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ORIGINAL RESEARCH

Standardization and quality control of the introduction of a noninvasive cardiac output monitor for pregnancy measurements in a low- and middle-income country

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Abstract

Introduction: There is increasing awareness of the role of the maternal cardiovascular system in complicated pregnancies. Despite the high disease burden, noninvasive cardiac output monitors have not been used extensively in low- and middle-income countries. The aim of this study was to evaluate the quality control of the use of the ultrasonic cardiac output monitor (USCOM) 1A® in a LMIC (low an middle income country).

Material and Methods: This was a quality assessment study of the introduction of the USCOM 1A® to measure maternal hemodynamic indices. Inter-observer agreement was assessed across all four study sites by intraclass correlation coefficient. Quality control was assessed using pre-defined acceptability criteria, rated by 2 independent scorers.

Results: On average, nurses or midwives needed to obtain 30.4 (range 24–36) Doppler waveform recordings to be deemed competent to undertake USCOM 1A® measurements. There was very good inter-observer agreement across all 4 sites (intraclass correlation coefficient 0.86–0.93, all $p < 0.001$). A total of 138 images were randomly selected for quality review. Overall, 79 (89.8%) images were considered acceptable by both scorers; 4 (6.9%) were considered unacceptable by both scorers; and there was disagreement in 5 (5.7%) cases. Overall agreement was 94.3%. Agreement as assessed by Fleiss' kappa, was moderate (0.585 [95% CI 0.376–0.794], $p < 0.001$).

Conclusions: Using a robust learning package and clearly defined image criteria, a novel cardiac-output monitor can be successfully introduced into low- and middle-income countries, in the context of research. Ongoing quality control measures are imperative to maintain the integrity of planned future studies using USCOM 1A®.

KEYWORDS
cardiac output, low and middle income countries, pregnancy, quality assessment

Abbreviations: BMI, body mass index; CO, cardiac output; ICC, intraclass correlation coefficient; LMIC, low and middle income countries.; USCOM, ultrasonic cardiac output monitor.

Helen Perry and Evalyne Tusiimirwe share first authorship with equal contribution.

1 | INTRODUCTION

Over the last decade, the role of the maternal cardiovascular system in the pathophysiology of pregnancies complicated by preeclampsia and fetal growth restriction has been increasingly recognized.[1–9] Different modalities have been used to study maternal cardiovascular function before, during and after pregnancy.[3–12] This includes noninvasive cardiac output (CO) monitors such as the ultrasonic CO monitor (USCOM) 1A® device. This technique uses a non-imaging Doppler to measure velocity time integrals (VTIs) at the left ventricular outflow tract, allowing the calculation of stroke volume. The device has been used extensively in pregnancy, it has been validated against echocardiography, and device-specific normal ranges have been created for pregnancy.[3–5,13–15]

The vast majority of studies examining maternal cardiovascular function in pregnancy have been conducted in high-income countries. However, the global burden of maternal and perinatal morbidity and mortality associated with preeclampsia and fetal growth restriction occurs in low- and middle-income countries (LMIC).[16,17] It is therefore imperative that these countries are included in future research. One of the challenges of conducting research with a novel device in a LMIC, is the training and acquisition of this new skill; as well as the subsequent reassurance that it is being performed to a high standard, even after the initial training period.

The aim of this study was to evaluate the quality control of the use of the USCOM 1A® (Uscom Ltd., Sydney, Australia) CO monitor in a LMIC under research conditions.

Key message

Using a robust learning package and clearly-defined image criteria, a novel cardiac-output monitor can be successfully introduced into low- and middle-income countries, as assessed by inter-observer agreement.

