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CLINICAL ARTICLE

Obstetrics

Reliability of ultrasound findings acquired with handheld apparatuses to inform urgent obstetric diagnosis in a high-volume resource-limited setting

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Abstract

Objective: To evaluate the reliability of obstetric handheld smartphone-based point-of-care ultrasound (POCUS) in a resource-limited high-volume setting.

Methods: A single-center prospective observational study among women requiring urgent diagnosis and admitted to a maternity referral hospital in Sierra Leone from March to April 2019. Pre-specified ultrasound findings were obtained with a handheld POCUS device; a comprehensive ultrasound examination was then performed by an experienced operator using conventional full-feature apparatus. Agreement was assessed by diagnostic accuracy and Cohen κ-statistics.

Results: Overall, there were 307 participants. The mean aggregated diagnostic accuracy was 95.5% (κ-statistic, 0.90; 95% confidence interval [CI], 0.89–0.93; $P < 0.001$). Highest accuracy was reported for detecting free fluid collection in the abdominal cavity (100%; κ-statistic, 1.00; 95% CI, 1.00–1.00; $P < 0.001$). Ultrasound findings obtained with the handheld device for intrauterine pregnancy, fetal heartbeat, cephalic presentation, multifetal pregnancy, and assessment of gestational age based on bi-parietal diameter were highly reliable (agreement, >90%; κ-statistic, >0.80). Detection of low-lying placenta or placenta previa was the least reliable (κ-statistic, 0.53; 95% CI, 0.13–0.93; $P < 0.001$).

Conclusion: Handheld POCUS findings were found to be reliable for detecting pre-specified urgent obstetric findings in a high-volume resource-limited referral hospital.

KEYWORDS
Obstetrics, Point-of-care ultrasound, Portable, Sierra Leone

1 | INTRODUCTION

Obstetric ultrasound examinations are crucial for identifying pregnancy-related complications and assessing fetal wellbeing. However, high cost and low availability of expertise limit access to conventional obstetric ultrasound in low- and middle-income countries (LMIC). Although using point-of-care ultrasound (POCUS) during prenatal visits in LMIC has not been found to improve perinatal outcomes or attendance rate,[1] it may have greater potential in emergency settings. POCUS can detect severe conditions, including multifetal

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pregnancy, breech presentation, or intrauterine fetal death at delivery, which are frequently encountered in the emergency departments of tertiary hospitals in LMIC.[2,3]

Ultrasound devices have become more compact and cost-effective with technologic advancements. In tertiary care hospitals in Rwanda and Tanzania, such devices substantially affect clinical decision-making processes.[4,5] In high-income settings, non-specialists can differentiate between normal pregnancy and other diagnoses among parturients with acute symptoms.[6-9] Simple ultrasound findings, including fetal presentation, fetal number, amniotic fluid volume, presence or absence of retroplacental hematoma, and gestational age assessment, all contribute to successfully managing obstetric emergency situations.[10] Similar to laboratory tests, early and precise knowledge of these findings is crucial for completing a comprehensive obstetric assessment.

Limited information exists regarding urgent POCUS obstetric applications in resource-limited settings. The aim of the present prospective observational study was therefore to understand the pragmatic role of handheld devices in a high-volume, low-resource hospital by assessing women in five clinical situations commonly encountered in African district or referral hospitals: vaginal bleeding in early pregnancy, pre-eclampsia/eclampsia, prolonged/obstructed labor, prepartum hemorrhage, and other high-risk pregnancies. The reliability of nine pre-specified ultrasound findings acquired at bedside with a low-cost handheld apparatus were compared with a reference standard (a comprehensive ultrasound examination performed with conventional apparatus by an obstetrics/gynecology specialist).

2 | METHODS

2.1 | Study design

The single-center, prospective observational study was conducted from January 1 to March 31, 2019, among pregnant women attending Princess Christian Maternity Hospital (PCMH), Freetown, Sierra Leone. PCMH is a tertiary referral hospital for obstetric and gynecologic cases that assists approximately 7000 deliveries and 4000 obstetric emergency cases annually. It is the only health facility providing comprehensive emergency obstetric care and neonatal services throughout the Western Area of Sierra Leone, the most populated district in the country.[11] The study was approved by the Office of the Sierra Leone Ethics and Scientific Review Committee, Ministry of Health and Sanitation, Freetown, Sierra Leone and is registered at ClinicalTrials.gov (NCT03856307).

