

## Clinical evaluation of USCOM ultrasonic cardiac output monitor in cardiac surgical patients in intensive care unit

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**Background.** The USCOM ultrasonic cardiac output monitor (USCOM Pty Ltd, Coffs Harbour, NSW, Australia) is a non-invasive device that determines cardiac output by continuous-wave Doppler ultrasound. The aim of this study was to evaluate the accuracy of the USCOM device compared with the thermodilution technique in intensive care patients who had just undergone cardiac surgery.

**Methods.** We conducted a prospective study in the 18-bed intensive care unit of a 600-bed tertiary referral hospital. Twenty-four mechanically ventilated patients were studied immediately following cardiac surgery. We evaluated the USCOM monitor by comparing its output with paired measurements obtained by the standard thermodilution technique using a pulmonary artery catheter.

**Results.** Forty paired measurements were obtained in 22 patients. We were unable to obtain an acceptable signal in the remaining two patients. Comparison of the two techniques showed a bias of 0.18 and limits of agreement of –1.43 to 1.78. The agreement may not be as good between techniques at higher cardiac output values.

**Conclusions.** The USCOM monitor has a place in intensive care monitoring. It is accurate, rapid, safe, well-tolerated, non-invasive and cost-effective. The learning curve for skill acquisition is very short. However, during the learning phase the USCOM monitor measurements are rather 'operator dependent'. Its suitability for use in high and low cardiac output states requires further validation.

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Thermodilution cardiac output measurements have been routinely performed as part of intensive care practice since the introduction of the balloon-directed thermistor-tipped pulmonary artery catheter in the 1970s.<sup>1</sup> However, controversy still exists regarding the use of this device and the risks of right ventricle and pulmonary artery catheterization remain significant, even though they are low with experienced operators.<sup>2,3</sup> A rapid, reliable and completely non-invasive cardiac output measurement device that is user-friendly would enable clinicians to determine this important haemodynamic variable more readily.

The USCOM ultrasonic cardiac output monitor (USCOM Pty Ltd, Coffs Harbour, NSW, Australia) provides non-invasive transcutaneous measurement of cardiac output. It was introduced for clinical use in 2001 and is based on continuous-wave Doppler ultrasound.

The flow profile is obtained by using a transducer (2.0 or 3.3 MHz) placed on the chest in either the left parasternal position to measure transpulmonary blood flow or the suprasternal position to measure transaortic blood flow. Standard ultrasound conducting gel is used. This flow profile is presented as a time–velocity spectral display showing variations of blood flow velocity with time. Once the optimal flow profile is obtained, the trace is frozen. The cardiac output is then calculated from the equation:

$$\text{cardiac output} = \text{heart rate} \times \text{stroke volume}$$

where the stroke volume is the product of the velocity time integral (VTI) and the cross-sectional area (CSA) of the chosen valve. VTI represents the distance that a column of blood travels with each stroke and is calculated from the peak velocity detected. In the USCOM monitor, this is

performed using a unique TouchPoint® semi-automated flow profile trace which requires the operator to mark out the flow trace for a chosen stroke of the heart. This also measures the heart rate at the same time. The CSA of the chosen valve is determined by applying height-indexed regression equations, which are incorporated into the USCOM device, or by using another imaging method (e.g. two-dimensional echocardiography). The regression equation used to calculate the aortic valve area is that proposed by Nidorf and colleagues.<sup>4</sup> The pulmonary valve area is calculated by a separate regression equation derived from the Nidorf equation (see Appendix).

The aim of this study was to evaluate the accuracy of the USCOM device compared with the thermodilution technique using a pulmonary artery catheter in intensive care patients who had just undergone cardiac surgery.