2 | MATERIAL AND METHODS

2.1 | Study design and participants

This was a cross-sectional quality assessment study undertaken as part of the wider iTECH Consortium Project. This project aims to study physical, biochemical and sonographic markers to predict and prevent pregnancy complications in Uganda. This study was designed and reported in accordance with the Guidelines for Reporting Reliability and Agreement Studies (GRRAS).[18] Inclusion criteria for the overall study were women with a viable, singleton naturally-conceived pregnancy between 11 and 23 weeks gestation; aged 14 years or older who were attending routine antenatal care and willing to deliver at the study site. Women with a fetus with a congenital anomaly, pregnancy complications (molar pregnancy, ectopic pregnancy and nonviable pregnancy) were excluded. Informed consent was obtained from all participants. Whilst girls as young as 14 years are typically excluded from research studies in high-income countries, we considered it important they be offered the opportunity to partake in this study. The adolescent birth rate in Uganda is 29 per 1000 aged 10–19 years (61 per 1000 aged 15–19 years) compared to 2 per 1000 aged 15–19 years in Norway.[19,20] Excluding this group would not make the study representative of the pregnant population in Uganda. Girls were assessed for suitability to give written informed consent as emancipated minors (based in similar principles to Gillick competence).

2.2 | Study setting

Participants for this quality assessment study were recruited between April 2023 and February 2024 across four high volume tertiary hospitals in Uganda: Kawempe National Referral Hospital and Hoima, Lira and Mbale Regional Referral Hospitals. Kawempe hospital is located in Kampala which is the capital city of Uganda and mainly attends to pregnant women from the surrounding urban and peri-urban areas. Hoima hospital is located in western Uganda, Lira hospital in northern Uganda, Mbale hospital in Eastern Uganda and these three mainly attend to women from rural settings. The annual number of deliveries across all four sites is 42 600. The wider study is ongoing.

2.3 | Hemodynamic measurements

All hemodynamic measurements were taken with the USCOM 1A® device. The study rooms were maintained at a consistent ambient temperature (16–21°C). Maternal height (cm) and weight (kg) were measured using standardized scales. Participants were asked to sit quietly in a semi-recumbent position for at least 5 min before brachial blood pressure was taken from the right arm of the patient. The hemodynamic measurements were then taken with the patient in a left lateral position. The left lateral position was chosen for all measurements to reduce the effect of aortocaval compression in the late second and third trimesters, as recommended by the International Working Group on Maternal Haemodynamics.[21] Maintaining this position for earlier pregnancy measurements allowed for longitudinal observations. Measurements in the main iTECH study are obtained longitudinally between 11 and 42 weeks of gestation. The USCOM 1A® probe was placed in the participant's supra-sternal notch and angled caudally towards the left ventricular outflow. Once an initial waveform was detected, the probe was slowly moved in three dimensions to obtain the tallest peak of a clearly defined triangle shape to represent velocity at the outflow tract rather than in the more distal ascending aorta. The USCOM 1A® displays the Doppler profiles in real-time on the computer screen in the devices flow tracer mode, allowing the user to make adjustments until an optimum profile has

been obtained, representing the peak velocity of blood at the aortic outlet. Once obtained, the screen can be frozen and the profiles reviewed. Each Doppler profile represents the VTI which represents the distance traveled by a column of blood during each cardiac cycle. A minimum of three Doppler waveforms were required for inclusion in the analysis. The measurement was repeated three times to ensure consistency in the result. For each patient, a single recording was selected for analysis after the Doppler acquisitions had been reviewed and checked for quality. The USCOM 1A® device uses an anthropometric algorithm, based on the participant's height, to determine outflow tract diameter and subsequently calculate over 30 variables. The following variables were recorded for each participant in this study: heart rate, mean arterial pressure, CO, stroke volume and systemic vascular resistance. The remaining variables will be the subject of future work by our group.

2.4 | Training and learning curve

A training package was devised by the Hemodynamic working group and delivered to the original study team of five nurses and two midwives. This package incorporated online training sessions led by a clinical researcher with extensive experience of maternal hemodynamic assessment and the USCOM 1A® monitor (HP). These sessions covered aspects of the theory of hemodynamics; the operation of the USCOM 1A® device; and suggested techniques to optimize the accuracy of the measurements as well an overview of pregnancy physiology and antenatal care. Additionally, the study team had online training with an USCOM 1A® representative, to further demonstrate the technique to perform the measurements required. Hands-on training was delivered by an expert user of USCOM 1A® (MK). These practical sessions involved demonstration on the setup of the device, the proper procedure for acquiring an optimal USCOM 1A® image using the 3D technique; data extraction; safety; and storage of the device. Two "core" nurses (ET and AN) from the original study team spent more time with the expert trainer to develop the skills and knowledge to become trainers themselves.

