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ORIGINAL ARTICLE

The diagnostic impact of limited, screening obstetric ultrasound when performed by midwives in rural Uganda

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OBJECTIVE: To evaluate the diagnostic impact of limited obstetric ultrasound (US) in identifying high-risk pregnancies when used as a screening tool by midwives in rural Uganda.

STUDY DESIGN: This was an institutional review board-approved prospective study of expecting mothers in rural Uganda who underwent clinical and US exams as part of their standard antenatal care visit in a local health center in the Isingiro district of Uganda. The midwives documented clinical impressions before performing a limited obstetric US on the same patient. The clinical findings were then compared with the subsequent US findings to determine the diagnostic impact. The midwives were US-naive before participating in the 6-week training course for limited obstetric US.

RESULT: Midwife-performed screening obstetric US altered the clinical diagnosis in up to 12% clinical encounters. This diagnostic impact is less (6.7 to 7.4%) if the early third trimester diagnosis of malpresentation is excluded. The quality assurance review of midwives' imaging demonstrated 100% sensitivity and specificity in the diagnosing gestational number, and 90% sensitivity and 96% specificity in the diagnosis of fetal presentation.

CONCLUSION: Limited, screening obstetric US performed by midwives with focused, obstetric US training demonstrates the diagnostic impact for identifying conditions associated with high-risk pregnancies in 6.7 to 12% of patients screened. The limited obstetric US improved diagnosis of early pregnancy complication as well as later gestation twins and malpresentation. Midwives who have undergone focused 6-week limited obstetric US training proved capable of diagnosing twins and fetal presentation with high sensitivity and specificity.

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INTRODUCTION

Since the United Nations implemented its Millennium Development Goals in 1990, there has been little improvement in the high rates of maternal and perinatal mortality in sub-Saharan Africa despite great efforts.[1] Although the explanation for this limited success in mortality reduction is clearly multifactorial, one potential contributing factor is that high-risk pregnancies go undetected and subsequent poor-outcome deliveries occur at home or in facilities without emergency obstetric care capability.

Obstetric ultrasound (US) has proven an effective means of identifying some of the most prevalent maternal and perinatal mortality risk factors.[2] Until recently, the cost, complexity and size of US equipment have prohibited its introduction into rural antenatal care (ANC) settings in sub-Saharan Africa. As advances in technology have overcome these restrictions, the potential exists to extend US's diagnostic capabilities into rural settings.[2–9] Multiple studies have demonstrated that selective obstetric US results in change in care for patients where there was a clinical concern.[10–12] These studies, however, do not evaluate the effectiveness of screening obstetric US, which we define as screening US for all women presenting for ANC. In our review of the literature, there is little-to-no published data on the diagnostic impact of screening obstetric US in rural, low-resource environments in developing countries.

This study investigates the diagnostic impact of limited screening obstetric US; it compares how the results of these screening USs performed in rural Uganda by midwives corrects the diagnosis when compared with the midwives' initial clinical assessment. In doing so, we demonstrate the potential of a sustainable training model—a limited obstetric US training designed for midwives and implemented by in-country trainers.

METHODS

All study procedures were approved by the human subject committees of participating institutions—the University of Washington (Seattle, WA, USA) and Mengo Hospital (Kampala, Uganda). Informed consent was obtained from patients undergoing and midwives performing the limited obstetric US.

Study location

The study took place in six health centers in the Ruhiira Millennium Villages Project in southwest Uganda. Five of the health centers (Kabugu, Kanywamaizi, Ntungu, Nyakitunda and Ruhiira) provided routine ANC and birthing facilities without operating rooms (levels II and III). The sixth health center (Kabuyanda, level IV) was the referral facility, providing comprehensive obstetric emergency care, including operating rooms and a blood bank.

Equipment

Five GE Logiq E ultrasounds (GE Healthcare Clinical Systems, Wauwatosa, WI, USA) and a single GE Logic Book XP (GE Healthcare Clinical Systems)

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were used for this study. All US examinations were conducted trans-abdominally with wide-band (2.0 to 5.5 mHz) convex array transducers.

