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Diagnostic accuracy of foot length measurement for identification of preterm newborn in rural Sindh, Pakistan

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ABSTRACT

Introduction Assessing gestational age accurately is crucial for saving preterm newborns. In low and middle-income countries, such as Pakistan, where access to antenatal ultrasonography (A-USG) is limited, alternative methods are needed. This study evaluated the diagnostic accuracy of foot length (FL) measurement for identifying preterm newborns in rural Pakistan using A-USG as the reference standard.

Methods A test validation study was conducted between January and June 2023 in rural Sindh, Pakistan, within the catchment area of the Global Network for Maternal Newborn Health Registry, Thatta. Singleton newborns whose mothers had an A-USG before 20 weeks of gestation were enrolled. A research assistant measured FL three times using a rigid transparent plastic ruler within 48 hours of birth and the average FL was reported. Sensitivity, specificity, positive and negative predictive values (PPV, NPV) and likelihood ratios were calculated. The optimal FL cut-off for the identification of preterm newborns was determined using the Youden Index.

Results A total of 336 newborns were included in the final analysis, of whom 75 (22.3%) were born before 37 weeks of gestation. The median gestational age of the newborns was 38.2 weeks, and the median FL was 7.9 cm. The area under the curve was 97.6%. The optimal FL cut-off for identifying preterm newborns was considered as ≤7.6 cm with a sensitivity of 90.8%, specificity of 96.0%, PPV of 86.7% and NPV of 97.3%. A lower cut-off of ≤7.5 cm had a sensitivity of 95.4%, specificity of 84.0%, PPV of 63.1% and NPV of 98.5%.

Conclusion In conclusion, this study highlights the utility of FL measurement for identifying preterm newborns in rural settings where A-USG is unavailable before 20 weeks of gestation. Optimal cut-offs of ≤7.6 and ≤7.5 cm provide a simple, cost-effective and reliable tool for clinicians and frontline healthcare providers in rural areas, respectively.

Trial registration number NCT05515211.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Globally, prematurity is a leading cause of neonatal mortality, affecting over 1 in 10 newborns.
⇒ In low and middle-income countries like Pakistan, access to antenatal ultrasonography, the gold standard for gestational age assessment, is limited.
⇒ Foot length is considered a simple method for identifying preterm newborns, with a limited number of validation studies primarily conducted in hospital settings.

WHAT THIS STUDY ADDS

⇒ This study produced high-quality evidence for identifying preterm newborns using foot length against early antenatal ultrasonography, enhanced by rigorous training and vigilant monitoring.
⇒ The optimal foot length cut-off to identify preterm newborns in Pakistan was ≤7.6 cm with high sensitivity and specificity.
⇒ An alternative foot length cut-off of ≤7.5 cm has high sensitivity.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Foot length measurement offers a simple and reliable tool for both clinicians and frontline healthcare providers in rural areas, especially when early antenatal ultrasonography is unavailable, helping to identify newborns requiring specialised care.
⇒ Further research is essential to validate the reliability and applicability of foot length measurement in diverse populations and healthcare settings, emphasising the need for external validation.

INTRODUCTION

Preterm birth poses a major public health concern, in line with Sustainable Development Goal (SDG) 3.2.2, aiming to reduce neonatal mortality. Effectively addressing challenges linked to preterm births is vital for reaching this SDG target, given the substantial impact of preterm newborns on neonatal morbidity and mortality.[1 2]

Annually, approximately 13.4 million babies are born before 37 weeks of gestation worldwide accounting for 10% of all live births.[2] Prematurity and its complications account for approximately 19% of all neonatal deaths in south Asia and 24% in sub-Saharan Africa.[3] In Pakistan, an estimated 860 000 babies are born preterm each year, disproportionately affecting 11% of the urban population and 23% of the rural population.[4]

Prematurity is an independent risk factor for neonatal morbidity and mortality.[5 6] The initial management in high-income and low-income countries of moderate to late preterm babies (32–36 weeks and 6 days of gestation) includes early feeding and skin-to-skin care. This management has the potential to reduce some of the complications of prematurity, such as hypoglycaemia, hypothermia and hyperbilirubinaemia.[7]

