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DIAGNOSTIC ACCURACY OF TRANSCUTANEOUS BILIRUBIN MEASUREMENTS IN NEONATES ADMITTED AT A TERTIARY TEACHING AND REFERRAL HOSPITAL IN NAIROBI, KENYA

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# DIAGNOSTIC ACCURACY OF TRANSCUTANEOUS BILIRUBIN MEASUREMENTS IN NEONATES ADMITTED AT A TERTIARY TEACHING AND REFERRAL HOSPITAL IN NAIROBI, KENYA

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## ABSTRACT

*Background:* **Neonatal jaundice is a serious medical issue affecting newborns and is associated with high mortality, hence the need for fast, simple, and accurate diagnosis.**

*Objectives*: **The study investigated the diagnostic accuracy of transcutaneous bilirubin measurements (TcB) using total serum bilirubin (TSB) as the gold standard among admitted neonates.**

*Methods*: **This was a prospective diagnostic accuracy(cross-sectional) study involving 158 term neonates with clinically suspected jaundice. Diagnostic performance was assessed using two complementary approaches: (i) application of the 2022 American Academy of Paediatrics (AAP) guideline TSB thresholds, along with Bhutani Nomogram TcB interpretation, and (ii) Receiver Operating Characteristic (ROC) curve analysis to evaluate discriminative performance across different TSB cut-off values (222, 256, and 291 μmol/L).**

*Results*: **The mean difference between TcB and TSB was –0.67 μmol/L (95% CI: –6.67 to 5.34), indicating close agreement between the two methods. Across TSB thresholds of at least 222, 256, and 291 μmol/L, a TcB cut-off of 222 μmol/L correctly identified 85.9%, 90.7%, and 100.0% of infants with elevated bilirubin, respectively. TcB showed high sensitivity in the first 24 hours of life (90.7%) and maintained good performance at 48 hours (80.0%). Overall, TcB correctly detected most infants with high serum bilirubin (88.9% sensitivity), correctly ruled out most without high bilirubin (88.5% specificity), and achieved an overall accuracy of 88.6%.**

*Conclusion*: **The study revealed a strong TcB-TSB correlation, supporting TcB as a fast, non-invasive screening tool for neonatal hyperbilirubinemia,**

**especially within 24-48 hours of life. A TcB cut-off of 222 μmol/L offers optimal performance.**

*Keywords*: **Transcutaneous bilirubin, total serum bilirubin, neonatal jaundice**

## INTRODUCTION

Newborn hyperbilirubinemia is a total amount of serum bilirubin level exceeding 86 μmol per liter (5 mg per dL), and can lead to severe illnesses such as endocrine disorders, haemolytic disease, anatomic and metabolic abnormalities of the liver, gaze paralysis, hearing loss, sensorineural cerebral palsy, or neonatal developmental delay and sepsis [1]. It affects approximately 60.0% of full-term and 80.0% of preterm infants, particularly during the first week of life. While it is a leading cause of hospitalization and readmission worldwide, its impact on illness and mortality is disproportionately high in sub-Saharan Africa [2, 3].

Globally, up to 84.0% of healthy newborns may develop elevated bilirubin levels, and severe cases continue to pose significant clinical risk, as higher total serum bilirubin (TSB) levels (≥25 mg/dL) have been linked to neurological abnormalities, hearing impairment, and developmental delays [4, 5]. Long-term impairments have also been observed among Kenyan survivors of neonatal jaundice and sepsis [6]. Current guidelines recommend hour-specific bilirubin nomograms and universal newborn screening using transcutaneous bilirubin measurements (TcB) or TSB, emphasizing individualized thresholds based on gestational age and neurotoxicity risk factors [7]. Despite TcB being recognized since 1980 as a reliable, non-invasive tool, its uptake remains limited in resource-constrained settings [8]. Studies have demonstrated strong correlations between TcB and TSB, supporting its diagnostic utility. For example, Italian research reported high agreement across devices [9]. Also, a study from Thailand showed that TcB had excellent diagnostic performance, with 97.3% negative predictive value (NPV), 62.1% positive predictive value (PPV), 94.2% specificity, 78.3% sensitivity, and an overall 92.5% accuracy in estimating bilirubin levels [10]. However, evidence from African populations indicates that TcB may both overestimate and underestimate TSB in darker-skinned infants [11].

Although TcB has been shown to correlate strongly with TSB globally, its diagnostic accuracy has not been fully validated in African populations, especially among darker-skinned neonates [12,13,14]. In Kenya, available studies have largely focused on the prevalence of neonatal jaundice, with no evaluation of TcB as a screening tool [15]. Moreover, visual assessment remains unreliable, and TSB testing, while the gold standard, is invasive, costly, and time-consuming, causing both significant blood loss in infants and anxiety for parents. To address this evidence gap and determine whether TcB can serve as a practical, non-invasive screening tool in Kenyan neonates, this study aims to evaluate its diagnostic accuracy in comparison to TSB. Establishing this relationship will provide evidence to support safe, efficient, and practical neonatal jaundice screening in local clinical settings.

