2.6 L/min/m² and a maximum increase of 1.5 L/min/m². Nineteen (49%) of the 39 paired measurements showed a change in TD CI >15%.

The percentage change in USCOM CI was significantly correlated with percentage change in TD CI for the overall group ($R^2 = 0.48$, $P = 0.002$) and for the subgroup defined

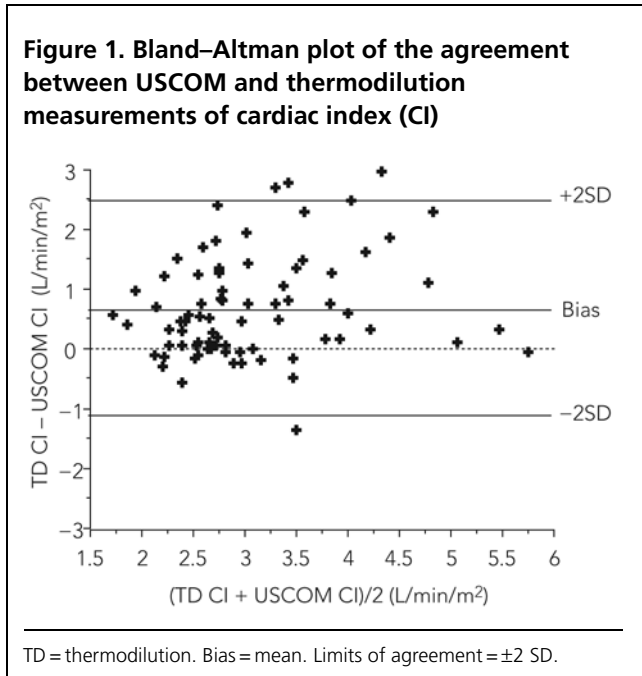


Table 2. Bland–Altman analysis of agreement between USCOM and thermodilution measurements of cardiac index

Group	Correlation (R^2)	Mean cardiac index (L/min/m ²)*	Bias (95% CLs) (L/min/m ²) [†]	2 SDs (95% CLs) (L/min/m ²)	LOA (L/min/m ²) [‡]	Mean % error (95% CLs) [§]
All (n = 78)	0.33 [¶]	3.1	0.6 (0.4–0.8)	1.7 (1.4–2.0)	–1.1 to 2.4	56% (45%–65%)
Acceptable (n = 22)	0.26 [¶]	3.7	0.7 (0.2–1.2)	2.3 (1.4–2.4)	–1.6 to 3.0	62% (38%–65%)
AF excluded						
All (n = 66)	0.42 [¶]	3.0	0.6 (0.4–0.8)	1.5 (1.2–1.8)	–0.9 to 2.1	50% (40%–60%)
Acceptable (n = 15)	0.62 [¶]	3.6	0.3 (–0.1–0.7)	1.6 (0.8–2.4)	–1.3 to 1.9	44% (22%–67%)

CL = confidence limit. * Mean cardiac index = (TD CI + USCOM CI)/2, where TD CI = thermodilution cardiac index, and USCOM CI = USCOM cardiac index. † Bias = mean difference of TD CI and USCOM CI. ‡ LOA (limits of agreement) = bias ± 2SD. § Mean % error = LOA/mean CI × 100. ¶ Significant.

Table 3. Receiver operating characteristics analysis of USCOM measurement identifying low, normal and high cardiac index values

Group	No. of measurements	Area under ROC curve	95% CLs	P
All	78	0.67	0.54–0.79	0.01
Acceptable only	22	0.58	0.33–0.83	0.55
AF excluded				
All	66	0.65	0.51–0.78	0.07
Acceptable only	15	0.37	0.07–0.68	0.47

ROC = receiver operator characteristics. AF = atrial fibrillation. CL = confidence limit.

by TD CI change > 15% ($R^2=0.32$, $P=0.01$). The plot of percentage change in TD CI versus percentage change in USCOM CI is shown in Figure 3.

