Validating a Sclera-Based Smartphone Application for Screening Jaundiced Newborns in Ghana

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abstract

OBJECTIVES: Reducing the burden of bilirubin-induced neurologic complications in low-resource countries requires reliable and accessible screening tools. We sought to optimize and validate a sclera-based smartphone application, Neonatal Scleral-Conjunctival Bilirubin (neoSCB), for screening neonatal jaundice.

METHODS: Using a cross-sectional design, consecutive eligible infants (aged 0–28 days, in the hospital, not critically ill) were enrolled in Ghana from March 2019 to April 2020. Jaundice screening was performed with neoSCB (Samsung Galaxy S8) to quantify SCB and JM-105 (Dräger) for transcutaneous bilirubin (TcB). Screening values were compared with total serum bilirubin (TSB) measured at the point of care.

RESULTS: Overall, 724 infants participated in the optimization and validation phases of the study. The analysis for validation included 336 infants with no previous treatment of jaundice. Single neoSCB image captures identified infants with TSB >14.62 mg/dL (250 μmol/L) with reasonably high sensitivity, specificity, and receiver operating characteristic area under the curve at 0.94 (95% confidence interval [CI], 0.91 to 0.97), 0.73 (95% CI, 0.68 to 0.78), and 0.90, respectively. These findings were comparable to the sensitivity and specificity of JM-105 (0.96 [95% CI, 0.90 to 0.99] and 0.81 [95% CI, 0.76 to 0.86], respectively). The TcB/TSB had a larger correlation coefficient ($r = 0.93$; $P < .01$) than SCB/TSB ($r = 0.78$; $P < .01$). Performance of both devices was lower in infants with previous phototherapy ($n = 231$).

CONCLUSIONS: The diagnostic performance of neoSCB was comparable to JM-105 and is a potential, affordable, contact-free screening tool for neonatal jaundice.

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Dr Enweronu-Laryea conceptualized and designed the study, coordinated and supervised data collection, drafted the initial manuscript, and reviewed and revised the manuscript; Dr Leung conceptualized and designed the study, developed the software, performed the analyses, drafted the initial manuscript, and reviewed and revised the manuscript; Dr Outlaw performed the initial analyses, developed the software, and reviewed and revised the manuscript; Dr Brako supervised data collection in the referral hospital; Dr Insaidoo supervised data collection in the district hospital; Dr Seneadza conceptualized and designed the study and contributed to the analysis; Dr Ani-Amponsah supervised data collection in rural communities; Mrs Nixon-Hill developed the software; Dr Meek conceptualized and designed the study and reviewed and revised the manuscript; and all authors reviewed the draft and approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

WHAT'S KNOWN ON THIS SUBJECT: Visual assessment for screening newborns with jaundice is subjective and unreliable but commonly practiced in low-resource settings where access to validated transcutaneous bilirubinometers is limited. Noninvasive screening methods are preferable to invasive blood sampling.

WHAT THIS STUDY ADDS: Smartphone applications that measure the yellowness of the sclera can be used to objectively identify newborn jaundice and is acceptable to mothers. In the same population, a sclera-based application has a similar diagnostic accuracy to a well-established transcutaneous bilirubinometer.

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Neonatal hyperbilirubinemia is a major global health problem. Bilirubin-induced neurologic complications still occur in industrialized countries, and severe neonatal jaundice remains an important cause of mortality and long-term impairment in countries with low sociodemographic index values.[1–3] Infants in sub-Saharan Africa are at greater risk because of the high prevalence of glucose-6-phosphate dehydrogenase deficiency, a genetic disorder associated with an increased risk of hemolysis and hyperbilirubinemia.[4,5]

Poor health outcomes associated with neonatal hyperbilirubinemia are largely preventable if affected infants are identified early and given appropriate and timely treatment to avert bilirubin neurotoxicity.[6] Most cases of hyperbilirubinemia occur in the first week after birth, and policies on routine screening during birth hospitalization and postdischarge monitoring in industrialized countries has significantly reduced bilirubin encephalopathy.[6,7] Most countries with a high burden of disease do not have the capacity to provide these services, and many infants present with severe neonatal jaundice due to several factors, including high prevalence of home births and early postnatal discharge after hospital birth.[1,3,8] In Ghana, neonatal jaundice is the major and most preventable cause of cerebral palsy in children.[9]

