Original Investigation

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Diagnostic Accuracy of an Integrated AI Tool to Estimate Gestational Age From Blind Ultrasound Sweeps

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Diagnostic Accuracy of an Integrated AI Ultrasound Tool for Gestational Age Estimation

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An AI-Enabled Ultrasonography Tool for Estimating Gestational Age

Key Points

Question Can novice clinicians accurately estimate gestational age using a low-cost, battery-powered ultrasonography probe with integrated artificial intelligence (AI) image interpretation?

Findings This prospective study enrolled 400 pregnant individuals with due dates confirmed by first-trimester ultrasonography. At follow-up visits randomly assigned throughout gestation, novice clinicians using an AI-enabled device estimated

gestational age as accurately as credentialed sonographers using traditional ultrasonography devices (difference, 0.2 days).

Meaning Obstetrical care in low-resource settings may benefit from reliable gestational age assessment using AI integration with point-of-care ultrasonography.

Abstract

Importance Accurate assessment of gestational age (GA) is essential to good pregnancy care but often requires ultrasonography, which may not be available in low-resource settings. This study developed a deep learning artificial intelligence (AI) model to estimate GA from blind ultrasonography sweeps and incorporated it into the software of a low-cost, battery-powered device.

Objective To evaluate GA estimation accuracy of an AI-enabled ultrasonography tool when used by novice users with no prior training in sonography.

Design, Setting, and Participants This prospective diagnostic accuracy study enrolled 400 individuals with viable, single, nonanomalous, first-trimester pregnancies in Lusaka, Zambia, and Chapel Hill, North Carolina. Credentialed sonographers established the “ground truth” GA via transvaginal crown-rump length measurement. At random follow-up visits throughout gestation, including a primary evaluation window from 14 0/7 weeks’ to 27 6/7 weeks’ gestation, novice users obtained blind sweeps of the maternal abdomen using the AI-enabled device (index test) and credentialed sonographers performed fetal biometry with a high-specification machine (study standard).

Main Outcomes and Measures The primary outcome was the mean absolute error (MAE) of the index test and study standard, which was calculated by comparing each method’s estimate to the previously established GA and considered equivalent if the difference fell within a prespecified margin of ±2 days.

Results In the primary evaluation window, the AI-enabled device met criteria for equivalence to the study standard, with an MAE (SE) of 3.2 (0.1) days vs 3.0 (0.1) days (difference, 0.2 days [95% CI, −0.1 to 0.5]). Additionally, the percentage of assessments within 7 days of the ground truth GA was comparable (90.7% for the index test vs 92.5% for the study standard). Performance was consistent in prespecified subgroups, including the Zambia and North Carolina cohorts and those with high body mass index.

Conclusions and Relevance Between 14 and 27 weeks’ gestation, novice users with no prior training in ultrasonography estimated GA as accurately with the low-cost, point-of-care AI tool as credentialed sonographers performing standard biometry on high-specification machines. These findings have immediate implications for obstetrical care in low-resource settings, advancing the World Health Organization goal of ultrasonography estimation of GA for all pregnant people.

Trial Registration ClinicalTrials.gov Identifier: NCT05433519

Introduction

Obstetrical sonography is a cornerstone of modern pregnancy care.[1] Among its many capabilities is the ability to obtain accurate measurements of fetal structures, which in turn are used to estimate gestational age (GA).[2,3] Obstetrical clinicians use GA to guide various aspects of antenatal care, such as when to screen for gestational diabetes[4] and when to administer certain vaccines to maximize maternal and neonatal benefit.[5] GA also critically informs clinical decision-making, such as whether to provide corticosteroids[6] or neuroprotective magnesium sulfate[7] for anticipated preterm delivery and whether clinician-initiated delivery is appropriate for a given condition.[8,9]

The World Health Organization recommends that all pregnant people receive at least 1 ultrasonography examination prior to 24 weeks.[10] Although this policy recommendation remains largely aspirational in many low- and middle-income countries (LMICs), recent advances in ultrasonography hardware[11,12] and artificial intelligence (AI)–enabled medical image analysis[13,14] could facilitate broader access to this critical diagnostic tool. In 2022, a deep learning algorithm developed in an international study of 4695 pregnant volunteers that could estimate GA from blindly obtained ultrasound sweeps of the gravid abdomen was examined.[15] Here, in a separate cohort, the diagnostic accuracy of that algorithm is reported when incorporated into the software of a low-cost battery-powered device and used by clinicians with no formal training in sonography.