These USs were run-off of a solar power-driven system. A 75-watt solar panel was securely attached to the roof of each health center. This panel was connected to a 10 amp solar controller, a 350-watt pure sine wave inverter and a 100 amp-hour battery.

Training

Fourteen midwives from the study health centers attended the 6-week course in limited obstetric US given by the Ernest Cook Ultrasound Research and Education Institute, Kampala, Uganda. Only one of these midwives had any prior US training.

The course content was derived through a collaboration between Ernest Cook Ultrasound Research and Education Institute and The University of Washington, Department of Radiology. The curriculum included US physics, relevant anatomy and physiology, instrumentation and basic maintenance. The training methodology utilized lectures, small-group tutorials, audiovisual materials and supervised clinical scanning. The project midwives returned to their assigned health centers after they completed US training and passed oral and practical competency tests.

In addition to the midwives, the level IV health center was staffed with an experienced radiographer/sonographer who scanned all referred patients and served as an ongoing training resource for midwives who had attended the course.

Midwife scanning expectations

The midwives were instructed to scan all patients presenting for their first routine antenatal visit after the start date of the intervention, regardless of gestational age (GA). Although the study was designed to evaluate the diagnostic impact of US in the second and third trimesters, the diagnostic utility of US was employed in the first trimester symptomatic patients as an adoption of best practice for patient care. The diagnostic utility in symptomatic patients is an added benefit of installing US as a primarily screening tool. For each routine antenatal visit in which US was performed, the midwives completed a form with the pregnancy findings based on their clinical and US exams. They completed the clinical exam and the clinical portion of the form before performing the US exam. Clinical categories were: cardiac activity (yes, no), fetal presentation (cephalic, breech and others) and fetal number.[1–3] They then performed the US exam and completed the US portion of the form. US categories were the same as clinical categories with the addition of placental position (normal, previa and low lying). The midwives were also instructed to scan all patients with abnormal vaginal bleeding or pain (defined as vaginal bleeding or abdominal/pelvic pain of undetermined etiology). US categories were: complete abortion, incomplete abortion, blighted ovum, ectopic pregnancy or placental abnormality.

Midwives were instructed to integrate the US into their regular antenatal visit routine. Total scanning time was targeted at 5 min or less for evaluating for high-risk pregnancies (breech presentation, twins and placenta previa). Given the large patient burden and the concomitant clinical responsibilities of the midwives in this study, we were concerned that scans lasting longer than 5 min would likely negatively affect the patient throughput at these health centers or crowd out elements of ANC provision. A full prenatal US takes longer than 5 min, but that was not the primary task of the midwives. From a practical standpoint, more complex anomalies and detailed biometry were pursued by midwives only when ample time was available as these components were expected to take longer.

Data collection

A logbook was provided to each midwife. A patient entry consisted of a clinical finding and subsequent sonographic finding. The clinical findings were to be entered before imaging with US. The clinical findings included maternal age, last menstrual period, fundal height, presence/absence of fetal heart rate, fetal number, fetal position and an overall clinical impression. The sonographic findings included presence/absence of fetal heart rate, fetal number, fetal position, placental position, GA by biometry, abnormal findings and overall sonographic impression.

These logbooks were then intermittently photographed to allow for conversion of data into an electronic format.

Quality assurance

The midwives were asked to save representative images from their exams to the US machine hard drives. Eighty-six exams were reviewed by two investigators (RN and JOS). Twenty-five patients who referred to the level IV health center for complicated pregnancy were rescanned by the radiographer/sonographer. Exams were evaluated for fetal position, fetal number, lower edge of the placenta and amnionic fluid. Patients referred for pain or bleeding were evaluated for findings of incomplete abortion, blighted ovum or ectopic pregnancy.

Statistical methods

The trimester of each fetus was determined by first approximating the GA as follows:

1. If fundal height was recorded and was no < 20, it was used as the GA in weeks
2. If fundal height could not be used, the number of weeks between the visit date and the last menstrual period was used, if available
3. If last menstrual period was not available and biometry was performed, the biometry findings were used

The first trimester was defined as GA $\leqslant 13$ weeks or the fetus was indicated as nonpalpable in the logbook. The second trimester was defined as GA>13 and GA $\leqslant 26$ weeks and the third trimester was defined as GA>26 weeks.