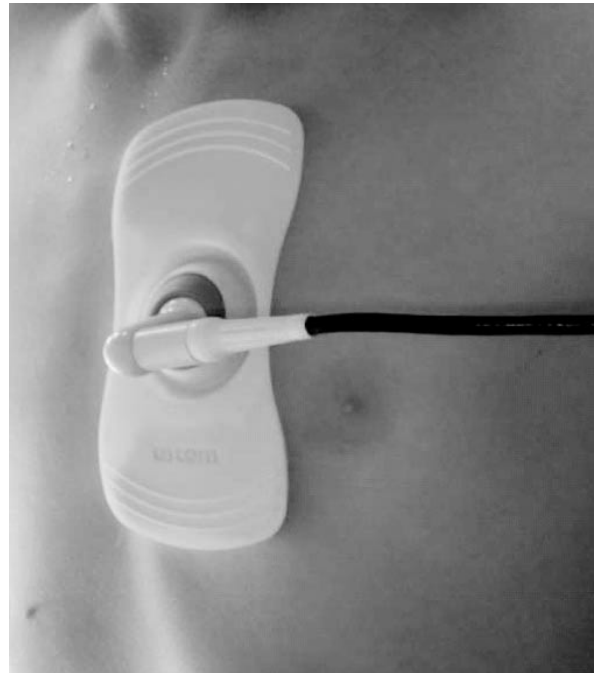
## Methods

Paired measurements of cardiac output were determined in patients admitted to the intensive care unit after cardiac surgery. Institutional ethics approval was obtained for the conduct of the trial. Informed written consent was obtained from the patients on the night prior to surgery. Patients were enrolled into the study only if they were haemodynamically stable and if a pulmonary artery catheter (7.5 gauge Arrow, Arrow International, Reading, PA, USA) had been inserted as part of intra-operative monitoring.

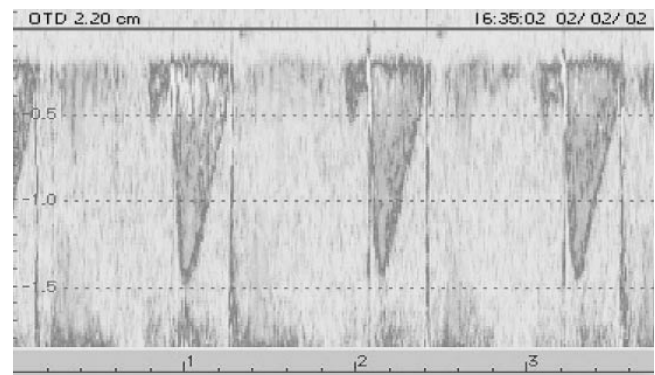
All the patients were sedated and their lungs were mechanically ventilated. Whenever the standard thermodilution cardiac output was measured using the pulmonary artery catheter ( $CO_{PAC}$ ) as part of routine management, a measurement was obtained using the USCOM device ( $CO_{USCOM}$ ),  $CO_{PAC}$  was measured using 10 ml bolus injections of 5% dextrose–water at approximately 4°C. Three to five thermodilution readings were performed and the mean value was recorded as the  $CO_{PAC}$ .

The USCOM transducer was placed on the patient's chest anteriorly (Fig. 1) and the optimal transpulmonary flow profile (Fig. 2) was obtained before the corresponding thermodilution measurements were performed. The USCOM real-time flow profile was recorded and  $CO_{USCOM}$  was determined on completion of measurement of  $CO_{PAC}$  in order to minimize the time difference between the paired sets of measurements. The time taken to obtain the optimal flow profile, the transducer site and the patient position were also recorded.

One to three sets of paired measurements were obtained from each patient. Measurements ceased when the patient was ready for weaning from mechanical ventilation. The USCOM measurements were performed by a single operator (HLT) who was blinded to the measurements obtained with the pulmonary artery catheter. Any complications encountered using the USCOM device were noted.



**Fig 1** The USCOM transducer placed on a patient's chest anteriorly.



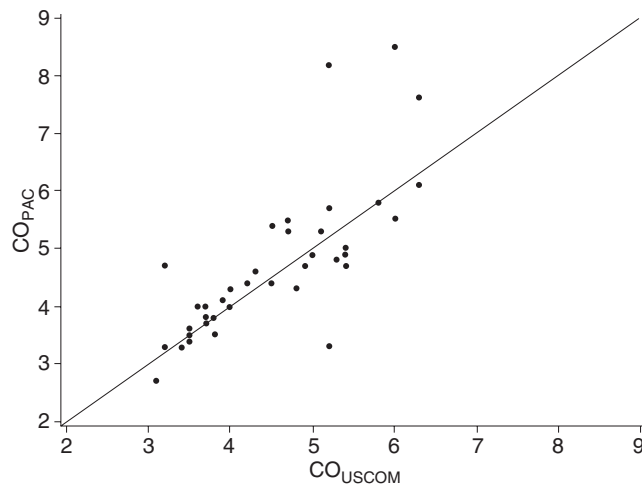
**Fig 2** The optimal transpulmonary flow profile as depicted on the display screen of the USCOM device.

## Statistics

The method of Bland and Altman<sup>5</sup> was used to estimate the bias and limits of agreement between the two techniques for estimation of cardiac output. A linear regression model was used to examine whether the bias was associated with gender, age or body mass index.