Reliable screening methods that are accessible to all people everywhere are needed for early diagnosis of neonatal hyperbilirubinemia. Early diagnosis is one of the important steps to reducing the burden of deaths and impairment associated with neonatal hyperbilirubinemia.[10] It is well known that yellowing of the sclera (the white part of the eye) is an early sign of neonatal jaundice and that visual inspection of the eye, the traditional method for diagnosis, is unreliable for quantifying the severity of jaundice.[11–13] Leung et al[14] investigated the possibility of using sclera color as a quantitative tool for jaundice detection in 110 newborns and found a linear correlation of 0.75 ($P < .01$) between the sclera color captured by a digital camera and total serum bilirubin (TSB). They investigated different color spaces to optimally quantify the yellowness of the sclera of the newborns with jaundice and developed a sclera-based smartphone application (app), Neonatal Scleral-Conjunctival Bilirubin (neoSCB).[15] Our aim in this study was to validate the methodology and optimize neoSCB for screening infants with jaundice in clinical settings. We report the process of optimizing and validating the smartphone app as a screening tool for neonatal jaundice in Ghana.

METHODS

Design

Using a cross-sectional design, we consecutively enrolled hospitalized newborns who met the inclusion criteria after written informed consent from their parents. The study protocol was reviewed and approved by 3 ethics committees (University College London; Noguchi Memorial Institute of Medical Research, University of Ghana; and Ghana Health Service).

Setting

The study was conducted in Ghana, a lower middle-income country in West Africa with a population of ~30 million. Ghana has 16 administrative regions; the capital city Accra is in the Greater Accra region. By 2018, ~82.4% of the total population and 67.3% of rural communities had access to electricity.[16] In 2020, 46.1% of the population owned a smartphone, and there was increasing use of mobile health technologies.[17,18] The study was conducted in a regional hospital in the Greater Accra Region and a district hospital in the Eastern Region from March 2019 to April 2020. The regional hospital, a referral center for maternal-newborn services, attends to ~10 000 deliveries annually. The district hospital provides primary- and secondary-level obstetric and pediatric services for nearby urban and rural communities and attends to ~4000 deliveries annually. To assess the acceptability of neoSCB by primary care providers and parents in rural settings, 3 rural communities in the Eastern region were included in the study.

Participants

Infants aged 0 to 28 days were eligible. Infants in the neonatal ward were enrolled if they had a clinical indication for a blood test as recommended by the attending clinician. Infants in the postnatal ward were enrolled if the parents gave additional consent for a blood test (a heel prick). Infants who were critically ill, required immediate care, had very low birth weight, or had congenital abnormalities of the eye and skin were excluded. Frontline health care workers and mothers of infants provided feedback on the procedure of screening for jaundice with the app.

Sampling

Sample size calculation was based on the prevalence of neonatal hyperbilirubinemia in low- and middle-income countries.[7] We also considered enrolling newborns with TSB across a wide range <14.62 and >14.62 mg/dL (250 μmol/L), the threshold for referral for a blood test when using transcutaneous devices in standard care.[19] A consecutive sampling approach was applied. Newborns who met the inclusion criteria were eligible irrespective of the presence or severity of clinical jaundice. Of the 13 eligible community health care workers in the rural districts, 11 were available to participate.

Procedures

After obtaining written informed consent from parents, we documented the environmental lighting source at the point of care, parental/clinician visual assessment of neonatal jaundice based on scleral color, the infant's characteristics (age, gestational age, sex, birth weight, and previous treatment of neonatal jaundice), and other variables of interest. Thereafter, digital images of the opened eye of the infant were obtained with neoSCB followed by transcutaneous bilirubin (TcB) measurement with the Dräger jaundice meter JM-105 and, finally, heel prick or venepuncture for blood samples. All procedures were conducted indoors in hospital wards with ceiling light and/or varying levels of natural light during the day.