USCOM CI varied in the same direction as TD CI on 84% of the occasions (16/19) that TD CI changed > 15% (and 88% [14/16] after exclusion of atrial fibrillation data). On 74% of the occasions (15/19) that TD CI changed > 15%, USCOM CI also changed > 15%, although on three occasions (16%) the change was in the opposite direction (75% [12/16] occasions after exclusion of atrial fibrillation data, with two occasions [17%] in the opposite direction). Conversely, USCOM CI

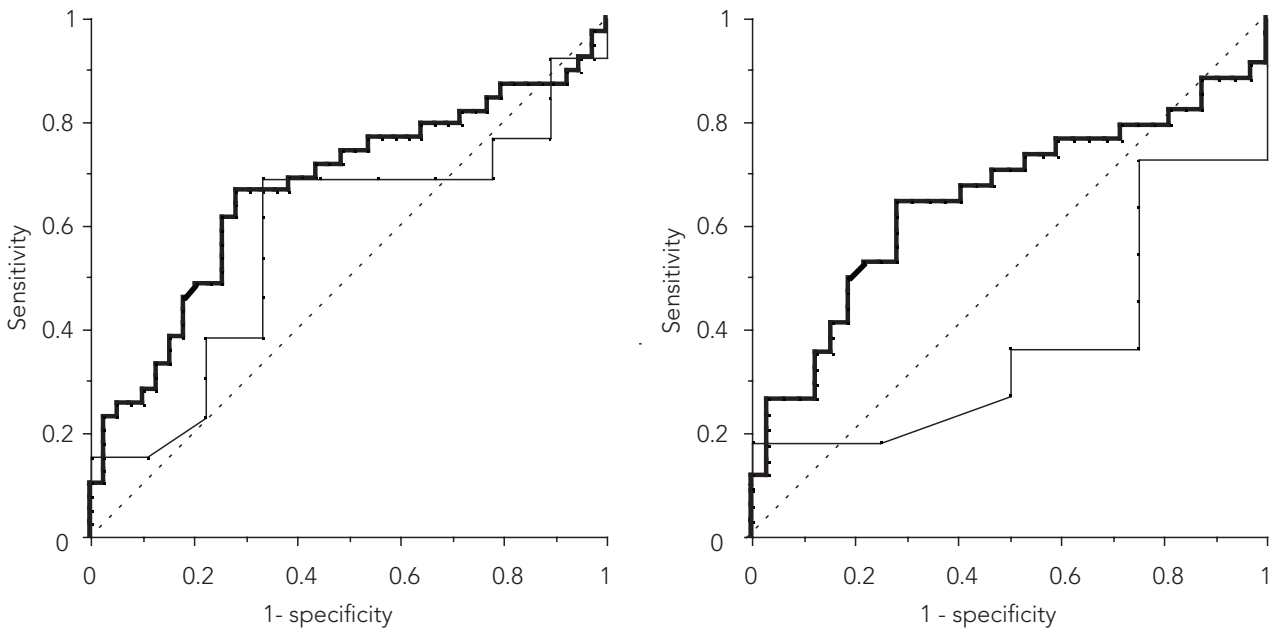
changed > 15% on 45% (9/20) occasions when TD CI did not (47%, 8/17 after exclusion of atrial fibrillation data).

Discussion

In this group of patients, USCOM measurements of CO did not show acceptable agreement with TD measurements of CO. The USCOM technique tended to significantly underestimate CI compared with thermodilution, with a bias of 0.6 L/min/m² and mean percentage error of 56%. Moreover, analysis of Doppler profiles that met strict criteria for acceptability did not result in improved agreement, with a bias of 0.7 L/min/m² and mean percentage error of 62%. An even smaller group (15 measurements) that met the strict Doppler profile standards and excluded measurement points in which the cardiac rhythm was atrial fibrillation did show improved, although still unacceptable, agreement, with a bias of 0.3 L/min/m² and mean percentage error of 44%. Furthermore, in this study, Doppler profiles were unable to be obtained in 16% of attempts, and only 28% of Doppler profiles included in the analysis were considered to meet an ideal clinical standard.

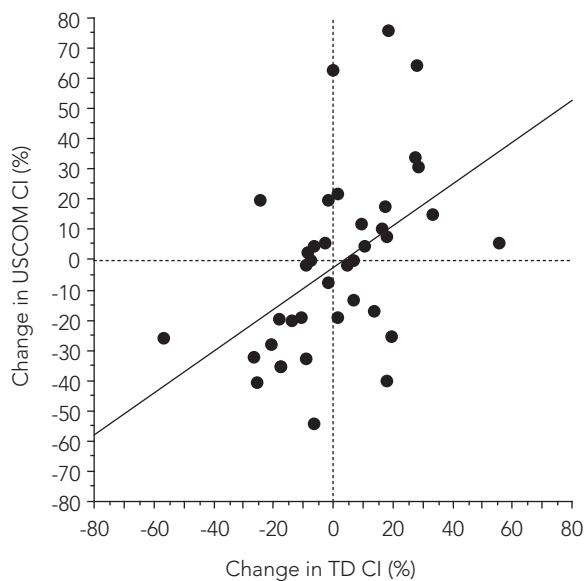
The poor bias and precision were consistent with our results for sensitivity and specificity for identifying low, normal and high CI values. In terms of meaningful changes to CI (>15%), the USCOM CI measurements tracked