Eligible women were identified by attending physicians who had undergone ultrasound training for the study and received complete written information on the study protocol at the end of the training program. Verbal informed consent from the patient, or a formal representative for those younger than 18 years of age, was obtained after the attending physician had explained the study procedure, objective, and privacy policy regarding study data, and had assured the patient that withdrawal from the study would not affect her successive management plan. This information was given to a patient immediately after admission to the emergency department or other ward when the attending physician considered ultrasound examination necessary for the diagnosis. Regardless of their consent to participate, all women underwent ultrasound examination with conventional ultrasound apparatus by the obstetrics/gynecology specialist at the hospital whenever deemed necessary by the attending physician.

2.2 | Study population

The inclusion criteria were admission to the emergency department, prenatal care clinic, labor ward, or in-patient ward during the study period, and diagnosis by attending physicians at PCMH with at least one of the following five clinical indications: 1) vaginal bleeding in early pregnancy; 2) pre-eclampsia or eclampsia; 3) prepartum hemorrhage; 4) obstructed labor; and 5) other high-risk pregnancy. Detailed definitions of these five clinical indications are given in Supplementary File S1.

2.3 | Study procedure

Women were prospectively recruited on a consecutive basis and received two ultrasound examinations regardless of the reason for admission. First, they were examined with a handheld low-cost smartphone-based ultrasound device using a US-304 convex probe with 64 elements (3–5 MHz; Lequio Power Technology, Naha, Okinawa, Japan) immediately on admission to the emergency room or when visited in the prenatal clinic or ward. Subsequently, the women were moved to the hospital's dedicated ultrasound room, where an experienced obstetrics/gynecology specialist performed the reference examination using a conventional full-feature imaging system with a 3–5-MHz convex probe and a 7–10-MHz trans-vaginal probe (Mindray SD-10, Shenzhen, China). If the patient was clinically unstable and unfit to be moved, the reference method examination was performed at the bedside in the emergency room using the same apparatus. Additional details on the ultrasound protocol are given in Supplementary File S1.

2.4 | Collection of ultrasound findings

Each study operator reported the ultrasound findings on a structured case report form immediately after the examination. Predefined combinations of ultrasound findings were allocated to each category of patients (Table e1 in Supplementary File S1). The following ultrasound findings were determined: 1) intrauterine pregnancy; 2) presence of fetal heartbeat; 3) fetal presentation; 4) maximum vertical pocket of amniotic fluid (<2 or >2 cm); 5) gestational age assessment based on bi-parietal diameter (BPD) of a fetus (<34 or >34 weeks); 6)

location of placenta (placenta previa/low-lying placenta; 7) number of fetuses (single or multiple); 8) presence of retroplacental hematoma; and 9_ collection of free fluid in abdominal cavity or Douglas pouch of a pregnant woman.

The reference standard operator was kept blind to the results of the ultrasound examinations conducted with the handheld apparatus and vice versa. A copy of the final expert ultrasound report was shared with the clinical team directly responsible for the patient's care.

Despite limitations after 24 weeks, BPD was used to estimate gestational age because it was a relatively easy measurement for ultrasound novices to learn and it was included as a POCUS technique in a previous study.[5] Placenta previa or low-lying placenta was diagnosed when the internal os was covered partially or completely by the placenta, or when the internal os was not covered by the placenta but the placental edge was within a 2-cm-wide perimeter around the os, respectively. Low-lying placenta or placenta previa was definitively diagnosed by the obstetrics/gynecology specialist using the vaginal probe of the conventional apparatus.