Encounters were grouped by trimester or by ranges of weeks for different analyses depending on when particular impressions or findings were most important. Continuous variables were summarized as mean $\pm$ s.d. and categorical variables as count (percentage). Confidence intervals (CIs) (95%) were computed to summarize the precision of estimated rates. All statistical calculations were done using R 2.14.1 (The R Project for Statistical Computing; www.r-project.org). Throughout, two-tailed tests were used with $P < 0.05$ denoting statistically significance.

RESULTS

Six sites in Uganda participated in the study. Between October 2010 and July 2011, 1000 patient encounters were logged and converted to an electronic format for analysis. After inspecting the data, 31 entries were excluded owing to inconsistencies between fields in the record, and 30 were excluded owing to lack of indication of which trimester the fetus was in. Those with some missing fields were retained except for analyses directly involving those fields. This left 939 (94%) observations available for subsequent analysis. Maternal age was not recorded for three encounters, but maternal age for the remaining patients ranged from 15 to 43 years, with mean 26 ± 6 years and a median age of 25 years.

Of the 939 patients, 22 (2%) were noted by US to have a nongravid uterus, 76 (8%) were patients scanned in their first trimester, 291 (31%) were patients in their second semester and 550 (59%) were patients scanned in their third trimester.

First trimester complications

Table 1 summarizes the major US diagnoses made in patients undergoing US in their first trimester. Excluding the diagnosis of a nongravid uterus, there were sixteen complications identified in the 98 mothers scanned in their presumed first trimester, 16% (95% CI: 9.6 to 25%).

Diagnostic impact of US examination

Table 2 details the degree of diagnostic impact by specific diagnoses and by GA. Again, diagnostic impact implies a correction of the clinical exam by the findings on US. The far-right columns of Table 2 detail the type of clinical error, be it false positive or false negative. Of note, the presentation by clinical exam was unknown in 11 (3%) and 2 (1%) encounters in the early and late third trimester periods, respectively. Those with unknown

presentation were only counted when the US exam indicated non-cephalic presentation.

Overall impact

Table 2 also summarizes the impact of US for the various findings as well as overall impact, computed multiple ways. If major diagnoses are conservatively defined as major first trimester complication, absence of cardiac activity/fetal demise ⩾20 weeks, multiple gestation at any time, non-cephalic presentation ⩾36 weeks, and placental malposition ⩾36 weeks, there were 939 encounters that fell within these intervals. Of these, change in diagnosis after US was noted in 63 patients whereas 91 records were not complete enough to definitively determine whether an important diagnosis change occurred. Thus the diagnosis impact rate was between 63 of 939 (6.7%) and 63 of 848 (7.4%). If a more inclusive definition of major diagnosis is used that combines all findings summarized in Table 2, including non-cephalic presentation diagnosed at 28 to 35 weeks, there were 100 changes of diagnosis after US, for an impact rate between 100 of 939 (11%) and 100 of 853 (12%).

Table 1. Rates of ultrasound detected complications or conditions in the first trimester (includes nongravid cases)

Condition	*N*	*Rate, % (95% CI)*
Molar pregnancy	4	4.1 (1.1, 10)
Ectopic	1	1.0 (0.0, 5.5)
Incomplete abortion	2	2.0 (0.2, 7.2)
Complete abortion	5	5.1 (1.7, 12)
Abnormal fluid	2	2.0 (0.2, 7.2)
Blighted ovum	3	3.1 (0.6, 8.7)
Nongravid uterus	22	22 (15, 32)
Combined ex nongravid	16[a]	16 (9.6, 25)

Abbreviation: CI, confidence interval.
Thirty-one observations with missing ultrasound impressions were excluded ($N=98$).
[a]One patient charted with both ectopic pregnancy and incomplete abortion.