After opening the neoSCB app on the smartphone, the mother or health worker facilitated the process of opening the infant's eye for an image capture of the sclera. The app takes 2 images, 1 with the flash on and 1 without the flash, automatically. During the early phase of the study, images were observed to be obtained from varying distances from the infant's eye, resulting in insufficient flash illumination of the eye. The early-phase data set was used to optimize the neoSCB app by establishing an appropriate subtracted signal-to-noise ratio (SSNR) for quality control,[15] displaying real-time SSNR on the app to make it easier to operate, and providing the option for the operator to zoom in on the captured image and manually choose an area of interest on the sclera using a small square for a real-time calculated SCB value (Fig 1).

The neoSCB app uses the rear light-emitting diode flash (equipped with an optical diffuser to lower the light

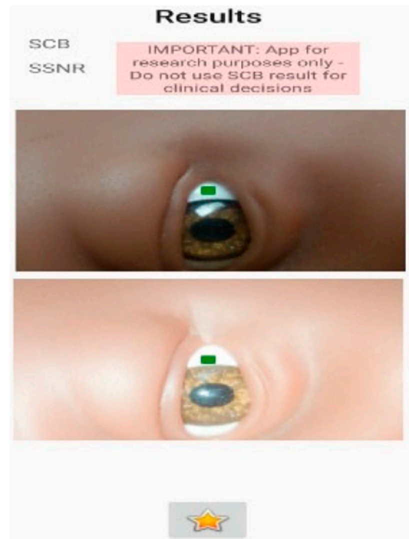

FIGURE 1
The neoSCB app showing 2 digital images.

intensity) and camera of Samsung Galaxy S8 smartphones to capture images of the infant's eye. For each capture, 2 images were taken, 1 with the light-emitting diode on and 1 with it off, so that ambient subtraction can be performed to minimize the effect of ambient lighting.[15] To ensure that different smartphones provide similar numerical results despite interphone variation in the cameras, a one-time calibration was performed on the study smartphones by taking a photo of a standardized color checker that allowed the characteristics of the smartphone camera to be measured and calibrated.[20]

Transcutaneous measurement of bilirubin with JM-105 was performed according to the manufacturer's protocol.[21] Blood sample collection by venepuncture was performed by physicians, and heel prick samples were obtained by nurses according to local guidelines. A sample of blood (~0.1 mL) was centrifuged (SciSpin Micro Hematocrit Centrifuge) and the supernatant used to obtain the TSB (Pfaff Bilimeter) at the point of care.

Mothers of infants referred to the hospital because of jaundice were asked about how their infant's jaundice was first diagnosed before referral. Mothers' assessment of the presence of jaundice during the procedure for digital eye image data collection and their feedback on the procedure were documented. Rural community health workers were trained to use neoSCB and were given the smartphones to use (but not for clinical decision-making) for a period of 2 weeks and provided feedback on their experience and acceptability by mothers.

Data Management and Analysis

The neoSCB app provides an SCB value, which is a measure of bilirubin concentration based on sclera color.[15] The screening threshold for neoSCB and JM-105 was TSB >14.62 mg/dL (250 μmol/L). Digital images were analyzed at study-defined intervals, and the neoSCB user interface was regularly improved as previously described.[15] Analysis was offline by manually tracing the scleral region for each eye image. The SCB was estimated by taking the mean of up to 3 captures, and the SCB predictive algorithm was optimized with a large data set. The correlation between SCB error (the difference between SCB and TSB values) and participant characteristics was analyzed. For validation, the SCB value was compared with the ground truth TSB value, and the screening performance of neoSCB was compared against the well-established TcB measurements with JM-105. We selected data sets that met both JM-105 manufacturer recommendations[21] and optimal performance of neoSCB.[15] Only data sets from infants who were gestational age >35 weeks and with subtracted SSNR >3.4 were included in the validation analysis.[15]

TABLE 1 Characteristics of Infants for Validation of the neoSCB App for Screening Jaundice