## Results

We obtained valid data on 16 male and 6 female patients with a mean age of 63.5 (range 43–78) years and a mean BMI of 28.9 (SD 5.2). Forty sets of paired measurements were obtained from 22 patients. Satisfactory flow profiles were obtained in the supine position in 30 examinations. In the remaining 10 examinations, changing to a 15°–30° left lateral tilt position allowed a satisfactory trace to be



**Fig 3** Graph showing the pairs of cardiac output estimates derived using the pulmonary catheter (CO<sub>PAC</sub>) and the USCOM device (CO<sub>USCOM</sub>). The line of complete agreement is superimposed for reference.

obtained. The pulmonary flow profiles were found over the second to fourth intercostal spaces (second intercostal space,  $n=11$ ; third intercostal space,  $n=25$ ; fourth intercostal space,  $n=4$ ). No difficulties were encountered in the placement of the transducer; adequate flow profiles were obtained with the transducer in positions that were at least 2 cm from the sternotomy wound. No measurements were performed in two other patients enrolled in the study, as a flow profile could not be obtained within 45 min.

Theoretically, shivering may cause movement artifacts, although even severe shivering did not appear to alter the measurements we obtained. However, in four patients who were shivering, we used only those measurements obtained after the shivering had stopped.

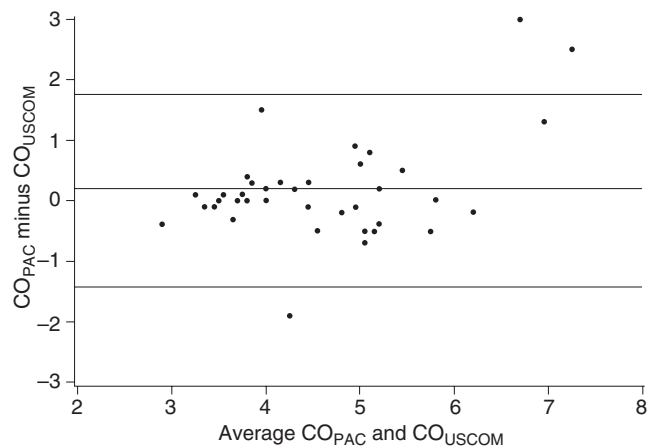
The cardiac output values obtained with the two methods are shown in Figure 3 and in the Bland–Altman plot in Figure 4. The mean of the differences (estimate of bias) between the two techniques was 0.18 (95% CI,  $-0.09$  to  $0.44$ ), with a standard deviation of 0.82 and a standard error of 0.13. The limits of agreement for the two techniques were  $-1.43$  ( $-1.88$  to  $-0.98$ ) and  $1.78$  ( $1.33$  to  $2.23$ ). The Bland–Altman plot showed that as the cardiac output increased, the difference between the two methods also increased.

Linear regression analysis was applied to the primary comparison of CO<sub>PAC</sub> with standard CO<sub>USCOM</sub> estimates. None of the variables, gender ( $P=0.46$ ), age ( $P=0.75$ ) or BMI ( $P=0.53$ ) showed any statistically significant association with bias.

There were no adverse events or complications related to the use of the USCOM device.

## Discussion

Our study found very good agreement between the cardiac output measurements determined by the USCOM device and



**Fig 4** The Bland–Altman plot showing the difference plotted against the mean of each pair of data points, with lines showing the bias and upper and lower limits of agreement superimposed.

those determined by the thermodilution method using a pulmonary artery catheter.

The Bland–Altman method was used because it measures the extent of deviations from the line of complete agreement (no bias) between the methods. This is different from the correlation coefficient which measures how close to a straight line the pairs of measurements lie, but that line need not be the one of complete agreement.

There are five apparent outliers in the graph showing the pairs of cardiac output estimates (Fig. 3). These were from five different patients, suggesting that the differences between the cardiac output measurements were not due to patient factors. These outliers were not present when we compared the pulse measurements obtained by the two methods. Hence the difference in the cardiac output is due to the stroke volume estimation which is derived from the flow profile obtained. This is confirmed by the presence of the same five outliers in the graph comparing the pairs of stroke volume estimates. In three of the outliers, the pulmonary artery cardiac output values were between  $7.6$  and  $8.5$  litre  $\text{min}^{-1}$  while the USCOM cardiac output values were between  $5.2$  and  $6.3$  litre  $\text{min}^{-1}$ . In these cases of relatively high cardiac output, the USCOM monitor appeared to underestimate the cardiac output. This is probably due to the failure to capture the peak flow. This error can be reduced in practice by making more frequent measurements and taking the average. The accuracy of the USCOM monitor at high cardiac output should also be evaluated in greater depth, for example a comparative study of the pulmonary artery catheter and USCOM monitor in septic patients.

The limits of agreement in the Bland–Altman plot are based on 95% inclusion; hence the three outliers are expected. We used the average of three thermodilution measurements as the gold standard to compare with the USCOM monitor for two reasons: this is our standard practice, and furthermore this method has been validated extensively in the literature.<sup>6</sup>

The analyses presented in this paper are based on more than one measurement per patient. Statistical analyses aimed at estimating mean values and confidence intervals would need to take account of this correlation. However, in this paper our interest is not in the actual values at any time, but on the agreement between the two methods of measurement. Although some correlation does exist between data points belonging to the same patients, this does not interfere with the estimates of bias and precision that we have presented.