Sensitivity and specificity of the clinical exam for the major findings are summarized in Table 3. Generally specificity was quite high, though sensitivity tended to be moderate (36 to 80%) except for detecting non-cephalic presentation at 36 weeks or later, where sensitivity was 100% (CI: 85 to 100%). In particular, multiple gestation was often missed before 32 weeks, though this was overall an uncommon finding.

Overreads of images archived by midwives

Midwives saved images from 86 patient scans and these images were overread by two radiologists from the University of Washington. In three cases, the images saved by the midwives were inadequate for review. Another case was found to be a probable mole, which was correctly categorized as 'abnormal intrauterine contents' by the midwife.

Among the 82 remaining patients, 3 multiple gestations were diagnosed by the radiologist. All three were correctly interpreted by the midwife on the original scan (sensitivity: 100%; CI: 29 to 100%). In the remaining 79 cases, singletons noted by the radiologists doing the overread were correctly interpreted by the midwives on the original scan (specificity: 100%; CI: 95, 100%).

Of the 79 singletons, 10 were in the first trimester and one had archived images that were inadequate to determine fetal presentation. Of the 68 remaining, 20 (29%) were found by the expert reader to have non-cephalic presentations. The midwives misinterpreted two scans as normal, which were subsequently overread by the radiologists as non-cephalic presentations (sensitivity: 90% (CI: 68, 99%)). The midwives misinterpreted two scans as representative of non-cephalic presentation, which were subsequently determined to be a normal lie by the radiologists (specificity: 96% (CI: 86, 99%)).

The placenta position could be evaluated in 60 patients, after excluding 12 where the cervix was not visible in the saved images. Low-lying placenta was found in one patient by the expert reader but was classified as normal by the midwife. All others were found to be normal.

Overreads of patients referred by midwives

As described above, 25 patients who were determined to have potential pregnancy complications or high-risk pregnancies by

Table 2. Diagnostic impact of US examination by individual findings and overall

Finding	*GA, weeks*	*No. usable*	*Diagnosis changed by US*		*Clinical error*	
			No.	*% (95% CI)*	*No. of FPs*	*No. of FNs*
A: Major first trimester complication	0–13	98	16	16 (9.6, 25)		
B: Absence of cardiac activity/fetal demise	20–40+	789	20	2.6 (1.6, 4.0)	18	2
C: Multiple gestation #1	0–31	552	9	1.6 (0.7, 3.1)	2	7
D: Multiple gestation #2	32–40+	355	9	2.5 (1.2, 4.8)	4	5
E: Non-cephalic presentation #1	28–35	361	41	11 (8.3, 15)	26	15
F: Non-cephalic presentation #2	36–40+	181	9	5.0 (2.3, 9.2)	9	0
G: Placental malposition #1	14–35	660	5	0.8 (0.2, 1.8)		
H: Placental malposition #2	36–40+	181	1	0.6 (0.0, 3.0)		
Overall impact (all relevant encounters)[a]						
Conservative: findings A–D, F or H	0–40+	939	63	6.7 (5.2, 8.5)		
Inclusive: findings A–H	0–40+	939	100	11 (8.7, 13)		
Overall impact (excluding missing)[b]						
Conservative: findings A–D, F or H	0–40+	848	63	7.4 (5.8, 9.4)		
Inclusive: findings A–H	0–40+	848	100	12 (9.7, 14)		

Abbreviations: FN, false negative; FP, false positive; GA, gestational age in weeks; US, ultrasound; Usable, records complete enough to make determination, as described in text.
[a]Including all encounters where there is opportunity for impact and assuming no impact in the case of missing values.
[b]Including only encounters with sufficiently complete records to definitively determine diagnostic impact.