## MATERIALS AND METHODS

### Study Design

This was a prospective diagnostic accuracy (cross-sectional) study comparing TcB

measurement with TSB, conducted in the maternity ward of Aga Khan University Hospital, Nairobi (AKUH, N), from March 2022 to July 2023. Eligible participants were term neonates (≥38 weeks' gestational age) with clinically suspected jaundice. Neonates were included if they were clinically jaundiced, not currently receiving phototherapy, and had obtained parental or guardian consent. Exclusion criteria included prior exposure to phototherapy or exchange transfusion, lack of informed consent, or bilirubin levels within the reference range.

**Participant Selection**

A non-probability consecutive sampling method was used, whereby all eligible neonates who met the inclusion criteria were recruited sequentially as they presented during the study period. This approach ensured that every qualifying infant available at the time of data collection was included, minimizing selection bias and allowing for a practical and systematic enrollment process within the clinical setting. Informed consent was obtained from each infant's parent or guardian. The sample size calculation was based on sensitivity and specificity [16]. Determination of n (the sample size) was as follows:

n= Sample size; z = 1.96, at 95% confidence level
nse= Sample size for the sensitivity of 92.9% study done in Thailand 2016 [17].
P= prevalence from Kenyatta National Hospital, Nairobi (16.0%) [15]
p= expected proportion of event p= (1-0.16) =0.84, d= (10.0%) allowable error/precision.
nse = (1.962 * 0.929(1-0.929)) / (0.12 *0.16) = 158

**Clinical Assessment**

Each neonate enrolled in the study was assessed for jaundice by an experienced paediatrician based on clinical evaluation. TcB screening was performed, followed by TSB blood sampling.

**TcB Measurements**

TcB measurements were obtained using the BiliCare device (Natus Medical Inc.), following the manufacturer's instructions. Readings were taken from the scaphoid region of the ear and recorded in the data collection form along with the study number, sex, and date of birth. The device was calibrated and maintained daily in accordance with the manufacturer's guidelines. For neonates with TcB levels above the reference threshold, results were communicated to the attending paediatrician, and serum sampling (TSB) was initiated within 30 minutes of the initial measurement.

**TSB Sampling and Measurements**

Blood samples were collected aseptically. The puncture site was cleaned with 70.0% alcohol and allowed to air dry before collection. Samples were dispensed into labelled microtubes, placed in biohazard bags, and transported in cooler boxes to minimize light exposure. In the chemistry laboratory, samples were centrifuged at 3500 rpm for 10 minutes to obtain serum, which was analysed using the Atellica chemistry analyser (automated equipment). Internal quality controls were run daily to ensure the accuracy of results. Processing and analysis took two hours, and the results were recorded and communicated to the paediatrician.

**Clinical Follow-Up**

Neonates with elevated bilirubin levels were reviewed, and appropriate interventions were initiated by the paediatrician. All procedures adhered to established Standard Operating Procedures (SOPs) for specimen collection, handling, processing, and reporting.

**Statistical Analysis**

Data from the collection forms were checked for completeness and accuracy, then entered into Microsoft Excel and exported to SPSS version 26.0 (IBM SPSS Statistics 26) for analysis. The relationship between TcB and TSB levels was evaluated using Deming regression to account for measurement error in both variables. The correlation coefficient (r) and coefficient of determination ($r^2$) were used to assess the strength of the association. The agreement between the two measurements was further analyzed using the Bland–Altman plot to detect systematic bias and outliers. Diagnostic performance was assessed using two complementary approaches, a 2×2 contingency table was constructed in MedCalc Statistical Software version 23.3.7, to calculate sensitivity, specificity, PPV and NPV, and overall accuracy following the 2022 AAP guideline–defined thresholds for TSB to classify hyperbilirubinemia, along with TcB interpretation based on the Bhutani Nomogram (as used by the institution), and ROC curve analysis was performed using TSB cut-off values of at least 222, 256, and 291 μmol/L, representing mild, moderate, and severe hyperbilirubinemia based on AAP phototherapy thresholds for term neonates. These cut-offs reflect clinically relevant decision points for initiating and escalating phototherapy, and these values have also been adopted in prior studies evaluating the diagnostic accuracy of transcutaneous bilirubinometry and serum bilirubin testing in similar populations [18], thereby supporting their comparability and clinical relevance in the present analysis. The area under the curve (AUC) quantified the test discrimination, and a $p < 0.05$ was considered statistically significant.

### Ethical Approval

The research was carried out after acquiring Institutional ethical approval from the AKUHN Ethics and Review Committee (Ref:2021/IERC-69(vol-3). In addition, the study received approval from the National Commission for Science, Technology, and Innovation (NACOSTI) (License No. NACOSTI/21/14039).

