Accuracy and precision of the ultrasound cardiac output monitor (USCOM 1A) in pregnancy: comparison with three-dimensional transthoracic echocardiography

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Editor’s key points
- This study aimed to measure agreement between the non-invasive ultrasound cardiac output monitor (USCOM) and three-dimensional transthoracic echocardiography (3D-TTE) in pregnant women.
- USCOM has acceptable agreement with 3D-TTE for the measurement of cardiac output (CO) in pregnancy.
- The mean percentage difference between both devices was around 32% and 27% for CO and stroke volume, respectively.
- The positive bias with the USCOM in the flowtrace mode may be due to the hyperdynamic pregnant state.

Background. Cardiac output (CO) monitoring is helpful in the assessment of critically ill pregnant women, but invasive monitors are often unsuitable for use. We aimed to measure agreement between the non-invasive ultrasound cardiac output monitor (USCOM) and three-dimensional transthoracic echocardiography (3D-TTE) in pregnant women.

Methods. Healthy pregnant women from 25 weeks gestation onwards participated. In the left lateral position at rest, CO was measured with the USCOM and 3D-TTE. A single operator performed all USCOM measurements, with a different operator performing all echocardiography. Both were blinded to results from the other device. Each USCOM trace was analysed using two modes: flowtrace (FT) and touchpoint (TP). A second, blinded USCOM reading was taken to assess reproducibility.

Results. USCOM readings were obtained in 92, and 3D-TTE images in 85 participants. The mean CO was 5.7, 7.7, and 6.2 litre min⁻¹ measured by 3D-TTE, USCOM FT, and USCOM TP, respectively. USCOM bias was +2.0 litre min⁻¹ (FT) and +0.4 litre min⁻¹ (TP). Limits of agreement were -0.2 to +4.2 litre min⁻¹ (FT) and -1.4 to +2.3 litre min⁻¹ (TP). The mean percentage difference was 32.6% (FT) and 31.4% (TP) for CO and 27.0% (FT) and 27.5% (TP) for stroke volume. Intraclass correlation between repeated USCOM readings was 0.9 (FT) and 0.86 (TP).

Conclusions. USCOM has acceptable agreement with 3D-TTE for the measurement of CO in pregnancy. The positive bias of the USCOM, particularly in the FT mode, may be due to the hyperdynamic cardiovascular state in pregnancy. We suggest using the TP mode in this patient population.

Keywords: heart, cardiac output; measurement techniques, cardiac output; monitoring, echocardiography; monitoring, ultrasound; pregnancy

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Women who become critically unwell during pregnancy present specific challenges for cardiovascular monitoring. During normal pregnancy, cardiac output (CO) increases by ~50% because of increased circulating volume, inotropy, and chronotropy.1 This additional cardiovascular reserve allows effective compensation for illness, but also means that the severity of illness may be underestimated. Pathological conditions of pregnancy such as preeclampsia have complex effects on the cardiovascular system.2 3 Haemodynamic information provided by CO monitoring can therefore be of value in both diagnosis and treatment of critically ill pregnant women.4 The use of an invasive device in this group is undesirable as such women are usually breathing spontaneously, not sedated, and may be labouring or coagulopathic.5 The ultrasound cardiac output monitor (USCOM 1A, USCOM Ltd, Australia) is entirely non-invasive, measuring CO via a Doppler probe placed on the suprasternal notch. Previous studies in non-pregnant subjects have compared the USCOM to thermodilution,5–10 pulse contour analysis,11 magnetic resonance imaging,12 two-dimensional transthoracic echocardiography (2D-TTE),13 orthotopic hearts,14 and the ultrasonic flowprobe15 with variable results. A small number of studies have used the USCOM in pregnant women to monitor changes in CO.16–18 Kager and colleagues19 demonstrated the ease of use and reproducibility of the USCOM in pregnant women, but did not compare with a reference method. Maternal haemodynamic changes that have the potential to affect measurement with the USCOM include increased aortic blood
flow and velocity, upward and leftward displacement of the heart by the gravid uterus, and a small increase in left ventricular outflow tract (LVOT) diameter. We therefore wished to assess the accuracy of the USCOM in this population.

In order to assess the accuracy of a device, it must be compared with a reference method. Thrombolysis via the pulmonary artery catheter has been widely used for this purpose, but the error with this method has been reported as ± 40%.