During this training period, these two core nurses (ET and AN) practised on fellow trainee nurses and volunteer pregnant women of various gestations after obtaining verbal consent. The expert trainer observed them performing multiple measurements on 15 different pregnant women and provided feedback. The expert trainer confirmed that both core nurses had acquired competence in the technique for performing USCOM 1A® hemodynamic measurements after 3 days of consistent hands-on training.

The two core nurses gave further training to the remaining members of the original study team at the primary study site (Kawempe hospital). In addition, they trained a further two nurses or midwives at each of the three other study sites (Hoima, Lira and Mbale Regional Referral Hospitals). Again, this training comprised of 2 days of theoretical training and 3 days of practical hands-on training using the USCOM 1A® device. These nurses and midwives became core nurses in their hospital and were subsequently able to train additional team members following the same methods described above. Each team member was assessed for competency before their measurements were included in the main study. A six-criteria objective checklist was devised by the study hemodynamic working group to standardize the waveforms accepted for analysis (Appendix S1) based on the requirements of the image to give an accurate evaluation of a patient's heart rate, stroke volume, CO and systemic vascular resistance, as per the manufacturer's guidance. The devised checklist was similar to the Freemantle criteria proposed for USCOM 1A use.[22] However, we also included correct measurement of heart rate as a criterion due to its influence on derived indices such as CO.

2.5 | Quality control

Once operating independently, each of the four study sites sent a random selection of acquired images ($n = 138$) for independent review. The distribution of image contribution was as follows: 33 from Kawempe National Referral Hospital, 37, 35 and 33 from Hoima, Lira and Mbale Regional Referral Hospitals respectively. The images were reviewed and scored by one of the original core nurses (ET), using the six-criteria checklist. Additionally, the images were sent to an external expert (HP) for additional review and scoring. Each assessor was blinded to the other's scores. The scores were dichotomised into 'Acceptable' and 'Unacceptable' based on pre-defined scores; a score of ≥5 was considered acceptable and a score of ≤4 was considered unacceptable. Additionally, any image where there were fewer than 3 waveforms included, or where heart rate was incorrectly recorded were automatically considered 'Unacceptable' regardless of the overall score. These scores were agreed by the Hemodynamic working group after considering what would be required to give accurate results. Examples of acceptable and unacceptable waveforms are shown in Figure 1A,B. Within each study site, inter-observer agreement was assessed after a period of established practice. Paired team members performed consecutive measurements in the same patient and values for CO, stroke volume and systemic vascular resistance were recorded for comparison. Demographic information was recorded for the patients included in this comparison in order to help understand any differences between sites.

2.6 | Statistical analyses

Data were recorded on a secure database (https://medscinet.com/studies.aspx) and managed by the central study team. Descriptive statistics were used for the analysis of the learning curve.

For the quality control image review, agreement was assessed by percentage agreement as well as by a Fleiss' kappa analysis. The following pre-determined cut-offs were used for interpretation: 0.00–0.20, slight agreement; 0.21–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, good agreement; and >0.80, very good agreement. Based on previous studies,[23–25] it was deemed that