Characteristic	Cases, No.	Proportion, %
Sex		
Male	404	55.8
Female	320	44.2
Gestational age, wk		
32–34	34	4.7
35–37	165	22.8
38–42	510	70.4
No data	15	2.1
Birth weight, g		
1500–2500	93	12.8
≥2500	626	86.5
No data	5	0.7
Postnatal age at enrollment		
<24 h	272	37.6
24–72 h	222	30.7
4–7 d	165	22.8
8–14 d	27	3.7
>14 d	9	1.2
Incomplete data	29	4.0
No exposure to previous phototherapy	416	57.5
Referred with clinical diagnosis of neonatal jaundice (n = 467)		
Diagnosed by yellow discoloration of the eye	364	77.9
Diagnosed by yellow discoloration of skin	66	14.1
Not sure	47	8.0
TSB (n = 804), mg/dL		
<8.77	209	26.0
8.77–14.59	366	45.5
14.60–20.41	159	19.8
>20.41	70	8.7
Parental vs frontline health worker subjective assessment of neonatal jaundice (n = 804)[a]		
Concordance: eye not yellow	213	26.5
Concordance: eye yellow	530	65.9
No concordance	51	6.3
Incomplete data	10	1.2

[a] Each time, we asked whether eye was yellow.

RESULTS

Of the 724 infants enrolled, 568 and 156 were from the regional and district hospital, respectively, and 416 had not received previous treatment (phototherapy) for jaundice. Participant characteristics are summarized in Table 1. Infants without a documented gestational age or birth weight were enrolled on the basis of clinical assessment at the hospital. Of the 804 data capture occasions when mothers assessed the eye of their infant for jaundice, the mother's assessment was similar to that of health workers in most cases (92.4%).

Overall, 847 data sets were collected during the study, as summarized in Fig 2. Most of the data sets excluded from the validation analysis were obtained during the early stages of the study before the optimization of neoSCB with real-time SSNR display.

Among the 416 infants who had not received phototherapy before enrollment, 111 (26.7%) had serum bilirubin level >14.62 mg/dL, and JM-105 did not return a numerical value in 50.4% (56 of 111) of these cases. Of the 416 study infants, 347 with sufficient SSNR had no significant correlation between SCB error (ie, SCB-TSB difference) and postnatal age (P = .07) or birth weight (P = .11). There was no significant difference in the mean SCB error between boys (n = 192) and girls (n = 155; unpaired 2-sample t test P = .31). However, there was a significant correlation coefficient of 0.2 (95% confidence interval [CI], 0.1 to 0.3; $P < .01$) between the SCB error and gestational age, indicating that neoSCB tended to underestimate bilirubin value in infants with younger gestational ages. The SCB error for preterm infants (≤37 weeks gestation, n = 46) was significantly biased compared with term infants, with a mean relative offset value of −2.57 mg/dL (95% CI, −1.46 to −3.74 mg/dL).

Of the 347 infants with sufficient SSNR, 336 were born at gestational age ≥35 weeks, the recommended gestational age for using JM-105. The analysis of single-image captures in this group revealed reasonably high sensitivity, specificity, and receiver operating characteristic (ROC) area under the curve (AUC) at 0.94, 0.73, and 0.90, respectively, with a cutoff SCB threshold of 11.58 mg/dL (Fig 3). When the average of 3 captures was used (n = 179), the sensitivity and specificity increased further to 1.00 and 0.76, respectively, with a cutoff SCB threshold of 11.52 mg/dL. These findings were comparable to JM-105 at a sensitivity of 0.97 and specificity of 0.79 in the same population (Table 2). For the JM-105, some TcB measurements, all with corresponding TSB >19.88 mg/dL, returned warning messages instead of numerical values. These were included in the TcB data for the purpose of estimating sensitivity and specificity but excluded in the scatter plot for the single-capture results in Fig 3. The sensitivity and specificity of the optimized neoSCB app improved compared with the prototype used in an earlier study[14] and were comparable to other smartphone skin color–based jaundice apps,[22–24] as shown in Table 2.

