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Comparative Performance of Low-Cost Portable Scanner in Pregnancy Profile Ultrasonography: A Promising Adjunct to Telemedicine

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ABSTRACT

Background and Objective: Ultrasound scanners are widely used in various clinical settings, but conventional devices are too expensive to deploy in every healthcare facility in low-resource countries. Alternative, less costly instruments with comparable efficacy are required to ensure this diagnostic service is available in even remotest areas. This study evaluated the effectiveness of a commercially available low-cost portable ultrasound machine, particularly focusing on pregnancy profiling.

Material and Methods: A total of 77 pregnant females were scanned for basic obstetric parameters with two devices, first the low-cost scanner, and then a conventional ultrasound machine, considering the latter as the gold standard. The key obstetric parameters observed were the number of fetuses, the presence of cardiac pulsation and fetal movement, fetal biometry including Crown Rump Length (CRL), Bi-Parietal Diameter (BPD), and Femoral Length (FL), gestational age, placental location, amniotic fluid volume, and presentation of the fetus.

Results: The portable device performed well compared with the standard machine in observing the fetal number, presentation, movement, heartbeat, placental location, and amniotic fluid volume. The correlation coefficients (r²) for measuring BPD, FL, CRL, and gestational age using the portable and standard devices were 0.9578, 0.9415, 0.8230, and 0.983, respectively. The mean absolute error (MAE) in the measurement of BPD, FL, CRL, and gestational age were 2.24 mm, 2.14 mm, 6.5 mm, and 0.94 weeks, respectively.

Conclusion: The results demonstrated the potential of low-cost portable ultrasound devices in pregnancy profile scanning. Further studies with larger sample sizes are needed to explore their full potential. With appropriate data transfer arrangements, these devices have significant potential for integration into telemedicine services.

Keywords – Portable ultrasound, Antenatal care, Pregnancy profiling, Maternal health, Telemedicine.

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INTRODUCTION

Ultrasonography (USG) is a non-invasive clinical imaging modality that has gained widespread acceptance as a reliable diagnostic tool. It requires less infrastructure and logistic support than instruments used for X-ray examinations, computed tomography, or magnetic resonance imaging, but it provides real-time information. This technology has found its way into various clinical settings, including gynecology and obstetrics. The acceptability of USG is more profound in this specialty due to a lower radiation hazard. Pregnant women are recommended to have at least one USG scan during the antenatal period to estimate gestational age, and improve detection of fetal anomalies and multiple pregnancies.¹

Maternal mortality rate is variable in different parts of the world reflecting inequalities in economic conditions and quality healthcare access. In 2020, around 95% of all maternal deaths occurred in low and lower-middleincome countries, which was 430 per 100,000 live births.² However, the sustainable development goal target is to reduce maternal mortality to less than 70 per 100,000 live births by 2030. Most of these deaths are due to preventable causes, so early detection of complications is crucial to ensure prompt clinical intervention, which can be lifesaving. Pregnancy complications also have long-term effects on maternal health.³ Therefore, implementing USG in remote healthcare facilities for expecting mothers should be urgently considered. However, USG devices are costly and not readily accessible to rural populations, especially in low-income countries.⁴

Currently, tablet- or smartphone-based portable USG scanners are available at relatively low prices.⁵ Portable USG allows healthcare providers to conduct real-time ultrasound examinations remotely. Through telemedicine platforms, clinicians can guide on-site healthcare workers or patients to perform ultrasound scans, providing valuable insights. Portable ultrasound devices are particularly valuable in low-resource settings, such as rural areas or underserved communities, where access to advanced medical facilities is limited. Telemedicine can bridge the gap by connecting local healthcare providers with specialists who can remotely interpret ultrasound images. In obstetrics, portable USG in telemedicine can

support prenatal care. Expectant mothers can undergo ultrasound scans locally, with the results transmitted to specialists for analysis. This approach ensures that pregnant women in remote areas receive timely and expert guidance throughout their pregnancy. Therefore, implementing USG in remote healthcare facilities for expecting mothers should be urgently considered.