## RESULTS

### Participants and Clinical Characteristics

A total of 158 term neonates with clinical jaundice who fulfilled the inclusion criteria were recruited in this study. The distribution of gender (Male/Female) was at 50.0% each, and the mean ± standard deviation (SD) postnatal age of neonates was 1.62 (± 0.86) days with a range of 0-5 days. The mean (± SD) of TcB and TSB values obtained were 216.21(± 51.78) umol/L and 216.88(± 73.60) umol/L (at a 95% CI), respectively (Table 1), with a mean difference of -0.67[95% CI: -6.67 to 5.34 umol/L] between the two methods. Among the serum samples, 64(40.5 %) had TSB above 222 μmol/L, 43(27.2%) above 256 μmol and 24(15.2%) above 291 μmol/L.

***Table 1: Demographic and clinical characteristics of study participants***

| **Variable Name** | **Value** |
|---|---|
| N | 158 |
| **Sex**<br>Male/Female | <br>79/79 |
| **Age (days)**<br>Mean (± SD)<br>Range | <br>1.62 (± 0.86)<br>0-5 |
| Paired TSB and TcB measurements | 158 |

| | |
|---|---|
| **TcB (µmol/L)**<br>Mean (± SD)<br>Range | <br>216.21 (± 51.78)<br>85 – 335.2 |
| **TSB (µmol/L)**<br>Mean (± SD)<br>Range | <br>216.88 (± 73.60)<br>96-511.0 |
| TSB-TcB mean difference (95% CI) | –0.67 (–6.67 to 5.34) |
| **Distribution of TSB levels**<br>TSB ≥ 291 µmol/L<br>TSB ≥ 256 µmol/L<br>TSB ≥ 222 µmol/L | <br>24(15.2%)<br>43(27.2%)<br>64(40.5%) |

**Distribution of TcB and TSB Measurements**

TcB measurements were normally distributed (Shapiro–Wilk test: W = 0.991, p = 0.437), whereas TSB measurements were not (W = 0.955, p < 0.001). The Wilcoxon signed-rank test showed no statistically significant difference between TcB and TSB measurements (p = 0.613).

**Correlation and Relationship Between TcB and TSB Measurements**

Pearson correlation analysis of 158 paired measurements showed a very strong positive linear relationship between TcB and TSB values, with a Pearson correlation coefficient of r = 0.87 (p < 0.001) and a coefficient of determination ($r^2$ = 0.76), indicating that higher TcB measurements are strongly associated with higher TSB levels. Deming regression comparing TcB and TSB showed a slope of 0.67 (95% CI: 0.61 to 0.73) and an intercept of 71.03 (95% CI: 57.35 to 84.71) (r= 0.87) (Figure 1).