Methods

This prospective diagnostic accuracy study enrolled 400 pregnant individuals with viable, single, nonanomalous, first-trimester pregnancies in Lusaka, Zambia and Chapel Hill, North Carolina. This study received approval from the institutional review board at the University of North Carolina, the University of Zambia Biomedical Research Ethics Committee, the Zambia Medicines Regulatory Authority, and the Zambia National Health Research Authority before initiation. An external auditor conducted quarterly site visits in both North Carolina and Zambia to ensure compliance with the study protocol, standard operating procedures, International Conference on Harmonization Good Clinical Practice, and US 45 CFR 46 regulations.

Credentialed sonographers established the “ground truth” GA via transvaginal crown-rump length measurement.[16] Participants were then assigned follow-up visits at random dates within a primary GA evaluation window (14 0/7 to 27 6/7 weeks’ gestation) and 2 secondary windows to ensure observations were evenly spaced in an unbiased manner throughout the pregnancy. At each follow-up visit, novice users with no prior training in sonography assessed GA with blind sweeps of the maternal abdomen using the AI-enabled device (index test). The technology for the index test comprised a previously described deep learning model[15] incorporated into the software of the Butterfly IQ+ handheld ultrasonography device (Butterfly Networks, Inc). To facilitate integration into the Butterfly IQ+ software, we made modifications to optimize the model for real-time inference on a mobile device. We also incorporated a fail-safe mechanism that required the user to repeat collection of blind sweeps that did not reach a certain quality threshold (see Supplement 1).

The study employed obstetrics-trained sonographers, each credentialed by the operant authority in their country (the American Registry for Diagnostic Medical Sonography or the Health Professions Council of Zambia). The credentialed sonographer used a high-specification ultrasound machine to assess GA with fetal biometry (study standard). The index test was performed first, using a software version that did not display the calculated GA at the completion of the procedures. Index test users were not allowed to consult with study sonographers while using the tool. During study implementation, both novice users and credentialed study sonographers were blinded to the participant's ground truth GA.

The study was conducted at the University Teaching Hospital and the Kamwala District Health Centre in Lusaka, Zambia and at the University of North Carolina Vilcom Center Clinic in Chapel Hill, North Carolina. We included people who (1) were 18 years or older, (2) had a viable intrauterine pregnancy at less than 14 0/7 weeks' gestation, (3) provided written informed consent, (4) intended to remain in the current geographical area of residence for the duration of study, and (5) were willing to adhere to study procedures. We excluded people who (1) had a body mass index (BMI) greater than or equal to 40, (2) were pregnant with twins or higher-order multiples, (3) had a known major fetal anomaly, or (4) had any social or medical condition that would make study participation unsafe or complicate data interpretation.

With anticipation that the principal use of the index test would be in LMIC settings in which initial presentation for pregnancy care typically occurs later in gestation[17] than in North America and Europe, we defined a primary evaluation window from 14 0/7 to 27 6/7 gestational weeks. This window corresponds to a range that would capture 85% of individuals attending their first antenatal visit in LMICs.[18] For secondary analyses, we defined a secondary evaluation window (28 0/7 to 36 6/7 gestational weeks) and a tertiary evaluation window (37 0/7 to 40 6/7 gestational weeks).

The study employed randomization to assign a participant's visit schedule and thus the GA at assessment within each evaluation window. A statistician not involved in study implementation designed the randomization scheme and pregenerated each participant's visit schedule prior to study commencement. The scheme did not allow a participant who was assigned to the last week in an evaluation window to also be assigned to the first week in the subsequent window (ie, to have 2 study visits only 1 week apart); this was the only constraint on the randomization.

Index Test

The index test was designed for use by novice clinicians without prior training in sonography. Before the study commenced, novice users were identified at each site (eTable 7 in Supplement 2) and underwent a 1-day training session. The curriculum covered software navigation, patient positioning, gel application, probe orientation and pressure, and blind sweep collection. Half of the training day was spent getting hands-on experience with patients in the research clinic using the tool under the supervision of an experienced sonographer.