2.5 | Ultrasound data quality scoring

A random subset of 14.7% (240/1632) of ultrasound examination images acquired with the handheld device was de-identified and uploaded onto an e-platform (KoBoToolbox., Cambridge, MA, USA) to assess image quality. The images were assessed by two independent obstetrics/gynecology specialists with a standardized scoring system from 0 to 4, where 0, 1, 2, 3, and 4 indicate, respectively, no meaningful images; poor images, not sufficient for interpretation; good images, acceptable for interpretation; excellent images, minor suggestions for interpretation; and outstanding images, no suggestions for interpretation.[5]

2.6 | Ultrasound operators

The ultrasound operators using the handheld device received a 3-week training course, with 1 week of theoretic knowledge and 2 weeks of hands-on training. The training was provided by a certified specialist in obstetrics and gynecology. The 27 initial participants included house officers (intern junior doctors) and medical officers (resident doctors in training). The lectures covered the basic science of ultrasound, tomography, and obstetric ultrasound data, focusing on the nine findings requested in the case report form. After the first week of the course, a formal multiple choice test of competency was performed, and five study participants (four ultrasound-naive operators and one experienced operator) were selected. These five operators received a

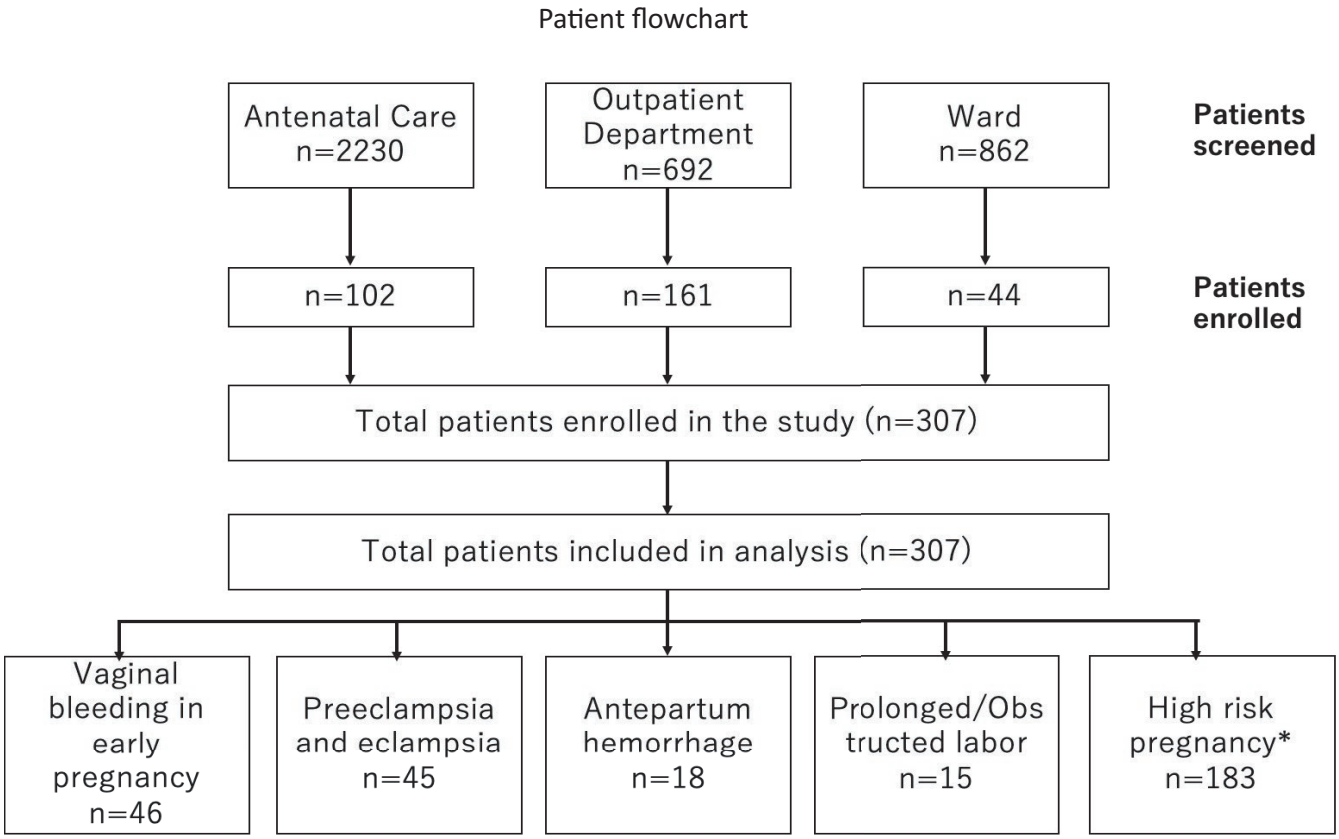

FIGURE 1 Flowchart showing recruitment of the study women and data analysis. High-risk pregnancy (asterisk) included the following clinical indications: previous cesarean delivery; previous stillbirth; fundal height greater than 40 cm; suspected rupture of membranes; no fetal movement; suspected multifetal pregnancy; and others

1-week practical training course on how to use the handheld device and were familiarized with the structured case report form. Their competency in acquiring ultrasound images and correctly completing the checklist with the handheld device was tested in a 1-week pilot phase.