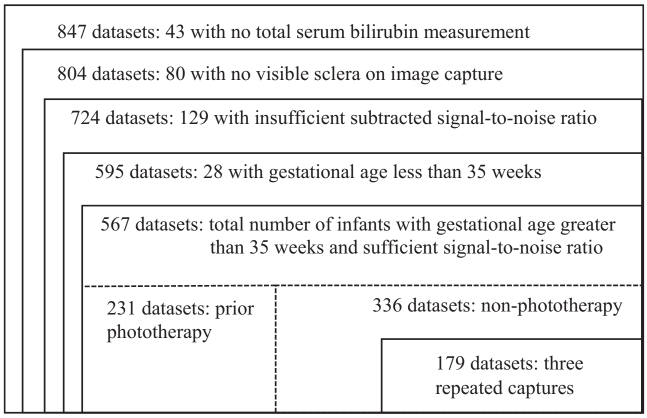

FIGURE 2
Description of segments of the whole data set for neoSCB optimization and validation.

TcB/TSB had a larger correlation coefficient ($r = 0.93$) than that of the SCB/TSB ($r = 0.78$), with both being statistically significant ($P < .01$). In general, the SCB/TSB data points had a higher error variance, especially when TSB >14.62 mg/dL (Fig 3). In Fig 4, the Bland-Altman plot[25] for SCB against TSB depicts the mean bias of 0.11 mg/dL (95% CI, −0.09 to 0.31 mg/dL) and the lower and upper limits of agreement of −7.13 mg/dL (95% CI, −7.48 to −6.78 mg/dL) and 7.36 mg/dL (95% CI, 7.01 to 7.70 mg/dL), respectively. It reveals that SCB tends to be increasingly smaller than TSB as TSB gets larger.

Among the 231 data sets of infants with previous phototherapy, sufficient SSNR, and gestational age >35 weeks, the sensitivity of neoSCB was 0.72 (95% CI, 0.59 to 0.80); specificity, 0.73 (95% CI, 0.66 to 0.79); and ROC AUC, 0.80 at a cutoff SCB threshold of 13.27 mg/dL (Fig 5).

Overall, the procedure was acceptable to mothers in hospital and rural settings. Two mothers refused to give consent, the reason being that the infants' fathers were unavailable to give permission for enrollment. Mothers easily devised ways to enable the infant to open the eyes, most often by breastfeeding. It took an average of 30 minutes (range, 10–60 minutes) to teach rural community health workers how to use the app.

DISCUSSION

Yellow discoloration of the sclera was the most common diagnostic criteria for hospital referral in the study population. The neoSCB app had similar diagnostic accuracies to