The index test began with the novice user assessing the symphysis-fundal height and entering the resultant measurement (in centimeters) into the device software. This

allowed the tool to set the number of required sweeps and configure the ultrasound probe's depth and gain settings. The software then guided the user through collection of a series of 10-second blind sweep videos (eFigure 1 in the Supplement 2). Although the software offered an instructional animation demonstrating probe movement, it did not display real-time ultrasonography images (see Video).

Study Standard

The study standard for GA assessment was fetal biometry.[16] At each study visit, a credentialed sonographer obtained 2 separate measurements of the fetal head circumference, biparietal diameter, abdominal circumference, and femur length on a high-specification ultrasonography machine (General Electric Healthcare). The mean of the 2 measures was used to calculate the GA on that day using either the 2-parameter Intergrowth 21 formula[3] (Zambia) or 4-parameter Hadlock formula[2] (North Carolina). Consistent with previous publications[15,19] we explored the impact of different biometry formulas on outcomes through sensitivity analyses.

Study Outcomes

This study assessed estimation error of the index test and study standard by comparing each test's estimate with the ground truth GA previously established in early pregnancy. Our primary outcome measure was the difference in mean absolute error (MAE) between the index test and the study standard, assessed in the primary evaluation window. Secondary outcome measures were the difference in MAE between the 2 tests assessed in the secondary and tertiary evaluation windows, the difference in root mean square error assessed in all 3 windows, and the difference in the proportion of studies correctly classified within 7 and 14 days of ground truth in all 3 windows.

Statistical Approach

We hypothesized that the index test would be equivalent to the study standard and, through consultation with experts in North Carolina and Zambia, established a mean estimation error no worse or better than 2 days as the equivalency margin[20] for this study. We used Monte Carlo simulation to establish a sample size that yielded at least 95% power for the ±2-day equivalency margin and type I error of 2.5% (further details are available in Supplement 3).

We calculated a 95% CI for the primary outcome. A difference for which the 2-sided 95% CI is contained entirely within the prespecified range of −2 to 2 days would indicate that the index test is equivalent to the study standard. To establish equivalence, 2 one-sided statistical tests on the difference between the MAE of the index test and the MAE of the study standard were carried out based on the predefined margin. As secondary analyses, we present the difference in root mean square error and its 95% CI. We also plot the empirical cumulative distribution function for the absolute error produced by the index test and expert biometry. We then present the difference in percentages with absolute error below 7 and 14 days between the index test and study standard, along with Wald-type 95% CIs.

Subgroup analyses prespecified in our statistical analysis plan included geographic location and high BMI (≥30). Additionally, because many LMICs do not have

ultrasound biometry widely available, we conducted an exploratory analysis comparing the performance of the index test with that of the de facto study standard in these settings: patient-reported last menstrual period[21] and measurement of the symphysis-fundal height.[22]

Results

Between July 27, 2022, and April 10, 2023, a total of 951 individuals who appeared eligible to participate were identified through clinical record review. Of these individuals, 480 were excluded because they were either unable to be reached, found to be ineligible after further investigation, or not interested in participation (Figure 1). The remaining 471 provided informed consent to participate and were randomly assigned dates for follow-up visits in the 3 evaluation windows. On May 31, 2023, the 400th participant attended visit 1 (primary evaluation window) and study enrollment was closed.

The 400 study participants had a median (IQR) age of 29 (25-33) years, a median (IQR) of 13 (10-16) years of education, and a median (IQR) BMI of 25.9 (22.6-29.9). Overall, 252 participants (63%) were parous and 25 (all in Zambia; 8.0%) were HIV-seropositive. Compared with the North Carolina cohort, participants in Zambia were younger with lower BMI, lower rates of chronic hypertension and diabetes, and higher parity (Table 1). No adverse events were attributed to the index test or the reference standard at any visit.