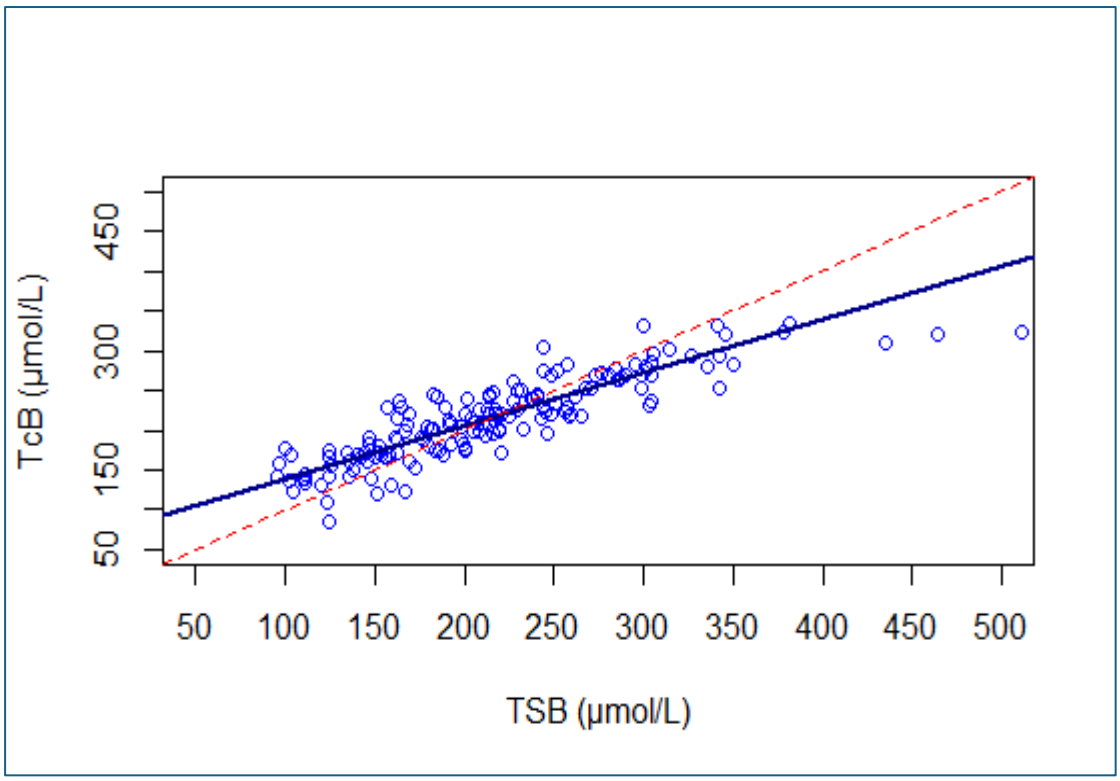


*Figure 1: Deming regression comparing TcB and TSB measurements.*

**Agreement between TcB and TSB measurements: Bland-Altman analysis**

Bland–Altman analysis showed a mean difference (bias) of −0.665 µmol/L, with 95% limits of agreement ranging from −75.563 to +74.233 µmol/L, indicating a slight underestimation of TSB by TcB. Most data points clustered around the mean difference between 100 and 300 µmol/L, showing relatively good agreement in this range, although several outliers were noted, particularly at higher bilirubin concentrations (Figure 2).

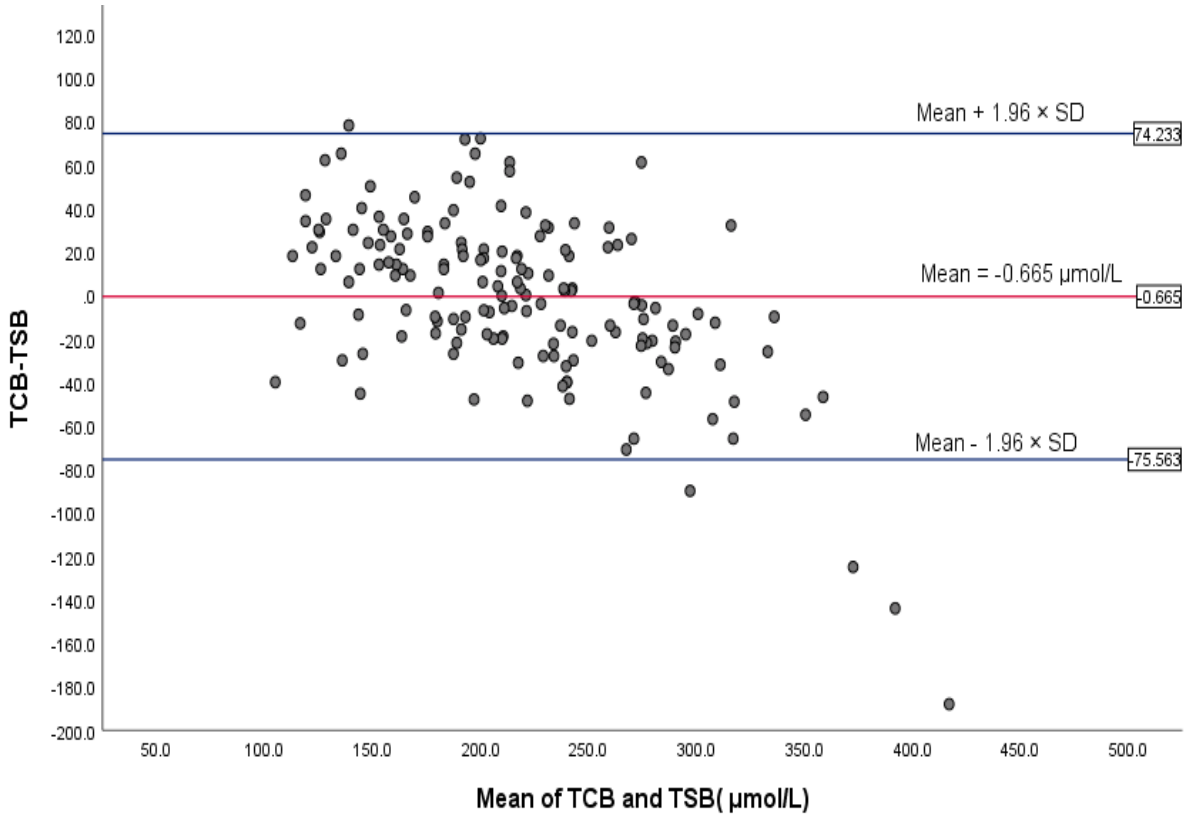


*Figure 2: Bland-Altman analysis*

**Predictive Performance of TcB at Varying TSB Thresholds: ROC Curve Analysis**

ROC curves were generated to evaluate the diagnostic performance of TcB in predicting elevated TSB levels at three clinical thresholds (222, 256, 291umo/L). The area under the curve (AUC) for predicting TSB ≥ 222 µmol/L was 0.949 (95% CI: 0.920–0.979), for TSB ≥ 256 µmol/L was 0.936 (95% CI: 0.899–0.974), and for TSB ≥ 291 µmol/L was 0.960 (95% CI: 0.928–0.992). All results were statistically significant ($p < 0.001$), indicating that TcB measurements demonstrated excellent diagnostic accuracy in identifying neonates with clinically significant hyperbilirubinemia (Figures 3–5).