We chose to use three-dimensional transthoracic echocardiography (3D-TTE) as a reference method, having minimal bias and a mean percentage error of 20% or less for the measurement of cardiac volumes. The intra- and inter-observer reproducibility of 3D-TTE has also been shown to be excellent (r > 0.95). The primary aim of this study was to assess the agreement between the USCOM and 3D-TTE for the measurement of CO in pregnant subjects. The secondary aim was to assess the intra-observer reproducibility of the USCOM.

Methods
The study was conducted after approval from the North West regional ethics committee (Ref.: 12/NW/0469). Written informed consent was obtained from all participants. Ninety-two women were recruited from antenatal clinics at a large obstetric unit (8000 deliveries per year). Inclusion criteria were pregnant women between 25 weeks gestation and term with a singleton pregnancy. Exclusion criteria were age < 18 yr, multiple pregnancy, cardiovascular disease (including preeclampsia), current cardiovascular medications, and women in labour.

Weight and height were recorded. Women were asked to lie in the left lateral position for 10 min before and during measurements, to minimize aortocaval compression and stabilize cardiovascular variables. Arterial pressure was measured using a calibrated manual sphygmomanometer, recording diastolic pressure at the 5th Korotkoff sound. CO was measured with both the USCOM (at the suprasternal notch) and 3D-TTE. One measurement was taken with each device as simultaneously as possible and the order of these two measurements was randomized (using a computer-generated random number spreadsheet). A second USCOM measurement was then taken immediately afterwards, to assess reproducibility with this device. The TTE images were all acquired and analysed by a consultant cardiologist specialized in cardiac imaging (V.S.). The USCOM measurements were all taken by a different single operator (H.M.) who had been trained by a representative of the manufacturer and had completed in excess of 30 prior examinations with the device (20 examinations being recommended for competency). Each operator was blinded to the results from the other device.

USCOM measurements
The USCOM uses Doppler ultrasound to measure the velocity of blood flow as it is ejected into the aorta from the left ventricle. A velocity vs time trace is displayed, and this was saved when optimal according to the Freemantle criteria (well-defined Doppler base and peak signal, start and cessation of flow, appropriate scale, and minimal interference). The device then offers two alternative modes of analysis: flowtrace (FT) and touchpoint (TP) (Fig. 1).

The FT mode draws a line AROUND the outer border of all complexes displayed. Reported values in this study are the average of all complexes on screen. The TP mode plots a sharp triangle around each complex. Reported values in this study are the average of three adjacent complexes. Both modes allow for manual adjustment, but <5% of measurements required this. Each participant had two USCOM measurements taken, both of which were analysed using the TP and FT modes. The USCOM operator was blinded to all measurements until both traces had been saved and calculations by the device completed.

TTE measurements
TTE was performed using a Philips IE-33 ultrasound machine (Philips Medical Systems, Eindhoven, The Netherlands) equipped with an X5-1 X-matrix transducer. Three-lead electrocardiogram monitoring was used to allow gating of the images. After image optimization, a full volume 3D data set of the left ventricle was acquired from the apical position. This was done in slight inspiration to optimize endocardial border definition of the anterior wall. In order to achieve the highest frame rate, the 3D volume was acquired over four cardiac cycles. Analysis of volumes throughout the cardiac cycle was performed offline using dedicated semi-automated software (3DQ-Advanced, Q lab 9.0, Philips Medical Systems). Stroke volume (SV) was calculated by subtracting the end-systolic volume from the end-diastolic volume. This was multiplied by heart rate (HR) at the time of acquisition to calculate CO. The LVOT diameter (LVOTd) was measured using 2D echocardiography in the parasternal long-axis view, according to the British Society of Echocardiography Guidelines. This was measured over three consecutive cardiac cycles and the mean used to estimate LVOT area using the formula (π/4 × LVOTd²).

Statistical analysis
Statistical advice was sought prospectively (A. Hart, Lancaster University). Agreement was assessed using Bland–Altman analysis. For each participant, the first USCOM measurement was compared with the 3D-TTE measurement, and the difference plotted against the average of these two measurements. Plots were constructed in this manner for CO, SV, HR, and LVOT cross-sectional area (CSA). According to recommendations by Critchley and Critchley, the following measures of agreement were reported: bias (mean difference between the two methods), precision [standard deviation (so) of the bias], limits of agreement (LOA) [bias (1.96) so], and the mean percentage difference (MPD) (LOA/mean CO). Sample size was calculated according to Bland, by prospective calculation of the expected 95% confidence intervals (CIs) for the LOA [95% CI = ± 1.96 (√(3/n))s, where n is the number of measurements and s the so]. Based on previous studies, we expected precision of the USCOM to be ~1.3 litre min⁻¹. A sample size of 90 would therefore be expected to result in 95% CI for the LOA of ± 0.4 litre min⁻¹.
Intra-observer reproducibility of the USCOM was assessed using scatter plots and intraclass correlation was calculated for the repeated USCOM measurements.