Identification of preterm newborns might be challenging despite the numerous antenatal and postnatal methods of assessing gestational age (GA). The last menstrual period and antenatal ultrasonography (A-USG) are the most frequently used antenatal methods of assessing GA. Postnatal methods of assessing GA are the Dubowitz Score, Ballard Score and Eregie model. The postnatal clinical scoring methods are generally complex and subjective, require a clinician[8 9] and are, therefore, rarely used especially in primary care health facilities. A-USG dating scan in the first trimester is the most reliable method for assessing the estimated day of delivery.[10] However, its availability and affordability is limited in low and middle-income countries (LMIC).[11]

In LMICs, there is a need for reliable, cheap and user-friendly methods for the identification of preterm birth. In this context, The Global Action Report on Preterm Birth, 'Born Too Soon' emphasised using simple approaches to estimating GA such as foot length (FL) for early identification of preterm newborns and their management.[12] Furthermore, in LMICs, only five studies[9 13–16] validated FL against antenatal ultrasonography dating, and of these, three studies were conducted in hospitals and two in community-based settings. Of the two community-based studies one each was conducted in Bangladesh and Tanzania. A meta-analysis by Folger *et al*[17] identified two main limitations in previous studies evaluating FL as a surrogate marker of GA; first, the poor quality of the studies and, second, that most studies have validated FL against last menstrual period. In a previous hospital-based study performed in Karachi, Pakistan, a linear relationship was observed between GA and FL.[18] Furthermore, in this study last menstrual period, ultrasound, Ballard Score or combination of these three methods was used as reference standard.[18]

The primary objective of the present study was to evaluate the diagnostic accuracy of FL in identifying preterm newborns in rural Sindh, Pakistan, using A-USG performed before 20 weeks of gestation as the reference standard.

METHODS

Study design

This is a test validation study examining the diagnostic accuracy of FL in the identification of preterm newborns using A-USG as a reference standard. The Standard for Reporting Diagnostic Accuracy Studies was used for reporting this study.

Study setting

The study was conducted in the catchment area of the Global Network for Maternal and Newborn Health Registry (MNHR), Thatta. MNHR is active in eight clusters of two subdistricts of Thatta with a population of the catchment area of around 70 000. There are 330 villages and 31 public sector health facilities in MNHR catchment area. According to the National Census in 2017, 72.1% of the population of Thatta is illiterate. Crop farming and fishing are the most common occupations.[19] MNHR aims to provide population-based estimates of stillbirth, neonatal mortality, maternal mortality, prematurity and low birth weight. In MNHR, registry administrators enrol pregnant women in early pregnancy both from home and health facilities. The pregnant women are then followed at the time of delivery and 42 days post partum.[20]

Study population and eligibility criteria

The study population was a subset of MNHR. All singleton babies born to women who had undergone the first A-USG before 20 weeks of gestation were included in this study after obtaining consent from the mothers. Stillbirths, multiple pregnancies, gross congenital malformations such as neural tube defects, omphalocele, foot deformities such as clubfoot, children with clinical signs of chromosomal anomalies and unavailability of ultrasound report at the time of enrolment of the baby were excluded.

Operational definition

Preterm newborn: a live birth before 37 weeks of gestation.

Data collection procedure

For this study, two research assistants (RA) (trained midwives) worked closely with MNHR field staff. The study RAs were trained in examining the newborn, including measuring FL. The study RA was supervised by a senior research coordinator in Thatta.

The study participants were selected using convenient sampling. The data management unit of MNHR generated a list of women to be delivered between January and June 2023, whose A-USG before 20 weeks of gestation was available. MNHR staff has a strong network of key informants including family members, as well as a phone hotline to capture information on pregnancies, deliveries and pregnancy outcomes. Once delivery was confirmed by MNHR staff, study RA visited the home of the newborn and examined the baby within 48 hours of birth, and measured the FL. The data were collected on tablets using an Android-based app, REDCap.[21] Information on variables such as antenatal care, GA at first ultrasound, maternal comorbidities, place of delivery, complications during delivery and the delivery attendant was collected from the MNHR birth registry.

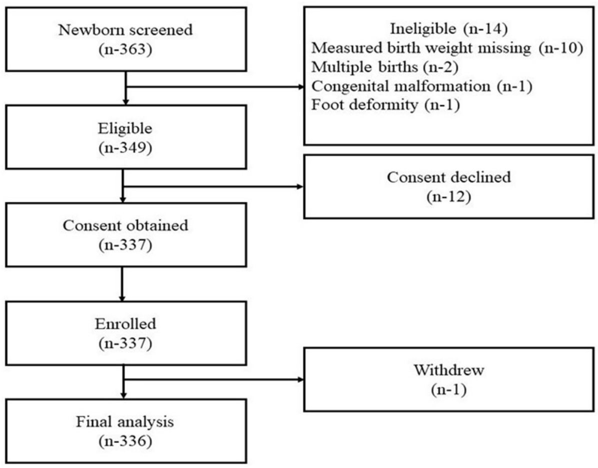

Figure 1 Study flow diagram.