Table 3. Sensitivity and specificity of clinical examinations for important findings

Finding	*GA, weeks*	*Positive by US*		*Negative by US*		*Frequency of important findings, %*
		N	*Sensitivity, % (95% CI)*	*N*	*Specificity, % (95% CI)*	
Absence of cardiac activity/fetal demise	20–40+	10	80 (44, 97)	779	98 (96, 99)	1.3
Multiple gestation #1	0–31	11	36 (11, 69)	541	99 (98, 100)	2.0
Multiple gestation #2	32–40+	16	69 (41, 89)	339	99 (97, 100)	4.5
Non-cephalic presentation #1	28–35	75	80 (69, 88)	286	91 (87, 94)	20.7
Non-cephalic presentation #2	36–40+	23	100 (85, 100)	158	94 (89, 97)	12.7

Abbreviations: CI, confidence interval; GA, gestational age in weeks; US, ultrasound.

screening obstetric US performed by a midwife were subsequently referred to the level IV referral center, where they were rescanned by a radiographer/sonographer with more complete US training. The findings from repeat scans of 25 referred patients were recorded. These repeat scans occurred between March 2011 and July 2011 and so relate to the performance of midwives late in the study period. The indication for referral was recorded in 22 of 25 and included: molar pregnancy,[2] incomplete abortion,[4] complete abortion,[1] unsuccessful pregnancy,[1] polyhydramnios,[2] adnexal mass,[1] uterine mass,[1] fetal demise,[3] nuchal cord,[2] malpresentation,[2] multiple gestation,[1] marginal previa[1] and fetal head not completely seen.[1] These findings were confirmed by a sonographer overread in 17 of 22 (77%) patients. The five confirmed diagnostic errors were no uterine mass,[1] no nuchal cord,[2] marginal previa not diagnosable at 12 weeks[1] and fetal head not visible owing to descent.[1] In the three patients without referral indications recorded, two were confirmed to be normal pregnancies, whereas one had complete previa. Thus the rate of referrals with confirmed abnormal diagnoses was 18 of 25 (rate: 72% (CI: 51, 88%)).

DISCUSSION

Screening obstetric US in rural settings in developing countries where the barriers to accessing physicians, comprehensive emergency obstetric care and skilled US has not yet been evaluated. Screening obstetric US, as we define it, refers to an intervention differing notably from those previously studied. It involves limited obstetric US screening by allied health professionals, including midwives, in remote health centers, as a means of identifying high-risk pregnancies and providing these women with the information necessary to encourage them to present at referral hospitals before delivery. Previous work has demonstrated diagnostic impact when limited obstetric US has been used selectively by allied health workers to clarify a clinical concern. In this role, sonographic findings altered the patient care plan from 17–86%.[10–12] However, US was not clearly used as a screening tool in these studies.

We have set out to evaluate the potential of limited obstetric US in rural Africa by approaching the question in a step-wise fashion. The initial step in evaluating limited obstetric US is to determine whether midwives, with focused obstetric US training, realize a positive diagnostic impact when screening US is incorporated into the standard of care for an antenatal visit.

Our study demonstrates that limited obstetric US used as a screening and diagnostic tool by midwives improves accuracy of diagnosis when compared with the clinical exam. This correction in diagnosis occurred in 6.7 to 7.4% of the obstetric patients screened by midwives by conservative standards, and 11 to 12% of the time with more inclusive standards. As expected, this rate of diagnostic impact is lower than the reported diagnostic impact of US when utilized purely to clarify a clinical concern.

The more inclusive standard includes US-driven change in diagnosis of fetal presentation in women scanned between 28 and 35 weeks. We feel it is important to consider this early third trimester malpresentation group given the high rate of persistent malpresentation in this gestational window.[13] In ideal circumstances, these early third trimester clinical misses would have been caught or clarified on follow-up ANC visits. However, mothers in rural Uganda have a low rate of attending all four recommended ANC visits. Therefore, the US diagnosis of a potential breech, even in the early third trimester, may have clinical importance on outcome. Following each pregnancy outcome was beyond the scope of our study, so we have provided this range for diagnostic impact.

Screening obstetric US, in its role of determining fetal presentation, reduced overcalling of breech by a clinical exam in addition to identifying potential high-risk pregnancies that clinical exams had missed. In the third trimester, sonography corrected the clinical diagnosis of fetal presentation 9.2% of the time. Of these corrections in diagnosis, 70% were clinical overcalls of breech. The midwife's clinical exam missed a non-cephalic presentation in 15 of the 542 patients. Thus, our study suggests that US identifies potential high-risk pregnancies that the clinical exam would have missed, and US decreases the patient and health-care system burden by limiting the number of clinical false-positive diagnoses of malpresentation.