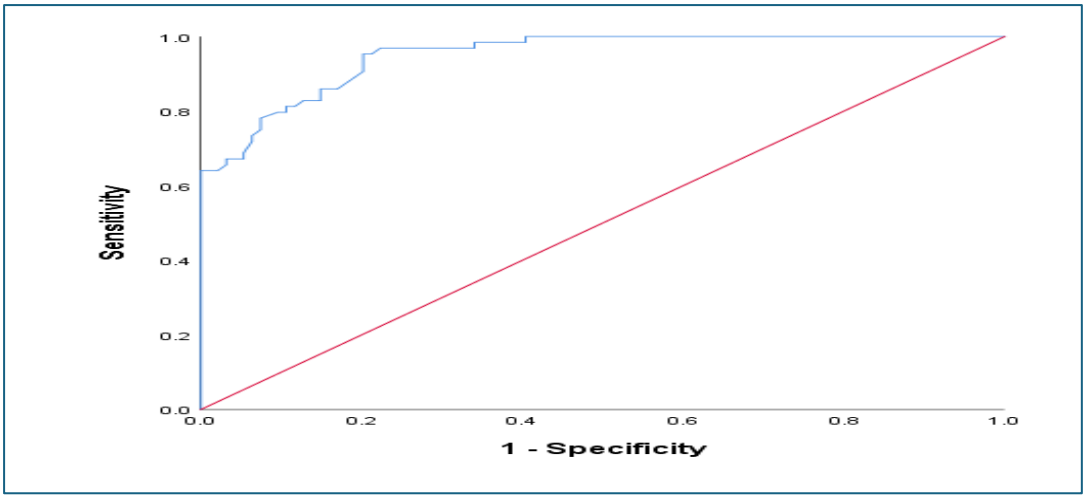


*Figure 3: Performance of TcB in identifying TSB ≥222 µmol/L (AUC 0.949, p < 0.001)*

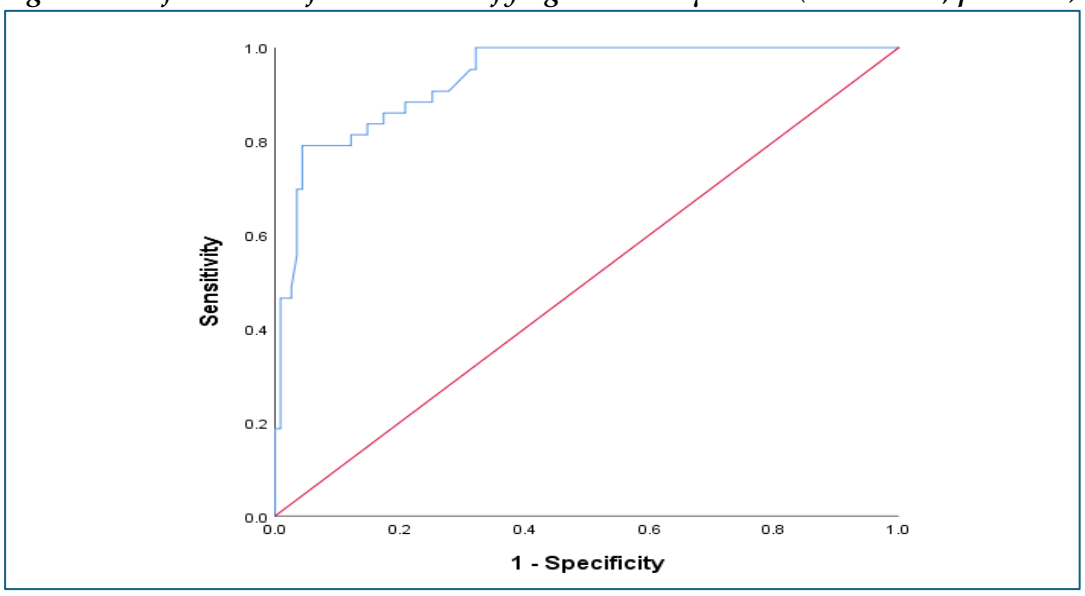


*Figure 4: TcB performance in identifying TSB ≥256 µmol/L (AUC 0.936, p < 0.001)*