However, USG devices are very expensive and not readily accessible to rural populations in low-income countries.⁴ Currently, tablet- or smartphone-based portable USG scanners are available at relatively lower prices.⁵ However, the utility of such low-cost portable scanners in pregnancy profiling must be investigated before deployment in any healthcare program.⁶ Heuvel et al. conducted a comparative analysis assessing the efficacy of low-cost ultrasound devices for estimating gestational age (GA) in resource-limited settings, suggesting the feasibility of utilizing such devices for GA estimation.⁷ Stock et al. compared the performance of pocket-sized ultrasound device with a premium machine in bedside examinations and reported limited utility.⁸ Bruns et al. explored the suitability of pocket ultrasound as a supplementary tool for clinical assessment specifically during the first trimester of pregnancy.⁹ Kodaira et al. conducted a study to evaluate the reliability of ultrasound findings acquired through hand-held devices in urgent obstetric scenarios, reporting good agreement ($\kappa > 0.8$) particularly concerning fetal number, presentation, and heartbeat.¹⁰ In another study focusing on routine antenatal third-trimester ultrasonography, researchers found substantial concordance between a pocket-sized USG machine and high-specification USG units regarding fetal presentation and development.¹¹ This study involved the scanning of 51 patients, concluding that portable devices are accurate tools for assessing various parameters, including fetal number, presentation, placental site, amniotic fluid volume, and the presence of key structures during the third trimester of pregnancy. However, prior studies primarily examined specific trimesters or focused on a limited number of obstetric parameters. Thus, the present study aims to investigate a comprehensive range of obstetric parameters across all three trimesters of pregnancy.

MATERIALS AND METHODS

Study design

This was a cross-sectional study conducted from June 2022 to December 2022. A total of 77 subjects were randomly selected from female patients who came to the hospital for pregnancy profiling with more than eight weeks of gestation according to their menstrual history. Pregnant patients with any emergency or life-threatening condition such as pervaginal bleeding, eclampsia, pre-eclampsia, premature rupture of membrane, severe abdominal pain, etc., or those who were in any stage of active labor were excluded. For a significance level of 0.05, a power of 80%, and a disagreement probability of 0.5, the sample size required to detect a Cohen's kappa value of 0.90 is 73.¹² The disagreement rate of 0.5 was chosen because it represents the midpoint where the sample size is the highest. Therefore, this study's sample size of 77 subjects can be considered statistically significant. The number of subjects in the first, second, and third trimesters of pregnancy was 3, 15, and 59, respectively. This study did not consider pregnancy cases earlier than 8 weeks to avoid potential hazards from ultrasound energy. This exclusion criterion explains the lower number of cases in the first trimester.

Ethical statement

This study was conducted under the principles embodied This study was conducted under the principles embodied in the Declaration of Helsinki and in accordance with local statutory requirements. Necessary ethical approval was obtained from the National Research Ethics Committee, Bangladesh (No: 45713122021) for this study. Informed consents were obtained from all participants.

Data collection

After receiving informed consent, each patient was scanned twice: first, with a low-cost tablet PC-based portable and hand-held device, and then with a sophisticated and expensive scanner by a sonographer. Adequate time interval was given between the two scans to avoid bias. The portable USG device (Sunbright P1), which comprises a wired probe (frequency 3–5 MHz, depth 24 cm), is connected to a smartphone or computer.¹³ The portable device was chosen considering its low cost, commercial availability, safety (CE [Conformité Européenne] certified), and data transfer ability to PC and smartphones. Data from the portable device was tested against a sophisticated and expensive machine (Samsung Medison Accuvix A30), conventionally used in hospital settings, which is an USG system with a 21.5-inch-wide LED monitor (screen resolution 1920 × 1080) and four probes (depth 2-30 cm).¹⁴ The frequency range of the convex probe of the conventional device used for this study was 2-6 MHz. This sophisticated machine's output was considered gold standard for comparison of the portable scanner mentioned above. However, the actual measurements taken of any imaged organ depend on the personal choice of selected points on the image by the sonologist, so there would be errors in the gold standard too. Therefore, this has to be kept in mind when comparing the performance of the portable device with that of the standard device.