### Results

Ninety-two healthy pregnant women participated over a 2 month period. Baseline characteristics are shown in Table 1. USCOM traces were obtained in all participants, but one trace was lost before TP analysis. The 3D-TTE images were excluded in seven women, as the endocardial border was poorly defined at either end-systole or end-diastole, as visually assessed by the cardiologist. Comparisons of agreement between USCOM and 3D-TTE were therefore possible in 85 women (FT) and 84 women (TP), respectively. Comparisons of agreement between the first and second USCOM measurements were made in 92 women (FT) and 91 women (TP).

When measured by 3D-TTE, USCOM FT, and USCOM TP, respectively, the mean (SD) CO was 5.7 (1.1), 7.7 (1.4), and 6.2 (1.1) litre min⁻¹, and the mean SV was 72 (12), 97 (14), and 77 (12) ml. The mean (SD) HR was the same in all groups, at 80 (11) beats min⁻¹.

Calculated values of agreement for both USCOM FT and USCOM TP with 3D-TTE are shown in Table 2. For the measurement of CO, USCOM bias was +2.0 litre min⁻¹ (FT) and +0.4 litre min⁻¹ (TP). LOA were −0.2 to +4.2 litre min⁻¹ (FT) and −1.4 to +2.3 litre min⁻¹ (TP), respectively. MPD was 32.6% (FT) and 31.4% (TP). For the measurement of SV, USCOM bias was 25 ml (FT) and 5 ml (TP). LOA for SV were −3 to +48 ml (FT) and −15 to +26 ml (TP). MPD for SV was 27.0% (FT) and 27.5% (TP).

The Bland–Altman plots (Fig. 2) show the agreement between USCOM and 3D-TTE for the measurement of CO, SV, and HR, in both the FT and TP modes.

#### Table 1  Participant characteristics (n=92). Values expressed as mean (sd) or median (range)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>FT</th>
<th>TP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>31 (21–48)</td>
<td>31 (21–48)</td>
</tr>
<tr>
<td>Booking weight (kg)</td>
<td>69.0 (15.5)</td>
<td>69.0 (15.5)</td>
</tr>
<tr>
<td>Current weight (kg)</td>
<td>79.1 (15.5)</td>
<td>79.1 (15.5)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>165.4 (7.0)</td>
<td>165.4 (7.0)</td>
</tr>
<tr>
<td>Booking BMI (kg m⁻²)</td>
<td>25.2 (5.4)</td>
<td>25.2 (5.4)</td>
</tr>
<tr>
<td>Current BMI (kg m⁻²)</td>
<td>28.9 (5.5)</td>
<td>28.9 (5.5)</td>
</tr>
<tr>
<td>Gestation (weeks)</td>
<td>29 (25–38)</td>
<td>29 (25–38)</td>
</tr>
<tr>
<td>Systolic AP (mm Hg)</td>
<td>113 (8)</td>
<td>113 (8)</td>
</tr>
<tr>
<td>Diastolic AP (mm Hg)</td>
<td>68 (9)</td>
<td>68 (9)</td>
</tr>
<tr>
<td>HR (beats min⁻¹)</td>
<td>80 (11)</td>
<td>80 (11)</td>
</tr>
</tbody>
</table>

The same USCOM Doppler trace (velocity vs time) is shown in the (a) FT mode and (a) TP mode. Stroke volume (SV) = π × (OTD/2)² × VTI where OTD is the outflow tract diameter, estimated from nomograms within the USCOM according to height and VTI the velocity–time integral (area under the trace). The red line indicates the area used to calculate the VTI.
Table 2  Agreement with 3D-TTE for USCOM FT and TP is reported as bias, precision, LOA, and MPD. 95% CIs are reported for bias. *P < 0.01