Antenatal ultrasonography

GA based on A-USG before 20 weeks was used as the reference standard. At the time of enrolment of pregnant women, trained sonographers for GA dating measured the crown-rump length of the fetus between 6 and 13 weeks of gestation, or biparietal diameter, and femur length between 14 and 20 weeks of gestation to assess the GA. The Hadlock criteria were used for GA and estimated date of delivery calculation.

Foot length

The right foot of the baby was selected for the FL measurement using a rigid transparent plastic ruler. The measurements were undertaken within 48 hours of birth from the midpoint of the heel to the end of the longest to by an RA. To minimise the effect of the plantar grasp reflex, midwives were trained to hold the ankle with a finger placed on the dorsum of the foot to keep the foot straight. The final FL was an average of three readings. For monitoring purposes, photographs of FL measurements were taken for 10% of the enrolled newborn. In addition to the primary assessment by study RAs, 10% of FL of enrolled newborns was taken by the principal investigator (PI).

Sample size

The prevalence of prematurity reported in the MNHR birth registry was 21.8% (*Pre*).[22] Taking sensitivity (*Se*) of FL in identifying prematurity of 80% and margin of error (*d*) 10%, a sample size of 292–300 was needed. Considering the 10% refusal or withdrawal from the study the final sample size is 330.

$$n_s e = \frac{(Z_{a/2})^2 (\hat{s}e)(1-\hat{s}e)}{pre*(d)^2}$$

Data analysis

STATA V.17 was used for data analysis. Continuous variables were assessed for normality. Those not normally distributed were presented as median and IQR while categorical variables were presented as frequencies and percentages. Non-parametric receiver operating characteristic curves were generated using MedCalc software. Various FL cut-offs were calculated against ultrasound-estimated GA, considering sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratios (LR) and area under the curve (AUC). The Youden (J) Index estimated the optimal FL cut-off to identify preterm newborns using the following equation[23]:

$$J = Sensitivity + Specificity - 1$$

Inter-rater agreement and intraobserver reliability

Bland-Altman plot was used to assess the inter-rater agreement for FL measurement between study RA and PI (SST). The mean difference between the two raters' measurements and limits of agreement (LoA) was reported. Bland-Altman plot was created using the 'batplot' command in STATA, shows bubbles to signify precision in FL measurements. The plot also indicates the average difference close to zero, demonstrating strong agreement between observers. Intraobserver reliability was assessed through intraclass correlation coefficient (ICC).

RESULTS

A total of 363 newborns were screened for eligibility and 349 (96.1%) were found to be eligible. Of eligible newborns, informed consent was obtained from 337 (96.6%). The remaining 337 newborns were enrolled. However, one withdrew from the study leaving 336 newborns for the final analysis (figure 1).

Newborn characteristics

The median age of enrolled newborns was 29 (IQR 19–41) hours, and 157 (46.7%) were females. A total of 293 (78.2%) newborns were born in a health facility. However, 255 (75.9%) were examined at home. The median GA at the first A-USG was 13 (IQR 9.5–17) weeks, and median GA at birth was 38.2 (IQR 37.0–39.3) weeks. The preterm prevalence was 75 (22.3%). The median birth weight was 2800 (IQR 2465–3057) g. Overall, the median FL was 7.9 (IQR 7.6–8.1) cm (table 1). The median FL for preterm and term births was 7.2 (IQR 6.7–7.4) and 8 (IQR 7.8–8.2) cm, respectively (figure 2).