The key obstetric parameters observed were:

- (i.) Number of fetuses
- (ii.) Presence of cardiac pulsation and fetal movement
- (iii.) Fetal biometry including CRL, for first-trimester pregnancies
- (iv.) BPD and FL, beyond the first trimester
- (v.) GA
- (vi.) Placental location
- (vii.) Amniotic fluid volume
- (viii.) Presentation of the fetus

Images captured on the portable device were saved and subsequently transferred to a computer to measure these obstetric parameters. Information was also recorded in a tabulated form. Diameters and lengths were measured using electronic calipers. CRL was measured from the top of the head (crown) to the bottom of the buttocks (rump) of the fetus. BPD was measured from the outer edge of the near calvarial wall to the inner edge of the far calvarial wall. FL was identified as the measurement of longest bright echo within the fetal femur. All measurements were taken three times, and the arithmetic mean was recorded for analysis.

Analysis and presentation

Firstly, the values of each parameter obtained using the portable device were plotted against the corresponding values obtained using the standard device to observe whether an overall correlation exists or not. The agreement between the two devices regarding categorical variables was assessed with Cohen's kappa value. If the value is within 0.61–0.8, it denotes substantial agreement while values above 0.8 (maximum possible: 1.00) represent almost perfect agreement.¹⁵ For continuous variables, Bland-Altman plot and paired t-test were applied. Statistical analyses were performed using SPSS software and Microsoft Excel. The Bland-Altman diagram is a statistical method that offers insight into the pattern and extent of any agreement. To draw the diagram, the difference between a pair is plotted on the vertical axis of the diagram against the mean of the pair on the horizontal axis. The upper and lower limits of the interval shows the limits of agreement; then it is decided subjectively whether the agreement between pairs of readings is acceptable.¹⁶

To evaluate the performance of the portable device, mean absolute error (MAE) was also calculated using equation (1).

$$MAE = \frac{\sum_{i=1}^{n} |X_{port} - X_{conv}|}{n} \quad (1)$$

Here, X_{port} is the obstetric parameter measured by the portable device, X_{conv} is the corresponding parameter measured by the conventional (standard) device and n is the number of subjects.

RESULTS

The total number of pregnant females was 77, aged 18 to 35 years with a mean age of (25.8 ± 4.27) years. The obstetric parameters we have focused on in this study are the number and presentation of fetus, presence of cardiac pulsation and fetal movement, fetal biometry (CRL, BPD and FL), estimation of GA, placental location, and amniotic fluid volume. Figures 1 to 5 present a selection of ultrasound images obtained using both conventional and portable devices, providing a representative overview of the typical study results. Notably, the images captured by the low-cost portable device exhibit lower resolution,

resulting in inferior image quality and a lack of detail in smaller tissue areas.



FIGURE 1. Figure 1. Ultrasound scan images of a first trimester fetal pole for Crown Rump Length (CRL) measurement taken with the standard device (left) and with the portable device (right).



FIGURE 2. Figure 2. Ultrasound images of two second-trimester fetal heads captured using standard device (A, C) and portable device (B, D).



FIGURE 3. Ultrasound images of a third-trimester fetal head for Bi-Parietal Diameter (BPD) measurement captured with standard device (left) and portable device (right).



FIGURE 4. Ultrasound images of a second-trimester fetal femur recorded with standard device (left) and portable device (right).



FIGURE 5. Ultrasound images of a placenta, with the left image captured by the standard device and the right image obtained using the portable device.

Figure 1 illustrates images of a first-trimester fetal pole intended for CRL measurement. The image on the left, taken with the standard device, demonstrates a clearer and more defined fetal pole compared to the image on the right, captured by the portable device. The fetal outline appears less distinct in the portable device's image, highlighting the difference in image clarity between the two scanners.