<table>
<thead>
<tr>
<th></th>
<th>USCOM FT</th>
<th>USCOM TP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac output</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bias (95% CI)</td>
<td>+2.0 (1.8–2.3)*</td>
<td>+0.4 (0.2–0.6)*</td>
</tr>
<tr>
<td>Precision</td>
<td>1.1</td>
<td>1.0</td>
</tr>
<tr>
<td>LOA</td>
<td>−0.2 to +4.2</td>
<td>−1.4 to +2.3</td>
</tr>
<tr>
<td>MPD (%)</td>
<td>32.6</td>
<td>31.4</td>
</tr>
<tr>
<td>SV (ml)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bias (95% CI)</td>
<td>+25 (23–28)*</td>
<td>+5 (3–8)*</td>
</tr>
<tr>
<td>Precision</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>LOA</td>
<td>+3 to +48</td>
<td>−15 to +26</td>
</tr>
<tr>
<td>MPD (%)</td>
<td>27.0</td>
<td>27.5</td>
</tr>
<tr>
<td>HR (beats min⁻¹)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bias</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Precision</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>LOA</td>
<td>−14 to +14</td>
<td>−13 to +14</td>
</tr>
<tr>
<td>MPD (%)</td>
<td>17.5</td>
<td>16.8</td>
</tr>
<tr>
<td>Outflow tract CSA (cm²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bias (95% CI)</td>
<td>−0.3 (−0.2 to −0.4)</td>
<td></td>
</tr>
<tr>
<td>Precision</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>LOA</td>
<td>−1.2 to +0.6</td>
<td></td>
</tr>
<tr>
<td>MPD (%)</td>
<td>29.5</td>
<td></td>
</tr>
</tbody>
</table>

Figure 3 shows the Bland–Altman plot for CSA of the LVOT. The mean (so) CSA was 2.9 (0.2) cm² when estimated by the USCOM and 3.1 (0.5) cm² when measured with TTE. Bias was −0.3 cm² for the USCOM compared with TTE. In addition to the overall underestimation of CSA by the USCOM, the pattern of data points on the Bland–Altman plot suggests that in estimating CSA according to height, the USCOM has a tendency to underestimate high values and overestimate low values.

Intra-observer reproducibility is shown in Figure 4. Intra-class correlation between repeated USCOM readings was 0.9 (FT) and 0.86 (TP).

Discussion

We wished to assess the accuracy of the USCOM in pregnancy for a number of reasons. The non-invasive nature of this device makes it highly suitable for use in pregnant women, but to our knowledge, its accuracy during pregnancy has not been assessed. Previous studies conducted in non-pregnant patients have shown variable results, with differing reference methods and different patient groups being investigated. A new monitor should be assessed in the patient population for which it is intended, particularly when there is the possibility that the device may perform differently in that population.

Our results showed that for the measurement of CO during pregnancy, there was a positive bias (over-reading) with the USCOM compared with 3D-TTE. This was greatest in the FT mode, at +2.0 litre min⁻¹ (95% CI 1.8–2.3 litre min⁻¹), whereas TP analysis of the same Doppler profiles produced a much lower bias of +0.4 litre min⁻¹ (95% CI 0.2–0.6 litre min⁻¹). This large positive bias observed in the FT mode has not previously been reported, but we suggest that it may be due to the hyperdynamic cardiovascular state of pregnancy. As the FT mode follows the outer contour of the Doppler profile, it may be prone to inclusion of additional artifact signal produced in high-velocity, high-flow states. The positive bias of the USCOM in this study contrasts with a meta-analysis of studies in non-pregnant subjects, which noted a tendency of the USCOM to underestimate CO. This supports our suggestion that the device may perform differently in pregnant subjects.

A large bias alone does not preclude the clinical use of a device; bias can be corrected for, as long as the magnitude of the bias is known, and consistently present. It is the predictability of the device which is most important, and this is defined by the precision and LOA. The relative clinical magnitude of any given LOA can be expressed as the MPD (LOA/mean CO). An MPD of <30% has been recommended as a threshold for clinical acceptability. In our study, we found the precision of the USCOM to be 1.1 litre min⁻¹ for the FT mode and 1.0 litre min⁻¹ for the TP mode. This equates to an MPD for CO measurement of 32.6% and 31.4%, respectively.

In order to explore the observed differences, we assessed agreement between individual components of the CO measurement that we were able to assess using both devices. This included HR, SV, and CSA of the LVOT. The MPD for SV measurement was 27.0% (FT) and 27.5% (TP), with a bias of +25 ml and +5 ml, respectively. As would be expected, there was no bias in the measurement of HR, although the LOA for HR were approximately ±14 beats min⁻¹. This indicates that there was often a slight change in HR between the two measurements, despite being taken at rest and as close together as possible. Given the increased SV in pregnancy, small differences in HR would result in large differences in CO. Therefore, agreement was best when SV was assessed as an independent variable. We also assessed agreement for the CSA. This was an important potential source of error, being estimated from a nomogram based upon the linear relationship of height to aortic annular diameter, rather than directly measured. Overall, there was a small negative bias in the USCOM value, with a mean CSA of 2.9 cm² (USCOM) compared with 3.1 cm² (TTE). This underestimation of CSA by the USCOM in such women is not surprising, given that aortic valve area has been shown to increase slightly during pregnancy. Interestingly, the Bland–Altman plot for CSA (Fig. 3) shows that there is a tendency of the USCOM to ‘normalize’, that is, higher values are underestimated and lower values are overestimated.