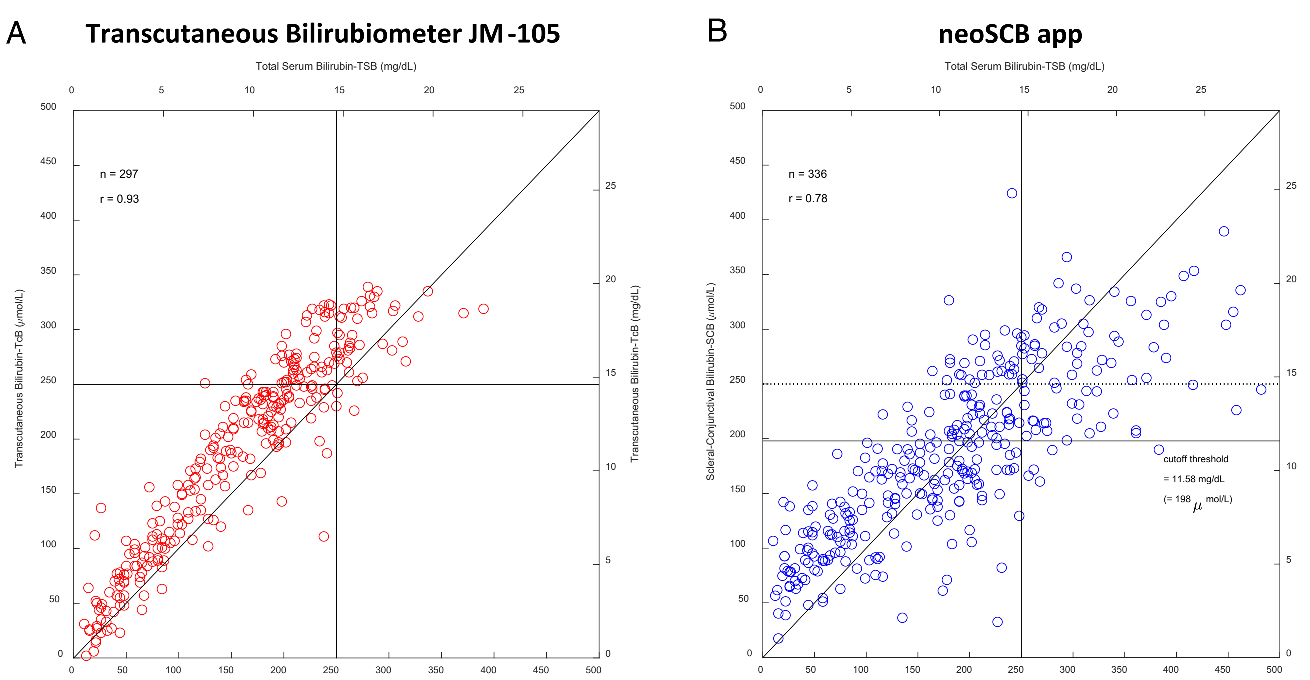

FIGURE 3
Association among total serum bilirubin, SCB, and TcB. (A) Scatter plot for TcB versus TSB. (B) Scatter plot for SCB (based on single-image capture) versus TSB. Both correlation coefficients (r) are statistically significant with $P < .01$. Although the sample size (n) for the SCB study was 336, only 297 are included here for the TcB study because in 39 measurements, the TcB returned warning messages instead of numerical values, indicating that the values were very high.

TABLE 2 Diagnostic Accuracies of Sclera-Based and Skin Color or Transcutaneous-Based Methodologies for Screening Newborns With Jaundice Without Previous Phototherapy

Study	Sample Size, No.	Sensitivity (95% CI)	Specificity (95% CI)	Screening Threshold, mg/dL (μmol/L)	ROC AUC
The Ghana validation study					
Single-image captures, neoSCB	336	0.94 (0.91 to 0.97)	0.73 (0.68 to 0.78)	14.62 (250)	0.90
JM-105 TcB	336	0.96 (0.90 to 0.99)	0.81 (0.76 to 0.86)	14.62 (250)	NA
Triple-image captures, neoSCB	179	1.00 (0.95 to 1.00)	0.76 (0.70 to 0.82)	14.62 (250)	0.92
JM-105 TcB	179	0.97 (0.95 to 1.00)	0.79 (0.73 to 0.85)	14.62 (250)	NA
Outlaw et al[15]					
Multiple image captures, neoSCB prototype	37	1.00 (0.88 to 1.00)	0.61 (0.43 to 0.76)	14.62 (250)	0.86
Taylor et al[22]					
Multiple image captures, BiliCam	530	1.00	0.76	17.02 (291)	0.99
Aune et al[23]					
Multiple image captures, Picterus	185	1.00	0.69	14.62 (250)	0.93
Ren et al[24]					
BiliScan	247	0.75	0.87	14.97 (256)	0.89

NA, not applicable.

JM-105 but had a higher error variance when TSB >14.62 mg/dL. The neoSCB app gave an underestimation of bilirubin at higher values of TSB, whereas JM-105 gave no numerical values under similar conditions. These findings are not clinically relevant for devices intended for use as threshold detectors for referral for additional clinical assessment and blood tests. JM-105 is not recommended for use in infants who have received previous phototherapy[21]; these infants were excluded in the validation analysis.