The diagnosis of twins is important at any GA, because, as mentioned above, not all mothers return for scheduled ANC. Our study suggests that US provides diagnostic impact compared with clinical exam alone in both early and late gestation. US resulted in a corrected diagnosis in 9 of the 339 third trimester encounters. In five of these nine cases, the clinical diagnosis of a singleton was corrected to twins. In the remaining four, the clinical diagnosis of twins was corrected to a singleton. These findings suggest that the clinical diagnosis of twins by midwives in rural Uganda can be improved by US, even in the third trimester.

Diagnosis of placenta previa and low-lying placenta by midwife-operated, screening obstetric US was infrequent. This may reflect the combination of the low incidence and sample size error from a small sample size. However, even the few cases of low-lying placenta discovered are clinically important. As Osmundson *et al*.[14] describe, placenta previa and low-lying placenta are associated with a threefold increased chance of postpartum hemorrhage. The low frequency of previa detection may reflect that this is the most difficult of the high-risk indications for midwives to detect by US. This is supported by the number of limited placenta views seen in our quality assurance (QA) process, as discussed below.

In the first trimester, non-screening US provided a diagnostic impact rate of 16%. This is similar to the first trimester rates reported by Kimberly *et al*.[10] Given the limitations of clinical exam in the first trimester, this degree of diagnostic impact is expected. The ANC visits in the first trimester are more likely driven by early pregnancy complications, and, in turn, US

is used more like a diagnostic tool than a screening tool when determining the etiology of the abnormal clinical presentation. Thus, the presence of an US for obstetric screening in a rural African clinic provides the added benefit of improving diagnostic accuracy in cases of clinical concern.

Our targeted QA review demonstrated that the 6-week limited obstetric US instruction course for US-naive midwives resulted in proficient imaging by these midwives. The image review demonstrated 100% sensitivity and specificity in the detection of singletons and twins. Fetal presentation determination by midwives showed a 90% and 96% sensitivity and specificity, respectively. Imaging of the cervix and placental position was less robust. The cervix was poorly captured in the submitted QA images in 12 of the 72 cases. Of course, the saved image does not always reflect what a midwife saw in real-time scanning. In the one submitted QA case that had a low-lying placenta, the midwife labeled the placenta as normal in position. The overread data collected by the local radiographer also support the proficiency of midwives. The radiographer confirmed 17 of the 22 (77%) abnormalities that initiated a referral to the level IV hospital. The additional five cases were deemed overcalls for subtle findings such as a nuchal cord.

There are certain limitations to this study that should be considered when interpreting the results. We cannot provide the sensitivity and specificity of the limited obstetric USs performed by midwives, as most these studies were performed independently by the midwives and the scope of this project did not allow us to determine the outcome of each pregnancy. We believe that the false negatives for fetal presentation and fetal number would be very low, given the relative proficiency that the midwives demonstrated in finding these entities in training. Placenta previa may have been missed, as the rate of detection seems lower than expected, but this low rate may be owing to small sample size. We attempted to evaluate the adequacy of the exams via our QA system. However, this QA analysis did not include all patients. The determination of true positives and false positives can be estimated by evaluating the change in diagnosis by the radiographer at the referral center.

This study evaluated diagnostic impact. The US's independent 'magnet' effect on process indicators such as number of ANC visits and use of referral centers for delivery was not evaluated in this study. We felt that the multiple concurrent interventions at this Millennium Village Project site would have confounded our analysis of the process indicators. The ultimate question is whether or not US has a positive impact on maternal and fetal mortality and if it does, at what economic cost. These questions are outside the scope of this study but beg further investigation, especially given that our results confirm the diagnostic impact of limited screening US performed by midwives.

CONCLUSION

Limited, screening obstetric US performed by midwives with focused, obstetric US training demonstrates diagnostic impact for the diagnosis of high-risk pregnancies in 6.7 to 12% of patients screened. Specifically, the routine limited, screening obstetric US demonstrated improved diagnosis of early pregnancy complications as well as later gestation twins and malpresentation.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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