Maternal characteristics

The median age, height, weight and body mass index of the mothers were 28 (IQR 24–30) years, 153 (IQR 150–157) cm, 48 (IQR 44–55) kg and 20.8 (IQR 18.63–23.3) kg/m^2, respectively. A total of 92 (28.0%) mothers were primiparous, 9 (2.7%) were hypertensive (two consecutive blood pressure readings of 140/90 mm Hg)

Table 1 Newborn and maternal characteristics

Characteristics of newborn	n (%)
Age at examination (hours)*	29 (19–41)
Sex	336
Female	157 (46.7)
Male	179 (53.3)
Gestational age at antenatal ultrasonography (weeks)*	13 (9.5–17)
Gestational age at birth (weeks)*	38.1 (37.04–39.3)
Gestational age categories, weeks	
28–30	6 (1.8)
31–33	13 (3.9)
34–36	41 (12.2)
37–39	176 (52.4)
≥40	100 (29.8)
Preterm	75 (22.3)
Birth weight (g)*	2801 (2465–3057)
Foot length (cm)*	7.9 (7.6–8.1)
Place of birth	
Home	41 (12.3)
Hospital/health facility	293 (87.7)
Place of assessment at screening	
Home	255 (75.9)
Hospital/health facility	81 (24.1)
Characteristics of mother	
Age of mother (years)*	28 (24–30)
Mothers' height (cm)*	153 (150–157)
Mothers' weight (kg)*	48 (44–55)
Body mass index (kg/m^2)*	20.8 (18.6–23.3)
Parity*	2 (0–8)
Primiparous	
<1	94 (28.0)
1–2	123 (36.6)
>2	119 (35.4)
Hypertensive disorder of pregnancy	9 (2.7)
Anaemia	265 (78.9)

*Median (IQR).

and 265 (78.9%) were anaemic (haemoglobin level <12 g/dl) (table 1).

Diagnostic accuracy

For determining preterm newborn, the potential cut-off of FL of ≤7.6 cm was identified using Youden Index, with a sensitivity of 90.8% (95% CI 86.6 to 94.0), specificity of 96.0% (95% CI 88.8 to 99.2), PPV of 86.7% (95% CI 68.3 to 95.2), NPV of 97.3% (95% CI 96.1 to 98.2), LR+ of 22.7 (95% CI 7.5 to 68.8) and LR− of 0.096 (95% CI 0.065 to 0.14) (table 2). The AUC was 97.6% (95% CI 95.3 to 98.9) (figure 3).

Setting the cut-off of FL to ≤7.5 cm for identifying preterm, the sensitivity was 95.4% (95% CI 92.1 to 97.6), specificity was 84% (95% CI 73.7 to 91.4), PPV was 63.1% (95% CI 50.5 to 74.2), NPV was 98.5% (95% CI 97.3 to 99.1), LR+ was 5.9 (95% CI 3.6 to 10.0) and LR− was 0.05 (95% CI 0.03 to 0.09) (table 2).

The mean difference between the two raters' measurements was −0.026 (LoA: −0.084 to 0.033, p=0.378) (figure 4). The ICC of 0.9 for three FL readings showed excellent intrarater reliability.

DISCUSSION

This community-based study identified two critical FL cut-off values, that is, ≤7.6 and ≤7.5 cm, for identification

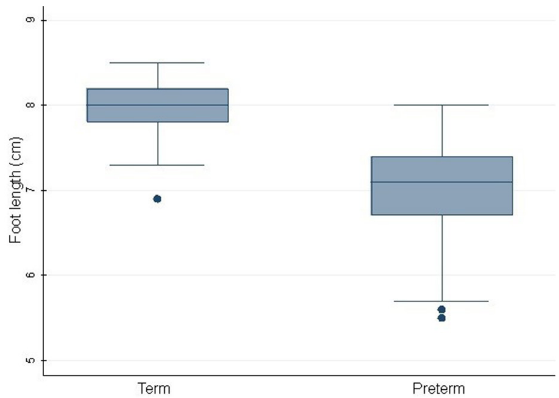

Figure 2 Box plot illustrating the median (IQR) of foot length categorised by preterm and term newborns.

of preterm newborn in rural Sindh province, Pakistan. An FL of ≤7.6 cm demonstrated high sensitivity and specificity, and correctly identified 90.8% of preterm newborns, with a consequently low proportion of false negatives. Conversely, it correctly ruled out preterm newborns in 96.0% of cases, thus reducing false positives. Therefore, this cut-off of FL is useful for practising clinicians in rural settings. However, in primary care health facilities in rural areas, an FL cut-off of ≤7.5 cm is optimal, ensuring a high sensitivity of 95.4% to minimise the chance of missing any preterm newborns. This highlights its potential efficacy as an accessible screening tool for frontline healthcare providers in identifying preterm infants. The high sensitivity facilitates early identification of preterm newborn, which is a crucial factor for timely interventions and improved outcomes.