Primary Evaluation Window (14-27 Gestational Weeks)

All 400 participants were assessed with both the index test and study standard during the primary evaluation window. In 1 case (0.25%) the index test failed to produce a GA estimate, while standard fetal biometry was successfully obtained from all 400 participants. Among the 399 individuals from whom paired assessments are available, the index test MAE (SE) was 3.19 (0.13) days, compared with 3.03 (0.12) days for the study standard (difference, 0.16 [95% CI, −0.14 to 0.45] days; Table 2; Figure 2), meeting the predefined equivalency margin. The proportion of assessments correctly classified within 7 days of the ground truth GA were comparable between the 2 methods (90.7% for the index test vs 92.5% for the study standard; difference, −1.8% [95% CI, −5.0% to 1.5%]). Both tests were highly accurate for GA estimates within a 14-day range, each misestimating 1 (distinct) participant by more than 14 days (99.8% for the index test vs 99.8% for the study standard; difference, 0% [95% CI, 0% to 0.7%]).

Table 2 displays the index test performance by geography and BMI, without adjustment to account for multiple comparisons. There was a similar difference in MAE between the index and study standard by site (Zambia [n = 199]: −0.18 [95% CI, −0.56 to 0.20] days; North Carolina [n = 200]: 0.49 [95% CI, 0.05 to 0.94] days). Among the subgroup whose first-visit BMI was greater than or equal to 30 (n = 97), the difference between tests was 0.70 (95% CI, 0.07 to 1.33) days (Table 2).

eTables 5 and 6 in Supplement 2 display results from 2 planned sensitivity analyses that assessed all biometry using a single uniform formula (ie, one analysis applying Intergrowth 21 to both countries and a second applying Hadlock to both). These

analyses revealed that employing distinct formulas by site did not materially influence findings or conclusions.

Secondary (28-36 Gestational Weeks) and Tertiary (37-40 Gestational Weeks) Evaluation Windows

The secondary evaluation window spanned the 9-week interval from 28 0/6 to 36 6/7 weeks' gestation. Between scheduled visits in the primary and secondary evaluation windows, 1 participant formally withdrew from the study and 19 had a miscarriage or preterm delivery, reducing the expected attendance in the secondary window to 380 participants (Figure 1). Of these participants, 359 (94.5%) attended as anticipated. In all 359 participants, both the index test and clinical standard produced a GA estimate. During the secondary window, the index test MAE (SE) was 6.07 (0.26) days, compared with 7.12 (0.30) days for the study standard (difference, −1.06 [95% CI, −1.72 to −0.40] days; eTable 1 and eFigure 2 in Supplement 2), meeting the study definition of equivalence. eTable 2 in Supplement 2 displays the percentage of assessments correctly classified within 7 and 14 days: 64.4% (95% CI, 59.4%-69.3%) and 91.4% (95% CI, 88.5%-94.3%), respectively, for the index test compared with 57.1% (95% CI, 52.0%-62.2%) and 87.2% (95% CI, 83.7%-90.6%), respectively, for the study standard (difference: 7.2% [95% CI, 0.7%-13.8%] for within 7 days and 4.2% [95% CI, 0.1%-8.3%] for within 14 days).

The tertiary evaluation window spanned the 4-week interval from 37 0/6 to 40 6/7 weeks' gestation. Of the 380 participants with a continuing, viable pregnancy at the second visit, 187 either delivered or experienced a stillbirth before their scheduled visit in the tertiary evaluation window. Thus, the expected attendance for the third visit was 193 participants, of whom 175 (91%) attended (Figure 1). In all participants both the index test and study standard produced a GA estimate; however, neither test performed particularly well. The index test had a MAE (SE) of 11.54 (0.49) days, compared with 9.10 (0.54) days for the study standard (difference, 2.43 [95% CI, 1.19-3.68] days; eTable 2 and eFigure 3 in Supplement 2). eTable 2 in Supplement 2 shows the percentage of assessments correctly classified within 7 and 14 days: 28.0% and 66.3%, respectively, for the index test and 46.3% and 74.3%, respectively, for the study standard (difference: −18.3% [95% CI, −27.9% to −8.64%] for within 7 days and −8.0% [95% CI, −16.7% to 0.74%] for within 14 days; eTable 2 in Supplement 2).