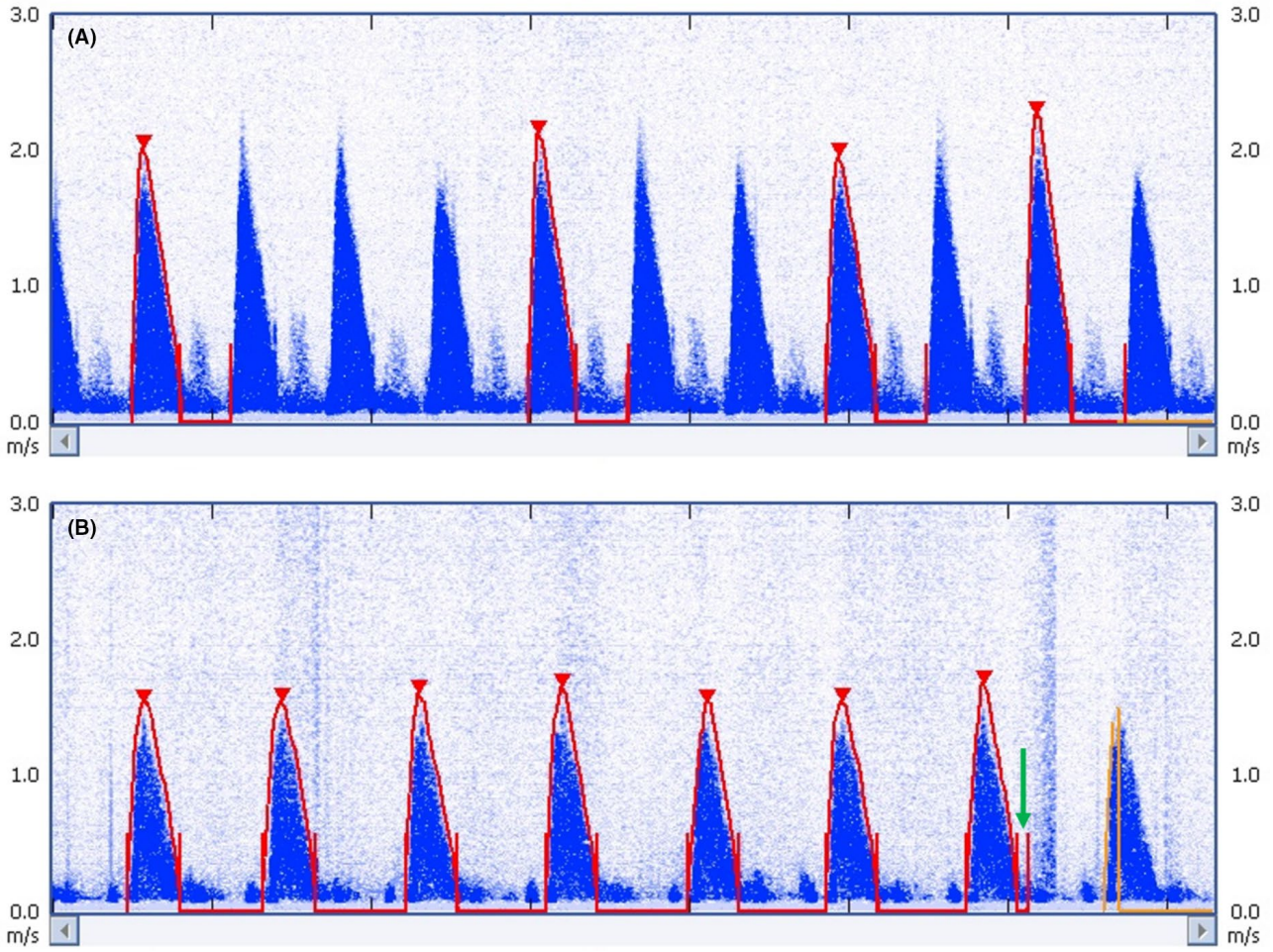

FIGURE 1 Examples of an acceptable (A) and unacceptable (B) waveform. In (B), the triangular waves are less well defined with some loss of fill toward the peak of the triangle. Additionally, the device has picked up artifact as a waveform (green arrow) and therefore incorrectly calculated heartrate.

a minimum of 125 images would be sufficient to detect a 10% difference in agreement between two scorers with 90% power, assuming an inter-observer agreement of 80%.

Inter-observer agreement at each of the four sites was analyzed using the intraclass correlation coefficient (2 way-mixed model assessed by absolute agreement). The cut-offs described above were used for interpretation of these results. Demographic details of the patients included in this study were assessed using descriptive statistics. Normality of data was assessed visually and with the Shapiro–Wilk test. Parametric data was assessed using a one-way ANOVA test with homogeneity of variances assessed by Levene's test for equality of variances. Nonparametric data was assessed using the Kruskal–Wallis *H* test. All statistical analysis was performed using SPSS (version 29).

3 | RESULTS

Between April 2023 and February 2024, four sites were established for recruitment. Thirteen study nurses or midwives were trained in the use of the USCOM 1A® monitor. A total of 2282 patients were recruited during this time.