2.7 | Study endpoints

The primary endpoint was the mean aggregated diagnostic accuracy of the ultrasound findings collected by the handheld devices as compared with the standard reference method. Secondary endpoints included individual diagnostic accuracy for each of the nine ultrasound findings; comparison of mean aggregate diagnostic accuracy of the naive ultrasound operators with that of the experienced operator; and image quality collected with the handheld devices.

2.8 | Data analysis

Data analyses were performed by using R (R Foundation for Statistical Computing, Vienna, Austria). The study was observational; thus, no formal sample size calculation was performed. Continuous data were reported as mean ± SD or median (interquartile range, IQR); categoric data were reported as number (percentage). Agreement between the handheld device and the standard ultrasound machine for scores of categoric findings was assessed by using diagnostic accuracy measures and the Cohen κ-statistic, which was interpreted as follows: 0, no agreement, 0.01–0.20, none to slight; 0.21–0.39, minimal; 0.40–0.59, weak; 0.6–0.79, moderate; 0.80–0.90, strong; and more than 0.9, almost perfect agreement.[12] The rate of agreement was interpreted as follows: 0%–4%, none; 4%–15%, minimal; 15%–35%, weak; 35%–63%, moderate; 64%–81%, strong; and 82%–100%, almost perfect agreement.[12] Rates of agreement between the ultrasound-naive operators and the experienced operator were compared by using the χ^2 test. A *P* value of less than 0.05 was considered statistically significant.

3 | RESULTS

3.1 | Study population and analysis

During the study period, 307 women were enrolled and the results of 1632 ultrasound findings were analyzed. Patient enrollment and ultrasound analysis are shown in Figure 1, and the baseline characteristics of the women are summarized in Table 1. The median (IQR) participant age was 26 years (22–36 years). The median gravidity and parity were 3 (2–3) and 1 (0–2), respectively. Furthermore, 183 (59.6%) of the 307 participants were categorized as high-risk pregnancy: 45 (14.6%) with pre-eclampsia/eclampsia, 45 (14.6%) with vaginal bleeding in early pregnancy, 18 (5.8%) with prepartum hemorrhage, and 15 (4.8%) with prolonged or obstructed labor.

3.2 | Study endpoints

Regarding the primary endpoint, the mean aggregated diagnostic agreement rate between the two modes of ultrasound examination was 95.5% (κ-statistic, 0.90; 95% CI, 0.88–0.92; *P* < 0.001) (Table 2).

In terms of secondary endpoints, the highest accuracy was found for detecting free fluid collection in the abdominal cavity or Douglas pouch of pregnant women (agreement rate, 100.0%; κ-statistic, 1.00; 95% CI, 1.00–1.00; *P* < 0.001). The identifications of intrauterine pregnancy, fetal heart, cephalic presentation, and multifetal pregnancy by the handheld device were highly reliable with excellent agreement rates (93.5%, 98.1%, 95.7%, and 96.7%,

TABLE 1 Characteristics of the study population[a]

Characteristic	Value
Age, years	26 (22–30)
<18	10 (3.3)
18–35	249 (81.1)
≥35	33 (11.1)
Unknown	14 (4.6)
Gravidity	3 (2–3)
1	62 (20.2)
2–3	177 (57.7)
≥4	61 (19.9)
Unknown	7 (2.3)
Parity	1 (0–2)
0	83 (27.0)
1–3	194 (63.2)
≥4	23 (7.5)
Unknown	7 (2.3)
Gestational age, weeks[b]	33 (26–36)
<14	35 (11.4)
15–28	60 (19.5)
29–36	137 (44.6)
≥37	64 (20.8)
Unknown	11 (3.6)
Body mass index	29.4 (26.7–33.4)
<18.5	0 (0)
18.5–25	28 (9.1)
≥25	195 (63.4)
Unknown	84 (27.4)

[a]Values are given as median (interquartile range) or number (percentage).