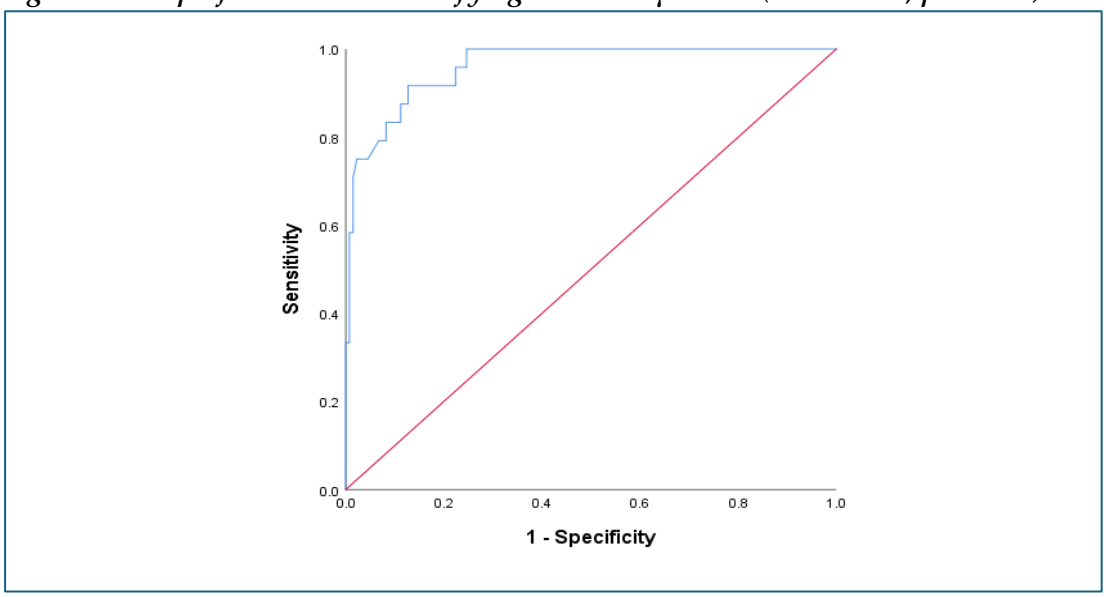


*Figure 5: TcB Performance in Identifying TSB ≥291 µmol/L (AUC 0.960, p < 0.001)*

At TSB threshold 222 µmol/L, a TcB cutoff of 197 µmol/L showed perfect sensitivity (100%) and NPV (100%) but with relatively low specificity (59.8%) and PPV (62.8%), while TcB of 222 µmol/L achieved a more balanced performance (85.9% sensitivity, 85.1% specificity, NPV 89.9%) and avoided 56.3% of blood sampling. At TSB threshold 256 µmol/L, a TcB cutoff of 197 µmol/L again ensured perfect sensitivity and NPV, though specificity (48.7%) and PPV (42.2%) were limited; raising the TcB cutoff to 256 µmol/L improved specificity (95.7%) and PPV (85.7%) and reduced sensitivity to 69.8%, while avoiding 77.8% of sampling. At TSB threshold 291 µmol/L, TcB cutoffs of 197–222 µmol/L maintained perfect sensitivity and NPV but at the cost of poor specificity (41.8–66.4%) and PPVs (23.5–34.8%) leading to high false positives; at TcB of 291 µmol/L, specificity (99.3%) and PPV (92.3%) were maximized, though sensitivity fell to 50.0%, with 91.8% of blood sampling avoided (Table 2).

***Table 2: TcB performance across TSB thresholds of 222, 256, and 291 µmol/L***

| TSB (µmol/L) | TcB (µmol/L) | Sensitivity (%) | Specificity (%) | NPV (%) | PPV (%) | False Negatives | % of blood sampling avoided |
|---|---|---|---|---|---|---|---|
| 222 | 197 | 100.0 | 59.8 | 100 | 62.8 | 0 | 35.4 |
| | 211 | 96.9 | 75.5 | 97.3 | 72.9 | 2 | 46.2 |
| | 222 | 85.9 | 85.1 | 89.9 | 79.7 | 9 | 56.3 |
| | | | | | | | |
| 256 | 197 | 100.0 | 48.7 | 100 | 42.2 | 0 | 35.4 |
| | 211 | 100.0 | 63.9 | 100 | 50.6 | 0 | 46.2 |
| | 222 | 90.7 | 73.9 | 95.5 | 56.5 | 4 | 56.3 |
| | 245 | 79.1 | 92.2 | 92.2 | 79.1 | 9 | 72.8 |
| | 256 | 69.8 | 95.7 | 89.4 | 85.7 | 13 | 77.8 |
| | | | | | | | |
| 291 | 197 | 100.0 | 41.8 | 100 | 23.5 | 0 | 35.4 |
| | 211 | 100.0 | 54.5 | 100 | 28.2 | 0 | 46.2 |
| | 222 | 100.0 | 66.4 | 100 | 34.8 | 0 | 56.3 |
| | 245 | 91.7 | 84.3 | 98.3 | 51.2 | 2 | 72.8 |
| | 256 | 83.3 | 88.8 | 96.8 | 57.1 | 4 | 77.8 |
| | 277 | 75.0 | 97.8 | 95.6 | 85.7 | 6 | 86.7 |
| | 291 | 50.0 | 99.3 | 91.7 | 92.3 | 12 | 91.8 |

**Overall Diagnostic Performance of TcB Measurements in Neonates**

The diagnostic performance of TcB risk stratification (Bhutani Nomogram) compared with TSB-defined hyperbilirubinemia based on the 2022 AAP guidelines, evaluated across different neonatal age groups, is presented in Table 3. At 24 hours, TcB showed high sensitivity (90.7%) and specificity (85.1%), with an overall accuracy of 87.8%. At 48 hours, TcB maintained good performance with a sensitivity of 80.0%, specificity of 86.7%, and accuracy of 85.0%. At 72 hours, although the specificity and negative predictive value

remained high (95.8% and 100.0% respectively), the sensitivity and positive predictive value dropped to 0.0% due to the absence of TSB-confirmed hyperbilirubinemia in that age group. The remaining age categories (0, 96, and 120 hours) had too few cases to meaningfully evaluate diagnostic metrics.