We also assessed the intra-observer reproducibility of the USCOM, which we found to be excellent, regardless of which tracing mode was used, with intraclass correlations of 0.9 (FT) and 0.86 (TP). The ease of use was not directly assessed, but it is of note that we were able to obtain USCOM traces in all participants, although previous studies have quoted failure rates of 5–24%. This may reflect an increased ease of use in pregnant subjects.
There are limitations to our study. We did not assess inter-observer reliability of the USCOM, although previous studies have shown this to be very good in pregnant subjects.\(^{19}\) Also, we chose to assess the USCOM in healthy pregnant women, and although this incorporated a wide range of normal COs, there is the potential that the device may perform differently in pathological conditions. A CO monitor should ideally be able to predict response to treatment. The ability of the USCOM to predict, for instance, fluid responsiveness would be hugely beneficial in the treatment of severely preeclamptic women. We were unable to assess the predictive power of the USCOM, and further studies would be useful in this respect.

Having reported the accuracy of the USCOM in pregnant subjects, we must consider how our results influence the choice of CO monitor in clinical practice. Attempting to compare our findings with reported accuracies of alternative devices in pregnancy reveals a paucity of data. The LiDCO plus monitor (LiDCO, UK) has been used to study haemodynamic changes in pregnant subjects after spinal anaesthesia, vasopressors, or oxytocics. However, we are aware of only one study assessing its accuracy in this population; a comparison

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**Fig 2** Bland–Altman plots showing the agreement between 3D-TTE and USCOM (FT, left; TP, right), for measurement of CO (A and B), SV (C and D), and HR (E and F).
with thermodilution in 18 preeclamptic women, reporting a negligible bias and a precision of 0.68 litre min⁻¹.³² Concerns have been raised regarding the accuracy of pulse contour devices in the presence of high or changing vascular resistance.³³ As the USCOM measures the flow of blood at a central point in the arterial system, it may in theory be more appropriate for use in preeclampsia than devices based upon peripheral measurements. Further studies in preeclamptic patients would be pertinent in this respect. Pulse contour devices also require insertion of an arterial cannula, which is not without morbidity and discomfort, and may preclude or delay the instigation of CO monitoring. Alternative non-invasive monitors include finger pressure and bioreactance devices. The finger pressure device has been found to have an MPD of 40% when compared with Doppler echocardiography in pregnant women.³⁴ Bioreactance devices have been used to study changes in CO in pregnancy, but accuracy data in this group are lacking. In a meta-analysis of studies in non-pregnant subjects,³⁵ the pooled MPD for each of four minimally invasive CO monitors (oesophageal Doppler, thoracic electrical bioimpedance, partial CO₂ rebreathing, and pulse contour analysis) was 40–45%. This led the authors to propose a new threshold of 45% MPD for clinical acceptability, challenging the 30% suggested by Critchley and Critchley. They also proposed that clinicians might accept lower accuracy of a monitor, in return for other advantages such as ease of use and non-invasiveness.

In choosing a CO monitor, we are therefore faced with a spectrum of options. The pros and cons of each must be taken into account and balanced in order to choose the most appropriate monitor for a given patient population and clinical situation. In the obstetric setting, the non-invasive nature of the USCOM is a significant advantage. We must ensure, however, that this does not come at the expense of accuracy, which must remain within acceptable limits.

We have reported an MPD for CO measurement with the USCOM which falls just outside the 30% limit set by Critchley and Critchley, but within the 45% limit suggested by Peyton and Chong, and is improved when SV is assessed as an independent variable. We detected a positive bias with the USCOM, particularly when the FT mode was used, which has not previously been reported, and may be due to the hyperdynamic pregnant state. We would advise using the TP mode in this patient group. We believe that the accessibility of this non-invasive monitor enables measurement of CO at an early stage in obstetric patients, before significant clinical deterioration has occurred.

**Authors’ contributions**

H.M.: study design, patient recruitment, performed all USCOM measurements, data collection, data analysis, and writing the manuscript; P.B.: study design and writing the manuscript; V.S.: study design, performed and analysed all echocardiograms, data collection, data analysis, and writing the manuscript.
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Declaration of interest

None declared.

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