[b]At time of examination based on prenatal card and/or self-report.

TABLE 2 Diagnostic accuracy of the handheld device relative to the reference standard method

Ultrasound finding	TP	FP	FN	TN	Agreement, %	κ (95% CI)	*p* value
Intrauterine pregnancy	33	2	1	10	93.5	0.82 (0.63–1.00)	<0.001
Fetal heart	264	3	3	46	98.1	0.92 (0.87–0.98)	<0.001
Free fluid collection	3	0	0	42	100	1.00 (1.00–1.00)	<0.001
Max vertical pocket of amniotic fluid <2 cm	20	9	10	239	93.2	0.63 (0.48–0.79)	<0.001
Gestational age ≥34 weeks based on BPD	115	5	16	112	91.5	0.83 (0.76–0.90)	<0.001
Cephalic presentation	194	6	5	51	95.7	0.87 (0.80–0.94)	<0.001
Low-lying placenta or placenta previa[a]	3	5	0	206	97.7	0.53 (0.13–0.93)	<0.001
Multifetal pregnancy	34	2	5	171	96.7	0.88 (0.80–0.96)	<0.001
Retroplacental hematoma	2	0	1	14	94.1	0.76 (0.32–1.00)	<0.001
Total	668	32	41	891	95.5	0.90 (0.88–0.92)	<0.001

Abbreviations: BPD, bi-parietal diameter; FN, false-negative cases; FP, false-positive cases; TN, true-negative cases; TP, true-positive cases.
[a]Low-lying placenta was diagnosed when the edge of the placenta was within the 2-cm perimeter around the internal os. Placenta previa was diagnosed when the internal os was completely or partially covered by the placenta.

respectively) and a strong κ-statistic: 0.82 (95% CI, 0.63–1.00; $P < 0.001$), 0.92 (95% CI, 0.87–0.98; $P < 0.001$), 0.87 (95% CI, 0.80–0.94; $P < 0.001$), and 0.88 (95% CI, 0.80–0.96; $P < 0.001$), respectively). Gestational age assessments based on BPD measurements were also moderately reliable (κ-statistic, 0.83; 95% CI, 0.76–0.90; $P < 0.001$) because their performance was the lowest among the nine ultrasound findings (91.5%).

The assessment of amniotic fluid volume and identification of retroplacental hematoma with the handheld device were relatively reliable with high agreement rates (93.1% and 94.1%, respectively) but a moderate κ-statistic: 0.63 (95% CI, 0.49–0.78; $P < 0.001$) and 0.76 (95% CI, 0.33–1.00; $P < 0.001$), respectively.

Despite the high agreement rate (97.1%), detection of low-lying placenta or placenta previa was the least reliable with a weak κ-statistic (0.53; 95% CI, 0.13–0.93; $P < 0.001$), indicating that matches between the two modes of ultrasound examinations were merely coincidental.

3.3 | Performance of different operators

There was no significant difference in the mean aggregated agreement rates of ultrasound findings between the ultrasound-naive operators and the experienced operator (93.6% vs. 97.2%; $P = 0.185$).

3.4 | Image quality

The quality of 240 (14.7%) images from 1632 ultrasound examinations obtained with the handheld device was reviewed and scored (Table 3). Representative images are shown in Figure 2. The aggregate mean quality score was 2.87 (95% CI, 2.77–2.97). The highest score was achieved in multifetal pregnancy (3.75; 95% CI, 3.46–4.00), whereas the lowest image quality was found in the images captured for BPD measurements (2.28; 95% CI, 2.12–2.43).

4 | DISCUSSION

Obstetric POCUS findings acquired with a low-cost smartphone-based ultrasound device were found to be as reliable as those obtained with standard ultrasound apparatus in a high-volume resource-limited setting. Agreement rates were higher than 90% for nine ultrasound findings with moderate to strong κ-statistics except for the detection of low-laying placenta or placenta previa. The lowest agreement rate was found for gestational age assessment based on BPD. The performance of naive users with the handheld ultrasound device was comparable to that of the experienced operator.