***Table 3: Diagnostic accuracy of TcB compared to TSB, stratified by neonatal age group***

| Age (hours) | TcB Risk | TSB-Positive | TSB-Negative | Sensitivity | Specificity | PPV | NPV | Accuracy |
|---|---|---|---|---|---|---|---|---|
| 0 | High Risk | 1 | 0 | | | | | |
| | Low Risk | 0 | 0 | | | | | |
| 24 | High Risk | 39 | 7 | 90.7% | 85.1% | 84.8% | 90.9% | 87.8% |
| | Low Risk | 4 | 40 | | | | | |
| 48 | High Risk | 8 | 4 | 80.0% | 86.7% | 66.7% | 92.9% | 85.0% |
| | Low Risk | 2 | 26 | | | | | |
| 72 | High Risk | 0 | 1 | 0.0% | 95.8% | 0.0% | 100.0% | 95.8% |
| | Low Risk | 0 | 23 | | | | | |
| 96 | High Risk | 0 | 0 | | | | | |
| | Low Risk | 0 | 1 | | | | | |
| 120 | High Risk | 0 | 0 | | | | | |
| | Low Risk | 0 | 2 | | | | | |

Overall, with TSB as a gold standard test, across the entire neonatal population, the TcB device demonstrated a sensitivity of 88.9% (95% CI: 77.4% to 95.8%) and a specificity of 88.5% (95% CI: 80.7% to 93.9%). At a disease prevalence of 34.2% (95% CI: 26.8% to 42.1%), the device yielded a PPV of 80.0% (95% CI: 69.9% to 87.3%) and the NPV of 93.9% (95% CI: 87.8% to 97.0%), and an accuracy of 88.6% (95% CI: 82.6% to 93.1%) (Table 4).

Table 4: Overall diagnostic accuracy of TcB compared to TSB

| | TSB: (Hyperbilirubinemia) | TSB: (No Hyperbilirubinemia) | **Total** |
|---|---|---|---|
| TcB: High risk for Hyperbilirubinemia | 48 (TP) | 12 (FP) | 60 |
| TcB: Low risk for Hyperbilirubinemia | 6 (FN) | 92 (TN) | 98 |
| **Total** | **54** | **104** | **158** |
| **Statistic** | **Value (95% CI)** | | |
| Sensitivity | 88.9% (77.4% to 95.8%) | | |
| Specificity | 88.5% (80.7% to 93.9%) | | |
| PPV | 80.0% (69.9% to 87.3%) | | |
| NPV | 93.9% (87.8% to 97.0%) | | |
| Accuracy | 88.6% (82.6% to 93.1%) | | |
| TP: True positive, FP: False positive, FN: False Negative, TN: True Negative | | | |

## DISCUSSION

Our findings showed an equal distribution of males and females (50% each), indicating no gender difference in the occurrence of hyperbilirubinemia among term neonates. This is consistent with what was reported in a previous study [18]. The mean values of TcB (216.21 ± 51.78 μmol/L) and TSB (216.88 ± 73.60 μmol/L) at a 95% confidence interval

were comparable with the findings of a study conducted in Nigeria. However, in that study, the mean TcB value (194.9 μmol/L) was significantly higher than the mean TSB value (174.4 μmol/L), although the study reported higher TcB values compared to TSB [19]. Also, the mean difference between the tests was −0.67 μmol/L (95% CI: −6.67 to 5.34 μmol/L), which is in agreement with the findings of a study conducted in Turkey, which reported a mean difference of −1.7 μmol/L (95% CI: −5.4 to 2.1 μmol/L) [18]. But other studies have reported positive mean differences of 11.9 μmol/L and 25.6 μmol/L, demonstrating that TcB overestimated TSB levels in those investigations [10, 20]. These variations across studies may be attributed to differences in sample characteristics, bilirubin ranges, and anatomical sites used for TcB assessment. In our study, bilirubin was measured at the ear's scaphoid, while other researchers used the forehead or sternum.