Measurement of cardiac output using Doppler-based echocardiography techniques has been extensively studied.<sup>7</sup> These techniques are based on either continuous-wave or pulsed-wave Doppler techniques.<sup>8</sup> Pulsed-wave and continuous-wave techniques have been compared with the thermodilution method and good agreement has been found.<sup>9</sup> The USCOM monitor is an improvement on the previously available devices in several respects. It is based on the continuous-wave Doppler technique and thus has two advantages over pulsed-wave Doppler: more accurate measurement of higher velocities, and the added simplicity which comes from the lack of the need to obtain a two-dimensional image of the heart and outflow tract and subsequent accurate selection of a sample area.

Continuous-wave Doppler devices have been studied since the early 1980s. The main problems encountered are an inability to obtain acceptable flow signals with the transthoracic approach and difficulty in measurement of the cross-sectional area of the flow.<sup>10,11</sup> In the study by Vandenberghe and colleagues,<sup>12</sup> 22% of the patients did not have an acceptable ascending aortic flow signal. The trans-oesophageal approach was found to be more reliable.<sup>13</sup>

The USCOM device has addressed both these issues. Using the USCOM transducer, Phillips<sup>14</sup> demonstrated 100% detection of flow signals in spontaneously breathing adult and paediatric patients. Our study has shown that the flow detection rate in patients whose lungs are mechanically ventilated was 91.7% (22 out of 24 patients). The transthoracic approach during mechanical ventilation may be limited by suboptimal signal detection because of excess soft tissue or gas. Both the patients in whom we were unable to obtain a flow profile suffered from significant chronic airflow limitation. In most of the patients, changing from a supine position to a 10°–15° left lateral tilt improved the Doppler signal. Estimation of the cross-sectional area of the flow is simplified in the USCOM device since the valve area is calculated from the patient's height using an incorporated algorithm.

The USCOM device has previously been compared with conventional echocardiographic assessment of cardiac output in healthy patients and good correlation has been found.<sup>14</sup> There are no published studies to date validating the accuracy of the USCOM monitor during mechanical ventilation. In our study, we found that transpulmonary derived cardiac output determined by the USCOM monitor

showed good agreement with that determined by the thermodilution method in post-cardiac surgical patients on mechanical ventilation. The accuracy of the USCOM device depends on obtaining accurate VTI and valve diameter measurements. An accurate VTI measurement requires a good flow signal and its correct interpretation. As in all Doppler techniques, inadequate beam alignment with the blood flow direction will lead to suboptimal Doppler signals.<sup>8</sup> Failure to trace the VTI spectrum correctly will also lead to measurement error. Our results suggested that there is better agreement between the two methods in the physiological cardiac output range than at higher cardiac outputs (Fig. 3). Further evaluation of the USCOM device in low and high cardiac output states is warranted.

At present, there is much controversy regarding the utility and safety of the pulmonary artery catheter. At the same time, recent evidence highlights the importance of early goal-directed therapy in critically ill patients.<sup>15</sup> A safe and reliable method of non-invasive cardiac output measurement is welcome. The USCOM device is attractive in many ways. As an ultrasound technique, it is very safe. In contrast with transoesophageal Doppler methods, it is well tolerated by awake patients and avoids the problems of an oesophageal probe. Although we used only the parasternal access to detect pulmonary flow, other access sites can be used to detect aortic and mitral flow. It is easy to use, gives a measurement rapidly and can be used repeatedly to measure the trend over time. Some instruction and practice is required to acquire the skill to obtain an acceptable signal, but this training time and cost is negligible compared with that of mastering conventional transthoracic echocardiography. There is no set-up time as the device can be used immediately. The USCOM device is also very cost effective. The machine is estimated to cost A\$40 000 and the cost of the consumables is negligible since only the standard ultrasound conducting gel is required. The same machine can be shared among many patients since it is very compact and mobile.

The role of the USCOM monitor in haemodynamic monitoring is evolving. It should be noted that the USCOM monitor is limited to cardiac output measurement and gives no indication of other haemodynamic variables, such as pressure measurements, vascular resistance or stroke work calculations. In addition, it does not provide the means to measure mixed venous oxygenation. Thus the USCOM monitor does not completely replace the pulmonary artery catheter. However, in situations where cardiac output measurement is most pertinent to patient management, the USCOM monitor is superior in speed, safety and cost. It has potential applications in intensive care, anaesthesia, cardiology and research.

## Acknowledgement

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## Appendix

The regression equation for calculating the pulmonary annular diameter (PV) is (data supplied by manufacturer):

$$PV(\text{cm}) = 0.11 \times (\text{height in cm}) + 0.274.$$

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