Table 2 Sensitivity, specificity, predictive values and likelihood ratio at different foot length cut-offs for preterm birth

FL (cm)	Sensitivity (95% CI)	Specificity (95% CI)	LR+ (95% CI)	LR− (95% CI)	PPV (95% CI)	NPV (95% CI)
7	99.6 (97.9 to 100)	38.7 (27.6 to 50.6)	1.6 (1.4 to 1.9)	–	31.8 (28.1 to 35.8)	99.7 (98.0 to 100.0)
7.1	99.6 (97.9 to 100)	52.0 (40.2 to 63.7)	2.1 (1.6 to 2.6)	–	37.4 (32.0 to 43.0)	99.8 (98.5 to 100.0)
7.2	99.6 (97.9 to 100)	54.7 (42.7 to 66.2)	2.2 (1.7 to 2.8)	–	38.7 (33.0 to 44.7)	99.8 (98.6 to 100.0)
7.3	98.9 (96.7 to 99.8)	70.7 (59.0 to 80.6)	3.4 (2.4 to 4.8)	–	49.2 (40.5 to 57.9)	99.5 (98.6 to 99.8)
7.4	98.5 (96.1 to 99.6)	78.7 (67.7 to 87.3)	4.6 (2.9 to 7.1)	–	57.0 (46.2 to 67.2)	99.4 (98.5 to 99.8)
7.5	95.4 (92.1 to 97.6)	84.0 (73.7 to 91.4)	5.9 (3.6 to 10.0)	0.055 (0.031 to 0.096)	63.1 (50.5 to 74.2)	98.5 (97.3 to 99.1)
7.6	90.8 (86.6 to 94.0)	96.0 (88.8 to 99.2)	22.7 (7.5 to 68.84)	0.096 (0.065 to 0.14)	86.7 (68.3 to 95.2)	97.3 (96.1 to 98.2)
7.7	82.8 (77.6 to 87.1)	97.3 (90.7 to 99.7)	31.0 (7.9 to 121.94)	0.2 (0.14 to 0.23)	89.9 (69.4 to 97.2)	95.2 (93.8 to 96.3)
7.8	71.7 (65.8 to 77.0)	98.67 (92.8 to 100.0)	53.7 (7.7 to 377.2)	0.3 (0.24 to 0.35)	93.9 (68.8 to 99.1)	92.4 (90.9 to 93.6)
7.9	56.7 (50.5 to 62.8)	98.7 (92.8 to 100.0)	42.5 (6.1 to 298.9)	0.4 (0.38 to 0.51)	92.4 (63.5 to 98.8)	88.8 (87.3 to 90.1)
8	45.2 (39.1 to 51.5)	100.0 (95.2 to 100.0)	–	0.6 (0.5 to 0.61)	100.0	86.4 (85.1 to 87.6)

FL, foot length; LR, likelihood ratio; NPV, negative predictive value; PPV, positive predictive value.

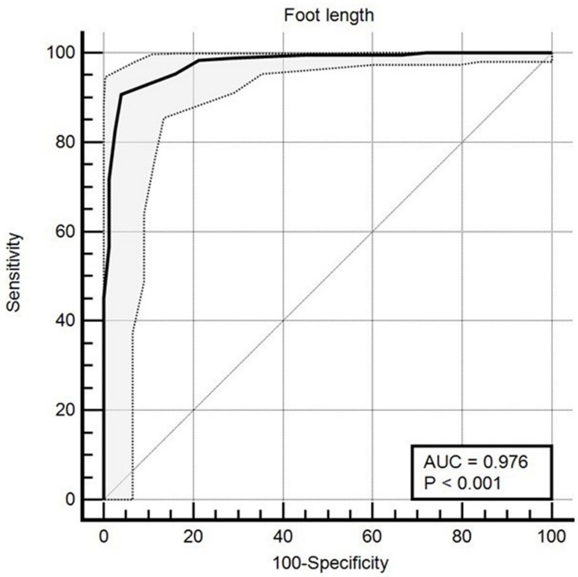

Figure 3 Receiver operating characteristic (ROC) curve and area under the curve (AUC) for diagnostic accuracy of foot length in identifying preterm birth.