Among the nine ultrasound findings, the agreement rate was highest for detecting free fluid collection. The agreement rate for detecting intrauterine pregnancy was also high. The combination of these results may have important implications for emergency department providers. Definitively diagnosing an ectopic pregnancy for a woman with vaginal bleeding but lacking other physical signs is frequently difficult and often confirmed only after laparotomy. Detecting abdominal free fluid collection and the absence of intrauterine pregnancy strongly indicates the possibility of ectopic pregnancy for a woman with a positive urine pregnancy test. In fact, all three true-positive cases with free fluid collection had a ruptured ectopic pregnancy subsequently diagnosed by dissection of fallopian tubes containing ruptured gestational sacs.

The high agreement rate in detecting fetal heartbeat with the handheld device is also promising. At present, midwives and physicians in LMIC detect the fetal heartbeat mainly by using a Pinard stethoscope.[13] Even for an experienced health worker, however, this technique requires additional time to reach a definitive diagnosis of intrauterine fetal death. The visual information provided by ultrasound may facilitate and benefit non-expert healthcare workers in recognizing a stopped fetal heart.

The agreement rate for assessing gestational age based on BPD was lowest among the nine ultrasound findings. This was unexpected and may indicate that it was difficult for sonographers to

TABLE 3 Quality of images acquired via the handheld device[a]

Ultrasound finding	Value (95% CI)
Amniotic fluid	2.97 (2.76–3.19)
Bi-parietal diameter	2.28 (2.12–2.43)
Cephalic presentation	3.30 (3.06–3.54)
Intrauterine pregnancy	2.90 (2.45–4.41)
Multifetal pregnancy	3.75 (3.46–4.00)
Placenta location	3.50 (3.34–3.65)
Retroplacental hematoma	3.50 (2.58–4.00)
Total	2.87 (2.77–2.97)

[a]Based on 240 ultrasound images acquired with the handheld devices and assessed by two independent obstetrics/gynecology specialists using a scoring system from 0 to 4 (0, no meaningful images; 1, poor images, not sufficient for interpretation; 2, good images, acceptable for interpretation; 3, excellent images, minor suggestions for interpretation; 4, outstanding images, no suggestions for interpretation).

locate the necessary landmarks in the image when measuring BPD with the handheld device. The BPD image quality score was also the lowest. The images that the participant operators used to measure BPD all lacked one or more of the required landmarks, namely symmetrically positioned thalami, cavum septum pellucidum, lateral ventricles, and midline falx cerebri of a fetal head. Although the precise estimation of gestational age may seem secondary when establishing fetus viability during obstetric emergencies in resource-limited settings, it is prerequisite for formulating effective management plans, particularly in cases with multifetal pregnancy, polyhydramnios, oligohydramnios, and fetal growth restriction. Further studies should investigate how to train medical practitioners to more efficiently learn how to evaluate fetal biometrics with handheld devices.

Interestingly, the diagnostic accuracy of the handheld device was not dependent on the operator's expertise. Less skilled healthcare workers can correctly detect fetal presentation, multifetal pregnancy, and placental positions.[14-16] In the present study, all study participants were physicians, guaranteeing a good knowledge of anatomy and obstetric management. Thus, the results cannot be directly extended to the use of handheld apparatuses by non-physician sonographers.

There are important limitations to the study. First, neither sample size calculation nor random assignment was performed. Second, despite predefined clinical indications, selection bias cannot be excluded because patient inclusion was dependent only on the attending physician's discretion. In addition, there was a tendency to recruit more women in the prenatal clinic than in the emergency department, and an underrepresentation of women with prolonged and/or obstructed labor was noted. This might be attributed to the difficulty in obtaining verbal consent for enrollment from a patient who is unable to communicate due to a critical condition. Third, after being scanned with the handheld device, some eligible women might have been lost if a life-saving intervention was required immediately due to the diagnosis of life-threatening disease such as