Figure 2 presents ultrasound scan images of two second-trimester fetal heads captured using both devices. Specifically, Figure 2A and Figure 2C display images obtained from the conventional device, while Figure 2B and Figure 2D depict the corresponding scans acquired with the low-cost portable device. The cross marks in the images indicate specific points identified by the sonologist for precise measurements along the marked dotted lines. Moving on to Figure 3, ultrasound scan images of a third-trimester fetal head for BPD measurement are showcased. The image on the right is obtained from the portable device, while the left image is captured using the conventional unit. Although not precisely identical, the image quality and details are considerably similar between the two. In Figure 4, ultrasound scan images of a second-trimester fetal femur are presented, with the left image taken using the standard device and the right image with the portable device. Figure 5 displays ultrasound images of a placenta, with the left image captured by the standard device and the right image obtained using the portable device. Notably, the echogenic layer adjacent to the anterior wall in the right-hand image exhibits a reverberation artifact, which is exaggerated compared to the left-hand image.

Correlation of measured values

Figure 6 shows a scatter plot for BPD with the values obtained using the portable device plotted against that obtained using the standard device. The linear correlation is very high with a squared correlation coefficient (r^2) of 0.9578. The slope is about 0.98, which is close to 1, meaning that the two values are almost identical.



FIGURE 6. Scatter plot showing correlation between BPD measurements taken with two devices.

In order to compare the two sets of values in more detail, a Bland-Altman plot is shown in Figure 7. For these plots, the values obtained using the conventional device (the gold standard here) were subtracted from the corresponding ones obtained using the portable device for each subject and plotted along the vertical axis. The means of the BPD values for each subject obtained using both the devices were plotted along the horizontal axis. It shows that the portable device tended to underestimate BPD in earlier pregnancies, while the deviations became less as the fetal size increased. Overall the mean value of BPD given by the portable device was 1.6 mm greater than those obtained using the conventional device. The plot also shows that 95% of the portable device measurements remained within +8 mm and -5 mm range of the actual values. The MAE for measuring BPD using the portable device was 2.24 mm.



FIGURE 7. The Bland-Altman plot shows the difference of the two paired BPD measurements plotted against the mean of the two measurements.

Figure 8 shows the correlation ($r^2=0.9415$) between FL measurements taken with two devices. There was no tendency towards under or overestimation in relation to GA, and 95% of the measurements fell within the range +6.2 mm to -7.2 mm, the mean being at -0.5 mm (Figure 9). The MAE in measuring FL was 2.14 mm.



FIGURE 8. Scatter plot showing correlation between FL measurements taken with two devices.

The portable machine produced wide variations for CRL measurements, about 9 to 17 mm from actual values (Figure 10). The correlation between the two devices in measuring CRL is relatively low (r^2 =0.823) as shown in Figure 11. The MAE in measuring CRL was found to be 6.5 mm.



FIGURE 9. The Bland-Altman plot shows the difference of the two paired FL measurements plotted against the mean of the two measurements.



FIGURE 10. Scatter plot showing correlation between CRL measurements taken with two devices.

In case of GA estimation, out of 77 pregnancies, three were in the first trimester i.e., below 12 weeks, 15 in the second trimester (12-26 weeks) and 59 cases were in the third trimester (beyond 26 weeks), as determined by the conventional USG machine. Figure 12 shows the correlation (r^2 =0.983) between FL measurements taken with two

devices. Bland-Altman plot in Figure 13 showed 95% of the values taken with the portable scanner to be within almost two two-week range of the actual values. The MAE in measuring GA was 0.93 weeks. It was also noted that GA was mostly underestimated by the low-cost device in first and second-trimester pregnancies, up to around 32 weeks of gestation; whether towards term pregnancies, it was more overestimated. Again, the percentage of deviation of the GA measured using the portable device decreased as the GA increased.



FIGURE 11. The Bland-Altman plot showing wide variations in CRL measurements from the two devices.



FIGURE 12. Scatter plot showing correlation between gestational age measurements taken with two devices.



FIGURE 13. The Bland-Altman plot where the difference of the two paired gestational age measurements is plotted against the mean of the two measurements.