3.1 | Learning curve and inter-observer agreement

On average, nurses or midwives needed to obtain 30.4 (range 24–36) Doppler waveform images to be deemed competent to undertake USCOM 1A® measurements. The results of the inter-observer reliability comparison are shown in Table 1. The raw values are provided in Table S1. There was very good agreement across all 4 sites (intraclass correlation coefficient [ICC] 0.86–0.93, all $p < 0.001$). The demographic details of the patients included in this comparison are shown in Table 2. Measurements at site 1 were performed at a statistically significant later gestation compared to the other sites (22.0 weeks vs. 18.6, 16.8 and 16.9 weeks, all $p < 0.05$). Site 1 had significantly higher body mass index (BMI) compared to sites 3 and 4 (26.2 vs. 21.4 and 21.9, both $p < 0.001$). There was no difference between groups in maternal age or mean arterial pressure at assessment.

3.2 | Quality control assessment

The dichotomised results are displayed in Table 3. The two assessors independently scored 138 images randomly selected from the four study sites. Overall, 127 (92.0%) of images were considered acceptable by both scorers; 5 (3.6%) were considered unacceptable by both scorers; and there was disagreement in 6 (4.3%) cases. In 5 (3.6%) cases, heart rate had been incorrectly calculated. No images had fewer than 3 waveforms included in the analysis. Overall agreement was 95.7%. Agreement as assessed by Fleiss' kappa, was moderate (0.60 [95% CI 0.44–0.77], $p < 0.001$).

4 | DISCUSSION

This study demonstrates that a novel technique for measuring maternal hemodynamic indices, can be successfully introduced in a LMIC. Inter-observer agreement at each of the four sites was very good (ICC 0.86–0.93, all $p < 0.001$). The percentage of acceptable images was high (92.0%) and agreement between the two quality control scorers was also high (95.7%).

To our knowledge, this is the first study to employ a hybrid (online and in-person) learning package for the USCOM 1A® device in a LMIC. A similarly successful learning curve and inter-observer agreement have been demonstrated in previous studies. In the UK, Vinayagam et al. found very good inter-observer agreement when two trained operators used the USCOM 1A® device in pregnant women.[13] Hodgson et al. demonstrated excellent inter-observer agreement after an intense learning curve (hands-on training with an experienced operator, totaling 5 h) in an emergency department setting.[26] Dhanani et al. also found very good agreement between trained operators measuring CO in anesthetized children.[27]

Regarding the introduction of new technologies in a LMIC, our group has previously described the standardization and quality control of ultrasound measurements in a similar population.[23] As in the current study, they had a well-documented training period and program, prior to study recruitment and reported good or very good agreement between ultrasound image scorers, and a similar rate of acceptable images (88%).

In our study, we used the widely accepted criteria suggested by Cohen[28] to rate ICC variability. Stricter criteria may be applied, such as the TRUST criteria.[29] However, we felt these were too stringent for a dynamic, constantly changing variable like CO, compared to a still image from a set plane.

As described in the introduction, there is increasing understanding about the role the maternal cardiovascular system plays in pregnancy complications. Having reliable means of assessing different cardiovascular indices, including hemodynamic measurements, is therefore of paramount importance, particularly in LMIC where the disease burden is highest. Having established a learning program for the USCOM 1A® device, and demonstrated quality control, it would be possible to follow a similar pathway for other measures of maternal cardiovascular function, such as arterial stiffness. Arterial stiffness has been studied in LMICs, but it is not clear if inter-observer agreement was recorded, and quality control maintained.[30]

By undertaking a quality assessment at a relatively early stage of the wider study, we have been able to demonstrate the integrity of the study, but also highlight areas to focus on most closely. Namely, ensuring that heart rate is correctly calculated for each of the images before the measurements are stored. This has been fed-back to the local team, with refresher training performed.

The main strength of this study was the robust and systematic approach to training in the use of the USCOM 1A® device. The approach of focussing the expert-delivered hands-on training on two core nurses, meant that they achieved a level of competence that allowed them to confidently disseminate their knowledge to the wider study team as the new sites opened for recruitment. The finding that our inter-observer agreement results were reproducible across all 4 study sites, further supports the strength of our training programme.