Figure 2. Receiver operator characteristics (ROC) analysis for total sample of cardiac index measurements (left panel) and sample with data excluded when atrial fibrillation was present (right panel)



The outcome parameter for ROC analysis was agreement of the USCOM cardiac index with the thermodilution cardiac index with respect to low (< 2.5 L/min/m²), normal (2.5–3.6 L/min/m²), or high (> 3.6 L/min/m²) cardiac index (thick line). The analysis was from lowest to highest value and ≤ criterion value. Agreement for the subgroup of Doppler profiles that met an ideal standard (“acceptable”) is indicated by the thin line.

Figure 3. Correlation of changes in cardiac index measured by the thermodilution and USCOM techniques



Correlation of percentage change (Δ) in cardiac index for measurement pairs in individual patients by the TD and USCOM methods.

Vertical lines represent Δ TD CI \pm 15%.

Δ USCOM CI = $-2.482 + 0.691 \times \Delta$ TD CI. $R^2 = 0.234$.

appropriately on 74% of occasions, but there was a high false-positive rate: USCOM CI changed $> 15\%$ on 45% of occasions when TD CI did not.

Two previous studies in postoperative cardiac surgery patients reported “very good agreement” and “good equivalence” of USCOM with TD measurements.^{4,10} However, neither study described a-priori criteria for agreement. Two other studies, also in cardiac surgery patients and both defining a-priori criteria for agreement, found lack of agreement, with a bias (LOA) of 0.2 (–1.17 to 1.62) L/min/m² (mean percentage error, 52%), and 0.79 (–2.07 to 3.65) L/min/m², respectively.^{12,13}

A number of factors may account for the poor agreement between USCOM and TD measurements. The quality of the CO measurement is operator-dependent and probably also influenced by patient factors. The angle of insonation can be affected by tissue swelling, intravenous catheter placement and mechanical ventilation. The Doppler signal may be damped by intrathoracic air.⁵ There may also be considerable inaccuracy in the estimation of valve diameter.¹² However, the change in ultrasonic CO in an individual is independent of the estimate of valve area. This, and the inaccuracy of CO determination even for Doppler profiles

that met the strict criteria for acceptability also suggest that factors other than those dependent on the operator are significant contributors to the poor agreement.

The failure to obtain a measurement in 18% of attempts raises questions regarding the applicability of the USCOM device. Tan et al reported that 25% of examinations with the patient in the supine position failed to produce a satisfactory Doppler profile, but that changing to a left lateral tilt of 15° to 30° enabled a satisfactory profile to be obtained.⁴ However, the researchers allowed up to 45 minutes for examinations.⁴ In our study, patients were supine, and examinations were abandoned after 15 minutes, as it is commonly considered undesirable to reposition patients, and time is often limited.

The precision of CO determinations is affected by irregular cardiac rhythms such as atrial fibrillation.¹⁶ The precision of the methods being compared determines the level of agreement considered acceptable, as well as the change in CO that indicates a real change.¹⁴ We did not adjust the mean percentage error limit to take account of any effect of atrial fibrillation. However, the result of poor agreement, whether or not atrial fibrillation was included in the analysis, is consistent with the findings of Van den Oever et al.¹²

Both TDpa and TDtp were used as the clinical standard against which to assess agreement. Although TDpa has been the clinical standard commonly used to assess measurement agreement, TDtp has been shown to give reliable results when compared with TDpa CO.¹⁷ TDtp CO demonstrates a slightly positive bias compared with TDpa CO.¹⁸ Although this may have had a slight effect on the bias of USCOM CI with respect to TD CI, the values for LOA will be valid, as the coefficients of variation for TDtp and TDpa were similar and consistent with reported values of 3.1% to 8.7%.^{19–23}

Conclusions

In this study, CO measured by the USCOM device did not show acceptable agreement with CO measured by thermodilution. Furthermore, the USCOM device did not reliably identify the presence of a low, normal or high CO as measured by thermodilution; nor did it reliably track changes in CO. The poor agreement and rate of failure in obtaining an acceptable Doppler profile suggest that this device, at present, has little clinical utility in intensive care.

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