Other parameters

This study had five qualitative variables: presentation, the fetus's movement and heartbeat, placental location and amniotic fluid volume. Majority of the fetus was in cephalic presentation (80.5%), followed by floating condition (15.6%) and breech (3.9%). Fetal movement was present in about 94.8% of the cases, with 3.9% being too early to comment and one case where movement was absent. We found 76 live pregnancies with regular cardiac pulsation and one case of intra-uterine death. Regarding placental location, in most cases, it was found in anterior uterine wall (53.2%), followed by posterior wall (29.9%). Fundal, anterofundal and posteriofundal locations were less common. In about 93.5% cases amniotic fluid volume was adequate, with 3.9% cases of oligohydramnios, and 1.3% cases of polyhydramnios. The portable machine's findings agreed with the standard device (Table 1). Chi square test also showed significant result (P value < 0.001).

Single or Multiple pregnancies

By scanning with the conventional USG machine, which was considered as the gold standard, 72 cases were found to have single pregnancy, while 4 cases had twin pregnancy and one case had a triplet. The portable device could detect a number of fetus accurately in all these cases.

Parameter	к statistic	P value	Interpretation
Fetal presentation	1.0	< 0.001	Perfect agreement
Fetal movement	1.0	< 0.001	Perfect agreement
Fetal heartbeat	1.0	< 0.001	Perfect agreement
Placental location	0.892	< 0.001	Very good agreement
Amniotic fluid volume	0.884	< 0.001	Very good agreement

TABLE 1. Kappa Values for Qualitative Variables Showing GoodAgreement between Two Devices

DISCUSSION

Portable USG scanner, by virtue of its affordability and mobility, is being contemplated for use in different lowresource settings like refugee camps, remote villages, etc. besides general practice.¹⁷⁻¹⁹ This study compared the performance of a low-cost portable ultrasound scanning device to a more expensive standard device, particularly for obstetric parameters. Very good agreement between the two devices in measuring most of the parameters was observed in this study, which are number and presentation of fetus, presence of cardiac pulsation and fetal movement, fetal biometry (CRL, Bi-Parietal Diameter, FL), estimation of GA, placental location, and amniotic fluid volume. However, CRL had more deviation as this was measured in the first trimester when the fetus was small, and marking out points with the low-cost portable device was challenging because of lower resolution. However, as the fetus increased, the errors in all parameters decreased and were within tolerable limits for acceptance.

GA was determined by measuring fetal biometry; CRL in first-trimester pregnancies, and BPD, FL in second and third trimesters. Sac diameter is another measure for GA determination in earliest pregnancies, but it was not used as this study only enrolled pregnant females with more than eight weeks of gestation.²⁰ Regarding CRL estimation, first-trimester fetal poles are very small, and it might be difficult for a low-resolution probe to outline the full length separately from yolk sac and inner wall of sac (see Figure 1). However, a positive linear correlation was observed between CRL values of both devices with r² higher than 0.8 (see Figure 10). The relationship with fetal size could be appreciated in the Bland-Altman plot, which shows that despite the variable discrepancy, deviation from reference value decreased as CRL approached 55 mm and higher (see Figure 11). Very few first trimester cases were included in this study, which was inadequate to reach any definite consensus regarding the efficacy of CRL measurement. A Norwegian study focused exclusively on hand-held trans-abdominal ultrasound's ability to evaluate first-trimester viable intra-uterine pregnancy.²¹ They investigated 100 women, comparing hand-held device findings to that of high-end trans-vaginal USG. According to their observation, viability could be confirmed with 79% positive and 100% negative predictive value from 7th week of gestation, and CRL measurements were comparable with a median difference of 1 mm. Of course, the error also depends on the image's resolution quality, and values obtained using one low-cost device may not apply to another device obtained from another manufacturer.

This study observed strong positive linear correlation between BPD, FL and GA measurements taken with both devices, r^2 being greater than 0.9 in all three cases (see Figures 6, 8, and 12). In a detailed assessment, the lowcost device usually underestimated BPD measurements in earlier pregnancies, up to about 58 mm, corresponding to nearly 24 weeks of gestation (see Figure 7). For the next 14–15 mm (up to around 30 weeks) portable device values were very close to standard ones, and after that deviation increased but uniformly. Figure 2 shows scan images of two fetal heads in second trimester. Both near and far calvarial walls are well outlined in the images from conventional machine, but in the portable device scans walls appear blurred, leading to incorrect estimation of BPD. This is because the hand-held scanner cannot capture relatively fast-moving fetuses of earlier pregnancies as accurately as the conventional machine. Accordingly, image quality improves when fetal size increases and the fetus is less mobile (see Figure 3).