A strong positive linear relationship was observed between TcB and TSB (r = 0.87) in our findings, confirming that TcB measurements closely approximate serum bilirubin values. This finding aligns with previous studies reporting correlations between 0.7 and 0.98 [17, 21, 22]. The coefficient of determination ($r^2$ = 0.76) observed in our study is comparable to the $r^2$ value of 0.70 reported in a previous study, though lower than what was observed in another study ($r^2$= 0.96) [10, 19]. These discrepancies across studies may be due to differences in gestational age, ethnicity, skin pigmentation, and the type of device used [23]. For instance, a study conducted in Nigeria reported the use of both the BiliCare and JM-103 devices, with an overall correlation coefficient of 0.98 between TcB and TSB measurements [19]. Similarly, a study from Malawi utilized the JM-103 and BiliCheck devices and found that, among infants not receiving phototherapy, the lowest TcB reading (taken from either the forehead or sternum) showed the strongest correlation with TSB, r = 0.83 for term infants and r = 0.71 for preterm infants, with a sensitivity of 91.0% and specificity of 90.0% [24]. Very few studies have been conducted using the BiliCare device; therefore, comparisons with the findings of the present study remain limited.

Furthermore, Deming regression in this study showed that TcB tended to underestimate TSB, particularly at higher bilirubin levels. These findings reinforce that TcB is suitable for screening, but serum confirmation remains necessary before treatment decisions, consistent with 2022 AAP guidelines [7].

The primary goal of hyperbilirubinemia screening is to avoid missing high-risk cases. Therefore, focusing on TcB cut-off values with higher sensitivity and specificity during the evaluation of results of ROC curve analysis is of great significance. At a TSB threshold of at least 256 and 291 μmol/L, the TcB cut-off of 222 μmol/L demonstrated strong diagnostic performance, with higher sensitivity (90.7% and 100.0%), respectively, and a meaningful reduction in the need for blood draws (56.3%). These findings are consistent with previous reports and Nigerian studies showing sensitivities between 74.0% and 100.0% [17, 18, 25].

ROC analysis in this study confirmed excellent diagnostic performance, supporting TcB as a reliable screening tool, particularly as this is the first evaluation of BiliCare in a maternity ward in a Kenyan hospital. We also observed that increasing the TcB cut-offs improved specificity and PPV while reducing sensitivity, reflecting the trade-off between minimizing missed cases and avoiding unnecessary invasive testing. Similar observations have been reported in a study showing that using a lower TcB cut-off could substantially reduce the need for serum sampling [26].

The 2022 AAP guidelines emphasize accurate bilirubin assessment for timely intervention. In our findings, TcB demonstrated its highest reliability in the early neonatal period (24–48 hours), with strong sensitivity and specificity, supporting its use for early screening [7]. By 72 hours, sensitivity decreased due to the absence of TSB-confirmed cases, although specificity remained high. Overall, in the entire neonatal population, the TcB device showed good diagnostic performance, with high (>88.0%) sensitivity, specificity, and accuracy, as well as a favorable PPV and NPV. These findings confirm that the TcB device is an effective and reliable screening tool for identifying neonates at risk of hyperbilirubinemia while minimizing unnecessary serum sampling.

**Limitations of the Study**

The study included a reasonably sized cohort of neonates (N=158), providing sufficient data to assess the correlation between TcB and TSB. However, the study primarily focused on term neonates (≥38 weeks' gestational age), leaving the performance of TcB in preterm neonates uncertain. Limitations of the BiliCare device, such as an upper measurement limit, further constrained comparisons at very high levels of bilirubin. Additionally, factors such as variations in skin pigmentation and the potential influence of phototherapy on TcB readings were not fully explored, which could affect device performance in more diverse populations. Despite identifying an optimal TcB cut-off for this cohort, further research is needed to validate these thresholds across different clinical settings.

## CONCLUSION

This study demonstrated a strong positive correlation between TcB and TSB measurements in neonates, confirming that TcB is a reliable non-invasive screening tool for hyperbilirubinemia, particularly between 24 and 48 hours of life. TcB can reduce unnecessary blood sampling while enabling early detection of at-risk neonates. Although the device showed good overall accuracy, TSB remains the gold standard for clinical confirmation. A TcB cut-off of 222 μmol/L provides an optimal threshold for screening, and guideline-based categorization supports its practical utility. BiliCare™ can be considered for routine use in maternity wards; however, further validation in larger, diverse populations and among neonates with varying gestational ages, skin tones, or those receiving phototherapy is recommended to refine cut-offs and ensure broad clinical reliability.

**Abbreviations:** TSB, Total serum bilirubin; TcB, Transcutaneous bilirubin; ROC, Receiver Operating Characteristic; SD, Standard deviation; CI, Confidence interval; WHO, World Health Organization guidelines; SPSS, Statistical Package for Social Sciences; AKUH, N, Aga Khan University Hospital, Nairobi; IQC, Internal Quality Controls.

**The author's contribution:**

The corresponding author affirms that all listed authors have fulfilled the necessary criteria for authorship. All authors made an equal contribution to this work, including conceptualization, methodology, data curation, formal analysis, investigation, writing original draft, review and editing, and they all approved the final version.

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**Conflict of Interest:** None

**Data availability statement:** The corresponding author will provide the dataset generated during this study upon reasonable request. Please contact ombutsianorah@gmail.com for more information regarding access to the data.

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