Developing a pre-agreed criteria for image acceptability meant that image assessment was more objective and even though the

TABLE 1 Inter-observer agreement between paired nurses at each recruitment site.

Site (N)	ICC (95% CI)	*p*
1 (31)	0.93 (0.86–0.97)	<0.001
2 (30)	0.93 (0.84–0.96)	<0.001
3 (32)	0.86 (0.71–0.94)	<0.001
4 (30)	0.86 (0.61–0.94)	<0.001

Abbreviation: ICC, intraclass correlation coefficient.

TABLE 2 Demographic and hemodynamic details of the patients included in the Inter-observer agreement study according to recruitment site.

	Site 1 (31)	Site 2 (30)	Site 3 (32)	Site 4 (30)	*p*
Maternal age (years)	24.0 (23.0–29.0)	24.0 (22.0–29.0)	25.5 (23.0–27.8)	23.5 (20.0–29.0)	0.532
Maternal BMI (kg/m^2)	26.2 (23.8–30-3)	23.8 (19.8–29.0)	21.4 (20.2–23.3)	21.9 (20.5–24.6)	**<0.010**
Gestational age at assessment (weeks)	22.0 (19.7–36.0)	18.6 (14.8–21.1)	16.8 (13.7–20.0)	16.9 (13.8–19.0)	**<0.010**
MAP (mmHg)	84 (±8)	84 (±6)	80 (±7)	83 (±7)	0.143
Cardiac output (L/min)	7.43 (6.79–8.27)	6.90 (6.08–8.03)	7.00 (6.20–7.88)	7.02 (6.23–8.29)	0.402

Note: Results are displayed as median (IQR) or mean (SD). Statistically significant *p* values are in bold.

Abbreviations: BMI, body mass index; MAP, mean arterial pressure.

TABLE 3 Agreement between the 2 scorers on the quality of obtained waveform images.

	Scorer 2		
	Unacceptable	Acceptable	Total
Scorer 1			
Unacceptable	5	2	7
Acceptable	4	127	131
Total	9	129	138

technique was relatively new to the local scorer, they demonstrated good agreement with the more experienced scorer.

Undertaking quality assessment and agreement analysis in two different methods is another strength of this study. The quality control assessment was adequately powered, as per the pre-performed calculations.

The main limitation of our study is that the inter-observer agreement assessment was performed at relatively early gestations (early-mid second trimester) in the majority of cases. Additionally, participants generally had a normal BMI and were normotensive. We therefore cannot comment on the agreement and quality for measurements performed at later gestations and in women with a higher BMI or pregnancy complications, such as preeclampsia. This assessment will be the subject of future work as the study progresses. This will also allow to assess if the level of agreement is reproducible after a longer lag-period from the initial training sessions.

Another limitation is that the quality control assessment involved an external expert. Whilst this gave reassurance to the overall quality of the study in its infancy, it is not a viable approach for the duration of the study, where ongoing quality control will need to be assessed by two local team members. In view of this, our group intends to repeat this analysis once two local quality control assessors are operating (at the time of this study, resources did not allow for this to happen). The external expert will act as a third reviewer, and we will compare the agreement between the two local assessors with that of the external expert.

5 | CONCLUSION

Using a robust learning package and clearly defined image criteria, a novel cardiac-output monitor can be successfully introduced into a LMIC, for the purposes of research. Ongoing quality control measures are imperative to maintain the integrity of the study and any future routine clinical application.

AUTHOR CONTRIBUTIONS

Aris T. Papageorghiou and Sam Ali conceived the study idea. Helen Perry and Evalyne Tusiimirwe wrote the main manuscript. Evalyne Tusiimirwe, Allen Nakayenga and Sam Ali oversaw data collection and handling. Helen Perry performed data analysis. All authors reviewed and contributed to the manuscript.

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CONFLICT OF INTEREST STATEMENT

No conflict of interest declared.

ETHICS STATEMENT

The main study was approved by Makerere University School of Medicine Research Ethics Committee (Mak-SOMREC-2022-535) on March 1, 2023 and the Uganda National Council for Science and Technology (HS2762ES) on April 6, 2023.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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