Two studies using A-USG as a reference standard reported an FL cut-off of ≤7.5 cm. Stevenson *et al*[13] reported a sensitivity of 98.9%, while our study observed a sensitivity of 95.4%. Lee *et al*[9] reported a sensitivity of 64%. There is a difference in specificity; Stevenson *et al*[13] reported a specificity of 60.9% and Lee *et al*[9] reported a specificity of 35%. Possible reasons for these differences include sample size variations, differing prevalence of preterm newborns and potential influences of population characteristics. In a previous hospital-based study based on stillbirth and preterm live born babies with a median GA of 34 weeks and 5 days, the median FL was 7.0 cm. This result is in line with the result from the present study, if data from the hospital-based study are extrapolated to a GA of 36 weeks and 6 days.[18] The current study was conducted for healthcare workers working in rural areas where healthcare resources are limited.

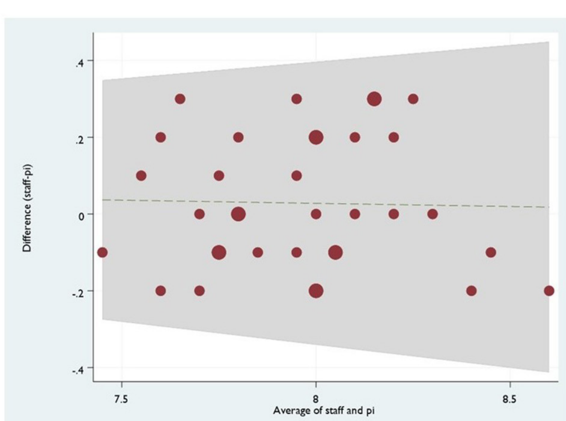

Figure 4 Bland-Altman plot showing agreement of measuring foot length between study research assistant (RA) and principal investigator (pi).

In daily clinical practice, management of newborn, particularly in rural and resource-limited areas, is ideally based on identification of factors that increase the risk of neonatal morbidity and mortality, either directly or by increasing the adverse effects of prematurity. Factors that increase the negative impact of prematurity include low Apgar score, low birth weight, simultaneous breathing problems, perinatal complications and infections.[24 25] However, such a multifactorial assessment including FL measurement combined with other risk factors of neonatal morbidity and mortality has not been the objective of the present study. Furthermore, in a rural setting, simplicity is crucial due to varying levels of education of the individuals assisting during delivery.

This study has some strengths. First, it was conducted in a rural Sindh community setting, potentially reflecting high preterm birth rates in the target population. Second, excellent inter-rater reliability and inter-rater agreement enhance the internal validity of the study. Third, the Youden (J) Index determined the optimal cut-off, balancing sensitivity and specificity effectively.

This study has limitations. First, it relied on a specific subset of newborns, those whose mothers had early antenatal ultrasonography, potentially limiting external validity and challenging generalisation to a broader population. Additionally, the findings may only be valid for the specific data collection period, with potential impacts on external validity due to changes in healthcare practices or population characteristics over time.

The findings of our study hold potential clinical implications. The study's identification of optimal FL cut-off values, specifically ≤7.6 and ≤7.5 cm, presents a practical and accessible tool for clinicians as well as frontline healthcare providers in resource-limited settings where access to A-USG may be limited. The simplicity and low cost of measuring FL make it a reliable option for early detection of preterm newborns. To upscale the usability of FL in clinical practice for widespread adoption, targeted training programmes can be implemented to educate healthcare workers on accurate measurement techniques and interpretation of FL. Additionally, integrating FL measurement into routine delivery and postnatal care protocols can contribute to the seamless incorporation of this low-cost and non-invasive screening method. Emphasising the simplicity and efficiency of FL measurement can facilitate early identification of preterm newborns and guide timely interventions, ultimately improving neonatal outcomes in resource-limited settings.

CONCLUSION

In conclusion, this study underscores the utility of FL in identifying preterm newborns when antenatal ultrasonography is unavailable before 20 weeks of gestation in rural settings. The identified optimal FL cut-offs (≤7.6 and ≤7.5 cm) present a simple, cost-effective and reliable tool for clinicians and frontline healthcare providers working in rural areas. Nevertheless, further research is essential to validate and generalise these findings. External validation studies in diverse populations and healthcare settings are crucial to ensure the robustness and applicability of FL measurement as a preterm birth screening tool.

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Contributors SST, NB, AM, SS and TM conceptualised this study and developed the methodology, data synthesis and interpretation. AI was responsible for data analysis and interpretation. SST wrote the first draft of this manuscript. SST is overall guarantor. SST accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Competing interests None declared

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Ethics approval This study involves human participants and was approved by the Ethical Review Committee of The Aga Khan University (Ref No 2023-7421-24941). Written informed consent was obtained from mothers before enrolling the newborns. Study registration: NCT05515211.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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