Index Test vs de Facto GA Assessment Standards

In an exploratory analysis, performance of the index test during the primary evaluation window was compared with the de facto GA assessment standard in many LMIC settings: last menstrual period and symphysis-fundal height. Among the 399 individuals from whom an index test estimate was available during the primary evaluation window, 23 (5.8%) could not recall their last menstrual period and were excluded. Among the remaining 376 participants, the MAE (SE) was 3.20 (0.14) days for the index test compared with 7.44 (0.51) days for last menstrual period (difference, −4.24 [95% CI, −5.27 to −3.20] days; Figure 3; eTable 3 in Supplement 2). The symphysis-fundal height could not be assessed because the uterus was not palpable in 4 of the 399 individuals from whom an index test estimate was available. Of the remaining 395 participants, the index test had an MAE (SE) of 3.18 (0.13)

days compared with 7.06 (0.34) days for fundal height (difference, −3.88 [95% CI, −4.61 to −3.15] days; Figure 3; eTable 4 in Supplement 2).

Discussion

This prospective, 2-country diagnostic accuracy study provides evidence that an AI-enabled ultrasonography tool used by novice clinicians with 1 day of training can provide GA estimates that are as accurate as credentialed sonographers performing standard fetal biometry. Specifically, over the critical GA window during which most people in LMIC settings attend their first antenatal visit (14-27 weeks' gestation), the index test met the predefined criteria for statistical equivalence to a credentialed sonographer using a high-specification machine. Although hypothesis testing was not performed in the subgroup analyses, these findings appear to be consistent across geography (Zambia and North Carolina) and among participants with high BMI (in whom ultrasonography can be more difficult to perform). The index test also met criteria for equivalency in a secondary GA window between 28 and 36 weeks' gestation, whereas results were inconclusive after term (≥37 weeks' gestation).

The selection of evaluation windows was informed by a report of more than 100 000 pregnancies in Zambia, which revealed that 85% of first antenatal visits occur by the end of the primary evaluation window and 97% by the end of the secondary window.[17] These figures are remarkably consistent across LMICs and confirmed by a recent comprehensive review.[18] In line with prior work,[15] the deep learning AI model appears to perform particularly well during the secondary evaluation window (28-36 weeks' gestation), a period during which meaningful variations in fetal size, attributable to pathological or constitutional factors, begin to emerge. Conversely, the model appears to underperform fetal biometry after term gestation (37-40 weeks' gestation) and, although these results are statistically inconclusive, it is not recommended to use this antenatal assessment tool to determine GA at term.

Unlike previous reports in which ultrasonography videos were processed and analyzed on a central server,[15,19] this study demonstrates the feasibility of integrating an AI tool into clinical practice. The deep learning model was incorporated directly into the ultrasonography device software, which runs on an Android tablet computer, allowing image processing, feature extraction, and inference to occur in real time on the local device, facilitating immediate clinical decision-making (see Video). This research has the potential to inform expansion of basic obstetrical ultrasonography, bringing previously unavailable diagnostic capacity to settings in which resources are scarce but clinical disease burden is high.

Several methodological strengths support the validity of these findings. The current study enrolled a socioeconomically diverse cohort whose GA was established by first trimester crown-rump length. In an effort to mitigate expected value bias,[23] both expert sonographers and novice users were blinded to participant ground truth GA and to the results of each other's assessments. The study employed a novel use of randomization to ensure unbiased allocation of participant visits across all possible gestational ages.

Limitations

There are important limitations to this research. First, the study enrolled a general obstetrical population and was not designed to assess performance of the AI-enabled tool among patients with high-risk conditions linked to inaccurate GA dating. Assessing performance of the index test in settings of hypertension, diabetes, and class III obesity—also challenging to traditional ultrasound biometry—will be important future work. Second, although the 3 sites in 2 countries provided socioeconomic diversity, inclusion of more geographic locations could improve generalizability of these findings. Third, because the protocol excluded participants with known fetal anomalies, the accuracy of the tool in such cases cannot be determined.

Conclusions

Between 14 and 37 gestational weeks, low-cost AI-enabled ultrasonography allowed novice users with no prior training in ultrasonography to estimate GA as accurately as credentialed sonographers performing standard biometry on high-specification machines. These findings have immediate implications for obstetrical care in low-resource settings, advancing the World Health Organization goal of ultrasonography estimation of GA for all pregnant people.

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