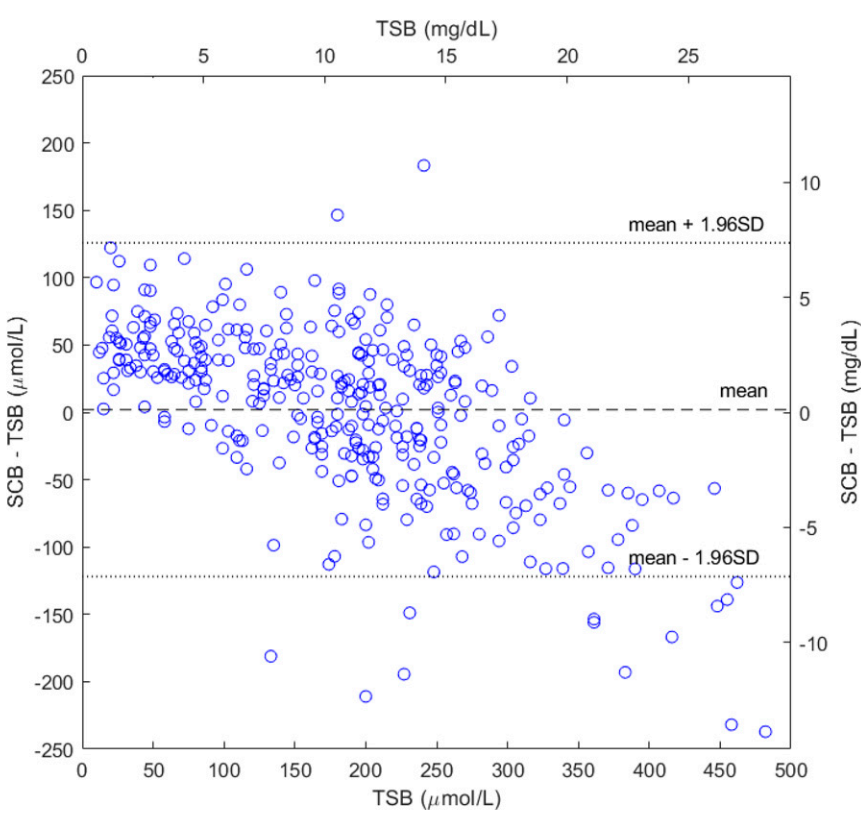

FIGURE 4
Bland-Altman plot for SCB against the TSB. SCB was estimated on the basis of single-image capture ($n = 336$).

The diagnostic accuracy of neoSCB is reasonably high and comparable to JM-105 and other skin color–based jaundice apps, namely BiliCam[22] and Picterus,[23] though the diagnostic results were based on higher screening thresholds (Table 2). The diagnostic accuracy of neoSCB increased when 3 captures were considered because processing multiple images tends to minimize random noise, but there was no significant difference between single- and triple-capture data in this study. The optimized neoSCB app in the Ghana study performed better than the prototype in the UK study,[15] which used a different smartphone (LG Nexus 5X), a front-facing camera, and screen lighting for illumination.

There was a high level of concordance between mothers' and health workers' subjective visual assessment of neonatal jaundice, although mothers' assessment may have been influenced by their participation in the study. The ability of mothers to assess scleral yellowness indicates that given the right tool and regulatory framework, mothers may play a vital role in settings with a limited health care workforce. The high acceptability of the neoSCB procedure was probably because it was similar to local practice of visual sclera assessment