In case of FL measurement by the low-cost instrument, there was no notable tendency towards over or underestimation (see Figure 9). Deviation from standard was minimal between a range of approximately 30–50 mm (corresponding GA about 19–26 weeks), and beyond second trimester there was uniform increase.

Most of the portable scanner calculations of GA are within two two-week range of actual values (see Figure 13). The Bland-Altman plot shows that the difference mostly lies between one week ranges for about up to 30 weeks of gestation, and then increases gradually. It is highest between 35 and 40 weeks. This might be considered clinically acceptable because, for GA measurement by USG, it has been studied and found that parameters like BPD and FL are less accurate during last weeks of pregnancy. According to Macgregor et al. the accuracy of gestational sac measurement as a predictor of GA is approximately ±1 week. In case of CRL, the accuracy is within ±5 to 7 days. During 12-26 weeks, GA determination by BPD and FL measurements falls within a range of 10-11 days and 10-20 days respectively, for 95% of the cases. After 26 weeks, this range extends to 2–3 weeks.²²

Fetal number, movement, presentation and cardiac pulsation were accurately detected by the portable device in all of the cases, which denotes the perfect efficacy of this instrument for assessing those parameters in more than eight weeks of gestation (see Table 1). An eight-week embryo reaches considerable development by completing organogenesis, therefore these parameters were all discernible despite low resolution. Earlier pregnancies were beyond the scope of this study to avoid potential hazard by ultrasound energy.¹⁹ Kodaira et al. performed a study to assess the reliability of ultrasound findings acquired with hand-held apparatuses in urgent obstetric settings. They reported high agreement ($\kappa > 0.8$) in the case of fetal number, presentation and heartbeat.¹⁰ Their overall diagnostic accuracy was still lower than ours, probably because they included emergency obstetric patients of any GA in a high volume low-resource setting, and scans were obtained by medical students with limited training.

Placenta is identified in ultrasound examination as a mostly uniform echogenic structure along uterine wall.²³ In our study, anteriorly placed placenta was the commonest location, followed by posterior; in accordance with a large population based cohort study in Sweden involving more than 74 thousand pregnant females.²⁴ A few fundal placentas were identified as anterior in location by the low-cost device, due to exaggeration of reverberation artifact along the anterior wall (see Figure 5). The same phenomenon might have contributed to the

underestimation of amniotic fluid volume in one case of polyhydramnios. However, despite these few exceptions, the portable device showed very good agreement with the conventional machine regarding both placental localization and amniotic fluid estimation (see Table 1).

LIMITATIONS

The study was conducted with a relatively small sample size, as a result there was not enough patients from each trimester. First-trimester subjects were especially scarce, as we could not enroll females with less than eight weeks of gestation. Besides, only stable pregnant women were enlisted for study, limiting the number and varieties of pathology that could be observed. Therefore, efficacy of the portable device in emergency conditions could not be evaluated. Further study with larger sample size must be done to explore its full potential.

CONCLUSIONS

The portable device used in this study showed remarkable efficacy in observing several obstetric parameters, namely fetal number, presentation, movement, heartbeat, placental location and amniotic fluid volume. Regarding other variables, the low-cost scanner measurements were closest to gold standard during 24-30 weeks for BPD and 19-26 weeks for FL. GA determination remains within one week range from the standard reference during second trimester and first six weeks of third trimester. Observing the above-mentioned efficiency, such portable device may be recommended to provide diagnostic service in remote areas, including refugee camps, hilly areas, and islands. There is significant potential for integrating low-cost and portable ultrasound scanning devices into telemedicine service systems with appropriate data transfer arrangements. However, further studies are needed to investigate interpersonal variability in the use of portable devices, ensuring consistency and accuracy across different users and settings.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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