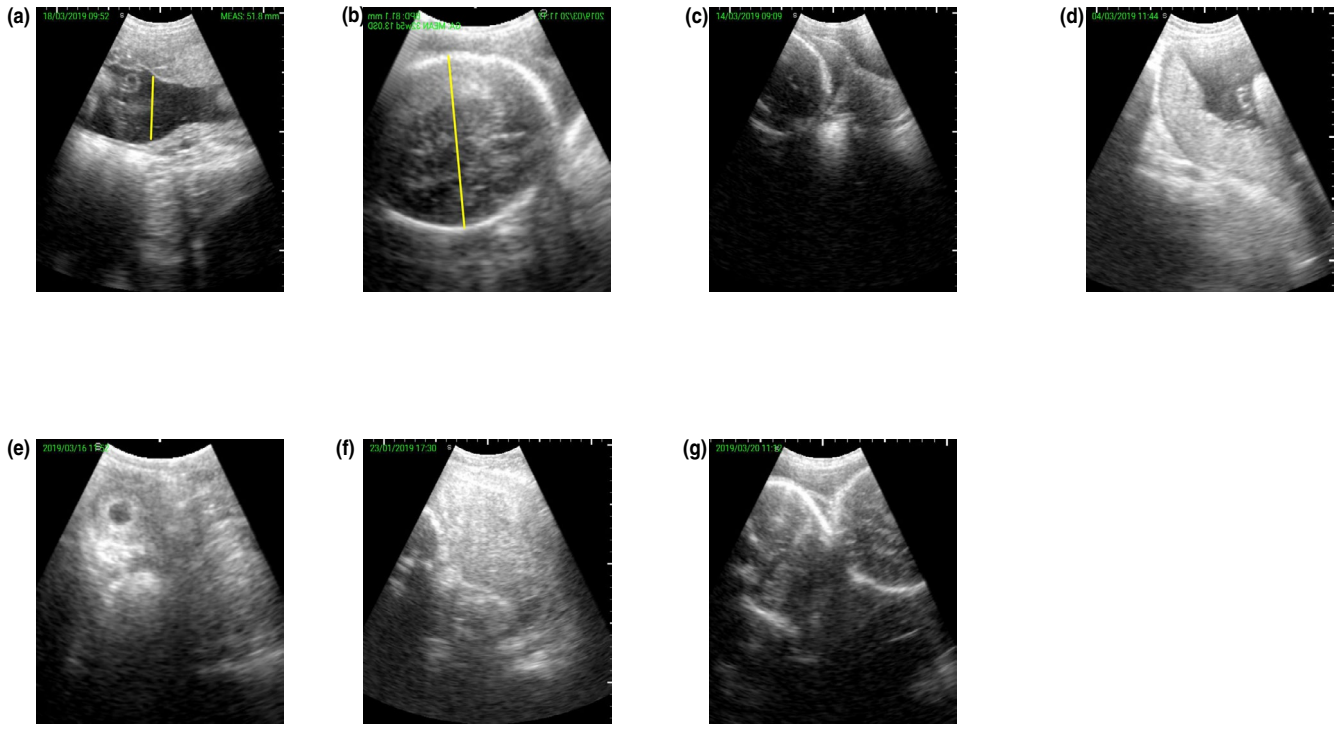

FIGURE 2 Representative images of the ultrasound findings recorded by the handheld ultrasound device. (a) Maximum vertical pocket of amniotic fluid. (b) Measurement of bi-parietal diameter. (c) Cephalic presentation. (d) Location of placenta. (e) Intrauterine pregnancy. (f) Retroplacental hematoma. (g) Multifetal pregnancy. No image of free fluid collection in the abdominal cavity was recorded. Fetal heartbeats were recoded as a video (Video S1)

placenta abruption or uterine rupture, or a high suspicion of ruptured ectopic pregnancy. Last, only 14.7% of the ultrasound images were assessed for image quality, and some degree of underreporting of inadequate ultrasound examinations to the online data archive cannot be excluded.

In summary, handheld smartphone-based ultrasound devices were found to be highly reliable when used for point-of-care structured obstetric examinations, even in a high-volume resource-limited setting. Assessing gestational age via BPD requires further investigation to improve its accuracy. These findings clarify the potential and limitations of handheld ultrasound devices in supporting the clinical decision-making process in busy resource-limited settings with difficult access to comprehensive ultrasound examinations.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

AUTHOR CONTRIBUTIONS

YK was responsible for study conception and design, data acquisition, statistical analysis, and manuscript drafting. LP contributed to study design, statistical analysis and interpretation, and manuscript drafting. EP and MZ contributed to study design and manuscript drafting. SB, SO, and MO were responsible for data acquisition and contributed to manuscript drafting. AOA, MMK, and GP supervised the project. All authors read and approved the final manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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