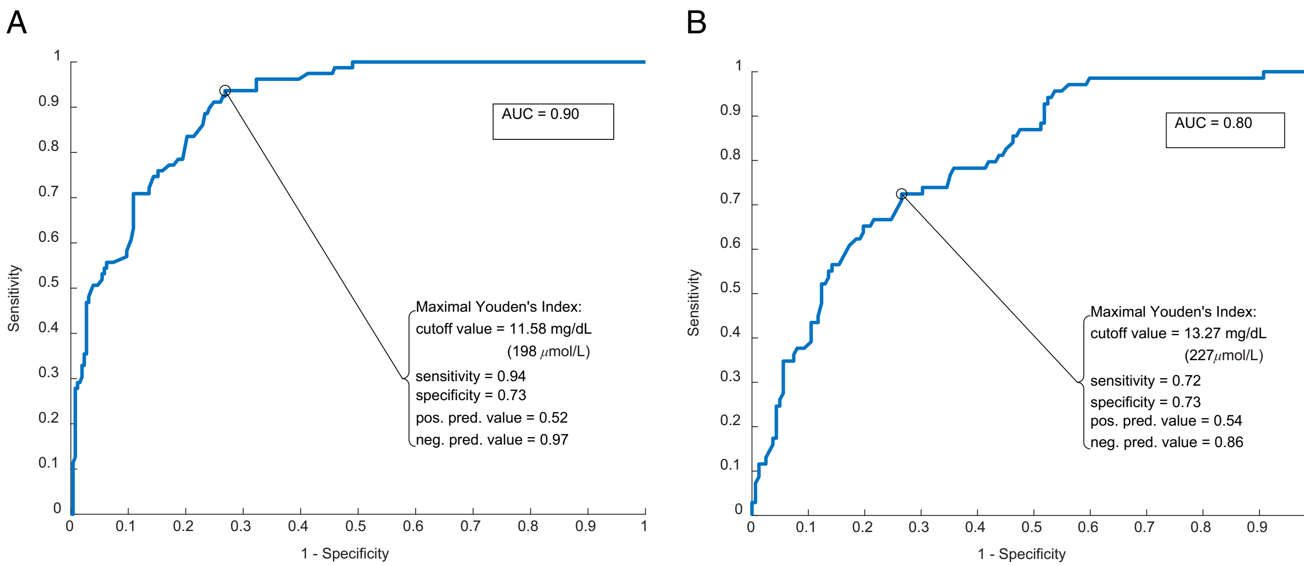

FIGURE 5
ROC curves of neoSCB for screening infants at the TSB >14.62 mg/dL (250 μmol/L) threshold. (A) Infants without previous phototherapy (*n* = 336). (B) Infants with phototherapy exposure within 24 hours (*n* = 231). neg. pred., negative predictive; pos. pred., positive predictive.

for neonatal jaundice. Training of community health workers was straightforward because of their previous experience with other phone-based health care programs. Documenting acceptability of new health care interventions is useful for implementation at scale.[26]

For clinical use, neoSCB would have additional advantages, such as storing and transferring information between hospitals, prompts for health care workers and/or parents to recognize red flags for health care seeking, and information for parents if approved for use by the general population. However, the app cannot be recommended for use in infants gestational age <37 weeks because it underestimates the scleral yellowness in preterm infants possibly because of the relatively thin and immature sclera of the preterm, which may allow underlying choroidal pigment to counteract yellowing due to bilirubin.[27] A correction factor for gestational age may improve the app's estimation accuracy in future versions.

For populations that depend on subjective visual assessment of the sclera for diagnosing neonatal hyperbilirubinemia, neoSCB may be an objective tool for screening. Although universal screening for neonatal jaundice is standard care in high-resource settings, most high-burden countries, including Ghana, do not have a similar policy possibly because of the limited capacity of the health system, including limited access to reliable screening tools. With increasing penetration of smartphone technology and integrated health care pathways, the capacity to screen newborns in low-resource populations may improve.

The neoSCB app was easy to use, but the SCB value depends on the quality of the digital photo and selection of the scleral segment of interest. These limitations can be reduced by training health care workers to (1) increase the SSNR by moving the smartphone closer to the infant's face during photo capture, (2) recognize and discard a blurred photo image, and (3) avoid the eyelid and iris when selecting the scleral segment of interest. Many health systems provide training to health care workers whenever a new clinical tool is provided for service delivery.[28]

Smartphones with similar specifications to Samsung Galaxy S8 are increasingly available, but cost could be a drawback for the uptake of neoSCB in low-resource settings. The COVID-19 pandemic has affected methods for delivering health services globally. With increasing penetration of smartphone technologies into rural communities,[17] the prospects for applying new health technologies in most settings are high.

CONCLUSIONS

The neoSCB smartphone app was validated as a potential contact-free screening tool for neonatal jaundice. It requires no consumables or extra utility costs to the health system and was acceptable to mothers. To reduce unnecessary hospital referrals for blood tests and delays in clinical decision-making, neoSCB may be considered a feasible tool for neonatal jaundice screening of term infants in settings similar to Ghana.

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ABBREVIATIONS

app: application
AUC: area under the curve
CI: confidence interval
neoSCB: Neonatal Scleral-Conjunctival Bilirubin
ROC: receiver operating characteristic
SCB: scleral-conjunctival bilirubin
SSNR: signal-to-noise ratio
TcB: transcutaneous bilirubinometer
TSB: total serum bilirubin

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